

**Intellectual Property, Developing Countries
and the Law and Policy of the European Union:
Towards Postcolonial Control of Development**

Daniel Opoku Acquah

The cover print is ‘Sankofa’, an *Adinkra* symbol of the Akan tribe of Ghana. Sankofa is a word in Twi language that translates as ‘Go back and get it’ (**san** - to return; **ko** - to go; **fa** - to fetch, to seek and take). The word is often associated with the proverb, ‘*Se wo were fi na wosankofa a yenkyi*’ – which translates as: ‘It is not wrong to go back for that which you have forgotten’.

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Dedicated to Ama and Nana

Abstract

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DANIEL ACQUAH: Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development.

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The control of knowledge and information in the 21st century is a battleground. The reason is simple: information has become a 'prime resource' in modern economic life. The complex ecosystem of information is encapsulated in legal parlance as intellectual property. Characteristically intellectual property regimes create policy restrictions, in the form of exclusive rights to commercial use, on the otherwise free availability of knowledge and information in order to compensate for the cost of production of the knowledge or information. The exclusive rights, in effect, make access a saleable commodity and create the basis of markets for knowledge and technology. While these exclusive rights enable knowledge and technology markets, they also create social tension over the price of access and the lack of access. We have seen this tension played out in relation to access to medicines and biomedical technologies.

This thesis attempted to provide the first integrative analysis of how the EU's rule-making on intellectual property, both at home and abroad, impacts the ability of developing countries to utilize the flexibilities flowing from the TRIPS Agreement to promote public health and access to medicines. The EU's intellectual property policy has been conceptualized as comprising two distinct but intertwined normative regimes – the internal and external. The thesis argues that the EU's internal and external intellectual property policies have developed in manners that are tightly intertwined and detrimental to developing countries' ability to promote public health and access to medicines. It problematizes the issue in the context of postcolonial theory, supplemented by other theories. This theory underscores the notion that the overly compliant attitude of *most* developing countries towards international intellectual property laws – despite their obvious effects on their economies – goes beyond contemporary political and economic circumstances. It can be attributed to the colonial roots and neo-colonial structures of

this body of law, perpetrated through the EU's internal and external policy. The development of this law has been complicit in legitimizing the economic control of developing countries at the expense of their development.

The overall finding is that the current EU intellectual property policy making approach, both at home and abroad, does not offer the necessary freedom for development in developing countries. It simply works to protect the EU's industrial interest, with serious implications for public health. This observation is supported by the findings of five individual essays, which recommends, among others, for the EU to streamline its development, industrial and trade policies in ways that could simultaneously meet the development and health care needs of developing countries and the EU's economic interest. Externally, it recommends that developing countries should not be forced to adopt the kind of laws discussed in this thesis through Free Trade Agreements. If they are, the following measures should be considered: (1) inclusion of a clause on transitional arrangements for developing countries specific to intellectual property in the Free Trade Agreements; (2) inclusion of a mandatory clause that clearly links the objectives for intellectual property protection and enforcement to a balance between the promotion of technological innovation and access to medicines; (3) framing the provisions on public health in the Free Trade Agreements as mandatory requirements or express exceptions, which will stipulate that the implementation of the Free Trade Agreement cannot lead to derogation from the protection of public health; (4) the inclusion of strong and comprehensive sustainable development chapters in the Free Trade Agreements, which are to be effectively implemented and enforced; and (5) allowing for reservations within the meaning of Article 19, Vienna Convention on the Law of Treaties in future Free Trade Agreements. Finally, the concept of *substantive equilibrium* has been proposed as a means of delinking the EU's intellectual property policy from post-colonialism.

Keywords: European Union, Developing Countries, Intellectual Property, Free Trade Agreements, Pharmaceutical Patents, Data Exclusivity, Patent Term Extension.

Tiivistelmä

Turun yliopisto

Oikeustieteellinen tiedekunta

Eurooppaoikeus

DANIEL ACQUAH: Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development.

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Informaation ja tiedon hallinta on 2000-luvun taistelukenttä. Syy tähän on yksinkertainen: tieto on nykypäivän talouselämän keskeisin resurssi. Tiedon monitahoinen ekosysteemi hahmottuu oikeuden näkökulmasta pitkälti immateriaalioikeuksien kautta. Tyypillisesti immateriaalioikeudet asettavat rajoitteita informaation ja tiedon muutoin vapaalle saatavuudelle määrittelemällä yksinoikeuden kaupalliseen käyttöön korvaukseksi tietämyksen ja tiedon tuottamiseen liittyvistä kuluista. Tosiasiallisesti tällainen yksinoikeus muuttaa käyttöoikeuden myytäväksi hyödykkeeksi ja luo pohjan tietämyksen ja teknologian markkinoille. Sen lisäksi, että yksinoikeudet mahdollistavat tietämyksen ja teknologian markkinat, ne luovat myös sosiaalista jännitettä siihen, millä hinnalla tietämys ja teknologia ovat käytettävissä, jos ylipäättään ovat. Näitä jännitteitä olemme jo nähneet, kun kyse on ollut esimerkiksi lääkkeiden saatavuudesta ja biolääketieteen tekniikoista.

Tämän väitöskirjan tavoitteena oli analysoida, miten EU:n immateriaalioikeuksia koskevat määräykset – sekä EU:n sisäisesti että sen ulkosuhteissa – vaikuttavat kehittyvien maiden kykyyn hyödyntää TRIPS-sopimukseen sisältyviä joustomahdollisuuksia kansanterveyden ja lääkkeiden saatavuuden edistämiseksi. EU:n immateriaalioikeuspolitiikka on käsitteellistetty kattamaan kaksi erillistä mutta toisiinsa kietoutuvaa normatiivista menettelytapaa: sisäinen ja ulkoinen politiikka. Väitöskirjassa argumentoidaan, että EU:n sisäinen ja ulkoinen immateriaalioikeuspolitiikka ovat kehittyneet tiiviisti sidoksissa toisiinsa. Ne vaikuttavat haitallisesti kehittyvien maiden kykyyn edistää kansanterveyttä ja parantaa lääkkeiden saatavuutta. Väitöskirjassa problematisoidaan tätä jälkikolonialisen teorian ja täydentävien muiden teorioiden valossa. Tässä teoriassa korostetaan, että *useimpien* kehittyvien maiden kovin alistuvainen suhtautuminen kansainvälisiin immateriaalinormeihin – huolimatta niiden ilmeisistä haitallisista

vaikutuksista kyseisten maiden talouteen – nousee vallitsevia poliittisia ja taloudellisia olosuhteita tärkeämmäksi. Syy tähän on löydettävissä näiden normien koloniaalisista juurista ja uuskoloniaalisista rakenteista, jotka heijastuvat EU:n sisäiseen ja ulkoiseen politiikkaan. Kyseisten normien kehitys on osaltaan ollut oikeuttamassa kehittyvien maiden talouden hallitsemista maiden kehityksen kustannuksella.

Johtopäätöksenä väitöskirjassa todetaan, että EU:n nykyinen sisäinen ja ulkoinen immateriaalioikeuspolitiikka ei tarjoa riittävää vapautta kehityksen mahdollistamiseksi kehittyvissä maissa. Se yksinkertaisesti suojelee EU:n elinkeinoelämän etuja, millä on vakavia kansanterveydellisiä seurauksia. Havaintoa tukevat viiden eri artikkelin tulokset, joiden pohjalta suositellaan muun muassa, että EU virtaviivaistaisi kehitys-, teollisuus- ja kauppapolitiikkojaan siten, että ne samanaikaisesti täyttäisivät kehittyvien maiden kehitys- ja terveydenhoitotarpeet ja olisivat EU:n taloudellisten etujen mukaisia. EU:n ulkosuhteiden osalta suositellaan, että kehittyviä maita ei pakotettaisi hyväksymään tässä opinnäytetyössä kuvattua kaltaisia normeja vapaakauppasopimusten kautta. Mikäli näin kuitenkin tehdään, seuraavia toimenpiteitä tulisi harkita: (1) kehittyvien maiden siirtymätoimenpiteitä koskevan lausekkeen lisääminen vapaakauppasopimuksiin immateriaalioikeuksien osalta; (2) pakollinen lauseke, jossa selkeästi yhdistetään toisiinsa immateriaalioikeuksien suojelun ja toimeenpanon tavoitteet ja pyrkimys löytää tasapaino teknisen innovoinnin edistämisen ja lääkkeiden saatavuuden välillä; (3) kansanterveyttä koskevien säännösten merkitseminen vapaakauppasopimuksissa pakollisiksi säännöksiksi tai erityisiksi poikkeuksiksi, joissa määrätään, että vapaakauppasopimuksen toteuttaminen ei voi johtaa kansanterveyden turvaamisen huonontumiseen; (4) voimakkaiden ja kokonaisvaltaisten, kestävästä kehitystä koskevien lukujen lisääminen vapaakauppasopimuksiin, joita tulee toteuttaa ja toimeenpanna tehokkaasti; ja (5) mahdollisuus valtiosopimus-oikeutta koskevan Wienin sopimuksen artiklassa 19 tarkoitettuihin varauksiin tulevissa vapaakauppasopimuksissa. Lopuksi on ehdotettu *aineellisoikeudellinen tasapaino* -käsitettä keinoksi tehdä selvä ero EU:n immateriaalioikeuspolitiikan ja jälkikolonialismin välille.

Avainsanat: Euroopan unioni, Kehittyvät maat, Immateriaalioikeudet, Vapaakauppasopimukset, Lääkepatentit, Yksinoikeus tietoihin, Patenttajan pidentäminen

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Daniel Opoku Acquah

Datacity, Turku

May 2017

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List of abbreviations

ACP	African, Caribbean and Pacific Group of States
ACTA	Anti-Counterfeiting Trade Agreement
AIDS	Acquired Immune Deficiency Syndrome
ARIPO	African Regional Intellectual Property Organization
ASEAN	Association of Southeast Asian Nations
BIRPI	United International Bureaux for the Protection of Intellectual Property
BITs	Bilateral Investment Treaties
BLA	Biologics Licensing Application
BMR	Border Measures Regulation
BPCIA	Biologics Price Competition and Innovation Act
CARIFORUM	Forum of the Caribbean Group of African, Caribbean and Pacific States
CCP	Common Commercial Policy
CETA	EU—Canada Comprehensive Economic Trade Agreement
CJEU	Court of Justice of the European Union
DG TAXUD	Directorate-General Taxation and Customs Union
DSU	Dispute Settlement Understanding
EC	European Community
EEAS	European External Action Services
EEC	European Economic Community
EFPIA	European Federation of Pharmaceutical Industries and Associations
EGA	European Generics Association
EPA	Economic Partnership Agreement
EPC	European Patent Convention
EP	European Parliament
ESARIPO	Eastern and Southern African Regional Intellectual Property Organizations
EU	European Union

FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTAs	Free Trade Agreements
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services
GCC	Gulf Cooperation Council
GNI	Gross National Income
GIs	Geographical Indications
HIV	Human Immunodeficiency Virus
HRFSP	High Representative for Foreign and Security Policy
IGC	Inter-governmental Conference
INN	International Non-proprietary Name
INPI	French National Institute for Intellectual Property
IPC	Intellectual Property Committee
IP	Intellectual Property
IPR	Intellectual Property Right
LDCs	Least Developed Countries
MDGs	Millennium Development Goals
MERCOSUR	Southern Common Market
MFN	Most Favoured Nation
MNCs	Multinational companies
MRSCA	Medicines and Related Substances Control Act
NAFTA	North American Free Trade Agreement
NT	National Treatment
OAMPI	African and Malagasy Patent Rights Authority
OAPI	Organization Africaine de la Propriété Intellectuelle
PCT	Patent Cooperation Treaty

QMV	Qualified Majority Voting
SPC	Supplementary Protection Certificate
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TPM	Technological Protection Measures
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UCC	Universal Copyright Convention
UNECA	United Nations Economic Commission for Africa
UNCTAD	United Nations Conference on Trade and Development
UNICE	Union of Industrial and Employers' Confederations of Europe
UN	United Nations
UPP	Unitary Patent Package
US	United States
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

List of publications

Daniel Acquah, 'Developments in the EU External IP and Trade Competence up to Lisbon: New Wine in Old Wine Bottles?', 5 *Nordiskt immateriellt Rättskydd*, NIR (2011), pp. 423-443.

Daniel Acquah, 'Balancing or Lobbying? On Access to Medicines, Border Measures and the European Parliament's Amendments to the Proposed EU Trademark Rules', 19 *Journal of Intellectual Property Rights* 6 (2014), pp. 404-412.

Daniel Acquah, 'Trends on the implementation of the EU Customs Regulation: for better or for worse?', 10 *Journal of Intellectual Property Law & Practice* 10, OUP, (2015), pp. 775-784. ***Re-published** in Issue 10 of GRUR International (2015) as editor's choice of excellent article.

Daniel Acquah, 'Extending the Limits of Protection of Pharmaceutical patents and Data Outside the EU: Is There a Need to Rebalance?', 45 *International Review of Intellectual Property and Competition Law* 3 – IIC (2014), pp. 256-286.

Daniel Acquah, 'The IP policy of the EU – An impediment to balancing IP and public health in FTAs?', (Submitted).

PART I

*We are writing a bill of rights for the world, and one of the most important rights is the opportunity for development.*¹

*It is simply not adequate to take as our basic objective just the maximization of income or wealth, which is, as Aristotle noted, 'merely useful and for the sake of something else.' For the same reason, economic growth cannot sensibly be treated as an end in itself. Development has to be more concerned with enhancing the lives we lead and the freedoms we enjoy.*²

I. Introduction

A. Background of the study

The control of knowledge and information in the 21st century is a battleground. The reason is simple: information has become a 'prime resource' in modern economic life.³ The complex ecosystem⁴ of information is encapsulated in legal parlance as intellectual

- 1 Eleanor Roosevelt, *My Day* (6 February 1947), The George Washington University. Available: https://www.gwu.edu/~erpapers/myday/displaydoc.cfm?_y=1947&_f=md000567 (Accessed 09.03.2017). The right to development has been proposed and has become part of the international debate on human rights for over 40 years. However it has not yet entered the practical realm of development planning and implementation. States tend to express rhetorical support for this right but neglect its basic precepts in development practice. See Declaration on the Right to Development, G.A. Res. 41/128, Annex, U.N., GAOR 41st Sess., No. 53, U.N. Doc. A/4/53 (Dec. 4, 1986); Stephen Marks, 'The Human Right to Development: Between Rhetoric and Reality', 17 *Harvard Human Rights Journal* (2004); Arjun Sengupta, 'Right to Development as a Human Right', 36 *Economic and Political Weekly* 27 (2001), pp. 2527-2536; Ruth L. Gana, 'The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development', 18 *LAW & POLICY* 315 (1996); Obiora L. Amede, Beyond the Rhetoric of a Right to Development, 18 *LAW & POLICY* 355 (1996); James C.N. Paul, 'The Human Right to Development: Its Meaning & Importance', 25 *J. MARSHALL L. REV.* 235 (1992).
- 2 Amartya Sen, 'Development as Freedom', (Oxford University Press, 1999), p. 14.
- 3 T. Mandeville, 'Understanding Novelty: Information, Technological Change, and the Patent System', (Abex Publishing Corporation, Norwood, New Jersey, 1996), p. 3.
- 4 Terminology borrowed from Charlotte Hess and Elinor Ostrom, 'Introduction: An Overview of the Knowledge Commons', in Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (Cambridge, Mass.; MIT Press, 2006), p. 3. In their work, Hess and Elinor posit that in the digital age, knowledge must be conceptualized as a complex ecosystem, one that is both (1) a resource to be shared digitally by a group of people and (2) an entity that is subject to social dilemmas. In the context of this thesis, knowledge or information is used to refer broadly to intellectual property as it is concerned with the recognition and protection of private rights in respect of expressive and informational subject matter.

property (IP),⁵ which refers to the legal rights that result from mental or creative labour. IP is the right of exploitation of the knowledge and information accruing from such labour. Characteristically IP regimes create policy restrictions, in the form of exclusive rights to commercial use, on the otherwise free availability of knowledge and information in order to compensate for the cost of production of the knowledge or information. The exclusive rights, in effect, make access a saleable commodity and create the basis of markets for knowledge and technology.⁶ Thus, everyday activities – from grandma telling children folk tales *by the fire side*⁷ to the Indian using efficacies from the local *Neem tree* as daily cure for malaria or ulcer – are identified and commodified as IP. Lawrence Lessig has for example, noted that major studios such as Walt Disney long profited by drawing upon the rich intellectual tradition of folk tales without compensating anyone for their exploitation.⁸ Similarly, the bio-piracy case of the Indian *Neem tree* and similar other cases are well known.⁹ While these exclusive rights enable knowledge and technology markets, they also create social tension over the price of access and over the lack of access. We have seen this tension played out in relation to access to medicines and biomedical technologies.¹⁰

- 5 Intellectual property encompasses patents, copyright and related rights; trademarks, design rights, plant variety rights, geographical indications, unfair competition and certain additional *sui generis* rights in respect of information and data. While the law has long granted property rights in intangibles, the law did not accept ‘intellectual property’ as a distinct and (relatively) non-controversial form of property until late in the eighteenth century. In fact, it was not called intellectual property until midway through the nineteenth century. For more, see: Lionel Bentley and Brad Sherman, ‘Intellectual Property Law’, (Oxford: Oxford University Press, 2009), p. 2.
- 6 Francis Gurry, ‘Re-thinking the role of Intellectual Property’, *University of Melbourne* (August 22 2013), p. 2.
- 7 *By the Fire Side* is a Ghanaian TV programme that re-enacts an old tradition of folk telling by ‘grandma’ or ‘grandpa’ in the evening – usually, after sunset. Typically, a number of village children sit round the hearth and listen as granny takes them thousands of miles back in time, telling them *Kweku Ananse* stories – depicting aspects of their traditions, culture and values; and communicating important moral lessons. *Kweku Ananse* in Ashanti folklore is the *Spider*. According to folk tradition, Mr ‘Spider’ is an embodiment of wisdom and wit.
- 8 Lawrence Lessig, ‘Free Culture: the Nature and Future of Creativity’, (Penguin Books, 2006) pp. 23–24.
- 9 Azadirachtin is one of many active compounds present in the bark, leaves, flowers and seeds of the *Neem tree* or ‘*Azadirachta indica*’. The remarkable properties of this compound have been utilized in India from ancient times in the form of extracts of various kinds produced by Indian farmers and small industrial firms in medicine and agriculture. *Neem* has been described as an air purifier and effective medicine for almost all types of human and animal diseases because of its insect and pest repellent properties. A US timber importer studied the curing properties of *neem* and began importing *neem* seed to his company headquarters in Wisconsin since 1971. He successfully extracted a pesticidal agent from *neem* extract called *Margosan-O*. In 1985, the bio-pesticide derived from *neem* tree received clearance for the product from the US Environmental Protection Agency (EPA). The patent for the product was sold to the multinational chemical corporation, W.R. Grace after 3 years. Since then, many US and Japanese firms gained patents on formulae for stable *neem*-based solutions and emulsions and other products. In May 2000, a coalition of groups successfully overturned the patent held by the US company, WR Grace and the US Department of Agriculture over the Indian *neem tree*. For more, see Sayan Bhattacharya, ‘Bioprospecting, biopiracy and food security in India: The emerging sides of neoliberalism’, *International Letters of Social and Humanistic Sciences* 23 (2014), p. 52.
- 10 Gurry, above n 6, p. 22.

Arguably, the economic justifications underlying the IP system enmeshes it in a paradox: while its protection enables the production of innovative and creative goods which are essential for the development of society and mankind, the exclusivity IP entails is usually a factor that prohibits or at least limits access to those goods by consumers, competitors and the public at large.¹¹ On the one hand, the protection of IP is necessary for the production of innovative new medicines, scientific texts, new pest resistant or higher yield promising seeds or climate change mitigating ‘green’ technology relating to solar or wind power.¹² On the other hand, it may enable the right holder to demand monopoly rents for goods protected by IP¹³ – thereby limiting access to these information goods unless of course competing goods exist which can be produced without infringing the IP rights vesting in the protected good.¹⁴ Even so, in the pharmaceutical field, the latter is not a guarantee for access.¹⁵ In the context of the issue of access to medicines, this dual impact of IP protection is well summarized in the paragraph 3 of the Doha Declaration on the TRIPS Agreement¹⁶ and Public Health¹⁷ (the Doha Declaration) where the World Trade Organization (WTO) Member States declare: ‘We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices’.

11 Henning Grosse Ruse – Khan, ‘Protecting Intellectual Property under BITS, FTAS, and TRIPS: Conflicting Regimes or Mutual Coherence?’, *Max Planck Institute for Intellectual Property & Competition Law Research Paper* No 11-02 (2011), p. 4.

12 Ibid.

13 For example, in August 2015, the Martin Shkreli-run company Turing Pharmaceuticals bought an older drug called Daraprim – which is used to treat a parasitic infection that can be deadly for people with HIV or cancer. Overnight, the company raised the price of the drug from \$13.50 per tablet to \$750. Many observers saw the move as price-gouging. Equally a recent Bloomberg analysis of 39 medicines with global sales of more than \$1 billion a year showed that 30 of them logged price increases of more than double the rate of inflation from 2009 to 2015, even after estimated discounts were factored in. Only six drugs had price increases in line with or below inflation. For details, see Robert Langreth, Michael Keller and Christopher Cannon, ‘Decoding Big Pharma’s Secret Drug Pricing Practices’, (Bloomberg, 29 June 2016). <http://www.bloomberg.com/graphics/2016-drug-prices/>.

14 Grosse Ruse – Khan, above n 11. (Emphasis added).

15 For instance, in a research on drug promotion in a competitive market, Kessler et al found that an incentive for introducing ‘me too’ drugs (drugs that are structurally very similar to brand-name drugs already on the market, with only minor differences) is that companies can sometimes charge more for a new drug, even in an already crowded class. For details, see David A. Kessler, M.D., Janet L. Rose, P.A.-C., M.B.A., Robert J. Temple, M.D., Renie Schapiro, M.P.H., and Joseph P. Griffin, J.D., ‘Therapeutic-Class Wars – Drug Promotion in a Competitive Marketplace’, *The New England Journal of Medicine* (1994), p. 1350.

16 Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 33 ILM 81 (TRIPS Agreement).

17 World Trade Organization, the Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference Declaration of 14 November 2001, WT/MIN(01)/DEC/2 (Doha Declaration).

This clash between IP and public health is an issue that has come to symbolize the tensions that have led to the paralysis in the Doha Round negotiations.¹⁸ In 2001, WTO Member States adopted the Doha Declaration in recognition of widespread concerns about the effects of expanded patent protection on public health and access to medicines.¹⁹ Importantly, it clarified that ‘the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all’. In 2003, the General Council acted on paragraph 6 of the Doha Declaration by waiving Article 31(f), TRIPS, thereby permitting member states lacking sufficient manufacturing capacity to import necessary medicines from any other member states. WTO Members adopted this waiver as an amendment to TRIPS (Article 31 *bis*) in 2005; however, this amendment only came into effect in January 2017 after the required number of members ratified the amendment.²⁰ This waiver has only been used once, between Rwanda and Canada, and that case has been widely criticized as having failed due to complexity and expense.²¹ Observers are concerned that originator firms are not as likely to see this possibility as real risk and thus will not be motivated to act favourably.²² It appears finding a ‘middle way’ to the issue has proved more complex than one would assume. IP thus remains a battleground for a balance of interest between right holders, emerging competitors and end users.

18 Billy A. Melo Araujo, ‘The EU Deep Trade Agenda: Law and Policy’, (Oxford University Press, UK, 2016), p. 140.

19 For the sake of simplicity, I will use access to medicines and public health interchangeably in this thesis.

20 See World Trade Organization News Items: ‘WTO IP rules amended to ease poor countries’ access to affordable medicines’, (23 January 2017). https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm. Also, William New, ‘It’s Official: TRIPS Health Amendment In Effect, First Ever To A WTO Agreement’, IP WATCH (23 January 2017).

21 Ibid; Also, Holgar P. Hestermeyer, Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines, 11 ASIL Insights 28 (10 Dec. 2007). <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and>.

22 Ibid.

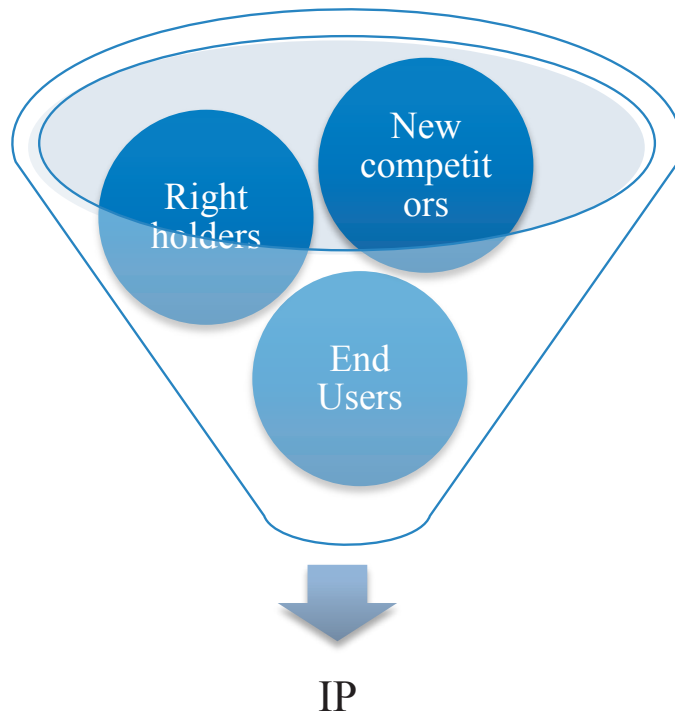


Figure 1.1 *Stakeholders with conflicting interest in the field of IP*

At the global level, this struggle has translated into a common tension between developed countries, which are often net producers and exporters of IP goods, and developing countries,²³ which are often net consumers and importers of IP goods and services.²⁴ While the developed countries are asking for new rights and enforcement tools, the developing countries are asking for flexibilities (exceptions and limitations) and access to IP protected goods. It is the task of IP regulation to offer a trade-off between a protection-incentive for market actors, and public access to and dissemination of the resulting

23 My use of 'developed' and 'developing' countries in this thesis is not an attempt to take sides or overemphasize the North-South divide, recognising that there may be shifting alliances between and among developed and developing countries as power blocs within the WTO. Instead, they are used as proxies for broad and enduring differences between the global intellectual property 'haves' and 'have-nots'. See Margaret Chon, 'Intellectual Property and the Development Divide' 27 *Cardozo Law Review* (2006), p. 2830.

24 A recent report by WIPO on 'patenting activity associated with six breakthrough innovations' found out that patents filed around the world that are associated with each of the six breakthrough innovations were geographically concentrated. High-income countries account for more than 80 percent of filings in all six cases. Even within high income countries, patent filings were concentrated within the US, Japan, Germany, France, the UK and the Republic of Korea. See report at: http://www.wipo.int/edocs/pubdocs/en/wipo_pub_944_2015.pdf. It should however be noted that the trend is changing, as newly industrialized countries like China, Brazil, India and South Africa are fast becoming producers of intellectual property intensive goods.

innovations and creations. In general terms, this balance is achieved by limiting the exclusive rights granted to innovators and creators in time and in scope.²⁵

The international IP system seems to have incorporated a standard domestic balancing test.²⁶ However, in recent years, commentators have increasingly questioned whether international IP regulation strikes the ‘right’ balance between exclusivity and access.²⁷ This is so because the international IP system generally has been created in order to address deficiencies in protection and hence – as its *raison d’être* – protects primarily the interests of net producers and exporters of IP protected goods.²⁸ The result is an ‘IP balance that has become increasingly lopsided in favour of producer interests, possibly to the detriment of overall global social welfare and clearly, to the detriment of the most vulnerable populations’.²⁹ This normative underpinning is particularly seen in the relationship between the two main IP conventions³⁰ to the WTO TRIPS Agreement, as well as in the relationship between TRIPS and Free Trade Agreements (FTAs).

IP had been traditionally regarded as a cultural concept until 1994, when IP rights were formally elevated to a trade issue in the TRIPS Agreement. Initially viewed by developing countries as serving primarily the interest of IP exporting industries in the

25 Grosse Ruse – Khan, above n 11. Citing for example Art. 28 TRIPS (which provides for certain exclusive rights for patent holders) on the one hand and Art.30 TRIPS (allowing to foresee certain exceptions to these exclusive rights), Art.31 TRIPS (allowing compulsory licenses) and Art.33 TRIPS (limiting the period of patent protection to the minimum of 20 years).

26 The TRIPS Agreement further incorporated the need for a balance as an objective in its Art. 7 which provides that: ‘the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations’.

27 Daniel J. Gervais, ‘Is There a “Middle Way” in International Intellectual Property?’, 47 *International Review of Intellectual Property and Competition Law* 2 (2016), pp. 135-137; Henning Grosse Ruse–Khan, ‘Policy Space for Domestic Public Interests Measures under TRIPS’, *South Centre Research Paper Series* No.22 (2009); Grosse Ruse – Khan, above n 11; Daniel Acquah, ‘Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a Need to Rebalance?’, 45 *International Review of Intellectual Property and Competition Law* 3 (2014), p. 256-286 (Chapter V).

28 Grosse Ruse – Khan, above n 11, p. 5.

29 Chon, above n 23, p. 2826. This is so because the provisions mentioning ‘balance’ and ‘development’ in TRIPS (Preamble, Arts. 7 and 8) are general provisions and not mandatory. For analysis on the implications of the differences in these Treaty provisions, see Grosse Ruse – Khan, above n 11; Acquah, above n 27 (Chapter V).

30 The two principal international treaties for intellectual property protection were concluded in 1883 and 1886 respectively: first was the Paris Convention for the Protection of Industrial Property (hereafter, ‘Paris Convention’), which governed ‘patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and repression of unfair competition’ (Art. 1.2). And the second was the Berne Convention for the Protection of Literary and Artistic Works (hereafter, ‘Berne Convention’), which governed copyright and related rights.

developed world, TRIPS is now often praised for the flexibilities³¹ it offers against a backdrop of recent developments on the international scene.³² On the other hand, the demanders of the TRIPS Agreement now complain that the Agreement – while being an important milestone – appears not to represent a conclusive and satisfactory response to what is perceived as a significant rise in levels of counterfeiting and piracy. Sir Hugh Laddie perfectly summarized the present situation in his foreword to the seminal report of the UK Commission on IP rights:

‘The process of implementing TRIPS has not resulted in a shrinking of the gap that divides these two sides, rather it has helped to reinforce the views already held [...] So firmly and sincerely held are these views that at times it has appeared that neither side has been prepared to listen to the other. Persuasion is out, compulsion is in.’³³

In this regard, the post-TRIPS era has seen countries interested in higher IP standards shifting IP negotiations away from the two main institutions of IP (the WTO and the World Intellectual Property Organization (WIPO))³⁴ towards FTAs, regional and other

31 TRIPS flexibilities refer to the degree of room for manoeuvre (policy autonomy) provided in the TRIPS Agreement for Member States in the implementation of the Agreement. Experts identify these flexibilities to include, among others, TRIPS Arts. 7 and 8, and the Doha Declaration. The term ‘flexibility’ is contained in certain provisions such as paragraph 6 of the Preamble to TRIPS, which stipulate that ‘[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base. The meaning of ‘flexibility’ as used in the Preamble is explained in Art. 66.1 which reads: ‘in view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Arts. 3, 4 and 5, for a period of [...]’.

32 Henning Grosse Ruse-Khan, ‘The International Law Relation Between TRIPS and Subsequent TRIPS-plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?’, 18 *Journal of Intellectual Property Law* 2 (2011), p. 4. (Emphasis added).

33 UK Commission on Intellectual Property Rights: *Integrating Intellectual Property Rights and Development Policy* (London September 2002), p. iii.

34 This is specific to the FTAs, which are commercially driven. When it comes to negotiating pure intellectual property treaties, WIPO is an exception in this regard. Since 1996, it has succeeded in negotiating five new international treaties on intellectual property – although not necessary in the scheme of the kind of enforcement of intellectual property being discussed in this context. See WIPO Copyright Treaty (1996), http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=295157; WIPO Performances and Phonograms Treaty (1996), http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=295477; Beijing Treaty on Audiovisual Performances (2012), http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=295838; Marrakesh Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired, or otherwise Print Disabled (2013), http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=301019; and the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications (2015), http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=370115.

plurilateral agreements.³⁵ On the bilateral front, countries which are otherwise reluctant to agree to increases in IP protection at the multilateral level are forced to agree to stronger IP protection and enforcement laws in order to attain preferential access to the markets of their FTA partners. The EU is one of the demanders of stronger protection and enforcement of IP. Against the background of increasing IP infringements globally, the EU has responded by working to promote the introduction of domestic regulatory discipline in third countries through its FTAs.³⁶ These are by no means new for the EU: the new development is the current approach of using them as tools to facilitate the enhanced protection and enforcement of IP abroad. In its early FTAs, the EU adopted a generalist approach to regulate IP, requiring contracting parties to ratify existing IP-related international agreements.³⁷ This drastic shift in policy – from a generalist to a more prescriptive approach – was outlined in two documents: the 2005 Strategy for the enforcement of IP rights in third countries (‘the Enforcement Strategy’)³⁸ and the 2006 Global Europe Communication (‘the Global Europe Strategy’).³⁹

1. The IPR Enforcement strategy and Global Europe strategy

The EU’s efforts to promote domestic regulatory discipline in third countries through FTAs came in the form of strategic proposals. In the Enforcement Strategy, the Commission proposed in its action lines that the IP chapters in bilateral agreements should be revisited to clarify and strengthen the enforcement clauses by, for instance, using the

35 For a working definition of (‘multilateral, ‘plurilateral’ and ‘regional’ Agreements), see Flynn S.M., Baker B., Kaminski M., Koo J., ‘The U.S Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement’, 28 *Am Univ Int L Rev* 1 (2012); Okediji R. L., ‘Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection’, *Univ Ottawa L Technol J* (2003-2004); Peter K. Yu, ‘Intellectual Property and Human Rights in the Nonmultilateral Era’, 64 *Fla L Rev* 4 (2012).

36 See Chapter VI.

37 Pugatch, M. Perez, ‘A Transatlantic Divide? The US and EU’s Approach to the International Regulation of Intellectual Property Trade-Related Agreements’, *European Centre for International Political Economy Working Paper* No. 02 (2007), p. 10; Billy A. M. Araujo, ‘Intellectual Property and the EU’s Deep Trade Agenda’, 16 *Journal of International Economic Law* 2 (2013), p. 439.

38 Strategy for the Enforcement of Intellectual Property Rights in Third Countries (2005/ C 129/03).

39 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, ‘Global Europe: Competing in the World – A Contribution to the EU’s Growth and Strategy’, Brussels, 4 October 2006, Publications Office of the European Union (2006) 567 final.

Enforcement Directive⁴⁰ and Customs Regulation⁴¹ as ‘important sources of inspiration and a useful benchmark’.⁴² In effect, when a comparison is made between the civil enforcement provisions of recent EU FTAs, it becomes clear that they include almost the same wording as the Enforcement Directive.⁴³ The Commission’s 2014 Communication on the Enforcement Strategy builds on this approach by focusing on ways to improve the existing approaches to keep pace with the times and the new realities in the field of IP.⁴⁴ Building on the Enforcement Strategy, the Global Europe Strategy signalled a move towards placing greater emphasis on bilateral trade relations with economically significant parties. The profile of countries or country groupings targeted, namely, ASEAN, MERCOSUR, Korea, India, Gulf Cooperation Council (GCC), Russia, China and more recently, Canada and US broadly fit the economic profile set out by the Global Europe Strategy in that these agreements were to be commercially driven.⁴⁵ The contents of these new competitive FTAs were to be comprehensive and ambitious in coverage, extending beyond tariffs to non-tariff barriers such as IP rights and investment. In addition, the provisions of the IP chapters in the FTAs were to be robust, and like the Enforcement Strategy, inspired by such Union laws as the Enforcement Directive. The 2010 Europe 2020 trade strategy emphasized its complete commitment to this approach. While these policy documents are not laws in themselves and are thus non-binding, they serve as important foundations for future development of the law, as seen in recent EU FTAs.

40 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, *Official Journal of the European Union* L 157 of 30 April 2004 (Enforcement Directive).

41 The EU has regulated border enforcement of intellectual property rights for nearly three decades. The first Regulation was passed in 1986. Since then, four further Regulations have been passed. *See* Council Regulation 3842/86 laying down measures to prohibit the release for free circulation of counterfeit goods, OJ L 357 (18 December 1987); Council Regulation 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods as amended by Council Regulation 241/1999 amending Regulation 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods, OJ L 27/1; Council Regulation 1383/2003 concerning customs actions against goods suspected of infringing certain intellectual property rights, OJ L 196/7 (2003); Regulation (EU) No. 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights. For details, *see* Daniel Acquah, ‘Trends on the implementation of the EU Customs Regulation: for better or for worse?’, 10 *Journal of Intellectual Property Law & Practice* 10, OUP, (2015), pp. 775-784 (Chapter IV).

42 Enforcement Strategy, above n 38, p. 5.

43 Xavier Seuba, ‘Checks and Balances in the Intellectual Property Enforcement Field: Reconstructing EU Trade Agreements’, in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Edward Elgar Publishing, Cheltenham, UK: 2013), p. 414.

44 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, ‘Trade, growth and intellectual property: Strategy for the protection and enforcement of intellectual property rights in third countries’, Strasbourg, 1 July 2014, Publications Office of the European Union (2014) 389 final, p. 3.

45 *See* Global Europe Strategy, above n 39, p. 9.

To date, the EU has only signed one FTA with one of the priority partners originally identified under the Global Europe Strategy: the EU-Korea FTA,⁴⁶ which was signed on 10 May 2010 and entered into force on 1 July 2011.⁴⁷ This Agreement forms part of the FTAs analysed in this thesis. The Union has also concluded an FTA with Singapore on 17 October 2014 but the approval and ratification of this agreement has delayed due to the Commission's decision to request an opinion of the Court of Justice of the European Union (CJEU) on whether the EU has the competence to conclude the agreement alone (discussed below).⁴⁸ Besides these two, the EU has so far failed to conclude FTAs with the majority of the countries identified by the Global Europe Strategy. This somehow suggests that the EU's comprehensive trade liberalization agenda may have been too ambitious from the outset.⁴⁹

At the same time, however, the EU has concluded, and continues to negotiate a number of FTAs, which, while not targeting countries identified by the Global Europe Strategy, apply the Global Europe ethos insofar as they are comprehensive in scope and have strong regulatory dimension focused on TRIPS plus issues.⁵⁰ This is the case of the Economic Partnership Agreement (EPA) signed between the EU and the Forum of the Caribbean Group of African, Caribbean and Pacific States (CARIFORUM),⁵¹ and the EU-Peru-Colombia FTA.⁵² These FTAs include specific chapters on IP whose provisions extend beyond the TRIPS enforcement standards, and export largely the EU's current internal architecture on the regulation of IP. Of relevance to the issue of access to medicines are the inclusion of TRIPS plus provisions in the form of patent term extension

46 Free Trade Agreement between the European Union and its Member States, of the one part, and Republic of Korea, of the other part (2011, OJ L 127/1).

47 Araujo, above n 18, p. 6.

48 Commission Decision, requesting an opinion of the Court of Justice pursuant to article 218(11) TFEU on the competence of the Union to sign and conclude a Free Trade Agreement with Singapore, C (2014) 8218 final.

49 Araujo, above n 18, p. 7 (emphasis added).

50 Ibid (emphasis added).

51 Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part (2008, OJ L 289/1). CARIFORUM is the body that comprises the Caribbean Group of African, Caribbean, and Pacific (ACP) States for the purpose of promoting and coordinating policy dialogue, cooperation, and regional integration, mainly within the framework of the Cotonou Agreement between the ACP and the EU, and also, the EU-CARIFORUM Economic Partnership Agreement. It must be noted that the EU-CARIFORUM Agreement encroaches less on public health related TRIPS flexibilities since it lacks any substantive TRIPS plus obligations on patent protection, such as patent term extension. However, regarding provisions on enforcement, and specifically on border enforcement of intellectual property rights, the same cannot be said about this agreement.

52 Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part. http://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf.

(referred to in Europe as Supplementary Protection Certificate ‘SPC’),⁵³ test data exclusivity and enforcement institutions such as border enforcement, which encompasses import, export, and particularly transit. For example, both the EU-Peru-Colombia and EU-Korea Agreements contain clauses on test data exclusivity whose relevant parts require that data submitted to obtain a marketing authorization for pharmaceutical products in the territory of the respective parties should be given an exclusivity period of normally (or ‘at least’ in the case of the EU-Korea FTA) five years, starting from the date of the first marketing authorization.⁵⁴ As I explain in detail in Chapters V and VI, data exclusivity has been noted to have effects on compulsory licensing and medicines pricing.⁵⁵ However, unlike patents, data exclusivity cannot be challenged. Consequently, it provides an additional protection to patented medicines by essentially submerging the existing exceptions into patent rights.⁵⁶

Paradoxically, the FTAs also include safeguard clauses that refer to the TRIPS flexibilities and the Doha Declaration. A good example is Article 139(2), EU-CARIFORUM EPA, under which parties ‘agree that the principles set out in Article 8 of the TRIPS Agreement apply to this Section and that adequate and effective enforcement of IP rights should take account of the development needs of the CARIFORUM States [...] to protect public health and nutrition’. It ends by noting that ‘nothing in this Agreement shall be construed as to impair the capacity of the parties and the signatory CARIFORUM States to promote access to medicines’.⁵⁷ This is a clear example of a safeguard clause that permits the CARIFORUM States to exceptionally derogate from the FTA obligations to protect public health in implementing the treaty. However, as I explain in Chapters V and VI (and also in this introduction), the inclusion of TRIPS plus norms in the FTAs can make it difficult for developing countries to make use of the TRIPS flexibilities while simultaneously fulfilling the new enforcement obligations. This is particularly relevant in the pharmaceutical field, in which access to medicines may be hugely impaired.

53 Regulation (EC) No. 469/2009 of The European Parliament and of The Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products (2009, OJ L 152/1). Supplementary Protection Certificates in the EU generally extend the term of patent protection for five more years to compensate for delays in obtaining regulatory approval for medicinal products. ‘Patent term extension’ and ‘Supplementary Protection Certificate’ are used interchangeably in this thesis.

54 Art. 231(2) EU-Peru-Colombia FTA and Art. 10.36(2) and (3) EU-Korea FTA.

55 Acquah, above n 27 (Chapter V), and Acquah, (Chapter VI).

56 Cynthia, M. Ho, ‘Beyond Patents: protecting drugs through regulatory laws’, *Loyola University Chicago School of Law Public Law and Legal Theory Research Paper* No. 34 (2011a), p. 269.

57 For details on all the safeguard clauses, see Chapter VI. (Emphasis added).

Developments in global health and specifically access to medicines policies are now at an important juncture. While impressive progress has been made in access to medicines for HIV (See figure 1.2 below),⁵⁸ trends in European and international IP law could impact many of the policy tools being used to scale up HIV treatment.⁵⁹ Even so, the progress made in regard to HIV treatment is not the same for other diseases such as cancer, tuberculosis and hepatitis C, among others, whose high prices cause huge access challenges especially in developing countries.⁶⁰ This is due in a large part to the way that innovation is currently rewarded through the patent system.⁶¹ Adding another layer of rules through FTAs only worsen the already precarious situation. The recent Report of the United Nations Secretary General’s High-Level Panel on Access to Medicines attests to this fact.⁶² However, the fact that industry players and the United States (US) govern-

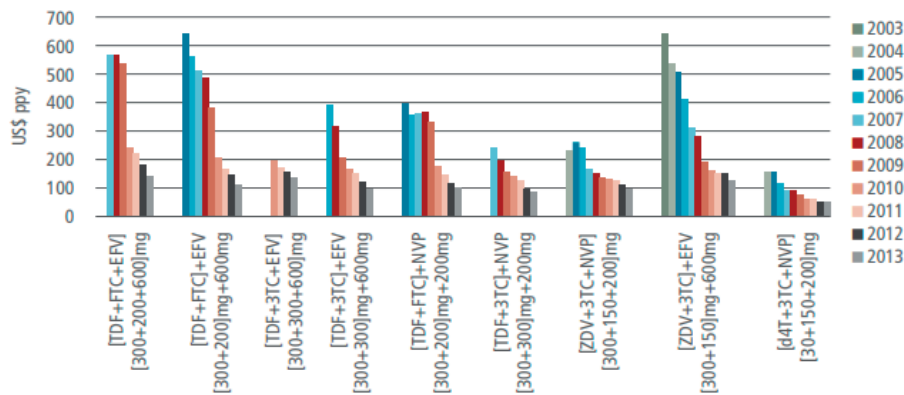


Figure 1.2 Median price (US\$ ppy) of the main ART regimens used in LMICs, 2003–2013

Source: WHO Global Price Reporting Mechanism (GPRM)

58 See http://www.who.int/hiv/pub/arv/global-AIDS-update-2016_en.pdf?ua=1; Ellen 't Hoen, 'Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines', (Heal Action International (HAI), Netherlands 2016).

59 Hoen, above n 58, p. 1.

60 Ibid, pp. 4-5. Citing Sofosbuvir and Gleevec as examples. Sofosbuvir is a medicine that is part of a 12-week treatment of hepatitis C, which can cause a potentially lethal infection of the liver. The production cost of Sofosbuvir is estimated to be US\$ 68–136 for a course of treatment. However, the company that holds the patent sells it for up to US\$ 84,000, a difficult price for even developed countries to afford.

61 See n. 13 above. Also, Hoen, above n 58.

62 See Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies (September 2016). Noting that trade rules and intellectual property laws were developed to promote economic growth and incentivize innovation. In this regard, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives of the WTO Members (Emphasis added).

ment IP specialists have criticized this report is an indication that the issue of access to medicines is unresolved.⁶³

Interestingly, the EU's campaign for enhanced protection and enforcement of IP does not end at the multilateral or bilateral level. In fact, it starts at home – as emphasized in the Global Europe Strategy and the Enforcement Strategy.⁶⁴ An example is developments in the area of its Customs Regulation.⁶⁵ The EU's Customs Regulation has in the past caused major disruptions for generic medicines making transit at its borders.⁶⁶ Between 2008 and 2010, 22 consignments of generic medicines en route from India to destinations in Latin America and Africa were seized at various European ports. These medicines had been lawfully manufactured and exported and would have been lawfully imported, marketed and consumed in the destination countries.⁶⁷ The legal basis of such seizures had been Regulation No (EC) 1383/2003.⁶⁸ This Regulation amended EU border control measures in such a way that supposedly implied permission to EU patent holders to demand seizure of infringing goods (including pharmaceutical products) in transit through EU ports as if they were counterfeits.⁶⁹

63 See William New, 'US Business, Government Work To Bring Down 'Dangerous' UN Panel Report On Access To Medicines – And Change The Debate In Geneva', IP WATCH (23.02.2017).

64 See Global Europe Strategy, above n 39, and Enforcement Strategy, above n 38.

65 For a list of the EU Customs Regulations, see above n 41.

66 Daniel O. Acquah, 'Balancing or Lobbying? On Access to Medicines, Border Measures and the European Parliament's Amendments to the Proposed EU Trademark Rules', 19 *Journal of Intellectual Property Rights* 6 (2014) (Chapter III). Also, Frederick, M. Abbott, 'Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare', *World Intellectual Property Organization Journal* No. 1 (2009), p. 43.

67 Ibid.

68 See Council Regulation 1383/2003, above n 41.

69 Abbott, above n 66. Commentators observe that in the debate about counterfeiting and public health, there is the tendency to conflate three distinct issues: first, counterfeit goods that infringe trademarks; second, medicines suspected of infringing patents; and third, falsified medicines, which contain the wrong or insufficient active ingredients. However, counterfeiting is a term that carries a specific meaning in intellectual property law. It describes the theft of brand owner's intellectual property, namely, a trademark violation. Footnote 14 of Article 51 TRIPS defines counterfeit goods as: 'any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation'. There are concerns that the use of this term to describe medicines that are generic drugs sold legitimately on the market will create confusion and risk prioritizing the enforcement of IP rights over public health. See Duncan Matthews, 'Counterfeiting and Public Health', in Christophe Geiger (ed) *Criminal Enforcement of Intellectual Property Rights: A Handbook of Contemporary Research* (Edward Elgar, Cheltenham, UK, 2012), pp. 42-45.

Against the backdrop of a WTO Dispute Settlement consultation,⁷⁰ the EU passed a new Customs Regulation in January 2014.⁷¹ In the process leading up to the passage of this new Regulation, the EU had promised to correct the issue of the seizure of generic medicines in transit. However, commentators have criticized the content of the new regulation as capable of limiting access to medicines.⁷² As I argue in Chapters III and IV, issues that are likely to pose challenges for access to medicines in the Customs Regulation are: first, the inclusion of SPCs to the definition of IP rights (Article 2(f));⁷³ second, reference to the word ‘suspensive procedure’ which has its origins from the Community Customs Code (Article 1(c)), and by definition, covers transit;⁷⁴ and third, broadly defining counterfeit goods to cover ‘any packaging, label, sticker, brochure, operating instructions, warranty document or other similar item, even if presented separately, which is the subject of an act infringing a trade mark or a geographical indication [...]’ (Article 2.5(c)).⁷⁵

Similarly, in its proposal for a revision of the Regulation on the EU trademark and for a recast of the Directive approximating the laws of the Member States relating to trademarks,⁷⁶ the EU Commission opted for transit (including generic medicines) to

70 See Request for Consultations by India, European Union and a Member State Seizure of Generic Drugs in Transit, WT/DS408/1, 11 May 2010; also, Request for Consultations by Brazil, European Union and a Member State Seizure of Generic Drugs in Transit, WT/DS409/1, 12 May 2010.

71 See Regulation (EU) No. 608/2013, above n 41.

72 Baker B K, Settlement of India/EU WTO dispute re seizures of in-transit medicines: Why the proposed EU border regulation isn't good enough, Program on Information Justice and Intellectual Property Research Paper Series, 1 (1) (2012); Saez C, New EU customs regulation might allow wrongful seizures of generic drugs in transit, NGOs say, *Intellectual Property Watch*, 17 October 2013; Acquah, above n. 66 (Chapter III).

73 Besides patents, generic medicines mostly infringe SPCs. Including patents and SPCs within the scope of the Customs Regulation effectively ensures that generic medicines in transit at EU borders can be legally intercepted because they infringed local patents or SPCs, especially, in the absence any substantive provision on transit of generic medicines. See also, Chapters III, IV and V.

74 Council Regulation 2913/92 establishing the Community Customs Code, OJ L 302/1 (‘the Community Customs Code’). Article 84(1)(a) defines suspensive procedure in relation to non-Community goods as those under ‘external transit, customs warehousing, inward processing, processing under customs control, and temporal importation’ giving it a wider coverage. Since October 2013, Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (recast) came into force. It repeals the Community Customs Code and from 1 May 2016, its provisions apply. The new Regulation comes with new numbering which changes the numbering of the articles as used in this thesis. The Union Customs Code does not contain any reference to ‘suspensive procedure’; however, since the Customs Regulation contains vocabulary from the Community Customs Code, it is uncertain how this will be resolved.

75 Art. 2(5)(c) of Regulation (EU) No 608/2013, above n 41. For detailed analysis, see Acquah, above n 66 (Chapter III); Acquah, above n 41 (Chapter IV).

76 European Commission COM (2013) 161 final; European Commission COM (2013) 162 final.

be actionable.⁷⁷ In the wake of criticism,⁷⁸ the originally proposed texts were amended and the need to safeguard legitimate international trade was recognized in the recitals of the proposed texts.⁷⁹ The new EU trademark Regulation and Directive uphold these provisions.⁸⁰ In spite of this, major developing countries have expressed their concerns over the new EU Trademark rules about transit of generic medicines in a recent WTO IP Council meeting.⁸¹ These developments certainly call for a second look at the EU's IP policy at both the *internal* and *external* levels,⁸² and how that could potentially affect developing countries' public health policies. The distinction, and yet, interlinkage between the EU's internal and external IP policy and its implications on the issue of access to medicines in developing countries is a key contribution of this research to the literature, and therefore deserves some attention.

77 Ibid. Articles 9(5) and 10(5) respectively.

78 Acquah, above n 66 (Chapter III).

79 See above n 76, Recitals 18 and 22 respectively.

80 Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015 amending Council Regulation (EC) no 207/2009 on the Community Trademark and Commission Regulation (EC) no 2868/95 Implementing Council Regulation (EC) no 40/94 on the Community Trademark, and repealing Commission Regulation (EC) no 2869/95 on the fees payable to the Office for Harmonization in the Internal Market (Trademarks and Designs) (OJ L 341/21); Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks (Recast) (OJ L 336/1).

81 Saez C, 'New Ideas Coming for WTO TRIPS Council; But also Old Debate over EU Drug Seizures', IP WATCH (09 June 2016). India, Brazil, China, South Africa and Indonesia expressed concerns. For example, the Indian delegate noted that 'it appears that an exception is being created for the purposes of "generics" but the same is limited to the active ingredients with international non-proprietary names (INNs) and not to the generic medicines in transit'. INNs, also known as a generic name, identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. As unique names, INN has to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available, they are formally placed by World Health Organization in the public domain, hence their designation as 'non-proprietary'. They can be used without any restriction whatsoever to identify pharmaceutical substances.

82 For convenience, I use the terms *internal* and *external* in connection with the EU's intellectual property policy in the generic sense. The *internal* law applies to all systems of intellectual property regulation at the EU level – even the external aspects of the EU's *internal* policies such as the Customs Regulation – being mindful that the legal basis for it is the Common Commercial Policy. The reason for this that even though the Customs Regulation is an external-oriented policy of the EU, it mostly consists of the adoption of an internal legislation, without the participation of third countries. Its categorization under EU law as external is therefore relevant for the purposes of allocation of competences. The external refers to all aspects of intellectual property regulation in which the EU engages third countries at the bilateral or multilateral level.

2. The EU's internal and external IP policy and its discontent

As a rule, all EU action is bound by the principle of conferral, according to which competences not conferred upon the EU by the Treaties remain with the Member States.⁸³ There are three general categories of EU competences: exclusive, shared and supporting. If the EU has exclusive competence in a specific area, Member States may not act in that area unless empowered to do so by the EU or for the purpose of implementing EU acts.⁸⁴ If the EU has shared competence in a specific area, Member States may only act in that area to the extent that the EU has either failed to act or decided not to act.⁸⁵ And finally, if the EU has supporting competence in a particular area, it may only take action to support, coordinate or supplement Member States' action, without thereby superseding their competences or harmonizing their own domestic laws.⁸⁶ As we shall see in this section, it appears the EU now enjoys broad competence to act internally and externally in the field of IP – which gives it the power to push through its economic agenda in ways discussed in this research. This was not the case from the beginning.

When the European Economic Community (EEC, now 'EU') was formed, it was decided to establish a customs union, an advanced form of trade integration, with the further aim of building a common (later internal) market, founded upon free movement of goods, persons, capital, and services, and promoting fair competition.⁸⁷ To this end, Article 30 EEC prohibited 'quantitative restrictions' on trade and provisions 'having equivalent effect'. In contrast to the ideals of the common market, however, the founding members decided that the EU shall have no competence to deal with IP rights under the EEC Treaty. This was enshrined in Articles 222 EEC⁸⁸ and 36 EEC,⁸⁹ whose contents essentially stipulated that the protection of IP rights justified derogation from the fundamental rules on the free circulation of goods. IP rights were thus perceived as a nationally defined restraint on internal trade and competition.

83 Art. 5(2) TEU.

84 Art. 2(1) TFEU.

85 Art. 2(2) TFEU.

86 Art. 2(5) TFEU. Also *see*, Justine Pila and Paul Torremans, 'The Foundations of European Union Intellectual Property Law', in Justine Pila and Paul Torremans (eds), *European Intellectual Property Law* (Oxford: Oxford University Press, 2016), pp. 47-48.

87 Pila and Torremans, *ibid.* p. 40; Bentley and Sherman, *above n 5*, p. 11; Piet Eeckhout, *EU External Relations Law*, (New York: Oxford University Press, 2011), p. 11 (Emphasis added).

88 Now, Art. 345 TFEU: 'The Treaties shall in no way prejudice the rules in the Member States governing the systems of property ownership'.

89 Now, Art. 36 TFEU.

However, developments at the time made one thing clear: IP rights had impact on the functioning of the internal market. Since the internal market is one of the shared competences of the EU,⁹⁰ the EU would rely on provisions from its treaties attributing it the power to regulate the internal market (and other general provisions) to legislate the field of IP. Commentators have noted that Article 95 EC (ex Article 100A EEC)⁹¹ and Article 308 EC (ex Article 235 EEC),⁹² among others,⁹³ served as the basis for the majority of the directives in this field and for the adoption of Community rights.⁹⁴ Relying on these provisions to regulate the field of IP resulted in approaching the subject from an *entirely economic perspective*, even though the essence of IP transcends that.⁹⁵ *This economic foundation strongly influenced most aspects of the EU's internal and external IP policy, and conditioned their evolution.*

With the entry into force of the Lisbon Treaty on 1 December 2009,⁹⁶ an entirely new development in terms of legal basis emerged. A new Treaty provision, Article 118 TFEU explicitly provides for the competence of the EU, in the context of the establishment and functioning of the internal market, to create European IP rights, to set up a uniform protection system, and to create centralized authorization, coordination and supervision arrangements.⁹⁷ This internal competence is a shared competence, allowing Member

90 Art. 4 TFEU.

91 Now, Art. 114 TEU. This Article permits the Union to act to approximate legislation with the object of the 'establishment and functioning of the internal market'.

92 Now, Art. 352 TFEU. This Article allows the Union to take measures when it is required to act in order to achieve one of the objectives of the Community, but where no explicit power has been granted.

93 Such as Art. 37 EC, now Art. 43 TFEU.

94 Pila and Torremans, above n 86, pp. 55-57; Christophe Geiger, 'The Construction of Intellectual Property in the European Union: Searching for Coherence', in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Cheltenham, UK: Edward Elgar Publishing, 2013), p. 7; Vincenzo Scordamaglia, 'The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights at European Regional Level', in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Cheltenham, UK: Edward Elgar Publishing, 2013), pp. 66-70.

95 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'A single Market for Intellectual Property Rights: Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe', Brussels, 24 May 2011 Publications Office of the European Union (2011) 287 final. Page 3 of this document observes that 'Intellectual property is indispensable to address the big challenges that mankind is facing in the 21st century such as: ensuring food security, containing climate change, dealing with demographic change and improving citizens' health'.

96 Consolidated Version of the Treaty on the Functioning of the European Union [2008] OJ C115/47 (TFEU).

97 Yole Tanghe, 'The Borders of EU Competences with Regard to the International Regulation of Intellectual Property Rights: Constructing a Dam to Resist a River Bursting Its Banks', 32 *Utrecht Journal of International and European Law* 82 (2016), p. 28; Scordamaglia, above n 94, p. 71.

State action in so far the Union has not exercised its competence.⁹⁸

Externally the Common Commercial Policy (CCP), which is the Union's external trade policy codified under Article 133 EC (ex Article 113 EEC), only contained a non-exhaustive list of examples of subjects belonging to the CCP but contained no clear definition of the boundaries of this policy.⁹⁹ For example, the provision did not specify the types of economic exchanges that would be covered by the CCP, and in particular, whether this competence extended beyond the traditional focus on trade in goods.¹⁰⁰ When the CJEU had the opportunity to clarify whether the scope of the CCP covered TRIPS, the Court said that apart from the provisions of the TRIPS Agreement which concerned the prohibition of the release into free circulation of counterfeit goods, IP was not included in the CCP.¹⁰¹ The Court observed that the internal harmonization of rules on IP at the time was subject to specific procedural rules involving unanimity and consultations with the European Parliament. Extending the scope of the CCP to the sphere of IP protection would effectively allow the EU to determine the content of internal legislation in the area through the backdoor,¹⁰² since it would be able to circumvent the much more cumbersome procedural rules applicable for the harmonization of EU legislation.¹⁰³

The exclusion of much of TRIPS from the scope of the CCP posed serious practical issues for the EU. As Araujo relates, if, for example, no consensus could be reached with regard to an area where competence was to be shared between the EU and the Member States, Member States could decide to act individually, thereby undermining the EU's unity of action and weakening its position in external trade relations.¹⁰⁴ This was the case with TRIPS. It was signed as a mixed agreement between the EU and Member States. It is no surprise that subsequent Treaty reforms in the EU all sought to expand

98 Art. 2(2) TFEU. The Court of Justice confirmed this in joined Cases C-274/11 and 295/11 *Kingdom of Spain v Council of the European Union* EU:C:2013:240.

99 Daniel Acquah, "Developments in the EU External IP and Trade Competence up to Lisbon: New Wine in Old Wine Bottles?", 5 *Nordiskt immateriellt Rättskydd* NIR (2011), p. 423-439 (Chapter II); Eeckhout, above n 87, pp. 12-13.

100 Araujo, above n 18, p. 51.

101 *Opinion 1/94*, EU:C:1994:384, para. 71.

