The impact of international global governance and regulatory frameworks in trade

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All errors remain the authors' own.

Executive Summary

This report forms part of the FRAME's project stream of research which analyses how human rights are integrated into EU policies on trade and development, and to what extent this is consistently and coherently translated into the EU's policy framework and implementing structures. Among other objectives, this stream of research aims to assess the extent to which the EU, through its trade and development cooperation policies, can contribute to human rights protection and promotion abroad. Previous deliverables under this work package have mapped out the EU's policy toolbox for human rights promotion in trade and development (D 9.1) and have assessed whether the EU system of ex-ante and ex-post impact assessments takes into account human rights concerns in trade and development policies, and what these impacts are (D9.2). The present report seeks to look at the potential of EU trade policies, which are explicitly designed to leverage human rights as per the EU's general commitment to promote human rights in all its policies, to actually act as a force for 'good global governance' and help protect third countries against an erosion of basic rights, such as access to food, to health, or to housing.

The EU trade policies' contribution to good global governance for human rights is analyzed through two extensive case-studies located in different fields.

First, the report addresses the issue of forestry management and the human rights issues associated with illegal logging, against which the EU has been trying to act for more than a decade. In this context, this report analyses the implementation of the EU Forest Law Enforcement, Governance and Trade (FLEGT) programme in Ghana in order to assess the extent to which the EU is able to promote instruments of good forestry governance through innovative bilateral instruments such as Voluntary Partnership Agreements and various systems of legality verification.

The report finds that FLEGT and the system of VPAs based are characterized by their voluntary character and the deference they show towards domestic legislation, up to the point that the focus on human rights may give way to mere legality verification. The outcomes of the system, though it is still quite young and more reliable data will only be available in a few years, are mixed, and its effectiveness as a driver of good governance specifically for human rights is not clear. The most obvious human rights benefits which our case-study uncovered had to do with so-called procedural rights, namely participation rights in the system, whereas the impact on substantive rights will only emerge after the new forestry legislations promoted by the scheme will have produced some effects.

The conclusion which this report suggests based on the case-study on FLEGT in Ghana is that such a unilateral trade policy seeking to leverage human rights in a sector in which the EU does not have a direct stake may raise doubts as to its effectiveness in countering the erosion of basic rights, owing to a number of factors.

Second, this report seeks to uncover the role of the EU in soothing the tensions which may exist between intellectual protection of pharmaceutical products, which grant marketing exclusivity to their manufacturers, and the human right to health which commands affordable access to medicines. This report addresses this question by looking at intellectual property chapters included in free trade agreements negotiated by the EU. In particular, this second case-study assesses the extent to which these treaty provisions achieve the correct balance between intellectual property

rights and the human right to health, or whether it favours one or the other interest. This chapter is illustrated with an extensive case-study of the place of intellectual property issues in the negotiations between the EU and India, which have widely diverging views on these questions.

The research finds that inclusion of IPR in EU FTAs is in turn characterized by its binding character, and by its distrust of the legal frameworks of EU partner countries. IPR chapters are aimed to ratchet up the level of IPR protection which EU IP owners will enjoy abroad. The direct stake which the EU has in this ratcheting up of standards plays a large role in how the EU views its role as a 'force for good global governance' for human rights, and these interests may make the EU lose sight of the balance to achieved between IPR and human rights, as was demonstrated through our study on the protection of pharmaceutical patents and access to medicines: the EU is attempting to use trade agreements to improve the former in ways which are likely to hurt the latter.

The conclusion which this report suggests in this regard is that the EU may at times risk undermining human rights protection when it pursues its trade policies with too little regard for the balance which must be achieved between its direct interests and the protection of human rights. In the case of access to medicines which we have presented, this lack of balance is only countervailed by the fierce resistance of partner countries such as India, and to other activities which the EU is conducting in non-trade areas to the effect of ensuring protection of the right to health despite the undermining effects of IPR.

List of abbreviations

ACTA	Anti-Counterfeiting Trading Agreement
AP	FLEGT Action Plan
BTIA	Broad-based Trade and Investment Agreement
CAR	Central African Republic
CBD	Convention on Biological Diversity
CHRAJ	Commission on Human Rights and Administrative Justice
CIFR	Centre for International Forestry Research
CL	Compulsory Licensing
COM	European Commission
CPP	Convention People's Party
CSO	Civil Society Organisations
DDS	Due Diligence System
DG DEVCO	Directorate-General for International Cooperation and Cooperation
DG ENV	Directorate-General for Environment
DPCO	Drug Price Control Order
DRC	Democratic Republic of Congo
EC	European Council
EIA	Environmental Investigation Agency
EU	European Union
FAO	Food and Agriculture Organisation of the UN
FCCC	Framework Convention on Climate Change
FCTC	Forestry Commission Training Centre
FF	Forest Forum
FLEGT	Forest Governance Enforcement and Trade
FSD	Forestry Service Division
FTA	Free Trade Agreement

GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
HRW	Human Rights Watch
IA	Independent Auditor
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IDEG	Institute for Democratic Governance
ILO	International Labour Organisation
IP	Intellectual Property
IPAB	Intellectual Property Appellate Board
IPR	Intellectual Property Rights
IUCN	International Union for the Conservation of Nature
JIC	Joint Implementation Committee
JMRM	Joint Monitoring and Review Mechanism
LAS	Legality Assurance System
LDC	Least developed country
LI	Legal Instrument
MFN	Most Favoured Nation
MLNR	Ministry of Land and Natural Resources
NCCE	National Commission on Civic Education
NDC	National Democratic Congress
NGO	Non-Governmental Organisation
NMC	National Media Commission
NMP	National Manufacturing Policy
NPP	New Patriotic Party
NT	National Treatment
OASL	Office of the Administrator of Stool Lands

OSIWA	Open Society Initiative West Africa
OSJI	Open Society Justice Initiative
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Substances
RMSC	Resource Management and Support Centre
RoC	Republic of Congo
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TIDD	Timber Industry Development Division
TLAS	Timber Legality Assurance System
ToR	Terms of Reference
TRF	Timber Rights Fee
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRMA	Timber Resource Management Act
TUC	Timber Utilization Contract
TUP	Timber Utilization Permit
TVC	Timber Validation Committee
TVD	Timber Validation Division
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNCED	UN Conference on Environment and Development
UNCTAD	United Nations Conference on Trade and Development
USTR	United States Trade Representative
WD	Wildlife Division
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization
WTS	Wood Tracking System

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I. General Introduction

This report forms part of the FRAME's project stream of research which analyses how human rights are integrated into EU policies on trade and development, and to what extent this is consistently and coherently translated into the EU's policy framework and implementing structures. Among other objectives, this stream of research aims to assess the extent to which the EU, through its trade and development cooperation policies, can contribute to human rights protection and promotion abroad. Previous deliverables under this work package have mapped out the EU's policy toolbox for human rights promotion in trade and development (D 9.1) and have assessed whether the EU system of ex-ante and ex-post impact assessments takes into account human rights concerns in trade and development policies, and what these impacts are (D9.2). The present report seeks to look at the potential of EU trade policies, which are explicitly designed to leverage human rights as per the EU's general commitment to promote human rights in all its policies, to actually act as a force for 'good global governance' and help protect third countries against an erosion of basic rights, such as access to food, to health, or to housing.

The EU trade policies' contribution to good global governance for human rights is analyzed through two extensive case-studies located in different fields.

First, Chapter II addresses the issue of forestry management and the human rights issues associated with illegal logging, against which the EU has been trying to act for more than a decade. In this context, this report analyses the implementation of the EU Forest Law Enforcement, Governance and Trade (FLEGT) programme in Ghana in order to assess the extent to which the EU is able to promote instruments of good forestry governance through innovative bilateral instruments such as Voluntary Partnership Agreements and various systems of legality verification. This case-study benefited from field study in Ghana, and was enriched by a significant number of interviews.