102 For instance, by negotiating free trade agreements with intellectual property chapters.

103 *Opinion 1/94*, above n 101, paras. 59 and 60. Also, see Araujo, above n 18, pp. 52-53; Tuomas Mylly, 'Constitutional functions of the EU's intellectual property treaties', in Joseph Drexel et al. (eds) *EU bilateral trade agreements and intellectual property: For better or worse?* (MPI Studies on Intellectual Property and Competition Law, Springer-Verlag Berlin Heidelberg, 2014), pp. 253-256.

104 Araujo, above n 18, p. 53.

the scope of the CCP to cover TRIPS – starting with Article 133 EC, as defined first by the Treaty of Amsterdam and subsequently modified by the Treaty of Nice, and culminating in the new Article 207 of the TFEU.

i. Exclusive competence in the CCP

The Treaty of Lisbon transformed considerably the Treaty provisions on the CCP, both in terms of substance and decision-making mechanisms.¹⁰⁵ Besides reaffirming the CCP as the exclusive competence of the EU,¹⁰⁶ it also matched the CCP with the subject matter of the WTO agreements by introducing the commercial aspects of IP and trade in services into the CCP.¹⁰⁷ It therefore removed any references to the possible existence of shared competence in the CCP and reduced procedural exceptions to the EU's power to act externally.¹⁰⁸ This meant that not only will the Member States be absent in the negotiation and ratification of international agreements involving IP, but also that the effects of the agreement in question are determined solely by EU law and thus ultimately by the judgment of the CJEU.¹⁰⁹ Even though the commercial aspects of IP are not defined, this addition gives the CCP new meaning and weight as proven by the CJEU in the *Daiichi Sankyo case*.¹¹⁰ Contrary to Opinion 1/94, the Court ruled in this case that the entire TRIPS Agreement now fall under the exclusive competence of the CCP. In this case, the Court had been asked whether, in accordance with case law preceding the entry into force of the Lisbon Treaty,¹¹¹ Article 27 TRIPS regulating patentable subject matter remained a shared competence.¹¹² The Court reasoned that the TRIPS Agreement had specific links to international trade;¹¹³ and since the authors of the TFEU could not have been unaware of the fact that the 'commercial aspects of IP' correspond almost literally

105 Art. 207(2) TFEU now subjects the CCP to the ordinary legislative procedure, with full involvement of the European Parliament and the Council. The former Treaty versions did not provide for any legislative role for the European Parliament. Eeckhout, above n 87, p 57.

106 Art. 3.1(e) TFEU.

107 Art. 207 TFEU.

108 Araujo, above n 18, p. 54.

109 Mylly, above n 103, p. 245.

110 *Daiichi Sankyo and Sanofi-Aventis Deutschland*, C-414/11 EU:C:2013:520, para. 50.

111 *Merck Genéricos-Produtos Farmacêuticos* C-431/05 EU:C:2007:496, para. 33.

112 Araujo, above n 18, p. 55.

113 *Daiichi Sankyo*, above n 101, para. 53.

to the very title of the TRIPS Agreement, TRIPS fell within the scope of the CCP.¹¹⁴

By confirming that all subject matter under the WTO framework now falls within the exclusive competence of the EU, the Court gave the Union the leverage to push through its economic agenda on the international scene.¹¹⁵ Hence, it is now possible for the EU to introduce enhanced IP norms (or even substantively new IP norms) in its CCP agreements, in the absence of prior EU legislation.¹¹⁶ The EU thus possesses the exclusive power to harmonize IP through international treaties, though, strictly, it lacks a comparable internal exclusive power.¹¹⁷ Tuomas Mylly has argued that, international agreements such as the FTAs that are likely having the capacity to produce direct effect may have profound constitutional implications in that they may enable judicial review of secondary EU norms on IP and guide their interpretation.¹¹⁸ The EPAs, FTAs, and other similar international measures might thus freeze the development of internal EU IP law, at least to the extent that they contain detailed enough blueprints of existing EU IP norms.¹¹⁹ In this regard, the EU has been making efforts to bring into coherence its internal and external IP policy – with implications for access to medicines in developing countries.

The pulse of this exclusivity is, however, being tested again in Opinion 2/15.¹²⁰ The procedure follows the decision by the European Commission to delay the approval and ratification of the EU-Singapore FTA and to request an opinion of the CJEU on whether the EU has the competence to conclude the agreement alone. The case is pending before the CJEU; however, the Advocate General has delivered her Opinion.¹²¹ In her Opinion, the Advocate General reaffirmed the CJEU's decision in *Daiichi*, but also concluded that the Agreement must be signed jointly between the EU and Member States. Her explanation was that chapter 11 of the EU-Singapore FTA includes provisions on

114 Ibid, para. 61.

115 Mylly, above n 103, p. 248.

116 Ibid. (This might possibly exclude, for example, provisions on moral rights and detailed criminal law measures, as these are excluded from TRIPS. Thus, aspects of the intellectual property chapters of EU FTAs and EPAs should probably fall outside the EU's exclusive CCP competence under the Lisbon Treaty. However, Mylly has noted that this is typically not very problematic, as the EU's trade agreements are often broad in their scope and, in any case, might contain subject matter falling outside the EU's exclusive CCP competence).

117 Ibid.

118 Ibid. p. 256.

119 Ibid.

120 Commission Decision, requesting an opinion of the Court of Justice pursuant to article 218(11) TFEU on the competence of the Union to sign and conclude a Free Trade Agreement with Singapore, C(2014) 8218 final.

121 Opinion of Advocate General Eleanor Sharpston in Opinion 2/15, EU:C:2016:992.

moral rights, among others, which are clearly non-commercial. As far as that chapter applies to non-commercial aspects of IP, the competence of the EU for concluding those parts of that chapter cannot be based on Article 207(1) TFEU. Those parts of the chapter therefore fall within the shared competence of the EU and Member States.

It is yet to be seen what the Court will say. However, it is without doubt that this opinion may further clarify the scope and delimitations of the CCP. Importantly, the outcome of this case is likely to affect the EU—Canada Comprehensive Economic Trade Agreement (CETA) concluded on 26 September 2014. The signature, provisional application, and conclusion of CETA have sparked similar fierce political debate across the Union and its member states. The parties therefore opted to wait for the outcome of the Court's opinion on the EU's competence before proceeding with the ratification of the agreement. However, the European Parliament voted to pass CETA on 15 February 2017, which means, the Agreement can become provisionally effective as early as May.¹²² These FTAs, though not the focus of discussion in this thesis, presents a good example of how sensitive and interconnected matters relating to the EU's internal and external IP policy are, and what that can mean not just for the EU, but also, developing countries.

ii. Linking the internal and external

As the EU opens up its market, regulatory barriers to trade and investment in third countries has gained increasing importance. Despite close monitoring and border control measures, the safety and reliability of certain imports still raises concerns, while the number of counterfeited goods seized at EU borders is increasing.¹²³ To this end, the EU foresees that an effective means to block the flow of counterfeit goods and to foster its competitiveness will be to link its internal and external policies. The Union has therefore endeavoured to harmonize regulatory approaches at the internal level with high-quality rules and practices that can be effectively transported abroad to defend its interests.¹²⁴

122 European Parliament News: CETA: MEPs back EU-Canada trade agreement.
http://www.europarl.europa.eu/pdfs/news/expert/infopress/20170209IPR61728/20170209IPR61728_en.pdf

123 Commission Staff Working Document: 'The external dimension of the single market review' - accompanying document to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A single market for 21st century Europe, Brussels, 20 November 2007, SEC(2007) 1519, p. 8; DG TAXUD, 'Report on EU Customs Enforcement of Intellectual Property Rights: Results at the EU border 2015' (2016).

124 Global Europe Startegy, above n 39.

This policy aligns with the EU's objective of maintaining its place as a global economic actor. With the intensification of international trade, the centre of wealth creation has been gradually shifting from tangible assets to intangible assets. This naturally provoked a change in the focus of competition, which has become increasingly targeted at the competitive advantage derived from knowledge-based capital. In line with this trend, the EU made innovation-based comparative advantage and growth its new objective policy.¹²⁵ IP has therefore become a driving force for the internal market and central to the economic activity of the Union.¹²⁶ For this reason, infringement of IP rights within and outside the EU is taken seriously. The European Parliament (EP) noted in a Resolution that 'the biggest challenge for the internal market lies in combating infringements of IP rights at the EU's external borders and in third countries'.¹²⁷ The higher standards of protection and enforcement achieved within the EU are jeopardized if such rights remain unprotected and unenforced elsewhere. An integrated policy for the internal and external in the form envisioned in the Enforcement Strategy and the Global Europe Strategy therefore appears optimal.

In recent times, the link between the internal market rules on IP and the external approach has become so strong that even policy documents on specific internal market proposals now discuss at length issues related to the external dimension of IP rights.¹²⁸ An example is the Commission's document entitled 'A single Market for Intellectual Property Rights'. This Communication emphasized the need to especially focus on the international dimension of IP rights by recommending that in negotiating FTAs, the clauses on IP should provide, as far as possible, the same level of protection as that existing in the EU, taking into account the level of development of the countries

125 Communication from the Commission: Europe 2020 – A strategy for smart, sustainable and inclusive growth. Brussels, 3.3.2010 COM(2010) 2020.

126 Ibid; Also, see European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: The Digital Agenda for Europe, Brussels, 26 August 2010, COM(2010) 245 final. Also, a recent study by the European Patent Office and the Office for Harmonization in the Internal Market (Now, the European Union Intellectual Property Office) found that, during the period 2008-2010, intellectual property right-intensive industries generated almost 26 per cent of all jobs in the EU. Eighty-eight per cent of EU imports consisted of products of intellectual property rights-intensive industries while its export sector accounted for an even higher share of 90 per cent. See European Patent Office and the Office for Harmonization in the Internal Market, *Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union. Industry-Level Analysis Report* (September 2013). http://ec.europa.eu/internal_market/intellectual-property/docs/joint-report-epo-ohim-final-version_en.pdf (accessed 15 May 2017).

127 European Parliament resolution of 22 September 2010 on enforcement of intellectual property rights in the internal market (2009/2178(INI)).

128 Araujo, above n 37, p. 449.

concerned.¹²⁹ Despite reference to the level of development of the countries concerned in the latter, it is to be borne in mind that, often, the purpose of these Acts is for Europe's economic growth, its ability to lead the way in setting rules and standards worldwide that would facilitate European exports and ensure that imports meet necessary standards, and thereby, effectively protect European citizens.¹³⁰ To this end, it appears that the harmonization of the commercial aspects of IP is a higher priority for the EU at both levels than that of guarantees related to public health for developing countries.

Against this background, this thesis attempts to provide the first integrative¹³¹ analysis of how the EU's IP rule making at both the internal and external level affects developing countries' ability to utilize the flexibilities flowing from the TRIPS Agreement to promote public health and access to medicines. The central argument is that the EU's internal and external IP policy have developed in manners that are tightly intertwined and detrimental to developing countries' ability to promote public health and access to medicines. To date, the focus of much of the commentary on the question has related to the TRIPS Agreement's relation to FTAs, the role of patents, border measures (transit), the human rights to health, the EU and US policy towards FTAs, and what is called 'the EU's deep trade agenda'.¹³² However, most of these popular narratives focus on the

129 See Communication from the Commission to the European Parliament, above n 95, p. 21.

130 See Commission Staff Working Document, above n 123, p. 2.

131 By integrative analysis, I mean combining both the internal and external aspects of the EU's IP policy in relation to the question of access to medicines in developing countries.

132 See for example, Grosse Ruse – Khan, above n 11; Grosse Ruse – Khan, above n 22; Grosse Ruse – Khan, above n 26; Henning Grosse Ruse – Khan, 'A Trade Agreement Creating Barriers to International Trade?: ACTA Border Measures and Goods in Transit', 26 *American University International Law Review* No. 3 (2011), 645-726; Araujo, above n 18; Araujo, above n 37; Hoen, above n 58; Abbott, above n 66; Frederick M. Abbott, 'Review: the trilateral study on health, intellectual property, and trade: the virtue in paving a cleared roadway', 16 *Journal of International Economic Law* 2 (2013), pp. 493–503; Baker, above n 72; Josef Drexler, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds) *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (MPI Studies on Intellectual Property and Competition Law, Springer-Verlag Berlin Heidelberg, 2014); Carlos M. Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', *World Health Organization – Health Economics and Drug Series* No. 012 (2002); Cynthia M. Ho, 'Access to medicine in the global economy: international agreements on patents and related rights', (Oxford University Press, Oxford, 2011); Sean Flynn and Bijan Madhani, 'CTA and Access to Medicines', *PJIIP Research Paper Series Paper 22* (2011); Matthew Duncans, 'When Framing Meets Law: Using human rights as a practical instrument to facilitate access to medicines in developing countries', *Queen Mary University of London, School of Law Legal Studies Research Paper* No. 92 (2011); Cindy Bors, Andrew Christie, Daniel Gervais, and Ellen W. Clayton, 'Improving Access to Medicines in Low-Income Countries: A Review of Mechanisms', 18 *The Journal of World Intellectual Property* 1-2 (2015); Xavier Seuba, 'Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border', *ICTSD Programme on IPRs and Sustainable Development Issue Paper* No. 27 (2010); Rochelle Dreyfuss and César Rodríguez-Garavito (eds), 'Balancing Wealth and Health The Battle over Intellectual Property and Access to Medicines in Latin America', (Oxford University Press, Oxford, UK, 2014); Susan Sell, 'Trips-Plus Free Trade Agreements and Access to Medicines', 28 *Liverpool Law Review* (2007); Joint Agency Briefing Paper: *HAI EUROPE and OXFAM*, 'Trading Away Access to Medicines Revisited: How the European Trade Agenda Continues to Undermine Access to Medicines', (Sept. 2014), pp. 1-39.

FTAs negotiated between the US and third countries. Those that cover the EU either are limited in scope, or are often, position papers by advocacy groups that do not cover in detail the question of access to medicines in developing countries as this thesis does.¹³³ More importantly, none of the existing studies so far combined the internal and external dimensions of the EU's IP policy in investigating the subject.¹³⁴ The unique combination of the normative regimes¹³⁵ offers innovative perspectives on the question.

Importantly, this thesis breaks new ground by proposing an analytical framework for studying the question of IP and access to medicines in developing countries: it problematizes the issue in the context of postcolonial theory. This theory, which is explored in more detail in Section B, is rooted in the idea that the EU's imposed model of IP, whose role in national development is measured only by its welfare-generating outcomes (economic growth), and not by its distributional effects, has contributed to the status quo. Taking the lead from scholars of postcolonial theory,¹³⁶ this thesis shows that the complicity of colonial relations is a vital tool in understanding the contemporary debate about IP and development (public health). Public health is in this sense explored as a developmental question. On this basis, the argument is made that the development of this body of law has been complicit in legitimizing the economic control of developing countries at the expense of their development. This may explain why 15 years on after the Doha Declaration, the question of access to medicines is still on the table.

This research brings fresh perspective to the discussion on the effects of the EU's IP policy on developing countries concerning the issue of access to medicines in ways distinct from the traditional approach used in the academic literature. The integrative approach further demonstrates that it is not only the external action of the EU that

133 Ibid. *HAI EUROPE and OXFAM* Joint briefing.

134 To the knowledge of the present author, only two books came close: that of Billy M. Araujo (*see above* n 18), and Joseph Drexel et al (*see above* n 132). But then again, both employ a unilateral approach. Araujo's book focuses exclusively on the EU's deep and comprehensive FTAs, specifically analyzing the investment, intellectual property, public procurement and competition chapters. Drexel et al edited book discuss the relationship between the intellectual property chapters of the EU FTAs with the WTO TRIPS, and other international law regimes such as human rights law in the broader sense, but with no specific focus on access to medicines.

135 The term 'normative regime' refers to groupings of norms of different bases. According to the International Law Commission, the notion of regime refers to 'whole fields of functional specialization, of diplomatic and academic expertise'. International Law Commission, *Fragmentation of International Law: Difficulties arising from the diversification and expansion of international law*, A/CN.4/L.682, 13 April 2006, par. 129. The normative regimes in this context are the EU internal norms, and the free trade agreements.

136 Arturo Escobar, 'Encountering Development: The Making and Unmaking of the Third World', (Princeton, Princeton University Press, 1995); Edward Said, 'Orientalism', (New York: Vintage Books, 1978); Gayatri Chakravorty Spivak, 'A Critique of Postcolonial Reason: Toward a History of the Vanishing Present', (Cambridge, Mass. Harvard University Press, 1999); Joanne Sharp, and John Briggs, 'Postcolonialism and Development: New Dialogues?' 172 *The Geographical Journal* 1 (2006).

can affect a developing country's ability to promote access to medicines; its internal rules, such as the EU's Customs Regulation, can in certain instances, impact developing countries as well. This novel approach permits to wholly explore the 'constitutional' limitations that this normative order places on national legal reforms and judicial interpretations intended to control socially harmful effects of IP. More specifically, the thesis will answer the research questions explained in the following Section.

3. Research questions and conceptual framework

The overarching research question is how the EU's rule making on IP, both at home and abroad, impacts developing countries' ability to utilize the flexibilities flowing from the TRIPS Agreement to promote public health and access to medicines. The main question can be divided into sub-questions. The first one relates to whether and how developments in the EU internal and external IP policy are interlinked and how they negatively affect access to medicines in developing countries. The second one concerns to what extent post-colonialism, EU constitutional law, legal transplants and the political economy of IP rights have influenced the development of EU IP policy, and whether that leaves a 'middle way' in striking a fair balance between IP and public health? The latter question is all the more important because, as already mentioned above, the EU has in recent times taken steps to balance IP and public health in its FTAs, and internally through its secondary legislations. However, this gesture has been criticized as empty due to the inclusion of counter IP norms in the same treaties.¹³⁷ The above research questions are further contextualized and explored in the thesis' chapters as follows:

1. Common Commercial Policy

The European Commission has over the years attempted to amend the CCP from Nice and Amsterdam to Lisbon to include TRIPS - stronger IP protection.

- a. Did the scope of the CCP to cover TRIPS expand in the Amsterdam and Nice inter-governmental conferences?
- b. Did the Lisbon Treaty lead to such a redesign in EU trade policy in order for it to become competitive on the global trade landscape?

¹³⁷ See *HAI EUROPE and OXFAM* Joint briefing, above n 132.

- c. Why did the Treaties of Maastricht, Amsterdam and Nice to some degree, fail to achieve what Lisbon achieved?

2. Customs regulation I (old and new regulations) and trademarks

The EU has updated its customs regulation and trademark rules – how has the impact on access to medicines changed?

- a. Do the former EU Customs Regulation and the proposed EU trademark rules adequately balance IP and access to medicines? In what ways do they stifle access?
- b. Does the new EU Customs Regulation appropriately balance IP and access to medicines?
- c. What should be done to strike a (more) appropriate balance between IP and public health?

3. Customs regulation II (New Regulation, enforcement, transplant)

Integration at EU's borders has become tighter in practice. How does the changes made to the EU's new Customs Regulation become integrated or impact the internal legal order of developing countries?

- a. In what ways is the EU exporting these rules into developing countries?
- b. How can improved and strong border enforcement rules contribute to limiting access to medicines in the EU and outside the EU?

4. FTAs – patent protection

EU has started to integrate tougher IP norms in its FTA. What are the patent related rules on pharmaceuticals in FTAs and how do they affect access to medicines?

- a. What are the typical patent related provisions in FTAs?
- b. Are they (patent term extension and data exclusivity regimes) in EU FTAs TRIPS compliant or even more stringent than TRIPS?
- c. What are the implications on developing countries?

5. FTAs – balancing the IP and public health aspects

EU integrates both IP and public health (development objectives) in FTAs – at least in

theory. Is the balancing of IP and public health in EU FTAs successful?

- a. What are the public health clauses integrated into FTAs?
- b. How do they interact with IP provisions? Are there contradictions?
- c. To what extent can this contradiction function to impede efforts at balancing IP and public health, especially, in the implementation of the FTA?

As can be seen, the EU's IP policy towards developing countries and its concomitant effects on their public health policies has been conceptualized as comprising two distinct but intertwined normative regimes – the internal and external. The internal regime has been construed to include the external aspects of the EU's internal regulation such as the Customs Regulation. The reason for this is that even though the Customs Regulation is an external-oriented policy of the EU, it mostly consists of the adoption of an internal legislation, without the participation of third countries. Its categorization under EU law as external is therefore relevant for the purposes of allocation of competences. The external regime refers to all aspects of IP agreements that the EU engages with third countries. These regimes are 'sites of governance'¹³⁸ the EU uses in the pursuit of its IP (economic) interest. Four legal sets of rules constituted and utilized by the EU at these sites of governance in pursuit of its economic interest are analysed in this research: the EU Customs Regulation and EU trademark rules (internal), the TRIPS Agreement and EU bilateral FTAs (external). As this thesis argues, the policies formulated at these levels are strongly influenced by a post-colonialist, economic approach.¹³⁹ To this end, the rules emanating from such regimes tend to be responsive to private ordering, while the distribution of access is jeopardized. Thus, the conceptual framework of research could be summarized in the following figure:

138 See Francis Snyder, 'The EU, the WTO and China: Legal Pluralism and International Trade Regulation', (Hart Publishing Ltd, UK, 2010).

139 See Section B below for information on the other theoretical approaches used in this research.

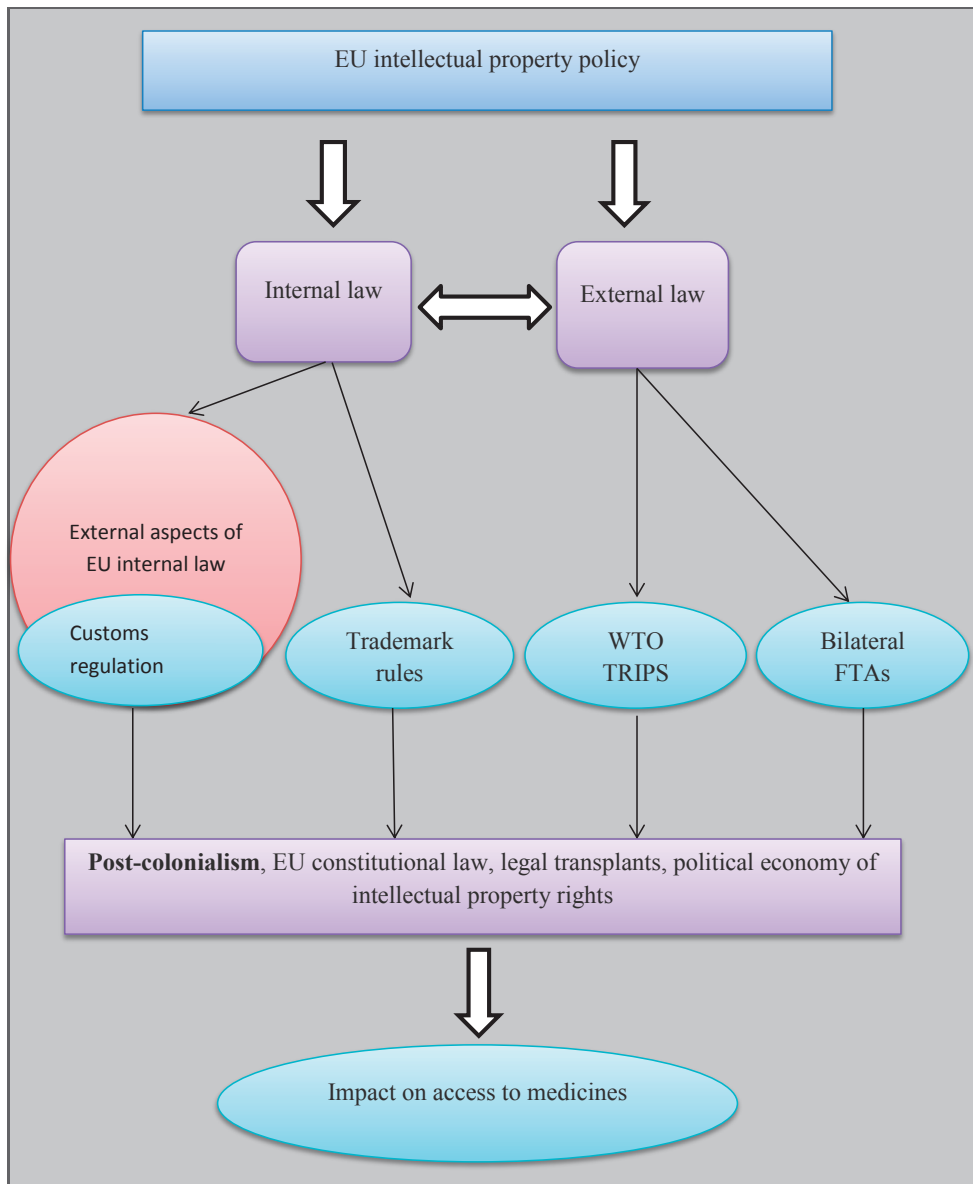


Figure 1.3 *Conceptual framework*

4. Scope and significance of the research

At face value, the title of this thesis looks broad. The challenge was what to include and exclude, considering the broadness of the concepts of IP, developing countries and development – especially, in the absence of any clear guiding principles within IP that truly address the central concerns of development. However focusing on the second part of the title, it became apparent to focus on what developmental question was currently pressing and posed a huge challenge not just for developing countries, but also for the international IP system. In the context of the current debate on IP in which IP is viewed as reflecting fundamentally binary and opposing positions of ‘right holders’ and ‘users’ and of ‘developed’ and ‘developing countries’, the issue of access to medicines appeared most timely. This thesis investigates the matter by focusing on the interfaces between the protection of pharmaceutical patents, data exclusivity, patent term extension, enforcement issues (mostly, border enforcement) and public health. These fields have been chosen because they are the ones that affect access to medicines most. The thesis provides an integrative account (see normative framework in figure 1.4 below) of the effects these norms can have on national development objectives of developing countries. Thus, *it frames the obstacles to development created by these norms in the context of access to medicines.*

The analysis is done from the perspective of selected developing countries (ACP countries,¹⁴⁰ Peru, Colombia and Korea)¹⁴¹ utilizing postcolonial theory, as well as some supplementary theories, as tools for the analysis. The findings emanating from this analysis are capable of being generalized for all developing countries and Least Developed

140 The African, Caribbean and Pacific Group of States (ACP) is an organization created by the Georgetown Agreement in 1975. It is composed of 79 African, Caribbean and Pacific states, with all of them, save Cuba, signatories to the Cotonou Agreement, also known as the ‘ACP-EU Partnership Agreement’ which binds them to the EU. There are 48 countries from Sub-Saharan Africa, 16 from the Caribbean and 15 from the Pacific. <http://www.acp.int/content/secretariat-acp>.

141 For the EPA between the EU-CARIFORUM, *see* above n 51; for the EU-Peru-Colombia FTA, *see* above n 52; for the EU-Korea FTA, *see* above n 46. These treaties are chosen for analysis because, in terms of the EU’s trade relations with developing countries, these are the most recent, concluded, and operative. These particular countries and organization have been chosen because the EU has entered into some form of bilateral agreement with them. According to the latest country classification by the Development Policy and Analysis Division (DPAD) of the Department of Economic and Social Affairs of the United Nations Secretariat (UN/DESA), Peru, Colombia, the CARIFORUM countries, and Korea are all developing countries. *See* http://www.un.org/en/development/desa/policy/wesp/wesp_current/2014wesp_country_classification.pdf (visited 6. 3. 2016).

Countries (LDCs).¹⁴² The underlying theme of the research is that strict and enhanced IP regimes are not conducive for promoting access to medicines (for that matter, development) in developing countries. In order to address the broader development and public health concerns of developing countries, something needs to change in regard to the posture of current international IP negotiation. This research therefore proffers some practical and theoretical means of addressing this challenge. To this end, questions about proposals or lines of action to develop or promote access to medicines in other normative regimes such as WIPO¹⁴³ and the World Health Organization (WHO),¹⁴⁴ or actions of not-for-profit drug development organizations working to fill gaps in drug development for certain neglected diseases are beyond the scope of this research – although references can be made to them.

The topic is significant both from a practical and theoretical perspective: the EU utilizes bilateral trade agreements (with IP chapters) and its internal secondary legislation to control and regulate developing countries in excess to the already far-reaching multi-lateral measures, such as the TRIPS Agreement.¹⁴⁵ These aggressive IP policies represent a continuation of past colonial policies in another form. Mostly driven by economic imperatives, this approach places a ‘one-sided’ emphasis on utility maximization,¹⁴⁶ which tends to favour countries with established industries and compounds a bias towards measuring the development effects of IP solely through economic growth¹⁴⁷ – thereby suppressing social welfare maximization. This is happening at a time when most developing countries are still struggling to provide adequate health care for their citizens in the form access to affordable medicines and health technologies. Yet, it is also the time

142 I say so with the understanding that the levels of economic, political and social development among developing/ least developed countries vary. It is also a fact that there are sharp variations in the levels of implementation of the TRIPS Agreement by the countries falling into this category. However, the choice of countries utilized in this research seems to take into account these various distributions. It is therefore likely that the problems identified are similar and, thus, the findings emanating capable of being generalized.

143 See the WIPO Development Agenda. <http://www.wipo.int/ip-development/en/agenda/>.

144 See World Health Organization: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. http://www.who.int/phi/implementation/phi_globstat_action/en/.

145 Through the agency of TRIPS, all 164 Member States of the WTO should have patent laws by now. This was not the case prior to the TRIPS Agreement.

146 This comes from the assessment of intellectual property through its instrumental goal – the promotion of ‘progress’ – which is dominated by the assumption that pure wealth or utility maximization serves adequately to evaluate social welfare. Chon, above n 23, p. 2823. Citing James Boyle, ‘The Second Enclosure Movement and the Construction of the Public Domain’, 66 *Law & Contemporary Problems* 33, 41 (2003).

147 Chon, above n 23, p. 2826. Citing Richard Peet with Elaine Hartwick, ‘Theories of Development 7 (1999), p. 13.

when spectacular progress has been made in medical innovation.¹⁴⁸ The present situation is exactly what led the United Nations (UN) Secretary-General Ban Ki-moon to convene a High-Level Panel on Access to Medicines with a remit to ‘review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.’¹⁴⁹ The findings in this report support the bases of this thesis.

This research should be useful for legislators, policymakers, the judiciary, teachers of IP, public health advocates, the pharmaceutical industry, students, lawyers and other professionals working in this field. For legislators, policymakers and the judiciary – who day in and day out are confronted with questions about the appropriate balance between IP and access, this research can offer multiple examples and guidance on how to strike a fair and appropriate balance in their policymaking, decision making or judgments. That is to say, this research may for example, lead to legislative, treaty-based and or interpretative renewals of the relevant norms. For other stakeholders, it would bring them up to speed with current happenings in this field within international IP, the EU, and the way forward.

5. Chapter outline

This thesis is divided into two main parts. Part I, including this introduction, presents an overview of the research topic and the conceptual framework. It further elaborates the theoretical framework of the research, its themes, and connects the chapters while also filling some of the key gaps between them. Part II comprises five chapters, each of them also an independent essay discussing particular aspects of the research topic, and ends with the conclusions.

Part I is divided into 4 Sections. Section 1 provides the background of the study, introduces the conceptual and normative framework of the research, and spells out the research questions. It further describes the scope and significance of the research, and ends with an outline of Sections. Section 2 follows with an account of the ‘main’ background theory and analytical framework utilized in this research. It also explores the narratives on the contribution of the EU towards the negotiation of TRIPS, the TRIPS

148 See Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines, above n 62. p. 13 ff.

149 See <http://www.unsgaccessmeds.org/the-process/>. For the outcome of this Panel, *see* *ibid*.

Agreements' outcome and implementation, and how that has informed EU IP policy – both at home and abroad. Section 3 elaborates on the intersection between IP and development, and the role post-colonialism plays in this. Section 4 presents an overview of the normative framework, and then follows with a summary of the individual essays in Part II. Part II comprise of five chapters, each of them published as independent essays in different journals in the field of IP, examining different aspects of the research topic, and projecting the thematic, theoretical and normative framework of the thesis. The final Chapter, which is the conclusion, ends by integrating the findings of the individual chapters back into the overall analytical framework and narrative of the research.

B. Background theories

The analytical and methodological approach utilized in this research draws on critical theory, especially postcolonial theory as articulated by international relations scholars and political sociologist.¹⁵⁰ It also utilizes EU constitutional law, political economy of IP rights, and comparative law approach (legal transplants) as background theories constituting a part of the main theoretical framework – postcolonial theory. The reason for choosing these approaches is rooted in the fact that an analysis of the effects of the EU's internal and external IP policy on third countries necessarily means having to deal with questions related to EU constitutional law, the political economy of IP rights and legal transplants – as it involves political and economic bargains, and transfer of norms. The constitutional dimension results from having to investigate the source of the EU's power to act internally and externally in the field of IP. The political economy underlying the EU's IP policy foregrounds the extent to which powerful interest groups, such as pharmaceutical multinational companies (MNCs) influenced and shaped the political dynamism underlying the IP system in Europe and on the international stage.¹⁵¹ This theme echoes in most chapters of this thesis.

150 Despite being the main analytical framework, a comprehensive review of post-colonial theory, even in the specific field of intellectual property, is beyond the scope of this thesis. What is presented here, therefore, is a general overview. For detail readings, refer to the various literature cited. I also try to focus the discussion in this section on patents as much as possible. However, there are times that it becomes necessary to refer to other intellectual property rights or Conventions as examples.

151 See Meir Perez Pugatch, 'The International Political Economy of Intellectual Property Rights', (Edward Elgar, Cheltenham, UK, 2004); Susan K. Sell, 'Private Power, Public Law: The Globalization of Intellectual Property Rights', (Cambridge University, 2003); Peter Drahos and John Braithwaite, 'Information Feudalism: Who Owns the Knowledge Economy?', (New Press, New York, US 2003).

Arguably, the international harmonization of IP through institutions such as TRIPS and subsequent bilateral FTAs externalizes legal transplants. The latter has therefore become a fertile technique to adopt new norms or amend existing ones in the area of IP law.¹⁵² This phenomenon becomes particularly puzzling when the transplantation happens in situations of asymmetric interests, that is, in situations in which the interests of the adopting state conflict with those of the state in which the rule originated.¹⁵³ The lack of relation of the transplanted norm to the local context is what actually brings about the challenges highlighted in Chapters V and VI of this thesis. Since the above approaches (with the exception of postcolonial theory) are well discussed in sections of this thesis,¹⁵⁴ what follows will concentrate on postcolonial theory.

Legal instruments from the EU, mostly, EU secondary legislation, Commission documents (White papers, Green papers etc.), CJEU case-law, the WTO Agreements (Mostly TRIPS), and bilateral treaty agreements between the EU and selected developing countries (see scope of research above), are the primary sources for this research. Secondary sources consisted of legal scholarship, and the research also utilized case-law and discussion from other legal systems, notably the US, as possible ideas and ways to balance the arguments in this research. This is necessary in order to appreciate the transnational and global nature of the research problem.

1. Postcolonial theory

Postcolonial theory is an approach particularly interested in the ways in which current arrangements can be critiqued from the point of view that they reflect and maintain colonial relations, and in particular, are complicit in subordinating, or silencing peoples from the 'global south'.¹⁵⁵ For proponents of this theory, colonialism did not end with

152 Pedro Roffe and Xavier Seuba, 'ACTA and the International Debate on Intellectual Property Enforcement: Framing the Enforcement Debate', in Pedro Roffe and Xavier Seuba (eds.), *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath* (Cambridge University Press, New York, 2015), p. 12; Peter, K. Yu, 'Currents and Crosscurrents in the International Intellectual Property Regime', 38 *Loy. L.A. L. Rev.* (2004).

153 Jean-Frédéric Morin and E. Richard Gold, 'An Integrated Model of Legal Transplantation: The Diffusion of Intellectual Property Law in Developing Countries', 58 *International Studies Quarterly* 4 (2014), p. 782.

154 For EU constitutional law, see for example, Section I.A.2 above. For legal transplants, see especially, Chapters IV, V and VI; and for political economy of intellectual property rights, see this Section B.

155 R. L. Doty, *Imperial Encounters: 'The Politics of Representation in North-South Relations'* (University of Minnesota Press, Minneapolis, 1996); B. Rajagopal, *International Law From Below: Development, Social Movements and Third World Resistance* (Cambridge, Cambridge University Press, 2003); Robert Cryer et al, 'Research Methodologies in EU and International Law', (Hart Publishing, 2011), pp. 69-72.

the decolonization process of the 1950s and 1960s; instead, it continued in a new form of domination – neo-colonialism.¹⁵⁶ Post-colonialism therefore commences by noting that capitalist development and colonial conquest or domination was coeval historical processes that were and are intimately related.¹⁵⁷ In this regard, growth through the project of economic globalization has always been highly unequal, producing prosperity for the few and immiserization for the many.¹⁵⁸ Post-colonialism therefore contests the claim that free-market ideology is a natural commonsense and that it produces prosperity or improved lives for all.¹⁵⁹

For scholars of post-colonialism, post-independence development policies have become mechanisms of control that are just as pervasive and effective as their colonial counterparts.¹⁶⁰ In this thesis, post-colonialism is construed as a mind-set or an ideology that underlies the IP policies of the EU (as a collective supranational organisation), and not the individual Member States. This aligns with the argument in this section that the reluctant participation, and yet, firm incorporation of developing countries into the international IP system can be attributed to the colonial roots and neo-colonial structures of this body of law.¹⁶¹ Three phases of the participation of developing countries in the international IP system illustrate this claim: the colonial period, the decolonization

156 The term 'neo-colonialism' is believed to have been coined by the first President of Ghana, Osagyefo Dr. Kwame Nkrumah in his book entitled: 'Neo-Colonialism, The Last Stage of Imperialism', (Thomas Nelson & Sons, Ltd., London, 1965). (Published in the USA by International Publishers Co., Inc., 1966). According to Kwame Nkrumah, 'the methods of neo-colonialists are subtle and varied. They operate not only in the economic field, but also in the political, religious, ideological and cultural spheres. Faced with the militant peoples of the ex-colonial territories in Asia, Africa, the Caribbean and Latin America, imperialism simply switches tactics [...] This means, so it claims, that it is 'giving' independence to its former subjects, to be followed by 'aid' for their development. Under cover of such phrases, however, it devises innumerable ways to accomplish objectives formerly achieved by naked colonialism. It is this sum total of these modern attempts to perpetuate colonialism while at the same time talking about 'freedom', which has come to be known as neo-colonialism. For the sake of simplicity, I will use the terms 'post-colonialism' and 'neo-colonialism' interchangeably in this thesis.

157 Sankaran Krishna, 'Globalization and Postcolonialism: Hegemony and Resistance in the Twenty-first Century', (Rowman & Littlefield Publishers Inc, 2009), pp. 3-4.

158 Ibid.

159 Ibid. p. 4.

160 Said, above n 136.

161 Alexander Peukert, 'The Colonial Legacy of the International Copyright System', forthcoming in: Mamadou Diawara and Ute Rösenthaler (eds), *Staging the Immaterial. Rights, Style and Performance in Sub-Saharan Africa* (Oxford, Sean Kingston, 2012), p. 3; Ruth L. Okediji, 'The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System', *Singapore Journal of International & Comparative Law* 7 (2003).

period, and the period of the Uruguay Round of trade negotiations leading to the WTO TRIPS Agreements.¹⁶² These are discussed in turn.

i. The colonial period

As a relatively recent legal innovation, the Western concept of privately held rights over IP had no local cultural or legal roots in most developing countries.¹⁶³ Commentators recount that the first formal encounters between developing countries, Western concepts of IP, and international IP rules began during the colonial era.¹⁶⁴ However even before the consolidation of colonial rule in developing countries, direct contact between Europeans and non-Europeans through trade had necessitated some form of pre-colonial commercial legal arrangements.¹⁶⁵ Colonization formalized these laws through imposition.¹⁶⁶ However the experiences of developing countries in regard to the development of IP law varied according to time and the approach of the colonizer. In Latin America and the Caribbean, the establishment of national IP laws began in the wake of independence from the Spanish and Portuguese in the early nineteenth century.¹⁶⁷ In Africa, Asia and the Pacific, the formal introduction of IP laws began later in the nineteenth century, and were undertaken by European colonial powers – with Britain and France being the major ones.

162 Carolyn Deere, 'The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries', (Oxford University Press, New York, 2009). For alternative periodization's, see Okediji, above n 161. p. 320 ff; Peter Drahos, 'The Universality of Intellectual Property Rights: Origins and Development', *WIPO* 8. http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf.

163 Deere, *ibid.* p. 35. (Emphasis added).

164 *Ibid.*; Peukert, above n 161; and Okediji, above n 161.

165 Richard Roberts and Kristin Mann, 'Law in Colonial Africa', in Richard Roberts and Kristin Mann (eds), *Law in Colonial Africa* (Heinemann: James Curry, 1991), pp. 11–24.

166 Okediji, above n 161; Deere, above n 162; Okechukwu T. Umahi, 'Access to Medicines: the Colonial Impacts on Patent law of Nigeria', *SSRN* (2011). http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1975928.

167 In this regard, several countries in this region promulgated formal intellectual property laws far earlier than other developing countries and indeed earlier than many developed countries. For instance in 1809, Brazil followed England, the United States, and France, to become the fourth country to adopt an industrial property law. In 1832, the first Mexican industrial property law was passed (replacing Mexico's first ordinance on industrial property established in 1820 by a Spanish court decree). By the 1850s, eight Latin American countries had formal intellectual property laws, several decades before some developed countries took similar action. See Deere, above n 162.

Britain transplanted its IP laws to its colonies, sometimes supplemented by local ordinances.¹⁶⁸ For example, under British colonial rule, India acquired a patent law in 1856. Similarly, the British Parliament passed the Gold Coast (now Ghana) Patent Ordinance in 1899¹⁶⁹ – modelled on the British Patents, Designs and Trade Marks Act 1883.¹⁷⁰ This Ordinance was replicated in other British West African colonies. Its replication in other colonies and protectorates, however, raised questions about its benefits since the legislation was not meant to spur local innovation, research and development, or transfer of technology, which would have enhanced access to medicines.¹⁷¹ Similarly, France and other European colonial powers¹⁷² extended their IP laws to their colonies. For instance, until 1962, French laws governed patent rights in the majority of francophone African countries, and the French National Institute for Intellectual Property (INPI) served as the central IP authority.¹⁷³ In so doing, customary institutions of the colonized were disregarded by the colonial powers – albeit on varying levels. In addition, colonial legal systems failed to tailor laws to build the innovation and technological capacity of their colonies or to develop local expertise on IP among the colonized.¹⁷⁴

In the late nineteenth century, a distinct legal development on IP happened at the international level that would impact developing countries as well. Countries which were net exporters of IP began to seek international agreements for the protection of IP, as it had become obvious that transnational commercial activities required more than mere national IP protection. Initial agreements included mainly European countries, most of whom were then major colonial powers (United Kingdom, France, Germany, Spain, Italy and Belgium). The first agreement was the Paris Convention and the second

168 Roberts and Mann, above n 165, pp. 11-24; Tshimanga Kongolo, 'Historical Developments of Industrial Property Laws in Africa', 5 *The WIPO Journal* 1 (2013), p. 105; Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', 5 *The Journal of World Intellectual Property* 5 (2005), p. 766 ff.

169 See Gold Coast Patent Ordinance 1899, No. 1 of 1899.

170 Sipa-Adjah G. Yankey, 'International Patents and Technology Transfer to less Developed Countries', (Grower Publishing Co., Avebury, 1987), p. 100. (Citing the Board of Trade's letter dated 16 May 1898 in C.O. 96 Gold Coast 1898, Vol. xx, 329).

171 Umahi, n 166 above, pp. 7-8.

172 Such as Germany, Belgium, Spain and Portugal.

173 Deere, above n 162, p. 2.

174 Ibid. (Explaining that in francophone Africa, France supplied legal experts and expertise from the *métropole*, devoting little attention to training colonial subjects in matters of legal administration in general and far less in the area of intellectual property. While the British had a greater emphasis on socializing the legal profession in its colonies and generating an English legal culture, this practice rarely extended to the realm of intellectual property, which remained largely administered from London. India, however, was a notable exception in that colonial administrators did take measures to foster the development of a cadre of local intellectual property experts.

was the Berne Convention.¹⁷⁵ The two fundamental principles of these conventions have been to provide for certain minimum rights and to guarantee that all right holders protected under the treaties enjoy in all countries of the two Unions the rights which national laws grant to their respective natives (National Treatment).¹⁷⁶ These principles have remained key cornerstones of the international IP system to date – as they have been replicated in all major international IP conventions.¹⁷⁷

In the absence of their colonies and without their consent, the contracting European countries decided to incorporate their colonial territories into the new IP Unions as ‘Countries of the Union’ without being regarded members thereof.¹⁷⁸ The precise method of utilizing this procedure comprised two steps. The first entailed the submission, by the colonizing state, of a declaration of the application of the applicable international agreement to the colonized state. Declarations of the application of the Berne Convention were made in accordance with Article 19 of the original text of the convention.¹⁷⁹ Declarations of the applicability of the Paris Convention were made in terms of Article 16 *bis* (1)-(2) of the London Act of 1934 and the Lisbon Act of 1958 of the convention.¹⁸⁰ Today, this provision can be found in Article 24 of the 1979 Act of the convention – albeit in a refined language. This procedure was further adopted in Article XIII of the 1952 Universal Copyright Convention (UCC)¹⁸¹ and in Article 27 of the 1961 International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations.¹⁸²

175 See above n 30. Although the Berne Convention focuses on copyright, it is appropriate to mention it here as an important part in the development of this body of law.

176 Art. 2 Paris Convention and Art. 5 Berne Convention.

177 For example, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention); the World Intellectual Property Organization Performance and Phonograms Treaty (WPPT); the World Intellectual Property Organization Copyright Treaty (WCT); the Universal Copyright Convention (UCC); and the WTO TRIPS Agreement.

178 Peukert, above n 161, p. 9 ff. It should be noted that this procedure was mostly utilized in the Berne Convention, for that matter, copyright. However, as noted, it applied in the case of patents as well.

179 Tshimanga Kongolo, ‘Historical Evolution of Copyright Legislation in Africa’, 5 *WIPO Journal* 2 (2014), p. 165 ff.

180 *Ibid.*, p. 115.

181 http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=172836. The Universal Copyright Convention (UCC), adopted in Geneva in 1952, is one of the principal copyright conventions. It was developed by the United Nations Educational, Scientific and Cultural Organization (UNESCO) as an alternative to the Berne Convention for those countries that disagreed with aspects of the Berne Convention, but still wished to participate in some form of multilateral copyright protection. The UCC was responsive to the specific needs of developing countries but also stressed the fundamental principle of exclusive copyrights.

182 http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=289795.

Second, the declaration of applicability of the international conventions was then followed by the extension of the colonizing states copyright or patent legislation to the colony, or the enactment of legislation applicable only to the colonized territory (some examples of which were mentioned earlier).¹⁸³ This act of incorporating the colonies made it possible for right holders from the Member Countries to enjoy protection not only within Member Countries of the Unions, but in all overseas territories. Such actions would lay the foundations for an enduring influence on legal and economic developments in developing countries and on how law and development is perceived and understood.

ii. The decolonization period

The decolonization process in the 1950s and 1960s subjected the fate of the numerous contracts between post-colonial states and private investors from European countries to the mercy of transnational law.¹⁸⁴ As newly independent states moved to promulgate national IP laws, one question that arose was whether the new states had to formally accede to the IP Unions or whether they were already members of the club. Two parallel developments can be identified during this period: first, the action taken by the newly independent states in crafting their national IP laws; and second, the action taken by the former colonial powers to ensure stability and continuity of their colonial agenda.

Action taken by the newly independent states: After independence, most developing countries emerged with weak institutions, fragile governments and little or no expertise on IP – based on the system of IP laws that were instituted during colonialism. Many of these states therefore maintained strong legal and policy links with their former colonizers: IP laws promulgated post-independence closely resembled earlier colonial laws, while adhering to relevant international agreements upon which they were based. For example, in many African countries, governments reregistered patents already approved in the United Kingdom, often irrespective of whether such patents were consistent with their new national patent laws.¹⁸⁵ As late as 2012, Sierra Leone had no provision in na-

183 Kongolo, above n 179, p. 106; Caroline B. Ncube, 'Intellectual Property Policy, Law and Administration in Africa: Exploring Continental and Sub-regional Co-operation', (Routledge, Oxon, 2016), p. 3.

184 Prabhakar Singh and Benoît Mayer, 'Critical International Law: Postrealism, Postcolonialism, and Transnationalism', (OUP, India, New Delhi, 2014), p. 12.

185 Tshimanga Kongolo, 'The African Intellectual Property Organizations: The Necessity of Adopting One Uniform System for All Africa,' 3 *Journal of World Intellectual Property* 2 (2000), pp. 269-70.

tional law for the registration of new patents; rather patent applications had to be filed in the UK.¹⁸⁶ In Lesotho, Britain's 1919 Patents, Trademarks, and Designs Protection Proclamation operated until 1989. Likewise, Mauritius continued to rely on the French Trademarks Act (1968) and Patents Act (1975) for over twenty years after independence.¹⁸⁷ What this meant was that IP laws instituted post-independence were not well adapted to the needs, priorities and situations of developing countries.¹⁸⁸

In the Americas and some Asian countries, however, the situation was different. Decolonization sparked efforts by countries to substantially revise their IP laws and related policies in advancing national interest and development. These countries adopted IP policies with the vision of building domestic industrial capacity and shifting their comparative advantage in the international economy.¹⁸⁹ India, for instance adopted a new Patent Law in 1970, after two national expert reports on appropriate reforms to its patent system.¹⁹⁰ This new law allowed patents on the methods or processes related to new medicines but not on medicines themselves. It also limited the term of patents in areas of social concern, such as food and health, to seven years (in contrast to fourteen years for other invention), including for pharmaceutical processes. This law then became the legal foundation for India's generic drug industry.¹⁹¹

Other larger developing countries followed suit. In the 1970s, Brazil, Argentina, Mexico and the Andean Pact countries all passed laws that saw patent rights in the pharmaceutical area weakened.¹⁹² Brazil, for instance, did not permit patents on chemical

186 Swedish International Development Cooperation Agency Supplementary Contribution to the WTO Global Trust Fund: 'Factual overview on technical & financial cooperation for LDCs related to the TRIPS Agreement: Identifying and responding to individual priority needs of LDCs', (May 2013), p. 20.

187 Mauritius gained independence in 1968.

188 An exception to this in Africa was Ghana, which enacted its first post-independence Copyright Act in 1961 and chose to accede to the Universal Copyright Convention (UCC) in 1962 instead of the Berne Convention, to which it only acceded in 1991. *See* Ncube, n 183 above.

189 Common strategies adopted by countries like Argentina, Brazil, Colombia, Mexico, and Peru included import controls to protect domestic markets, subsidies to channel investment into new sectors, regulations on foreign investment to spur backwards linkages and technology transfer, and the reform of IP regimes to make modern technologies cheaper and foreign innovations more widely available. Specific IP reforms included restrictions on the private rights of (largely foreign) patent holders and licensing practices that were more favourable to local producers. For more on these countries and their strategies post-independence, see Deere, above n 162, p. 39.

190 Drahos, above n 162, p. 767; Pedro Roffe, 'The Political Economy of Intellectual Property Rights: A Historical Perspective', in J. Foudez, M. Footer, and J. Norton (eds.), *Governance, Development and Globalization*, (London: Blackstone Press, 2000), pp. 396–413.

191 Drahos, above n 162, p. 768; S., Vedaraman, 'The New Indian Patents Law,' 3 *International Review of Industrial Property and Copyright Law* (1972), pp. 39–54.

192 Drahos, above n 162, p. 768.

products or on pharmaceutical and nutritional processes and products until 1996.¹⁹³ While some of these countries delayed their adherence to international IP Conventions due to skepticism, an increasing number of them joined existing Conventions. By 1973, developing country membership of the Paris Convention had reached forty-four.¹⁹⁴ This led to a certain voice from the developing country side which advanced for reforms in international IP regulation.¹⁹⁵ Such actions on the part of developing countries would not go down well with the developed countries and their MNCs, particularly, the pharmaceutical companies.¹⁹⁶ They would act quickly to ensure that steps taken by countries such as India, Brazil, Argentina, and Mexico to lower IP protection would not set a precedent for other countries to follow.¹⁹⁷

Action taken by the former colonial powers: Various legal and political efforts were undertaken to stabilize the foundations of the colonial IP regime during the decolonization period. Fearing that the international IP system might break down, the United International Bureaux for the Protection of Intellectual Property (BIRPI) – in charge of administering the Berne and Paris Unions, moved swiftly to facilitate a system whereby newly independent states in Africa and Asia that were no longer bound by Berne's colonial clause could issue 'declarations of continued adherence'.¹⁹⁸ Many developing countries declared their adherence to or acceded to the Berne Convention.¹⁹⁹ In the area of patent law, BIRPI did not assume that newly independent states were still bound by colonial obligations.²⁰⁰ Instead, it came out with a Model Law in 1964, whose emphasis

193 Gontijo, C., 'Changing the Patent System: From the Paris Convention to the TRIPS Agreement – The Position of Brazil,' *Global Issue Papers*, Berlin: Heinrich-Böll Stiftung (2005).

194 Deere, above n 162, p. 41.

195 For instance, in 1961, Brazil proposed for a study on patents and developing countries at the UN General Assembly which resulted in a General Assembly Resolution calling on the UN Secretary General to prepare a study that would include analysis of the effects of patents on developing country economies and a survey of patent legislation. The 1964 report highlighted a range of challenges for developing countries with respect to the patent system but fell short of calling for an international conference to examine problems related to patents.

196 This was so because, for instance, when Mexico entered into the manufacture of steroids in the 1960s, it contributed to the end of the European cartel that had dominated production up until then. See G. Gereffi, 'The Pharmaceutical Industry and Dependency in the Third World', (Princeton University Press, New Jersey, 1983).

197 Deere, above n 162, p. 47.

198 Sam Ricketson, 'The Berne Convention for the Protection of Literary and Artistic Works: 1886–1986, (London: Kluwer Centre for Commercial Law Studies, 1987). pp. 799-806.

199 Peukert, above n 161; Ncube, above n 183; Deere, above n 162; and Kongolo, above nn 179 and 185.

200 Bodenhausen, Georg H.C., 'Guide to the Application of the Paris Convention for the Protection of Industrial Property', *Geneva: United International Bureaux for the Protection of Intellectual Property (BIRPI)*, p. 19.

was on inventions for developing countries.²⁰¹ This model law had been drawn in response to pressure from industrialized nations for developing countries to join the ‘community of nations’ in the Union. Just as the case of copyright, many developing countries modelled their patent and design laws on BIRPI’s Model Law.²⁰²

In Africa, for example, regional arrangements facilitated the enduring influence of former colonial powers on IP laws. In 1962 the French National Patent Rights Institute and BIRPI assisted twelve former French colonies to create the African and Malagasy Patent Rights Authority (OAMPI), establishing a unified IP system with a central patent office.²⁰³ OAMPI was therefore the first regional agreement to create a common patent office with a centralized procedure for granting patents. Today, this organization is the Organization Africaine de la Propriété Intellectuelle (OAPI) and has 16 Member States.²⁰⁴ OAPI Member States all subscribe to uniform IP laws contained in the Bangui Protocol and its Annexes.²⁰⁵

For English-speaking Africa, WIPO and the United Nations Economic Commission for Africa (UNECA) moved the agenda forward for the creation of an Industrial Property Organization (ESARIPO) in 1970, when responding to a formal request from Anglophone African countries for assistance.²⁰⁶ The UNECA and WIPO served jointly as the Secretariat of ESARIPO until 1981 when the organization established an independent Secretariat. This organization today is the African Regional Intellectual Property Organization (ARIPO) and has 19 members.²⁰⁷ While the OAPI system serves as the equivalent of a regional IP law for most aspects of IP and derives primarily from French IP laws, the ARIPO system co-exists with the national IP laws in its member states and draws primarily from British IP law.²⁰⁸ A visit to the webpages of these insti-

201 United International Bureaux for the Protection of Intellectual Property (BIRPI), Model Law for Developing Countries on Inventions, *BIRPI Pub.* no. 801(E) (1965); Suzanne F. Greenberg, ‘The WIPO Model Laws for the Protection of Unpatented Know-How: A Comparative Analysis’, 3 *International Tax and Business Law* 52 (1985), p. 54.

202 Umahi, above n 166, p. 5.

203 See Deere, above n 162, p. 38. Citing Cazenave, B., ‘The African Intellectual Property Organisation (OAPI): From Libreville to Bangui’, *Industrial Property: Monthly Review* (1989).

204 They are: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d’Ivoire, Gabon, Guinea, Equatorial Guinea, Mali, Mauritania, Niger, Guinea Bissau, Senegal and Togo.

205 Tshimanga Kongolo, ‘African Contributions in Shaping the Worldwide Intellectual Property System’ (Routledge 2013), p. 83.

206 This history draws from ARIPO’s website: <http://www.aripo.org/about-aripo>.

207 They are Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, São Tomé and Príncipe, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

208 Deere, above n 162, pp. 38-39.

tutions reveals the scope of their services, which, in many ways, aligns with international standards, and puts the two institutions on a ‘catching up’ path with the more advanced IP offices.

Meanwhile globally, a network of international organizations continued to promote the idea of IP internationally. WIPO,²⁰⁹ the UCC, the WTO TRIPS, and other regional groupings, such as the EU, have since been at the forefront of propagating this Western model of privately held rights over IP in the form of providing technical assistance to former colonies on IP matters, including model drafts for appropriate IP legislation.²¹⁰ The policy of technical assistance is often criticized for introducing levels of IP protection that are mostly inappropriate for the socio-economic development of developing countries.²¹¹ For example, the EU has been criticized for using technical assistance programmes as a way to export its IP standards, even to LDCs.²¹² A recent WIPO Patent Cooperation Treaty (PCT) working paper also noted that developed countries ‘help’ developing countries build capacity by training their patent examiners, either at WIPO or by hosting trainees in their patent offices.²¹³ As Drahos has shown, either way, the training process socializes these new examiners into the practices of high-protection countries and tends to bias their decision-making.²¹⁴

209 WIPO has contributed significantly to expanding IP’s empire. Since the Convention establishing WIPO in 1967, the organization has risen from administering the Paris and Berne Conventions to administering 26 treaties today. <http://www.wipo.int/treaties/en/>. Besides, WIPO signed a cooperation agreement with the WTO to assume the obligation of providing technical assistance to developing country WTO Members on TRIPS matter. See *Agreement between the World Intellectual Property Organization and the World Trade Organization*, 1995, Art. 4.

210 Peukert, above n 161, p. 19.

211 Health Action International (HAI) and Médecins Sans Frontières (MSF), ‘Empty gestures: The EU’s commitments to safeguard access to medicines: Review of the European Union’s Trade & Investment Policy’, (September 2015), p. 6.

212 Ibid. (Citing the controversial EU funded Uganda IP Enforcement Counterfeit Goods Bill of 2010. This proposed law threatened access to life-saving generic medicines by defining counterfeiting so broadly that it criminalized the production and importation of generic medicines. The financing of this project was part of Uganda’s implementation of the economic partnership agreement (EPA) between the EU and East African countries. Uganda, being an LDC, was under no obligation to implement TRIPS, let alone implement TRIPS-plus IP enforcement standards as envisaged in the (now rejected) draft Counterfeit Goods Bill.

213 WIPO, Patent Cooperation Treaty (PCT) Working Group, Training of Examiners, PCT/WG/9/18 (Arl 26, 2016); Rochelle Dreyfus, ‘Harmonization: Top Down, Bottom Up—and Now Sideways? The Impact of the IP Provisions of Megaregional Agreements on Third Party States’, in Benedict Kingsbury, David Malone, Richard B. Stewart, and Atsushi Sunami (eds), *Contested Megaregulation: Global Economic Ordering After TPP* (forthcoming, Oxford University Press, 2017); Peter Drahos, ‘The Global Governance of Knowledge: Patent Offices and their Clients’ (CUP, Cambridge 2010).

214 Dreyfus, above n 213. Citing Peter Drahos, ‘Trust Me: Patent Offices in Developing Countries’ 34 *American Journal of Law & Medicine* (2008), pp. 151-74.

WIPO's development-friendly approach to IP standard setting which eventually led to the adoption of a Development Agenda²¹⁵ is an exception in this regard, as it specifically seeks to promote technical assistance, capacity building, technology transfer, flexibilities in international IP and access to knowledge, among others, in developing countries. However, commentators have noted that the advocacy of WIPO toward the interests of developing countries is compromised by its heavy reliance on the management of the PCT, primarily by pharmaceutical, agricultural, and financial service industries, which constitute 90 percent²¹⁶ of WIPO's budget.²¹⁷ WIPO has also been criticized for 'creating and expanding monopoly privileges in developing countries, often without regard to the consequences that may arise such as social and economic costs that hamper and threaten creativity and innovation' instead of enhancing it.²¹⁸ This is borne from its mandate in the WIPO-WTO Cooperation Agreement, which require WIPO to provide legal and technical assistance to developing country WTO Members on TRIPS matters whether or not those countries are members of WIPO.²¹⁹ Obviously, the way to help these countries avoid the WTO dispute settlement system is to leverage faster compliance and higher standards than TRIPS requires.²²⁰ This puts WIPO in a compromised position.

Commentators are therefore doubtful whether issuing IP laws in developing countries and LDCs, based on WIPO's recommendations, have resulted in any kind of economic, social, cultural, or political development in these countries.²²¹ It thus appears that the strategies put in place during the decolonization period by the developed countries

215 <http://www.wipo.int/ip-development/en/agenda/recommendations.html>.

216 WIPO, Program and Budget for the 2014/15 BIENNIUM (December 12, 2013), p. 17. http://www.wipo.int/export/sites/www/about-wipo/en/budget/pdf/budget_2014_2015.pdf.

217 Sell, above n 151, p. 175; Rami M., Olwan, 'Intellectual Property and Development: Theory and Practice', (Springer-Verlag Berlin Heidelberg 2013), p. 54.

218 Consumer Project on Technology (now Knowledge Ecology International), 'The Geneva Declaration on the Future of the World Intellectual Property Organization', (October 2000). <http://www.cptech.org/ip/wipo/future-of-wipodeclaration.pdf>. See also the Geneva Declaration on the Future of WIPO: <http://www.futureofwipo.org/futureofwipodeclaration.pdf>; Michael Blakeney and Getachew Mengistie, 'Intellectual Property and Economic Development in Sub-Saharan Africa' 14 *Journal of World Intellectual Property* (2011), pp. 238, 247.

219 See WIPO-WTO Agreement, above n 209.

220 Drahos, above n 162, p. 777.

221 Debora Halbert, 'What if WIPO Never Existed?', (November 2008) *Copysouth*, https://www.researchgate.net/publication/292966927_What_If_WIPO_Never_Existed. She investigated whether being a member of WIPO has helped LDCs (mainly Chad and Mali) to gain economic development and spur domestic innovation and foreign investment. She found that WIPO has neither been necessary nor sufficient for economic development and spurring foreign investment or domestic innovation in these countries.

‘skillfully obscured the substantive retention of the indices of colonial rule’.²²² As TRIPS is now the centrepiece of the global system of rules, institutions and practices governing IP, and one of the key treaties that this thesis focuses on, it may be instructive to now pay attention to its formation, implementation and subsequent TRIPS Plus developments, and how that was informed by, and contributes to the post-colonial argument.

iii. Developing country resistance, the Uruguay Round and TRIPS

Against the backdrop of series of actions taken by the developed countries (some of which are noted above), developing countries led by Brazil (in the field of patent) and India (in the field of copyright), began to call for reforms to the international patent and copyright system in the 1960s and 70s. Even though these efforts at reforms were considered generally unsuccessful,²²³ developing countries achieved a ‘package deal’ at the Paris Revision Conference on the Berne Convention in 1971. A special provision regarding developing countries was provided for in an Appendix to the Convention (Article 21 BC 1971).²²⁴ However, the provisions are more restrictive, and the procedures to grant such a compulsory license are extremely complicated.²²⁵ In addition, developing countries succeeded in pushing for the incorporation of the principle of special and differential treatment, and other provisions designed to favour them in the General Agreement on Tariffs and Trade (GATT) through the United Nations Conference on Trade and Development (UNCTAD).²²⁶ To the dismay of the developed countries, the growing numbers of developing country membership at WIPO and other fora such as the UCC and UNCTAD had meant that they faced the problem that developing country blocs could defeat their proposals on IP. For example, developing countries frustrated the US effort to include an anti-counterfeiting code to deal with cross-border infringements of IP during the Tokyo Round of GATT (1973-79).²²⁷

222 Okediji, above n 161, p. 330.

223 Drahos, above n 162, p. 768.

224 Developing countries are allowed to issue compulsory licenses for translations and reproductions, mostly for the purpose of teaching, scholarship or research. Similar provision appeared in Articles *Vbis* to *Vquater* UCC.

225 Peukert, above n 161, p. 21; Drahos and Braithwaite, above n 151, p. 77 ff.

226 Deere, above n 162, p. 43.

227 Drahos and Braithwaite, above n 151, p. 109 ff.

With the rising voice of developing countries on the international stage, amidst rising competition from cheaper products produced in newly industrializing countries in East and Southeast Asia, such as Korea and Taiwan,²²⁸ developed countries launched an economic and diplomatic counteroffensive to strengthen international IP protection in the 1980s.²²⁹ Considerable advances in information and communication technology during this period had meant opportunities for international trade in information goods. At the same time, this development enabled possibilities for imitation, copying and unauthorized use of technology. This was so despite the fact that the Paris and Berne Conventions were in operation. A study undertaken by WIPO in 1988 for the negotiating group that was dealing with TRIPS in the Uruguay Round showed that the Paris Convention did not stand in the way of States adopting quite different standards of industrial property protection.²³⁰ Of the ninety-eight developed and developing country members of the Convention, forty-nine excluded pharmaceutical products from protection, forty-five excluded animal varieties, forty-four excluded methods of treatment, forty-four excluded plant varieties, forty-two excluded biological processes for producing animal or plant varieties, thirty-five excluded food products, thirty-two excluded computer programs, and twenty-two excluded chemical products.²³¹

Pharmaceutical companies in the developed world, facing competitive threats from cheaper generic versions of medicines from India, Mexico and elsewhere complained about the narrow scope and short term of patent protection in many developing countries, lack of transparency in the patent granting process, and limited legal security in respect of the enforcement of patent rights.²³² They expressed concern that competitors were 'free-riding' on their R&D investments and that stronger IP rights were central to their business model both at home and abroad. An account on TRIPS has it that, like-minded leaders of major US corporations mobilized to consolidate a US agenda for a trade-based conception of IP rights and to integrate IP into international trade.²³³

228 Fred C. Bergsten, 'The Threat from the Third World,' *Foreign Policy* 11 (1973), pp. 102–24.

229 Deere, above n 162, p. 46.

230 Drahos, above n 162, p. 768. Citing the WIPO Report: Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, WO/INF/29, September 1988 (MTN.GNG/NG11/W/24).

231 Ibid.

232 Deere, above n 162, p. 47.

233 Sell, above n 151; Drahos and Braithwaite, above n 151. Key actors included the International Intellectual Property Alliance, the Pharmaceutical Manufacturers Association, the Chemical Manufacturers Association, the National Agricultural Chemicals Association, the Motor Equipment Manufacturers Association, the Auto Exports Council, the International Anti-counterfeiting Coalition, and the Semiconductor Industry Association.

These MNCs felt that the only way their government could help halt the imitation and reverse engineering abroad was to link IP to trade. They believed that the inclusion of a multilateral IP agreement in the GATT system would enable the US to use trade remedies to push for stronger IP enforcement. This idea was sold to the US government by a group of twelve CEOs of MNCs,²³⁴ which resulted in reforms to US trade law – giving US corporations greater access to, and influence on the US trade policy-making process.

By this time, the US had lost confidence in WIPO as the prime forum for negotiation of international IP rules and for improving their enforcement.²³⁵ It therefore worked to enlist the support of the EU and Japan in building a case for stronger IP rights, and why IP negotiation should be shifted from WIPO and be included in the Uruguay Round of negotiations leading to the WTO Agreements.²³⁶ Three factors motivated the US and EU to shift IP lawmaking from WIPO to GATT. First, compared to WIPO and other UN fora, developing countries were poorly organized in the GATT context. Second, the GATT negotiation process would give the EU and US the possibility to leverage progress on their international IP agenda in exchange for movement on developing country market access priorities. Lastly, the inclusion of TRIPS in the GATT system would enable both the EU and US to use trade remedies to push for stronger IP enforcement.²³⁷

Initially, the developing countries resisted. However, the combined efforts of the US and EU (through unilateral and bilateral measures) would force developing countries to give in to TRIPS being part of the WTO Agreements. In what commentators refer to as carrot and stick diplomacy, the US and EU worked to dilute opposition to negotiations in Geneva by forcing domestic IP reforms at the national level in developing countries

234 Ibid.

235 John Braithwaite and Peter Drahos, 'Global Business Regulation', (Cambridge: Cambridge University Press, 2000), p. 566. Noting that negotiations in WIPO followed the one-state-one-vote rule and 'so the US could never expect to get its way on intellectual property issues through a voting contest'.

236 Drahos, above n 162, p. 769; Deere, above n 162, p. Susan K. Sell, 'TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TTP', 18 *Journal of Intellectual Property Law* (2011).

237 Deere, above n 162, p. 51; Laurence R. Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking', 29 *Yale Journal of International Law* (2004), pp. 19-20.

and isolating the most defiant countries.²³⁸ TRIPS therefore became part of the package of trade law that entered into force in 1995 with the creation of the WTO. The shift in IP negotiation from WIPO to the WTO has had unanticipated effects on international IP negotiations.²³⁹ Since the entry into force of TRIPS, there has been an explosion of interest in IP issues in a broad array of international fora such as: the World Health Organization (WHO), the World Food Organization (FAO), the Convention on Biological Diversity's Conference of the Parties and the Commission on Genetic Resources for Food and Agriculture, the United Nations Commission on Human Rights and its Sub-Commission on the Promotion and Protection of Human Rights.²⁴⁰ These have been complemented by bilateral FTAs, regional and megaregional agreements.

Lawrence Helfer describes this strategy as 'regime shifting'.²⁴¹ Through this strategy, countries and their allies shift IP negotiations to international regimes whose institutions, actors, and subject matter mandates are more closely aligned to their interest. According to Helfer, powerful nations are likely to be adroit regime shifters in the area of IP. Benvenisti and Downs corroborate this claim. They argue that the active regime-shifting activities and the growing complexity of the international IP regime may harm less developed countries more than they harm their developed counterparts.²⁴² They describe three ways in which the growing proliferation of international regulatory institutions with overlapping jurisdictions and ambiguous boundaries can help powerful states to preserve their dominance in the international arena. First, by creating institutions along narrow, functionalist lines and restricting the scope of multilateral agreements, it limits the opportunities for weaker actors to build the cross-issue coalitions that could

238 An example is the use of Section 301 of the US Trade and Tariff Act, authorizing the US administration to link its trading partners' trade benefits to performance in the area of intellectual property protection. The US also used the Generalized System of Preferences (GSP) Renewal Act as one of the criteria governing the eligibility of countries for GSP treatment of their exports to the US. The Act authorized the President to withdraw GSP tariff concessions from a developing country considered to have 'weak' intellectual property protection. The final straw was the introduction of the Special 301 provisions which instructed the USTR to remedy 'unfair' trade practices through the use of monitoring and the threat or actual imposition of trade sanctions. For action of the EU, see n 245 below. This combined force of unilateral pressures worked. Between 1985 and 1995, at least eighteen developing countries undertook reforms to strengthen patent protection, namely Argentina, Bangladesh, Benin, Brazil, Burkina Faso, Chile, China (twice), Colombia, Ecuador, Indonesia, the Republic of Korea, Malaysia, Mali, Mexico, Paraguay, Peru, Thailand, and Venezuela. For details on these unilateral and bilateral measures, see Deere, above n 162, p. 48 ff; Drahos above n 162, p. 772 ff.

239 Helfer, above n 237, pp. 4-6.

240 Ibid. (Emphasis added).

241 Ibid. p. 14. He defines regime shifting as an attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another. According to Helfer, both state and non-state actors, strong and relatively weak parties can engage in forum shifting.

242 Eyal Benvenisti and George W. Downs, 'The Empire's New Clothes: Political Economy and the Fragmentation of International Law', 60 *Stanford Law Review* 2 (2007).

potentially increase their bargaining power and influence. Second, the ambiguous boundaries and overlapping authority created by fragmentation dramatically increase the transaction costs that international legal bodies must incur in trying to reintegrate or rationalize the resulting legal order. Third, by suggesting the absence of design and obscuring the role of intentionality, fragmentation frees powerful states from having to assume responsibility for the shortcomings of a global legal system that they themselves have played the major role in creating. The result is a regulatory order that reflects the interests of the powerful that they alone can alter.²⁴³

According to Benvenisti and Downs, ‘powerful states are drawn to this strategy because they know that weaker states are not only more numerous than they are, but they are also far more diverse with respect to size, wealth, and their level of development’.²⁴⁴ This weakness in the camp of the developing countries played to the advantage of the EU and US during the Uruguay Round. This somehow affirms the argument in this thesis that the EU’s role in the negotiation of TRIPS, as well as subsequent bilateral treaties and regional measures are informed by a neo-colonialist economic agenda – the implications of which is the lack of access to medicines. The next section explores the role of the EU in the formation of TRIPS and its subsequent implementation.

2. The role of the EU in the formation of TRIPS

Buoyed by the success of the internal market as well as benefits reaped from external trade liberalization, the EU became one of the staunchest proponents of the Uruguay Round negotiations, and for the inclusion of TRIPS.²⁴⁵ When faced with initial resistance from the developing countries, the EU would follow the US strategy of carrot and stick diplomacy by reforming its trade law to include provisions protecting IP – creating a Special ‘301’-style new CCP instrument to protect European commercial interests in 1984.²⁴⁶ This Regulation ‘empowered the European Commission to engage in trade

²⁴³ Ibid.

²⁴⁴ Ibid. p. 610.

²⁴⁵ Araujo, above n 18, p. 30; Cohn, T., ‘Securing Multilateral Trade Liberalisation: International Institutions in Conflict and Convergence’, in J. Kirton and M. Von Furstenberg (eds), *New Directions in Global Economic Governance: managing globalisation in the twenty-first century* (Aldershot: Ashgate, 2001), pp. 205–7. Due to word and space requirement, this section will stick to narratives about the role of the EU in the formation of TRIPS and not go into particular details on all the areas of TRIPS – for example, substantive issues or enforcement.

²⁴⁶ Drahos and Braithwaite, above n 151, p. 121; Council Regulation (EEC) No 2641/84 of 17 September 1984 on the strengthening of the common commercial policy with regard in particular to protection against illicit commercial practices, (OJ L 252/1).

retaliation against illicit commercial practices (defined as violations of ‘international law or generally accepted rules’) by non-EU countries that affected EU economic interests’.²⁴⁷ The EU used this new instrument against Thailand and Indonesia for record piracy and suspending Korea’s trading privileges for failures in IP protection for European businesses.²⁴⁸ In contrast to US practice, however, the EU instrument focused primarily on violations of obligations in international treaties, such as the Berne and Paris Conventions.²⁴⁹

Having said this, it is important to note however that the EU was initially less keen on trying to harmonize IP standards through the trade regime. Having had difficulties trying to harmonize IP standards in Europe, the EU would rather prefer pressing on with initiatives on counterfeiting in the GATT.²⁵⁰ It took a coalition of business interests from the US, Europe, and Japan, called the Intellectual Property Committee (IPC) to submit a comprehensive draft of a proposed TRIPS text to their governments in 1988²⁵¹ before any progress could be made. This proposal swept away the idea that the negotiations would be confined to border control issues and the problem of counterfeiting. The IPC followed with a consensus-building effort to garner the support of the US, the EU, and Japan in promoting this draft.²⁵² The draft proposal therefore represented a ‘multilateral blueprint’ for the trade negotiators.²⁵³

In March 1990, the EU was the first participant in the TRIPS negotiating group to submit its own complete legal draft of an agreement on TRIPS.²⁵⁴ The Union of Industrial and Employers’ Confederations of Europe (UNICE), which had collaborated with the IPC on the need for global protection of IP, influenced this draft proposal. Drahos and Braithwaite recount that when UNICE was given an opportunity to comment on the EU’s negotiating position and drafts, UNICE produced a position paper arguing that the EU’s approach was ‘deemed too narrow by European industry’ and that the

247 Deere, above n 162, p. 50.

248 Drahos and Braithwaite, above n 151, p. 121.

249 Deere, above n 162, p. 50.

250 Ibid. pp. 117-123.

251 See Intellectual Property Committee (IPC), ‘Basic Framework of GATT Provisions on Intellectual Property,’ *Statement of Views of the European, Japanese and United States Business Communities*, Washington, DC, (1988).

252 Deere, above n 162, p. 53.

253 Drahos and Braithwaite, above n 151, p. 123. (Quoting Edmund Pratt, then CEO of Pfizer).

254 See Communication from the Commission: Follow-Up to the Green Paper, Working Programme of the Commission in the Field of Copyright and Neighboring Rights, COM(90)584 final, p. 22; Also, Guidelines Proposed by the European Community for the Negotiations on Trade-Related Aspects of Intellectual Property Rights, GATT Doc. MTN.GNG/NG11/W/16 (Nov. 20, 1987).

‘scope of the negotiations must be broadened’ to include other areas of IP where European industry was making heavy R&D investments.²⁵⁵ ‘In the following months this became the position of EU negotiators’.²⁵⁶ A Communication by the European Commission titled ‘Follow-Up to the Green Paper, Working Programme of the Commission in the Field of Copyright and Neighboring Rights’ appears to testify to this fact. It notes that:

On this draft the Commission has received on the whole very positive reactions, including from among developing countries. Thus, the Community has become a leading force in its commitment to the highest possible level of intellectual property protection, particularly in the field of copyright and neighbouring rights.²⁵⁷

To buttress this point, Al J. Daniel Jr. has indicated that the Dunkel proposals on enforcement of IP rights, which was part of the *Draft Final Act*²⁵⁸ proposed in December 1991 by Arthur Dunkel, then Director-General of the GATT, appears to have been derived largely from a draft agreement tabled by the EU.²⁵⁹ Al J. Jr. notes that a comparison of the Dunkel Draft with the Final Act reveals that all of the enumerated articles in the TRIPS Agreement – including those on trade in counterfeit goods in the Dunkel Draft – remained in the Final Act. There were exceedingly few changes in the text.²⁶⁰ Similarly, Marius Schneider and Olivier Vrans have pointed out that the first generation of the EU’s Border Measures Regulation, Council Regulation 3842/86,²⁶¹ served as a

255 Drahos and Braithwaite, above n 151, p. 128. Citing the UNICE Position Paper, ‘GATT and Intellectual Property’, 12 May 1987, p. 2.

256 Ibid. (Emphasis added).

257 Communication from the Commission, above n 254, p. 22.

258 Al J Daniel Jr., ‘Intellectual Property in the Uruguay Round: The Dunkel Draft and a Comparison of United States Intellectual Property Rights, Remedies and Border Measures’, 25 *NYU Journal of International Law and Politics* (1992–1993), p. 754. Citing the *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (Annex II)*, GAIT Doc.MTN.TNG/W/FA (Dec. 20, 1991).

259 Ibid.

260 Ibid.

261 See above n 41.

model for the elaboration of the corresponding provisions of the TRIPS Agreement²⁶² (although the TRIPS border measures focus almost exclusively on importation issues).²⁶³

Furthermore, the provisions on the protection of geographical indications (GIs) in the Dunkel Draft are among those said to have derived primarily from the EU proposal.²⁶⁴ Even though GIs are not the focus of this thesis, it deserves mention because GIs have been noted as perhaps the most ‘European’ of all IP rights²⁶⁵ – as it occupies a special place in EU external trade policy. Equally, GIs are considered the best legal tool for the protection of goods in developing countries. They can be utilized as tools for sustainable development capable of protecting traditional knowledge and promoting local community production.²⁶⁶ The EU’s particular interest in GIs relates to the economic value attached to European GIs. Europe is home to many reputed GIs such as Bordeaux wines, Scotch whisky, Feta Cheese, and Parmigiano Reggiano, among others. ‘The global recognition and protection of GIs would allow the EU to differentiate the myriad of agricultural products (wines, spirits, and foodstuff) developed in Europe over time from those produced by competitors and would stop other countries from usurping their regional names and free riding on the reputation and quality of their products’.²⁶⁷

The same applies to developing countries. An example is the South African Rooibos or the Phu Quoc fish sauce of Vietnam. In the absence of legal protection, GIs would lose their economic value: their reputation will be undermined, become generic, and create consumer confusion on the nature and characteristics of the product.²⁶⁸ The EU’s call for the inclusion of GIs in TRIPS was, however, contested by the US, Canada and Australia. These countries traditionally protected GIs through a mixture of consumer protection laws and trademark law.²⁶⁹ As producers of goods whose manufacturing practices and know-how had been imported from Europe, these countries did not look

262 Marius Schneider and Olivier Vrins, ‘Regulation (EC) 1383/2003’ in Marius Schneider and Olivier Vrins (eds), *Enforcement of Intellectual Property Rights Through Border Measures: Law and Practice in the EU* (2nd edn, OUP 2012) 107.

263 Art. 51 TRIPS only stipulates the obligation for Member States to have in place customs measures for imported goods that are counterfeit and for pirated goods.

264 Al J Jr., above n 258, p. 779.

265 Araujo, above 18, p. 145.

266 See Kaitlin Mara, ‘Advocates Say Geographical Indications will Benefit Developing Countries’ IP WATCH (11.07.2011).

267 Araujo, above n 18, p. 145.

268 Ibid.

269 Ibid. p. 146.

kindly upon the recognition of GIs in the context of the WTO.²⁷⁰ In the end, TRIPS protected GIs as a separate category of IP but allowed member states the freedom to determine the kind of GI regime they wanted. The EU has since called for enhanced levels of GI protection. Developing countries support this.

The protection of patents was another area that the EU made significant input, and acted as a sort of ‘check and balance’ to the US position (philosophy) – endorsed by its Supreme Court then that ‘everything under the sun made by man’ is patentable.²⁷¹ On the one hand, the Member States of the EU, which were also members of the European Patent Convention (EPC) were bound by provisions of the EPC expressly prohibiting the grant of patents on plants and animal varieties, as well as provisions prohibiting the grant of patents on inventions that contravene morality.²⁷² For this reason, the EU advocated for provisions on patent that would not lead to any difficulty in implementation. On the other hand, European industry players had been unhappy with aspects of US patent law, especially, the first-to-invent patent policy that they found to be discriminatory. They somehow thought that ‘TRIPS might give them the opportunity to fix the problem’, and it did.²⁷³ With the support of Canada and Japan, the final TRIPS provisions on patents turned out to be more flexible than originally advocated by the US²⁷⁴ (although developing countries resented the patenting of pharmaceuticals).

Finally, the EU is noted to have supported India’s bid for the inclusion of a provision for the grant of compulsory licenses subject to certain conditions being met. This was out of India’s understanding of the importance of a compulsory license provision to the pharmaceutical sector in developing countries. Sensing a loss in the battle over the patenting of pharmaceuticals,²⁷⁵ India drafted and tabled a provision with a more permissive language for compulsory licenses. This draft eventually made it into TRIPS with the support of the EU.²⁷⁶ In this regard, concerning certain issues, the EU was seen more as an ally than foe to the developing world. This approach of the EU somehow presented

270 Emily C. Credit, ‘Terroir vs. Trademarks: The Debate over Geographical Indications and Expansions to the TRIPS Agreement’ 11(2) *Vanderbilt Journal of Entertainment & Technology Law* (2009), p. 445.

271 See *Diamond v Chakrabarty*, 447 U.S. 303 (1980), U.S. Supreme Court; Drahos and Braithwaite, above n 151, p. 144.

272 See Art. 53(a) and (b) of the European Patent Convention.

273 Drahos and Braithwaite, above n 151, p. 127. Art. 27.1 TRIPS require that patents be available ‘without discrimination as to the place of invention’. The US changed its patent law to allow the establishment of a date of invention by reference to knowledge in a WTO member country.

274 Drahos and Braithwaite, above n 151, p. 144.

275 *Ibid.*, p. 145.

276 *Ibid.*

it as moderate and, at times, sensitive to the plight of developing countries (probably because of its colonial relations with most of the developing countries). In the aftermath of TRIPS, however, this perception of the EU has been sinking based on various actions undertaken by the Union in the field of IP at both the multilateral (Doha Round), bilateral and regional levels. What follows will examine the role of the EU post-TRIPS.

3. TRIPS outcome and implementation

Arguably, the TRIPS Agreement largely solidified and continued the neo-colonial agenda of the developed countries. As Gervais observes, when the EU and other Western lobbies successfully arranged the marriage of IP and trade rules, it became inevitable that IP rules would be measured using an economic yardstick.²⁷⁷ By concluding the TRIPS Agreement, developed countries made the protection and enforcement of IP rights a precondition for participation in the global market, thereby ensuring protection for their domestic IP-related assets and industries.²⁷⁸ What they essentially said to developing countries was, if you want to access our markets for your textile and tropical fruits, you need to protect our IP. Thus, TRIPS entailed huge concessions on the part of developing countries. They had to give up their national sovereignty on matters such as public health in exchange for access to Western markets. Critics of the Agreement therefore lament that while TRIPS generates revenue for developed countries, it represents cost for developing countries that have to pay to access technologies developed by the former.²⁷⁹ They charge that developing countries signed the agreement with poor understanding of its provisions and implications.²⁸⁰ To the pre-existing minimum level of protection, TRIPS added many further requirements, for example with regard to the subject matter and scope of patents,²⁸¹ enforcement of IP rights,²⁸² and a dispute set-

277 Daniel J. Gervais, 'Intellectual Property, Trade & Development: The State of Play', 74 *Fordham L. Rev.* 2 (2005), p. 505. (Emphasis added).

278 Pila and Torremans, above n 86, p. 34.

279 Araujo, above n 18, p. 139; Sell, above n 151, p. 9.

280 Gervais, above n 277, p. 509; Deere, above n 162, p. 56; Keith Aoki, 'Neocolonialism, Anticommons Property, and Biopiracy in the (not-so-brave) New World Order of International Intellectual Property Protection', 6 *Indiana Journal of Global Legal Studies* 11 (1998), p. 20.

281 Arts. 27-34 TRIPS.

282 Arts. 41-64 TRIPS.

tlement system (DSU)²⁸³ which gives teeth to these substantive obligations, helping to enforce the implementation of TRIPS in the WTO Member States.

Consider, for example, the area of patent protection or enforcement of rights. TRIPS mandated a 20-year minimum patent term for all WTO Member States.²⁸⁴ It further required that patents are available for any inventions, whether products or processes, in all fields of technology and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.²⁸⁵ Proprietors have the right to prohibit certain acts from being undertaken without their consent, including making the patented product or using the patented process, offering the product for sale or selling the product, and importing the patented product or the product obtained directly by the patented process.²⁸⁶ Prior to TRIPS, matters were not as clear-cut. For example, the Paris Convention was silent on the term of patent. For this reason, many countries (both developing and developed) did not provide for the protection of pharmaceutical patents at all or those who did only provided for process and not product patents.²⁸⁷ To this end, India, for example, exempted pharmaceutical products from patentability, and offered limited patent terms in areas of social concern (as explained earlier). With the ratification of TRIPS, however, India had until 2005 to amend its patent laws to comply with TRIPS standards.²⁸⁸

India's approach to the implementation of TRIPS – at least, in the area of pharmaceutical patents – is what led to seizures, in the EU, of in transit generic medicines coming from India in the early 2000s, and what has come to be known in recent times as the Indian patent wars.²⁸⁹ India, known as the pharmacy of the developing world, has come

283 Art. 64 TRIPS.

284 Art. 33 TRIPS.

285 Art. 27(1) TRIPS.

286 Art. 28 TRIPS.

287 Pedro Roffe, Gina Vea, 'The WIPO development agenda in an historical and political context', in Netanel N. W. (ed), *The development agenda: global Intellectual Property and Developing Countries*, (Oxford University Press, Oxford, 2008), pp. 79–111; WIPO, document HL/CE/IV/INF/1, prepared for the consideration of the Committee of Experts on the harmonization of certain aspects of laws protecting inventions, fourth meeting, 14 October 1987; Simon Walker, 'The TRIPS agreement, sustainable development and the public interest, vol 23. IUCN Environmental Policy and Law Paper No. 41 (2001).

288 Art. 65(4) TRIPS. For details on TRIPS transitional arrangements, see below n 311.

289 See Tim Smedley, 'Patent Wars: Has India Taken on Big Pharma and Won?' *Guardian Sustainable Business* (14 May 2013); Andrew Ward and Amy Kazmin, 'Bayer loses bid to block cheap version of cancer drug in India', *Financial Times* (12 December 2014); Selina McKee, 'Bayer loses appeal in Indian compulsory licence case', *PharmaTimes Online* (13 March 2013). These series make references to the Supreme Court of India's decision in *Novartis v Union of India*, A.I.R. 2013 S.C. 1311 (India), and Bayer's lose on its appeal in the Indian compulsory license case.

under intense international pressure and criticism from the US, Europe and MNCs for its patent policy that supports its strong generic industry with a high ‘inventive step’, and for its issue of a compulsory license.²⁹⁰ Under Indian Patent Act § 3(d), many important pharmaceuticals – most prominently Gleevec, a treatment for leukemia – are not patentable in India. In 2012, India issued its first-ever compulsory license allowing the company Natco to legally manufacture and sell a low-cost version of Nexavar (sorafenib tosylate), which is used to treat kidney and liver cancer, in order to secure a more affordable alternative in the interest of public health.²⁹¹ Bayer held the patent on the said drug and had been selling the product under the brand name Nexavar in India for \$ 5,500 a month.²⁹²

Bayer’s compulsory license case is a clear example of how originator companies try to downplay the effectiveness of the compulsory license system by responding to treats of a license by lowering prices and increasing supply. Even so, without strong generic industry to lend credibility to the threat, the originator companies are less likely to continue to react that way.²⁹³ Such actions by India have earned it a permanent spot in the US Special 301 priority watch list since 2006.²⁹⁴ Similarly, a recently released US Chamber of Commerce Annual International IP Index places India near the bottom.²⁹⁵ India also appeared on the list of ‘second priority countries’ – trailing only behind China – in the

290 Ibid.

291 See McKee, above n 289.

292 Ibid; Ward and Kazmin, above n 289.

293 Dreyfus, above n 213, p. 10.

294 See Office of the US Trade Representative (USTR), 2016 Special 301 Report, (April 2016). <https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf>.

295 See <http://www.theglobalipcenter.com/ipindex2017-details/?country=in>. Among the key reasons for India’s placement are that, overall, India’s National Intellectual Property Rights Policy does not address fundamental weaknesses in India’s IP framework, limited framework for protection of life sciences IP, India’s patentability requirements outside international standards, previously used compulsory licensing for commercial and nonemergency situations.

EU's recent report on the protection and enforcement of IP rights in third countries.²⁹⁶ Arguably, such actions by the EU and US can be seen as an attempt to prevent India from applying TRIPS compliant access to medicine policies, and to further deter other developing countries from emulating India.

Concerning enforcement, TRIPS operates a distinction between general infringements of IP rights and the more particular infringements of trademark (counterfeiting) and copyright (piracy).²⁹⁷ Concerning general infringements of IP rights, TRIPS require members to make available civil, judicial and administrative procedures in their legal systems. In addition, members are to provide remedies to prevent infringements (injunctions)²⁹⁸ or rectify damages caused by infringements as well as remedies that can act as deterrents to further infringements (forfeiture and disposal of infringements).²⁹⁹ In the specific case of counterfeiting and piracy, TRIPS recognizes the need for border measures and criminal proceedings. Although TRIPS border measures focus almost exclusively on issues related to importation, members may enable a procedure for the suspension by customs authorities of goods which involve other infringements of IP rights.³⁰⁰ Criminal procedures apply to cases of willful trademark counterfeiting or copyright piracy on a commercial scale. On this, TRIPS require Member States to make available remedies such as imprisonment and/or monetary fines, seizure, forfeiture, and destruction of infringing goods and of any materials and implements, the predominant use of which has been in the commission of the offence.³⁰¹ For developing countries, im-

296 See European Commission, 'Commission staff working document report on the protection and enforcement of intellectual property rights in third countries' Brussels, 5 February 2013, SWD(2013) 30 final. The report notes that, in India, limited improvements have been noted in IPR legislation, e.g. regarding enforcement by customs services, as well as co-operation between various enforcement departments, IPR awareness amongst officials, and increased manpower in the Patent Office. It further notes that, several constraints applicable to the protection of patents are detrimental to EU companies. This applies in particular to certain aspects of patent law where restrictive patentability criteria combined with difficulties to enforce patents granted, and with extremely broad criteria being applicable for granting compulsory licenses or for the revocation of patents, make the effective patent protection in India very difficult, notably for pharmaceuticals and chemicals but also for other sectors where local innovation is being promoted. Another area of concern is the apparent absence of an effective system for protecting undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products against unfair commercial use, as well as unauthorized disclosure.

297 Araujo, above n 18, p. 159. For TRIPS' definition of counterfeits, *see* above n 69. Footnote 14(b) of Art. 51 TRIPS defines pirated copyright goods as 'any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation'.

298 Art. 44 TRIPS.

299 Arts. 45 and 46 TRIPS.

300 Art. 51 TRIPS.

301 Art. 61 TRIPS.

plementing such institutions, for sure, was going to entail financial costs and regulatory burdens in upgrading their IP systems to meet these standards.

In addition, TRIPS reproduces the National Treatment (NT) provision of the former Conventions,³⁰² and further extends this to the realm of interstate relations by means of a ‘Most-Favoured-Nation’ (MFN) principle (Articles 3 and 4). The MFN provision requires that any state that confers benefits on the nationals of another state must extend the same benefits immediately and unconditionally to the nationals of all other Member States, except in few cases of exemptions.³⁰³ The MFN and NT provisions are crucial in the analysis of the impact of the IP provisions of the FTAs on developing countries. As explored in details in Chapters V and VI, unlike the GATT Article XXIV and GATS Article V³⁰⁴ which permit derogation from the MFN principles to form *inter se* Agreements,³⁰⁵ TRIPS does not contain any relevant exception from the MFN or NT principles that would limit TRIPS plus protection to the FTA partner. Commentators argue that this lack of exceptions to the TRIPS Articles 3 and 4 effectively globalizes these TRIPS Plus standards to become the internationally relevant norm.³⁰⁶ Thus, any TRIPS plus norms in FTAs with a developing country that has direct effect on access to medicines is likely to extend to others as well.

On the contrary, what developing countries got was meagre. Besides the mention of ‘development objectives’ in the Preamble of TRIPS, the concerns of developing countries were reflected in large part in two provisions – Articles 7 and 8 (titled objectives and principles),³⁰⁷ which allude to national policy and public interest concerns related

302 Art. 2 Paris Convention and Art. 5 Berne Convention.

303 For a list of these exceptions, *see* Art. 4 (a)-(d) TRIPS.

304 The GATT Art. XXIV permits further liberalization of trade through Customs Union and Free Trade Areas while the GATS Art. V does not prevent any of its Members from being a party to or entering into an agreement liberalizing trade in services between or among the parties to such an agreement.

305 *Inter se* agreements or modifications refer to situations where some of the parties to a multilateral treaty conclude an agreement which modifies the treaty amongst themselves. Under general international (treaty) law, Art. 41(1) of the Vienna Convention on the Law of Treaties (VCLT) allows two or more of the parties to a multilateral treaty to ‘conclude an agreement to modify the treaty as between themselves’.

306 Grosse Ruse-Khan, above n 11, p. 11; Annette Kur and Henning Grosse Ruse-Khan, ‘Enough is Enough—the Notion of Binding Ceilings in International Intellectual Property Protection’, *Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series* No. 09-01 (2008). On this issue, Robert Howse has a different opinion. *See* Robert Howse, ‘Regulatory Cooperation, Regional Trade Agreements, and World Trade Law: Conflict or Complementarity?’, 78 *Law & Contemporary Problems* (2015), pp. 137-151.

307 For the language of Art. 7 TRIPS, *see* above n 26. Art. 8 TRIPS carries that ‘Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.’

to development.³⁰⁸ According to WTO jurisprudence,³⁰⁹ these objectives and principles should guide WTO Members when interpreting and implementing the agreement (e.g., the protection of public health, promotion of technological innovation, and the transfer and dissemination of technology, etc).³¹⁰ However, it appears in the implementation of TRIPS, international pressures such as trade threats, diplomatic intimidation, and capacity-building on developing countries has eroded such possibilities.³¹¹ This stands in sharp contrast to Article 1.1 TRIPS, which allows WTO Members to determine the appropriate manner in which to ensure the minimum standards of IP protection mandated by the agreement. Another important flexibility is the provision for transitional periods in the implementation of TRIPS.³¹²

Despite the above, for developing countries, a second battle began after the TRIPS negotiations ended. As they struggled to complete extensive reforms of IP laws, administration and enforcement, they faced mounting pressures from the EU, US, MNCs, and some international organizations to adopt even higher IP standards than TRIPS requires and to abstain from using the flexibilities available in the Agreement.³¹³ As mentioned earlier, one of the channels the EU uses for such endeavours is the FTAs. By entering into FTAs with developing countries, the EU is able to use its bargaining leverage to impose its economic interest. Through these FTAs, developing countries are forced to accept TRIPS plus standards – the very policies they successfully rejected at the multilateral level. An example of the latter is the requirement in FTAs for developing countries to ‘adequately and effectively implement TRIPS’ in their national laws

308 For details, *see* Chapter VI.

309 Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, 2000, adopted 7 April 2000.

310 Peter K. Yu, ‘The Objectives and Principles of the TRIPS Agreement’, 46 *Houston Law Review* (2009), 797–1046.

311 Deere, above n 162 p. 198.

312 According to TRIPS Art. 65, developed country members had one year to implement TRIPS. Developing country members could delay implementation until 2000, and in the specific case of product patents in areas of technology not yet protected in that country, until 2005. For LDC members, TRIPS Art. 66.1 allowed 10 years from 1995 to apply the bulk of TRIPS obligations except Arts. 3, 4, and 5. This transition period has been extended twice for all LDC members in response to a specific request by the LDC Group. In November 2005, the TRIPS Council extended the period until 1 July 2013, and in June 2013, the Council further extended this period until 1 July 2021 – or when a particular country ceases to be in the least developed category if that happens before 2021. For pharmaceuticals, the 2001 Doha Ministerial Declaration on TRIPS and Public Health instructed the TRIPS Council to extend the period for LDCs to comply with TRIPS provisions on pharmaceuticals until 2016. The TRIPS Council formally adopted a decision implementing this in 2002. In November 2015, it took a decision that further extended this transition period until 1 January 2033 or when a particular country ceases to be in the least developed category if that happens before 2033.

313 Deere, above n 162, p. 1.

without recourse to the Agreement’s transitional arrangements.³¹⁴ A recent report found that, of the 36 LDC members of the WTO, 17 of them had already implemented major legislative reforms (including enforcement provisions) by 2013 – in advance of their general mid-2021 TRIPS deadline.³¹⁵ Deere reported similar outcome in her study of the same question between 1995 and 2007 (table 1 below). Only one explanation can be given for this development – post colonialism.

Table 1: *Examples of variation in timing of TRIPS legislative reforms (1995-2007)*

<p>Developing country members with most major TRIPS-related legislative reforms completed in advance of their year 2000 deadline for implementation’</p>	<p>Argentina, Bolivia, Brazil, Brunei Darussalam, Cameroon, Chile, Colombia, Congo, Costa Rica, Côte d’Ivoire, Dominica, Dominican Republic, El Salvador, Gabon, Guatemala, Honduras, India, Indonesia, Malaysia, Mexico, Morocco, Peru, Singapore, South Korea, Thailand, Trinidad & Tobago</p>
<p>Developing country members with significant legislative reforms outstanding when their deadlines for TRIPS implementation expired in 2000</p>	<p>Antigua and Barbuda, Barbados, Bahrain, Belize, Egypt, Ghana, Grenada, Guyana, Jamaica, Kenya, Namibia, Nigeria, Pakistan, Papua New Guinea, Paraguay, Philippines, Saint Lucia, Sri Lanka, Surinam, Tunisia, Turkey, United Arab Emirates</p>
<p>LDC members which implemented major legislative reforms in advance of their general mid-2013 TRIPS deadline</p>	<p>Benin, Burkina Faso, Cambodia, Central African Republic, Chad, Guinea, Guinea Bissau, Mali, Mauritania, Nepal, Senegal, Togo</p>

Source: Carolyn Deere (2008)

314 See above n 312; Also, Art. 10.2(1) EU-Korea FTA; Art. 196(1) EU-Peru-Colombia FTA (which uses different formulation: ‘Parties affirm their rights and obligations under the WTO Agreement on TRIPS’). An exception is the EU-CARIFORUM EPA (Art. 140) which includes an exception to TRIPS implementation until January 2021. Even so, this is still limiting based on the Council for TRIPS decision above, n 312.

315 Swedish International Development Cooperation Agency’s Report, above n 186. These countries are: Bangladesh, Burundi, Cambodia, Lesotho, Madagascar, Malawi, Mali, Mozambique, Nepal, Rwanda, Samoa, Senegal, Sierra Leone, Tanzania, Uganda, Vanuatu, and Zambia. Laws vary from copyright to trademark laws, patent laws, Design laws, Utility Model laws, Geographical Indications laws, traditional Knowledge, new plant varieties, unfair competition and enforcement.

Another example relevant for the issue of access to medicines is the inclusion of clauses on patent term extension in the FTAs. TRIPS is silent on patent term extensions; however, in both the EU-Peru-Colombia and the EU-Korea Agreements, there is scope to extend the duration of the rights conferred by patent protection for pharmaceutical products. The EU-Korea Agreement prescribes a period of not more than five years for this, while the EU-Peru-Colombia Agreement has no specific time limit.³¹⁶ As I describe in Chapters V and VI, the inclusion of such provisions means five or even more years during which drugs whose patents have expired will continue to enjoy full patent protection. During this extra period of protection, local generic companies cannot produce generic versions of the drugs, nor can governments import or export generic versions of such drugs. Given the relative effects of stronger IP laws on public health and development as described above, one would reasonably expect developing countries, and especially, LDCs to take full advantage of the possibilities the TRIPS Agreement provided to tailor implementation to respond to national economic and social priorities. However, from the foregoing, it appears that is not the case: TRIPS was an experiment to draft developing countries into a bigger agenda – to socialize them into the post-colonial conceptions of IP and its role in national development.

C. Intellectual property and development: Brief account

In the early 2000s, a leading observer aptly noted that when IP globalization encounters development, even in debates that prominently feature development concerns, dysphoria ensues.³¹⁷ This observation is still relevant today – as evident through this introductory chapter, and in Chapters III to VI. The problem is, IP, while purporting to heed to the issues of development, often runs rough-shod over the central concerns of development.³¹⁸ Commentators generally agree that the cause for this has been the question of ‘free trade’ and its relationship with the idea of ‘development’.³¹⁹ The Western model of IP propagated through these agreements often projects a unidirectional vision of IP

316 Art. 230(4) EU-Peru-Colombia FTA and Art. 10.35(2) EU-Korea FTA.

317 Chon, above n 23, p. 2817.

318 *Ibid.* p. 2815.

319 Free trade in this context is interpreted broadly to cover TRIPS, bilateral treaties and Economic Partnership Agreements. For details, *see* Chon, above n 23; Mario Cimoli, Giovanni Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, and Joseph E. Stiglitz (eds), ‘Intellectual Property Rights: Legal and Economic Challenges for Development’, (Oxford University Press, UK, 2014); Aoki, above n 279; Gana, above n 1; Escobar, above n 136; Paul, above n 1; Obiora, above n 1.

and development. Yet, it has also been recognized that what separates developed from developing countries is a gap in knowledge, and that inappropriately designed IP rights regimes can present an important impediment to closing the knowledge gap, and therefore to development.³²⁰

Indeed, the relationship between IP rights and development has a long history. The question facing the post-war architects of the world economic order was, now that colonialization has ended, how do we move on? In the aftermath of independence, development of the Third World was seen as crucial, and the means whereby development would occur was via technological transfers.³²¹ An explicit assumption of development theories of this period was that the US and Western European nations achieved a high level of development because of their IP systems that fostered innovation. Therefore, what worked for the West should work for the rest.³²² IP was, thus, initially pushed as an element of development for developing countries. This had meant the transplantation of IP norms from the US and Europe to developing countries, laying the foundations for post colonialism.

In pushing for the adoption of IP rules, the developed countries projected the idea that the level of economic development of developing countries would be dependent on the availability and enforcement of IP laws in those countries.³²³ The better and stronger IP rights are, the more innovative the economy will be, the argument goes.³²⁴ Developing countries that have no (or weak) IP protection will ultimately experience a low level of economic development.³²⁵ They argue that IP can accelerate economic and technological development in developing countries by significantly reducing 'the transaction costs involved in licensing technologies and supporting growth in technological

320 Giovanni Dosi and Joseph E. Stiglitz, 'The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction', in Mario Cimoli, Giovanni Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, and Joseph E. Stiglitz (eds), *Intellectual Property Rights: Legal and Economic Challenges for Development*, (Oxford University Press, UK, 2014), p. 1.

321 Aoki, above n 280, p. 18.

322 Aoki, above n 280, p. 19; Richard Warren Perry, 'Rethinking the Right to Development: After the Critique of Development, After the Critique of Rights', 18 *Law & Policy* 225 (1996), pp. 237-8.

323 Olwan, above n 217, p. 107. Citing Robert M. Sherwood, 'Intellectual Property and Economic Development', (Westview, 1990) chapter 1.

324 Dosi and Stiglitz, above n 320, pp. 3-4.

325 Olwan, above n 217; Michael P. Ryan, 'Knowledge-Economy Elites, the International Law of Intellectual Property and Trade and Economic Development', 10 *Cardozo International and Comparative Law Journal* 271 (2002), p. 301.

trade'.³²⁶ That is to say, protecting IP would create a favourable climate for transfer of technology by means of the security it provides for the patentee.³²⁷ It could also affect the inflow of FDI into developing countries – which is essential for attracting capital and for development. IP can also help in disseminating knowledge, particularly when patent applications are published and competitors are allowed to use such information to develop further inventions.³²⁸ Developing countries could rely on such information for their developmental purposes.³²⁹ The reverse would happen in the absence of appropriate IP laws in developing countries.³³⁰

What the West (or advocates for stronger IP regimes) did not take into account was that, an IP regime that might be appropriate for one country or one sector might be inappropriate for another, and that this was likely to be especially the case in the health and agricultural sector. Commentators have pointed out that the link between IP and innovation is not just about questions of 'weak' or 'strong' IP rights. Rather, the design of the whole IP regime, with its myriad of provisions, is what matters.³³¹ Poorly designed IP rights may not enhance welfare, both in the short run and long; and such systems may well impede innovation.³³² Moreover, as the area of development economics shows, economic growth is not synonymous with economic development.³³³ In this regard, developing countries have claimed that the IP rights regime that the West advocates impairs their development not only by failing to give them access to knowledge, but also by failing to protect their IP – both traditional knowledge and the knowledge embedded in biodiversity.³³⁴ As Dosi and Stiglitz note:

326 Keith Maskus, 'Incorporating a Globalized Intellectual Property Rights Regime into an Economic Development Strategy', in Keith Maskus (ed), *Intellectual Property, Growth and Trade* (Elsevier, 2008), p. 501.

327 World Intellectual Property Organization, 'Introduction to Intellectual property: Theory and Practice', (Kluwer Law International Ltd, 1997), pp. 54-56.

328 Olwan, above n 217; Maskus, above n 326, p. 506.

329 This statement takes into account the fact that the legal protection that patents enjoy is subject, among others, to a time limitation and a territorial limitation.

330 For example, economic development will suffer as a result of either non-existent or insufficient protection. Consumers will run the risk of using poor quality goods and accepting sub-standard services. As a result, investment of MNCs will stay away from developing countries that do not respect and enforce IP. They will also experience a degree of isolation from modern technologies as MNCs will refuse to transfer them to those countries. Subsequently, such countries will have to develop their own technologies, which could be expensive and time-consuming. Such countries experience fewer 'spillover' benefits, less production techniques and know-how.

331 Dosi and Stiglitz, above n 320, p. 4; Cimoli et al, above n 319.

332 Ibid.

333 Chon, above n 23, p. 2877.

334 Dosi and Stiglitz, above n 320, p. 2.

This asymmetry too has adverse effects on development, for it necessitates developing countries paying large rents to Western firms for their intellectual property, but not receiving in return rents from what the developing countries view as their intellectual property. Indeed, in some cases, developing countries would have to pay Western firms rents for what developing countries view as their own property.³³⁵

Additionally, developing countries complain of high administrative cost in introducing IP laws and a system of enforcement which ultimately affect the distribution of resources for development in other areas such as healthcare and education.³³⁶ Interestingly, these concerns are being raised at a time when almost all developing countries have joined the WTO, and have implemented the TRIPS Agreement in their national laws in one way or the other – with the exception of the transitional arrangements discussed above. The incentive for TRIPS to bring the desired development to developing countries has thus been questioned. It has been suggested that TRIPS may be a hindrance to the process of development and catching-up, precisely because it impedes many of the ways by which knowledge is transferred to developing countries.³³⁷ For instance, it hinders imitation by domestic firms and accumulation of local technological capabilities – the very instruments developed countries like the US, Japan and Germany, among others, used abundantly during the course of their catching up.³³⁸ Today, these same countries have ‘kicked away the ladder’,³³⁹ re-writing history as they seek to depict their earlier success as because of free trade with strong IP rights.³⁴⁰ In the area of pharmaceuticals, as indicated above, before TRIPS, generic medicines obtained under loose IP rights

335 Ibid. In this regard, commentators found out that under the new TRIPS regime the flow of international licenses from developed to developing countries in monetary terms significantly increased. See Keith E. Maskus, ‘The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer’, in Fink C. and Keith E. Maskus (eds), *Intellectual Property and Development* (Oxford University Press, New York, 2005).

336 Costs for establishing and updating intellectual property systems include upgrading offices for registering and examining patents and trademarks; accepting deposits of plant materials; training examiners, judges, and lawyers; improving courts to manage intellectual property litigation; and training customs officers and undertaking border and domestic enforcement actions.

337 Dosi and Stiglitz, above n 320, p. 34.

338 Ibid.

339 Odagiri, H., A. Goto, A. Sunami and R. R. Nelson (eds), *Intellectual Property Rights, Development, and Catch Up: An International Comparative Study* (Oxford University Press, New York, 2010).

340 Chang H. J., ‘Kicking Away the Ladder—Development Strategy in Historical Perspective’, (London: Anthem Press, 2002).

regimes led to a dramatic reduction in the cost of medicines in developing countries like India and Thailand.³⁴¹ Today, these are significant barriers – as those described above, and in the essays of Part II – have been imposed on the production and marketing of generic medicines. For this reason, innovation in developing countries, as well as access to medicines is impeded.

The present situation has been exacerbated by trends in FTAs that seek to further tighten IP standards. The worry, however, is that the IP chapters in the FTAs do not make explicit references to development – except one³⁴² – although they do include what I describe in Chapter VI as ‘legislation by reference’ or the ‘bilateral safeguard clause’³⁴³ (i.e., reference to TRIPS flexibilities or the Doha Declaration). A key impediment, however, is that, the language referencing development in both TRIPS and the FTAs are not mandatory, but rather hortatory, and are placed within parts of the treaty that are not in the main treaty body – with the exception of the few instances discussed in the next Section.³⁴⁴ This unequivocally renders development related interest secondary. It thus appears that, despite efforts to place developmental objectives in the broader context of IP policy, the human capability approach to development proposed by Amartya Sen,³⁴⁵ which is based on the idea that a society is not fully developed until certain basic needs are provided for all of its people, has not yet informed internationalization of IP. It is in this regard that a proposal is made for a concept of *substantive equilibrium*, a balancing mechanism that may likely curtail the challenges to access presented by the current EU IP policy framework. This is elaborated next.

341 Benjamin Coriat and Luigi Orsenigo, ‘IPRs, Public Health and the Pharmaceutical Industry: Issues in the Post-2005 TRIPS Agenda’, in Mario Cimoli, Giovanni Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, and Joseph E. Stiglitz (eds), *Intellectual Property Rights: Legal and Economic Challenges for Development*, (Oxford University Press, UK, 2014).

342 See Art. 139(2) EU-CARIFORUM EPA.

343 Legislation by reference implies that one state undertakes the compromise to respect or access a treaty. The relevant treaty in this context is the WTO/TRIPS. Conversely, bilateral safeguard clauses provide a temporary escape for parties when, by implementing the treaty, a nation’s public health and other development priorities would be impaired. See Xavier Seuba, ‘Intellectual Property in Preferential Trade Agreements: What Treaties, What Content?’, 16 *The Journal of World Intellectual Property* 5–6 (2013), at 247.

344 See Art. 231(4) EU-Peru-Colombia FTA; Art. 10(34) EU-Korea FTA; and Art. 147.B EU-CARIFORUM EPA.

345 See above n 2.

1. Proposal for a ‘substantive equilibrium’

Building on the conclusions and recommendations drawn in Chapters II to VI, I propose the concept of *substantive equilibrium* specific to the FTAs and the EU internal norms as an alternative means of managing the access to medicines conundrum in developing countries. By substantive equilibrium, I mean moving the provisions on development (public health) and other references to the TRIPS flexibilities in the FTAs and relevant EU secondary norms from the Preamble or ‘general provisions’ to the substantive part of the treaty or legislation. What this means is elevating the said provisions from an ‘optional’ status to ‘mandatory’ one. This should grant the said provisions equal weight and effect in implementation (through the laws and regulations adopted at state level) and interpretation as the others in the main body of the treaty. This way, national courts, decision makers and arbitration panels in the case of dispute settlement (as provided for in the FTAs)³⁴⁶ would be forced to accord the same level of respect and gravity to which they apply the substantive provisions on IP to those on development and related provisions. This would represent a shift from the present latent nature of the provisions on development in the FTAs, to making them more explicit. Being optional means the FTA partner is free to choose whether to implement those provisions in its domestic IP laws or not. For developing countries, pressure to enforce the mandatory requirements of the treaty could limit their ability to take advantage of the ‘optional’ TRIPS flexibilities to promote access to medicines. Indeed, as Graeme Dinwoodie and Rochelle Dreyfus note in a different context:

Thoughtful interpretation can lessen some of the pressures, but it cannot deal with all of them as the rules, standards, and norms often cut in opposite directions and are of differing legal stature. While instruments raising the level of protection are usually hard law, those that further access and other public-regarding interests tend to be softer.³⁴⁷

In this climate, there is the need for such a proposal that aims at striking a fair balance between IP and access to medicines. This is partly so because the push for norm

³⁴⁶ See Art. 266 EU-Peru-Colombia FTA; Art. 11(8) EU-Korea FTA; and Chapter II, Section 1 EU-CARIFORUM EPA.

³⁴⁷ Graeme B. Dinwoodie and Rochelle Dreyfuss, ‘An International *Acquis*: Integrating Regimes and Restoring Balance’, in Daniel J. Gervais (ed), *International Intellectual Property: A Handbook of Contemporary Research* (Edward Elgar Publishing, Cheltenham, UK, 2015), p. 124.

formation in IP (such as TRIPS plus norms in the FTAs) is unlikely to abate due to its place as a high-stakes commodity in the knowledge economy.³⁴⁸ Moreover, since the MFN and NT principles cannot entirely help in the particular context of the FTAs (for reasons well espoused earlier),³⁴⁹ there is the need to resort to devising alternative principles that may well leverage the status quo. Importantly, this concept may function to delink the FTAs from the post-colonial critique labelled against it in this thesis, at least, with regard to its IP chapters.

There are instances of this suggestion in the FTAs already. When setting standards for the protection of data of certain regulated products, the EU-Peru-Colombia FTA exceptionally allows Parties to regulate ‘exceptions for reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to those data to third parties’.³⁵⁰ Similarly, the section on patents in the EU-Korea FTA includes a title on patents and public health (Article 10.34) – that allow Parties the freedom to rely upon the Doha Declaration in interpreting and implementing the rights and obligations under that Sub-section. Although these exceptions either come with strict conditions or lack clarity, they nonetheless constitute a good example of what I mean by substantive equilibrium. The challenge, however is, the functionality of such provisions have been questioned because they are often subdued by counter norms on IP that come immediately before or after. To this end, moving the provisions on public health into the main body of the treaty should not be an end in itself. Rather, a clause should be added that would stipulate that the implementation of the FTA cannot lead to derogation from the protection of public health. This would entail a binding obligation to act in the public interest, however, without prescribing the measures to be taken.³⁵¹ When framed in this fashion, such exceptions can be interpreted and implemented in a way that allows for real and effective use of all TRIPS flexibilities referenced in the Doha Declaration, among others. It could also give guidance to panels and national courts for the interpretation of the FTA provisions in cases involving public health issues.

348 Ibid. p. 121.

349 See Chapter I, Section B above.

350 Art. 231(4) EU-Peru-Colombia FTA.

351 Kur and Grosse Ruse-Khan, above n 306, p. 31. (Who suggest a similar idea using the term ‘mandatory limitations’).

Furthermore, since the FTAs are binding on their Parties, individuals may invoke directly effective³⁵² norms from the FTAs, and national courts and public authorities would be obliged to apply them.³⁵³ In the EU, direct effect is possible if a treaty establishes rules intended to apply directly and immediately to individuals and confers upon them rights or freedoms capable of being relied upon against states.³⁵⁴ When direct effect is invoked, Member State courts must set aside conflicting national laws in favour of the directly effective norms of international treaties. Depending on whether the FTA norms are self-executing in the national system of the FTA partner, similar situation may apply. In the particular case of the EU, all secondary EU law are also to be interpreted in conformity with international treaties binding the EU.³⁵⁵ Thus, in addition to having interpretive and direct effect, international treaties may enable judicial review of EU secondary norms. They may thus be used to quash secondary EU law, such as directives and regulations.³⁵⁶ What this means, in effect is that, with substantive equilibrium, individuals may have a strong basis to rely on public health related provisions in the FTA to, for instance, challenge the validity of the current EU Customs Regulation and Trademark rules. This may ultimately lead to a review of the said instrument by the CJEU and if found conflicting, could trigger a declaration of invalidity and subsequent amendments. For such reasons, the EU legislature tried to exclude direct effect before EU or Member State courts in the EU's internal decision accepting the EU-Korea FTA.³⁵⁷ However, observers argue that such acts are not binding on the CJEU as such, as

352 The principle of direct effect is a fundamental principle of European law enshrined by the CJEU. This principle enables individuals to immediately invoke European law before courts, independent of whether national law test exist. However, the CJEU defined several conditions in order for a European legal act to be immediately applicable. In addition, the direct effect may only relate to relations between an individual and an EU country or be extended to relations between individuals. See <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3A114547>.

353 Mylly, above n 103, p. 252-253.

354 Ibid. pp. 254-255. The test is fulfilled when the provisions relied upon contain a clear and precise obligation that is not subject, in its implementation or effects, to the adoption of subsequent measures. The provisions in question must thus enable a judicial decision based on them, without recourse to additional implementing measures.

355 Ibid. Citing *Commission v Germany*, C-61/94, EU:C:1996:313, para. 52; *Portugal v Council*, C-149/96, EU:C:1999:574; *IATA and ELFAA*, C-344/04, EU:C:2006:10, para. 35 in reference to the fact that the Court has expressed that it treats directly effective international agreements binding the EU as having primacy over secondary law, but not over primary EU law.

356 Ibid.

357 See Art. 8 of Council Decision of 16 September 2010 on the signing, on behalf of the European Union, and provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part (2011/265/EU), OJ L 127/1. (Stating that 'the Agreement shall not be construed as conferring rights or imposing obligations which can be directly invoked before Union or Member State courts and tribunals').

the Court may base direct effect on the contents of the treaty itself.³⁵⁸

Another good reason for such a proposal, I would argue, is that the EU has a primary legal obligation to meet other core objectives in its external trade policy. In addition to including the commercial aspects of IP and foreign direct investment to the CCP – alongside its objective of trade liberalization – the CCP ‘shall be conducted in the context of the principles and objectives of the Union’s external action’.³⁵⁹ These principles and objectives, listed in Article 21 TEU, include a wide array of targets ranging from political and social to economic. However, one that closely relates to development is Article 21.2(a) TEU. It carries that the Union shall define and pursue common policies and actions, and shall work for a high degree of cooperation in all fields of international relations, in order to ‘foster the sustainable economic, social and environmental development of developing countries, with the primary aim of eradicating poverty’. Marise Cremona has argued that linking the CCP to these objectives accentuates that the EU does not only have an economic agenda, but that other core objectives must also be taken into account in its multilateral and bilateral trade agreements.³⁶⁰ In this regard, the social and economic development of developing countries is a primary treaty objective that the EU is obligated to achieve in its FTAs. Moreover, the CJEU has long accepted that the incorporation of development objectives in CCP instruments were compatible with the CCP.³⁶¹ However, considering the action of the EU articulated in this thesis, the core question is compliance. Adherence to the concept of substantive equilibrium could bring the EU into compliance with this primary treaty objective.

Finally, this proposal consolidates ‘the right to development’ – which I referred to in the beginning of this introduction. Development as a concept first entered the human-rights edifice through the debate on the right to development, which provided legal and ethical authority to developing countries’ request for the international redistribution of resources.³⁶² In 1986 the ‘right to development’ was adopted as a UN General Assembly resolution (not a treaty, and thus without binding force).³⁶³ This soft law instrument was to champion the right to development, and by extension, health as inalienable right

358 Mylly, above n 103, p. 253; Opinion of Advocate General Saggio in case C-149/96, EU:C:1999:92, para. 20.

359 Art. 207(1) TFEU.

360 Marise Cremona, ‘A Constitutional Basis for Effective External Action? An Assessment of the Provisions on EU External Action in the Constitutional Treaty’, *EUI Working Papers Law* No. 30, (2006), p. 30.

361 *Commission v Council*, Case 45/86, EU:C:1987:163, para. 19; Opinion 1/78, EU:C:1979:224, paras. 47-50.

362 Peter Uvin, ‘From the right to development to the rights-based approach: how ‘human rights’ entered development’, 17 *Development in Practice* 4-5 (2007), p. 598.