Second, Chapter III seeks to uncover the role of the EU in soothing the tensions which may exist between intellectual protection of pharmaceutical products, which grant marketing exclusivity to their manufacturers, and the human right to health which commands affordable access to medicines. This report addresses this question by looking at intellectual property chapters included in free trade agreements negotiated by the EU. In particular, this chapter assesses the extent to which they achieve the correct balance between intellectual property rights and the human right to health, or whether it favours one or the other interest. This chapter is illustrated with an extensive case-study of the place of intellectual property issues in the negotiations between the EU and India, which have widely diverging views on these questions.

The report closes with short concluding remarks.

II. FLEGT in Ghana: legality, sustainability and human rights

A. Introduction

The international community has increasingly come to recognise the considerable human rights implications of forestry policies and the impact of illegal logging. Defined as the harvesting, processing and trading of wood in violation with the laws of the country of origin, illegal logging generally occurs in a context characterised by broader governance challenges, often including corruption, a lack of rule of law and social conflict. As a result, illegal forest activities and the associated spillover effects of corruption often result in a variety of human rights violations, including labour rights and rights to land, food and livelihoods. International human rights organisations, as well as local CSOs have become increasingly vocal about the human rights implications of illegal and unsustainable forest activities while producer countries and the international community have made important progress over the past decade to curb illegal forest practices. Despite international efforts however, Illegal logging and the associated trade remain rampant, causing environmental damage, loss of biodiversity and government revenue, while fracturing the livelihoods of vulnerable communities living in and off the forest (Hoare, 2015, viii).

Disappointed with the lack of binding multilateral measures to regulate forest governance, and in addition to the use of private, voluntary, certification regimes, progressive international actors have increasingly started to focus on bilateral approaches based on enforcing domestic legislation and capacity building in timber-exporting countries (Beke et al., 2014 48). Arguably the most ambitious initiative in this regard is the EU's 2003 Action Plan on Forest Law Enforcement, Governance and Trade (FLEGT). FLEGT aims to tackle illegal timber and the associated trade by using a combination of demand- and supply-side measures, respectively focused on banning illegal timber from the EU market, while supporting forest governance reforms and law enforcement in timber-producing countries. At the heart of the action plan is a system of Voluntary Partnership Agreements (VPA), bilateral trade agreements which frame the legal, institutional and governance reforms required to ensure that all timber exports from VPA countries to the EU are legal, in turn allowing them to enjoy preferential and exclusive access to the EU market.[1]

Over the past decade, legality verification has gained widespread global support from different stakeholders as a means to tackle the problem of illegal logging, and has been lauded for its novel, uniquely iterative and pragmatic way of regulating. As the world's most advanced multi-level legality verification regime, FLEGT has successfully managed to 'govern through trade' among supranational, national, and sub-national levels, between private and public actors, and to reorient the international community towards promoting –rather than challenging- domestic governance and law enforcement (Nathan et al., 2014: 4). Cashore and Stone have argued in this regard that FLEGT owes much of its potential to its ability to align support from so-called grand coalitions of 'bootleggers and Baptists', bringing environmental groups and businesses interests together, for very different, self-interested reasons, in support of the same policy intervention (Cashore and Stone, 2012: 14). Others, like Overdest and Zeitlin see FLEGT as the key driver behind an emerging experimentalist transnational regime for sustainable forest governance, in the sense that FLEGT integrates and coordinates some of the interconnected but overlapping and sometimes competing sets of

[1] Only FLEGT licensed timber from VPA countries can enter the EU, while timber from non-VPA countries is subjected to considerable due diligence requirements.

regulatory regimes that have long characterised global regime complexity on the issue of forest governance (Overdest and Zeitling, 2014: 6).

Regardless of its merits however, a number of design issues have been identified as well, which – if not addressed with caution- could hamper FLEGT's long-term effectiveness and generate negative effects in terms of social sustainability. Among other issues beyond the scope of this contribution, widespread concerns have been voiced about whether legality verification risks undermining different types of legal pluralism, including traditional and cultural modes of governance. Notably, a formalised approach to law, such as the one proposed under FLEGT, could negatively affect small scale operators, often working in a legal grey zone between the formal and informal economy, as well as local communities in general. Whereas FLEGT explicitly aims to improve governance and strengthen access to resources and participation among vulnerable communities, legal formalisation and standardisation often tends to favour the interests and administrative capacity of powerful commercial interests over those of local SMEs or indigenous cooperatives (Desai, 2013: 153). More fundamentally perhaps, others have pointed out that, whereas legality verification can indeed be a good first step toward sustainable forest management, legality in itself is no guarantee of sustainability, and setting the bar too low when defining legality risks institutionalising unsustainable practices, in particular those of a social (rather than a purely environmental) nature, touching upon the human rights of local communities (Buhmann and Nathan, 2012:58).

This case-study aims to contribute to the above discussion, focusing on the potential impact of the FLEGT programme on human rights and social sustainability, drawing on Ghana as a case-study. Whereas FLEGT policy documents explicitly seek to achieve a number of social issues related to sustainable forestry governance, there are but few formal requirements for the legality definitions under a VPA to comply with in terms of human rights and social sustainability. As a result, much depends on how domestic actors design and implement their systems of legality verification, and in how far local communities directly affected by these systems have a voice in the process. In order to assess the potential impact of the VPA on local communities and their rights, we take a two-pronged approach, focusing on the following two research questions, notably i) whether the VPA creates the political space for community actors to engage in the VPA process and have their voice heard; and ii) in how far do domestic legal and policy reforms under the VPA process take into account, and accommodate, the rights, needs and ambitions of local forest communities?

Ghana presents a particularly interesting case-study since it was the first country to agree a VPA with the EU, and the only one to do so before the adoption of the EU Timber Regulation (EUTR) in 2010. As the first country to negotiate and implement a VPA, the experiences in Ghana later significantly informed and shaped the VPA process in the VPA countries that followed afterward. Finally, whereas Ghana's VPA process has been lauded for its inclusiveness and genuine ownership among a broad base of domestic actors, the particular political economy of its forest sector has raised a number of interesting reform and implementation challenges, which are worth discussing from a human rights point of view.

The findings presented below are based on desk research of primary and secondary sources, as well as an array of some 25 interviews conducted in Accra and Kumasi as well as over Skype. Primary sources include both EU, multilateral and Ghanaian policy and legislative documents, while secondary sources cover a variety of academic, policy and political economy literature. Interviewees

in Accra and Kumasi included officials from the EU Delegation to Ghana, representatives of the Ghanaian NGOs and research centres involved in the FLEGT process, a domestic lumber trade association representing small- and medium-size timber companies, the sustainability manager of a large, export-oriented, timber company in Kumasi, multiple people within the Forestry Commission and a former Ghanaian diplomat to the EU. In addition, we held interviews over Skype with a limited number of international experts involved in the FLEGT program in Ghana, including at the European Forestry Institute (EFI). In order to protect the anonymity of our interviewees however, statements from interviews will not be attributed to particular people or, where deemed necessary, their affiliation.

The case-study proceeds over the following four parts. Part **Errore. Il segnalibro non è definito.**. sets out the theoretical and policy framework in which FLEGT was developed and implemented, followed by a detailed description of its regulatory and institutional features and how these have been operationalised over time. Chapter 2 then introduces Ghana as a case-study, including a profile of its political economy and how these dynamics relate to the forest sector. Chapter two further proceeds with an analysis of the key features of the VPA process so far, focusing on a number of key achievements and outstanding challenges. The third chapter looks into the questions arising from FLEGT's legality approach with regard to social sustainability and human rights, focusing in particular on the experiences so far in the Ghanaian context, notably with regard to stakeholder involvement and the impact of legal and policy reforms on local forest communities and their livelihoods. Finally, chapter five concludes by listing how some of the lessons learnt from the Ghanaian VPA could inform an improved governance reform process for social sustainability and the human rights of vulnerable forest communities.

B. Introducing FLEGT as a transnational experimentalist regime

1. Theoretical framework: regime complexity and experimental governance

Many of today's international institutions were created at the end of World War II. They were issue-specific, state-cantered and enjoyed a de facto monopoly in a given policy field. The creation of the United Nations (UN) and its specialized agencies, the Bretton Woods Institutions and the General Agreement on Tariffs and Trade (GATT) established a number of international regimes – sets of rules, norms and practices governing particular issue areas – and facilitated a hierarchical concentration of power among like-minded member states. Ever since, these institutions and their respective jurisdictions have constituted a comprehensive, hierarchical system of global governance, designed to address the challenges of the 20th century (Keohane, 1984).

Such global challenges at the time included global security and post-war reconstruction, socioeconomic development, environmental protection and global economic integration. From the 1990s onward, the prospect of coherent and comprehensive global governance became ever more challenged as focus areas for global cooperation changed. Efforts to establish global trade and climate regimes stagnated and issue-specific global institutions proved incapable of dealing with the opportunities and challenges raised by the increasing interconnectedness of today's global challenges. Notable examples include the global interdependency in financial, energy and food markets. Established regulatory regimes fragmented and, at times, were openly challenged, particularly in view of changing demographic and economic imbalances and technological

innovation. As a result, Multilateral negotiations in several fields are at a stalemate and concluding internationally binding agreements -let alone ensuring their enforcement- has become increasingly difficult (Bradford and Linn, 2007; Marx et al., 2015:1-4).[2]

In response to institutional inertia and political deadlock at the multilateral level, global governance has become ever more pluralist. New forms of regulation are rapidly being developed alongside traditional international law as countries, supranational institutions, as well as transnational corporations, civil society organizations and public-private partnerships are joining an unordered patchwork of regulatory regimes, be it legally binding or non-binding, public or private, situated at various levels of governance: multilateral, regional, bilateral and informal (Hale and Held, 2011).

This evolution from multilaterally agreed, single-issue regimes, to a proliferation of novel, often multi-stakeholder, initiatives has been particularly apparent in areas concerning sustainable development and environmental protection as global governance in this area is widely recognized as fragmented, complex and often incoherent (Biermann et al., 2009: 21-23). Scholarship on International Relations has captured this trend under the concept of 'regime complexity', referring to a policy domain or issue-area characterized by partially overlapping, parallel and nested transnational agreements lacking hierarchical order. As a result, regime complexity has allowed actors to choose strategically from a variety of overlapping and often competing regimes, institutions and service providers, essentially engaging in what scholars call 'forum shopping' or 'regime shifting' (Betts, 2013: 69-70).

Since complexity implies overlapping and competing sets of regulations, institutions and jurisdictions, it often results in a fragmentation of international law and contributes to regulatory ambiguity. Where actors share similar preferences and interests, they will coordinate –after a transitory period of ambiguity- toward a clear(er) set of dominant rules. Whereas if interests diverge, actors tend to pick the regime or the interpretation that is most favourable to them and block attempts to clarify the rules, benefitting from a persistence of ambiguity. Because international regime complexity allows actors to select which rules to follow, implementation politics end up defining which regimes or interpretations eventually gain dominance. Understanding the implementation politics of a regime, identifying which domestic actors stand to win or lose from a reform initiative, and which ones are able to influence regime interpretation and the relative prioritization among regimes, is therefore a fundamental prerequisite to establishing the desirable conditions for an international agreement to establish itself beyond reframing or reinterpretation (Meunier and Alter, 2009: 13-16).

One significant response to the regulatory stagnation at the multilateral level and the subsequent emergence of regime complexity in certain policy areas, has been the emergence of a new, 'experimentalist' type of governance, which consists of deliberatively temporary action-frameworks, prone to systematic comparison, peer review and self-correction. Whereas Meunier and Alter still assume that regime complexity eventually leads to either regulatory ambiguity or the eventual dominance of one rule or regulatory interpretation over the other, experimentalist governance offers a third way out. By assembling the interconnected bits and pieces from different regimes, a state of regime complexity offers a starting point to build a joined-up, flexible and adaptive

[2] Notable examples include the climate change negotiations, multiple failed efforts to establish a global forest governance regime and the stalling of the Doha Development Round (Marx et al., 2015).

international governance regime. As such, the scope conditions for 'experimentalist governance' are precisely the opposite of those for standard regime formation. Whereas traditional, comprehensive transnational regimes require either a convergence of interests and beliefs among actors, or a hegemonic power to impose its regime upon others, experimentalist governance stems from strategic uncertainty, notably conditions of disagreement and polyarchy. Where standard multilateral regimes cannot be established, regime complexity thus creates an opportunity for experimentalist types of transnational regimes with a different governance architecture. Rather than being established as a comprehensive, unified whole through conventional multilateral procedures, Overdest and Zeitlin identify a set of emergent pathways and causal mechanisms through which such experimentalist regimes can be assembled, piece by piece. Each pathway has a different starting point (public/private, national/international), follows different causal mechanisms, and operates at different levels (within and between separate regulatory regimes), though all lead to the emergence of a similar experimentalist regime architecture (Overdest and Zeitling, 2014: 25-43).[3]

As defined by de Búrca et al. (2013), experimentalist governance describes 'a set of practices involving open participation by a variety of entities (public or private), lack of formal hierarchy within governance arrangements, and extensive deliberation throughout the process of decision making and implementation'. Ideal-type experimentalist regime designs generally involve a multi-level architecture based on five deliberation-fostering steps linked to one another in an iterative process:

- First, stakeholders reflect upon a broadly shared understanding of a common problem.
- In a second phase, this shared understanding results in the articulation of an open-ended framework of objectives.
- A third step consists of local units translating and pursuing these objectives in a context-specific manner.
- Fourth, to balance the relative discretion enjoyed by these local units, their performance is monitored through regular reporting mechanisms and peer reviews comparing their results to those of other local units. Such monitoring then informs possible corrective measures to ensure good progress against an agreed set of indicators.
- Fifth and finally, both goals and practices are periodically and routinely re-evaluated and, where necessary, revised in response to the aforementioned findings of lower-level review processes.

Because of their reflexive, self-revising and adaptable design, experimentalist governance architectures are considered to be well-suited to operate in today's volatile and changing policy environments, particularly in policy- or issue-areas where the establishment of a multilateral, ex-ante designed, regime is deemed unfeasible. Transnational experimentalist regimes often operate in combination with a penalty default to incentivize cooperation by sanctioning non-cooperation, generally by imposing a comparatively less beneficial regime (de Búrca et al., 2013: 16; Sabel and Zeitlin 2008 and 2010).

The following section discusses how the lack of a comprehensive, legally-binding global forestry regime gave rise to a variety of voluntary certification systems, designed to hold companies

[3] These ideal-type trajectories are not exhaustive; neither are they mutually exclusive as multiple pathways can be combined in specific cases.

accountable, and how later, focus shifted toward forestry law enforcement initiatives. EU's transnational experimentalist Forest Law Enforcement, Governance and Trade (FLEGT) programme launched by the EU in 2003 is arguably the most ambitious in that latter category.