363 See Declaration on the Right to Development, above n 1.

of all persons. Although this declaration has not been without criticism,³⁶⁴ it has nonetheless, in recent times been linked to the Millennium Development Goals (MDGs) of the UN.³⁶⁵ Among the eight MDGs, two are particularly relevant for the discussion on access to medicines, namely: (1) to combat HIV/AIDS, malaria, and other diseases, and (2) to develop a global partnership for development. As the UN MDG Gap Task Force Report 2015 indicates, generic medicines are significantly less available in public health facilities compared to private facilities, and sometimes poorly available even in private facilities in developing countries and LDCs.³⁶⁶ The report therefore recommends that the health systems of developing countries are strengthened in a way that will ensure access to essential medicines. It further encourages these countries to implement and use TRIPS public health flexibilities, as well as other means such as voluntary license agreements – in order to improve access to medicines that are patent protected.³⁶⁷ These are the very issues that substantive equilibrium addresses. The developing country FTA partner would be able to put such mechanisms in place if this concept is adhered to.

The goal of this concept is to make the idea of balancing IP and public health as realistic, practical and effective as possible. The proposal does not seek to ask for the abrogation or modification of TRIPS, the IP chapters of existing FTAs or relevant EU secondary norms – as that would be unrealistic in the present climate. What this proposal seeks to do, instead, is to prospectively serve as a guide for future negotiations (and drafting) of the IP chapters in the FTAs and EU secondary legislation in a way that reduces the incidence of contradictions between the provisions on IP and public health, or, the latent nature of the provisions on development. To this end, in addition to the balancing mechanisms already introduced by the EU, the content of this concept could, for instance, draw from non-IP institutions such as human rights – for example, the right to health and development, as discussed above. Equally, well established principles and values in the national systems of the FTA partners, such as fundamental constitutional values, could be taken into account and not just the transplantation of EU norms and institutions.

364 Obiora, above n 1, pp. 355–418; Allan Rosas, ‘The right to development’, in Asbjorn Eide, Catarina Krause and Allan Rosas (eds.), *Economic, Social and Cultural Rights. A Textbook* (Dordrecht: Martinus Nijhoff, 1995), pp. 247–256; Slinn, Peter ‘The international law of development: a millennium subject or a relic of the twentieth century?’, in Wolfgang Benedek, Hubert Isak, and Renate Kicker (eds.), *Development and Developing International and European Law* (Frankfurt: Peter Lang, 1999), pp. 299–318.

365 Philip Alston, ‘Ships Passing in the Night: The Current State of the Human Rights and Development Debate seen through the Lens of the Millennium Development Goals’, 27 *Human Rights Quarterly* 3 (2005), p. 759; For the UN Millennium Development Goals, see <http://www.un.org/millenniumgoals/>.

366 United Nations, MDG Gap Task Force Report 2015, Millennium Development Goal 8: Taking Stock of the Global Partnership for Development. http://www.un.org/millenniumgoals/pdf/MDG_Gap_2015_E_web.pdf.

367 Ibid.

The advantages of utilizing such a proposal in the negotiation and drafting of future treaties and legislations are that, it could have wider effects and applicability as any changes made to one instrument or institution will necessarily affect others. It may eventually become the established norm. It could also inject some level of legal certainty in the provisions of the treaty or legislative instrument as developing countries would be assured of their ability to protect IP in such a way that further their own cultural policies, fit their local economic needs and capacities, and adapt to new technological challenges.³⁶⁸ It would also impede the ability of the EU to compel developing countries to adopt high standards of IP that ignore local interest. This might further prevent the tactic of regime shifting between the EU and developing countries, and the fragmentation of laws that seems to shape the present IP climate. To forestall abuse of this proposal, however, a mechanism should be provided to ensure that only those measures that involve the least negative impact on IP protection, while being equally effective at enabling the chosen level of public health protection, would be taken.

D. Overview of publications

As indicated earlier, Part II of this thesis consists of five essays distributed along the normative framework adopted in this research. This framework, illustrated in figure 1.4 (below), and in figure 1.3 (above) shows the distribution of the essays into ‘EU level’ and ‘international level’. The first three essays focus on the EU’s internal action while the latter two focuses on its external action. These essays are complementary in terms of pointing to the effects of IP rights on access to medicines – although they do so from varied angles and themes. All five chapters rely on the theoretical framework, while applying it in diverse implicit and explicit ways. In addition, they all aim to explicate how these different norms promoted by the EU impact developing countries on the issue of access to medicines in a detailed and practical way. In what follows, I present an overview and justification of each essay, show the interrelation between the chapters aim, and conclude by summarizing their findings against the overarching research theme. These essays were written at different times and intervals; as such, there have been changes in some of the legal regimes and shifts in case law. These updates are already included in Section I.A. (above) and in the descriptions below. For the full-length essays, the reader is directed to the Chapters of Part II.

³⁶⁸ Dinwoodie and Dreyfuss, above n 347.

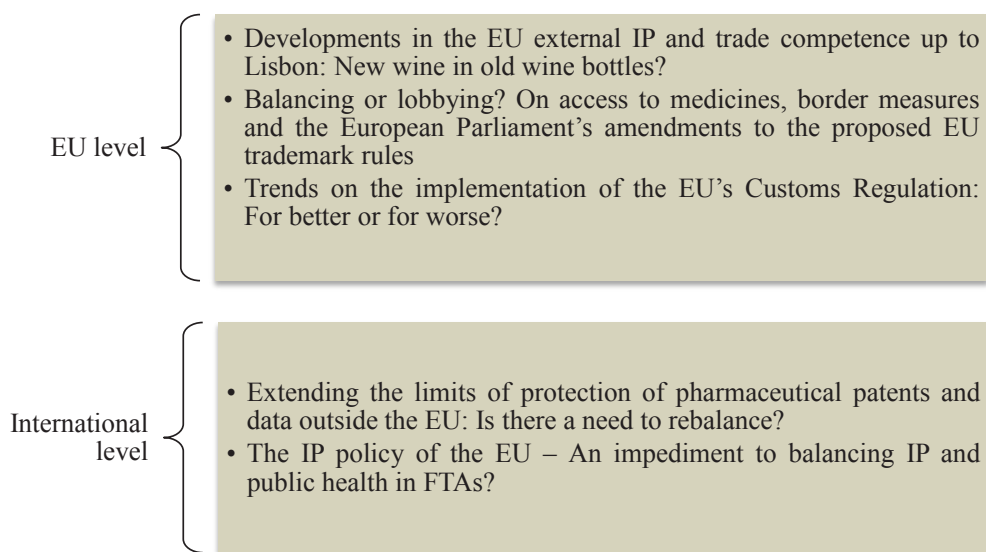


Figure 1.4 *Normative framework for essays*

1. Developments in the EU external IP and trade competence up to Lisbon: New wine in old wine bottles?

Based on the theme of this research, it became obvious from the beginning that a good place to start from will be to investigate the legal basis for the EU's action in the field of IP. While that of the internal is left for the last essay, the first publication investigates the EU's competence to negotiate IP and trade agreements internationally. It comprises a historical analysis of the evolution and developments in the CCP from the Treaty of Rome to the Treaty of Lisbon. It summarizes its key contribution as follows: 'this essay contributes to the discussion on the changes brought by the Lisbon Treaty to the CCP by emphasizing that, "nothing little is too little"'. It starts by illustrating the problem with Article 133 EC on the CCP and how that ended up being interpreted by the CJEU.³⁶⁹ It further narrates the difficulties encountered by the European Commission in its effort to amend the CCP to include trade in services and IP at the Amsterdam and Nice intergovernmental conferences. Finally, it outlines the changes that the Lisbon Treaty brought to the CCP, and how that could potentially boost the Union's activities

369 See Opinion 1/94, above n 101.

on the international stage concerning IP rule making.

It concludes that, the changes brought by Lisbon, as much as will increase consistency and effectiveness in the EU's external trade policy and action, also brings about important changes that re-align the EU to the new realities of international trade and economic relations, far different from the previous Treaties. If nothing, at least on paper, there is now a legal basis for the Commission to act solely on these fronts – curtailing the possibility of legal challenge between the EU institutions on who is competent to do what and when, which has been fashionable with previous Treaties. To a large extent, the conclusions of this essay is a reality of our time, as the EU has capitalized on its new found power to negotiate IP treaties (and still in the process of negotiating more) whose contents implicate access to medicines – as exemplified in Chapters V and VI. More importantly, the case law of the CJEU following the entry into force of the Lisbon Treaty have all confirmed that the TRIPS Agreement now falls within the scope of the CCP and exclusively the competence of the Union.³⁷⁰

2. Balancing or lobbying? On access to medicines, border measures and the European Parliament's amendments to the proposed EU trademark rules

The second essay explores the question of balancing and lobbying in the negotiation and passage of two of the EU's recent secondary legislation on IP: the EU Customs Regulation and the EU trademark Regulation and Directive; and how they affect developing countries on the issue of access to medicines. One may ask how an internal norm of the EU can affect a developing country. An internal norm of the EU, in as much as has nothing to do with developing countries, can indirectly affect them, especially, when those norms, such as the EU Customs Regulation and the EU trademark rules, can lead to the seizure of generic medicines making transit at EU borders that infringe local patents or trademarks.³⁷¹ When an EU internal norm on IP is designed to target infringing activities in developing countries, it begins to have relevance on national policy and

370 See *Daiichi Sankyo*, above n 110; Opinion of Advocate General Sharpston in Opinion 2/15, above n 121. More recently, the Grand Chamber of the Court delivered its Order in Opinion 3/15, C:2017:114, where the Court ordered that the conclusion of the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled falls within the exclusive competence of the European Union – although not on the basis of the CCP, but on the ERTA principle.

371 See generally Press Release, Health Action International, Another Seizure of Generic Medicines, (June 5, 2009). <http://haieurope.org/wp-content/uploads/2010/11/5-Jun-2009-Press-release-Seizure-of-generic-medicines-in-Frankfurt.pdf>. (Where German customs authorities detained generic medicines for bearing the INN name (mandated for labels in most countries) that was thought to be 'confusingly similar' to a brand name on grounds of trademark infringements).

development of those countries. In substance, this essay highlights the challenges confronting the EU as it works to counter the international trade in counterfeiting through border measures, and how that affects the transit of generic medicines in the EU. It also shows how powerful lobby by the European Federation of Pharmaceutical Industries and Associations (EFPIA) affect IP policy-making at the European level, and the institutional tension this sometimes generate.

The essay's exposition on the potential effects of the EU's Customs Regulation and the then proposed EU trademark rules on access to medicines have proven to be timely. As I indicated earlier, since their passage, advocacy groups, academics and major developing countries have criticized both regimes as capable of limiting access to medicines.³⁷² This essays' finding, therefore, is of much relevance since the newly passed trademark rules uphold the very provisions that were discussed in the essay as problematic.³⁷³ The essay concludes, in part that, increasingly, IP laws being promulgated by the EU are becoming broader and more exclusive. Accordingly, while one regime of law could be criticized for stifling access to medicines, amendments to existing laws, or the negotiation of new ones, more often than not, tend to create more ambiguities or even worsen the situation. If anything, their purpose is to modify (enhance) the rules to meet modern trends; meaning, to improve the framework conditions for businesses to innovate and to boost economic growth, but not much to do with public health or welfare, despite the fact that these rules tend to have impact on the latter. This essay underpins the political economy of IP rights and EU constitutional law theories. As far as the transplantation of these norms is concerned, it conveys the neo-colonial agenda as a thread that reflect in the EU's IP policy.

3. Trends on the implementation of the EU's Customs Regulation: for better or for worse?

The third essay builds on, and complements the second one – but this time, with specific focus on the Customs Regulation. It elaborates the improvements made to the EU Customs Regulation and how that can effectively lead to the suppression of the international trade in counterfeiting and piracy. It also depicts how the EU is working

372 See Section I.A above.

373 See *ibid.*

to transplant its internal norms on border enforcement to developing countries through not just treaty negotiations, but also, diplomacy.³⁷⁴ The underlying assumption is that if the current EU Customs Regulation would be more effective, then it may well impact the transit of generic medicines – a critique already levelled against it by commentators.³⁷⁵ Three points substantiating this claim has been mentioned already in an earlier Section,³⁷⁶ and thoroughly discussed in Chapters III and IV. One of the points is broadly defining counterfeit goods to cover ‘any packaging, label, sticker, brochure, operating instructions, warranty document or other similar item, even if presented separately, which is the subject of an act infringing a trade mark or a geographical indication [...]’

Commentators agree that generic medicines do not only infringe patents and SPCs, but in certain situations, could also infringe trademarks.³⁷⁷ By relying on the same or similar words identifying the active ingredient, the labels used to identify generics or the packaging often may be to some extent similar or close to the trademarks of the original manufacturer.³⁷⁸ A trademark holder could hence rely on the Customs Regulation to detain such medicines at the EU borders on allegations of ‘ordinary’ trademark infringements. The European legislature, in recognition of the potential effect the new rules might have on access to medicines, inserted a provision concerning transit of generic medicines in the Regulation. However, it appeared in a Recital, which unfortunately ends with a conflicting statement.³⁷⁹ When compared to the fact that transit can be read into the meaning of Article 1 of the Regulation,³⁸⁰ it leaves room for concern as

374 In the context of non-legislative action (diplomacy), China has been chosen for analysis in this essay –although China is not one of the focus countries in the thesis. China was chosen because it made a perfect example in reference to the EU’s Customs data on counterfeiting and the Union’s response to such threat. It is worth noting, however, that this procedure is not limited to China. The EU applies similar tactics to other developing countries that have no trade agreement with the EU – an example is India.

375 See Section I.A. above.

376 See above nn 73, 74, and 75 respectively.

377 Acquah, above n 66. (Chapter III).

378 Ibid; Grosse Ruse-Khan, above n 132, p. 674-7; Sean Flynn and Bijan Madhani, ‘ACTA and Access to Medicines’, *PJIIP Research Paper Series* 22 (2011), p. 7.

379 For more on this, see Acquah, above n 41 (Chapter IV). Recital 11 of the EU Customs Regulation states that ‘Under the ‘Declaration on the TRIPS Agreement and Public Health’ [...], the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. Consequently, in line with the Union’s international commitments and its development cooperation policy, with regard to medicines, the passage of which across the customs territory of the Union, with or without transshipment, warehousing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the territory of the Union, customs authorities should, when assessing a risk of infringement of intellectual property rights, take account of any substantial likelihood of diversion of such medicines onto the market of the Union’. (Emphasis added).

380 Ibid.

to why the provision on transit of generic medicines was not included as a substantive provision, void of any ambiguity, but rather, as aspirational. This essay utilizes EU constitutional law, legal transplants and implicitly, post-colonial theory as background theories in its argumentation.

4. Extending the limits of protection of pharmaceutical patents and data outside the EU: Is there a need to rebalance?

The fourth essay is the first to focus on the international agreements. It concentrates on pharmaceutical patents. The analysis focuses on how the EU's internal norms on IP, specifically, *sui generis* protections such as patent term extension (SPC) and data exclusivity are being transplanted through FTAs to developing countries. It further analyses how these exported norms tend to go even beyond existing EU and internal standards. It argues that such acts further prolong the lifespan of protection given to existing products and limit generic market entry. In doing so, the essay brings to the fore the impact enforcement of these rules can have on developing countries – in terms of increasing the need for allocation of additional human, financial and institutional resources, among others, to the detriment of their public health systems and development.

Technically, these rules are supposed to be implemented by both the EU and the developing country partner that are Party to the treaty. Since similar laws exist in the internal regime of the EU, incorporating them into the EU would not be technically difficult. However, to an extent this regime is simulated in developing countries, implementation will bring major difficulties to the health sector and economies of these countries. Here again, the linkage between the 'internal and the external' in the EU's IP policymaking becomes obvious. The essay thus proposes that developing countries should not be forced to adopt such laws through FTAs, and if they are, there should be the compulsory inclusion of both (1) a clause on transitional arrangements for developing countries specific to IP; and (2) a clause that clearly links the objectives for IP protection and enforcement to balancing between the promotion of technological innovation and access to medicines. Background theories employed in this essay include all the theories utilized in this thesis: post-colonial theory, EU constitutional law, legal transplants, and political economy of IP rights.

5. The IP policy of the EU – An impediment to balancing IP and public health in FTAs?

The last essay explore in more details, efforts by the EU to balance IP and public health in its FTAs and the contradictions that emerge because of conflicting provisions – what is seen as the EU's own creation, and hence, an impediment to the efforts at balancing. Relying on the background theories utilized in the thesis, this essay first attempts to show the link between the internal and external norms in an elaborate way by tracing the development of the law at the European level. Just like the CCP, an initial lack of competence to legislate the field of IP internally would force the EU to rely on provisions from its treaties attributing it the power to regulate the internal market to legislate the field of IP. The essay argues that relying on this and other general provisions to regulate IP resulted in approaching the subject *from an entirely economic perspective*. There is thus a structural bias inherent in the EU's internal system, which seemingly promotes economic values over non-economic values in its IP policymaking. This reflects the neo-liberal (neo-colonial) agenda being pursued at both the internal and external levels.

The second part of the essay builds on the first part by focusing on the tensions underlying the IP chapters in the FTAs. It illustrates how on the one hand, the EU advocates for stronger protection and enforcement of IP, and on the other, the protection of public health. Focusing on selected FTAs, the essay highlights the contradictions therein. It argues that seeking to balance IP and public health in instruments with enhancement of IP supposedly one of their core objectives is dubious. It therefore seems the harmonization of the commercial aspects of IP has progressed significantly faster than that of guarantees related to public health. Although public health clauses may have interpretive value, this does not change the substantive IP protection that must be offered. They thus seem to function as a façade of norms that conceal the potential effects of the TRIPS Plus norms. The essay proposes possible means of restoring a fair balance. One way, it suggest, may be to frame the provisions on public health in the FTAs as mandatory requirements or express exceptions. Alternatively, a proposition is made for the EU to include strong and comprehensive sustainable development chapters in its trade agreements, which are to be effectively implemented and enforced.

PART II

Chapter II

Publication I

**Developments in the EU external IP and trade competence up to Lisbon:
New wine in old wine bottles?**

Daniel Opoku Acquah

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Developments in the EU external IP and trade competence up to Lisbon: New wine in old bottles?

By LL.M. Daniel Opoku Acquah¹

1. Introduction

Since the Treaty of Rome, the European Community (EC) now the European Union (EU)² has become party to an impressive network of international agreements. However, its competence to conclude such agreements has not gone unchallenged, especially, in the absence of an explicit general Treaty basis.³ One of such areas has been the Union's external trade policy – the Common Commercial Policy (CCP).⁴ Until Lisbon, the Union's competence to negotiate and conclude international agreements under the CCP in the areas of trade in services and the commercial aspects of intellectual property rights has been a terrace of heated debates and legal battles. The cause has been with the scope and content of Article 133 EC. The Treaty of Rome only included a non-exhaustive list of examples of subjects belonging to the CCP but contained no clear definition of the boundaries of this policy. The aftermath of such confrontations was the eventual jurisdiction of the European Union Court (EUC)⁵ in the infamous Opinion 1/94⁶ – whose legal ramifications for EU trade policy remained with subsequent Treaties until the Lisbon Treaty.⁷ With Lisbon, important amendments have been made to the CCP that completely changes its scope and content.

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² Article 1 TEU, as amended by the Treaty of Lisbon. Unless indicated otherwise, all articles referred to in this essay are articles of the Treaty on European Union, or the Treaty on the Functioning of the European Union. With the ToL, the EU formally replaces the European Community, so that now, one must refer to the European Union and not the European Community.

³ Wouters, Jan; Dominic Coppens and Bart De Meester, 'The European Union's External Relations after the Lisbon Treaty', in Stefan Griller and Jacques Ziller (eds), *The Lisbon Treaty. EU Constitutionalism without a Constitutional Treaty?* (Wien, Austria: Springer, 2008), p. 167.

⁴ Article 206 and 207 TFEU.

⁵ Formerly, European Court of Justice (ECJ).

⁶ ECJ Opinion 1/94, WTO-Opinion, (1994) ECR I, p. 5267.

⁷ Official Journal C 306 of 17 December 2007.

It should be recalled that at both the Amsterdam and Nice inter-governmental conferences (IGC's), the Commission tabled for the General Agreement on Trade in Services (GATS)⁸ and the Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁹ to be added unto the CCP. Changes were effected in both Treaties but did these changes measure up to the expectations of the Commission? Many commentators have argued that the changes that took place – especially, with regards to the Treaty of Nice – only reflected the outcome of Opinion 1/94. Could it be concluded then that attempts to extend the scope of the CCP at the Amsterdam and Nice IGC's were just 'new wines being poured into old wine bottles?' Could the same be said about the Lisbon changes or rather, should Lisbon be seen as a bid by the EU to redesign its trade policy in order to become competitive on the global trade landscape? If so, why did the Treaties of Maastricht, Amsterdam and Nice (to a lesser degree), fail to do this?

This paper contributes to the discussion on the changes brought by the Lisbon Treaty to the CCP by emphasising that, 'nothing little is too little'. The changes brought by Lisbon, as much as will increase consistency and effectiveness in the EU's external trade policy and action, also brings about important changes that re-align the EU to the new realities of international trade and economic relations, far different from the previous Treaties. If nothing, at least on paper, there is now a legal basis for the Commission to act solely on these fronts – curtailing the possibility of legal challenge between the EU institutions on who is competent to do what and when, which has been fashionable with previous Treaties.

The paper is organised as follows: section two draws a quick summary of the EU as an actor in international trade and how the EU could be said to have fallen short in some of the attributes of 'actorness'. This links very well with the challenges posed by Opinion 1/94 and its impact on the EU trade policy in section three. This is followed in section four by outlining amendments to the CCP in the Amsterdam and Nice IGC's. Section five analyses the scope of the changes brought by Lisbon to the CCP and how different they are from previous Treaties. The sixth section discusses possible reasons why previous Treaties failed to extend the scope of the CCP to cover GATS and TRIPS. In the seventh section, I draw some conclusions.

2. The EU as an actor in international trade

Even before the ratification of the Lisbon Treaty, the EU had been seen as an actor in trade due to its market power, recognition (or presence), capability, normative power and legitimacy/parliamentary accountability. However, with time, the sustainability of the Union as an actor in terms of these attributes became questionable due to external/internal challenges to the Union's trade policy.

⁸ See document at: http://www.wto.org/english/docs_e/legal_e/legal_e.htm#services (Last visited 15.7.2011).

⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, OJ 1994 L336/213.

2.1 Market power and normative power. The EU derives much of its economic power from the size of the domestic market which gives it some form of ‘presence.’¹⁰ This is pretty much so because, in the field of trade – and to a somewhat lesser extent intellectual property (IP) and investment policy – there is a fairly straightforward metric in the shape of market power derived from the size of the domestic market.¹¹ This makes the EU an actor. According to Bretherton and Vogler, ‘Actorness’ can be derived from EU presence, including the unintended effects of its policies, due to its weight on world economy, such as the impact of the Common Agricultural Policy on trade relations.¹²

To date, it is still central to EU trade policy to negotiate for reciprocal concessions on market access so that the larger the domestic market, the greater the negotiator’s power by virtue of his or her ability to withhold or withdraw access to this market.¹³ And even though in recent decades, binding commitments to tariff reductions and other liberalising measures have reduced the scope for withdrawing market access concessions, there remains scope for discretion in many fields of trade. The creation of the Customs Union in the 1950s, the European Single Market in the 1970s and the enlargement of the EU in the 1990s all boosted EU market power.¹⁴ Equally important have been the recent changes regarding trade and IP policy of the Union. EU interest in trade has increasingly become one of persuading its trading partners to adopt rules and standards that address non-tariff and regulatory barriers. The Single European Market and the strengthening of the EU *acquis* have established liberal rules for such issues.

2.2 Recognition. The Union gained its recognition as an actor during the Dillon and especially the Kennedy Rounds of the General Agreement on Tariffs and Trade (GATT) negotiations where the Commission emerged as the negotiator. Since then, the EU has had this recognition as an actor distinct from the Member States.¹⁵ The authority of the EU to negotiate for the Member States is seen as an important attribute of ‘actorness’. The more authority the EU has for trade and trade-related topics, the more other countries will recognise it as the sole negotiator and the less they will seek out Member State governments. As noted already, the Treaty of Rome granted exclusive competence to the EEC for the

¹⁰ See Allen, D. and Smith, M., ‘Western Europe’s presence in the contemporary international arena’, 16 *Review of International Studies* 1 (1990), pp. 19–38.

¹¹ See Leal-Arcas, Rafael, ‘The European Union’s Trade and Investment Policy after the Treaty of Lisbon’, *Queen Mary School of Law Legal Studies Research Paper* No. 64 (2010), pp. 463–513.

¹² Bretherton, C. and Vogler, J., *The European Union as a Global Actor*, 2nd edition, (Oxford: Routledge, 2006).

¹³ See Woolcock, Stephen, ‘The Treaty of Lisbon and the European Union as an Actor in International Trade’, *European Centre for International Political Economy Working Paper* No. 01 (2010), p. 3.

¹⁴ For detail discussions on this, see Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper*, No. 64 (2010), pp. 463–513; also Woolcock, Stephen, *European Centre for International Political Economy Working Paper*, No. 01 (2010), pp. 1–17.

¹⁵ This was however not the case with the OECD in the 1970s and 80s where the Member States were recognised and the Commission was only an observer.

CCP. As the international trade and IP agenda deepened, new issues were added for which the EU had no exclusive competence. Even then, it became the norm that the Member States authorised the Commission to negotiate on their behalf and the EU in order to maximise their collective influence. With the Lisbon Treaty, the EU now has more powers of recognition in terms of trade with full exclusivity in the CCP.

2.3 Capability. Even though the EU has been recognised as a major actor in trade negotiations, there is still the question of how the EU uses its power and influence. This brings us to the rather more complex issue of capability. The literature on this has identified a number of elements that influence the EU's capability to use its influence effectively. The more discussed of these are autonomy and cohesion.¹⁶

Autonomy of the EU as an actor is seen in the nature of the principal-agent relationship between the Member States and the Commission. In other words, how much scope or autonomy does the Commission have in international negotiations? The answer to this is: not a great deal.¹⁷ As EU Member States are involved in decisions concerning negotiating strategies as well as the adoption of what has been negotiated by the Commission, one can conclude that it has less autonomy than its counterpart in the US.¹⁸ This situation rather poses the question whether the EU is greater than the sum of the Member States' policies. In present times, a much wider *acquis* means that trade, IP and investment policy positions are more and more based on common EU policies.

Cohesion has been seen as part of the capabilities of the EU as an actor and hence, an important attribute. On this, the historical evolution of EU trade policymaking over 50 years has created a solid set of rules and precedents that impose real disciplines on individual member state behaviour in the Council.¹⁹ With regards to output, as will be seen in following chapters, there have been times when Member State differences could only be accommodated in a common position with some difficulty,²⁰ but the number of cases in which differences have seriously damaged EU credibility in trade has probably decreased over time. Even so, it is contended that reaching a common position is not the

¹⁶ For more on this, see Jupille, J. and Caporaso, J. A., 'States, Agency, and Rules: The European Union in Global Environmental Politics,' in Rhodes, C. (ed.) *The European Union in the World Community* (1998).

¹⁷ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper*, No. 64 (2010), p. 470.

¹⁸ See Woolcock, S., 'External Trade Policy: A Further Shift Towards Brussels', in Polack, M., Young, A. and Wallace, H. (eds.) *Policy Making in the European Union*, 6th ed., (Oxford: Oxford University Press, 2010).

¹⁹ See Leal-Arcas, R., 'Is EC Trade Policy Up to Par?: A Legal Analysis Over Time – Rome, Marrakesh, Amsterdam, Nice, and the Constitutional Treaty', 13 *Columbia Journal of European Law*, No. 2 (2007), pp. 305–399.

²⁰ On agriculture in the Uruguay Round, for example, see Hodges, M. and Woolcock, S., 'The European Union in the Uruguay Round: the story behind the headlines', in Wallace, H. and Wallace, W. (eds.) *Policy-Making in the European Union*, OUP (1996).

same as being effective as an actor in international trade. To be effective would mean the EU using its market power, autonomy and capability to further EU interests and bring about changes in other countries' trade policies. So far, the EU did not succeed in its objective of shaping a comprehensive multilateral trade agenda in the 2000s so on capability, the picture is less clear cut. There are questions about the EU's autonomy in trade and perhaps also about its effectiveness in negotiations.

2.4 Legitimacy and accountability. Public and parliamentary support has been projected as an attribute of an actor. The history about this is particularly not good as the EU's international trade policy has never been seen as especially marked by explicit parliamentary or public support. Formal legitimacy for EU trade policy was ensured by national governments adopting the results of negotiation in the Council. Many Member State governments have preferred to keep trade policy insulated from detailed interference from national or European parliaments for fear that these would be captured by protectionist interests.²¹ As late as the Maastricht Treaty on European Union, the Member States made a conscious decision to keep the European Parliament (EP) out of trade policy. Most Member State parliaments have never been able – or perhaps interested enough – to provide effective scrutiny of EU external trade policy as they are at two steps removed from the real negotiations.

As a consequence, the attribute of legitimacy, or perhaps more accurately parliamentary control of policy, was not very well established in the EU before the Treaty of Lisbon. Even after Lisbon, Leal-Arcas has argued that, due to the exclusion of national parliaments from the decision-making process in the CCP, the seed of democratic deficit in EU trade decision-making has still not been completely uprooted.²² Thus, when it comes to effective parliamentary control, a factor that is important when one considers the sustainability of 'domestic' support for EU policy and capabilities, the EU could be said to have fallen short. In the next section, we discuss a case that seems to have impacted much of the EU's capabilities as an actor in trade.

3. Opinion 1/94 and the future of the CCP

Member States concerned about the uncontrolled encroachment of the EU into their constitutionally guaranteed competences²³ went into the 1991 IGC determined to limit further EU encroachment. Hence, the proposal by the Commission that the GATS and TRIPS be included in the CCP at Maastricht was rejected. Following this, the World Trade Organisation (WTO) Agreement was signed as a mixed one between the Member States and the Union. Though the

²¹ See Woolcock, Stephen, *European Centre for International Political Economy Working Paper* No. 01 (2010), p. 7.

²² See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper*, No. 64 (2010), p. 477.

²³ See Mark, A. Pollack, 'The End of Creeping Competence? EU Policy-Making Since Maastricht', *Journal of Common Market Studies*, Vol. 38, No. 3 (2000), p. 525.

Commission did not act against the EU Member States signing the WTO Agreement, it showed its dissatisfaction by requesting the legal opinion of the EUC on the matter. The Court had to examine the question of whether the EU had the exclusive competence to conclude all aspects of the WTO Agreement, including the GATT, GATS, the TRIPS Agreement, and the dispute settlement understanding (DSU).²⁴

In its judgment, the EUC rejected the Commission's argument that all trade in services and IP rights were included in the CCP, or that they were covered by implied exclusive powers.²⁵ According to EUC case law, the CCP in its conventional form as defined in Article 133(1) EC belonged to the exclusive competence of the Union.²⁶ However, this only covered trade in goods and some provisions dealing with cross-border supplies.²⁷ The exclusivity of the competence under Article 133(1) EC therefore did not necessarily extend to the competence under Article 133(5) EC which concerned trade in services and commercial aspects of intellectual property. This was so because according to the EUC, the EU had neither completely harmonised all services sectors nor all matters covered by the TRIPS Agreement at the time.²⁸ Therefore, the competence to conclude certain types of services and intellectual property was shared between the EU and the Member States. The Court demanded for a duty of co-operation and unity of representation in matters where the Union and Member States are jointly competent. However, it did not specify how such unity was to be achieved.

In many ways, the outcome of Opinion 1/94 did not only reflect the division of competences between the Union and Member States, but also, showed the tension between the forces of integration and autonomy in the Union's legal process. It also had important repercussions for future developments in the CCP. For example, the Court for the first time expressly stated that trade in services could not in principle be excluded from the scope of Article 133 EC.²⁹

²⁴ For Scholarly analysis, see W. Zdouc, 'WTO Dispute Settlement Practice Relating to the GATS', in Ortino, F. and Petersmann, E. (eds.) *The WTO Dispute Settlement System 1995–2003*, (Kluwer International, 2004), p. 381.

²⁵ For a legal analysis of the Court's problems with international (trade) agreements, see: Leal-Arcas, R., 'The European Court of Justice and the EC External Trade Relations: A Legal Analysis of the Court's Problems with Regard to International Agreements', 72 *Nordic Journal of International Law* 215, (2003).

²⁶ See for example Opinion 1/94, (WTO) [1994] ECR I-5267, at paragraphs 22, 27 and 34.

²⁷ See footnote 29 in Leal-Arcas, R., '50 Years of Trade Policy: Good Enough or as Good as it Gets?', *Queen Mary School of Law Legal Studies Research Paper* No. 13, (2009), where he explains that the exceptions were the GATS provisions dealing with cross-border supplies which were encompassed in the common commercial policy and the TRIPS prohibitions of the release of goods into free circulation of counterfeit, for which internal Community legislation was in place. Council Regulation (EEC) No 3842/86 of 1st December 1986 laying down measures to prohibit the release for free circulation of counterfeit goods (O.J. [1986] L.357/1). As for the rest of the areas of the TRIPS Agreement, harmonisation was either partial or non-existent (Opinion 1/94, para.103).

²⁸ Opinion 1/94, (1994) ECR I-5267, para. 96–97 and 102 et seq.

²⁹ *Ibid.*, para. 41.

It reasoned the mode of supply did not concern the nature of the services rendered but rather, the way in which the services concerned are provided.³⁰ This flexibility possibly meant the chances of a future inclusion of GATS and TRIPS in the CCP.

On the other hand, the Court reverted from its case-law³¹ of giving the CCP a dynamic and non-restrictive interpretation, to a more self-restraining and cautionary allocation of powers between the Union and the Member States in the field of external relations. In as much as it will be overly simplistic to conclude that the Court was only affirming the Member States rejection of the inclusion of GATS and TRIPS into the CCP, it could be criticised for its negative answer which seemed to negate the fact that a coherent commercial policy including intellectual property was necessary for the EU at the time as a strategic factor in obtaining control of international markets and of determining the flow of trade in technology-based products.³² This was necessary because at the WTO level, GATT had been extended to GATS and TRIPS. For the EU to maintain its place as a global economic actor on the international trade scene, it was important for it to align its CCP to the present trend. Any restrictive interpretation of the CCP risked causing disturbances in intra-Union trade by reason of the disparities which would then exist in certain sectors of economic relations with third countries.³³

Also, at the WTO level, this was bound to create some challenges between the Union and Member States. For example, in TRIPS cases, Member States could not cross-retaliate by taking sanctions in the goods sector as the Union had competence in that area.³⁴ More so, retaliation under the WTO dispute settlement system would be more beneficial to member states when handled by the Union as third countries could be hurt most in the area of goods if the Union retaliated. Hence, it has been held that it does not make sense for Member States (especially, small ones) to enter into dispute settlement cases in the new trade areas on their own. Their purposes would be better served if competence for the disputed areas was transferred to the Union. This on the other hand, would save third country trade partners from the ordeal of who to take responsibility when EU Member States breached trade contract terms.

³⁰ See Krenzler, H.G. and Pitschas, C., 'Progress or Stagnation?: The Common Commercial Policy After Nice', 6 *European Foreign Affairs Review* 291, (2001), p. 296.

³¹ Opinion 1/75, *Local Cost Standard* [1975] ECR 1355; Opinion 1/76, *Laying Up Fund* [1977] ECR 741; Opinion 1/78, *Natural Rubber* [1979] ECR 2871.

³² See Appella, Andrea, 'Constitutional Aspects of Opinion 1/94 of the ECJ Concerning the WTO Agreement', *International and Comparative Law Quarterly*, Vol. 45, (1996), p. 452.

³³ *Ibid.*, p. 453.

³⁴ See Arne, Niemann, 'Conceptualising Common Commercial Policy Treaty revision: Explaining Stagnancy and Dynamics from the Amsterdam IGC to the Intergovernmental Conference 2003/2004', Paper presented at the Workshop on 'Diverging Paradigms on EU Trade Policy', Catholic University of Leuven, Belgium (16–17 December 2010), pp. 13–14.

4. The CCP from Amsterdam to Nice: new wine in old wine bottles or otherwise?

4.1 *The Amsterdam IGC.* In what could be considered as a reaction to Opinion 1/94, the scope of the CCP was amended by the Treaty of Amsterdam.³⁵ Paragraph 5 was added to Article 133 EC as a possible means for the extension of the CCP to new areas by the Council of Ministers. It read:

The Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament, may extend the application of paragraphs 1 to 4 to international negotiations and agreements on services and intellectual property insofar as they are not covered by these paragraphs.

The clause never clearly extended the CCP to include trade in services and IP rights, but only created a new procedure whereby services and IP rights could become part of the EU's exclusive competence in the future. This constituted a minor reform to the scope of the CCP as per what the Commission had wanted. However, it laid the foundation for a broader scope of EU powers in this field.³⁶ Article 133(5) EC was not used in the short period of time between the entry into force of the Treaty of Amsterdam and the Treaty of Nice, when it was abolished and replaced – judging by the fact that the threshold for transferring this competence from the national to the supranational level was high (unanimity).

4.2 *The Nice amendments.* The Treaty of Nice extends the Treaty of Amsterdam in areas where it failed to do so.³⁷ For the first time, the CCP appeared on the list of items to be considered under Qualified Majority Voting (QMV) at the Nice IGC. The latter extended the CCP into the fields of GATS and TRIPS by qualified majority voting without ratification by member states.³⁸ Nonetheless, unanimity was required if only one of the services sectors or IPRs covered by the agreement came under Article 133(5)(2) EC. Also, ratification by the EU Member States was needed if one of the services sectors in question came under Article 133(6)(2) EC. Consequently, only agreements on specific services sectors, such as the GATS protocols on telecommunications or financial services, could be concluded in accordance with the rules of Article 133(1–4) EC.³⁹

³⁵ For a discussion of the Amsterdam amendments of Article 133 EC Treaty see: Cremona, M., 'External economic relations and the Amsterdam Treaty', in: O'Keefe/Twomey, *Legal Issues of the Amsterdam Treaty*, (1999), pp. 225–247.

³⁶ See Leal-Arcas, Rafael, '50 Years of Trade Policy: Good Enough or as Good as it Gets?', *Queen Mary School of Law Legal Studies Research Paper No. 13*, (2009), p. 169.

³⁷ Yataganas, A. Xenophon, 'The Treaty of Nice: The Sharing of Power and the Institutional Balance in the European Union – A Constitutional Perspective', 7 *European Law Journal*, No. 3 (2001), p. 243.

³⁸ Krenzler, H.G. and Pitschas, C., 6 *European Foreign Affairs Review* 291, (2001), p. 310.

³⁹ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 13* (2009), p. 172.

Thus, the Nice provisions still had some important drawbacks such as: (1) FDI was not included within the scope of Article 133; (2) unanimity was still required for the negotiation and conclusion of horizontal agreements, if one of the above derogation areas formed part of broader negotiations. Furthermore, ratification by the Member States was needed in such cases; (3) the European Parliament remained excluded from decision-making in the CCP as not even a formal right of consultation was obtained; (4) Member States were still allowed to maintain and conclude agreements in the fields of trade in services and the commercial aspects of IPRs.⁴⁰

It thus appears that even though progress made at Nice was substantial, it still missed the opportunity to give the EU greater weight in all aspects of international trade negotiations. The changes brought by it only represented a small step forward in strengthening the EC's capacity to act on the international scene. To this end, many commentators⁴¹ argue that the Treaty of Nice reflected the outcome of *Opinion 1/94* to the extent that, the new Article 133 continued to be shared competence with regard to the GATS and the TRIPS.⁴² It would thus suffice to firmly remark then that, attempts at Maastricht, Amsterdam and Nice to bring GATS and TRIPS into the CCP amounted to pouring new wine into old wine bottles.

5. The CCP after Lisbon

The Treaty of Lisbon is a substantive legal document that introduces significant legal, procedural, and institutional changes to the EU external relations.⁴³ Aside giving the Union legal personality,⁴⁴ it for the first time specifies the various types of competences that exist in the EU⁴⁵ – something that previous Treaties lacked. The entire CCP is now the exclusive competence of the Union. The Lisbon Treaty introduces three main changes to the CCP: first, it explicitly extends exclusive EU competence to cover trade in services, commercial aspects of intellectual property, and for the first time, to foreign direct investment; second, it enhances the role of the EP by granting it joint powers with the Council to adopt measures for the legislative framework of trade, and by facilitating a more active role for the EP in the negotiation and ratification of international trade agreements; and third, it brings external trade under the same heading as EU external action along with foreign policy, development, humanitarian aid, and international environment policy. These are discussed in turn.

⁴⁰ See Arne, Niemann, 'Diverging Paradigms on EU Trade Policy', Catholic University of Leuven, Belgium, (16–17 December 2010), p. 10.

⁴¹ See, among others, Pescatore, P., Guest Editorial: Nice – Aftermath, 38 *Common Market Law Review* 265, (2001); Krenzler, H.G. and Pitschas, C., 6 *European Foreign Affairs Review* 291, (2001); Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper* No. 13 (2009), pp. 157–182.

⁴² See Article 133(5) EC as modified by the Nice Treaty.

⁴³ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper* No. 64, (2010), p. 465.

⁴⁴ See Article 47 TEU.

⁴⁵ See Article 2 and 3(2) TFEU.

5.1 *Exclusive competence in the CCP.* The CCP determines the legal basis for Europe's place in its global economic relations. This is now affirmed through Article 3(1)(e) TFEU. This was not the case before Lisbon. Article 207(1) TFEU, whose substantive part is no different from the previous Article 133(1) EC,⁴⁶ has broadened the scope of the CCP to provide for exclusive competence over trade in services, commercial aspects of intellectual property, and foreign direct investment. It specifies the 'the conclusion of tariff and trade agreements relating to trade in goods and services, the commercial aspects of intellectual property, and foreign direct investment' making them subject to the Union's exclusive competence.⁴⁷

This departs from the Nice provisions which rendered services and IP shared competence between the Union and Member States. Nice did not add FDI to the CCP but Article 207(1) of the TFEU adds FDI as a new area of CCP competence, although it does not cover intra-EU bilateral investment treaties (BITs). This gives the Union the authority now to conclude international investment treaties. Placing investment treaties within the scope of the CCP means that the Union has exclusive competence over foreign direct investment.⁴⁸ It follows that EU Member States will lose their competence to negotiate and conclude such treaties when these deal with foreign direct investment. More exclusive EU competence can be expected to strengthen the EU presence in trade as will the extension to include FDI.

With this explicit shift of competences, international agreements on trade in services and the commercial aspects of intellectual property rights will thus exclude the Member States and their national parliaments from the ratification process. Some scholars have been commenting that the implication of the Union's exclusive competence in trade policy is the assurance of the unitary representation of interests within the WTO for the first time in the EU.⁴⁹ The changes introduced tend toward greater centralisation of trade and IP policy and toward reducing the EU Member States' influence in these areas.⁵⁰ This obvi-

⁴⁶ For the legal situation after the Treaty of Amsterdam, see Cremona, M., 'EC External Commercial Policy after Amsterdam: Authority and Interpretation within Interconnected Legal Orders', in J.H.H. Weiler (ed.), *The EU, the WTO and the NAFTA: Towards a Common Law of International Trade?* (Oxford: Oxford University Press, 2000), pp. 5 et seq.; Cremona, M., 'Rhetoric and Reticence: EU External Commercial Policy in a Multilateral Context', 38 *CML Rev.* (2001), p. 139; Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 13* (2009), p. 168 et seq.

⁴⁷ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 64*, (2010), p. 479.

⁴⁸ Article 207(1) TFEU in conjunction with Article 3 TFEU, Official Journal C 115 of 9 May 2008, 2008/C 115/1.

⁴⁹ For detail discussion on this, see Bungenberg, Marc, 'Going global? The EU Common Commercial Policy after Lisbon', in Hermann, C & Terhechte, J.P. (eds), *European yearbook of international Economic Law* (Springer – Verlag Berlin Heidelberg, 2010), pp. 123–151; J. Wouters et al., in Stefan Griller and Jacques Ziller (eds.), *The Lisbon Treaty. EU Constitutionalism without a Constitutional Treaty?* (Wien, Austria: Springer, 2008), pp. 144–203; Reference to Cases C-1/94 and C-13/07 respectively.

⁵⁰ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 13* (2009), p. 179.

ously has profound impact on the ability of the Member States and their national parliaments to influence new trade agreements dealing with IP and trade in services.

This is so because the improved CCP allows the Commission, after a qualified majority votes in the Council of Ministers, to make deals in the GATS and the WTO Agreement on what the Commission itself defines as the commercial aspects of these services. The commercial aspects of them are not defined in the Treaty of Lisbon or elsewhere. The implication of the fact that the commercial aspects of these services are not defined in the Treaty of Lisbon or elsewhere is that an EU Member State would have to go to the EUC to challenge the Commission, arguing a defense that would have to show that the Commission was opening trade in non-commercial aspects of them.⁵¹ This would be a very difficult legal argument to make since many parts of them can be broken into individual functions and contracted out.

Even so, the TFEU includes a provision for the use of unanimity in some politically sensitive sectors. Article 207(4) TFEU states generally that the Council shall vote by qualified majority in the negotiation and conclusion of CCP agreements with third countries, but specifies that for fields of trade in services and commercial aspects of IP, the Council shall act unanimously where such agreements include provisions for which unanimity is required for the adoption of internal rules.⁵² This is intended to secure that voting in the Council run in parallel in the internal and external spheres of the Union. To achieve this aim, the rule should apply whenever a trade agreement includes provisions on IPRs.⁵³ This provision is similar to former Article 133(5) EC, except that the new provision does not require unanimity where the agreement 'relates to a field in which the Community has not yet exercised the powers conferred upon it by this Treaty by adopting internal rules'.⁵⁴

Similarly, according to the second and third subparagraphs of Article 207(4) TFEU, unanimity is required in the negotiations and conclusion of agreements in the fields of culture and audiovisual services, where the agreements risk prejudicing the Union's linguistic and cultural diversity. There are similar unanimity rules for social, education, and health services in Article 207(4)(b) TFEU where the agreement at stake risk 'seriously disturbing the national organisation of such services and prejudicing the responsibility of Member States to deliver them'. This is a change from Article 133(6) EC in that now, agreements relating to trade in cultural and audiovisual services, educational services, and social and human health services are no longer a shared competence of the Union and the

⁵¹ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 64*, (2010), p. 496.

⁵² See Article 207(4) TFEU.

⁵³ For varied opinions on this, see Mylly, Tuomas 'Criminal Enforcement and European Union Law' in Christophe Geiger (ed.), *Criminal Enforcement of Intellectual Property*, (Edward Elgar publication, forthcoming 2011), where he explains that Pitschas' position that the criterion should be non-incident intellectual property provisions in several international agreements could effectively frustrate the purpose of Article 207(4) and the voting rights of the member states.

⁵⁴ Article 133(5) EC as amended by the Nice Treaty.

Member States. Therefore, a Member State seeking unanimity will, it seems, have to provide explanations as to how the agreement in question would represent a risk to 'the Union's cultural and linguistic diversity' or a risk to the national organization of social, educational, and health services. Presumably, if the other EU Member States did not agree, the Council would act by QMV and it might be the EUC which would have the final say.⁵⁵

5.2 European Parliament's Role Enhanced. The Lisbon Treaty gives new role and powers to the European Parliament when it comes to international trade negotiations in three ways: first, co-decision making powers with the Council for trade legislation; second, a greater say in negotiations; and third, the power to grant 'consent' to the adoption of all trade agreements negotiated by the EU. The implication is that the EP now has significant influence over the content of provisions in agreements relating to trade in services and the commercial aspects of intellectual property, including measures to fight counterfeiting and piracy in third countries.⁵⁶ This is vividly seen in the provisions of the TFEU on the CCP.

Unlike the previous treaties, Article 207(2) TFEU explicitly stipulates that, the EP and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall adopt the measures defining the framework for implementing the CCP. This provision fundamentally increases the role of the EP in that, the adoption of regulations defining the framework for implementing the CCP requires the joint adoption by the EP and the Council under the so-called "ordinary legislative procedure"⁵⁷ which legal scholars believe resembles the co-decision procedure under the EC Treaty.⁵⁸ This process will for example, as Matthews indicates, give the EP the opportunity 'to ensure that the common commercial policy deals explicitly with the fight against counterfeiting and piracy and that aspects relating to intellectual property rights enforcement are proportionate, effective and balance the interests of EU stakeholders with the avoidance of onerous enforcement burdens on third countries, particularly low-income developing or least-developed countries.'⁵⁹

Further, when it comes to international negotiations, the Commission is obliged to report regularly to the EP on the progress of negotiations and not

⁵⁵ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper* No. 64, (2010), p. 481.

⁵⁶ See Matthews, Duncan, 'The Lisbon Treaty, Trade Agreements and the Enforcement of Intellectual Property Rights', 32 *European Intellectual Property Review* 3, (2010), p. 15.

⁵⁷ See Article 294 TFEU.

⁵⁸ On this, see footnote 51 in Matthews, 32 *European Intellectual Property Review* 3, (2010) where he explains that under the TFEU the co-decision procedure, as provided for in Article 251 of the EC Treaty, is retained unchanged, becoming the "ordinary legislative procedure"; Also, Müller-Graff, Peter-Christian, 'The Common Commercial Policy Enhanced by the Reform Treaty of Lisbon?', in Alan Dashwood and Marc Maresceau (eds), *Law and Practice of EU External Relations. Salient Features of a Changing Landscape* (New York, US: Cambridge University Press, 2008), p. 198.

⁵⁹ See Matthews, Duncan, 32 *European Intellectual Property Review* 3, (2010), p. 15.

just to the special committee set up by the Council.⁶⁰ Also, even though the TFEU confers upon the Council, acting upon a proposal from the negotiator, the competence to adopt a decision concluding international agreements,⁶¹ in several cases listed in Article 218 TFEU, the Council is required to obtain the consent of the EP, except where the agreement relates exclusively to the Common Foreign and Security Policy.⁶² This consent of the EP in such matters goes as far as in urgent situations where the Council and the EP will have to agree upon a time-limit. Even where time limits are agreed, consent must still be given by the EP before the Council can adopt the decision concluding the agreement.

The present Treaty's enhancement of the powers of the EP is appropriate, especially, in light of the several confusions among the various Nice Treaty provisions regarding the CCP. The EP did not benefit a great deal from the reform of Article 133 EC. It was not given any new rights at the Nice Summit, not even a formal right of consultation, even if Article 133(7) EC provided that the EP be consulted concerning the negotiation and conclusion of international agreements on IPRs.⁶³ The EP was required to deliver its opinion within a time limit which the Council could lay down according to the urgency of the matter and, in the absence of an opinion being delivered by the EP within that time limit, the Council could act.⁶⁴ Thus, in part, the TFEU has been an attempt to bridge the democratic deficit that has characterised most past treaties by including the EP in the decision-making process, and thereby encouraging more democratic legitimacy and increased consistency in the EU external action.

5.3 The CCP under Union's external action. The Lisbon Treaty dispenses with the formal division between the three pillars of the EU and, at least on paper, creates a unified set of objectives and decision-making procedures for all EU external policies. Under Part Five on external action in the TFEU, the CCP is for the first time brought under the same external action heading as other elements of EU external policy.⁶⁵ It is therefore to be conducted within the context of the framework of the general principles and objectives of the Union's external action⁶⁶ which are, inter alia, advancement of democracy, rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity as well as the principles of equality and solidarity.⁶⁷ To this end, the CCP and the other elements of the EU external action must be pur-

⁶⁰ See Article 207(3) TFEU.

⁶¹ See Article 218(2) and (4) TFEU.

⁶² See Article 218(6) (a) TFEU.

⁶³ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper* No. 13 (2009), p. 175.

⁶⁴ Article 300(3) of the EC Treaty, as amended by the Treaty of Nice.

⁶⁵ Articles 206 and 207 TFEU.

⁶⁶ Articles 205 and 207 TFEU.

⁶⁷ See Article 21(1)–(3) TEU.

sued and developed alongside these principles and objectives. Cremona, commenting on this development, determines that, the binding linkage of the CCP to these principles and objectives points out that the EU does not only have a liberalisation agenda, but that other objectives must also be taken into account in the negotiation of bilateral trade and investment agreements.⁶⁸

This new development could also be seen as a move by the drafters of the Lisbon Treaty geared towards avoiding dichotomies between the economic and political external policy of the Union, and to bring increased consistency. This is seen through the number of substantive amendments made such as the centralisation of the objectives of external action; bringing the different areas of EU external relations under the same heading of external action (even though the Treaty formally separates the Common Foreign and Security Policy from the other areas of EU external relations); and other institutional modifications such as the new function of the High Representatives of the Union for Foreign Affairs and Security Policy (High Representative), and laying the basis for the European External Action Services (EEAS).⁶⁹ Even though there are concerns as to how the Council, the Commission, and the High Representative could work to ensuring consistency in the external relations of the Union – especially, considering the tension that has often existed between these institutions, it has been argued that the dual role of the High Representative and the requirement by the Treaty that these institutions cooperate to that effect, signals the determination to bridge these tensions and to call for greater efficiency and coherence in the Unions external action.⁷⁰

This is further consolidated through Article 218 TFEU which covers the procedure to be followed when negotiating all international agreements. Article 218(3) TFEU requires that either the Commission or the High Representative will negotiate on behalf of the Union if the agreement relates exclusively or principally to the common foreign and security policy. However, the Council nominates the negotiator. When it comes to trade, Article 218(1) TFEU states that the procedures set out in that article are without prejudice to the specific provisions of Article 207 TFEU, which deals with external trade and indicates that the Commission will negotiate.⁷¹

5.4 Delimitation of competences. Unlike the previous complex Article 133(5) to (7) EC, the new Article 207 TFEU contains no language that hint at a non-exclusive competence which would be subject to the principle of subsidiarity and

⁶⁸ Cremona, M., 'A Constitutional Basis for Effective External Action? An Assessment of the Provisions on EU External Action in the Constitutional Treaty', *EUI Working Papers Law* No. 30, (2006), p. 30, para. 52.

⁶⁹ See J. Wouters *et al.*, in Stefan Griller and Jacques Ziller (eds), *The Lisbon Treaty. EU Constitutionalism without a Constitutional Treaty?* (Wien, Austria: Springer 2008), p. 145.

⁷⁰ J. Wouters *et al.*, in Stefan Griller and Jacques Ziller (eds), *The Lisbon Treaty. EU Constitutionalism without a Constitutional Treaty?* (Wien, Austria: Springer 2008), pp. 147–155.

⁷¹ Article 207(3).

which might entail specific procedures.⁷² Moreover, the first and second subparagraphs of Article 133(6) EC have been removed.⁷³ These measures notwithstanding, the drafters of the TFEU made sure there are limits to the Union's exercise of these competences. Provisions in the TFEU makes it clear that the Union's exercise of the external competences does not confer on it an implied internal competence to implement such agreements. Article 218 TFEU outlines the procedure for the negotiation and conclusion of international agreements, but among other things, adds 'without prejudice to the specific provisions laid down in Article 207'. This latter provision crucially leads to the so-called 'parallelism-clause' – Article 207(6) TFEU under the CCP. This clause states that, 'the exercise of the competences conferred by this Article in the field of the Common Commercial Policy shall not affect the delimitation of competences between the Union and Member States, and shall not lead to harmonisation of legislative or regulatory provisions of the Member States in so far as the Treaties exclude such harmonisation.'⁷⁴

This Article reflects the general principle of conferred powers in the context of the CCP, as expressed on a general level in Article 5(1) TEU, which embodies the overriding Union principles of conferral, subsidiarity, and proportionality, which must govern all Union activity.⁷⁵ It is however important to note that, the present form of shared competence in the TFEU is different from the previous Article 133(6)(2) EC. The new Article 2(2) TFEU provides that, the Union and the Member States may legislate and adopt legally binding acts in the area of shared competence but that, Member States shall exercise their competence to the extent that the Union has not exercised, or has decided to cease exercising its competence. The only exception is in the area of international agreements on transport services. Article 207(5) explicitly stipulates that agreements in this area shall be subject to the specific transport provisions of Article 90 *et seq.* TFEU.⁷⁶ These articles, it seems, rather offer little protection against the exclusivity of the powers granted the Union from Articles 3(1)(e) and 2(2)

⁷² Müller-Graff, Peter-Christian, 'The Common Commercial Policy Enhanced by the Reform Treaty of Lisbon?', in Alan Dashwood and Marc Maresceau (eds), *Law and Practice of EU External Relations. Salient Features of a Changing Landscape* (New York, US: Cambridge University Press, 2008), p. 191.

⁷³ See Mylly, Tuomas, in Christophe Geiger (ed.), *Criminal Enforcement of Intellectual Property*, (Edward Elgar publication, forthcoming 2011).

⁷⁴ According to Müller-Graff (2008), this in other words mean, the TFEU will not change the present situation – referring to Article 133(6) EC.

⁷⁵ See de Mestral, A., 'The Lisbon Treaty and the Expansion of EU Competence over Foreign Direct Investment and the Implications for Investor-State Arbitration', in Sauvant, K.P. (ed.), *Yearbook on International Investment Law and Policy*, (New York: Oxford University Press, 2009/2010).

⁷⁶ See Part III Title VI TFEU, and Article 218; also, see Müller-Graff who comments that the requirement of mixed agreements survives in all cases where the transport policy fulfils more than a simple subordinate or ancillary function. If it is anything to go by that the structure of external competence could mirror internal competences, then this is reasonable. He anticipates that on the basis of the internal order of competences within the Union, the mixed procedure would continue to be required where agreements involve competences of the Member States that are required to be equally important part thereof (2008, p. 192).

of the TFEU. However, the European Parliament's ability to veto international trade agreements to a large extent could serve as a check on the powers of the Council and the Commission.

5.5 The CCP and the 'effectiveness or increased consistency' argument. Does the changes brought by Lisbon to the CCP only amount to increasing consistency and effectiveness of Union external action? Certainly, there is more to the Lisbon changes that seek to transform the Union as an efficient global actor than merely making it effective or consistent in its external policy. At least, Leal-Arcas' argument that there will be little immediate change due to the inclusion of external trade in common EU external action seeks to justify this. The effectiveness of the EU external policies have more to do with the existence of well established procedures and expectations of decision-makers than formal competence⁷⁷ as exemplified in chapters two and six of this paper. In this context, the expectation must be that it will be some time before the High Representative for Foreign and Security Policy (HRFSP) and the European External Action Service (EEAS) will have much influence on trade policy procedures in the Commission and the Council that have evolved over half a century.

Even so, there is no denial of the eventual increase in consistency and effectiveness of the Union's external policy. The issue of formal competence cannot be downplayed compared to the 'well established procedures and expectations of decision-makers' seemingly suggested by Leal-Arcas in this context. It is crystal clear over the years that in the absence of proper formal allocation of competences in the external field, differences in strategy and priorities of the EU institutions have led to more delays and legal challenges⁷⁸ that somehow slowed progression in the Union's ability to act as an actor both in the economic and political sphere. At least, now that there is a clear division and allocation of competences, it could hasten up decision-making at the Union level and also, possibly do away with most legal challenges. *Ceteris paribus*, if it wouldn't contribute to the smooth realisation of the aims of Union policies, the Treaty wouldn't for the first time draw a clear demarcation of Union competences.

One central aim of the Treaty of Lisbon is to ensure that the EU remains effective and consistent in policymaking following enlargement. The extension of exclusive competence could perhaps add something to effectiveness by removing some of the EU Member States' ultimate power to use unanimity. Also, the end to shared competence and thus the absence of EU national parliaments in the ratification of agreements should also enhance efficiency (in terms of speed

⁷⁷ Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 64*, (2010), p. 465.

⁷⁸ See ECJ, Opinion 1/76, *Draft Agreement establishing a European laying-up fund for inland waterway vessels*, [1977] ECR 741; Opinion 2/91, *Convention N° 170 of the International Labour Organization concerning safety in the use of chemicals at work*, [1993] ECR I-1061; ECJ Opinion 1/94, *WTO-Opinion*, (1994) ECR I, p. 5267; Case C-91/05, *Commission v. Council ('ECOWAS' or 'Small Arm and Light Weapons')*, Grand Chamber Judgment of 20 May 2008, nyr.

of decision-making) of the EU in the implementation of legislation. This should strengthen the EU as an actor as its negotiating partners will view the risk of non-ratification (involuntary defection) as even less likely than under the pre-Lisbon Treaty arrangements.⁷⁹

On the other hand, Woolcock has been commenting on the possible impact of the Lisbon Treaty on the efficiency of EU trade policy. First, there is the possibility that in the longer term the increased powers of the EP could result in a reduced efficiency in the sense that political debate in the EP could delay and/or complicate decision making.⁸⁰ This stems from the fact that the increased powers of the EP gives it co-decision powers with the Council on trade legislation and an opportunity to have more say in trade negotiations, as opposed to any direct involvement in negotiating or implementing trade policy. So political intervention from the EP, in the relatively effective technocratic processes that shape EU policy today, will depend on whether the EP can bring about a shift in the *de facto* balance of influence. This seems to be unlikely in the short term. In the medium to long term (i.e. over the life of the new EP and beyond) much will depend on how the International Trade Committee works and the degree to which the EP becomes a channel for interest group lobbying.⁸¹

The other potential source of inefficiency lies in the influence of other external policy objectives on trade. EU trade policy over the years has been relatively consistent in its pursuit of progressive trade liberalisation on the basis of reciprocal trade concessions. Thus, a greater desire for coherence across external policies (foreign, environmental and developmental) could result in more extensive and conflicted inter-service consultations.⁸² The greater Member State powers in foreign policy, and to a lesser degree in environmental and development policies, could also complicate efforts to ensure vertical coherence between EU trade policy and Member State policies in other areas. Could this be the new model of stagnancy for the CCP?