2. Regime complexity in forestry management

Efforts to establish a global forestry regime date back to the 1980s and culminated in the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro. Contrary to the successful adoption of global agreements on climate change mitigation and biological diversity however, – respectively the Framework Convention on Climate Change (FCCC) and the Convention on Biological Diversity (CBD) - attempts to forge a transnational forestry treaty at the Rio Earth Summit failed amidst contesting views alongside a strong North South divide (Wang, 2001:1). From the outset, forest negotiations were seen as part of broader discussions on international trade and economic development, pitting Northern states like the US and Canada against developing countries led by Malaysia and India. The latter perceived global forest governance as an impediment to their own economic development and as a hidden form of protectionism for the developed markets of the global North. As a result, the Rio Summit produced nothing but declaratory principles, and despite various attempts since, there is still no comprehensive, legally binding, multilateral, instrument on forest management- a stagnation which Bernstein and Cashore (2004, 47-48) largely attribute to the persistent challenge of reconciling free trade, development and forest protection.

While the Rio Earth Summit failed to establish a multilateral convention on forestry, Agenda 21, the Rio Forest Principles and the UN Intergovernmental Panel of Forests – which are all non-binding multilateral instruments – did put the objective of combating deforestation high on the international agenda. As a response to the vacuum created by the lack of a global consensus, environmental and social NGOs, industry associations and private foundations developed a variety of voluntary certification initiatives, fair-trade standards and eco-labelling schemes. The first forest certification organisation to arise was the Forest Stewardship Council (FSC), established in 1993. Together with the Programme for Endorsement of Forest Certification (PEFC), an umbrella organisation which endorses other, mostly European, forest certification schemes, the FSC today constitutes the largest scheme of its kind (Rametsteiner and Simula, 2003: 87-90). In total, certified forests cover some 439 million ha., 11% of the world's forest area that is. In terms of timber volume, an estimated 527 million m3, or 30% of the total roundwood production, comes from certified forests (UNECE and FAO, 2015: 17). The global coverage of private forest certification schemes, including chain-of-custody certificates that audit the entire supply-chain, has however been slowing down over the past five years, and coverage is heavily regionally dispersed. With slightly less than 90% of the globally certified area situated in the Northern Hemisphere, the global South's share of certified acreage is limited. While private certification offers a creative and promising response to the absence of a multilateral forest regime, their limited introduction in developing countries - where deforestation and illegal logging are most rampant – hampered their effectiveness in tackling unsustainable forest practices worldwide (UNECE and FAO, 2015: 15-18).

In addition to voluntary certification schemes, the international community increasingly focused on bilateral approaches based on enforcing forestry legislation and capacity building in timber-producing countries. Indeed, whereas voluntary certification schemes focused on holding companies accountable, using consumer awareness to generate demand for sustainable wood products,

observers witnessed a shift around the early 2000s, as NGOs, governments and international organisations increasingly focussed on combatting illegal logging, notably by holding national governments accountable to improve their enforcement of domestic forest legislation. A first public statement about the importance of timber legality was made at the 1998 G8 summit in Birmingham when the G8 countries adopted an Action Program on Forests which acknowledged the need for more information on the extent of the problem of illegal logging, before moving to countermeasures.[4] To do so, an expert working group was set up after Birmingham and reported its findings at the 2002 G8 Summit in Kananaskis, offering recommendations for the identification and verification of legal production, timber tracking, labelling and certification, in combination with development assistance for capacity building and market access mechanisms to encourage forestry governance reform (G8, 2002). In a similar vein, the World Bank began organising regional Ministerial Conferences on Forest Law Enforcement and Governance (FLEG), first in 2001 in Bali for the East Asia and Pacific region, and later also for the African, European and North Asian regions. In hindsight, the Bali Ministerial declaration represented a major advance in rallying high-level political support from producer-countries, to reinforce the rule of law in the forest sector, effectively joining 'governance reform' and 'law enforcement' to tackle illegal logging and the associated trade. Additional global momentum further generated from the second session of the UN Forum on Forests (UNFF-2), which provided a 'Ministerial Message' to the World Summit on Sustainable Development (WSSD), held in 2002 in Johannesburg, calling for immediate action on domestic forest law enforcement and in international trade in forest products (Guertin, 2003: 1-3). As such, the WSSD's Plan of Implementation included a commitment to '[t]ake immediate action on domestic forest law enforcement and illegal international trade in forest products', 'with the support of the international community, and provide human and institutional capacity-building related to the enforcement of national legislation in those areas' (WSSD, 2002:29).

This new approach, focusing on domestic forest governance and capacity support linked up with the broader governance agenda of international development cooperation, which emerged during the late 1990s. Following this new development paradigm, budget support and sector-based programmes gained ground over project-based aid. In order to support decentralisation, national ownership and good governance donors focused on providing capacity support to improve governmental functioning in order to allow them to fulfil public services and enforce the rule of law. In the forestry sector as well, international NGOs increasingly acknowledged the virtues of promoting capacity building and learning within tropical countries since such efforts, unlike certification, contributed to strengthening national sovereignty, notably in terms of domestic forest policy development and implementation. As a result, European development agencies began implementing projects aimed at capacity building and fostering policy learning to share ideas and resources on sustainable forestry management (Cashore and Stone, 2012: 4).

3. FLEGT as an experimentalist regime

Arguably the most ambitious international initiative to come out of the post-Bali momentum was the EU's Forest Law Enforcement, Governance and Trade (FLEGT) Action Plan, launched in May 2003. Ever since, FLEGT, through its interaction with public timber legislation and private legality and sustainability standards, has become what Overdest and Zeitlin coined 'the core of an emergent

[4] The five focus areas were: i) monitoring and assessment; ii) national forest programs; iii) protected areas; iv) private sector; and v) illegal logging.

experimentalist governance architecture'. Based on an innovative, multi-stakeholder and dynamic combination of market measures –both public and private- capacity support and governance reform, FLEGT has arguably consolidated an increasingly homogeneous international forest governance regime at a time when the sector was characterised by a myriad of actors and regulatory frameworks (Overdest and Zeitlin, 2014: 6).

The two sections below will discuss the scope and objectives of the FLEGT programme as a policy process, analyse what can be described as the distinctively experimentalist features of its implementation design as well as provide a state of affairs about the implementation process so far.

4. The EU FLEGT Action Plan

Backed by a strong international commitment to address illegal logging, EU officials engaged in a highly inclusive process of workshops and stakeholder consultations to draft the EU FLEGT Action Plan (from here on referred to as the Action Plan or AP). The AP was adopted into law by the European Council in November 2003, welcomed as 'a first step to tackle the urgent issue of illegal logging and its associated trade in a collaborative and coordinated way with consumer and producer countries, the private sector and other stakeholders'. The Council further acknowledged the need for FLEGT to be addressed 'within the framework of sustainable development, sustainable forest management and poverty reduction, as well as social equity and national sovereignty' (EC, 2003: par. 4 and 6).

The Action Plan serves as the umbrella policy framework for a set of regulatory and policy instruments. As such, it provides the broad outlines of a system that is to be developed over time, suggesting a package of measures relating both the demand- and supply side of the trade in illegal timber. Understandably, given its all-encompassing nature, the AP's objective is formulated in a rather general manner, as 'to address the growing problem of illegal logging and related trade'. This overarching objective implies action on three fronts, notably i) to reduce the consumption of illegally harvested timber in the EU; ii) to improve forest governance in producer countries; and iii) to contribute to the development of a multilateral forest governance regime. Across these three fronts, the AP comprehends a hierarchy of overlapping and interlinked objectives. Yet, rather than presenting a clearly defined project management, log frame and timeline, the AP aims to set in motion a process in seven action areas, where the Union and its Member States (MS) are to develop the necessary legislative and/or policy-initiatives.

1. **Support to timber-producing countries.** Including i) the promotion of equitable and just solutions to ensure that interventions to address illegal logging –particularly enhanced law enforcement – do not harmfully affect or exclude local people and their access to forest resources; ii) the promotion of legality verification systems, iii) transparency measures; iv) donor support for capacity building; and v) policy reform to update, clarify and simplify the often outdated, top-down legal forestry frameworks in many forest rich countries.
2. **Trade in timber.** Including i) the promotion of multilateral forestry regime, notably by engaging with other major timber consumers to explore ways to work together towards a more comprehensive framework against illegal timber; ii) the launch of a voluntary licensing scheme to ensure that only legal timber is imported from 'FLEGT partner countries'; and iii)

additional legislative measures to control imports of illegally harvested timber into the EU, notably through legal changes at the MS level.