6. Explaining stagnancy and dynamics in changes to the CCP pre-Lisbon

Why did the EU have to wait for over 50 years to extend the CCP to GATS and TRIPS? While it is convincing that exogenous pressures (often related to the changing international trade agenda or the strengthening of the institutional framework of the WTO) led to cries for the extension of the CCP to GATS and TRIPS, it is nonetheless determined here that endogenous factors such as: (i) functional pressures; (ii) the role of supranational institutions; (iii) socialisa-

⁷⁹ See Leal-Arcas, Rafael, *Queen Mary School of Law Legal Studies Research Paper No. 64*, (2010), p. 509.

⁸⁰ See Woolcock, Stephen, *European Centre for International Political Economy Working Paper No. 01* (2010), p. 15.

⁸¹ Woolcock, Stephen, *European Centre for International Political Economy Working Paper No. 01* (2010), p. 15.

⁸² *Ibid.*

tion, deliberation and learning processes; and (iv) countervailing forces⁸³ actually contributed to the stagnancy and dynamics in changes to the CCP.

6.1 Functional pressures. This is explained to mean the tensions, contradictions and interdependencies closely related to the European integration project, its policies, politics and polity which induce policy-makers to take additional integrative steps in order to achieve their original goals.⁸⁴ The outcome of Opinion 1/94 to a lesser degree, contributed to such functional pressures. This reflected at Maastricht, where neither the Commission, nor any other negotiating party attempted to argue along the lines of the internal powers doctrine which the EUC had rejected. Also, fears about future enlargement and possible extension of QMV also added to the pressure as it became a frequent rationale used to substantiate the need for further CCP reform. This logic of anticipated problems was also argued in various Commission papers on the modernisation of Article 133 EC.⁸⁵

Reluctant Member States worried that there may be a transfer of internal competences from the Member States to the Community in some fields coming under exclusive Community competence externally. They were afraid that external liberalisation could foster a process of internal liberalisation and that the Commission could use the backdoor of Article 133 EC to regulate in areas which fall under Member States' competence.⁸⁶ Such moderate functional pressures continued till the Laeken Declaration on the Future of European Union⁸⁷ which rendered changes to the CCP a necessity.

⁸³ For extensive discussions on this, see Arne, Niemann, 'Diverging Paradigms on EU Trade Policy', Catholic University of Leuven, Belgium, (16–17 December 2010), p. 2.

⁸⁴ See loc. cit.

⁸⁵ Commission of the European Communities, DG I, Speaking Briefing Anpassung des Artikels 113, 15 October (1996).

⁸⁶ See Arne, Niemann, 'Diverging Paradigms on EU Trade Policy', Catholic University of Leuven, Belgium, (16–17 December 2010), p. 17.

⁸⁷ The European Convention (also known as the Convention on the Future of Europe) was set up in December 2001. It had 105 members, representing the presidents or prime ministers of the EU Member States and candidate countries, their national parliaments, the European Parliament and the European Commission. Its Chairman was former French President Valéry Giscard d'Estaing. The Convention's job was to draw up a new Treaty that would set out clear rules for running the European Union after enlargement. It was, in effect, to be the Constitution of the EU. The Convention completed its work on 10 July 2003. In order to reach a compromise for all parties present, the Convention consulted diverse groups of civil society (citizens, social partners, NGOs, economic sectors, *et cetera*) in various ways, one of which was the Forum on the Future of the Union. The Forum on the Future of the Union was created by the Convention Secretariat, with the technical assistance of the Commission, and received contributions from interested national and supranational organizations. Eight contact groups were set up to prepare auditions for the academic world, study groups, the social sector, the environment, human rights, development, regions and local authorities, culture, and citizens and the EU institutions. The Convention also created an online forum on the future of Europe to connect with civil society. See online document at: <http://european-convention.eu.int/pdf/LKNEN.pdf> (last visited on 28.07.11).

6.2 The role of supranational institutions. It has been theorised that, institutions once established, tend to take on a life of their own and are difficult to control by those who created them.⁸⁸ These institutions tend to work towards increasing their own powers and by so doing, become agents of integration since they are likely to benefit from the progression of this process. Such institutional structures have an effect on how actors understand and form their interests and identities. During the 1996 IGC, the role of supranational institutions provided little integrative impetus. Haven failed to push through the CCP dossier at Maastricht; it became even harder for the Commission to do same at Amsterdam especially, in the wake of the Commission's representatives recurrently arguing that the Commission will not seek to expand its competence. Member States therefore became irritated later when the Commission asked for what was perceived as 'new competences in disguise'.⁸⁹

Again, the role played by the EUC in Opinion 1/94 was detrimental to the course of extending Article 133 EC. It could be argued that due to the Courts ruling, the Commission's wish for an extension of Article 133 lacked critical legal endorsement by the very institution that had supported a dynamic integrationist interpretation of the CCP and EU law in general.⁹⁰ Even more, the various Presidencies did little to help the Commission's quest for extension in the CCP. The EP likewise was lukewarm towards the Commission's bid because the Commission's proposal at the time did not (explicitly) foresee greater EP involvement. The fact that the EP was not out rightly supportive may have taken some legitimacy away from the Commission's proposal.⁹¹ On the other hand, the EP sought the introduction of co-decision for Article 133 EC and to extend assent to all international agreements as a way of strengthening its position. The impact of such internal scuffles continued until Nice when things however changed.

6.3 Socialisation, deliberation and learning processes. In recent years, there have been the gradual increase in working groups and committees on the European level and that has led to a complex system of bureaucratic interpenetration that brings thousands of national and EU civil servants in frequent contact with each other on a recurrent basis. The dynamics of socialising and deliberations at this level is thus important for Treaty revision preparations and negotiations. This was not the case for the Amsterdam IGC hence, the minimalist outcome on the CCP. Possible reasons that could account for this was: the nature of the subject area combined with the background of negotiators; too little time devoted to the CCP reform as it was not regarded as a high priority issue compared to the CFSP; the fact that the negotiating group had only worked together for one

⁸⁸ See Pierson, Paul, 'The path to European integration: a historical institutionalist analysis', 29 *Comparative Political Studies*, No. 2 (1996), 123–163.

⁸⁹ See Arne, Niemann, 'Diverging Paradigms on EU Trade Policy', Catholic University of Leuven, Belgium, (16–17 December 2010), p. 24.

⁹⁰ *Ibid.*, p. 25.

⁹¹ *Ibid.*, p. 26.

year and a half; basic distrust by some Member States of the role of the Commission in representing the Union in international negotiations and keeping the Member States abreast of what is going on; and the wider issue of bureaucratic politics.

Hence, breakthrough in changes to the CCP came later through the Convention which allowed for greater socialisation, deliberation and learning through the plenary listening. In the Working Group on External Action, there was sufficient time for substantial debate and a more thorough exchange of arguments and counterarguments concerning the merits of CCP reform, increase in the quantity of interaction, and a free atmosphere for negotiating.

6.4 Countervailing forces. Aside the dynamics of integration, countervailing forces also impacted the decision-making process. For instance, at Amsterdam and Nice, domestic constraints could explain for the restrictive outcome. On specific trade policy issues, bureaucratic resistances played an important role. For example, officials at the French Ministry of Economy, Finance and Industry blocked the issue of investment to come under the scope of Article 133 EC largely. Further, France asked for derogation on cultural services to safeguard its cultural diversity policy behind which there was strong public support and strong lobbies.⁹² Similarly, officials from the Dutch, UK, Danish, Greek, German and Austrian national transport ministries are said to have been very reluctant to introduce QMV for trade in transport services – mainly in order to avoid having to cede competence to their respective economic ministries. As a consequence, these issues tend to be politicised, which made the transfer of competences to the Union more difficult.

Also, there was the more diffused issue of sovereignty-consciousness which constituted another strong countervailing pressure during the IGC. The intrusion of the new trade issues into domestic spheres close to the heart of national sovereignty had increased the sensitivity in terms of delegating powers to the Union on these issues. Several countries, including France and the UK, came out against an extension of Union competence contrary to their national interest, and joined the ‘sovereignty camp’, largely on ideological grounds.⁹³ However, during the Convention, countervailing forces grew weaker. This was as a result of the absence of inter-departmental coordination. Bureaucrats, who have been identified as important agents of sovereignty consciousness and as a principal source of domestic constraints, were thus largely shut out from the process. Due to this, the results of the Convention had a much greater significance than

⁹² See Arne, Niemann, ‘Diverging Paradigms on EU Trade Policy’, Catholic University of Leuven, Belgium, (16–17 December 2010), p. 29.

⁹³ See Meunier, S. and Nicolaidis, K., ‘Who speaks for Europe? The delegation of trade authority in the EU’, 37 *Journal of Common Market Studies*, No.3 (1999), pp. 477–501. Contrary, Both France and the UK are very competitive internationally in terms of trade in commercial services and have a positive trade balance in this sector. Their interest would have been best served by a Community with exclusive trade competence, since its collective negotiating position cannot be held up by the Member State least ready to confront international competition.

normal IGC preparation exercises. And even though the Constitutional Treaty failed, much of what Lisbon brings is actually, a reflection of most part of the Constitutional Treaty especially, when it comes to the CCP.

7. Conclusion

It is apparent that even before Lisbon, the EU had been an actor in trade due to its market power, exclusive EU competence and adequate capabilities. However, the EU could be said to have fallen short in some of the attributes of 'Actorness' such as with regard to effective parliamentary control and questions about its capabilities. Much of the decline in the economic power of the EU happened in the 1990's and 2000's when events in the multilateral trading system (WTO) as well as internal challenges to the Union (such as the effects of the outcome of Opinion 1/94, and the struggle on the extension of Article 133 EC to include GATS and TRIPS) all pointed to the direction that the EU needed to transform its trade policy if it wanted to remain significant as a major trade actor. Changes were effected to the CCP at both the Amsterdam and Nice IGC's but then these changes were minimal in the area of services and the commercial aspects of intellectual property such that, they amounted to pouring new wine into old wine bottles.

With the passage of the Lisbon Treaty, there is no doubt that the EU has re-established itself strategically as a global superpower in international trade negotiations. Changes to the CCP enhance the EU as an actor in trade and IP. Lisbon has transformed decision-making in trade policy such that, it is most likely to improve the transparency and efficiency of EU trade policy by the streamlining and simplification of EU competence. With the greater role of the European Parliament now, accountability will be enhanced. Aside this, it is expected to bring consistency and effectiveness to the trade policy of the Union as the CCP is now brought under the umbrella of the Union's external action. However, as the EP will need to further develop its capacity before it can be effective in close scrutiny of the Commission during negotiations, the impact of the Lisbon Treaty in this respect is only likely in the medium term, perhaps over the life of a European Parliament.

In as much as exogenous pressures have been cited as accounting for delays in changes to the CCP, it has been argued particularly that endogenous factors could actually account for different outcomes in past Treaty revisions. The failure to modernise Article 133 EC at the Amsterdam IGC has been explained as the result of overall weak dynamics combined with strong countervailing pressures. Also, sovereignty-consciousness complemented by domestic constraints due to increasing politicisation of the new trade issues contributed to the stagnation of changes to the CCP. At Nice, some concessions were made which partially explains for the extension of QMV. However, what obviously made a difference was the Convention which somehow laid the foundation for the failed Constitutional Treaty, and subsequently, the Lisbon Treaty.

Chapter III

Publication II

Balancing or lobbying? On access to medicines, border measures and the European Parliament's amendments to the proposed EU trademark rules

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Balancing or Lobbying? On Access to Medicines, Border Measures and the European Parliament's Amendments to the Proposed EU Trademark Rules

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Enhanced intellectual property rules are noted as among the forces limiting the global access to medicines. In the European Union (EU), it is the Border Measures Regulation that has caused major disruptions for generic medicines in transit at its borders in the past. However, the Commission's recent proposal for changes to the EU trademark rules promises another layer of restraint on access. In adopting the proposal, the European Parliament has moved to correct this syndrome by suggesting amendments that balance intellectual property and public health interest. But, can that pass the influence of corporate lobbyist? This essay argues that for the sake of certainty, the European Parliament's amendments are good law and should be maintained.

Keywords: Intellectual property rights, access to medicines, EU trademark rules, border measures, European Parliament

Since the incorporation of intellectual property into the World Trade Organisation (WTO) Agreements,¹ the issue of balancing the protection and enforcement of intellectual property rights on the one hand, and access to medicines (generic medicines)² on the other, has gained currency. Two incidents spawned this awareness: the first was the South African case³ in 1998, when about 39 multinational pharmaceutical companies took the South African government to court over the introduction of the South African Medicines and Related Substances Control Act (MRSCA),⁴ which contained a new Section 15C explicitly permitting parallel import of patented pharmaceuticals.⁵ The second, which is central to this essay, was the continuous seizure of generic medicines in transit at various European Union (EU) ports between 2008 and 2010 en route from India to destinations in Latin America and Africa.⁶ The legal basis of such seizures had been Regulation No (EC) 1383/2003⁷—the Border Measures Regulation (BMR), which sets out the conditions for action by the customs authorities when goods suspected of infringing an intellectual property right come under their supervision. Consequently, it has been the BMRs that have caused major disruptions for generic medicines in transit through the EU. For trademarks, the Court of Justice of the European Union (CJEU)

has long ruled that goods in transit did not constitute an infringement under the EU trademark rules.⁸ So where do trademarks come in? Against the background of a WTO dispute consultation for the seizure of generic medicines in transit at its borders,⁹ the EU agreed in principle to amend its BMR.¹⁰ It was anticipated that the new BMR¹¹ would balance these two conflicting, but related, policy objectives: intellectual property rights and access to medicines. However, with regard to its content the new BMR fell short of expectations. Whilst commentators decry the content of the new BMR as limiting access;¹² anti-counterfeiting stakeholders complain that the new regulation did not do enough to correct the *Philips* and *Nokia* impact¹³ (explained later), despite the fact that it has been the subject of heavy lobbying.¹⁴ The European Commission since proposed changes to EU trademark rules.¹⁵ Based on its content, it is argued that the proposed revisions are an attempt by the Commission to correct the *Philips* and *Nokia* impact with implications for global access to medicines.¹⁶

The European Parliament (EP) has moved to correct this “imbalance” by effectuating important amendments to the proposal package that balance intellectual property rights and public health. However, whether these amendments can withstand the influence of corporate lobbyists is uncertain based on previous and present developments. This paper posits that for the sake of certainty (erasing all

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ambiguities), the amendments suggested by the EP are good law and should be maintained. In what follows, it will be instructive to first discuss how the BMR(s) led to the seizure of generic medicines in transit in the EU, and in what ways the new BMR falls short of addressing the *Philips* and *Nokia* impact. This will be followed by a detailed analysis of the contents of the proposed EU trademark rules and how they could affect the transit of generic medicines, the amendments suggested by the EP and the role of corporate lobbyists in the outcome of amendments.

BMR and the Seizure of Generic Medicines

It is important to clarify from the outset that the detention or seizure of generic medicines in transit at EU ports has been a major concern and a threat to public health for two reasons: Europe's geographic position and its transportation strength automatically makes it a transit hub for a significant percentage of the international medicines trade, and even South-South trade.¹⁷ In addition, many health-related NGOs have their headquarters in Europe, and the products they send into the field go through European customs territory.¹⁷ If pharmaceutical products are going to be regularly intercepted in transit through EU ports on grounds of alleged intellectual property infringement, the international generics trade may be seriously hampered, thereby putting public health at risk.

More than a decade ago, the third generation of the EU's BMR: Council Regulation 1383/2003 amended EU border control measures in such a way that supposedly implied permission to EU patent holders to demand seizure of infringing goods (including pharmaceutical products) in transit through EU ports as if they were counterfeits.¹⁸ Unlike its predecessors,¹⁹ Article 2(1)(c) of the Regulation defined goods infringing an intellectual property right to include patents and supplementary protection certificates (SPCs). SPCs in the EU generally extend the term of patent protection for five more years to compensate for delays in obtaining regulatory approval for medicinal products.²⁰ Including patents and SPCs within the scope of the BMR, effectively ensured that generic medicines in transit at EU borders could be legally intercepted because they infringed local patents or SPCs.

Furthermore, the language of Recital 8 and Article 10 of the Regulation turned out to be problematic. Recital 8 read: "Proceedings initiated to

determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe intellectual property rights [...]". Interpretation of the ambiguous language of this Recital and Article would generate legal challenges both at the national and Union level.²¹ Two of such cases from Belgium and the UK which eventually ended up at the CJEU are discussed in this article. Although none of these cases actually concerned generic medicines, the outcome of the rulings would determine whether generic medicines in external transit²² could be seized at EU ports or not. These cases involve similar situations as those of generic medicines where the goods at issue had been seized at EU ports (whilst in transit) because they infringed local intellectual property rights. It is to be borne in mind that the seizure of generic medicines and other intellectual property related infringing goods at EU borders were conducted on the basis of the BMR and other EU secondary norms such as the EU Trademark Regulation.

In the Netherlands, for instance, where most of the seizures had taken place, the courts interpreted the text of Article 6(2) of Regulation 3295/94 (the second generation of the EU's BMR), and Recital 8 of Regulation 1383/2003 simply to mean that all goods falling under the scope of these regulations could be regarded by way of a "legal fiction", as goods produced in the Member State of the customs action – "the manufacturing fiction"²³—thus circumventing the burden of proving that the goods concerned would be traded in the Union, a condition which is, in principle, obligatory for the purposes of obtaining protection for all forms of intellectual property.²⁴ Hence, generic medicines making transit in the Netherlands that infringed local patents were seized under the pretext that they were illegally manufactured in the Netherlands and thereby infringed patent rights.

Furthermore, the CJEU somehow gave credence to this "fictional theory" in its early caselaw when it declared that the Regulation 3295/94 was applicable to non-Community goods in transit to a non-member country without particular reference to any need to prove that they were destined for the internal market.²⁵ Hence, EU Member States had to prohibit and punish the mere placing in external transit of counterfeit goods through their territories.²⁶ However, varying rulings by the CJEU over time led to a background of rather confused caselaw²⁷ until *Philips* and *Nokia*.

Impact of the *Philips* and *Nokia* decision

The CJEU's decision in *Philips* and *Nokia* seems to have finally resolved the controversy over whether counterfeit and pirated goods in transit could be seized or not. *Philips* concerned the suspension of release by customs authorities (in the port of Antwerp) of goods suspected of infringing Philips design shavers protected in the Benelux countries through an international design registration. The cargo of electric shavers was from China and bound for an unknown destination. It was not disputed that the detained shavers could classify as "pirated goods" within the meaning of the BMR if they were put on sale in Belgium or in another EU Member State where Philips held a copyright and enjoyed design right protection.²⁸ Upon notification from customs officers, Philips brought an action against Lucheng, Far East Sourcing, and Röhlig before the Court of First Instance of Antwerp, seeking a ruling confirming infringement and an order to pay damages.²⁹

Nokia involved the inspection at Heathrow Airport by the UK Customs of a consignment of mobile phones and accessories from Hong Kong en route to Colombia. The items carried a sign identical to the Community trademark registered by Nokia. Suspecting that the goods were counterfeits, the UK Customs informed Nokia about the goods but when Nokia requested seizure of the goods, the UK Customs refused Nokia's application for seizure arguing that their destination was Colombia and there was no evidence that they were going to be diverted to the EU market. As Nokia could not provide evidence that the goods would be diverted to the EU market, the UK customs decided to release the goods. Nokia brought an action against the UK Customs before the High Court of Justice of England and Wales. When the Court reasoned along similar lines as the UK customs, Nokia appealed to the Court of Appeal for England and Wales. Both the Antwerp Court and the Court of Appeal for England and Wales referred these questions to the CJEU.

The referring courts in both cases essentially asked the CJEU to determine whether or not the customs regulations had an effect on the substantive rules governing intellectual property in the context of goods in transit and also on the action which customs authorities could take in relation to goods in transit. The CJEU replied that goods coming from a non-Member State which are imitations of goods protected by a trademark, or copies of goods protected

by a copyright, cannot be classified as counterfeit goods or pirated goods within the meaning of the Customs Regulation merely on the basis of the fact that they are brought into the Union under a suspensive procedure. Those goods may only infringe intellectual property rights where, during their placement under a suspensive procedure in the customs territory of the EU, or even before their arrival in that territory, goods coming from non-Member States are the subject of a commercial act directed at EU consumers, such as sale, offer for sale, or advertising.³⁰ This ruling of the CJEU made the EU borders transit-friendly, thereby granting generic medicines a safe passage.

Does the New BMR Fail to Address the *Philips/Nokia* Impact?

Following the CJEU's decision in *Philips* and *Nokia*, anti-counterfeiting stakeholders expressed concerns that the Court had, by its ruling, seemingly made transit a safe harbour for the global trade in counterfeiting,³¹ by placing an inappropriately high burden of proof on right holders. Thus, it was highly anticipated that, the new BMR would seek to correct this "unsatisfactory solution"³² by making transit actionable under the law of the country of detention. In this direction, De Meyer and Gommers had proposed the inclusion of a 'rebuttable presumption' in the Regulation that would indicate that: "the goods detained will be put on the EU market in violation of the intellectual property right in question"³²

"Once this rebuttable presumption was raised, the declarant, the consignor or any other party interested in the trans-shipment shall be allowed to rebut that presumption by providing conclusive evidence that the goods are legitimate and have a destination where the intellectual property right in question shall not be violated."³² In as much as such an idea is convincing, making transit automatically actionable in the form recommended here would bring the EU norm into conflict with international law – the GATT Article V on freedom of transit. Specifically, the Article V(2) of the latter states that "there shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of

vessels or of other means of transport.” According to Abbott, until the EU Member States started seizing generic medicines in transit at their borders, “this fundamental principle of ‘freedom of transit’ had been so widely and consistently implemented that there had been virtually no controversy about it in the history of the WTO/GATT, despite the fact that goods were constantly moving in transit through its members.”³³ As the CJEU rightly pointed out in *Philips* and *Nokia*, it appears from Recital 2 of the Regulation that the objective of the EU legislature is restricted to preventing goods infringing intellectual property rights from being “placed on the internal market” and to adopting measures for that purpose “without impeding the freedom of legitimate trade.”³⁴

In its bid to address the matter, the EP suggested amendments (but not in the form of a rebuttable presumption) when it proposed in its legislative resolution of 3 July 2012 that Article 16(3) of the proposed BMR should be amended to include: “Where goods suspected of infringing intellectual property rights are not counterfeit or pirated goods, customs authorities shall communicate their intention to the declarant or, in cases where goods are to be detained, the holder of the goods before suspending the release or detaining the goods. The declarant or the holder of the goods shall be given the opportunity to express his/her views within three working days of receipt of that communication.”³⁵ This would have given the declarant or holder of infringing goods the opportunity to provide adequate evidence that the final destination of the goods is beyond the territory of the EU. However, for some unknown reasons, this clause was omitted from the final Regulation which is in force.

The EU Commission has since opted for transit to be actionable in its proposal for a revision of the Regulation on the EU trademark and for a recast of the Directive approximating the laws of the Member States relating to trademarks.³⁶ That, such a move is motivated by the *Philips* and *Nokia* decision reflects clearly in Recital 5.3(6) of the Explanatory Memorandum to the proposal which underscores the implications of *Philips* and *Nokia*, and then continues by adding: “[...] It is therefore proposed to fill the *existing gap* by entitling right holders to prevent third parties from bringing goods, from third countries, bearing without authorisation a trademark which is essentially identical to the trademark registered in respect of those goods, into the customs territory of the Union, regardless of whether they are released for

free circulation.” For anti-counterfeiting stakeholders, this may be a validation of the fact that there was something inherently wrong with the *Philips* and *Nokia* decision or the BMR. For advocates for access to medicines on the other hand, this would mean taking the law too far with regard to prevailing international norms.

Proposed Amendments to EU Trademark Rules and Implications for Access

The original proposal for amendments to the EU trademark rules as sent by the Commission to the EP came with provisions that threatened to stifle access. First, Recital 18 of the proposed Regulation entitled EU trademark right holders to stop counterfeit goods at the borders even if they are destined for a country outside the EU. Thus, the customs status of the counterfeit product did not matter anymore, contrary to what the CJEU had arrived at in *Philips* and *Nokia*. Generic medicines not only infringe patents and SPCs, but also, in certain situations, could infringe trademarks. By relying on the same or similar words identifying the active ingredient, the labels used to identify generics or the packaging often may be to some extent similar or close to the trademarks of the original manufacturer.³⁷ A trademark holder could hence rely on the BMR to detain such medicines at the EU borders on allegations of “ordinary” trademark infringements.

Second, Article 9(5) of the Regulation enables action to be taken against goods in transit when the packaging or labels infringe local trademarks, even if the packaging or labels are imported with the intention of subsequently attaching them to the goods.³⁸ The Article reads: “The proprietor of a European trademark shall also be entitled to prevent all third parties from bringing goods, in the context of commercial activity, into the customs territory of the Union without being released for free circulation there, where such goods, including packaging, come from third countries and bear without authorisation a trademark which is identical to the European trademark registered in respect of such goods, or which cannot be distinguished in its essential aspects from that trademark”. For trade in generic medicines, granting such a broad trademark right to cover all forms of trademark infringements including packaging could be particularly problematic; more so, when it is included as a substantive part of the Regulation.

It is a known fact that traffickers intentionally ship trademark symbols and packaging materials separately from counterfeit goods, so that the goods are “branded” afterwards, once they are within the EU. Such a tactic allows infringers to limit their losses if the goods are intercepted.³⁹ Thus, although the clause as mentioned above may be defended on the basis that it is aimed at traffickers of counterfeit products; it is not axiomatic that only traffickers engage in such activity. It may be possible that genuine products (such as generic medicines) are shipped under similar circumstances where the labels or packaging are separate from the product. It is important to clarify that, although generally speaking, “counterfeiting” is defined these days as covering infringements of an intellectual property right,⁴⁰ generic medicines are not counterfeits.⁴¹ Generic medicines are marketed in compliance with international patent law. They are identified either by their internationally approved non-proprietary scientific name (INN) or by their own brand name⁴² which is important for clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.⁴³ Hence, generic medicines have become essential contributors for governments of developing countries in their efforts to contain public health care budgets, as prices of generic medicines tend to be 20%–80 % lower than those of originator medicines.⁴⁴ It is in this direction that the EP’s amendments to the Commission’s proposal package that aims at balancing protecting trademark rights and at the same time, access to medicines is commendable and should be maintained.

EP’s Amendments and the Role of Corporate Lobbyist

As one among the EU legislative institutions, the EP moved to curtail the possible effects of the Commission’s proposal for changes to the EU trademark rules on transit of generic medicines as enumerated above. Before the EP adopted the report, its Committee on Legal Affairs made substantial amendments to Recital 18 and Article 9(5) of the proposed package by introducing clear and specific additions to the said provisions seeking to erase all ambiguities. Recital 18 has now been amended to include this: “With the aim of strengthening trademark protection and combatting counterfeiting more effectively, and without prejudice to WTO rules,

in particular Article V of the GATT on freedom of transit; the proprietor of a European Union trademark should be entitled to prevent third parties from bringing goods into the customs territory of the Union without being released for free circulation there, where such goods come from third countries and bear without authorisation a trademark which is essentially identical to the European Union trademark registered in respect of such goods. This should be without prejudice to the smooth transit of generic medicines, in compliance with the international obligations of the European Union, in particular as reflected in the ‘Declaration on the TRIPS agreement and public health’⁴⁵ adopted by the Doha WTO Ministerial Conference on 14 November 2001.”⁴⁶

The specific reference in this recital to the GATT Article V and the Doha Declaration underpins the EP’s efforts at fairness and transparency and further portrays the EP as an institution that is genuinely working to ensure that the EU complies with its international obligations (e.g., freedom of transit) in its intellectual property rule-making. The Doha Declaration affirmed the right of WTO Member States to implement TRIPS in such a way as to protect public health and to promote access to medicines for all. The subsequent waiver of Article 31(f) of TRIPS permitted Member States lacking sufficient manufacturing capacity to import necessary medicines from any other Member State. In 2005, the WTO Member States adopted the waiver as an amendment to TRIPS (Article 31bis). Such an addition therefore corroborated the fact that the European legislature does not want the EU’s internal system to hinder global access to medicines.

On the other hand, due to its increased powers, the EP has also become the target of corporate lobbyists.⁴⁷ This has led to the possibility that laws are watered down by the time they go through parliamentary vote. A typical example of this is Article 9(5) of the proposed Regulation. The Committee on Legal Affairs of the EP had intended to fill the gap (which it failed to accomplish with regard to the BMR) when it introduced the “right to be heard” clause for transiting trademark infringing goods in its amendments to the Commission’s proposal by adding that:

“Without prejudice to the obligations of customs authorities to carry out adequate customs controls in accordance with Article 1 of Regulation (EU) No 608/2013, this provision

shall not apply if the third party proves that the final destination of the goods is a country outside the Union and if the proprietor of the European Union trademark is not able to prove that his trademark is also validly registered in that country of final destination. In cases where the country of final destination has not yet been determined, the proprietor of the European Union trademark shall have the right to prevent all third parties from bringing the goods out of the Union again unless the third party proves that the final destination of the goods is a country outside the Union and the proprietor of the European Union trademark is not able to prove that his trademark is also validly registered in that country of final destination.”⁴⁸

Again, for unknown reasons, the latest adopted report by the EP on the proposal package shows some modifications to this provision which only reverts to the original language in which the Article appeared when it came from the Commission. The only new change is that the Article now starts with: “Without prejudice to WTO rules, in particular Article V of the GATT on freedom of transit [...]”.⁴⁹ In as much as a reference to the GATT Article V is laudable, the form in which the present modification comes makes it particularly obscure (adding somewhat only an aesthetic touch or a feel-good dose to the provision) in that the latter part of the provision permitting trademark holders to block counterfeit goods in transit contradicts the GATT Article V.⁵⁰ Until this contradiction is clarified, this provision may well negate or weaken Recital 18 as it stands now for the obvious reason that the former is a substantive part of the Regulation. It can be inferred that if Article 9(5) as originally entered by the EU Commission were not problematic, the Committee on Legal Affairs would not have contemplated amending it in the first place.

It may be conjectured that such an outcome could no doubt be linked to heavy lobbying from corporate stakeholders in Brussels⁵¹ whose interests many a times shape intellectual property rules to suit their businesses and ambitions. The story of the 2011 battle around food labelling rules is a telling example of how a massive investment in industry lobbying could be rewarding. Members of the European Parliament (MEPs) opted for a labelling scheme that had been developed and promoted by industry, instead of the more consumer-friendly “traffic-light” option.⁵² Such developments often show the extent to which not just

the Commission, but also the EP, has become the target of high industrial influence.⁵² On the other hand, the EP’s rejection of the Anti-Counterfeiting Trade Agreement (ACTA) in summer 2012, which effectively precluded the Union and its Member States from acceding to the Agreement, speaks volumes about what the EP can do in its bid to consolidate democracy and societal interest. Thus, on the issue of finding a balance between access to medicines and intellectual property, it may be crucial for the EP to use its powers (in a similar way) to strike the proper balance without compromising in favour of corporate lobbying.

Conclusion

Increasingly, intellectual property laws being promulgated by the EU are becoming broader and more exclusive. Accordingly, whilst one regime of law could be criticised for stifling access to medicines, amendments to those (existing) laws, or the negotiation of new ones, more often than not, tend to create more ambiguities or even worsen the situation. This could be the case with regard to the Commission’s proposal for changes to the EU trademark rules. The form in which the proposal came from the Commission inherently suggests that the new rules do not seek to deviate from the enforcement regimes already in place. If anything, their purpose is to enhance the rules to meet modern trends; meaning, to improve the framework conditions for businesses to innovate and to boost economic growth, but not much to do with public health or welfare, despite the fact that these rules tend to have impact on the latter.

It is in this direction that the EP’s Committee on Legal Affairs’ amendments to the proposal package is to be commended. The Committee, acting in line with its powers, sought to align the new Regulation with international law by including explicit (and implicit) references to the WTO Agreements and the Doha Declaration in Recital 18 and Article 9(5). Such indications are significant for the global access to medicines and therefore, are good law and should be maintained. This is particularly crucial because the EP recently adopted the Regulation at its first reading after voting on the report from its Legal Committee. Interestingly, the adopted Regulation comes with some modifications to Article 9(5) which only reverts to the original language in which the Article appeared when it came from the Commission. For the sake of unambiguity concerning the transit of generic

medicines, the EP will have to reconsider those amendments proposed by its Legal Committee. The adopted Regulation is still subject to scrutiny and debate. Thus, it is likely that further compromises and amendments may follow as seen with Regulation 608/2013. However, how that will turn out, it remains to be seen.

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- 2 The European Generic Medicines Association defines generic medicine as a medicine that is developed to be the same as a medicine that has already been authorised (the ‘reference medicine’). A generic medicine contains the same active substance(s) as the reference medicine, and it is used at the same dose(s) to treat the same disease(s) as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine, <http://www.egagenerics.com/index.php/generic-medicines/introduction>.
- 3 In 1996, a National Drug Policy Committee constituted by the Health Minister of South Africa released a revised National Drug Policy, setting forth a number of different objectives designed to address the issue of access to medicines, including lowering drug prices, supporting the development of a local pharmaceutical industry for the local production of essential drugs, and promoting the prescription of generic drugs in both the public and private sectors. Out of this came a controversial legislative proposal – the South African Medicines and Related Substances Control Act (MRSCA) which contained a new Section 15C which explicitly permitted parallel imports of patented pharmaceuticals. This was signed into law by President Nelson Mandela on 12 December 1997. Fearing a domino effect in the developing world, the US pharmaceutical industry, backed by the US Government, vigorously opposed the enactment of Section 15C. In an attempt to block the implementation of the amendments, the pharmaceutical companies took the matter to court and challenged the constitutionality of the amended MRSCA before the High Court of South Africa in February 1998. This controversy between the United States, the pharmaceutical companies and South Africa attracted a great deal of attention in the media, among NGOs and activists in 1999 which ultimately led to a shift in the US Administration’s policy towards South Africa. At about the same time, the plaintiffs in the MRSCA case announced the suspension of their lawsuit against the South African government.
- 4 See Medicines and Related Substances Control Amendment Act No. 90 of 1997, South African Government Gazette No. 18,505 of 12 December 1997 (amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Acts Nos. 65/1974, 17/1979, 20/1981 and 94/1991).
- 5 See Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98.
- 6 Cepuch C, Fighting counterfeits without endangering public health, *Bridges*, 14 (3) (2010) 13.
- 7 See Council Regulation (EC) No. 1383/2003, concerning customs actions against goods suspected of infringing certain intellectual property rights (2003, O.J. L 196/7), amending Council Regulation (EC) No. 3295/94 of 22 December 1994 laying down measures concerning the entry into the Community and the export and re-export from the Community of goods infringing certain intellectual property rights.
- 8 Case C-405/03, *Class International v Colgate-Palmolive*, 18 October 2005 [2005] ECR I-8735, para 61; Case C-281/05, *Montex Holdings Ltd v Diesel SpA*, [2006] ECR I-10881, paras 26-27. In both cases, the CJEU ruled that the transit of goods did not constitute an infringement under the Trademark Harmonisation Directive and Community Trademark Regulation. For trademarks rules, see Council Regulation (EC) No. 207/2009 of 26 February 2009 on the Community Trade Mark (2009, O.J. L 78/1); and Directive 2008/95/EC of the European Parliament and of the Council on 22 October 2008 to approximate the laws of the Member States relating to trademarks (2008, O.J. L 299/25).
- 9 See Request for Consultations by India, European Union and a Member State Seizure of Generic Drugs in Transit, WT/DS408/1, 19 May 2010; also, Request for Consultations by Brazil, European Union and a Member State Seizure of Generic Drugs in Transit, WT/DS409/1, 19 May 2010. The global significance of the matter is reflected by the fact that on 28 May 2010, Brazil, Canada and Ecuador requested to join the consultation and on 31 May 2010, China, Japan and Turkey requested to join the consultation.
- 10 See European Commission: Proposal for a Regulation of the European Parliament and of the Council Concerning Customs Enforcement of Intellectual Property Rights, COM (2011) 285 final, 25 May 2011). Also, see EU reach an understanding on issue of seizure of Indian generic drugs in transit, Press Release, Government of India Ministry of Commerce and Industry, 28 July 2011, <http://pib.nic.in/newsite/erelease.aspx?relid=73554> (accessed 12 August 2014).
- 11 See Council Regulation (EU) No. 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No. 1383/2003 (new BMR) in force since January 2014.
- 12 Baker B K, Settlement of India/EU WTO dispute re seizures of in-transit medicines: Why the proposed EU border regulation isn’t good enough, Program on Information Justice and Intellectual Property Research Paper Series, 1 (1) (2012); Saez C, New EU customs regulation might allow wrongful seizures of generic drugs in transit, NGOs say, *Intellectual Property Watch*, 17 October 2013.
- 13 Joined cases C-446/09 and C-495/09, *Philips and Nokia*, judgment given 1 December 2011, not yet reported. By the CJEU’s decision, European customs could check on counterfeit goods transiting through the EU borders but could only stop them if there was a risk of those goods being diverted onto the Single Market. This meant in practice that customs were powerless against counterfeit goods en route to a third country. Provisions of the proposed trademark regulation seek to correct this by allowing customs to stop

- counterfeit trademarks goods even if destined for a country outside the EU.
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 - 15 For the original proposals from the Commission, see European Commission COM (2013) 161 final: Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community Trade Mark (Brussels, 27 March 2013), <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CO M:2013:0161:FIN:EN:PDF>; Also, European Commission COM (2013) 162 final: Proposal for a Directive of the European Parliament and of the Council to approximate the Laws of the Member States relating to Trade Marks, <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CO M:2013:0162:FIN:EN:PDF>.
 - 16 This is explicitly stated in the Recital 5.3(6) of the explanatory memorandum to the proposed package.
 - 17 Seuba X, Free trade of pharmaceutical products: The limits of intellectual property enforcement at the border, ICTSD Programme on IPRs and Sustainable Development, Working Paper No. 27 (ICTSD, Switzerland), 2010 p. 1.
 - 18 Abbott F M, Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: A threat to international trade, development and public welfare, *World Intellectual Property Organization Journal*, 1 (2009) p. 43.
 - 19 See Council Regulation No. 3842/86 laying down measures to prohibit the release for free circulation of counterfeit goods (OJ L 357, 18 December 1987, 1); and Council Regulation (EC) No. 3295/94 of 22 December 1994.
 - 20 See Regulation (EC) No. 469/2009 of The European Parliament and of The Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products, O.J. (L 152) 1 (2009). That means, for patented medicinal products that obtained an SPC in the EU, their generic equivalents cannot be placed on the EU market or permitted to "transit" at its borders without any form of licensing agreements for five years after the patent has expired. That is, five more years after patent expiry, generic medicines shall not be available in the markets of developing countries. For more on this, see Acquah D, Extending the limits of protection of pharmaceutical patents and data outside the EU – Is there a need to rebalance?, *IIC International Review of Intellectual Property and Competition Law*, 45 (3) (2014) 256-283.
 - 21 Case C-383/98, *Polo Lauren* [2000] ECR I-2519; Case C-60/02, *Montres Rolex* [2004] ECR I-651; Case C-281/05, *Montex Holdings Ltd v Diesel SpA*, [2006] ECR I-10881; and *Philips and Nokia*, etc. In *Montex*, the goods were detained due to the application of BMR. However, the questions referred to the CJEU were limited to the Trademark Directive.
 - 22 Article 91 of Council Regulation (EEC) No. 2913 /92 of 12 October 1992 establishing the Community Customs Code defines external transit as "allowing the movement from one point to another within the EU customs territory of (1) non-Community goods, without such goods being subject to import duties and other changes or to commercial policy measures [...]".
 - 23 The "manufacturing fiction" appears to have been applied for the first time in a patent case by the Hoge Raad der Nederlanden in its judgment of 19 March 2004 (LJN AO 0903, *Philips v Postec and Princo*), and it was subsequently adopted by the president of the Rechtbank Den Haag in a decision of 18 July 2008 and by the Rechtbank van eerste aanleg te Antwerpen itself in a judgment of 9 October 2008.
 - 24 Opinion of Advocate General Crux Villalón, in joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 3.
 - 25 Case C-383/98, *Polo Lauren* [2000] ECR I-2519; Case C-60/02, *Montres Rolex* [2004] ECR I-651.
 - 26 See *Montres Rolex* [2004] ECR I-651 at para 58. The CJEU had reached that conclusion by making reference to Articles 2 and 11 of Regulation 3295/94).
 - 27 See Opinion of Advocate General Crux Villalón, in joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 5. Contrary to its decisions in *Polo Lauren* and *Rolex*, the CJEU ruled in *Class International*, *Montex* and in *Philips/Nokia* that intellectual property owners could no longer rely on Union trademark and customs laws to demand seizure of counterfeit and pirated goods in transit unless there was clear evidence of a substantial risk of diversion onto the EU market.
 - 28 Schneider M & Vrins O, Regulation (EC) 1383/2003, in *Enforcement of Intellectual Property Rights Through Border Measures: Law and Practice in the EU*, edited by O Vrins & M Schneider, 2nd edition (Oxford University Press), 2012, p. 159.
 - 29 Micara A G, Court of Justice balances IP rights and international trade, *Journal of Intellectual Property Law & Practice*, 7 (4) (2012) 239-241.
 - 30 Joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 57.
 - 31 De Meyer C and Gommers C, Urgent memo to the EU: Don't let transit be a safe harbour, *Journal of Intellectual Property Law & Practice*, 7 (5) (2012) 346-349.
 - 32 De Meyer C and Gommers C, Urgent memo to the EU: Don't let transit be a safe harbour, *Journal of Intellectual Property Law & Practice*, 7 (5) (2012) 349.
 - 33 Abbott F M, Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: A threat to international trade, development and public welfare, *World Intellectual Property Organization Journal*, 1 (2009) 45-6.
 - 34 Joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 64.
 - 35 See European Parliament legislative resolution of 3 July 2012 on the proposal for a regulation of the European Parliament and of the Council concerning customs enforcement of intellectual property rights [COM (2011) 0285 – C7-0139/2011 – 2011/0137(COD)] (Amendment 52).
 - 36 European Commission COM (2013) 161 final; European Commission COM (2013) 162 final.
 - 37 Ruse-Khan H G, A trade agreement creating barriers to international trade?: ACTA border measures and goods in transit, *American University International Law Review* 26 (3) (2011) 674.
 - 38 Recital 20 of the proposed EU Trademark Regulation.
 - 39 See Schneider M & Vrins O, Regulation (EC) 1383/2003, in *Enforcement of Intellectual Property Rights Through Border Measures: Law and Practice in the EU*, edited by O Vrins & M Schneider, 2nd edition (Oxford University Press), 2012, p. 119.
 - 40 The economic consequences of counterfeiting (OECD, France), 1998, p. 5-6, <http://www.oecd.org/sti/ind/2090589.pdf> (accessed 9 August 2014).

- 41 Acquah D, Extending the limits of protection of pharmaceutical patents and data outside the EU – Is there a need to rebalance?, *IIC International Review of Intellectual Property and Competition Law*, 45 (3) (2014) 256-283. (Noting that the TRIPS Article 51 (footnote 14), and WHO all define counterfeits to cover trademark infringements. It should however be noted that Article 2 of the EU Border Measures Regulation extend the definition of goods infringing an intellectual property rights to cover a broad range of intellectual property including patents, supplementary protection certificates etc., and those protected in the Member State of action.
- 42 International Nonproprietary Names (INN), also known as a generic name, identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. As unique names, INN have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available they are formally placed by WHO in the public domain, hence their designation as “nonproprietary”. They can be used without any restriction whatsoever to identify pharmaceutical substances.
- 43 See <http://www.who.int/medicines/services/inn/innquidance/en/> (accessed 9 August 2014).
- 44 Simoens S & De Coster S, Sustaining generic medicines markets in Europe, *Journal of Generic Medicines*, 3 (4) (2006) 262.
- 45 The Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference Declaration of 14 November 2001, WT/MIN(01)/DEC/2 World Trade Organization.
- 46 See European Parliament legislative resolution of 25 February 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community trade mark (COM(2013)0161 – C7-0087/2013 – 2013/0088(COD)) (Ordinary legislative procedure: first reading), (Amendment 115, Recital 18).
- 47 Who’s driving the agenda at the DG Enterprise and Industry? The dominance of corporate lobbyist in DG Enterprises Expert Group, Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU), July 2012, http://www.alter-eu.org/sites/default/files/documents/DGENTR-driving_0.pdf. Further corroborating this claim is the more recent report, A year of broken promises: Big business still put in charge of EU expert groups, despite commitment to reform, ALTER-EU, November 2013. Also see Europe Inc. in crisis – The EU’s alliance with big business is dead-end, Corporate Europe Observatory, 16 April 2014, <http://corporateeurope.org/lobbycracy/2012/04/europe-inc-crisis-eus-alliance-big-business-dead-end> (accessed 8 August 2014).
- 48 See Committee on Legal Affairs: Report on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community trademark [COM (2013)0161 – C7-0087/2013 – 2013/0088 (COD)], 12 February 2014 (Amendment 28, Article 9).
- 49 COM (2013)0161 – C7-0087/2013 – 2013/0088 (COD) (Amendment 28 and 116).
- 50 The WTO system essentially binds governments to keep their trade policies within agreed limits to everybody’s benefit. It is therefore telling that the EU as a signatory to the WTO Agreements would possibly come up with a law that would seemingly contradict the freedom of transit. Indeed, the GATT Article XX(d) permits exception for rules on customs enforcement, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices but only when such rules “are not inconsistent with the provisions of this Agreement”. Equally, the TRIPS Article 51 requires WTO Members to adopt procedures permitting intellectual property owners to prevent counterfeit trademark and pirated copyright goods from entering national markets through detention at the border and notification by customs authorities but does not extend to goods in transit.
- 51 Vrins O, European Commission’s proposal for a regulation concerning customs enforcement of IP rights, *Journal of Intellectual Property Law & Practice*, 6 (11) (2011) 774.
- 52 Europe Inc. in crisis – The EU’s alliance with big business is dead-end, Corporate Europe Observatory, 16 April 2014, <http://corporateeurope.org/lobbycracy/2012/04/europe-inc-crisis-eus-alliance-big-business-dead-end>, p.1-2 (accessed 8 August 2014).

Chapter IV

Publication III

**Trends on the implementation of the EU's Customs Regulation:
for better or for worse?**

Daniel Acquah

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Trends on the implementation of the EU Customs Regulation: for better or for worse?

Daniel Acquah*

EU at war

The EU is at war against counterfeiting and piracy.¹ A survey of the Directorate-General Taxation and Customs Union (DG TAXUD) webpage and other related documents graphically illustrates this with terminology that supports this claim,² as do the various regulatory mechanisms and non-legislative initiatives instituted by the EU Commission to manage this global phenomenon.³ As the dynamics of this illegal enterprise change over time and become increasingly sophisticated, the European law-maker has no other choice but to find a means of controlling this global assault—considering that their effects are dire.⁴ Customs enforcement of intellectual property rights and other strategic action plans are tools effectively utilized by the EU to manage this enterprise. To monitor the efficiency of its action, the European Commission publishes annually a report on customs activity to enforce intellectual property rights based on its Customs Regulation.

In July 2014, the DG TAXUD published its report for 2013.⁵ Compared to the 2012 report, the new report shows a slightly downward trend in the number of cases and articles detained by customs. Council Regulation 1383/2003⁶ (the former Customs Regulation) served as the legal basis for this report. The new Customs Regulation (Regulation 608/2013),⁷ which came into force in January 2014, brought modifications, such as expanding the range of intellectual property rights infringements covered and adjustments in

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This article

- Customs enforcement of intellectual property rights remains the most important means the EU uses to block the trade in counterfeit goods. As a monitoring mechanism, the Commission publishes annually a report on customs action to enforce intellectual property rights based on its Customs Regulation.
- A new Customs Regulation (Regulation 608/2013) came into force in January 2014 and serves as the legal basis for the 2014 customs report.
- Analysing the content of this new Regulation and those of the Commission's annual reports from the years 2008–2013, and based on recent case law, this article argues that the new Regulation would more likely 'do a better job' in the fight against counterfeiting compared to its predecessor, based on: (1) the novel inclusion of devices which enable circumvention of technology; (2) a new simplified procedure for the destruction of small consignments of goods; (3) an EU-wide simplified procedure for all (other) infringements of intellectual property rights; and (4) a non-legislative Union Customs Action Plan(s) to combat intellectual property rights infringements.

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1 The term 'counterfeiting and piracy' should be understood as covering the infringements of all intellectual property rights. See OECD, 'The Economic Impact of Counterfeiting and Piracy', OECD Publishing (2007), 8. Available at <http://www.oecd.org/sti/38707619.pdf> (accessed 20 August 2015). (In this article, 'counterfeiting' is used occasionally to represent both).

2 Specifically, the repeated use of the words 'combat' and 'fight' against counterfeiting and piracy or goods infringing intellectual property rights brings imageries of war. See eg Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'Towards a Renewed Consensus on the Enforcement of Intellectual Property Rights: An EU Action Plan', COM (2014) 392 final (1 July 2014); Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'A Single Market for Intellectual Property Rights: Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe', COM (2011) 287 final (24 May 2011) 17–22; Council Resolution on the EU Customs Action Plan to combat IPR infringements for the years 2013 to 2017 (2013/C.80/01).

3 See eg Regulation 608/2013 concerning customs enforcement of intellectual property rights (the so-called new Customs Regulation); Directive 2008/48 on the Enforcement of Intellectual Property Rights, OJ L 157/16 (2004); Union's Strategy for the Enforcement of Intellectual Property Rights in Third Countries, C.129/03 (2005); The European Observatory on Infringements of Intellectual Property Rights, <https://oami.europa.eu/ohimportal/en/web/observatory/home> (accessed 20 August 2015); and generally, references cited above, n 2.

4 Counterfeiting and piracy are noted to have effects on innovation and creativity, jobs, consumer health and safety, and even linked to organized criminality among others. For more on the impact of counterfeiting and piracy, see C Geiger (ed), *Criminal Enforcement of Intellectual Property: A Handbook of Contemporary Research*, (Edward Elgar, 2012) 9–75.

5 DG TAXUD, 'Report on EU Customs Enforcement of Intellectual Property Rights: Results at the EU border 2013' (31 July 2014).

6 Council Regulation 1383/2003 concerning customs actions against goods suspected of infringing certain intellectual property rights, OJ L 196/7 (2003) ('the former Regulation').

7 Regulation 608/2013, above n 3.

existing procedures and serves as the legal basis for the 2014 customs report (to be published later this year). It is therefore appropriate to assess whether, compared to its predecessor, the new Regulation fares better or worse in the fight against counterfeiting and piracy.

As well as presenting a general overview of the new Customs Regulation, this article argues that the new Regulation is more likely to 'do a better job' against international trade in counterfeit goods, contrary to the view, discussed later in the article, that in the case of the new Regulation 'it must be feared that' an even smaller percentage of counterfeit goods would be effectively stopped at EU borders.⁸ This line of argument is based on: (1) the novel inclusion of devices which enable circumvention of technology to the scope of the new Regulation;⁹ (2) a new, simplified procedure for the destruction of small consignments of goods;¹⁰ (3) an EU-wide simplified procedure for all (other) infringements of intellectual property rights;¹¹ and (4) a non-legislative Union Customs Action Plan(s) to combat intellectual property rights infringements. Although the latter two are not completely new, they have been significantly enhanced. Thus these additions and initiatives have the benefit of building on the previous legal regime which, in the framework of the 2013 Customs Report, seems already to have provided a sound legal basis for the blocking of counterfeit goods. These points are discussed in turn.

Background to the Customs Regulation

The EU has regulated border enforcement of intellectual property rights for nearly three decades. Since the first Regulation was passed in 1986,¹² four further Regulations

have been passed.¹³ These adjustments were made to bring the Customs Regulation into line with the Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS Agreement) and to respond to the globalization of counterfeiting and piracy, and the growing trade in counterfeit goods over the internet.¹⁴ The legal basis for the Customs Regulation is Article 207 of the Treaty on the Functioning of the European Union (TFEU), formerly, Article 133 (EC) on the Common Commercial Policy which is now the exclusive competence of the EU and covers the commercial aspects of intellectual property. Although increasingly reflective of a TRIPS-plus regime, it would appear from the Preamble to successive Customs Regulations¹⁵ that their legislative objective is restricted to preventing goods infringing intellectual property rights from being 'placed on the internal market' and to adopting measures for that purpose 'without impeding the freedom of legitimate trade'.¹⁶ This article focuses primarily on the preventive function of the Regulation, that of blocking goods that infringe intellectual property rights from being placed on the internal market.

The scope of the Customs Regulation

The original Customs Regulation only regulated counterfeit goods.¹⁷ With time, however, the scope of the Customs Regulation was amended to cover not only counterfeit and pirated goods but also certain intellectual property rights.¹⁸ Also, besides Regulation 3842/86, the reference in the Customs Regulation to the Community Customs Code (now the Union Customs Code)¹⁹ and the specific use of terminology²⁰ from the latter instrument in the

8 C De Meyer and C Gommers, 'The Transit Dilemma Revisited: The New Customs Regulation and the Legislative Package on Trademarks' (2013) 8(10) JIPLP 771.

9 Regulation 608/2013, above, n 3, Art 2(7)(b).

10 Ibid, Art 26.

11 Ibid, Art 23.

12 Council Regulation 3842/86 laying down measures to prohibit the release for free circulation of counterfeit goods, OJ L 357 (18 December 1987).

13 See Council Regulation 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods as amended by Council Regulation 241/1999 amending Regulation 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods, OJ L 27/1; Regulation 1383/2003, above, n 6, and Regulation 608/2013, above n 3.

14 M Schneider and O Vriens, 'Regulation (EC) 1383/2003', in M Schneider and O Vriens (eds), *Enforcement of Intellectual Property Rights Through Border Measures: Law and Practice in the EU* (2nd edn OUP 2012) 107; O Vriens and M Schneider, 'Cross-border Enforcement of Intellectual Property: The European Union', in Paul Torremans (ed), *Research Handbook on Cross-border Enforcement of Intellectual Property* (Edward Elgar, 2014) 170 ff.

15 See Regulation 3842/86, above, n 12, para 1; Regulation 3295/94, above, n 13, para 2; Regulation 1383/2003, above, n 6, recital 2; and Regulation 608/2013, above, n 3, recital 3.

16 *Philips and Nokia*, C-446/09 and C-495/09, EU:C:2011:796, para 64.

17 Regulation 3842/86, above, n 12.

18 To that effect, see Regulation 1383/2003, above, n 6, Art 2 which covers a variety of intellectual property rights but not all.

19 Council Regulation 2913/92 establishing the Community Customs Code, OJ L 302/1 ('the Community Customs Code'). Since October 2013, Regulation 952/2013 laying down the Union Customs Code (recast) repealing Regulation 450/2008 laying down the Community Customs Code, OJ L 145 (4 June 2008) ('Modernized Customs Code') came into force. The new Regulation comes with new numbering which changes the numbering of the articles as used in this essay. However, since its substantive provisions do not apply until 1 May 2016, the old Regulation applies.

20 Besides Regulation 3842/86 (above, n 12), Art 1 of the successive Customs Regulations makes reference to the words 'suspensive procedure, free zone or free warehouse' which have their origins from the Community Customs Code, above, n 19, Arts 84(1)(a) and 166–167. Article 84(1)(a) defines suspensive procedure in relation to non-Community goods as those under 'external transit, customs warehousing, inward processing, processing under customs control, and temporal importation'—giving it a wider coverage. The Union Customs Code does not contain any reference to 'suspensive procedure'; however, the term is used in this context because the Union's Customs Code is yet to be implemented.

Customs Regulation logically brings all goods (1) which are subject to customs declaration and (2) which are not subject to customs declaration²¹ under the scope of the Customs Regulation. This ensures that customs authorities can take action against all goods that come within their control and means that Regulation should be interpreted by reference to the language of the Community Customs Code, in order to guarantee that the original meanings and requirements of the EU legislator are respected.

Regulation 608/2013 extends the definition of counterfeit goods to include 'geographical indications' which rather adds to the criticism that the previous definition of counterfeit goods was beyond TRIPS requirements.²² It also now covers all intellectual property rights with the addition of design,²³ topography of semiconductor products, utility models and trade names (in so far as they are protected by exclusive intellectual property rights under national law or Union law). Further, trade marks registered under the Madrid System for international registrations are now explicitly covered.²⁴ This addition could be seen as a legislative attempt to correct the circumstances leading to *Zino Davidoff*.²⁵ Put together, the potential effects of the changes brought by the new Customs Regulation and the Union's non-legislative Customs Action Plans (discussed below) questions the assumption made by De Meyer and Gommers in their article²⁶ that, with the new Regulation, 'it must be feared that' an even smaller percentage of counterfeit goods will be effectively stopped at the EU borders. This is taken up next.

A smaller percentage of counterfeit goods to be stopped?

The claim above, although linked to transit, questions the effectiveness of a seemingly improved customs regime. Until *Philips* and *Nokia*,²⁷ external transit had been contentious in the EU; even after, it is still being debated.²⁸ However, transit is not the only medium through which counterfeit goods are distributed.²⁹ Moreover, no single regime (eg customs enforcement) can effectively eliminate international trade in counterfeiting. A holistic approach, such as discussed in this article, is therefore paramount.

In the absence of any explicit reference to transit in the new Customs Regulation, the language of its Article 1 automatically brings transit under its scope by specifying that:

[T]his Regulation sets out the conditions and procedures for action by the customs authorities where goods suspected of infringing an intellectual property right are, or should have been, subject to customs supervision or customs control within the customs territory of the Union in accordance with Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code, particularly goods in the following situations:

- (a) when declared for release for free circulation, export or re-export;
- (b) when entering or leaving the customs territory of the Union;
- (c) when placed under a suspensive procedure or in a free zone or free warehouse.

21 Art 84(1)(a) of the Community Customs Code, above, n 19. Further Art 170(1) of the latter stipulates that 'without prejudice to Art. 168(4), goods entering a free zone or free warehouse need not be presented to the customs authorities, nor need a customs declaration lodged'. However, Art 168(4) carry that the 'customs authorities may check goods entering, leaving or remaining in a free zone or free warehouse ...'.

22 ET Biadgleng and VT Munoz, 'The Changing Structure and Governance of Intellectual Property Enforcement' (2008) 15 South Centre Research Paper 20; BK Baker, 'Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough' (2012) 2 PIIP Research Paper Series 11.

23 Regulation 608/2013, above n 3, Art 2(1)(b). Article 2(3) defines Community design as a 'design' under Council Regulation 6/2002 on Community designs, OJ L 3 (5 January 2002). This differentiates it from its inclusion under Regulation 1383/2003 (above, n 6) as constituting 'piracy'.

24 Regulation 608/2013, above, n 3, Art 2(2). See also A Deutsch and R Zimmerman, 'Customs Seizure Proceedings in the European Union and the United States' (2014) 9(4) JIPLP 277.

25 *Zino Davidoff*, C-302/08, EU:C:2009:442. The case concerned an appeal lodged by Davidoff on the basis of Regulation 1383/2003, above, n 6, Art 5(4) at the Finanzgericht München (Germany) based on the dismissal of its application by the Bundesfinanzdirektion Südost for the seizure of goods suspected of infringing 12 of its internationally registered trade marks. Considering that the Community provision at issue posed interpretation problems, the Finanzgericht stayed the proceedings and referred to the CJEU the question whether, in the light of the accession of the Community to the Madrid Protocol, Regulation 1383/2003, above, n 6, Art 5(4) should be interpreted as meaning that, despite the use of the term 'Community

trade mark', marks with international registrations within the meaning of Articles 146 ff of Regulation 40/94 are also covered. The CJEU responded in the affirmative.

26 De Meyer and Gommers, above, n 8.

27 *Philips* and *Nokia*, above, n 16. The CJEU's decision in *Philips* and *Nokia* seems to have finally resolved the controversy over whether counterfeit and pirated goods in transit at EU borders could be seized or not. *Philips* addressed the detention by customs authorities at the port of Antwerp of goods under temporal storage procedure which they suspected of infringing *Philips* design shavers protected in the Benelux countries through an international design registration. *Nokia* involved the inspection at Heathrow Airport by the UK Customs of a consignment of mobile phones and accessories from Hong Kong on its way to Colombia which carried signs identical to *Nokia*'s registered Community trade mark.

28 O Vriens, 'The Real Story of a Fiction: Transit after Montex under Regulation (EC) 1383/2003' (2010) 5(5) JIPLP 358; AG Micara, 'Court of Justice Balances IP Rights and International Trade' (2012) 7(4) JIPLP 239; C De Meyer and C Gommers, 'Urgent Memo to the EU: Don't Let Transit be a Safe Harbor' (2012) 7(5) JIPLP 346–349; DO Acquah, 'Balancing or Lobbying? On Access to Medicines, Border Measures and the European Parliament's Amendments to the Proposed EU Trademark Rules' (2014) 19 JIPR 404. The debate after *Philips/Nokia* mostly centred on the high burden of proof placed on right-holders to show in proceedings that goods under external transit are actually meant for the EU market, and the risk that such goods could be diverted into the EU market. It is also about whether transit should be actionable at all.