3. **Public procurement.** A revision of EU public procurement legislation in order to take into account both sustainability and legality considerations. Here again, the role of EU MS legislative action is considered key.
4. **Private sector initiatives**. The EU will seek to encourage EU private sector actors to work with companies in timber producing countries - based on principles of corporate social responsibility and voluntary codes of conduct for sustainable timber harvesting and processing.
5. **Financing and investment.** To encourage responsible investment by banks and financial institutions, including by taking into account social and environmental impacts when conducting due diligence.
6. **Supporting the Action Plan with existing legislative instruments.** Encourage EU Member States (MS) to elaborate their anti-money laundering legislation to include (revenues from) illegal logging.
7. **Conflict timber.** To contribute towards an international definition of conflict timber and to discuss and accommodate the role forests can play in the context of conflicts, including in the EU's development cooperation programmes and in its FLEG work with MSs, other donors and timber-producing countries.

Together, the above listed action areas lay down the broad strokes outlining a system based on, on the one hand, the adoption of voluntary, legally-binding, bilateral trade agreements with timber-exporting countries – in turn grounded and conditional upon the development of a domestic legality verification systems- and on the other hand, internal regulatory measures to drastically cut the import and consumption of illegal timber in the EU (COM, 2003).

Coordinating the implementation of this AP however, has been a complex and challenging task for EU officials and the broader FLEGT community worldwide. While the overall implementation of the Action Plan is to be done jointly by the European Commission, the EU Member States and partner countries engaged in a Voluntary Partnership Agreement (VPAs), it is mainly the Commission who is in the driving seat – at least on the EU side that is. Notably, the Commission's Directorate-General for International Cooperation and Development (DG DEVCO) and DG Environment (DG ENV) have been mandated to negotiate VPAs, while other DGs are also involved albeit to a much lesser extent and based on ad hoc needs rather than a systemic cooperation (TEREA, 2016: 28).

VPA negotiations in particular have been a time- and resource-consuming undertaking. Since VPAs are essentially trade agreements, the EU mandate to negotiate them rests with the Commission, who has geographically distributed the burden, putting DG International Cooperation and Development (DG DEVCO) in charge of the negotiations with African countries while DG Environment (DG ENV) takes care of the negotiations with Asian countries. Finally, negotiations with the Latin American countries have been split between the two DGs, though distributing those countries remains an ongoing discussion it seems (Interview EFI FLEGT Facility, 23 August 2016). Beyond the negotiation of VPAs, both DGs are involved in more general support measures to help shape and implement the AP. Notably, DG DEVCO is responsible for the mobilisation and

management of development aid to support initiatives aimed at curbing the production of, and trade in, illegal timber in producer countries. DEVCO further leads the so-called FLEGT Expert Group (formerly called the Ad Hoc Working Group), which is in charge of coordinating EU MSs and key stakeholders in a uniform implementation of the EU Timber Regulation (EUTR) and other FLEGT Regulations.[5][6] Meanwhile, DG ENV as well is responsible for the implementation of the EUTR and leads the FLEGT committee, which considers comitology issue, as well as the general implementation of the demand side measures stipulated in the EUTR.[7] Overall, only a small number of around five people from DG DEVCO and another four within DG ENV work on FLEGT full-time (TEREA et al, 2016: 28-29). As VPAs move from the negotiation into the implementation phase, their follow up shifts somewhat, depending on a country-by-country basis. While VPA negotiations are generally heavily top-down and lead by headquarters, it is often up to the EU Delegations (EUD) in the respective partner country to manage their implementation and administer support programmes, albeit still with the support and guidance from headquarters. Such a shift in responsibility has at times been rather challenging for some of the EUDs since VPA processes can be quite burdensome and a transfer of responsibilities in that regard did not always come with accompanying resources (interview EFI FLEGT Facility, 23 August 2016).

Before discussing the AP's two-fold implementation structure, it is worth stressing that the implementation of FLEGT, as an open-ended policy strategy, continues to be subject to change and has been a unique, though at times challenging, experience for many of the people involved. Apart from the legal regulations establishing the FLEGT licensing scheme (EC, 2005 and COM, 2008 – see fn. 5) and the European Timber Regulation (EUTR, 2010), formal guidance on how to implement the AP and its two main instruments (discussed below) is somewhat limited. For VPAs in particular, guidance is largely based on a series of informative Briefing Notes published by the European Commission. VPAs therefore draw heavily on the learning by doing and a dynamic exchange of expertise and experiences across countries and regions. Beyond a number of broad and relatively flexible mechanisms for engagement and implementation, VPA processes thus rely on implementers to work creatively and experimentally to tailor these guidelines to local needs and circumstances. As such, Commission staff, usually project managers who are used to working with time-bound, clearly defined objectives and benchmarks, initially found it challenging to comprehend the iterative approach of FLEGT as a political process (TEREA et al, 2016: 26; interview EFI FLEGT Facility, 23 August 2016).

[5] The Commission Expert Group on EU Timber Regulation and the Forest Law Enforcement, Governance and Trade (FLEGT) Regulation (E03282), available online: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailandgroupID=3282

[6] In addition to the EUTR (see below), the legal basis for FLEGT is based on a Council Regulation adopted in 2005, establishing a FLEGT licensing scheme for legal timber, and an Implementing Regulation issued by the Commission in 2008. Together, they stipulate the rules to control timber imports into the EU from VPA countries.

[7] The comitology-system consists of some 250 comitology committees which oversee the delegated acts implemented by the European Commission. Composed of representatives of the MSs and chaired by the Commission, these committees are mandated to regulate certain delegated aspects of the secondary legislation adopted by the Council and, in case of co-decision, the European Parliament. Some 2600 measures are adopted by comitology committees each year (ECA, 2010: 9).

5. Implementation structure

To kick off the FLEGT process as envisioned under the Action Plan, the Commission identified a set of 'next steps' for the Council and the European Parliament to take the Plan forward, notably by establishing a three-pronged implementation structure based on i) FLEGT Voluntary Partnership Agreements with timber producing countries; ii) an EU Timber Regulation that shields the EU market from illegal timber imports and requires due diligence from operators - including complimentary support measures from MSs to identify relevant national legislation which could contribute to addressing the issue of illegal logging; and iii) the promotion of multilateral cooperation and private and public initiatives aimed at curbing illegal logging and the associated trade (TEREA et al., 2016: 27).

Given our focus on in-country experiences with the implementation of the FLEGT VPA, the initiatives undertaken under the latter component, notably the one concerning multilateral and private initiatives, would go beyond the scope of this paper. The two sub-sections below therefore focus on the two 'legs' of the FLEGT implementation design. Notably, on the supply side, the negotiation and operationalisation of VPAs and, on the demand side, the 2010 EUTR. While it would take us too far to discuss the details of the implementation of each of these instruments, particularly the different ongoing VPA-processes in partner countries[8], a number of general, cross-country experiences can be identified about the identified achievements, challenges and shortcomings identified so far, focusing in particularly on FLEGT's experimentalist design features.

a) FLEGT Voluntary Partnership Agreements

Voluntary Partnership Agreements (VPA) are legally binding trade agreements between the EU and a timber-producing partner country or regional organisation. VPAs are designed to ensure that any wood exported from a VPA partner country is legally sourced and verified as such by a national legality verification system.

(1) Key provisions

Under a VPA, partner countries who successfully manage to develop a system to verify the legality of their timber exports gain EU market access through a green lane, exclusively reserved for FLEGT licensed timber imports into the EU market.[9] VPAs flow from the EU's explicit recognition, as discussed in the AP, that European consumers are responsible for significant quantities of wood imports from ambiguous origins. By ensuring the legality to timber imports of VPA partner countries, the EU thus aims to create economic incentives for improved forest governance. As such, the aim of VPAs goes beyond merely curbing illegal timber and the trade therein, VPAs are also meant to promote better poverty reduction and sustainable forest management. As the name suggests, VPAs are entirely voluntary - and thus WTO-compliant - yet once they are adopted they become legally binding to both of the contracting parties, committing them to verify the legality of timber exports to the EU. To do so, the FLEGT Action Plan and a series of Briefing Notes prepared by an expert group convened by the European Commission - eight in total - outline some key elements that are to be met and operationalised under each VPA before partner countries can obtain a FLEGT license that allows them 'green lane' access to the EU market (COM, 2007a: 1-2).

[8] For a detailed overview of the specifics of the six VPAs concluded so far, please see Bollen and Ozinga (2013), available online: http://www.fern.org/sites/fern.org/files/VPAComparison_internet_0.pdf

[9] CITES-licensed products also enjoy green lance access to the EU under the EUTR, see below on pg. 23.

First, at the core of each VPA is a **legality definition**, based on several legal and procedural requirements, which together constitute a comprehensive understanding of what can and cannot be regarded as 'legal timber'. Since FLEGT is based on the enforcement of existing national laws, the development of the legality definition is based, by and large, on a multi-stakeholder review of the domestic legal framework and it is the right of each partner country to decide what exactly should comprise its legality definition. However, additional considerations are to be taken into account in order for the existing legal framework to qualify as a comprehensive, yet workable, legality definition in the context of a VPA. First and foremost, the European Commission stipulates that the long-term objective of the FLEGT AP is to contribute to sustainable forest management. Any definition of what constitutes legally-produced timber should therefore include legislation covering the three pillars of sustainability, thus incorporating social, economic and environmental objectives. Defining 'legal timber' is thus likely to imply respect for harvest, tenure or usage rights, compliance with environmental, labour and community welfare legislation, as well as compliance with tax, import and export regulations, royalties and fees. Secondly, since these legality requirements are to be converted into a legality grid, including matching indicators to verify compliance, practicality of assessment and degree of contribution to the definition's objectives constitute another set of considerations to take into account. Since the legality definition features at the heart of a national legality assurance system (see below), the legality grid will serve as a performance tracker and thus requires clear, operational and objectively verifiable variables. In order to test conformity against the FLEGT licence, criteria and indicators are developed and field-tested to ensure their workability in practice. Moreover, operationalising a legality definition in practice may require significant capacity and training, and its criteria-stipulations should be comprehensible for governmental enforcement agencies as well as for forest operators and other stakeholders involved or affected. Third and finally, while the formulation of a legality definition is ultimately the responsibility of the partner country's government, the nature of the process will to a large extent decide its acceptability to different stakeholders, and ultimately it's also its traction in practice. As such, the Commission prescribes that 'the process to decide which laws should be included in a definition should generally involve wide consultation with all interested parties'. In some countries, developing a clear definition may be a challenging process due to inadequate, conflicting or inequitable laws, requiring multiple rounds of stakeholder consultation (COM, 2007b: 1-2; FERN, 2011: 7; Overdest and Zeitlin, 2014: 8).

Second, each VPA is based on the establishment of a **national timber legality assurance system** (TLAS) which ensures that the wood products destined for the EU market are produced from legally harvested timber in accordance with the national legislation, or from timber that was legally imported into the partner country, notably in conformity with the national legislation of that third country. On the EU side, a 2005 Council Regulation established a FLEGT licensing scheme for timber imports, which ensures that timber imports from VPA countries will be prohibited from entering the EU unless they are covered by a FLEGT license. It is worth noting however, that imports from non VPA-partner countries remains unaffected by such regulation (EC, 2005, Chapter II, Art. 4, Par. 1.). The issuance of such FLEGT licenses is done by a dedicated national authority, based on a TLAS consisting of regular checks and process tracing mechanisms intended to monitoring both forest operations and the chain of custody from harvesting to the point of export. Each TLAS includes five core components: i) a definition of what constitutes 'legal timber' (see above), translated into a 'legality grid', or matrix which identifies which national legislation is to be met, and verifiers and

indicators to test enforcement and compliance with that legislation; ii) a wood tracing system which monitors wood products through the value chain to separate legal from illegal timber in order to ensure that only the former will be exported or sold (to the EU); iii) a verification mechanism to check compliance with the legality definition, conducted by the government or a third party, and to protect the supply chain against illegally sourced timber entering the chain of custody; iv) details on the issuance of FLEGT licenses, allowing timber to be shipped to the EU; and v) provisions for an independent monitoring system, managed by a third party in order to provide credibility to the TLAS' functioning (COM, 2007c: 1; FERN, 2011: 8).

Third, all VPAs require the partner country at hand to engage the services of an **Independent Auditor** (IA) who reports its findings to the government and the EU at the Joint Implementation Committee (JIC, see below) at least twice a year.[10] It is the IM's responsibility to monitor the implementation of relevant procedures and control measures, particularly those relating to the implementation and effectiveness of the TLAS. Every IA is to be completely independent from the partner country government and its tasks, methodology, qualifications, reporting-requirements and institutional arrangements are set out in an annex attached to the VPA (Duffield and Ozinga, 2014: 16-17).

Finally, VPAs establish a **Joint Implementation Committee** which includes representatives of the European Commission and EU MSs and of the partner country government. The JIC, through annual dialogue and exchange of information oversees the implementation of the VPA. This generally includes monitoring and reviewing the functioning of the TLAS, mediating and resolving any disputes that may arise, reviewing annual progress reports on the VPA's implementation as well as the reports of the IA, assessing the VPA's social, economic and environmental impacts, and provide recommendations regarding the needs for capacity-building in view of a successful implementation of the VPA (COM, 2007a: 1).

Beyond legal and administrative frameworks, and the technical systems to enforce and verify their compliance, VPAs also recognise that national forest law enforcement is conditioned by the local context in which they operate. As such, VPAs take into account domestic and sectoral contextual elements such as ongoing forest sector initiatives, capacity constraints among the various stakeholders, traditional forest, harvesting and land rights, domestic and regional timber trade flows and the political economy of the timber industry as a whole. In order to take into account these local conditions, and manoeuvre among them, the Commission recommends including social safeguards 'to minimize adverse impacts on local communities and poor people by taking account of indigenous and local communities' livelihoods associated with forests'. Moreover, partner countries are generally encouraged to link FLEGT related issues to their poverty reduction strategies and VPAs should identify areas in need of technical and/or financial capacity support, including for government agencies and civil society. Regarding the latter, VPAs include provisions ensuring stakeholder involvement, including, but not limited to, regular stakeholder consultations during both the design and implementation of VPAs (EC, 2007a:1-2). In addition to these formal consultations, most VPA countries also established informal committees or 'VPA secretariats', which bring together

[10] It is worth noting that the EU-Ghana VPA does not mention an Independent Auditor, although it uses the term 'independent monitoring' to refer to independent auditing (EU-Ghana VPA, 2008: Art. 10).

government, private sector and civil society representatives and meet in between JIC meetings. Such associated structures are considered to be of great importance since they help prepare and exchange documents in advance of the JIC and 'ensure continuation of the multi-stakeholder participatory process during the implementation phase'. Moreover, through its multi-stakeholder approach, and the checks and balances provided throughout the national implementation process, VPAs tend to develop a deeper understanding of the broader political economy issues at play behind the formal reform processes they intend to support (Bollen and Ozinga, 2013 :33).