29 Counterfeits also diffuse through imports, exports and re-exports. Analysis and statistics relating to some of these channels is given below.

As explained earlier, Article 84(1)(a) of the Community Customs Code defines 'suspensive procedure' in relation to non-Community goods to cover 'external transit' among others.³⁰

This observation was rightly confirmed when the Court of Justice of the European Union (CJEU) held in *Philips* and *Nokia* that customs authorities may detain goods in transit in application of the Customs Regulation when they infringe intellectual property rights.³¹ However, mindful of the objective of the Customs Regulation,³² the CJEU added that, in the ensuing substantive proceedings, the right-holder must prove the actual infringement by providing the national courts with evidence that the goods are intended to be put on sale in the EU, such proof being in the form of evidence of actual sale, an offer for sale or advertising addressed to a consumer in the EU.³³

Recognizing the challenge these criteria might pose for right-holders and the risk that counterfeiters might capitalize on this to abuse the system, the CJEU prescribed that other indications such as where the destination of the goods is not declared, the lack of precise or reliable information as to the identity or address of the manufacturer or consignor of the goods, a lack of co-operation with the customs authorities or the discovery of documents or correspondence concerning the goods in question suggesting that there is liable to be a diversion of those goods to EU consumers, could form the basis for customs detention and proof in court.³⁴ The CJEU justified the need for such criteria on the basis that goods under external transit could not, merely by the fact of being so placed, infringe intellectual property rights in the EU. If detaining such goods were to be based merely on the abstract consideration that they could be fraudulently diverted to EU consumers, all goods in external transit could be detained without the slightest concrete indication of irregularity.³⁵

The court reaffirmed the role customs play in risk management which helps to determine (and block or destroy) goods coming into the EU that infringe intellectual property rights or that pose a health risk to its

citizens. It further reaffirmed that goods under suspensive procedure are still under customs control until they are re-exported from the EU³⁶—which might make it possible for customs authorities to detect signs of intended diversion of goods to the EU market—to emphasize that there are already measures in place to effectively manage this risk if efficiently utilized. Since customs can only examine a small part of all goods that enter or leave the EU, they therefore rely on risk management methods. However, only when used to identify shipments by known or suspected violators, entering via sea, air or road, can this method be successful.³⁷

Finally, statistics from the European Commission's annual customs reports appear to neutralize the fear that a smaller percentage of counterfeit goods will be seized as a consequence of the new regulation. Figures from the 2008–2013 reports show that in over 85–93 per cent of cases of detention, customs action was started while the goods concerned were under an import procedure. Goods seized while under transit procedure ranged from 9 per cent to 4 per cent for situations where the destination of the goods was in the EU and, in 3.5 per cent to 1 per cent of the cases, goods were under a re-export procedure with destination outside the EU.

Having said this, goods under transit procedure mostly fall under the sea transport of containers category—the main transport modality when it comes to number of articles. From the customs reports, the numbers of articles detained under this category are usually high whereas low in the number of cases.³⁸ In this regard, statistics from the 2008 customs report show that, in almost 90 per cent of cases, customs action was started while the goods concerned were under an import procedure, whereas in 7 per cent of cases goods were discovered while in transit. Amazingly, when it comes to amount of articles detained, 43 per cent were under an import procedure whereas the rest were blocked while in transit or under a customs warehousing procedure.³⁹ Overall, until 2011 when the CJEU gave its ruling in *Philips/Nokia*, the amount of articles detained annually at the EU borders remained high. This dropped significantly in 2012 and 2013.⁴⁰ It may thus be

30 This brings into perspective the analysis on Community Customs Code, above, n 19, Art 84(1)(a).

31 While this decision was based on the basis of the former Customs Regulation 1383/2003, it applies to the new Regulation as well.

32 *Philips* and *Nokia*, above, n 16.

33 *Ibid*, paras 70–71.

34 *Ibid*, paras 60–61.

35 *Ibid*, paras 56 and 62.

36 *Ibid*, paras 77 and 74 (making reference to Community Customs Code, above, n 19, Art 37).

37 DG TAXUD, 'Report on EU Customs Enforcement of Intellectual Property Rights: Results at the EU border 2008' 5 (emphasis added). This can be especially so when linked to other pragmatic strategies such as the EU's

'Multi-annual Action Plan to combat intellectual property rights infringement' and the 'EU–China Strategic Framework for Customs Cooperation 2014–2017' (discussed in detail below).

38 This is because goods shipped in containers usually come in larger quantities. Thus, despite the low number of cases, transits are significant in terms of number of articles. The low number of cases may be due to the popularity in recent times of postal and courier traffic as means of transport for counterfeit products (discussed in detail below).

39 DG TAXUD, 'Report 2008', above, n, 37, 20.

40 In 2008, the total number of articles detained was 170 million. In 2011, when the CJEU gave its ruling in *Philips/Nokia*, it was almost 115 million. This figure dropped in 2012 to almost 40 million. In the latest 2013 report, the total number of articles further dropped to almost 36 million.

fair to say that a large proportion of counterfeit and pirated goods *en route* to third countries are no longer seized.⁴¹ However, when checked against the objectives of the EU Customs Regulation, it will seem the latter is the right thing to do⁴² even though commentators consider that such goods may afterwards be diverted back into the EU.⁴³

This article next concentrates on specific aspects of the scope of the new Regulation that are considered to be most beneficial.

Devices enabling or facilitating the circumvention of technology

An element of the new Regulation that is bound to have particularly significant effects in regard to goods that infringe intellectual property rights is the novel inclusion of

... devices, products or components which are primarily designed, produced or adapted for the purpose of enabling or facilitating the circumvention of any technology, device or component that, in the normal course of its operation, prevents or restricts acts in respect of works which are not authorized by the holder of any copyright or any right related to copyright and which relate to an act infringing those rights in that Member State.⁴⁴

Including this provision within the scope of the new Regulation is timely and complements efforts being made by the EU to protect its right-holders. The previous Regulations, lacking such a provision, could not be the basis for the interception of circumvention devices unless they infringed a trade mark or copyright, even though circumvention devices including mod chips and game copiers were (and still are) being offered for sale worldwide, potentially affecting a great number of right-holders.⁴⁵ The need to block the flow of such devices at the external borders of the Union had therefore long been recognised. This finds support in how national courts

of the Member States such as Belgium,⁴⁶ Germany,⁴⁷ the Netherlands,⁴⁸ the UK⁴⁹ and Italy,⁵⁰ had taken the issue up, albeit in the context of copyright infringement.⁵¹ All these courts, after considering EU law⁵² and other laws such as the Union and its Member States' international obligations, for example, under the WIPO Copyright Treaty, had concluded that the importation and distribution of circumvention devices were criminal offences.⁵³

By including this provision as a substantive part of the new Regulation, it is not only counterfeit forms of these devices that can be intercepted by customs; all circumvention devices that arrive at the external borders of the Union are already 'suspect' goods.⁵⁴ They automatically infringe intellectual property rights if there are 'reasonable indications' that, in the Member State where they are found, their purpose is to enable or facilitate the circumvention of technology. Thus even if the device neither bears a trade mark nor contains a copy of any copyright material protected in that Member State, the mere fact that it can enable or facilitate circumvention is enough to warrant its interception by customs.⁵⁵ By formulating the article in this manner, the EU has indicated its approval of how some of its Member States have previously reacted to circumvention devices (based on copyright laws) and now requires that similar policy be implemented at the external borders of its Member States—a move that ultimately criminalizes such devices in the EU and further strengthens the existing anti-counterfeiting framework. The recent decision of the CJEU in *Nintendo and Others v PC Box*,⁵⁶ which this article will now consider, consolidates the latter claim as it highlights further the place of circumvention devices in the EU.

How the CJEU's decision in *Nintendo and Others* consolidates the status quo

Internally, EU copyright laws prohibit circumvention devices, though with some exceptions.⁵⁷ The CJEU

41 See Vrins and Schneider, 'Cross-border Enforcement of Intellectual Property', above, n 14, 277 (emphasis added).

42 *Philips and Nokia*, above, n 16.

43 Vrins and Schneider, 'Cross-border Enforcement of Intellectual Property', above, n 14, 276 ff; De Meyer and Gommers, above, n 28.

44 Regulation 608/2013, above, n 3, Art 2(7)(b).

45 The legality of the use of mod chips and game copiers has been at the forefront of most of Nintendo's legal battle in Europe, eg in Spain, France and those countries mentioned below, nn 46–50.

46 *Nintendo v Dimitri Vande Bergh*, Criminal Court of Leuven, Case No LE24.L6.310-08, 13 March 2009.

47 *Nintendo v Pineapple GmbH*, Regional Court of Munich, case No 6 U 223/09, 21 January 2010.

48 *Nintendo v Webwinkels*, District Court of The Hague, Case No 324867/ HA ZA 08-3879, 21 July 2010.

49 *R v Gilham* [2009] EWCA Crim 2293.

50 The Italian case (citation not yet available since the action is still pending) actually gave the CJEU the opportunity to express its opinion on the matter in *Nintendo Co Ltd and Others v PC Box Srl and 9Net Srl*, C-355/12, EU:C:2014:25.

51 These cases mostly concerned EU and national copyright laws.

52 Directive 2001/29 on the harmonisation of certain aspects of copyright and related rights in the information society, OJ L167/10 (2001) and Directive 2009/24 on the legal protection of computer programs (codified version), OJ L111/16 (2009). See in particular, *ibid*, Art 7(1).

53 Schneider and Vrins, 'Regulation (EC) 1383/2003', above, n 14, 130.

54 Within the meaning of Regulation 608/2013, above n 3, Art 2(7) and 2(7)(b).

55 Regulation 608/2013, above n 3, Art 2(7) read in conjunction with Art 2(7)(b).

56 *Nintendo and Others*, above, n 50.

57 See Directive 2001/29/EC, above, n 52, Art 6(1)–(3). The Directive requires Member States to provide adequate legal protection against the circumvention of any effective 'technological measure' intended to prevent

clarified this in *Nintendo and Others v PC Box*. Even though the case did not specifically concern border measures, it nonetheless consolidated the effectiveness of the new provision on circumvention devices in the new Customs Regulation. The ruling followed a reference by the Tribunale di Milano in proceedings brought by Nintendo undertakings⁵⁸ against PC Box Srl and 9Net Srl concerning the sale by PC Box of mod chips and game copiers through the website managed by PC Box and hosted by 9Net Srl. PC Box marketed the mod chips and game copiers together with original Nintendo consoles. Nintendo had adopted technological protection measures (TPM) which had the effect of preventing the use of illegal copies of videogames. However, PC Box's mod chip, specifically created to be used in Nintendo's consoles, required a prior installation of PC Box's equipment which deactivated Nintendo's TPM. Nintendo considered that PC Box mod chip sought principally to circumvent the TPM of its 'DS' and 'Wii' consoles. PC Box, however, maintained that Nintendo's purpose was to prevent the use of independent software intended to enable movies, video and MP3 files to be read on the consoles (although that software did not constitute an illegal copy of videogames),⁵⁹ so as to increase sales.

The referring court asked the CJEU two questions, the relevant one for our discussion being the second:

[S]hould it be necessary to consider whether or not the use of a product or component whose purpose is to circumvent a technological protection measure predominates over other commercially important purposes or uses, may Article 6 of (Directive 2001/29) be interpreted, including in the light of recital 48 (thereof), as meaning that the national court must adopt criteria in assessing that question which give prominence to the particular intended use attributed by the right-holder to the product in which the protected content is inserted or, in the alternative or in addition, criteria of a quantitative nature relating to the extent of the uses under comparison, or criteria of a qualitative nature, that is, relating to the nature and importance of the uses themselves?

The CJEU responded, in short, that circumvention devices are illegal under Union copyright rules but, when assessing whether they infringe copyright, it is

necessary to examine the purpose of the device provided for circumvention of technology, taking into account, according to the circumstance at issue, of the use which third parties actually make of them.⁶⁰ This was in clear reference to the language of Article 6(2)(b) and recital 48 of the Infosoc Directive to the effect that the

protection against circumvention devices should not prohibit those devices or activities which have commercially significant purpose or use other than to circumvent technical protections.

Such an exception is clearly missing from the corresponding Article in the Customs Regulation, so that no proportionality is necessary in customs matters, as opposed to matters covered by the Infosoc Directive, when it comes to assessing circumvention devices—thereby further strengthening the Member States and their customs capacity to block circumvention devices.

Simplified procedure for small consignments of goods

Another layer of distinctiveness to the new Regulation is the inclusion of a provision that specifically permits customs authorities to destroy small consignments⁶¹ of counterfeit and pirated goods at the request of the right holder. This provision, Article 26, may be a legislative recognition of the recent changes in the distribution channel for counterfeit goods resulting from internet sales. Statistics from the annual reports of the European Commission show an increase in the use of post and courier traffic for counterfeit goods. In 2013, cases related to postal and courier traffic accounted for 72 per cent of detentions⁶²—indicating a 10 per cent increase over the 2010 estimate which represented 62 per cent,⁶³ and about 41 per cent increase over the 2008 estimate which represented 31 per cent.⁶⁴ Medicines remained, for the fourth consecutive year, the top category in terms of the number of articles detained in this stream.⁶⁵ This has been made possible through the availability of online pharmacy shops where counterfeit medicines are easily sold.⁶⁶ Since the risks of counterfeit medicines for the health of the consumer are

or restrict unauthorized acts of reproduction, communication, public offer, or distribution. Thus it only protects the copyright holder against acts which require his authorization.

58 Nintendo Co Ltd, Nintendo of America Inc and Nintendo Europe GmbH.

59 *Nintendo and Others*, above, n 50, para 15.

60 *Ibid*, para 38.

61 Regulation 608/2013, above, n 3, Art 2(19) defines small consignments as 'a postal or express courier consignment, which contains three units or less, or has gross weight less than two kilograms'.

62 DG TAXUD, 'Report 2013', above, n 5.

63 DG TAXUD, 'Report on EU Customs Enforcement of Intellectual Property Rights: Results at the EU border 2010' (14 July 2011).

64 DG TAXUD, 'Report 2008', above, 37.

65 This is the case even though the volume of medicines has decreased over the years. In the 2010 report, medicines represented 69% of goods seized through postal or courier traffic compared to 36% in 2011. In 2012, medicines represented 23% in this category compared to 19% in 2013.

66 The internet is a virtual market place where all kinds of online pharmacies exist, many of which are genuine. However, the growth in this sector has also opened up a new channel for the distribution for fake medicines.

well known,⁶⁷ a measure that could effectively block such products is for the better, not for the worse.

This measure, however, only applies to goods covered by prior application by the right-holder and which are not perishable.⁶⁸ Thus customs authorities cannot take *ex officio* action against small consignments of goods that infringe intellectual property rights. This should, however, not affect the effectiveness of this procedure since over 90 per cent of customs seizures in the EU happen with prior application. To be certain, customs authorities may only liaise with the right-holder where they need further information in order to determine whether an intellectual property right has been infringed. Apart from that, all other relevant decisions such as detention of goods or their destruction are the province of customs authorities.⁶⁹ Only in the case of opposition by the holder of the goods will the right-holder be involved, when it might be necessary to initiate legal proceedings.

In contrast, while customs authorities do not liaise with the holder of the goods at the point of deciding whether to detain the goods, once they do detain the goods they are required to inform the holder of the goods of their action within one working day—indicating their intention to destroy the goods. To strike a fair balance, the holder of the goods would be given ‘the right to be heard’, where he will have within 10 working days to express his agreement or disagreement to the destruction of the goods.⁷⁰ Failure to do so will mean his consent to destruction. In the event that the holder of the goods opposes destruction, customs must immediately inform the right-holder with necessary information to enable him to initiate legal proceedings. If the right-holder should fail to initiate proceedings within 10 working days of notification, customs shall release the goods. In the context of this procedure, there is also case law from the CJEU, *Martin Blomqvist*,⁷¹ which complements the effectiveness argument.

Martin Blomqvist

Martin Blomqvist involved reference for a preliminary ruling from the Højesteret (Danish Supreme Court) to the CJEU on the interpretation of the Customs Regulation (former Customs Regulation 1383/2003) and others

(not relevant here) in proceedings brought by Rolex concerning the destruction of a counterfeit watch which Mr Blomqvist had bought through a Chinese online sales website and which was seized by customs authorities in Denmark on suspicion that it was counterfeit. When Blomqvist was contacted to consent to the destruction of the watch, he refused on the ground that he had lawfully purchased the watch. Rolex then brought an action before the Sø- og Handelsretten (Maritime and Commercial Court)⁷² seeking an order that Blomqvist allow the suspension of release and the destruction of the watch without compensation. That court granted Rolex’s claim.⁷³ Blomqvist then appealed to the Højesteret, which referred the question to the CJEU.

The CJEU responded that the Customs Regulation must be interpreted as meaning that the holder of an intellectual property right over goods sold to a person residing in a territory of a Member State through an online sales website in a non-Member State enjoys the protection afforded to that holder by that regulation at the time when those goods enter the territory of that Member State merely by virtue of the acquisition of those goods. It is not necessary for the goods at issue to have been the subject, prior to the sale, of an offer for sale or advertising targeting consumers of that State.⁷⁴ This decision was based on the former Customs Regulation, which had no specific provision for small consignments of goods. If under those circumstances the CJEU could go as far as to say that one fake Rolex watch purchased online from outside of the EU by a private citizen for private use could be seized in application of the Customs Regulation when they reach the customs territory of the Union, with this new procedure it may not be an exaggeration to anticipate that we are likely to see an increase in this category.

Simplified procedure for goods other than small consignments

The new Customs Regulation makes mandatory⁷⁵ the pre-existing simplified procedure for all Member States of the Union (albeit at the time of negotiating the Regulation, nearly all Member States had implemented this procedure based on Article 11 of Regulation 1383/

67 On the effects of fake drugs, see K Hans-Georg, ‘Strategies Against Counterfeiting of Drugs: A Comparative Criminal Law Study’, in C Geiger (ed), *Criminal Enforcement of Intellectual Property Rights: A Handbook of Contemporary Research* (Edward Elgar, 2012) 353–68.

68 Regulation 608/2013, above n 3, Art 26(1)(b) and (c). Article 2(20) defines ‘perishable goods’ as goods considered by customs authorities to deteriorate by being kept for up to 20 days from the date of their suspension of release or detention.

69 Ibid, Art 26(2) specifies that when the procedure set out in this article is applied, Arts 17(3), 17(4), 19(2) and 19(3) shall not apply.

70 Ibid, Art 26(4).

71 *Rolex SA and Manufacture des Montres Rolex SA v Martin Blomqvist*, C-98/13, EU:C:2014:55.

72 *Rolex SA and Manufacture des Montres Rolex SA v Martin Blomqvist*, Sø- og Handelsrettens Dombag, Case V 29/10.

73 *Martin Blomqvist*, above, n 71, para 20.

74 Ibid, para 35.

75 Note the language of Regulation 608/2013, above, n 3, Art 23(1). Also, the latter part of recital 16 which carries in reference to the simplified procedure that it should be made compulsory.

2003).⁷⁶ The manner in which Article 11 was formulated left it to Member States to decide whether to enforce this procedure.⁷⁷ Now this procedure is not only mandatory, but also applies to all categories of goods that infringe intellectual property rights other than those in small consignments. Under this procedure, goods intercepted by customs may be destroyed without having to undergo formal and costly legal proceedings after confirmation by both the right-holder and the holder of the goods that the goods are indeed infringing and that they should be destroyed.

Implementing this procedure, however, requires some formalities. Initially, before customs authorities detain suspect goods, they may ask for information from the right-holder to help them determine whether the goods actually infringe intellectual property rights. They may in turn provide the right-holder with some limited information.⁷⁸ If the goods are detained, customs authorities will inform the holder of the goods and the right-holder of their action within one working day (including information about their rights and obligations). From this point on, both the right-holder and the holder of the goods have 10 working days (or a non-extendable three working days in the case of perishable goods) within which to submit written notices to customs: for the right-holder, that the goods are actually infringing and that they should be destroyed; for the holder of the goods, his agreement or opposition to the destruction of the goods. Before doing this, the right-holder and the holder of the goods can inspect the goods⁷⁹ (with the right-holder having the right to ask for more information).⁸⁰

Where the holder of the goods does not meet the requirements within the stipulated deadlines, the customs authorities may take that as consent for destruction.⁸¹ The explicit inclusion of the ‘right to be heard’ clause for the holder of the goods is new and positive—it injects some balance and legitimacy into the procedure. The previous regime had attracted criticism for permitting right-holders to liaise with customs authorities to destroy goods on assumption of the ‘implied consent’ of

the holder of the goods. Even though the holder of the goods could contest destruction, the provision did not make clear how and through whom, thus giving pre-eminence to the right-holder in the process.⁸² On the part of the right-holder, if he fails to meet the deadline requirements for confirmation of infringement or consent to destruction of goods, customs authorities must immediately terminate their detention unless they receive notification of initiation of proceedings.⁸³ Should the right-holder need more time, for instance, to initiate legal proceedings, he can request a further extension of 10 working days provided the goods are not perishable.⁸⁴

In contrast, even where proceedings have been initiated, the holder of the goods can seek the early release of the goods if they infringe a design, patent, utility model, topography of semi-conductor product or plant variety before the completion of proceedings by providing a security deposit,⁸⁵ unless the applicant for customs action secures a preliminary injunction to restrain that process.⁸⁶ It is uncertain why such a provision would cover specifically these intellectual property rights, when supplementary protection certificates (SPCs) have been removed from the list.⁸⁷ Removal of SPCs from this list as indicated above could potentially harm the generic pharmaceutical industry and countries that utilize their services. In the form that the Regulation currently stands, generic medicines in transit at EU borders could be intercepted by customs on the mere suspicion that they might be diverted into the EU market.

Generic medicines not only infringe patents but also SPCs. SPCs in the EU generally extend the term of patent protection for five more years to compensate for delays in obtaining regulatory approval for medicinal products.⁸⁸ With this provision for early release of goods infringing specific intellectual property rights, the holder of a consignment of generic medicines that gets intercepted could file for the early release of the goods with the assurance that he is able to prove in proceedings that the goods are not meant for the EU market, but not where they infringe an SPC.

76 Schneider and Vrins, ‘Regulation (EC) 1383/2003’, above n 14 at 258 (indicating that the Member States of the EU had gradually come to understand that the simplified procedure was an absolute must after initial hesitation).

77 Note the language of Regulation 1383/2003, above, n 6, Art 11(1). See also Regulation 608/2013, above n 3, recital 16.

78 Such as the actual or estimated quantity of the goods, their actual or presumed nature and images.

79 Regulation 608/2013, above n 3, Art 19.

80 The latter part of *ibid*, Art 17(4) carries that the customs authorities shall upon request, and where available to them, inform the right-holder of the names and addresses of consignee, the consignor and the declarant or holder of the goods, of the customs procedure and of the origin, provenance and destination of the goods (emphasis added).

81 *Ibid*, Art 23(1)(c).

82 *Ibid*, Art 11(1).

83 *Ibid*.

84 *Ibid*, Art 23(4).

85 *Ibid*, Art 24. For example, among the conditions to be fulfilled, the amount provided as guarantee should be sufficient to protect the interest of the holder of the decision.

86 *Ibid*, Art 24(2)(b).

87 *Ibid*, Art 14(1) included Supplementary Protection Certificates in this list.

88 D Acquah, ‘Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU. Is there a need to rebalance?’ (2014) 45(3) *IIC* 256.

The potential effect of this procedure cannot be underestimated. Statistics from the Commission's annual reports already show a major increase in cases of goods that get destroyed through this procedure following detention, from 47 per cent in 2009 to 75 per cent in 2010 and 77 per cent in 2013. Combined with situations where legal proceedings are initiated, this procedure represents between 70 per cent and 92 per cent of detentions for the same period.⁸⁹ On account of these figures, one can say that this procedure has proved impressive (as is also the opinion of the EU legislator),⁹⁰ and may likely continue. We will now turn to the EU Customs Action Plan which further highlights, in a more pragmatic way, efforts to ensure that customs enforcement of intellectual property rights is efficient in the EU.

The EU Customs Action Plan to combat intellectual property rights infringements

Apart from the measures identified above, the EU and its Member States are also engaged in a multi-annual Action Plan⁹¹ that aims to improve the effectiveness of customs control, strengthen cooperation with industry and international partners, and raise awareness of consumers to the negative consequences of buying goods which infringe intellectual property rights.⁹² On international partnership, the EU has engaged China in a bilateral agreement on customs matters⁹³ that aims to promote effective communication and cooperation between customs authorities on both sides, to ensure proper application of customs legislation and prevent breaches. Both schemes adopt very practical and strategic measures that have clear objectives, effective enforcement structures, and which are linked to indicators allowing for the measurement of results. They are thus extra layers of action that, if properly implemented, could effectively contribute to curbing the international trade in counterfeit goods.

European level

At the European level, the Council in its new Resolution on EU Customs Action Plan to combat intellectual property rights infringements has tasked the Commission

and Member States to form an expert group to work out a comprehensive intellectual property framework of protection that should complement customs' ability to enforce intellectual property effectively at the borders. In fact, the new Action Plan has economic preoccupations: 'it is designed to bring added value and enhanced outcomes in a climate of financial austerity'.⁹⁴ Thus, among the objectives specified for the expert group to work out the plan are

- the effective implementation and monitoring of the new EU legislation on customs enforcement of intellectual property rights; and
- the strengthening of cooperation with the European Observatory on infringements of intellectual property rights and law enforcement authorities.

As a template for action, the expert group has the mandate to develop tools for the implementation of the new Customs Regulation. Such tools should include production of a manual for right-holders intending to file applications for action which should be published on the website of the Commission and the Member States, preparing specific guidelines for customs in all EU official languages on new procedures (such as on small consignments), and further developing training schemes in cooperation with the European Observatory on infringements of intellectual property rights to facilitate the implementation of the Regulation, possibly including e-learning tools for customs and right-holders. To ensure effective monitoring, the expert group will have to submit yearly reports to the Council on the progress of implementation of the Action Plan.

While the development and implementation of these strategies will be costly for the Union (for instance, translating new customs procedures in all official languages of the Union and staff training), the fact that the Union is willing to commit all tools and resources at its disposal to carry out this plan indicates that the EU is committed to its success. From the outline of the strategy, the European legislative intent is not just to educate or make information more accessible to all stakeholders in this sector, but also to promote an EU-wide normative action towards customs enforcement of intellectual property rights (even though this is an area already harmonized) and to further extend this to third country partners such as China.

89 The statistics cover the period 2009–2013 because the 2008 report does not provide information for this category.

90 Regulation 608/2013, above, n 3, recital 16.

91 EU Customs Action Plan 2013–2017, above, n 2.

92 Taxation and Customs Union, 'EU Customs Action Plan: Commission Initiatives for Combating Counterfeiting and Other Intellectual Property Rights'. Available at http://ec.europa.eu/taxation_customs/customs/

[customs_controls/counterfeit_piracy/commission_initiatives/index_en.htm](http://ec.europa.eu/customs_controls/counterfeit_piracy/commission_initiatives/index_en.htm) (accessed 20 August 2015).

93 'Agreement between the European Union and the Government of the People's Republic of China on cooperation and mutual administrative assistance in customs matters', L 375/20–25 (23 December 2004).

94 See EU Customs Action Plan 2013–2017, above, n 2.

Cooperation with China

China is the main country of origin of goods entering the European market that are suspected of infringing intellectual property rights.⁹⁵ The Agreement between the EU and China on customs matters therefore serves as an important medium for normative interaction between both sides, and also as a platform to manage or reduce the flow of counterfeit goods into the European market. Like the EU internal action, a joint customs cooperation committee established at this level has only recently come out with a new 'Strategic Framework for Customs Cooperation 2014–2017'.⁹⁶ This strategy, which prioritizes four areas of customs cooperation, has 'combating intellectual property rights infringements' as its number one item. In this framework, customs authorities from both sides are to cooperate among others on

- exchange and joint analysis of seizure statistics to detect general trends and risks, which will lead to better targeting of high risk consignments;
- exchange of case-specific information on detentions through a network of customs officers in seaports and airports in the EU and in China; and
- enhancement of cooperation between customs and other law enforcement authorities in order to dismantle production and distribution networks of goods infringing intellectual property rights.⁹⁷

As can be seen, these are pragmatic measures that go beyond just border controls to deal with the roots of counterfeiting—disrupting the production and distribution channels of goods infringing intellectual property rights. This is aimed at providing a long-term solution to the trade in counterfeit goods since border enforcement alone is proving to be inadequate. The Strategy also falls in line with the recent communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee which proposes a new enforcement tool—such as the 'follow the money' approach⁹⁸—to deprive commercial-scale infringers of their actual or potential revenue flows.⁹⁹ To ensure this, the EU–China customs action plan systematically requires that customs authorities from both the EU and China share information on detentions and seizures on a quarterly basis. Statistics from these sources would serve as a tool for joint analysis

by risk management experts from both sides with a view to detecting general trends and other risk information. As with the EU internal system, this evaluation should be done at least annually.

The strategy also builds on the existing network of frontline officers networking from main ports in the EU and China, possibly via a specially developed IT system. This would allow for direct and easy interaction to ensure successful targeting, for example, of high-risk consignments that may be coming into the EU. Further, the framework requires both sides to exchange knowledge and experience of each other's intellectual property rights enforcement policies and practices. As the EU is known for its technical expertise and institutional superiority on customs matters, this could lead to the gradual transfer of norms from the EU to China. In this way, Chinese export rules may be adjusted and enforced in such a way that should effectively limit the amount of intellectual property-infringing goods that are exported from China.

Good legal basis

As the international trade in counterfeit and pirated goods grows and becomes even more sophisticated, Europe faces the challenge of adjusting its laws to counter the threats coming from such an illegal enterprise. This article argues the current European Customs Regulation and other non-legislative mechanisms instituted by the EU to govern this phenomenon appear to fulfil that objective. If statistics from the Commission's annual reports on customs are anything to go by, the new Regulation, which comes with modifications such as the inclusion of devices that enable circumvention of technology to the list of goods infringing intellectual property rights, in addition to a simplified procedure for the destruction of small consignments of goods, is better placed to manage the trade in counterfeit and pirated goods considering that these are timely interventions that respond well to present challenges. Also, the Commission's internal and external strategic action plans aimed at effective implementation of its customs rules are an extra layer of measures that could lead to the desired outcomes. If nothing at all, at least on paper, there is now a legal basis for the interception of goods that fall into any of the categories outlined in this article which, to an extent, responds well to modern trends in the distribution of counterfeit and pirated goods.

95 DG TAXUD, 'Report 2013', above, n 5.

96 DG TAXUD, 'Ensuring Smooth and Safe Trade Between the EU and China—Strategic Framework for Customs Cooperation 2014–2017' (13 May 2014). Available at http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/142577.pdf (accessed 20 August 2015)

97 Ibid.

98 Communication from the Commission COM (2014) 392 final, above, n 2.

99 D Acquah and K He, 'Customs Enforcement of Intellectual Property in Europe and China' in N Lee, N Bruun and M Li (eds), *Governance of Intellectual Property Rights in China and Europe* (Edward Elgar, forthcoming 2016) ch 19.

Chapter V

Publication IV

**Extending the limits of protection of pharmaceutical patents
and data outside the EU: Is there a need to rebalance?**

Daniel Acquah

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Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a Need to Rebalance?

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Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a Need to Rebalance?

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Abstract The European Union (EU) has instituted internal and external measures aimed at protecting and enforcing intellectual property rights. In the area of pharmaceutical patents, the Union has also sought to protect its industries through patent term extension and data exclusivity. Recent EU Free Trade Agreements (FTAs) with developing countries contain chapters on intellectual property that extend patent terms and data exclusivity for pharmaceutical products. Such acts further prolong the lifespan of protection given to existing products and limit generic market entry. This article identifies the issue as one of “cross-pollination” of laws and argues that since similar laws exist in the internal regime of the EU, incorporating them into the EU would not be technically too difficult. However, to an extent this regime is simulated in developing countries, implementation will bring major difficulties to the health sector and economies of these countries. The article thus proposes that developing countries should not be forced to adopt such laws through FTAs, and if they are, there should be the compulsory inclusion of both (1) a clause on transitional arrangements for developing countries specific to intellectual property; and (2) a clause that clearly links the objectives for intellectual property protection and enforcement (in this context, patent term extension and data exclusivity) to balancing between the promotion of technological innovation and access to medicines.

Keywords Pharmaceutical patents · Patent term extension · Data exclusivity · Intellectual property · Free trade agreements

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1 Introduction

Since the TRIPS Agreement,¹ patents have become the primary target of critique for their negative impact on access to medicines. However, recently patent term extension and data exclusivity have become the new frontiers in the debates about this topic.² This is partly due to the swing away from multilateralism, which is characterised by the upsurge in bilateral, plurilateral and regional trade agreements.³ These agreements come with intellectual property (IP) chapters that commit contracting parties to protecting IP beyond the TRIPS minimum requirements.⁴ The EU and the US are at the forefront of negotiating such agreements and are often the demanders for patent extension and data exclusivity.⁵ While the EU and the US already have such extensive IP measures in their laws, these measures are more often new to developing countries. The EU, for instance, includes clauses on patent term extension (referred to in Europe as Supplementary Protection Certificate [SPC])⁶ and data exclusivity in its recent Free Trade Agreements (FTAs), which directly transpose its internal laws. Such actions further prolong the lifespan of protection given to existing products and limit generic market entry resulting in enormous consequences on the health sector and economies of developing countries. The question is, are patent term extension regimes and data exclusivity regimes TRIPS compliant?

This article compares how patent term extension and data exclusivity provisions appear in the internal and external⁷ dimensions of the EU's IP rule-making and

¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement is Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization (WTO), 15 April 1994, 33 I.L.M. 1125, 869 U.N.T.S. 299 (Hereinafter, the TRIPS Agreement).

² Ho (2011a), p. 262. (emphasis added).

³ For a working definition of ("multilateral", "plurilateral" and "regional" Agreements), Flynn et al. (2012); Yu (2012); Grosse Ruse-Khan (2011a); Okediji (2003–2004); Helfer (2004).

⁴ TRIPS Art. 1.1 permits contracting countries to adopt more extensive IP laws domestically than is required by the Agreement provided that "such protection does not contravene the provisions of this Agreement." For a varied opinion on how this clause could lead to "ceiling rules" in international IP, see Kur and Grosse Ruse-Khan (2008); also, Grosse Ruse-Khan (2009).

⁵ It is, however, worth noting that in 2007, the US Congress and the Bush administration reached a bipartisan compromise on a "New Trade Policy for America", which called for more balance on the position of the US in FTA negotiations regarding issues related to IP, labour standards, and the environment. In response to concerns over US FTAs undermining TRIPS flexibilities, the provisions on data exclusivity, patent extensions, and the linkage between patent protection and drug approval were relaxed substantially, while the new template for FTAs now also includes specific provisions on public health. (See Grosse Ruse-Khan (2011a), at 331, emphasis added). However, it may seem the US is turning its back on this compromise at the Trans-Pacific Partnership Agreement (TPP) negotiations as it is reported that the US tabled two IP chapter proposals to TPP negotiators in 2011. Included in those proposals are provisions dealing with traditional data exclusivity for pharmaceutical products involving new chemical entities and a placeholder for biologics (see Flynn et al. (2012), at 149–183).

⁶ Broadly, Supplementary Protection Certificate (SPC) is the EU equivalent to patent term extensions under the US Hatch-Waxman Act. Contrary to patent term extension, an SPC is not an extension of the respective patent as such, but an exclusive right per se which refers to a given basic patent. For convenience, I use patent term extension to mean both throughout this article.

⁷ By internal, I mean the EU level of regulation (regional) and by external, I mean the EU's bi/multilateral agreements with state entities and international organisations.

argues that the comparable clauses appearing in EU FTAs are far-reaching and could have serious implications for developing countries⁸ with regard to access to medicines. The article first identifies this issue as one of “cross-pollination” of laws and argues that since similar laws exist in the internal regime of the EU, incorporating them into the EU would not be technically too difficult. However, to the extent this regime is simulated in developing countries, implementation will bring major difficulties to the health sector and economies of these countries. The present article thus proposes that developing countries should not be forced to adopt such laws through FTAs, and if they are, there should be the compulsory inclusion of both (1) a clause on transitional arrangements for developing countries specific to IP; and (2) a clause that clearly links the objectives for IP protection and enforcement (in this context, patent term extension and data exclusivity) to balancing between the promotion of technological innovation and access to medicines.

The article is divided into six parts. Part 2 starts with a brief exposition on the dynamics of patent term extension and data exclusivity. Part 3 traces the historical developments of patent term extension and data exclusivity in the US and in the EU – arguing how these reflect a cross-pollination of legal norms from the US into the EU and in turn, from the EU to developing countries through FTAs. Part 4 discusses the failure of multilateralism, the TRIPS requirements on patent term extension and data exclusivity, and the example of India resisting such regulatory mechanisms. Part 5 outlines how these EU-plus measures are transposed into FTAs and how they could impact developing countries – all the time, making reference to the European level of regulation. In Part 6, some conclusions are drawn.

2 Dynamics of Patent Term Extension and Data Exclusivity

The concepts of patent term extension and data exclusivity are relatively recent ones in the international IP field. Both concepts gained recognition for the first time through their incorporation into the North American Free Trade Agreement (NAFTA), which came into force on 1 January 1994.⁹ Data exclusivity subsequently appeared in the TRIPS Agreement.¹⁰ Essentially, patent term extension and data exclusivity laws respond to the challenges being faced by the originator pharmaceutical companies with the patent and regulatory systems in place in most countries. With or without patent protection, all drugs that come to the market have to undergo regulatory approval in all countries. Regulatory authorities usually require test data from pharmaceutical companies in order to evaluate whether the research data support the safety, effectiveness and quality control of a new drug product to serve the public health.¹¹ This process is known to be complex, costly

⁸ Used here to refer to both Developing Countries and Least Developed Countries (LDCs).

⁹ See Arts. 1709(12) and 1711(5)–(7) respectively of NAFTA.

¹⁰ See Art. 39.3 TRIPS.

¹¹ Mulaje et al. (2013).

and time consuming.¹² Because, usually, a patent application is often filed right at the beginning of drug development, much of the nominal 20-year patent term is lost during the lengthy premarket development period for a new drug.¹³ In the absence of patent protection,¹⁴ the data submitted for marketing authorisation, if not protected, can be relied upon by generic competitors to produce alternative versions of originator drugs to compete on the market.¹⁵ To prevent this from happening, and to encourage continuous innovation in the pharmaceutical sector, developed countries introduced patent term extension and data exclusivity laws.

Patent term extension is a unique IP right that provides an additional monopoly that comes into force after the expiry of a patent upon which it is based. This special right is given to compensate for the long amount of time needed to obtain regulatory approval for medicinal products (i.e. authorisation to put these products onto the market). Data exclusivity, on the other hand, prevents a potential generic company from relying on the clinical data submitted by an originator company for marketing approval when the generic company wants to establish a bioequivalence during the period of exclusivity. Data exclusivity usually takes effect immediately after an applicant successfully obtains marketing authorisation for a new drug. It is granted independent from patent protection and as such does not preclude other companies from generating their own registration test data. However, in practice, the huge financial resources and time needed to gather and generate pharmaceutical registration data for a new drug creates a market barrier that is too high for generic-based manufacturers.¹⁶

Thus, patent term extension and data exclusivity laws as originally promulgated in the US and the EU were intended to strike a balance between two conflicting, but related, policy objectives: ensuring timely, affordable access to drugs, by allowing for expedited regulatory approval of generic drugs, and encouraging drug innovation, by restoring some years of patent protection that are lost by firms

¹² Di Masi et al. (1994, 2003); *see also* Grabowski (2007). Available at: <http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf>.

¹³ Di Masi et al. (1994, 2003); Grabowski (2007).

¹⁴ This also includes “provisional patent protection” as known in the US or, “right of priority” under the European Patent Convention (EPC). A provisional patent protection in the US is a one-year placeholder offering no rights other than the filing date priority claim. During that year, the United States Patent and Trademark Office (USPTO) ignore the application until the applicant takes some additional steps – typically filing a non-provisional application or an international PCT application. At the end of the year, the provisional application is automatically abandoned. In Europe, Art. 87(1) EPC states: “A person, [or his successors in title], who has duly filed in or for any State party to the Paris Convention for the Protection of Industrial Property, an application for a patent or for the registration of a utility model or for a utility certificate or for an inventor’s certificate, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of 12 months from the date of filing of the first application”.

¹⁵ Patents protect inventions and not data. However, during its lifetime, patents grant an exclusive market monopoly that prevents others from competing on the market. In this sense, firms with strong patent portfolios do not actually benefit from data exclusivity unless they go beyond the patent term. Data exclusivity becomes truly beneficial when there is no patent protection, a patent has expired, or a patent is found invalid, etc.

¹⁶ Pugatch (2005), p. 21.

during the approval process,¹⁷ and a period of data exclusivity. Although these policy choices have, to a large degree, proved to be successful in the US and in the EU; the question is whether developing countries should be forced to adopt such laws?¹⁸ Effectively answering this question may entail first trying to find out whether the clauses introducing these provisions in the FTAs have the same balancing mechanism as the laws in the US and the EU, or whether there is a need to rebalance? The next Part will explore the evolution of patent term extension and data exclusivity laws in the US and EU before turning to these questions.

3 The Cross-Pollination of Laws

Historically, the use of patent term extension and data exclusivity to supplement patents is grounded in the Hatch-Waxman Act of 1984 in the US.¹⁹ This Act sought to correct the imbalance in existing practice where, aside from the 17-year period of patent protection,²⁰ pioneer pharmaceutical companies in the US could treat undisclosed clinical trials and data that they submitted to the Food and Drug Administration (FDA) for marketing authorisation as trade secrets.²¹ This gave the absolute monopoly over data to pioneer pharmaceutical companies, even in cases where patents had expired, thus making it difficult for generic entry and competition in the drug market. For generic companies to be able to bring generic versions of drugs to the market, they needed to conduct their own clinical trials in order to obtain marketing authorisation to market their products in the low-margin, highly competitive post-patent market.²²

Generic companies thus often depended on the preclinical and clinical test data of originator pharmaceutical companies to support their own new drug applications. To allow for this, and at the same time make sure the originator companies are not

¹⁷ Higgins and Graham (2009).

¹⁸ The relevance of this question lays in the fact that to date, most developing countries still lack manufacturing capacity, and are struggling to fully implement the TRIPS Agreement. This explains why there have been series of extensions on implementation deadlines for least developed and developing countries, the most recent being the (Decision by the Council for TRIPS of 11 June, 2013 [Extension of the Transition Period Under Art. 66.1 for Least Developed Country Members, IP/C/64]) which further extends until 1 July 2021 the deadline for least developed countries to protect IP under the WTO TRIPS Agreement, with a further extension possible when the deadline comes. This follows from earlier decisions (*see, e.g.* Council for TRIPS, Extension of the Transition Period Under Art. 66.1 for Least Developed Country Members, IP/C/40, [Decision by the Council for TRIPS of 29 November, 2005] to extend the transition period for least developed countries to July 2013 from originally 1 January 2006). By the decision of 27 June 2002 (Council for TRIPS, Decision by the Council of TRIPS of 27 June 2002, IP/C/25), the transition period for least developed countries in regard to the introduction of patent protection for pharmaceutical and agricultural products had already been extended to 2016. Subscribing to FTAs with TRIPS-plus provisions on IP will simply render these extensions void.

¹⁹ *See* the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1585–1605 (codified as amended at 21 U.S.C. Sec. 355 [2006]).

²⁰ Until the Hatch-Waxman Act of 1984, patents had a term of 17 years from grant in the US whereas it is now 20 years from application. *See* note 23 *infra*.

²¹ Soehnge (2003); *see also*, Sanjuan (2006), available at: <http://www.keionline.org/miscdocs/>.

²² Baker (2008). (Also, the use of animals and humans for clinical trials raise ethical questions).

disadvantaged, the Hatch-Waxman Act struck a balance between the needs of the pioneer pharmaceutical companies and those of the generic companies. For the pioneer drug producers, the Act lengthened the duration of patents to 20 years;²³ introduced five years of data exclusivity for new chemical entities that had never previously been approved by the FDA;²⁴ introduced an additional three years of data exclusivity for new indications of an existing medicine upon the submission of clinical evidence;²⁵ and introduced a five-year patent term extension in the case of administrative delays in the registration of patents.²⁶

In return, generic drug manufacturers were permitted an abbreviated new drug application, which, rather than requiring independent proof of safety and efficacy of a new drug, simply required the generic manufacturer to demonstrate that the new drug was bioequivalent to the pioneer drug which had been deemed safe and effective.²⁷ Furthermore, the Act created an exception where generic manufacturers could make a limited amount of patented drugs for the purposes of obtaining regulatory authorisation without infringing the original patent (the so-called Bolar exemption).²⁸ For the pioneer pharmaceutical company, this trade-off compensated for some of the effective patent term lost during the FDA regulatory review process, and helped to offset the tremendous expense in terms of time and money required for FDA approval.²⁹ For the generic industry, these provisions provided a less-expensive regulatory approval path for generic copies of pioneer drugs and a greater incentive to challenge the extended protection of the pioneer drug.³⁰

The success of the Hatch-Waxman Act led to a growing consensus within American society that an adequate abbreviated approval process can be similarly

²³ This was so because the 17-year patent term was measured from the date that the patent was granted (*see* 35 U.S.C. Sec. 154(a)(2)). The time that the USPTO took to issue a patent was three years or less, measured from the earliest referenced application, and the fact that a patentee's rights do not begin until a patent issues from that application (*see* 35 U.S.C. Sec. 154(a)(1)).

²⁴ *See* 21 U.S.C. Secs. 355(c)(3)(E)(ii), (j)(5)(F)(ii) (Supp. 2005). The actual length of marketing exclusivity is usually 6.5 years because of the 18 months it takes the FDA to approve a generic application. *See* Baker (2008), at footnote 21.

²⁵ *See* 21 U.S.C. Secs. 355(c)(3)(E)(iii), (j)(5)(F)(iii). Also, *see* Baker (2008), at footnote 23 where he explains that the pharmaceutical industry gained another six-month period of data exclusivity as a reward for conducting pediatric trials on drugs via the Food and Drug Administration Modernization Act of 1997. 21 U.S.C. Sec. 355a(b).

²⁶ *See* 35 U.S.C. Sec. 156. Subsection (a) describes the basic requirements to be met before a patent can be extended. For a list of these, refer to note 50 in Soehnge (2003).

²⁷ Fisher (1986); also, Baker (2008), at 306; Soehnge (2003), at 53.

²⁸ The Hatch-Waxman Act reversed the decision of the Court of Appeals for the Federal Circuit in *Roche Products v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir. 1984). The U.S. "Bolar" exception is found in Sec. 35 USC 271(e)(1), which reads in part: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products". The underlying logic of the Bolar provision is that it reduces delays in the launch of a generic product, because the generics industry is entitled to conduct the necessary bioequivalence and quality manufacturing studies while the reference product is still under patent protection.

²⁹ *See* Soehnge (2003), at 53.

³⁰ *See* Soehnge (2003), at 53. Citing Atkinson (2002).

designed for follow-on biologics,³¹ also referred to as “biosimilars” in Europe. Until 2009, when the Patient Protection and Affordable Health Care Act (H.R. 3590),³² which contains provisions that enable the FDA to approve follow-on biologics products, passed the US Congress and was subsequently signed into law by President Obama,³³ the FDA had made it clear that no equivalent statutory pathway existed for follow-on biologics.³⁴ Thus, any generic company wishing to introduce competing follow-on biologics prior to the Biologics Price Competition and Innovation Act (BPCIA) was required to submit an entirely new Biologics Licensing Application (BLA), the equivalence of a New Drug Application for small molecule drugs, which required the completion of clinical trials for safety and efficacy.³⁵

Compared to small molecule drugs, biologics take longer to develop and have higher estimated cost.³⁶ Paired with the history of biologics regulation,³⁷ this would ensure that the biologics industry was largely impervious to generic entry and price competition, and had been expected to remain so even after patents on key products expired.³⁸ Thus, a crucial debate leading up to the passage of the BPCIA legislation was whether and to what extent it should provide originator biologics companies with a period of FDA data exclusivity protection as an incentive for innovation. In the end, the law permitted a 12-year period of data exclusivity for manufacturers of new biologics,³⁹ passing the EU regime of data exclusivity for small molecule drugs and biosimilars. However, unlike in the EU, the BPCIA lacks implementation guidelines.⁴⁰ This has raised questions about exactly how the exclusivity provisions

³¹ Gitter (2008). (Follow-on biologics are the generic alternative of biologics. Biologics are drugs generally derived from living materials, including blood-derived products, vaccines, and most protein products. They cannot be described in simple terms or using simple formulae because they are the output of a highly complex and nuanced laboratory processes). See FDA, “Frequently Asked Questions About Therapeutic Biological Products”: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm>.

³² See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, Secs. 7001-03, 124 Stat.119 (2010) (enacting Biologics Price Competition and Innovation Act of 2009, H.R. 3590, 111th Cong. (2009)). The BPCIA provides for the licensing of “biosimilar” and “interchangeable” biological products.

³³ Sheryl Gay Stolberg and Robert Pear, “Obama Signs Health Care Overhaul Bill, With a Flourish”, *N.Y. Times*, 23 March 2010, available at <http://www.nytimes.com/2010/03/24/health/policy/24health.html> (accessed 1 November 2013).

³⁴ The FDA’s refusal to permit follow-on biologics manufacturers to utilise the abbreviated Hatch-Waxman pathway stemmed from the inherent difficulty of meeting the statutory requirement of “bioequivalence” in the context of large bio-molecules. Given the nature of biological products and the complexity of the science involved, it has been difficult for lawmakers to reach a consensus on approval standards and IP protections for innovators. For more on this, see Vernon et al. (2010).

³⁵ See Vernon et al., *id.*

³⁶ Di Masi and Grabowski (2007); also, Grabowski (2008).

³⁷ On the difference in regulation and history of biologics in the US, see Vernon et al. (2010), at 57.

³⁸ Maxwell (2010).

³⁹ See 42 U.S.C. Sec. 362(K) generally and Sec. 362(7)(A) specifically with respect to the period of exclusivity.

⁴⁰ Simoens et al. (2011).

in the BPCIA are to be interpreted as market or regulatory data exclusivity.⁴¹ Furthermore, there seem to be uncertainties with the 12-year exclusivity period for biologics in the US now as the Obama administration's FY-14 budget proposes shortening the exclusivity period to seven years and bars evergreening of such extensions based on minor variations to an existing biologic.⁴²

3.1 The European Experience

In Europe, the United Kingdom has had provisions for extending patent terms in its patent law since 1949 for reasons of inadequate remuneration or war loss.⁴³ However, these provisions did little for innovation, as they could not be relied upon when decisions concerning development of a product were being made.⁴⁴ The reason for this was that petitions for extension could only be made near the end of a patent's term. Thus, this law was repealed in 1977 when the United Kingdom extended patents for a period of 20 years from filing.⁴⁵ In the EU, the European pharmaceutical industry waged an effective campaign for legislation on patent term extension, against the backdrop of developments in the US and Japan, where patent term restoration legislations had been passed in 1984 and 1988.⁴⁶ The European Commission became convinced that for pharmaceutical research to survive in Europe, the pharmaceutical industry needed to be supported and encouraged.⁴⁷ The only way to accomplish this was to introduce patent term extension. After a protracted period of negotiations, France and Italy, who could no longer hide their impatience, went on to pass their own pharmaceutical extension laws.⁴⁸ Following the passage of these laws in France and Italy, the European Parliament subsequently moved to pass the Supplementary Protection Certificate legislation on 2 July 1992,⁴⁹ which entered into force on 2 January 1993 in the European Economic Community (EEC). This regulation has now been codified as Regulation (EC) No. 469/2009⁵⁰ after several substantial amendments.

⁴¹ See http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/01/bpcias-principal-authors-seek-to-clarify-congressional-intent-with-respect-to-12-year-exclusivity-pe.html.

⁴² See Office of Budget and Management, Fiscal Year 2014: Budget of the United States Government, 40, available at: <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf>.

⁴³ Lourie (1985), making reference to the Patents Act 1949, Secs. 23–25.

⁴⁴ Lourie (1985), making reference to the Patents Act 1949, Secs. 23–25.

⁴⁵ Lourie (1985), making reference to the Patents Act 1949, Secs. 23–25, (citing Patents Act 1977, Sec. 25).

⁴⁶ Law No. 27 of 1987, reprinted in *Official Gazette*, 28 May 1987, at 2. These statutes became effective on 1 January 1988 in Japan.

⁴⁷ Moore (1998).

⁴⁸ See French Law No. 90-5 10 of 25 June 1990, and French Implementing Decree No. 91-1180 of 19 November 1991; Italian Law No. 349 of 19 October 1991; also Mazer (1993).

⁴⁹ See Council Regulation (EEC) No. 1768/92, *OJ EC* of 2 July 1992 No. L 182/1 concerning the creation of a supplementary protection certificate for medicinal products (Hereinafter, Patent Term Extension Law).

⁵⁰ Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, 1 *O.J.* (L 152) (2009).

This regulation, just like its predecessor, provides for an extension of the term of patent protection for medicinal products for a maximum of five years, to compensate for the time lost during the process of securing the first marketing authorisation to place the product on the market in the Community.⁵¹ Article 3(a) stipulates that the product must be protected by a basic patent that is in force in the country where the extension is sought, and para. (c) requires that the product should not have already been the subject of a certificate. Only one patent term extension is allowed for any particular product.⁵² Article 15 of the regulation also clearly outlines the conditions under which a declaration of invalidity of a certificate for a patent term extension could be brought before the body responsible under national law for the revocation of the corresponding basic patent.

According to the terms of the 1992 Regulation, only 12 out of the 15 Member States of the EEC were able to implement its provisions as of January 1993. Greece, Portugal and Spain were unable to enforce the law because their national laws did not offer product patents for pharmaceuticals by 1990.⁵³ They therefore had to wait until 1998 (a further five years from the date the regulation came into effect) to enforce it. The underlying rationale for this was that it would probably be too much to expect these countries to accept and implement laws on pharmaceutical patents and patent term extension within such a short period of time. However, since patents last for 20 years and extensions cannot take effect until the patent(s) expire, it was not until 2012 that pharmaceutical firms in these countries could begin enjoying patent term extensions for pharmaceutical products.

The introduction of data exclusivity in the EU came somewhat earlier, in 1987.⁵⁴ Before then, pharmaceutical test data were protected as trade secrets in the EU just as in the US. Protection varied from country to country and even though Council Directive 65/65/EEC⁵⁵ required generic manufacturers to obtain their own marketing approval, permissive indirect use of data of originator companies by some national authorities of Member States became a source of concern for the European pharmaceutical industry and the Commission.⁵⁶ Having felt the immediate impact of its introduction in the US, the European Commission came under enormous pressure from the local pharmaceutical industry to introduce data exclusivity in the EU. The pharmaceutical industry cited the need to boost local pharmaceutical research and innovation in the EU as reasons for this introduction. This, the industry believed, could serve as an incentive for the cost of developing new drugs in Europe that was dwindling as a result of a lack of data exclusivity provisions, which gave their American counterparts a competitive edge.⁵⁷ They also

⁵¹ See Recital 10 and Art. 13(2) of Regulation (EC) No. 469/2009.

⁵² Recital 10 and Art. 13(2) of Regulation (EC) No. 469/2009, Art. 4.

⁵³ Recital 10 and Art. 13(2) of Regulation (EC) No. 469/2009, Art. 4, Art. 21.

⁵⁴ Council Directive 87/21/ECC of 22 December 1986, amending Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.

⁵⁵ Council Directive 65/65/EEC.

⁵⁶ See Sanjuan (2006), at 8 (emphasis added).

⁵⁷ See Mazer (1993), at 571.

wanted data exclusivity rules to be harmonised in the EU, partly because not all Member States provided the scope of patent protection desired by the pharmaceutical industry.⁵⁸

In response to this, the Commission put forward a proposal for ten years of data exclusivity, after which generic companies could rely on the same data for marketing authorisations. After a process of negotiations, Directive 87/21/EEC⁵⁹ was passed which provided for six years of data exclusivity for most pharmaceutical products from the first marketing approval, and ten years for biotechnological and high-technology medicinal products.⁶⁰ Member States could also extend the period to ten years of data exclusivity for all pharmaceutical products if they considered this “in the interest of public health”. This clause led to differences in the national applications of the law. To curtail the situation, the Commission in 2001 again proposed the harmonisation of national differences in data exclusivity. The outcome was Directive 2004/27/EC⁶¹ amending Directive 2001/83/EC.⁶² The new Directive introduced the 8 + 2 + 1 formula for data exclusivity in the EU for new drugs (both small molecule drugs and biosimilars⁶³) approved either through the centralised procedure or the mutual recognition procedure.⁶⁴

What this means is eight years of uninterrupted data exclusivity plus another two years of marketing exclusivity, during which time the Bolar exemption applies.⁶⁵ This effective ten-year market exclusivity can be extended by an additional one year maximum if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one more new therapeutic indication which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies. The 2004 Directive simplified the abridged procedure for generic applications by requiring the generic applicant not to reveal the results of preclinical tests and of

⁵⁸ See Ho (2011a) at 261. In particular, Greece, Spain and Portugal did not provide product patents to pharmaceuticals at that time. (See also *supra* note 53.)

⁵⁹ See Council Directive 87/21/ECC, *supra* note 54.

⁶⁰ Until the new Directive in 2004, data exclusivity of ten years applied for biologics applications filed before the European Medicines Agency (EMA), while for national applications or mutual recognition procedures, a data exclusivity period of six years applied, with some countries (the United Kingdom, Belgium, France, Germany, the Netherlands, Italy, Luxembourg and Sweden) expanding this term to ten years. (See Storz 2012). For an overview of high-technology medicinal products, see the annex of Council Directive 87/22/EC (Council of the European Communities 1987b).

⁶¹ Council Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

⁶² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

⁶³ Article 10.4 Directive 2004/27/EC.

⁶⁴ See Sanjuan (2006) at 12.

⁶⁵ Adamini et al. (2009).

clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product.⁶⁶

3.2 Consolidating Reasons for the Status Quo

In all instances, legislation on patent term extension and data exclusivity received strong criticism and opposition from the European Generics Association (EGA) due to the possible impact on the generic industry in Europe.⁶⁷ If the EGA found these laws to be inappropriate for the development of the drug industry in Europe, how much more inappropriate are they in developing countries? The recent ruling of the Court of Justice of the European Union (CJEU) in the *Daiichi Sankyo and Sanofi-Aventis Deutschland*⁶⁸ case further elucidates EGA's position. In this case, Daiichi Sankyo Co. Ltd. and Sanofi-Aventis Deutschland GmbH initiated proceedings at the Court of First Instance, Athens (Polymeles Protodikeio Athinon) on 23 September 2009, requesting that DEMO AVEE Farmakon (a Greek generic pharmaceutical company) cease placing a generic version of their original drug "Tavanic" on the market because it was protected by an SPC. The SPC was issued by the Greek authorities to Daiichi Sankyo based on its Greek national patent which expired in 2006. Pursuant to Regulation No. 1768/92, the SPC expired in 2011.

The Greek court explained that the main proceedings had to determine whether the SPC held by Daiichi Sankyo from 2006 to 2011 – the period during which DEMO was preparing to market the medicinal product containing the pharmaceutical product – covered the invention of the pharmaceutical product or only the invention of its process of manufacture. This followed from the fact that until 1992, the Greek government did not recognise patentability of pharmaceutical products.⁶⁹ It however ratified the TRIPS Agreement in 1995, which required protection for pharmaceutical products and processes. In the end, the Court ruled that a patent granted before the entry into force of the TRIPS Agreement for the process of manufacture of a pharmaceutical product does not, after its entry into force, cover the actual invention of the product.⁷⁰

⁶⁶ Article 10(2)(b) of Directive 2004/27/EC defines "generic medicinal product" as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies ... bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

⁶⁷ For a review, see Adamini et al. (2009), at 979–1007; Mazer (1993), at 571–576.

⁶⁸ Case C-414/11, *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18 July 2013).

⁶⁹ See Case C-414/11, *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18 July 2013), paras. 15 and 21. Greece ratified the Convention on the Grant of European Patents (EPC) in 1986, but it was only from 1992, on the expiry of a reservation previously expressed, that Greece also recognised the patentability of pharmaceutical products.

⁷⁰ See Case C-414/11, *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18 July 2013), paras. 15 and 21. Greece ratified the Convention on the Grant of European Patents (EPC) in 1986, but it was only from 1992, on the expiry of a reservation previously expressed, that Greece also recognised the patentability of pharmaceutical products, para. 83 (emphasis added).

The importance of this case to the subject matter of this article lies in the fact that an originator company has relied on an SPC to initiate proceedings to prevent a generic company from placing its product on the market. This development in the EU gives credence to the idea that similar situations could arise within the domestic legal systems of developing countries who enter into FTAs with the EU containing clauses on patent term extension and data exclusivity. Thus, what becomes of these rules when they get into the external dimension of trade and IP agreements involving the Union is what is important here. The EU has, since the TRIPS Agreement, entered into a new regime of bilateralism that seeks to enforce IP rights through what commentators have christened TRIPS-plus measures.⁷¹ Patent term extension and data exclusivity are two such regulatory laws that fit into this category in relation to third countries. The TRIPS Agreement permitted countries to exceed the TRIPS minimum standards⁷² but certainly not to the levels required in these agreements, outside of TRIPS. The EU has cited failure on the part of developing countries to implement TRIPS minimum standards as one reason for this move.

4 The Failure of Multilateralism

Multilateral treaties for patent protection date back to the Paris Convention.⁷³ However, until the TRIPS Agreement, many countries did not provide for the protection of pharmaceutical patents at all or those who did only provided for process and not product patents.⁷⁴ TRIPS mandated a 20-year period of patent protection for pharmaceutical products (starting from the date of filing of application). This development meant a considerable change to the legislation of developing countries. While some countries have yet to come to terms with these changes, a plethora of new forms of bilateral trade agreements have emerged.⁷⁵ By signing up to such trade agreements, the contents of which are binding, governments

⁷¹ TRIPS-plus refers to provisions that either exceed the requirements of TRIPS or eliminate flexibilities in implementing TRIPS. For a review, see Sell (2007); Abbott (2002); Drahos (2001); Tandon (2008); Ho (2011a), at 2; Kur and Grosse Ruse-Khan (2008).

⁷² On a challenge to this assumption, see Grosse Ruse-Khan (2009). He laments how this concept, although seldom used in the treaty language of international agreements on IP protection, has almost universally been perceived. Obligations emerging from international IP Agreements such as TRIPS, create a “floor” consisting of a minimum level of protection, which is available to all WTO Members – with presumably the sky being the only limit as to the further extension of IP protection.

⁷³ See Paris Convention for the Protection of Industrial Property, 20 March 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as last revised in Stockholm, 14 July 1967) (hereinafter Paris Convention).

⁷⁴ Roffe and Veal (2008); see also WIPO, document HL/CE/IV/INF/1, prepared for the consideration of the Committee of Experts on the harmonization of certain aspects of laws protecting inventions, fourth meeting, 14 October 1987; see also, Walker (2001), available at <http://data.iucn.org/dbtw-wpd/edocs/EPLP-041.pdf>.

⁷⁵ For details, refer to *supra* notes 3 and 18.

in developing countries increasingly face difficulties in creating the proper and adequate public health regimes that will ensure the availability of and access to essential medicines for their populations.⁷⁶ Access to essential medicines and health technologies, now and in the future, has come to represent a huge public health challenge for the governments of developing countries due to the fact that they face many stumbling blocks in their bid to ensure equitable access.⁷⁷ Furthermore, some of these challenges are local, adding an external dimension in the form of FTAs becomes more disturbing. Without access to essential medicines, it is the poor who suffer.

From the beginning, the differences in perspective and approaches to the TRIPS Agreement from the point of view of the developed and developing countries were manifestly clear. The developed countries tended to see TRIPS as a minimum baseline for IP protection that could be built upon, whilst developing countries saw it more as a maximum standard of protection beyond which they are unwilling to go.⁷⁸ The European Commission is of the view that TRIPS is too weak and does not provide adequate protection to incentivise the high cost of developing new drugs and innovation.⁷⁹ Besides, the Commission has been concerned about the reluctance of most developing countries to implement TRIPS minimum requirements.⁸⁰ The developing countries, on the other hand, see TRIPS as failing in relation to the promotion of transfer of technology, access to trade and essential medicines.⁸¹ They made several concessions during the Uruguay Round of negotiations leading to the World Trade Organisation (WTO/TRIPS) Agreements based on the promise of getting these gains back.⁸²

⁷⁶ El Said (2010).

⁷⁷ For a thorough review, see El Said (2010).

⁷⁸ Sell (2011); also, Sell, *supra note* 67.

⁷⁹ This theme is apparent in many of the documents often circulated by the EU Commission on the need to strengthen IP enforcement, for example, the European Commission Staff Working Document, "Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries", SWD (2013) 30 final. Available: http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150789.pdf; Directorate General for Taxation and Customs Union of the European Commission, Customs Controls – A serious problem for everyone (2010). Available at http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/combating/index_en.htm; The Union's Strategy for the Enforcement of Intellectual Property Rights in Third Countries (2005/C 129/03).

⁸⁰ This theme is apparent in many of the documents often circulated by the EU Commission on the need to strengthen IP enforcement, for example, the European Commission Staff Working Document, "Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries", SWD (2013) 30 final. Available: http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150789.pdf; Directorate General for Taxation and Customs Union of the European Commission, Customs Controls – A serious problem for everyone (2010). Available at http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/combating/index_en.htm; The Union's Strategy for the Enforcement of Intellectual Property Rights in Third Countries (2005/C 129/03); also, Correa (2001).

⁸¹ Govaere (2008).

⁸² See for instance Daniel Gervais, "TRIPS and Development", *Selected Works* (2013), available http://works.bepress.com/daniel_gervais/42; also, Dommen (2005) (who insinuates that even staunch World Trade Organization supporters agree that, during the negotiations creating the WTO, developing countries agreed to substantially more obligations than developed countries did).

These differences have led both sides to seek alternative forums⁸³ in which they could negotiate their interest, especially with regard to the protection of pharmaceutical products and access to essential medicines. While the EU has turned to bilateral agreements,⁸⁴ developing countries have gone to institutions like the World Health Organisation (WHO) and the World Intellectual Property Organisation (WIPO).⁸⁵ The recent 45 adopted recommendations under the WIPO Development Agenda of 2007⁸⁶ as well as the Doha Declaration waivers,⁸⁷ which a decade ago gave prominence to the public health issues of Member States of the WTO, have been seen as major victories for developing countries in their quest for fairness in development and access to essential and affordable medicines.

The Doha Declaration affirmed the right of WTO Member States to implement TRIPS in such a way as to protect public health and to promote access to medicines for all. The subsequent waiver of Art. 31(f) of TRIPS permitted Member States lacking sufficient manufacturing capacity to import necessary medicines from any other Member State. In 2005, WTO Member States adopted the waiver as an amendment to TRIPS (Art. 31^{bis}). On the part of the EU, its success in this regard seems to revolve around its ability to push for stronger IP protections in its recent FTAs. The EU's FTAs therefore stand to undermine any gain developing countries might have bargained for at the multilateral level. This brings us back to the core question of whether patent term extension and data exclusivity provisions are TRIPS compliant, or in what ways they reflect TRIPS-plus standards.

4.1 TRIPS Provisions on Patent Term Extension and Data Exclusivity

To be sure, the extension of patent terms outside the domestic regime is not a TRIPS requirement.⁸⁸ TRIPS only committed WTO Member States to a 20-year term of patent protection, so the provision in most FTAs requiring developing countries to provide for extensions in patent terms in case of administrative delays in patent registrations or in obtaining marketing authorisations are extra-multilateral efforts that eliminate much of the legally permissive TRIPS flexibilities.⁸⁹ This has been

⁸³ Known as “forum-shifting”, the term is used in contemporary legal writings to refer to L.R. Helfer’s “regime shifting” in his paper (*supra* note 3, at 14) where he defines the term to mean an “attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another”.

⁸⁴ Okediji (2003–2004), at 136. (Often, these agreements are negotiated in secret and without proper consultations enabling the front-runners to push for IP laws that put third countries in a situation where they could violate their obligations under international human rights law).

⁸⁵ Sell (2010); also Sell (2011), at 469–505.

⁸⁶ The 45 Adopted Recommendations under the WIPO Development Agenda are available at <http://www.wipo.int/ip-development/en/agenda/recommendations.html>.

⁸⁷ World Trade Organization, the Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference Declaration of 14 November 2001, WT/MIN(01)/DEC/2 (hereinafter, the Doha Declaration).

⁸⁸ TRIPS Art. 33.

⁸⁹ TRIPS Arts. 7 and 8.1 read in conjunction with Art. 1.1. The key areas of TRIPS flexibilities for public health include: compulsory licenses (Art. 31), parallel importation (Art. 8.1), and the Doha Declaration waivers.

possible partly because industry lobbyists seem to have succeeded in arguing that nothing in the TRIPS Agreement prevents states from adopting stronger forms of IP protection.⁹⁰ Although this posture is correct, it is important to remember that this particular provision came with a qualification that requires that such protections do not *contravene* the provisions of TRIPS.⁹¹ Kur and Grosse Ruse-Khan have observed that the qualification not to “contravene” could suggest “ceiling rules” where IP protection laws may not go beyond apart from the usual rules on exceptions and limitations.⁹² However, by the very nature of the WTO/TRIPS law, it may be unbalanced to thrive on the idea that TRIPS flexibilities could at all times prevail over TRIPS-plus FTA rules⁹³ – except in cases where one can point to conflicts with a mandatory TRIPS provision instead of an optional one.⁹⁴ This is why a more balanced approach to IP standard setting in FTAs is important in the context of this discussion.

Furthermore, other international norms such as the human right to health (in this direction, access to medicines)⁹⁵ could also serve as ceilings to IP law.⁹⁶ This may occur where “other treaties confer rights or otherwise protect the interests of individuals or certain groupings within a society in a way which may conflict with the protection IP offers to right holders”.⁹⁷ In such a case, because WTO law does not contain a general conflict rule,⁹⁸ depending on the specific conflict rules of the other

⁹⁰ See Sell (2007), at 51 and 58.

⁹¹ See Kur and Grosse Ruse-Khan (2008).

⁹² See Kur and Grosse Ruse-Khan (2008), at p. 14 *et seq.* (Kur and Grosse Ruse-Khan observe that this concept might offer a way to ensure and maintain a balanced approach towards IP protection, and to protect member States’ autonomy in preserving public policy goals vis-à-vis pressure exerted against them in FTAs. The weakness of this proposal however is the risk that, a principle of maximum rules might reduce instead of enhance member States’ ability to utilise TRIPS flexibilities – as well as institutional and procedural questions such as how this would fit with the current WTO/TRIPS system).

⁹³ TRIPS only laid down minimum standards for IP protection and gave room for “optional” flexibilities, which member States could either choose to implement or choose not to. Thus, in case of a conflict, applying the notion of “contravening” in Art. 1.1 TRIPS so as to prevent a WTO member from deciding how to exercise this flexibility in effect turns the optional rule into a mandatory one. Also, given the very general terms used in the balancing objectives and public interest principles of TRIPS Arts. 7 and 8, it may be difficult to say that TRIPS-plus FTAs cannot derogate from TRIPS flexibilities taking into account the language of Art. 41 VCLT. (See Grosse Ruse-Khan 2011a) at 338 *et seq.*

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⁹⁵ Enshrined in Art. 25 of the Universal Declaration of Human Rights (UDHR), adopted and proclaimed by the UN General Assembly in resolution 217 A (III) of 10 December 1948 at Paris. It is further incorporated in Art. 12 of the International Covenant on Economic Social Cultural Rights (ICESCR) where states recognise the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.

⁹⁶ See Kur and Grosse Ruse-Khan (2008).

⁹⁷ See Kur and Grosse Ruse-Khan (2008), at 22.

⁹⁸ See Kur and Grosse Ruse-Khan (2008), at 10.

treaty or on general conflict rules in international law, post-WTO treaties (or other treaties) may prevail over WTO law and curtail or modify its rights and obligations.⁹⁹

With regard to data exclusivity, the wording of the TRIPS Art. 39(3) permits, but does not require, data exclusivity. The provision only mandates that countries that require the submission of undisclosed test data which shows the safety and efficacy of drugs from pharmaceutical companies before granting them marketing authorisation, must take steps to protect such data against “unfair commercial use” or “disclosure”, however, certainly not to the levels prescribed in these FTAs.¹⁰⁰ The form in which data exclusivity is captured in recent EU FTAs could prohibit trading partners from manufacturing, exporting, or importing cheap generic medicines.¹⁰¹ Commentators argue that TRIPS Art. 39(3) did not intend to prohibit authorities from relying on test data for the approval of competing products. Such a practice would fall outside the definition of unfair commercial use.¹⁰² Others contend that there is no obligation in the TRIPS Agreement to grant exclusive rights in test data and thus, it is inappropriate to ask developing countries for more extensive and higher levels of IP protection for pharmaceuticals than are set out in TRIPS.¹⁰³ In any case, this provision does not apply when it is not necessary to submit such data – for instance, when marketing authorisation is granted by the national authority relying on the existence of a prior registration elsewhere. In such a case, the authority does not require test data, but takes its decision on the basis of the registration granted in a foreign country.¹⁰⁴ These are important considerations that are often overlooked in the FTAs.

4.2 India’s Resistance, an Example

The problematic nature of data exclusivity and patent term extension provisions in FTAs seemingly explains why the EU has, since 2007, been in negotiations with India to agree on a bilateral FTA but has to date failed to finalise matters on this Agreement.¹⁰⁵ Similar reasons could also possibly account for why India has no

⁹⁹ See Kur and Grosse Ruse-Khan (2008), pp. 10, 23–24 (emphasis added). Generally speaking, any treaty must be applied with a presumption in favour of continuity and against conflict in the sense that all pre-existing international rules continue to apply unless there is clear evidence that the parties to the treaty wished to depart from a specific pre-existing rule. Only if the relevant norms are not sufficiently open to allow such a mutual supportive understanding, the conflict has to be resolved by means of the relevant conflict norms of either treaty (if any) or those of general international law, in this case, the VCLT Arts. 30 or 41 applies.

¹⁰⁰ Reichman (2009) *et seq.*

¹⁰¹ Adamini et al. (2009) at 987.

¹⁰² Reichman (2009); also, Ho (2011a); Sanjuan (2006).

¹⁰³ See Sanjuan (2006); Ho (2011a).

¹⁰⁴ TRIPS Art. 39(3), Introduction: terminology, definition and scope, p. 520 *et seq.*

¹⁰⁵ Negotiations were launched in June 2007; after 11 full rounds, negotiations are now in a phase where negotiators meet in smaller more targeted clusters rather than full rounds, i.e. expert level inter-sessionals, chief negotiator meetings and meetings at Director General level. Following the EU–India Summit on 10 February in Delhi negotiations are currently in an intense phase focusing on the hard core issues but work remains to be done. Important issues include market access for goods (improve coverage of both sides’ offers), the overall ambition of the services package and achieving a meaningful chapter on government procurement and Data Exclusivity; also, David (2010).

FTA with the US. Due to their binding effect, IP clauses appearing in FTAs can limit a nation's ability to use public health flexibilities under TRIPS. The present atmosphere gives India (which has been described as the "pharmacy of the developing world" both because of its huge market in generic medicines and its developing research-based pharmaceutical industry),¹⁰⁶ the opportunity and the leeway to negotiate for favourable terms with regard to how much of these TRIPS-plus provisions should or should not be included in its bilateral FTAs with the EU or other developed countries. If India should, for instance, give in to data exclusivity provisions in the EU FTA, it will prevent its generic industry from producing cheaper versions of originator drugs to meet the health care needs of its huge population and that of other developing countries in the fight against treatable diseases.

In retrospect, India could not have possibly opted for different provisions on patent term extension and data exclusivity with the EU if it had already agreed on similar terms with the US. Even though that could be possible, it would be unnecessary. By the principles of the Most Favoured Nation (MFN)¹⁰⁷ and National Treatment (NT),¹⁰⁸ a Member of the WTO cannot discriminate against another Member or nationals of other Members with regard to the protection of IP. That is to say, if the EU concluded an FTA containing TRIPS-plus patent requirements with India, those patent rules will automatically also affect other countries. For instance, a Japanese citizen who applies for an Indian patent would benefit from the increased patent protection negotiated by the EU, even though Japan was not party to the EU–India Agreement. This is because unlike the GATT Art. XXIV and the GATS Art. V,¹⁰⁹ which permit derogation from the MFN principles to form *inter se* Agreements,¹¹⁰ TRIPS does not contain any relevant exception from MFN or NT principles that would limit TRIPS-plus protection to the FTA trading partner. This lack of exceptions to the TRIPS Arts. 3 and 4 effectively globalises these TRIPS-plus standards to become the internationally relevant norm.¹¹¹ Thus, each country that adopts TRIPS-plus measures affects other nations. In much the same way, any developing country that adopts tougher TRIPS-plus patent measures through an FTA with the EU or US makes it considerably difficult for other developing

¹⁰⁶ See Medecins Sans Frontieres, *Briefing Paper* "How A Free Trade Agreement Between the European Union and India Could Threaten Access to Affordable Medicines for Millions of People Worldwide" (9 Feb. 2012), available at: <http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines>.

¹⁰⁷ TRIPS Art. 4.

¹⁰⁸ TRIPS Art. 3.

¹⁰⁹ The GATT Art. XXIV permits further liberalisation of trade through Customs Union and Free Trade Areas while the GATS does not prevent any of its Members from being a party to or entering into an agreement liberalising trade in services between or among the parties to such an agreement.

¹¹⁰ See Kur and Grosse Ruse-Khan (2008) at note 23: *Inter se* agreements or modifications refer to situations where some of the parties to a multilateral treaty conclude an agreement which modifies the treaty amongst themselves. Under general international (treaty) law, Art. 41:1 of the Vienna Convention on the Law of Treaties (VCLT) allows two or more of the parties to a multilateral treaty to "conclude an agreement to modify the treaty as between themselves".

¹¹¹ Grosse Ruse-Khan (2011b); see also Kur and Grosse Ruse-Khan (2008).

countries not to accept similar provisions in negotiating trade agreements with these countries.¹¹²

India, as an example, has since 2005 succeeded in adopting domestic rules on patents that accommodate access to medicines while simultaneously complying with TRIPS.¹¹³ Much of its success has come through: (1) restricting the scope of patentability, for example, what constitutes an invention in India; (2) creating opportunity for third parties to challenge patent applications and patents; (3) increasing exceptions to patent rights, for example, compulsory licenses; and (4) the role of its courts.¹¹⁴ These cannot be expatiated on for lack of space, but if, for example, India should go against its present approach to permit IP provisions proposed in the FTAs with the EU, it could have a range of harmful effects on the production and dissemination of generic medicines, and how the Indian courts can handle disputes over IP rights. However, if India should maintain its ground in defending its IP policy in its bilateral free trade negotiations, it will continue to be a shining example of how developing countries can institute domestic rules on IP that would take into consideration the public health needs of its citizens and, simultaneously, comply with TRIPS. The next Part will focus on to how patent term extension and data exclusivity clauses appear in the EU FTAs.

5 Patent Term Extension and Data Exclusivity in EU FTAs

The analysis in this Part will focus mainly on the FTAs between the EU and its Member States on the one hand, and the Republic of Peru, Colombia and Korea on the other. The simple reason being that these FTAs represent well, both the old and the new generations of EU FTAs;¹¹⁵ they are fully concluded, are in force, and are provisionally applied in the EU.¹¹⁶ Also, in terms of the upward adjustment of IP laws discussed in this contribution, these FTAs show a good balance.

5.1 Patent Term Extension

As outlined above, the EU now also includes patent term extension requirements in its FTAs with developing countries. Such provisions stand on par with the TRIPS nominal term of 20 years for patent protection, regardless of delays in the patent examination or marketing authorisation procedures. In the EU agreement with Peru–Colombia, it is included that:

¹¹² Ho (2011b); also Ho (2011a).

¹¹³ Ho (2011c).

¹¹⁴ For a general overview, see Ho (2011c).

¹¹⁵ See http://trade.ec.europa.eu/doclib/docs/2012/november/tradoc_150129.pdf.

¹¹⁶ For the FTA between the EU–Korea, see <http://www.consilium.europa.eu/policies/agreements/search-the-agreementsdatabase?command=details&id=&lang=en&aid=2010036&doclang=EN>; Concerning that of Peru, <http://trade.ec.europa.eu/doclib/press/index.cfm?id=873>; and for Colombia, see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=953>.

With respect to any pharmaceutical product that is covered by a patent, each Party, may, in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that Party. Such mechanism shall confer all of the exclusive rights of a patent, subject to the same limitations and exceptions applicable to the original patent.¹¹⁷

For the mere fact that “unreasonable curtailment” is not defined, this clause could lead to the arbitrary extension and imposition of patent terms should there be some delays. That is to say, after 20 years when the patent on a medicinal product expires, generic manufacturers will have to wait again for the certain number of years that the pioneer company will deem appropriate to cover for the delays in patent registrations or in obtaining marketing authorisation. This is arguably so because no provision is made for the time limit on how long the patent extension should be. As Correa perfectly observes, “since the grounds for the extension of patent terms under FTAs are independent, cumulative and with no maximum period, nothing seems to prevent a patent from being extended for x years due to a delay in its granting process, and for y more years due to delay in the marketing approval process”.¹¹⁸ These mechanisms, as Correa rightly argues, will have the effect of making the public pay for any administrative delays and generate increased flow of payments to pharmaceutical companies that can hardly be justified by any additional benefits to patients in developing countries.¹¹⁹

Moreover, the section does not specify whether this clause covers only new chemical entities or new uses of drugs, as it does not define what a pharmaceutical product is. Lack of clarity on this could lead to a situation where pioneer pharmaceutical companies would obtain multiple patents on a single drug for new uses (provided that the country’s law on patents does not prohibit this process) and subsequently seek marketing authorisation for such drugs with the view of delaying generic competition and maximising profits. This is not the case with the present EU internal laws.¹²⁰ Technically, the EU is equally bound by the obligations arising from its international agreements and therefore a domestically adopted approach should be consistent with the IP provisions of these FTAs.¹²¹ However, an important component to this development is the fact that the EU cannot conclude agreements

¹¹⁷ Article 230.4. Peru–Colombia.

¹¹⁸ Correa (2006).

¹¹⁹ Correa (2006), pp. 399–402.

¹²⁰ Article 4 of Regulation (EC) No. 469/2009 clearly stipulates that “within the limits of the protection conferred by the basic patent, the protection conferred by the certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.” Article 1(c) defines the “basic patent” as meaning a patent that protects a product as such, a process to obtain a product or an application of a product, and that is designated by its holder for the purpose of the procedure for grant of a certificate. Article 1(b) defines a “product” to mean the active ingredient or combination of active ingredients of a medicinal product. What is not clear is whether this definition extends to cover new uses of drugs. These Articles, read in conjunction with Art. 3(c) and (d) of the regulation, place enormous limitations on the possibility for “evergreening”, in the EU at least, with respect to patent term extensions.

¹²¹ See Art. 216(2) TFEU.

that conflict with the provisions of the TEU and the TFEU.¹²² Commentators believe this rule also aims at guaranteeing conformity of agreements concluded by the EU with secondary EU law.¹²³ It does not, however, prevent the EU from negotiating agreements that require amendment of existing EU law.¹²⁴ Admittedly, both situations (identified above) could potentially lay a foundation for the smooth incorporation of international agreements into the EU legal system as they only reflect standards already in place.

Furthermore, with regard to duration, it is important to note that for most products in the EU, the full five-year extension is not obtained; the average is more like two to three years.¹²⁵ Moore reported in 1993 that out of the top ten products in the United Kingdom, only four were eligible for patent term extensions, with periods varying from one to five years.¹²⁶ Currently, the scope of Art. 13(1) of the internal regulation could make the period of time permitted for patent term extension in the EU less than five years. However, since the FTAs between the EU and the Republic of Korea, Peru and Colombia have all been provisionally applied in the EU,¹²⁷ it remains to be seen how final ratification by Member States and implementation will transform the situation described above or even the law on data exclusivity.

In addition, Council Regulation (EEC) No. 1768/92, which introduced patent term extension, included transitional provisions on the implementation of the regulation for various Member States of the Union while exempting countries like Greece, Portugal and Spain – which did not provide for product patents of pharmaceutical products as of 1992 – to effectively implement the laws on patent term extensions by 2012 at the latest.¹²⁸ And even though the 2009 regulation came with changes to the previous transitional measures, similar transitional provisions are not included in the IP chapters of the EU's FTAs. Although it cannot be said for certain that all developing countries have in place patent laws that adequately protect pharmaceutical products to date, the lack of similar transitional provisions in FTAs (which could mitigate the burden of immediate implementation on third countries) could have far-reaching consequences on the health sectors and economies of developing countries. Generic medicines have become essential contributors for governments of developing countries in their efforts to contain public health care budgets, as prices of generics tend to be 10–80 % lower than those of originator medicines.¹²⁹ Hence, any single agreement or policy that delays the market access of generic medicines runs counter to the public welfare of

¹²² See Art. 207(3)(2) TFEU; also, Drexl (2012).

¹²³ See Art. 207(3)(2) TFEU; also, Drexl (2012).

¹²⁴ For an overview see Mylly (2014); also, Drexl (2012).

¹²⁵ See Moore (1998), at 139.

¹²⁶ See Moore (1998), at 139.

¹²⁷ See *supra* note 116.

¹²⁸ Article 21 of Regulation (EEC) No. 1768/92. Even though the law would take effect in those countries as of 1998, it was not until 2012, when patents on pharmaceutical products which were registered in 1992 are expired, that the full benefits of patent term extensions were realised.

¹²⁹ Simoens and De Coster (2006).

millions of poor patients who cannot afford originator medicines in the developing world.

In the EU–Korea FTA, Art. 10.35(2) provides for the extension of the duration of the rights conferred by patent protection for pharmaceutical products. The Parties shall provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the first authorisation to place the product on their respective markets. The extension of the duration of the rights conferred by the patent protection may not exceed five years. Footnote 66 attached to this article indicates: “this is without prejudice to a possible extension for paediatric use, if provided for by the Parties”. Thus, the extension of patent rights for up to five years shall compensate for time lost during the application phase. This extra five-year period is time when local generic companies cannot produce generic versions of drugs and also when the government cannot import or export generic versions of such drugs.¹³⁰ Moreover, this provision is also quiet on the concept of “one term of extension per product” which makes it possible for new uses of known drugs to be patented, resulting in the very issues raised in previous paragraphs. Lastly, there are no provisions in the FTAs that permit third parties to challenge the invalidity of a certificate for patent term extensions on a medicinal product, as is the case internally.¹³¹

Due to a lack of staff and resources, patent offices in developing countries are often pressured by high demands for patent registrations from firms in Europe and the US.¹³² Delays in patent registrations and marketing authorisations are therefore likely in developing countries. The requirement for patent term extension in FTAs in the event of delays in registration and marketing authorisation is therefore unfair, and at best anti-competitive, seeing that this would delay generic entry into the drug market and as a consequence, prevent the millions of patients in the developing world (who cannot afford originator medicines) access to cheap and affordable medicines. Without competition from generic producers, patented originator medicines can be sold at higher prices due to their monopoly position.¹³³ This could also lead to a lack of substantial quantities on the open market. Either of these scenarios will negatively affect the public health of developing countries: poor patients cannot afford expensive medicines, and an insufficient supply of drugs in the market could lead to epidemics and other emergencies. Given the substantial

¹³⁰ Either side of the story will go strongly against developing countries. About a third of all drugs are produced by India. See <http://www.indiabusiness.nic.in/industry-infrastructure/industrial-sectors/drug-pharma.htm>. India produces a large number of high-quality, affordable generic medicines in part due to competition stemming from Indian generics. The price of first-line ARVs dropped from more than US\$10,000 per person per year in 2000 to around \$150 per person per year to date. This significant price decrease has helped to facilitate the massive expansion of HIV treatment worldwide. More than 80 % of the HIV medicines used to treat 6.6 million people in developing countries comes from Indian producers, and 90 % of paediatric HIV medicines are Indian-produced. MSF and other treatment providers also rely on Indian generic medicines to treat other diseases and conditions. Credit: <http://www.msfacecess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines>.

¹³¹ See Art. 15(2) of Regulation (EC) No. 469/2009.

¹³² Drahos (2007).

¹³³ Dahrendorf (2009).

effects that patents can have on competition, and hence prices of medicines, patent registration alone can directly affect the health and lives of people in a country, not to mention its extension.

5.2 Data Exclusivity in EU FTAs

As should probably be clear by now, data exclusivity is increasingly becoming an important strategy for delaying generic competition as its appearance in FTAs undoubtedly constrains the reliance on such data by generic manufacturers. Article 231 of the Peru–Colombia Agreement and Art. 10.36 of the EU–Korea FTA all capture data exclusivity provisions. The EU–Korea Agreement provides for protection of data submitted to obtain a marketing authorisation for pharmaceutical products. The period of data protection should be at least five years, starting from the date of the first marketing authorisation obtained in the territories of the respective Parties.¹³⁴ The same goes for the Peru–Colombia Agreements, except that for Colombia, this protection will include data protection of biological and biotechnology products. For Peru, the protection of undisclosed information on such products shall be granted against disclosure and the practices that are contrary to honest commercial practices, in accordance with Art. 39.2 of the TRIPS Agreement, in the absence of any specifically related legislation.¹³⁵ For Central America, data exclusivity is not incorporated because these countries have already introduced data exclusivity in their national regimes as a result of their obligations with the US.

One may argue that the five years stipulated for data exclusivity in the FTAs do not amount to the 8 + 2 + 1 duration provided for data exclusivity in the internal laws of the Union.¹³⁶ In as much as this is true, a careful assessment of the wording of these provisions as they appear in the FTAs, and a consideration of the differences in the regulatory aspects of drug distribution and pricing between the EU and these third countries will show the imbalance. The wording of Art. 10.36 of the EU–Korea Agreement, for instance, indicates that the duration of protection for data exclusivity “should be at least five years from the date of the first marketing authorisation”. The fact that a lower limit is given but no maximum limit, means that this could be interpreted as something more than five years. In any case, the 8 + 2 + 1 formula does not necessarily imply the full 11 years for all who seek protection for pharmaceutical data in the EU.

With regard to the situation in developing countries, it is important to note that when it comes to data exclusivity, issues about the duration of protection and availability of drugs is less important. What becomes important is access and affordability: the fundamental right of people to health and the enjoyment of its medicinal element. After all, the availability of expensive originator drugs, which will surely be out of the reach of the ordinary citizen of a developing country, does

¹³⁴ Article 10.36(3) EU–Korea.

¹³⁵ See footnote 78 to Art. 231(1) Peru–Colombia.

¹³⁶ As already noted, the said FTAs are provisionally being applied in the EU-pending ratification by all Member States. It therefore remains to be seen the impact implementation will have on existing laws. Refer to *supra* note 116.

not solve the problem. Hence, what matters is the net effect of the five years of data exclusivity on developing countries with regard to its restrictions on compulsory licensing and drug pricing, and what that could lead to – also taking into account the economic situation and living conditions of the majority of the people.

TRIPS permitted compulsory licenses; however, unlike patent protection, data exclusivity cannot be challenged and as a consequence provides additional protection to patented medicines by essentially submerging the existing exceptions into patent rights.¹³⁷ Although WTO Member States (for instance) have the right to issue compulsory licenses on patented drugs, the ability to make and sell the patented drug could be undermined, as the patent owner will be able to prevent marketing of the equivalent medicine by way of not consenting to the use of (his or her) data for marketing authorisation. In this way, the generic medicine cannot be put on the market on regulatory grounds, regardless of the grant of license with respect to the patent.¹³⁸

Additionally, because there is generally no requirement for originator pharmaceutical companies to seek permission to sell their drugs in all countries simultaneously, most of them now first seek marketing approval in wealthy countries, but delay seeking similar approval in countries with a more modest ability to pay.¹³⁹ This results in delays in the availability of new drugs for poorer countries. Moreover, if these poorer countries also subsequently grant data exclusivity, their citizens will not have access to low-cost generics until long after consumers in wealthy countries have such drugs.¹⁴⁰ The situation is further exacerbated by the fact that, unlike in most European countries where individuals often pay lower prices for their drugs because their governments both impose price controls on drugs and often have insurances that further subsidise their out-of-pocket expenses, citizens of the developing world often have to pay for the entire cost of medicines.¹⁴¹ Thus, ironically, drugs constitute a much larger percentage of an individual's budget in poor countries than in wealthy countries. This becomes a significant barrier to obtaining access to medicine since the average person cannot afford originator drugs.¹⁴² Ho has argued that, considering the fact that originator companies already make substantial profits on drugs from the global market and have data exclusivity protection in the wealthiest markets, there does not seem to be a strong case to charge higher prices for the poorest citizens through data exclusivity.¹⁴³ Thus, completely leaving data exclusivity provisions out of FTAs should be the answer.

¹³⁷ Ho (2011a), at 269.

¹³⁸ Abbott (2004). It must however be noted that there is an exception to this in the Peru–Colombia Agreement (Art. 231.4[a]), where parties may regulate “exceptions for reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to these data to third parties”.

¹³⁹ Ho (2011a), at 269 *et seq.*

¹⁴⁰ Ho (2011a), at 269 *et seq.*, citing Shaffer and Brenner (2009); and Baker (2008) at 310–311.

¹⁴¹ Ho (2011a) at 269 *et seq.*

¹⁴² Ho (2011a) at 269 *et seq.*

¹⁴³ Ho (2011a) at 269 *et seq.*

Also worrying is the fact that with data exclusivity, medicines that are off-patent, or whose patents are invalid, may become subject to exclusive rights in developing countries through FTAs. The EU–Korea and Peru–Colombia Agreements all link data exclusivity to market authorisations. Thus, less innovative drugs that do not meet patentability criteria may obtain marketing authorisation and become subject to stronger protection,¹⁴⁴ even if, for instance, the national laws of Colombia and Peru prohibit data exclusivity protection for new uses or new indications of pharmaceutical products.¹⁴⁵ Also, it could be the case that a company does not own the patent rights or the patent had expired because a medicine was discovered long ago, and yet they are protected through data exclusivity. For example, data exclusivity provided a key market protection for the unpatented Taxol, which was discovered by the US National Cancer Institute in 1962 and marketed by Bristol-Myers Squibb in 1994.¹⁴⁶

Such developments could lead to situations where originator companies intentionally wait until patents on drugs expire, or after they have gained commercially from less innovative drugs in wealthy countries, only to turn to developing countries to register for authorisations to sell these drugs at high prices for additional profits. This also gives undue advantage to generic companies and patients in wealthy countries as this same period could have been used by generic companies in developing countries to produce cheaper versions for patients, or for their governments to import such drugs if not for the data exclusivity provisions in the FTAs. It is on record that data exclusivity provisions included in the 2001 Jordan–US FTA resulted in the delay of registration of generic versions of 79 % of medicines between 2002 and mid-2006. Without generic competition, Jordan spent additional sums of between US\$6.3 million and US\$22.04 million on drugs during this time period.¹⁴⁷ Similarly, a study by Health Action International and Oxfam on the effects of data exclusivity in the EU–Andean FTA showed that in Colombia

¹⁴⁴ This is without prejudice to the counter argument that research into less innovative drugs that may not necessarily meet patentability criteria but are nonetheless, promising drug candidates should be encouraged. However, such a conception also raises questions about the relevance of the patent system—as it is believed the patent system is tailored to ensure that the government-imposed market barrier is only granted to those who have earned the reward by giving something of value back to society? It is also a question about how much investment go into the development of such drugs, how they should be priced and how much that benefits developing countries (which goes beyond the scope of this paper).

¹⁴⁵ Article 1 of Data Protection Decree No. 2085 of 19 September 2002 of Colombia and Art. 2 of Legislative Decree 1072 of Peru on the Protection of Undisclosed Test Data or Other Undisclosed Data Related to Pharmaceutical Product.

¹⁴⁶ Love (1997).

¹⁴⁷ *Medecins Sans Frontieres*, (9 February 2012), Briefing Document “How a Free Trade Agreement between the European Union and India could threaten access to affordable medicines for millions of people worldwide”, available at: <http://www.msfaaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines>; see also Oxfam International, “All Costs, No Benefits: How TRIPS Plus IP Rules in the US Jordan FTA Affect Access to Medicine” pp. 7–8 (Oxfam Briefing Paper No. 102, 2007), available at http://www.oxfam.org.uk/resources/issues/health/downloads/bp102_trips.pdf.

alone, the introduction of a ten-year period of test data exclusivity would have led to an increase in expenditure of US\$340 million on medicines by 2030.¹⁴⁸

In Europe, when similar laws on patent term extension and data exclusivity were introduced, national governments and health authorities of Member States, anticipating the changes to these laws, could in effect, regarding increases in pharmaceutical expenditure, have moved to introduce successive reforms and initiatives that addressed the challenges of possible rises in pharmaceutical expenditure (to be discussed in the next Part).¹⁴⁹ This is unfortunately not the case with most developing countries. Most lack the resources and institutions for such reforms and the capacity to manufacture medicines (with the exception of India and a few others). They therefore have no say when it comes to the determination of prices of pharmaceuticals. Equally, strict and effective enforcement mechanisms are usually lacking in most of these countries, which then compounds the situation.¹⁵⁰ It thus becomes apparent that the net effect of patent term extension and data exclusivity laws on the citizens and governments of the developing world far outweighs those in Europe.

5.3 European Governments' Cost Containment Measures for Pharmaceuticals

With a recent report indicating the cost of pharmaceutical expenditure rising at between 4 and 13 % per annum in Europe (notwithstanding the health care reforms already introduced in the 1990s to reduce costs),¹⁵¹ many European countries have instigated other initiatives and reforms to address this unsustainable rise through regulation. Many of the measures introduced have centred on policies surrounding generics, as they have been found to provide high quality treatment at lower costs – resulting in considerable savings.¹⁵² Some of the initiatives introduced include: measures to engineer low prices for generics and originator drugs; linking the perceived degree of innovation of new products to reimbursed prices; limiting payer exposure to new expensive drugs given their potentially significant budget impact (e.g. prescribing and dispensing generic drugs); and more recently, patient access schemes where drugs are typically provided for free for a period of time.¹⁵³ This ensures that quality and affordable health care delivery systems are made available to their citizens in the midst of regulation.

¹⁴⁸ Oxfam and Health Action International (October 2009), "Trading away access to medicines. How the European Union's trade agenda has taken a wrong turn", <http://www.oxfam.org/sites/www.oxfam.org/files/bp-trading-away-access-to-medicines.pdf>.

¹⁴⁹ For a review of such reforms, see Adamski et al. (2010). (It must, however, be emphasised that data exclusivity and patent term extension laws were not the only prevailing reasons for such mitigating measures; other important health-related factors such as the instigation of stricter clinical targets, launch of new expensive drugs, rising patient expectations and ongoing demographic changes stood tall among the reasons).

¹⁵⁰ For example, see Clarke (2003).

¹⁵¹ Godman et al. (2010); see also Vogler et al. (2011).

¹⁵² Simeons (2008); also, Godman et al. (2010).

¹⁵³ Godman et al. (2008); Seeley and Kanavos (2008).

As already pointed out, this is unfortunately not the situation with most developing countries. Research shows that pharmaceutical expenditure is proportionally higher in middle and lower income countries, at between 20 and 60 % of total health care spending.¹⁵⁴ Contributing to this is the fact that up to 90 % of the populations in developing countries purchase medicines through out-of-pocket payments,¹⁵⁵ making medicines the largest family expenditure item after food.¹⁵⁶ Consequently, many families in the developing world struggle to access quality health care due to the unavailability of cheaper medicines. This places an enormous burden and responsibility on their governments to come up with measures responsive to such situations. Adding another layer of regulation in the form of patent term extension and data exclusivity through FTAs (which undoubtedly reduces the policy space for public interest regulations, such as those that promote access to essential and affordable medicines) will further exacerbate the present situation.

It is true that developing countries are more often the seekers of these FTAs because of their inherent linkage to another universe of issues – such as market access, foreign direct investment, government procurement and electronic commerce, among others – which makes them attractive to developing countries. However, conflating these issues with tougher IP chapters in FTAs makes it hard to distinguish the role of trade agreements. It is important that private interest in maximising profit through trade is not placed above the fundamental right of access to health and medicines. If, for instance, a country like Germany opposed the Europe-wide patent term extension regulation in 1992 because it stood against its interest in reducing pharmaceutical expenditures, owing to the fact that it frequently paid a significant percentage of the cost of the pharmaceuticals used by its citizens,¹⁵⁷ how much more relevant would this be for a least developed country like Vanuatu?

6 Conclusion

The organisation of a country's pharmaceutical sector and policy obviously has implications for medicine availability, price and affordability. It is therefore important that policy options such as promoting generic medicines (which are proving to be an effective health care remedy to access and availability) both in Europe and in developing countries is encouraged. This does not, however, mean that laws protecting *sui generis* IP rights (such as patent term extension and data exclusivity) should not be promoted. Rather, agreements setting such standards should strive to strike the right balance between these policy options: that is, promoting pharmaceutical innovation through incentivising investments made in research and development in the form of market monopolies, at the same time,

¹⁵⁴ Cameron et al. (2009).

¹⁵⁵ WHO (2004).

¹⁵⁶ Cameron et al. (2009), at 1.

¹⁵⁷ Mazer (1993), at 571.

promoting generic pharmaceutical production and market entry. On the contrary, promoting laws on patent term extension and data exclusivity through FTAs in ways discussed in this contribution will rather derail such policy outcomes and place the health sector and economies of developing countries in austere positions.

Relatively new on the international IP landscape, patent term extension and data exclusivity laws have crossed over the Atlantic into Europe. The EU adopted these laws but enacted something different with regard to its data exclusivity law (the introduction of the 8 + 2 + 1 formula) such that as it stands now, the European level of protection far outweighs the US level of protection for small molecular drugs. In a twist, the American pharmaceutical industries have called for 11 years of data exclusivity – citing the European example – which could possibly lead to some form of harmonisation of law in this area especially with the start of negotiations on a comprehensive Transatlantic Trade and Investment Partnership.¹⁵⁸ It must, however, be noted that things changed in the US when in 2009, the Obama administration signed into law the Biologics Price Competition and Innovation Act which introduced an Abbreviated Biologics Licence for follow-on biologics and a 12-year period of data exclusivity¹⁵⁹ for originator biologics companies – surpassing the 11-year exclusivity period in the EU.

The increasing flow of FTAs (with extensive IP chapters) comes at the expense of early on developments such as the TRIPS Agreement and the Doha Declaration. The TRIPS Agreement came with flexibilities that provided the means for developing countries to implement its provisions in ways that best fit their development and health care needs. The Doha Declaration further sought to allow for reconciliation between the conflicting needs of the global pharmaceutical industry and the public health requirements of developing countries. These developments, if taken seriously, could be seen as ceilings to which all IP measures (within and outside the multilateral framework) should not go beyond. Whilst a country like India has effectively used TRIPS flexibilities to lessen the impact of patents on access for the world's poor, the EU has resorted to patent term extension and data exclusivity as strategies to further strengthen the protection and enforcement of IP rights. Increasing standards of protection for pharmaceutical products, without recourse to balancing, increases barriers to access. It is a known fact that many developing countries have limited resources as well as serious public health challenges. Accordingly, to the extent that a developing country adopts a TRIPS-plus standard that requires more protection for patents, more drugs are likely to be protected and priced out of reach of the poor.¹⁶⁰

Even though arguably there are similar laws in Europe, due to differences in the legal and regulatory environment, simulating and implementing similar extensive IP rules in the domestic systems of developing countries will bring major difficulties to their health sector and economies in ways that cannot be justified under the guise of

¹⁵⁸ See the Transatlantic Trade and Investment Partnership (TTIP) available at <http://ec.europa.eu/trade/policy/in-focus/ttip/>. Touted as the biggest bilateral trade deal ever negotiated, first round talks took place in Washington, D.C. between 8 and 12 July 2013. The negotiations are set cover about 20 various areas.

¹⁵⁹ See *supra* note 42.

¹⁶⁰ Ho (2011b), at 251.

obtaining market access and other concessions through FTAs. It is therefore proposed that developing countries should not be forced to adopt such laws through FTAs, and if they are, the following measures should be considered: internally, the EU should streamline its development, industrial and trade policies in ways that could meet the development and health care needs of developing countries at the same time as the EU's economic interest. This should mean openly linking the discussion on access to the technological and economic environment in which the drug industry operates and finding the right balance when drafting related policies. This is particularly important because on the one hand, the EU's development policy prioritises access to affordable medicines for developing countries, and yet its industrial and trade policy can delay or complicate access in these countries.

Externally, the Union should take steps to ensure the compulsory inclusion of both: (1) a clause on transitional arrangements for developing countries specific to IP in the FTAs; and (2) a mandatory clause that clearly links the objectives for IP protection and enforcement (in this context, patent term extension and data exclusivity) to a balance between the promotion of technological innovation and access to medicines. The former suggestion could be achieved through the incorporation of transitional arrangements similar to what the TRIPS Agreement produces or what the EU's Regulation (EEC) No. 1768/92 prescribes. In this way, developing countries could have the policy space to put in place the appropriate structures and mechanisms that will ensure their citizens do not endure hardships as a result of the implementation of the FTA. With the latter suggestion, including such a mandatory clause into the FTA will ensure that it is part of treaty provisions. Being part of treaty law presupposes being part of the treaty's rights and obligations to which developing countries can fall back on to derogate from the other IP provisions (like data exclusivity) that do not support their ability to come up with policies that meet the healthcare needs of their citizens. Thus, in case of conflict, one provision cannot override the other because they are both relevant and carry equal weight. Such a clause may also function to safeguard the TRIPS flexibilities and the Doha Declaration, which are often referred to in these FTAs (whether specific or permissive) by removing every shadow of ambiguity in the interpretation of such provisions in so far as the ultimate objective should be to bring about balance.

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Chapter VI

Publication V

**The IP policy of the EU – An impediment to balancing IP
and public health in FTAs?**

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The IP Policy of the EU – An Impediment to Balancing IP and Public Health in FTAs?

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ABSTRACT

The intellectual property (IP) policy of the EU concerning developing countries has evolved from a generalist to a more prescriptive one. The inclusion of enhanced IP rules in the IP chapters of recent EU Free Trade Agreements (FTAs) is a testament. An underlying tension, however is that, in these FTAs, the EU also advocates for the protection of public health. Seeking to balance IP and public health in instruments with enhancement of IP supposedly one of their core objectives is dubious. Focusing on the Economic Partnership Agreement (EPA) between the EU and the CARIFORUM Group of States and the FTAs with Peru-Colombia and Korea, this article analyses the relevant IP and public health provisions by highlighting the contradictions therein. It argues that the present situation is a consequence of a structural bias inherent in the EU's internal system which seemingly promotes economic values over non-economic values in its IP policy-making. This is also reflected at the external level. It further argues that although public health clauses may have interpretive value, this does not change the substantive IP protection that must be offered. They thus seem to function as a façade of norms that conceal the potential effects of the TRIPS Plus norms.

Keywords: European Union; intellectual property; free trade agreements; public health; balancing

1. INTRODUCTION

On 27 April 2006, the European Council adopted a Decision¹ on the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights² (the ‘TRIPS Agreement’), done at Geneva on 6 December 2005.³ This amendment was in response to the instruction contained in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health⁴ (the ‘Doha Declaration’ or ‘the Declaration’). This paragraph recommended an expeditious solution to the problem of the difficulties that the World Trade Organization (WTO) Members with insufficient or no manufacturing capacities in the pharmaceutical sector face in making effective use of compulsory licensing under the TRIPS Agreement. The rapid adoption of the Decision by the European Council signalled the EU’s (also ‘the Union’) commitment to the implementation of the WTO Decision.

However, in the following years, a new trend soon emerged that immediately jeopardized the gains made at Doha, and the EU’s action on this front: bilateral Free Trade Agreements (FTAs). FTAs are the new technique being utilized by the EU to manage its IP interests abroad, especially, in relation to developing countries whose IP laws are deemed inadequate. Fundamental to the content of this new generation of FTAs are the chapters on IP containing an inherent contradiction: while they include safeguard clauses that refer to the TRIPS

¹ Commission of the European Communities, Proposal for a Council Decision accepting, on behalf of the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005, Brussels, 27.4.2006 COM(2006) 175 final.

² Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 33 ILM 81 (TRIPS Agreement).

³ World Trade Organization General Council, Amendment of the TRIPS Agreement, Decision of 6 December 2005, WT/L/641 (8 December 2006). https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. In 2003, the General Council acted on paragraph 6 of the Doha Declaration by waiving Article 31(f), TRIPS, thereby permitting member states lacking sufficient manufacturing capacity to import necessary medicines from any other member states. This waiver was adopted by WTO Members as an amendment to TRIPS (Art. 31 *bis*) in 2005.

⁴ World Trade Organization, the Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference Declaration of 14 November 2001, WT/MIN(01)/DEC/2. The adoption of the Doha Declaration by the Member States of the WTO in 2001 signalled recognition of widespread concerns about the effects of expanded patent protection on public health and access to medicines. Importantly, it clarified that ‘the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all’.

flexibilities and the Doha Declaration, their corresponding substantive IP provisions extend beyond the TRIPS enforcement standards. This makes it difficult for countries to make use of the TRIPS flexibilities while, simultaneously fulfilling the new enforcement obligations. This is particularly relevant in the pharmaceutical field, in which access to medicines may be hugely impaired.⁵ Fundamental questions arise:

- Why does the EU insert clauses that affirm recognition for public health in its FTAs and yet counter them with corresponding substantive IP clauses?
- To what extent can this contradiction function to impede efforts at balancing IP and public health, especially, in the implementation of the FTA?

This article approaches these questions in two parts. Part I traces the answer to an important but often neglected matter in the discourse on this subject: the IP policy of the EU. It argues that the present situation is a consequence of a structural bias inherent in the EU's internal system.⁶ It seemingly promotes economic values over non-economic values in its IP policy-making, which is also reflected at the external level. This development, it is argued, is not accidental; rather, a gradual process of institutions and norms implicitly nurtured the status quo. Two stages illustrative of this development are discussed: (1) the common market stage; and (2) the legislative stage.⁷

⁵ Essentially, IP converts innovation into a saleable commodity. While this enables technology markets, it also creates social tension over the price and/or lack of access. Enhancing existing IP rules further stifle access and deepens this tension. For convenience, public health and access to medicines will be used interchangeably in this article.

⁶ For the sake of simplicity, I use the terms 'internal' and 'external' in connection to the EU's IP policy in the generic sense. The internal development of the law refers to all systems of IP regulation at the EU level (substantive, procedural, enforcement and border measures). The external refers to aspects of IP regulation in which the EU engages third countries or at the international level.

⁷ The two stages are a synthetization of similar but slightly varied periodization by Tuomas Mylly, *Intellectual Property and European Economic Constitutional Law: The Trouble with Private Informational Power*, (Publications of IPR University Center, Gummerus Kirjapaino Oy, 2009), p. 261 *et seq*; Vincenzo Scordamaglia, 'The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights at European Regional Level', in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Cheltenham, UK: Edward Elgar Publishing, 2013), p. 61-93; Christophe Geiger, 'The Construction of Intellectual Property in the European Union: Searching for Coherence', in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Cheltenham, UK: Edward Elgar Publishing, 2013). Mylly characterized this period into three phases: common

Part II, which focuses on the external development of the law and answers the second question, analyses the contradictions in the relevant IP chapters of the Economic Partnership Agreement (EPA) between the EU and the Forum of the Caribbean Group of African, Caribbean and Pacific States (CARIFORUM),⁸ the EU-Peru-Colombia FTA⁹ and the EU-Korea FTA.¹⁰ Specifically, provisions on test data exclusivity, patent term extension, and border enforcement that encompass import, export, and transit are analysed in parallel to those on public health. It is argued that the interest underlying the negotiation of these treaties intrinsically neutralizes efforts at balancing IP and public health. Although references to the TRIPS flexibilities and the Doha Declaration may have interpretive value, this does not change the substantive IP protection that must be offered in the context of the FTA. Public health clauses thus seem to function as a façade of norms that conceal the potential effects of the TRIPS Plus standards. To reform this situation, this article concludes by suggesting some possible means to ensure that the right balance can be struck in the future.

market, reconciliation, and proprietary. Conversely, Scordamaglia identified two phases: traditional intergovernmental approach and legislative approach. Geiger elaborated three distinct stages.

⁸ Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part (2008, OJ L 289/1). CARIFORUM is the body that comprises the Caribbean Group of African, Caribbean, and Pacific (ACP) States for the purpose of promoting and coordinating policy dialogue, cooperation, and regional integration, mainly within the framework of the Cotonou Agreement between the ACP and the EU, and also, the EU-CARIFORUM Economic Partnership Agreement.

⁹ Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part. http://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf.

¹⁰ Free Trade Agreement between the European Union and its Member States, of the one part, and Republic of Korea, of the other part (2011, OJ L 127/1). These treaties have been chosen for particular analysis because, in terms of the EU's trade relations with developing countries, these are the most recent, concluded, and operative. They all contain IP chapters that are adequately nuanced and are representative of the kind of balancing mechanisms analysed in this article. According to the latest country classification by the Development Policy and Analysis Division (DPAD) of the Department of Economic and Social Affairs of the United Nations Secretariat (UN/DESA), Peru, Colombia, the CARIFORUM countries, and Korea are all developing countries. http://www.un.org/en/development/desa/policy/wesp/wesp_current/2014wesp_country_classification.pdf.

2. INTERNAL DEVELOPMENT OF THE EU'S IP LAW

It is said nowadays that no area of private law has been Europeanized to the extent IP law has been.¹¹ This was not the case from the beginning. Commentators have characterized the internal development into historical phases based on the case law of the EU Courts and legislative developments in the area of IP.¹² What follows is a synthesis of these early characterizations. Each stage connects to a distinct period in the development of European integration and represents a progression in the development of its IP law – substantively and structurally – elucidating aspects of the argument in this article.

A. THE COMMON MARKET STAGE

1. TENSION BETWEEN IP TERRITORIALITY, FREE MOVEMENT OF GOODS, AND COMPETITION

When the European Economic Community (EEC, also ‘the Community’) – now the EU – was formed, it was decided to establish a customs union, the most advanced form of trade integration, with the further aim of building a common (later internal) market, founded upon free movement of goods, persons, capital, and services, and promoting fair competition.¹³ To this end, Article 30 EEC prohibited ‘quantitative restrictions’ on trade and provisions ‘having equivalent effect’. In contrast to the ideals of the common market, however, the founding members decided that the Community shall have no competence to deal with IP rights under the EEC Treaty. This was enshrined in Articles 222 EEC¹⁴ and 36 EEC,¹⁵ whose contents

¹¹ Justine Pila and Paul Torremans, ‘The Foundations of European Union Intellectual Property Law’, in Justine Pila and Paul Torremans (eds), *European Intellectual Property Law* (Oxford: Oxford University Press, 2016), p. 39.

¹² See T. Mylly, *Intellectual Property and European Economic Constitutional Law*; V. Scordamaglia, *The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights*; C. Geiger, *The Construction of Intellectual Property in the European Union*.

¹³ J. Pila and P. Torremans, *The Foundations of European Union Intellectual Property Law*, p. 40; Lionel Bentley and Brad Sherman, *Intellectual Property Law*, (Oxford: Oxford University Press, 2009), p. 11; Piet Eeckhout, *EU External Relations Law*, (New York: Oxford University Press, 2011), p. 11 (Emphasis added).

¹⁴ Now Article 345 TFEU: ‘The Treaties shall in no way prejudice the rules in the Member States governing the systems of property ownership’.

essentially stipulated that the protection of IP rights justified derogation from the fundamental rules on the free circulation of goods. IP rights were thus perceived as a nationally defined restraint on internal trade and competition. This territorial conception of IP rights was considered as antagonistic to the integration objectives of the EEC.¹⁶

This stage, which lasted from the late 1950s to the late 1980s, is characterised by the active application of the EEC Treaty provisions on the free movement of goods and competition to IP rights.¹⁷ This was aimed at limiting the undesirable effects of IP rights on European integration. The Court of Justice of the European Union (CJEU, also ‘the Court’) spearheaded the process by creating the ‘doctrine of exhaustion’ of rights at the Community level.¹⁸ To avoid contravening Article 36, EEC Treaty, the Court initially presented the doctrine of exhaustion as invalidating the exercise of IP rights, while preserving their existence.¹⁹ Later, the concept of the right’s existence was refined in terms of its ‘specific subject matter’²⁰ and the ‘essential function’²¹ of the IP right.²²

Another measure taken at this stage to minimize the territorial effects of IP rights on the internal market was the intergovernmental approach. The founding members envisaged the conclusion of conventions unifying the laws on patents, trademarks, and design through strictly intergovernmental working methods.²³ To this end, three Intergovernmental Working

¹⁵ Now Article 36 TFEU.

¹⁶ T. Mylly, *Intellectual Property and European Economic Constitutional Law*, p. 262.

¹⁷ *Ibid*; also, L. Bentley and B. Sherman, *Intellectual Property Law*, p. 12.

¹⁸ The doctrine of exhaustion prohibits an IP right owner from utilising their rights to control the resale, import, or export of any goods that have been placed on the market in the EU by them or with their consent. This is based on their idea that the ‘first sale’ gives the IP owner the reward that constitutes the ‘specific subject matter’ of the right.

¹⁹ The distinction between existence and exercise was first developed in the context of Arts. 85 and 86 EEC in *Consten and Grundig v Commission*, C-56/64 and 58/64, EU:C:1966:41; *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG*, C-78/70, EU:C:1971:59, para. 11.

²⁰ *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, C-15/74, EU:C:1974:114, para. 8.

²¹ *Hoffmann-La Roche & Co. AG v Centrafarm*, C-102/77, EU:C:1978:108.

²² L. Bentley and B. Sherman, *Intellectual Property Law*, p. 13.

²³ V. Scordamaglia, *The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights*, p. 62.

Parties were established in 1958 to perform this mandate. Thus the ambiguity of IP being regulated, institutionally separated but functionally linked to the Union has been present from the entry into force of the EEC.²⁴ While most legislative initiatives outside IP's competition law interface failed during this period,²⁵ there were some achievements. For example, the European Patent Convention (EPC) which was negotiated through the intergovernmental process became a success.²⁶ To date, the intergovernmental approach is still utilized at the European level to negotiate IP laws in the form of enhanced cooperation. A clear example is the unitary patent package (UPP), whose implementation will establish a European patent with unitary effect and a new patent court.²⁷ The latter is an institution supposedly governed by international law only.

B. THE LEGISLATIVE STAGE

This stage represents the period of positive integration,²⁸ when the EU took steps to regulate the field of IP both internally and externally. We will first consider the efforts made to regulate this field internally before turning to the external dimension.

²⁴ Ibid.

²⁵ T. Mylly, *Intellectual Property and European Economic Constitutional Law*, p. 262; V. Scordamaglia, *The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights*, p. 61-66. For instance, the Convention for the European Patent for the common market (Community Patent Convention, 'CPC') OJ L 17 of 26 January 1976 was first agreed in 1975, but due to lack of political will, among other matters, the Convention was never implemented. The CPC was one of two conventions (the other being the European Patent Convention, 'EPC') proposed by France in 1968, both to be realized by internationally negotiated conventions. The entry into force of the CPC was expected around the same time as the EPC.

²⁶ The text of the 15th edition of the EPC can be found at:

[http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461C0D5C1257C060050C376/\\$File/EPC_15th_edition_2013.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461C0D5C1257C060050C376/$File/EPC_15th_edition_2013.pdf).

²⁷ Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ L361/1 (31 December 2012). Translation arrangements are regulated by Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ L361/89 (31 December 2012). For the court, see Agreement on a Unified Patent Court, OJ C175/1 (20 June 2013). The Unified Patent Court Agreement was signed by 25 EU Member States on 19 February 2013. Although it is not a Union measure, it has been published as a notice from EU institutions.

²⁸ T. Mylly, *Intellectual Property and European Economic Constitutional Law*, p. 263.

1. DOMESTIC RECONCILIATION PERIOD

This period lasted from the late 1980s to the mid-1990s. It coincided with the ambitious *internal market programme*²⁹ and the general relaxation of the CJEU's case law on the free movement of goods and state-based restrictions of competition.³⁰ It also coincided with the Uruguay Round of negotiations leading to the TRIPS Agreement. The negotiation of TRIPS strengthened the view that adequate protection of IP rights promoted free trade and innovation-based growth. However, an understanding of the implications of the TRIPS Agreement's conclusion on the Union and its Member States,³¹ and the territorial effects of IP rights on the internal market would push the Union to act. Thus, this period witnessed the emergence of Community-level protection regimes, functioning alongside harmonized national laws and establishing rights with unitary character.³²

However, for the latter to happen, the EU needed a treaty basis.³³ Since the internal market is one of the shared competences of the EU,³⁴ the EU would rely on provisions from its treaties attributing it the power to regulate the internal market (and other general provisions) to legislate the field of IP. Commentators have noted that Article 95 EC (ex Article 100A EEC)³⁵ and Article 308 EC (ex Article 235 EEC),³⁶ among others,³⁷ served as the basis for

²⁹ Commission of the European Communities, *Completing the Internal Market*, Brussels, 14 June 1985, COM (85) 310 final.

³⁰ T. Mylly, *Intellectual Property and European Economic Constitutional Law*, p. 262; J. Pila and P. Torremans, *The Foundations of European Union Intellectual Property Law*, p. 55-56. On case law, see *Pharmon BV v Hoechst AG*, C-19/84, EU:C:1985:304; *SA CNL-SUCAL NV v HAG GF AG*, C-10/89, EU:C:1990:359; *Keck and Mithouard*, C-267/91 and C-268/91, EU:C:1993:905; *Criminal proceedings against Meng*, C-2/91 EU:C:1993:885.

³¹ The TRIPS Agreement was negotiated and signed as a mixed agreement by both the EU and its Member States.

³² T. Mylly, *Intellectual Property and European Economic Constitutional Law*, p. 263.

³³ Article 5(1) and 5(2) TEU.

³⁴ Article 4 TFEU.

³⁵ Now Article 114 TEU. This Article permits the Union to act to approximate legislation with the object of the 'establishment and functioning of the internal market'.