Once a VPA is agreed and moves into implementation, the process becomes subject to regular, almost continuous, reviews of their effectiveness and impact, based on iterative evaluations of what works and what does not. A first review should be carried out no later than two years after the VPA was initiated, and additional reviews can be organised as implementation issues arise. Such 'learning by doing' is to a large extent facilitated by the knowledge exchange among a broader community of national and international experts, including researchers, NGOs, consultants and policy institutions (Overdest and Zeitlin, 2014: 8).

In addition, VPAs are bound by formal reporting and public disclosure provisions. Based on the information gathered by both parties, the JICs are expected to publish annual reports on the development and implementation of the VPA, including details on progress toward agreed objectives and time-bound actions. Once a VPA is operational, such annual reports should also include details on the number of FLEGT licenses issued so far, and on the quantities of timber exported to the EU. In case a review of the VPA's implementation process identifies serious shortcomings a dispute settlement mechanism can be triggered to help the parties to resolve the issue by means of bilateral consultations, or, if necessary through mediation by a third party. When a dispute cannot be settled within a mutually agreed timeframe, the VPA can be temporarily suspended, reverting the partner country back to non-partner status, which implies losing its 'green lane' access to the EU market. In general, notwithstanding serious infringements of the agreements, VPAs are there to stay and remain in force until one of the contracting parties decides to terminate the Agreement with a 12-month advance notice (COM, 2007a: 3).

(2) State of play

VPA negotiations with timber-exporting countries started in 2004 and soon identified the need for additional guidance and technical assistance to support both the negotiation and implementation processes in VPA countries (interview EFI FLEGT Facility, 23 August 2016). As such, two complementary units were created with funding from the EU and some EU MSs, namely an EU FLEGT Facility in the European Forest Institute (EFI) and the EU FAO FLEGT Programme. While neither of them are part of the EU's formal delivery architecture for FLEGT, they both provide valuable guidance and technical support to the implementation of FLEGT, in cooperation with other EU funded support projects (TEREA et al, 2016: 30).

The EU (EFI) Facility was created in 2007 with funding from the EU, Finland, France, Germany, the Netherlands, Spain, Sweden and the UK. Its task is to provide technical expertise and communication assistance in support of the national dialogues in VPA countries, or countries considering to get involved. The Facility thus provides advice and expertise to partner countries, particularly concerning multi-stakeholder processes and the development and implementation of national TLASs. Given its involvement in VPA processes worldwide, the FLEGT Facility is particularly well-placed to gather and

disseminate knowledge and experiences across the participating partner countries, and functions as a knowledge hub for both general and applied information on FLEGT and the VPA processes. The EU FAO FLEGT Programme was established in 2008 and enjoys funding from the EU, the UK, Sweden and the FAO. It operates outside of the AP's VPA component, in the sense that it provides direct technical assistance as well as small grants to over 200 FLEGT related projects in over 40 timber-producing countries, whether or not these are, or interested in becoming, VPA countries (TEREA et al, 2016: 30; Interview EFI FLEGT Facility, 23 August 2016).[11]

The first country to sign a VPA was Ghana, in 2009, and in the following four years, five others followed, notably Cameroon and the Republic of Congo (RoC) in 2010, and the Central African Republic (CAR) and Liberia in 2011. The last country to engage in VPA negotiations was Indonesia in 2013 - bringing the current total to six VPA countries. Meanwhile, nine more VPAs are being negotiated (Côte d'Ivoire, the Democratic Republic of Congo (DRC), Gabon, Guyana, Honduras, Laos, Malaysia, Thailand and Vietnam) and almost a dozen others have requested more information about VPA processes.[12] Since 2014 however, no new countries have been admitted to enter into VPA negotiations since the Commission wants to focus on bringing the nine outstanding negotiations to a good end while implementing the ongoing six ongoing VPA processes (TEREA et al, 2016: 30). The implementation of VPAs has proven to be a highly time- and resource-consuming process and as a result, no VPA country has yet been permitted to issue FLEGT export licenses, although Ghana and Indonesia are coming close to that point. Indonesia in particular, has met the final requirements to start licensing, becoming the first country to issue FLEGT licenses after a positive joint evaluation of its national TLAS and the implementation of the VPA. As such, the first FLEGT licensed timber to reach the EU market is to be expected as of mid-November 2016 (COM, 2016a: 1-2).

The different VPAs concluded so far all follow a common, basic format, essentially containing a set of standardised provisions in the main text, while annexes cover the country-specific details (e.g. concerning the legality definition, the TLAS and the ToR for the IA). The respective agreements however differ considerably when it comes to the country-specific details outlining the details of the domestic understanding and operationalisation of legality verification. Such differences are the outcome of a multi-stakeholder negotiation process and reflect not only the specific conditions of the local and sectoral context, but also the sequence in which the different VPAs have been negotiated. Ghana for instance did not initially have a transparency index, whereas all following VPAs did.[13] Similarly, all VPAs, except for the one with the CAR, apply equally to timber production for the export as well as for the domestic market - predominantly in order to avoid creating a double standard of legality. Likewise, the formal provisions in VPAs to ensure an adequate inclusion of civil society in the implementation and monitoring of VPA processes has become comparatively more elaborate over time. In sum, it is fair to say that, from the Ghana VPA to the agreement with Indonesia, VPA negotiations and their implementation have been an adaptive learning process based

[11] In 2016, the FAO FLEGT Programme was extended for a third 4-year phase until 2020, for more information about the Programme, please see: http://www.fao.org/in-action/eu-fao-flegt-programme/en/

[12] Other countries who have expressed an interest in concluding a VPA with the EU include Bolivia, Cambodia, Colombia, Ecuador, Guatemala, Myanmar/Burma, Papua New Guinea, Peru, the Philippines, Sierra Leone and the Solomon Islands

[13] Ghana's civil society has submitted a transparency matrix to government to compensate for the lack of a transparency annex in the VPA (Forest Watch, 2014:

on experiences across countries, regions and stakeholder groups (Bollen and Ozinga, 2013: 5 and 31; Overdest and Zeitlin, 2016: 10).

VPA experiences so far allow us to draw two broad sets of provisional conclusions regarding the impact and comparative effectiveness of FLEGT's experimentalist design features, vis-à-vis other transnational forest governance regimes. First, VPAs seem to be exceptionally well equipped to accommodate the political economy of the local context in which they operate. Given the intrinsically political implications of forest governance reforms, VPAs have proven to be a very challenging process for partner country governments, both politically and technically in terms of the capacity-demands they require. Whereas some of the key implementation challenges indeed include practical difficulties, e.g. the design and functioning of an effective wood tracking system in developing country circumstances, other challenges predominantly stem, albeit sometimes indirectly, from the national, local or sectoral political economy and the resulting behavioural dynamics among the different actors involved. Forest governance reform thus touches upon deep-rooted power- and incentive structures, often characterized by patronage and a widespread culture of corruption. Moreover, forestry issues are often closely interconnected to broader, often thorny, issues, concerning e.g. natural resource exploitation, community relations, land use and property rights. Overdest and Zeitlin argue in this regard that is the virtue of FLEGT's inclusive and iteratively problem-solving design, that VPAs have been able to progressively expose and accommodate these underlying dynamics. VPA provisions regarding independent monitoring, civil society involvement and joint implementation committees are considered crucial to overcome such political and administrative obstacles and help understand the underlying causes of flaws in the existing regulatory system (Overdest and Zeitlin, 2016: 11-12; Williams, 2012).