³⁶ Now Article 352 TFEU. This Article allows the Union to take measures when it is required to act in order to achieve one of the objectives of the Community, but where no explicit power has been granted.

³⁷ Such as Article 37 EC, now Article 43 TFEU.

the majority of the directives in this field and for the adoption of Community rights.³⁸ Relying on these provisions to regulate the field of IP resulted in approaching the subject from an entirely *economic* perspective, even though the essence of IP transcends that.³⁹ The first IP directive to be issued in reliance on Article EC 95 was the Semiconductor Directive in 1986.⁴⁰ Since then, the EU has engaged in a process of harmonization and unification⁴¹ of IP rights so that it can today boast of harmonization of laws in the areas of copyright,⁴² trademark,⁴³ design,⁴⁴ and biotechnology,⁴⁵ in addition to several other directives adopted over the last two decades.⁴⁶ The Union has also unified laws in the areas of the Community trademark,⁴⁷ Community design,⁴⁸ and Community plant variety right⁴⁹; more recently, it has

³⁸ C. Geiger, *The Construction of Intellectual Property in the European Union*, p. 7; J. Pila and P. Torremans, *The Foundations of European Union Intellectual Property Law*, p. 55-57; V. Scordamaglia, *The Legal Framework of the Legislative Activity Concerning Intellectual Property Rights*, p. 66-70.

³⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'A single Market for Intellectual Property Rights: Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe', Brussels, 24 May 2011 Publications Office of the European Union (2011) 287 final. Page 3 of this document observes that 'IP is indispensable to address the big challenges that mankind is facing in the 21st century such as: ensuring food security, containing climate change, dealing with demographic change and improving citizens' health'.

⁴⁰ Council Directive 87/54/EC of 16 December 1986 on the legal protection of topographies of semiconductor products (OJ L24 of 27.01.1987, 36).

⁴¹ In the EU, harmonization of national laws is typically achieved by means of Directives, whereas unitary protection titles generally materialize through Regulations. Directives are not directly applicable in the Member States, but require implementation into their national laws. They are binding only on their addressees, that is, the Member States. Conversely, Regulations do not normally require any implementing action: they are directly applicable and effective in the Member States, becoming part of their national law at the date of their entry into force. See Olivier Vrins and Marius Schneider, 'Cross-border Enforcement of Intellectual Property: The European Union', in Paul Torremans (ed), *Research Handbook on Cross-border Enforcement of Intellectual Property* (Cheltenham, UK: Edward Elgar Publishing, 2014), p. 169.

⁴² Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society (2001, OJ L 167/1). This Directive partially harmonised copyright laws in the EU.

⁴³ Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (2008, OJ L 299/25). Now codified as Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trademarks (recast) (2015, OJ L 336/1).

⁴⁴ Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs (1998, OJ L 289/28).

⁴⁵ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (1998, OJ L 213/13).

⁴⁶ For example, Directive 2008/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (2004, OJ L 157/16) and Directive 96/6/EC of the European Parliament and of the Council on the legal protection of databases.

⁴⁷ Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trademark (2009, OJ L 78/1). Now codified as Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015 amending Council Regulation (EC) No 207/2009 on the Community trademark and Commission

sought to unify EU patent law through a unitary patent package.⁵⁰ These have been supplemented by the numerous decisions of the CJEU, which has ‘contributed to the elaboration of a new legal framework in this field, so that it is today possible to speak of a veritable European IP law’.⁵¹

Nonetheless, efforts to regulate the field of IP internally did not avoid difficulties. For example, recourse to Article 308 EC required unanimity of the votes in the European Council (‘the Council’). A dissenting country could thus block the passage of the law. This potentially explains why politically sensitive issues like the EU patent has, until recently, been difficult to conclude.⁵² Externally the Common Commercial Policy (CCP), which is the Union’s external trade policy codified under Article 133 EC (ex Article 113 EEC), only contained a non-exhaustive list of examples of subjects belonging to the CCP but contained no clear definition of the boundaries of this policy.⁵³ In Opinion 1/94, the CJEU clarified that apart from the provisions of the TRIPS Agreement which concerned the prohibition of the release into free circulation of counterfeit goods, IP was not included in the CCP.⁵⁴ Neither was it covered by implied exclusive powers. This was because the Community had only achieved partial harmonization of certain areas covered by TRIPS, and in other areas, no

Regulation (EC) No 2868/95 implementing Council Regulation (EC) No 40/94 on the Community Trademark, and repealing Commission Regulation (EC) No 2869/95 on the fees payable to the Office for Harmonization in the Internal Market (Trademarks and Designs) (2015, OJ L 341/21).

⁴⁸ Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs (2002, OJ L3/1).

⁴⁹ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (1994, OJ L 227/1).

⁵⁰ Regulation (EU) No 1257/2012 and Agreement on a Unified Patent Court, OJ C175/1.

⁵¹ C. Geiger, *The Construction of Intellectual Property in the European Union*, p. 5; J. Pila and P. Torremans, *The Foundations of European Union Intellectual Property Law*.

⁵² Aurora Plomer, ‘A Unitary Patent for a (Dis) United Europe: The Long Shadow of History’, 46 *International Review of Intellectual Property and Competition Law* 5 (2015), p. 508-533; J. Pila and P. Torremans, *The Foundations of European Union Intellectual Property Law*, p. 113-154; C. Geiger, *The Construction of Intellectual Property in the European Union*, p. 7-8.

⁵³ Daniel Acquah, ‘Developments in the EU External IP and Trade Competence up to Lisbon: New Wine in Old Wine Bottles?’, 5 *Nordiskt immateriellt Rättskydd NIR* (2011), p. 423-439; P. Eeckhout, *EU External Relations Law*, p. 12-13.

⁵⁴ *Opinion 1/94*, EU:C:1994:384, para. 71.

harmonization had been envisaged.⁵⁵ Technically, this would impact the extent of the EU's ability to negotiate international agreements involving IP until the Lisbon Treaty.⁵⁶

2. INTERNATIONALIZATION PERIOD

During this period, the Union initiated legislative and non-legislative measures that emphasized the protection of investments in the form of stronger protection of IP rights, both domestically and abroad. The protection of other interests, whether competition, fundamental rights or cultural interests, is left for other legislation.⁵⁷ This period, which spans from the second half of the 1990s to date, also coincides with the coming into force of the TRIPS Agreement. As TRIPS prescribed rules in fields lacking Union harmonization measures, the signing of TRIPS by the EU and its Member States led the EU to take steps to harmonize those fields at the regional level. Thus, this period witnessed the passage of (and amendments to) most of the directives and regulations noted above. The CJEU's judgments also provided the EU legislators with broad substantive discretion to enact IP legislation with a proprietary bias.⁵⁸

This shift in policy aligns with the EU's objective of maintaining its place as a global economic actor on the international scene. With the intensification of international trade, the centre of wealth creation had been gradually shifting from tangible assets to intangible assets. This naturally provoked a change in the focus of competition, which became increasingly

⁵⁵ Ibid, para. 103.

⁵⁶ Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007 (2007/C 306/01).

⁵⁷ T. Mylly, *Intellectual Property and European Economic Constitutional Law*, p. 265-266.

⁵⁸ Ibid. See also Opinion 1/94, supra note 52; *Spain v Council*, C-350/92, EU:C:1995:237 and *Netherlands v European Parliament and Council*, Case C-377/98, EU:C:2001:523. For instance, it was with reference to an expansive interpretation of Art. 95 EC that the CJEU in the *Netherlands* case rejected a competence-based challenge to the validity of the Biotech Directive.

targeted at the competitive advantage derived from knowledge-based capital.⁵⁹ Thus, the EU made innovation-based comparative advantage and growth its new objective policy. Since IP captures and secures the competitive advantage conferred by innovation,⁶⁰ it became a driving force for the internal market. In this regard, the EU's IP policy became the centre of economic activity.⁶¹ Infringement of IP within and outside the EU was thus taken seriously. The European Parliament (EP) noted in a Resolution that 'the biggest challenge for the internal market lies in combating infringements of IP rights at the EU's external borders and in third countries'.⁶² The higher standards of protection and enforcement achieved within the EU are jeopardized if such rights remain unprotected and unenforced elsewhere. The Union would go on to institute measures aimed at tackling IP infringements both at home and abroad, key among which are discussed next.

a. *ATYPICAL ACTS IN EU EXTERNAL TRADE AND IP POLICY*

Against the background of increasing IP infringements globally, the EU has responded by working to promote the introduction of domestic regulatory discipline in third countries through its FTAs. These are by no means new for the EU: the new development is the current approach of using them as tools to facilitate the enhanced protection and enforcement of IP abroad. In its early FTAs, the EU adopted a generalist approach to regulate IP, requiring contracting parties to ratify existing IP-related international agreements.⁶³ This drastic shift in policy – from a generalist to a more prescriptive approach – was outlined in two documents:

⁵⁹ Francis Gurry, 'Re-thinking the role of Intellectual Property', *Law School of the University of Melbourne* (August 22 2013), p. 5.

⁶⁰ *Ibid.*

⁶¹ European Commission, *Europe 2020 Strategy*, Publications Office of the European Union (2010); European Commission, *The Digital Agenda for Europe*, (2010), p. 245.

⁶² European Parliament resolution of 22 September 2010 on enforcement of intellectual property rights in the internal market (2009/2178(INI)).

⁶³ Pugatch, M. Perez, 'A Transatlantic Divide? The US and EU's Approach to the International Regulation of Intellectual Property Trade-Related Agreements', *European Centre for International Political Economy Working Paper* No. 02 (2007), p. 10; Billy A. M. Araujo, 'Intellectual Property and the EU's Deep Trade Agenda', 16 *Journal of International Economic Law* 2 (2013), p. 439.

the 2005 Strategy for the enforcement of IP rights in third countries ('the Enforcement Strategy')⁶⁴ and the 2006 Global Europe Communication ('the Global Europe Strategy').⁶⁵

In the introduction to the Enforcement Strategy, the European Commission ('the Commission') acknowledged that the policy was 'a logical consequence' of the recently enacted TRIPS Plus enforcement legislation⁶⁶ and a Customs Regulation.⁶⁷ As Araujo observed, this 'assertion reflects an understanding that the EU's own legislation would not suffice to combat IP infringements at the border, since cross-border infringements of IP do not only occur in the country of importation'.⁶⁸ Stopping infringement at source was therefore crucial. Thus, in the Enforcement Strategy, the Commission proposed in its action lines that the IP chapters in bilateral agreements should be revisited to clarify and strengthen the enforcement clauses by, for instance, using the Enforcement Directive and Customs Regulation as 'important sources of inspiration and a useful benchmark'.⁶⁹ The Commission's 2014 Communication on the Enforcement Strategy builds on this approach by focusing on ways to improve the existing approaches to keep pace with the times and the new realities in the field of IP.⁷⁰

⁶⁴ Strategy for the Enforcement of Intellectual Property Rights in Third Countries (2005/ C 129/03).

⁶⁵ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'Global Europe: Competing in the World – A Contribution to the EU's Growth and Strategy', Brussels, 4 October 2006, Publications Office of the European Union (2006) 567 final.

⁶⁶ Directive 2008/48/EC of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights (2004, OJ L 157/16).

⁶⁷ Council Regulation 1383/2003 concerning customs actions against goods suspected of infringing certain intellectual property rights (OJ L 196/7 2003). This Regulation has been repealed by Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights.

⁶⁸ B. M. Araujo, 16 *JIEL* (2013), p. 448.

⁶⁹ Strategy for the Enforcement Intellectual Property Rights, p. 5.

⁷⁰ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'Trade, growth and intellectual property: Strategy for the protection and enforcement of intellectual property rights in third countries', Strasbourg, 1 July 2014, Publications Office of the European Union (2014) 389 final, at 3.

Building on the Enforcement Strategy, the Global Europe Strategy signalled a move towards placing greater emphasis ‘on bilateral trade relations with economically significant parties’.⁷¹ The contents of these new competitive FTAs were to be comprehensive and ambitious in coverage, extending beyond tariffs to non-tariff barriers such as IP rights and investment. In addition, the provisions of the IP chapters in the FTAs were to be robust, and like the Enforcement Strategy, inspired by such Union laws as the Enforcement Directive. The 2010 Europe 2020 trade strategy emphasized its complete commitment to this approach.⁷² The link between the internal market rules on IP and the external approach has become so strong that even policy documents on specific internal market proposals now discuss at length issues related to the external dimension of IP rights.⁷³ An example is the Commission’s document entitled ‘A single Market for Intellectual Property Rights.’ This emphasized the need to especially focus on the international dimension of IP rights by recommending that in negotiating FTAs, the clauses on IP should provide, as far as possible, the same level of protection as that existing in the EU, taking into account the level of development of the countries concerned.⁷⁴ While these policy documents are not laws in themselves and are thus non-binding, they serve as important foundations for future development of the law, as seen in recent EU FTAs.

b. *EXCLUSIVE COMPETENCE IN THE CCP*

The Treaty of Lisbon transformed considerably the Treaty provisions on the CCP, both in terms of substance and decision-making mechanisms.⁷⁵ Besides designating the CCP as the

⁷¹ Alasdair R. Young, ‘Liberalizing trade, not exporting rules: the limits to regulatory co-ordination in the EU’s ‘new generation’ preferential trade agreements’, 22 *Journal of European Public Policy* 9 (2015), at 1255.

⁷² *Ibid.*

⁷³ B. M. Araujo, 16 *JIEL* (2013), p. 449.

⁷⁴ Communication from the Commission, COM (2011) 287 final, p. 21.

⁷⁵ Article 207(2) TFEU now subjects the CCP to the ordinary legislative procedure, with full involvement of the European Parliament and the Council. The former Treaty versions did not provide for any legislative role for the European Parliament. P. Eeckhout, *EU External Relations Law*, p 57.

exclusive competence of the EU,⁷⁶ it also matched the CCP with the subject matter of the WTO agreements by introducing the commercial aspects of IP and trade in services into the CCP.⁷⁷ Even though the commercial aspects of IP and trade in services are not defined, these additions give the CCP new meaning and weight as the CJEU recently proved in the *Daiichi Sankyo case*.⁷⁸ Contrary to its previous case law,⁷⁹ the Court ruled in this case that the TRIPS Agreement had specific links to international trade;⁸⁰ since the authors of the TFEU could not have been unaware of the fact that the ‘commercial aspects of IP’ correspond almost literally to the very title of the TRIPS Agreement, TRIPS fell within the scope of the CCP.⁸¹

By confirming that all subject matter under the WTO framework now falls within the exclusive competence of the EU, the Court gave the Union the leverage to push through its economic agenda on the international scene.⁸² Hence, it is now possible for the EU to introduce enhanced IP norms (or even substantively new IP norms) in its CCP agreements, in the absence of prior EU legislation.⁸³ The EU thus possesses the exclusive power to harmonize IP through international treaties, though, strictly, it lacks a comparable internal exclusive power.⁸⁴ The pulse of this exclusivity in the CCP is, however, being tested again in Opinion 2/15.⁸⁵ In her Opinion,⁸⁶ Advocate General Sharpston reaffirmed the CJEU’s

⁷⁶ Article 3(1)(e) TFEU.

⁷⁷ Article 207 TFEU.

⁷⁸ *Daiichi Sankyo and Sanofi-Aventis Deutschland*, C-414/11 EU:C:2013:520, para. 50.

⁷⁹ *Opinion 1/94*. It is to be noted that this case was decided on the basis of Article 113 EC Treaty.

⁸⁰ *Ibid.*, para. 53.

⁸¹ *Ibid.*, para. 61.

⁸² Tuomas Mylly, ‘Constitutional Functions of the EU’s Intellectual Property Treaties’, in Josef Drexler, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds) *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (MPI Studies on Intellectual Property and Competition Law, Springer-Verlag Berlin Heidelberg, 2014), p. 248.

⁸³ *Ibid.* (This might possibly exclude, for example, provisions on moral rights and detailed criminal law measures, as these are excluded from TRIPS. Thus, aspects of the IP chapters of EU FTAs and EPAs should probably fall outside the EU’s exclusive CCP competence under the Lisbon Treaty. However, Mylly has noted that this is typically not very problematic, as the EU’s trade agreements are often broad in their scope and, in any case, might contain subject matter falling outside the EU’s exclusive CCP competence).

⁸⁴ *Ibid.*

⁸⁵ Opinion 2/15, pending before CJEU.

⁸⁶ Opinion of Advocate General Eleanor Sharpston in Opinion 2/15, EU:C:2016:992.

decision in *Daiichi*, but also concluded that the EU-Singapore FTA must be signed jointly between the EU and its Member States.⁸⁷ It is yet to be seen what the Court will say. However, it is without doubt that this Opinion may further clarify the scope and delimitations of the CCP. In what follows, attention will be paid to how these internal developments manifest and influence the Union's external action.

3. THE EXTERNAL DEVELOPMENT OF THE LAW

A. FRAMING THE IP CHAPTERS IN FTAS

In line with its internal strategy, the EU utilizes openings in the multilateral system to engage in negotiating new FTAs with third countries. Irrespective of whether the FTA partner is a developed or developing country, they usually include a specific chapter on IP whose provisions are detailed and extensive; in the case of developing countries, these provisions export to a large extent the EU's current internal architecture on the regulation of IP. The chapters usually include the following IP categories:

- copyright and related rights;
- patents;
- trademarks;
- geographical indications;
- industrial designs;
- utility models;
- plant varieties;

⁸⁷ The basis of her conclusion was that, Chapter 11 of the EU-Singapore FTA includes provisions on moral rights, among others, which are clearly non-commercial. As far as that chapter applies to non-commercial aspects of intellectual property, the competence of the European Union for concluding those parts of that chapter cannot be based on Article 207(1) TFEU. Those parts of the chapter therefore fall within the shared competence of the EU and Member States.

- genetic resources; and
- traditional knowledge and folklore.

They also contain secondary norms of adjudication, such as those related to detailed enforcement institutions and dispute settlement. In addition, TRIPS Plus provisions in the form of patent term extension and test data exclusivity are included, in addition to such enforcement institutions as border enforcement, which encompasses import, export, and transit. These provisions have been chosen for analysis because, for practical purposes, they are the ones that limit the policy space available for access to medicines in the FTAs. The aim is to demonstrate the extent to which these provisions diverge, and whether, to the extent that they conflict, substantive IP provisions could prevail over norms on public health or vice-versa. In so doing, it also highlights how these conflicting provisions transform into impediments at balancing IP and public health.

B. LEGISLATION BY REFERENCE OR THE BILATERAL SAFEGUARD CLAUSE

A technique common to the IP chapters of all the FTAs under discussion is legislation by reference or the inclusion of bilateral safeguard clauses, sometimes understood as ‘conflict clauses’. Legislation by reference implies that one state undertakes the compromise to respect or access a treaty.⁸⁸ The relevant treaty in this context is the WTO/TRIPS. Conversely, bilateral safeguard clauses provide a temporary escape for parties when, by implementing the treaty, a nation’s public health and other development priorities would be impaired. Depending on their level of generality or specificity, these clauses can impact the implementation of the FTA. In the context of the FTAs, ‘these conflict clauses are *lex specialis* to the general rule in Article 1:1, TRIPS.’⁸⁹ If their application does safeguard TRIPS

⁸⁸ Xavier Seuba, ‘Intellectual Property in Preferential Trade Agreements: What Treaties, What Content?’, 16 *The Journal of World Intellectual Property* 5—6 (2013), p. 247.

⁸⁹ Henning Grosse Ruse-Khan, ‘The International Law Relation Between TRIPS and Subsequent TRIPS-plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?’, 18 *Journal of Intellectual Property Law* 2

flexibilities, this result in turn arguably prevails over the one flowing from the application of the more general TRIPS conflict norm'.⁹⁰ This analogy also applies generally to the substantive IP provisions in the FTAs.

Among the general provisions, which usually appear first in the IP chapters, there are often references that reaffirm Parties' 'right and obligations under' or 'commitment to ensure adequate and effective implementation of' the TRIPS Agreement and other multilateral treaties related to IP to which the Parties are signatories.⁹¹ The EU-Peru-Colombia FTA further adds that '[...] therefore, no provision of this title will contradict or be detrimental to the provisions of such multilateral agreements'.⁹² The differences in the levels of generality of the provisions above are obvious: while it may be difficult to extract concrete consequences from the former, the latter has more practical implications. It appears to be a conflict of treaty rule which implies that in the event of conflict, TRIPS provisions should prevail over the FTA provision, even though *lex specialis* rules indicate that precedence must be given to the TRIPS Plus provision contained in the FTA.⁹³

However, Grosse Ruse-Khan has argued that such general references cannot lead to a result which would render specific TRIPS Plus provisions ineffective, as discussed in detail

(2011), p. 26. TRIPS Article 1:1 permits WTO members to grant more extensive protection than is required by the Agreement, provided that such protection does not contravene the TRIPS provisions. Although a caveat to this principle directs it at domestic laws of member states and not to subsequent treaties in the same field, ultimately, it leads to the same result as the FTAs are implemented domestically.

⁹⁰ Ibid, p. 24-26 (where he observes that instances where the qualification of TRIPS Art. 1:1 may apply are most likely to be found in cases where one can identify a mandatory TRIPS provision instead of an optional one).

⁹¹ See Article 139(1) EU-CARIFORUM EPA; Article 196(1) EU-Peru-Colombia FTA, and Article 10.2(1) EU-Korea FTA.

⁹² Article 196(2) EU-Peru-Colombia FTA.

⁹³ Seuba, X., 'Checks and Balances in the Intellectual Property Enforcement Field: Reconstructing EU Trade Agreements', in C. Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Cheltenham, UK: Edward Elgar Publishing, 2013), p. 417.

below.⁹⁴ Others even argue that these references may add nothing to the existing compromises of the parties since all are WTO Members.⁹⁵ These provisions may only have relevance if dispute settlement mechanisms set forth in the respective treaties are triggered.⁹⁶ In the context of the FTAs, such provisions may seem retrograde, if not contradictory. The purpose of negotiating the FTA is to seek enhanced protection of IP rights beyond that provided by the TRIPS Agreement. If adequate and effective implementation of the TRIPS Agreement were sufficient, negotiating the IP chapters in the FTAs would not be necessary. However, it may also be that the EU includes these references to pre-emptively counter any allegations that the FTAs infringe the TRIPS Agreement.

Another layer is the inclusion of provisions that replicate TRIPS flexibilities in the FTAs. A good example is Article 139(2), EU-CARIFORUM EPA, under which parties ‘agree that the principles set out in Article 8 of the TRIPS Agreement apply to this Section and that adequate and effective enforcement of intellectual property rights should take account of the development needs of the CARIFORUM States [...] and to protect public health and nutrition’. Since both parties are signatories to the TRIPS Agreement, repeating the TRIPS objectives and principles in the FTA seems unnecessary. However, it may be that both parties intended to emphasize the subject’s priority which is evident in, for instance, the latter part of that provision, which states that ‘nothing in the agreement shall be construed as to impair the capacity of the parties and the signatory CARIFORUM States to promote access to medicines’.⁹⁷ This is a clear example of a safeguard clause that permits the CARIFORUM

⁹⁴ H. G. Ruse-Khan, *The International Law Relation Between TRIPS and Subsequent TRIPS-plus Free Trade Agreements*, p. 29; Henning Grosse Ruse – Khan, ‘Protecting Intellectual Property under BITS, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?’, *Max Planck Institute for Intellectual Property & Competition Law Research Paper* No 11-02, p. 1-34; B. M. Araujo, 16 *JIEL* (2013), p. 464.

⁹⁵ Xavier Seuba, 16 *JWIP* 5—6 (2013), p. 250; B. M. Araujo, 16 *JIEL* (2013), p. 463.

⁹⁶ Xavier Seuba, 16 *JWIP* 5—6 (2013), p. 250.

⁹⁷ Article 139(2) EU-CARIFORUM EPA. A similar formulation is enshrined in Article 197(1) EU-Peru-Colombia FTA although not as specific.

States to exceptionally derogate from the FTA obligations to protect public health in implementing the treaty.

A practical example of a situation in which public health clauses may function to uphold TRIPS Plus provisions are instances where references are made to the Doha Declaration in the FTAs. Such is the case with Article 197(2), EU-Peru-Colombia Agreement; Article 147(B), EU-CARIFORUM Agreement; and Article 10.34(1), EU-Korea Agreement. By expressly referencing the Doha Declaration in the FTAs, the Parties commit to implement and interpret the provisions of the FTA in a manner consistent with the Declaration. However, this may only be possible where the Doha-reference is more concrete and specific, such as Article 197(2), EU-Peru-Colombia Agreement.⁹⁸ Even in that case, to prevail against a more specific TRIPS Plus obligation, the Doha-reference ‘should be understood to allow a wider understanding of the “exceptions for reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to those data to third parties” foreseen in Article 231(4) EU-Peru-Colombia Agreement’.⁹⁹

Unfortunately, there are no similar provisions in the other treaties analysed. However, the Doha Declaration does not cover all the areas in which flexibility of the TRIPS Agreement exists, such as the exceptions to patents rights (Article 30) and the protection of data submitted for the registration of pharmaceutical (and agrochemical) products (Article 39.3)¹⁰⁰; neither does it prohibit patent term extension or cover border enforcement, as

⁹⁸ Article 197(2) of the EU-Peru-Colombia Agreement reads: ‘Parties recognize the importance of the Declaration of the Fourth Ministerial Conference in Doha and especially the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the WTO Ministerial Conference and its subsequent developments. In this sense, in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration’.

⁹⁹ H. G. Ruse-Khan, 18 *JIPPL* 2 (2011), p. 31.

¹⁰⁰ Carlos M. Correa, ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health’, *World Health Organization – Health Economics and Drug Series* No. 012 (2002), p. 46.

discussed in detail below. This somewhat limits the ability to interpret the Doha Declaration in the broadest sense construed above.¹⁰¹ In a regulatory environment dominated by trade rules (or values) and applied in a trade forum, it is uncertain whether non-IP (or more generally, non-trade) values such as the provisions in the Doha Declaration would be given this broad effect, and whether the Parties to the FTA actually intended this to be given.¹⁰²

C. CONFLICTING SUBSTANTIVE IP PROVISIONS

1. DATA EXCLUSIVITY

An obvious paradox regarding the above analysis is that, while parties to the FTAs are free to use the flexibilities flowing from TRIPS to tailor the new IP enforcement provisions to their needs and level of development, substantive IP provisions deriving from the same FTAs seem out of balance. From the above analysis, it is obvious that public health references may have interpretive value; however, the fashion in which substantive IP provisions are formulated leaves open the possibility that the public health related TRIPS flexibilities could be undermined. For example, both the EU-Peru-Colombia and EU-Korea Agreements contain clauses on test data exclusivity whose relevant parts require that data submitted to obtain a marketing authorization for pharmaceutical products in the territory of the respective parties should be given an exclusivity period of normally (or ‘at least’ in the case of the EU-Korea FTA) five years, starting from the date of the first marketing authorization.¹⁰³

¹⁰¹ The negotiating history leading to the Doha Declaration testifies to this. Developing countries had to abandon their original position asking for the declaration to state that ‘*Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health*’ which had been one of the main points of contention during the preparatory work. See (IP/C/W/312, WT/GC/W/450, 4 October 2001).

¹⁰² This assertion can find basis in for instance, the ‘Concept Paper by Pakistan: Creating an Enabling Environment to Build Respect for IP’, in WIPO Advisory Committee on Enforcement: Fifth Session, WIPO/ACE/5/11 Annex I, 2 (2009), in which Pakistan stated, among other matters, that ‘invariably, in bilateral free trade agreements, higher standards of IPR protection are demanded in return for trade and market access. This reinforces the view that IP rights are an external imposition, rather than a domestic need’.

¹⁰³ Article 231.2 EU-Peru-Colombia FTA and Article 10.36(2) and (3) EU-Korea FTA.

As I have argued elsewhere, data exclusivity has been noted to have effects on compulsory licensing and medicines pricing.¹⁰⁴ However, unlike patents, data exclusivity cannot be challenged. Consequently, it provides an additional protection to patented medicines by essentially submerging the existing exceptions into patent rights.¹⁰⁵ In essence, while WTO member states have the right to issue compulsory licenses on patented drugs, the ability to make and sell the patented drug could be undermined as the patent owner will be able to prevent marketing of the equivalent medicine by not consenting to the use of their data for marketing authorization. In this way, the generic medicine cannot be placed on the market on regulatory grounds, regardless of the grant of a patent license.¹⁰⁶ This could, to some degree, also affect the FTA partner's ability to utilize parallel importation to increase access to medicines, since cheaper versions of the originator drug may not be available on the market in other countries either, where there are similar data exclusivity rules.

There is a provision in the EU-Peru-Colombia Agreement which permits parties to regulate exceptions to data exclusivity for specific issues.¹⁰⁷ However, recent developments have shown that governments in developing countries may not be keen to utilize these exceptions or policy spaces available through the multilateral system or the FTA, as exemplified in the case of Colombia. The Colombian government has been criticized for its inability to declare, on the grounds of public interest, a compulsory license based on the excessive pricing of the cancer drug Imatinib, marketed by Novartis as Gleevec, to the detriment of its citizens.¹⁰⁸ This drug costs \$ 15,161 per patient per year in Colombia – nearly double the country's GNI

¹⁰⁴ Author's work elsewhere.

¹⁰⁵ Cynthia, M. Ho, 'Beyond Patents: protecting drugs through regulatory laws', *Loyola University Chicago School of Law Public Law and Legal Theory Research Paper* No. 34 (2011a), p. 269.

¹⁰⁶ For detailed analysis on the effects of data exclusivity, see Author's work elsewhere.

¹⁰⁷ Article 231.4(A) EU-Peru-Colombia FTA.

¹⁰⁸ James Love and Andrew S. Goldman, 'Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License', *IP WATCH* (3/12/2015).

per capita of \$ 7,970 in 2014¹⁰⁹ – for a drug that is taken as a chronic treatment, not as a cure.¹¹⁰ The Colombian government can rely on the Doha Declaration to issue a compulsory license which would allow the introduction of a generic version of Imatinib, a situation which would reduce prices dramatically. However, it has been suggested that Colombia's Ministry of Health and Social Protection may be hesitant due to political pressure from the Swiss government.¹¹¹ Such day-to-day scenarios on the ground bring to question the viability of the public interest exceptions in the FTAs while parallel TRIPS Plus norms are being strictly enforced.

2. PATENT TERM EXTENSION

A second layer of TRIPS Plus norms that affect access to medicines is the inclusion of clauses on patent term extension in the FTAs. In the EU, this is called a Supplementary Protection Certificate (SPC).¹¹² In both the EU-Peru-Colombia and the EU-Korea Agreements, there is scope to extend the duration of the rights conferred by patent protection for pharmaceutical products. The EU-Korea Agreement prescribes a period of not more than five years for this, while the EU-Peru-Colombia Agreement has no specific time limit.¹¹³ This means five or even more years during which drugs whose patents have expired will continue to enjoy full patent protection. The extension compensates for the reduction in the effective patent life resulting from the delayed first authorization to place the product on their respective markets. During this extra period of protection, local generic companies cannot

¹⁰⁹ See <http://data.worldbank.org/country/colombia>.

¹¹⁰ J. Love and A. Goldman, IP WATCH (3/12/2015).

¹¹¹ See <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/patent-of-Imatinib-glive-closing-arguments.pdf>.

¹¹² Regulation (EC) No. 469/2009 of The European Parliament and of The Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products (2009, OJ L 152/1). Supplementary Protection Certificates in the EU generally extend the term of patent protection for five more years to compensate for delays in obtaining regulatory approval for medicinal products. 'Patent term extension' and 'Supplementary Protection Certificate' are used interchangeably in this article.

¹¹³ Article 230.4 EU-Peru-Colombia FTA and Article 10.35(2) EU-Korea FTA.

produce generic versions of the drugs, nor can governments import or export generic versions of such drugs.

In addition, the provisions in both treaties are silent on the concept of ‘one term of extension per product’ which makes it possible for new uses of known drugs to be patented (known in IP circles as ‘ever greening’). Such practices can unnecessarily expand the life-span of the patent and block generic market entries. Finally, the provisions on patent term extension do not allow scope for third parties to challenge the validity of a certificate for the extension of a patent term of a medicinal product. Depending on how it is implemented in national law, this could lead to the arbitrary issue of certificates to extend patent terms without any opportunity to curtail their spiral effects. Of course, in exceptional cases,¹¹⁴ the FTA partner can issue a compulsory license if the effects of such rules are detrimental to public health. However, it is a known fact that in the licensing and working of a patent, cooperation between the patent owner and the potential licensee leads to the disclosure of non-patented know-how, which is necessary to make quality and safe products, but which is not necessary to satisfy the disclosure requirement to obtain a patent.¹¹⁵ Since this kind of cooperation is absent in the case of the compulsory license, the disclosure of important non-patented know-how is also absent.

The EU-CARIFORUM Agreement encroaches less on public health related TRIPS flexibilities since it lacks any substantive TRIPS Plus obligations on patent protection, such as patent term extension. However, regarding provisions on enforcement, and specifically on border enforcement of IP rights, the same cannot be said about the EU-CARIFORUM

¹¹⁴ Doha Declaration, para. 5.

¹¹⁵ World Intellectual Property Organization, ‘Introduction to Intellectual Property: Theory and Practice’ (Kluwer Law International, London, 1997), p. 146.

Agreement or the other agreements under consideration, although the levels of regulation and enforcement of border measures vary in details and in strength from treaty to treaty.

3. BORDER ENFORCEMENT

Border enforcement of IP can be effective in restricting access to medicines where the rules allow customs officials to seize or detain goods suspected of infringing any IP rights in all customs situations. Despite this, the Doha Declaration does not explicitly address questions related to border enforcement of IP. Border enforcement is thus not foreseen to be part of the waivers granted by the Declaration.¹¹⁶ Including it in the enforcement sections of the FTAs therefore constitutes an expansion of the exclusivity rights for right holders,¹¹⁷ while leaving its effects unchecked. In the EU-Korea Agreement, the relevant provision state that:

each Party shall (...) adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, customs transit, transshipment, placement under a free zone, placement under a suspensive procedure or a bonded warehouse of goods infringing an intellectual property right may take place, to lodge an application (...) for the suspension by the customs authorities of the release into free circulation or the detention of such goods¹¹⁸

¹¹⁶ This is without prejudice to para. 5(a) of the Doha Declaration, which requires that, in applying the customary rules of interpretation of public international law, every provision of the TRIPS Agreement should be read in the light of the object and purpose of the Agreement as expressed in its objectives and principles.

¹¹⁷ X. Seuba, J. Rovira and S. Bloemen, 'Welfare Implications of Intellectual Property Enforcement Measures', *Program on Information Justice and Intellectual Property* Research Paper No. 5 American University Washington College of Law, Washington, DC (2010), p. 5-8.

¹¹⁸ Article 10.67(1) EU-Korea FTA.

A footnote attached to this provision defines goods infringing an IP right as counterfeit goods, pirated copyright goods, and ‘goods which, according to the legislation of the Party in which the application for customs action is made, infringe a patent, a plant variety right, a registered design, or a geographical indication’. By their nature, generic medicines often infringe patents, SPCs, and, to a lesser extent, trademarks.¹¹⁹ In formulating the rule this way, both the EU and Korea could, in effect, block the importation, transit, or re-exportation of generic medicines coming from a third country that infringe local patents, SPC, or trademarks, even if the said goods are legally produced in the country of exportation and are meant for a third country market. The *EU medicines detention case* is a clear example.¹²⁰ As highlighted by Xavier et al, such enforcement norms are likely to have negative effects for consumers, health systems, and generic manufacturers in developing countries as they could potentially lead to increases in the cost of medicines, reduce access, and weaken the marketing opportunities for generic manufacturers and parallel imports.¹²¹

While provisions on border enforcement in the EU-Peru-Colombia and the EU-Korea FTAs are modest (as they do not include patents),¹²² it should be remembered that unlike the other areas of international economic regulation,¹²³ TRIPS lacks the applicable exceptions which

¹¹⁹ While scholarship on the question of access to medicines mostly focuses on the role of patents and SPCs in limiting access, the implications of trademark rules cannot be dismissed as inconsequential. By relying on the same or similar words identifying the active ingredient, the labels used to identify generics or their packaging may often be to some extent similar or close to the trademarks of the original manufacturer. A trademark holder could hence rely on the trademark rules to request the detention of such medicines at the EU borders on allegations of ‘ordinary’ trademark infringements.

¹²⁰ Between 2008 and 2010, when the Doha Declaration was nearly a decade old and the EU already accepted the Protocol from the Council on behalf of the European Community amending the TRIPS Agreement (2007/768/EC), about 22 consignments of generic medicines were seized at various European ports while in transit, on the grounds that they allegedly infringed local IP Rights. India and Brazil had to launch a WTO dispute settlement consultation against the EU before it would agree to amend its laws. See: European Union and a Member State – Seizure of Generic Drugs in Transit, WT/DS408 and WT/DS409.

¹²¹ X. Seuba et al, *PIJIP Research Paper* No. 5 (2010), p. 13 (emphasis added).

¹²² However, a footnote attached to Article 163.1 EU-CARIFORUM EPA states that the EC Party and signatory CARIFORUM States agree to collaborate to expand the scope of the definition of ‘goods infringing an intellectual property right’ to cover goods infringing all intellectual property rights.

¹²³ Article XXIV of the General Agreement on Tariffs and Trade (GATT) and Article V of the General Agreement on Trade in Services (GATS) both allow departure from the ‘Most Favoured Nation’ (MFN)

allow countries to derogate from the Most Favoured Nation (MFN) and National Treatment (NT) principles.¹²⁴ The scaled-up enforcement provisions in the EU-Korea Agreement could thus effectively globalize these standards to become the relevant international norms.¹²⁵ What this means is that right holders from any WTO member can exploit these extra layers of protection, thereby multiplying the quantitative negative impact that such protections may have on public interests or individual fundamental rights.¹²⁶ Korea has already amended its customs legislation, which initially covered only trademark and copyright infringements, to provide for the possibility of border measures against patents.¹²⁷ This reifies the argument made in this article and the consequences of agreeing to such rules in an FTA.

4. INTERNALIZING NON-TRADE VALUES IN A TRADE REGIME

The move by the EU to include references to the TRIPS flexibilities and the Doha Declaration in its new generation of FTAs is a fundamental shift that showcases its commitment to engage with the question of balancing IP and public health. However, as discussed earlier, the extent to which this balance can be achieved depends, to some degree, on how general or specific a particular reference is, and the ability of the FTA partner to fully

principle to form customs unions and FTAs. Unlike the GATT and GATS, however, TRIPS does not contain any relevant exception which permits countries to derogate from the MFN principle to form inter se Agreements.

¹²⁴ The MFN and ‘National Treatment’ (NT) principles are non-discriminatory principles that require that member countries cannot normally discriminate between their trading partners or nationals. See H. G. Ruse-Khan, *MPIPL Research Paper* No 11-02, p. 11 (where he clarifies in a footnote that ‘distinct to the effects of Article XXIV GATT and Article V GATS, where WTO Members can limit the benefit of further trade liberalization to partners in regional trade agreements, any TRIPS-plus protection secured by one trading partner via an FTA is automatically and unconditionally available to right holders from all other WTO Members’).

¹²⁵ *Ibid.*

¹²⁶ Annette Kur and Henning Grosse Ruse-Khan, ‘Enough is enough—The Notion of Binding Ceilings in International Intellectual Property Protection’, *Max Planck Institute for Intellectual Property, Competition & Tax Law Research paper Series* No. 09-01 (2008), p. 13.

¹²⁷ Kyu-Bin Lim and Alice Young-Ran Choi, ‘Korea-EU Free Trade Agreement regarding Intellectual Property Rights’, *Kim & Chang Intellectual Property Newsletter* (2009/10). http://www.kimchang.com/UserFiles/files/IPNewsletter_0201.pdf; H. H. Nahm, ‘New Policy Amendments to Take Effect on July 1, 2011: Plant Variety Protection and Geographical Indication are now Implemented at Korea Customs for Protection of Intellectual Property Rights’, *Barun IP & Law* (July 2011). http://patentkorea.com/english/bbs_view.asp?boardid=6&num=62.

exploit these flexibilities. General references that merely acknowledge the existing obligations of the Parties to comply with TRIPS cannot be construed as entitling the Parties to derogate from the TRIPS Plus obligations to which they have willingly signed up in the FTA.¹²⁸ This is so because the FTAs do not contain ‘general exceptions’ provisions that will allow Parties to derogate from their IP-related obligations to pursue national policy interests.¹²⁹ Second, TRIPS Articles 7 and 8 (which allow for balancing of IP against public interest considerations) are framed as optional and not mandatory rules.¹³⁰ This means that a WTO member is free to choose whether to implement these flexibilities in its domestic IP laws. By agreeing to higher standards of IP protection in the FTAs, the Parties agree to waive their rights to use certain TRIPS flexibilities, which are equally a way of exercising that optional flexibility.¹³¹ It has, therefore, been argued that ‘inconsistency with TRIPS does not include scenarios where the contracting Parties agree not to exercise a right under TRIPS’.¹³²

Commentators have rightly observed that, regarding most of the TRIPS Plus elements currently under debate in the context of FTAs, the problem is not that the provisions as such are excessive or scandalous; rather, it is the fact that such norms have been transplanted into an environment where they do not fit, thereby causing irritation and side effects.¹³³ IP rights are private rights; once new enforcement standards are transposed into national laws, it becomes the responsibility of the right holders (mainly multinational pharmaceutical companies) to primarily enforce them. In reality, rent-seeking multinational pharmaceutical companies are often not as keen on policies relating to public health as they are on

¹²⁸ H. G. Ruse-Khan, *MPIPL Research Paper* No 11-02, p. 31-32; B. M. Araujo, 16 *JIEL* (2013), p. 463.

¹²⁹ B. M. Araujo, 16 *JIEL* (2013), p. 463.

¹³⁰ With the exception of a few cases, provisions containing limits to IP protection, especially when codified as exceptions and limitations to exclusive rights within IP regimes, are seldom mandatory in the sense of non-derogatory contract law. For a list of examples, see A. Kur and H. G. Ruse-Khan, *MPIIPCTL Research paper Series* No. 09-01 (2008), p. 14-17.

¹³¹ H. G. Ruse-Khan, *MPIPL Research Paper* No 11-02, p. 31.

¹³² *Ibid.*, p. 32.

¹³³ A. Kur and H. G. Ruse-Khan, *MPIIPCTL Research Paper* No. 09-01 (2008), p. 33.

maximizing profits from their investments. They are thus more likely to capitalize on the data exclusivity, patent term extension, and border enforcement provisions in the FTAs to extend their market monopoly. An obvious consequence is that the market dominance of these right holders is extended, while the position of other actors, such as national industries and consumers, will be weakened.¹³⁴

Concerning specific references that replicate TRIPS flexibilities or the Doha Declaration in the FTAs, it is clear from the foregoing that they may function as ‘exceptions’ or bases allowing Parties to derogate from the requirement to ensure the level of IP protection provided for under the FTAs. However for this to happen, it has been suggested that those exceptions must be interpreted and implemented in a way that allows for real and effective use of all the TRIPS flexibilities referenced in the Doha Declaration.¹³⁵ As discussed above, the Doha Declaration does not cover data exclusivity, patent term extension, and border enforcement. Since the TRIPS flexibilities are also framed as optional, rather than mandatory, rules, it seems that the reach of the Doha Declaration is constrained. This somewhat reinforces the long held view that the internalization of non-trade interests within the body of trade rules (whether multilateral or bilateral) bears the danger of subjecting the former to the latter.¹³⁶ The inclusion of public health clauses in the FTAs has, therefore, often been noted as an empty gesture, given that they do not supersede parallel efforts to impose more stringent TRIPS Plus rules on developing countries that conflict with the spirit and intent of the Doha Declaration.¹³⁷ In this regard, the public health clauses thus seem to function as a façade of norms that conceal the potential effects of the TRIPS Plus standards.

¹³⁴ X. Seuba et al, *PIJIP Research Paper* No. 5 (2010), p. 13.

¹³⁵ H. G. Ruse-Khan, 18 *JIPL* 2 (2011), p. 31.

¹³⁶ A. Kur and H. G. Ruse-Khan, *MPIIPCTL Research paper* No. 09-01 (2008), p. 35 (emphasis added).

¹³⁷ Joint Agency Briefing Paper: *HAI EUROPE and OXFAM*, ‘Trading Away Access to Medicines Revisited: How the European Trade Agenda Continues to Undermine Access to Medicines’, (Sept. 2014), p. 13.

One way to address this problem may be to frame the provisions on public health in the FTAs as mandatory requirements or express exceptions, which will stipulate that the implementation of the FTA cannot lead to derogation from the protection of public health. An example would be an explicit clause stating that: ‘the provisions on border enforcement or trademarks shall not affect the transit of generic medicines’. This would entail a binding obligation to act in the public interest, however, without prescribing the measures to be taken.¹³⁸ Instead, it would provide the policy space and discretion for the FTA partner to define both the conflict and the necessary measures for the purposes of promoting access to medicines.¹³⁹ To curtail the abuse of this provision, however, a mechanism should be provided to ensure that only those measures that involve the least negative impact on IP protection, while being equally effective at enabling the chosen level of public health protection, would be taken.

Second, a proposition is made for the EU to include strong and comprehensive sustainable development chapters in its trade agreements, which are to be effectively implemented and enforced.¹⁴⁰ In such chapters, the EU could outline the priority nature of access to medicines as a developmental issue and implement safeguard measures to protect generic medicines’ distribution and access, against the effects of conflicting policy fields such as IP. Another way, the third, would be to allow for reservations within the meaning of Article 19, Vienna Convention on the Law of Treaties in future FTAs.¹⁴¹ Such an entry would enable the FTA

https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf.

¹³⁸ A. Kur and H. G. Ruse-Khan, *MPIIPCTL Research paper* No. 09-01 (2008), p. 31 (Who suggest a similar idea using the term ‘mandatory limitations’).

¹³⁹ *Ibid.* (emphasis added).

¹⁴⁰ This idea is also shared by the European Parliament’s Committee on International Trade: see ‘The EU 2015 Report on Policy Coherence for Development’, (2015/2317(INI)), Amendment 25.

¹⁴¹ Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331.

partner to request to exclude or vary the legal effect of IP rights in the implementation of the treaty. For now, the EU-Peru-Colombia Agreement expressly disallows such reservations, while the EU-Korea and EU-CARIFORUM Agreements are silent on this issue.

5. CONCLUSION

This article has analysed the EU's IP policy and how that, in a way, functions to impede efforts at balancing IP and public health in its new generation of FTAs with developing countries. What is clear is that, to an extent, substantive IP provisions included in some of the FTAs discussed above curtail the flexibilities flowing from the TRIPS Agreement and the Doha Declaration. Contributing to this normative framework is how the law in the field of IP evolved over time at the European level. Initially linked to the internal market for lack of an express competence on IP, and only recently becoming the exclusive competence of the Union at the external level under the Lisbon Treaty, the EU's policy on IP (internal and external) has, to a large extent, been influenced by economics. This has led to certain structural biases which implicitly favour economic interests over non-economic interests in IP policy-making. TRIPS Plus standards, such as test data exclusivity, patent term extension, and border enforcement provisions, in the FTAs testify to this assertion: they are direct transpositions of the EU's internal laws that specifically protect the interests of right holders over consumers. Norms on IP enforcement also become tools at the disposal of right holders.¹⁴²

Conversely, incorporating balancing mechanisms in the form of references to the TRIPS flexibilities and the Doha Declaration in the FTAs cannot be overlooked: it is a demonstration that the FTAs are not meant to simply concern trade and economic objectives but rather

¹⁴² X. Seuba et al, *PIJIP Research Paper* No. 5 (2010), p. 7.

should consider other core objectives, such as access to medicines. However, as the analysis above has demonstrated, regarding the balance between IP and public health, it seems the harmonization of the commercial aspects of IP has progressed significantly faster than that of guarantees related to public health in these treaties. Although specific references to TRIPS flexibilities and the Doha Declaration may have interpretive value, considering the forum and the context in which these FTAs are negotiated, it is unlikely that the protection and enforcement of IP would be compromised. The TRIPS Plus provisions would not be enshrined if they were not intended to be enforceable. There is, therefore, good reason to recommend slowing the pace at which IP enforcement is being pushed through in the FTAs for the development of public health related concerns to come at pace.

Alternatively, the following are recommended as possible means to resolve the perennial question of balancing IP and public health in the FTAs. First, a suggestion is made to frame references to the TRIPS flexibilities or the Doha Declaration in the FTAs as mandatory requirements or express exceptions. Second, a proposition is made for the EU to include strong and comprehensive sustainable development chapters in its trade agreements, which are to be effectively implemented and enforced. Another way, the third, would be to allow for reservations within the meaning of Article 19, Vienna Convention on the Law of Treaties in future FTAs.

VII. Conclusions

This research aimed to provide an integrative account of the impact the EU's rule making on IP, both at home and abroad, has on developing countries' ability to utilize the flexibilities flowing from the TRIPS Agreement to promote public health and access to medicines. The work seemed essential against the present context in IP circles in which countries in the West, with an interest in commodifying their knowledge-based output, have continued to shop for (or create new) institutions that endorse or develop higher standards of IP, while those countries at the opposite end of the development spectrum continue to search for fora more solicitous to user interest, distributive justice, health and development. The EU operates actively in this context both regionally and internationally. The consequences are that a subset of the EU's internal rules on IP, and the IP chapters of its FTAs with developing countries usually contain provisions whose implementation can be harmful to the health sector and development of developing countries. Examples are Article 231.2 EU-Peru-Colombia FTA and Article 10.36(2) and (3) EU-Korea FTA (providing for data exclusivity for five years and above), and Article 163.1 EU-CARIFORUM EPA and Article 10.67(1) EU-Korea FTA (providing for border enforcement of IP that include transit). The effects of these provisions have been elaborated in Chapters I to VI.

As noted earlier, the organization of a country's pharmaceutical sector and policy has implications for medicine availability, price and affordability. It is therefore important that policy options such as promoting generic medicines (which are proving to be an effective health care remedy to access and availability) both in Europe and in developing countries is encouraged. In this regard, agreements or laws setting standards on IP should strive to strike a fair balance between promoting pharmaceutical innovation through incentivizing investments made in research and development in the form of market monopolies, and at the same time, promoting generic pharmaceutical production and market entry. Promoting laws on IP in ways discussed in this thesis will rather derail such policy outcomes and place the health sector and economies of developing countries in austere positions. It is in this connection that I have proposed the concept of substantive equilibrium, among the many other proposals of the individual Chapters – which are also summarized below.

The overall finding is that, the current approach of the EU towards IP policy making, both at home and abroad, does not offer the necessary freedom for development in developing countries. It simply works to protect the EU's industrial interest, with serious

implications for public health. This observation is supported by the findings of the five (individual) essays in Part II, and resonates with the post-colonial theoretical framework of the thesis. This theory underscores that the overly compliant attitude of *most* developing countries towards international IP laws – despite its overt effects on their economies – goes beyond contemporary political and economic circumstances. It can be attributed to the colonial roots and neo-colonial structures of this body of law, perpetrated through the EU's internal and external policy. To this end, post colonialism laid the foundations for an enduring influence on legal and economic developments in developing countries and on how law and development is perceived and understood. When measured against the fact that the development of IP law in Europe has evolved to the point where IP has become a driving force for the internal market and the centre of economic activity, it becomes meaningful, both in theory and practice, to understand why the EU's IP policy is the way it is. As long as post colonialism continues to inform the EU's IP policy, it may be difficult to resolve the issue of access to medicines. It is in this direction that the concept of substantive equilibrium has been suggested as a means of delinking the EU's IP policy from post colonialism.

Another important finding is the link between the internal and external in the EU's IP policy. As discussed in the introduction, and in Chapter VI, with an eye to eliminating the international trade in counterfeits, the EU in the 2000s launched two documents: the Enforcement Strategy and the Global Europe Strategy. These documents (strategies), which were aimed at enhancing the EU's IP interest abroad, essentially projected the EU's internal market rules on IP to the external in the context of the FTAs concluded with developing countries. At the bilateral level, the EU is able to use its higher bargaining power to push through TRIPS plus regulatory reforms whose inclusion at WTO level remains controversial. No wonder the provisions on test data exclusivity, SPC, and border enforcement analysed in the FTAs are direct transpositions of the EU's internal norms. This binary approach to fighting the international trade in counterfeiting laid the groundwork for a strong link between the internal and external, which today, while representing a success for the EU, represents a major challenge for access to medicines in developing countries.

Both the EU's internal and external action can be effective in limiting access to medicines. Internally, the EU Customs Regulation and trademark rules are effective partly because they require shippers to engage in costly litigation far from their bases of operation.¹ This can deter legitimate generic producers from exporting their drugs – which

1 Dinwoodie and Dreyfuss, above n 346, p. 148.

will mean the lack of access to these medicines in countries that lack manufacturing capacity, who depend on supplies from generic strongholds like India. Universal access to medicines depends on their timely availability and their affordability for everyone, without any geographical discrimination.² Thus, while modernization of these laws has rendered them effective, they have nonetheless been criticized as capable of limiting access to medicines. Externally, specific provisions of the IP chapters in the FTAs analysed in this thesis (mentioned earlier) are those that pose challenges for access to medicines. What is clear is that, to an extent, these provisions can curtail the flexibilities flowing from the TRIPS Agreement and the Doha Declaration. Since these provisions are usually direct transplantations from the EU's internal regime, incorporating them into the EU would not be technically difficult. However, to an extent this regime is simulated in developing countries, implementation will bring major difficulties to the health sector and economies of these countries.

TRIPS do not contain an exception that permits derogation from the MFN and NT principles to form *inter se* agreements. Neither do the FTAs contain provisions on 'general exceptions' that will allow Parties to derogate from their IP-related obligations to pursue national policy interests. Moreover, the TRIPS Articles 7 and 8 (which allow for balancing of IP against public interest considerations) are framed as optional and not mandatory rules. The same applies to the references to the TRIPS flexibilities and the Doha Declaration in the FTAs, apart from few exceptions. This means that a WTO member or the FTA partner is free to choose whether to implement these flexibilities in its domestic IP laws. By agreeing to higher standards of IP protection in the FTAs, the Parties agree to waive their rights to use certain TRIPS flexibilities, which are equally a way of exercising that optional flexibility.³ It has therefore, been argued that inconsistency with TRIPS does not include scenarios where the contracting Parties agree not to exercise a right under TRIPS.⁴ Meanwhile, the lack of exception to derogate from the MFN and NT principles in the TRIPS Agreement effectively globalizes the effects of the FTAs.⁵

Despite the above findings, the EU has made efforts to incorporate balancing mechanisms in the form of references to the TRIPS flexibilities and the Doha Declaration in the FTAs. This cannot be overlooked: it is a demonstration that the FTAs are not meant

2 European Parliament: Report on EU options for improving access to medicines, Committee on the Environment, Public Health and Food Safety, 14.2.2017 (2016/2057(INI)), p. 6.

3 Grosse Ruse – Khan, above n 11, pp. 31-32.

4 Ibid.

5 Ibid.

to simply concern trade and economic objectives but rather should consider other core objectives, such as access to medicines. However, as the analysis shows, regarding the balance between IP and public health, it seems the harmonization of the commercial aspects of IP has progressed significantly faster than that of guarantees related to public health in these treaties. There is, therefore, good reason to recommend slowing the pace at which IP enforcement is being pushed through in the FTAs for the development of public health related concerns to come at pace. In this regard, the findings of the case studies in Chapters II to VI, and the proposal made in Chapter I would lead me to the following *proposals*.

Internally, the EU should streamline its development, industrial and trade policies in ways that could meet the development and health care needs of developing countries at the same time as the EU's economic interest. This would mean openly linking the discussion on access to medicines to the technological and economic environment in which the drug industry operates and finding the right balance when drafting related policies. This is particularly important because on the one hand, the EU's development policy prioritizes access to medicines for developing countries, yet its industrial and trade policy can delay or complicate access in these countries.

Externally, it is recommended that developing countries should not be forced to adopt the kind of laws discussed in this thesis through FTAs, and if they are, the following measures should be considered: (1) inclusion of a clause on transitional arrangements for developing countries specific to IP in the FTAs; (2) inclusion of a mandatory clause that clearly links the objectives for IP protection and enforcement to a balance between the promotion of technological innovation and access to medicines; (3) framing the provisions on public health in the FTAs as mandatory requirements or express exceptions, which will stipulate that the implementation of the FTA cannot lead to derogation from the protection of public health; (4) the inclusion of strong and comprehensive sustainable development chapters in the FTAs, which are to be effectively implemented and enforced;⁶ and (5) allowing for reservations within the meaning of Article 19, Vienna Convention on the Law of Treaties in future FTAs.⁷

The first proposal could be achieved through the incorporation of transitional arrangements similar to what the TRIPS Agreement produces. This period should be long enough to give developing countries the space to put in place the appropriate structures and mechanisms that will ensure their citizens do not endure hardships as a result of

6 This idea is also shared by the European Parliament's Committee on International Trade: see 'The EU 2015 Report on Policy Coherence for Development', (2015/2317(INI)), Amendment 25.

7 Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331.

the implementation of the FTA. The second proposal should be something akin to the TRIPS Articles 7 and 8, but this time, inserted in the main body of the FTA. Being a substantive part of the treaty would mean that developing countries can rely on it to develop their laws in such a way that protect public health interest without breaching the treaty. For the third proposal, an example would be an explicit clause stating that: ‘the provisions on border enforcement or trademarks shall not affect the transit of generic medicines’. This would entail a binding obligation to act in the public interest, however, without prescribing the measures to be taken. In this way, it would provide the policy space and discretion for the FTA partner to define both the conflict and the necessary measures for the purposes of promoting access to medicines.⁸ With the fourth proposal, the EU could, in this chapter, outline the priority nature of access to medicines as a developmental issue and implement safeguard measures to protect generic medicines’ distribution and access, against the effects of conflicting policy fields such as IP. The last proposal could actually enable the FTA partner to request to exclude or vary the legal effect of IP rights in the implementation of the treaty. For now, the EU-Peru-Colombia Agreement expressly disallows such reservations, while the EU-Korea and EU-CARIFORUM Agreements are silent on this issue.

Finally, as elaborated above, I propose the concept of *substantive equilibrium* specific to the normative regimes utilized in this thesis – the FTAs and EU internal norms. By substantive equilibrium, I mean moving the provisions on development (public health) and other references to the TRIPS flexibilities in the FTAs and relevant EU secondary norms from the Preamble or ‘general provisions’ to the substantive part of the treaty or legislation. What this means is elevating the said provisions from an ‘optional’ status to ‘mandatory’ one. This should grant the said provisions equal weight and effect in implementation (through the laws and regulations adopted at state level) and interpretation as the others in the main body of the treaty. This way, national courts, decision makers and arbitration panels in the case of dispute settlement would be forced to accord the same level of respect and gravity to which they apply the substantive provisions on IP to those on development and related provisions. This would represent a shift from the present latent nature of the provisions on development in the FTAs, to making them more explicit.

There are instances of this suggestion in the FTAs already. When setting standards for the protection of data of certain regulated products, the EU-Peru-Colombia FTA exceptionally allows Parties to regulate ‘exceptions for reasons of public interest, situations

8 Kur and Grosse Ruse-Khan, above n 305, p. 31.

of national emergency or extreme urgency, when it is necessary to allow access to those data to third parties'.⁹ Similarly, the section on patents in the EU-Korea FTA includes a title on patents and public health – that allow Parties the freedom to rely upon the Doha Declaration in interpreting and implementing the rights and obligations under that Sub-section.¹⁰ Since the FTAs are binding on their Parties, individuals may invoke directly effective norms from the FTAs, and national courts and public authorities would be obliged to apply them. In addition to having interpretive and direct effect, international treaties may enable judicial review of EU secondary norms such as the EU Customs Regulation and Trademark rules. Another good reason for such a proposal, I have argued, is that the EU has a primary legal obligation to meet other core objectives in its external trade policy.

As indicated earlier, this proposal does not seek to call for the abrogation of TRIPS or the IP chapters of the FTAs. Instead, what it seeks to do is to prospectively serve as a guide for future negotiations (and drafting) of the IP chapters in the FTAs and EU secondary legislation in a way that reduces the incidence of contradictions between the provisions on IP and public health, or, the latent nature of the provisions on development. Understandably, this concept has been proposed because the ferment for norm formation in IP is unlikely to abate due to its place as a high-stakes commodity in the knowledge economy. The MFN and NT principles have been found not to be particularly helpful in the context of the FTAs either; there is therefore the need to resort to devising alternative principles that may leverage the status quo.

All in all, an important lesson to be learnt in the context of the discussions in this thesis is that, trade rules and IP laws are developed to promote economic growth and incentivize innovation, and not development in the broadest sense. They do better serving that purpose and not vice versa. In recent times, however, IP has been forced to encounter development. Yet, the policy levers within IP law to address the core concerns of development are latent. Thus, despite efforts to place developmental objectives in the broader context of IP policy, the human capability approach to development proposed by Amartya Sen, which is based on the idea that a society is not fully developed until certain basic needs are provided for all of its people, has not yet informed internationalization of IP. The imperative to respect patents on health technologies, and other forms of IP rights enumerated in this thesis, could in certain instances, create obstacles to the public health objectives of developing countries. To curtail this, the IP policy of the

9 See Chapter I, Section C.1 above.

10 Ibid.

EU must aim to promote diversity and a fair balance in line with the proposals of this research. Until this is achieved, the issue of access to medicines will continue to be on the table.