Secondly, by stressing the involvement and empowerment of various domestic stakeholders, VPAs are said to have 'radically altered the negotiating and policy-making landscape', particularly under this type of transnational trade regimes. Indeed, the level of civil society inclusion in both the negotiation and implementation of FLEGT processes has been described as unparalleled in forestry management and arguably beyond, as, often for the first time, CSOs have been genuinely involved in the negotiation of a legally binding trade agreement. It was noted in several interviews how the EU had very much stressed that any VPA, and in particular the adoption of a legality definition, should be based on a domestic, multi-stakeholder consensus. Not only were CSOs in countries negotiating a VPA impressed, and often surprised, with the unprecedented level of involvement they enjoyed throughout the legality definition and the overall negotiations, on the EU-side as well, it is the first time that non-state actors have been this engaged and influential in shaping the mechanisms and provisions under trade agreements. As a result, Ozinga argues, there has never been 'a process in which different stakeholder groups, including the trade and NGO sectors, have designed a trade agreement that they all consent to'. Ownership of the VPA process thus hinges for a large part on this multi-stakeholder approach and will continue to be crucial throughout the implementation phase (Ozinga, 2012:65-68; interviews with civil society and forestry officials in Accra, 8-12 August 2016). Observers add in this regard that increased NGO participation has in turn opened up the VPA discussions content-wise, from timber legality to a broader variety of, often complex, socio-economic issues such as community rights, rural livelihoods, anti-corruption, revenue governance and biodiversity. Moreover, due to the VPA process and the space and support for CSO-inclusion attributed therein, various observers have also noted significant improvements in the effectiveness,

coherence and capacity of the domestic CSO-environment (Arts and Beeko, 2010: 224-225; Overdest and Zeitlin, 2014: 10) and in the quality of engagement between civil society and the Ghanaian government (Interviews with civil society and forestry officials in Accra, 8-12 August 2016).

While VPAs have rendered undeniable successes, notably in bringing about a sustainable local process of legal and governance reform in forestry and related policy areas, VPAs alone cannot constitute a comprehensive and forceful response to curbing illegal logging and the related trade. VPAs rely on the willingness of timber-exporting countries and, in the absence of EU domestic legislation, could easily be circumvented through third, non-VPA, neighbouring countries to export illegal timber into the EU. Such concerns ultimately highlighted the need for the EU to level the playing the field and, as envisioned under the AP, to develop legislation to prevent operators from importing illegal timber into the EU market (COM, 2016b: 8).

a) The EU Timber Regulation

The other 'leg' of the FLEGT AP's implementation framework is the EU Timber Regulation (EUTR), which was adopted in 2010 and entered into force in March 2013. The aim of the EUTR is to curb the EU's import and consumption of illegally harvested timber, by demanding elaborate due diligence procedures from operators placing wood and wood products on the EU market. The EUTR therefore lays down a number of obligations for operators to comply with and in order to avoid discrimination among supply countries, which would be in violation of WTO rules, the EUTR applies to wood-based products originating from both inside and outside the EU.

(1) Key provisions

The EUTR's main objective is to rid the EU market of illegal timber and illegality in this regard is again defined as timber produced in violation of the laws and regulations of the country in which it was harvested. In order to verify such compliance, the Regulation requires operators to exercise 'due diligence', meaning EU operators are expected to minimize the risk of illegal timber entering the value chain. The EUTR therefore requires operators placing timber on the EU market for the first time, whether imported or harvested within the EU, to have access to information about the origin and species of the wood, the volume of the load, and compliance with national laws and regulations. Based on that information, the operator importing the timber and timber products into the EU should assess the risk of illegality and, if necessary, mitigate that risk by demanding additional information and verification from the supplier. In addition, after placing timber on the EU market, operators have to keep track of the timber, based on documentation and records about their suppliers and clients To fulfil these obligations, operators can either develop their own due diligence system (DDS) or use one designed by a Monitoring Organization (MO) recognized by the EU.[14] MOs are private, EU-based companies, which can be contracted by operators to provide them with the guidance and monitoring required to verify timber legality (EUTR, 2010: Art. 4-6).

It is up to the MSs, whose responsibility it is to implement the EUTR, to establish 'competent authorities' to carry out regular checks on these MOs to verify if they fulfil the obligations laid down in the Regulation. To do so, and in order to ensure a uniform implementation of the EUTR, the Commission has issued detailed guidance on the nature and frequency of the checks MS's competent authorities should conduct to verify if DDS live up to the standards set out in the EUTR

[14] So far, 13 MOs have been recognized, for more information see: http://ec.europa.eu/environment/forests/mos.htm

(COM, 2012: Art. 4-6). Moreover, MSs should also carry out checks 'when in possession of relevant information, including substantiated concerns from third parties'. This means that third parties, including NGOs, can raise complaints to MS authorities about illegal timber entering the EU market under the EUTR (EUTR, 2010 Art. 6-8).[15]

Despite such detailed monitoring of the MOs, legal liability remains with the operators, and it is up to the MSs to define appropriate sanctioning measures to penalize any infringements. According to Article 19.2 of the EUTR, the nature of such penalties must be 'effective, proportionate and dissuasive', granting wide discretion to the MSs as to their form and severity. The severity of penalties is a particularly important consideration since strong corrective measures would arguably incentivize timber-exporting countries to negotiate VPAs in order to overcome the uncertainties faced by operators trading in their timber (Fishman and Obidzinski, 2015: 12). Moreover, a 2016 independent evaluation of the FLEGT AP pointed to a number of broader considerations in this regard. As EU MSs are to implement the EUTR within their own national context, legislation, monitoring and enforcement capacity, types of penalties and corrective measures will differ, leading to uneven degrees of implementation and enforcement of the EUTR, creating a situation in which operators can pick the country offering the lowest threshold for them to import their timber into the EU – potentially instigating a regulatory 'race to the bottom'. In order to ensure a correct implementation of the EUTR across all MSs, an infringement procedure can be launched against non-complying MSs, which may result in substantial fines. Whereas this is generally considered to be a costly and lengthy procedure, with negative repercussions for intra-EU relations, the option in itself may be sufficient to forge compliance (TEREA et al., 2016: 54).

Interestingly, under the risk assessment procedures of DDSs, the EUTR encourages the use of 'certification or other third party verified schemes which cover compliance with applicable legislation' (EUTR, 2010: Art. 6, b). The EUTR implementing regulation clarifies in this regard that private certification schemes can indeed be taken into account in the risk assessment and risk mitigation procedures of the due diligence system, but only if they i) are publicly available and include, as a minimum, the same requirements as those stipulated under the EUTR; ii) conduct regular (at least annual) and appropriate checks, including field visits; iii) have the means to trace timber across the supply chain before it reaches the market; and iv) provide controls to ensure that non-verified or illegal timber does not enter the supply chain (COM, 2012: Art. 4). While certification alone does not suffice to prove legality under the EUTR, notably since illegality can still incur after an initial certification has taken place, it does integrate private standards into a broader transnational legality regime by putting them under some form of public oversight. As a result, some of the biggest

[15] Greenpeace, among others, has repeatedly raised concerns regarding the rigidity of the EUTR's market access provisions, particularly about the use of CITES as a legitimate way for operators to gain 'green lane' access. Greenpeace Belgium in particular highlighted in 2013 how illegal timber imports from the DRC have made their way into Belgium, making use of CITES to gain market access, '*thus demonstrating the inherent weaknesses of the CITES system with regard to timber legality and privileges afforded under the EUTR's green lane'*. In response to the Greenpeace Belgium case, the Belgium Timber Importers Federation (BTIF) has instructed its members to exercise due diligence on imports of CITES wood, even though it falls under the EUTR's green lane. For more information about the Belgian case: http://www.greenpeace.org/belgium/Global/belgium/report/2015/la_forestiere.pdf

private forest certification schemes like the FSC and the PEFC have adjusted their legality requirements across the chain-of-custody, in order to conform with the EUTR's due diligence requirements (Jonsson et al., 2015: 9). Overdest and Zeitlin argue in this regard that, through this type of interaction with private certification schemes as well as with similar public legal timber regulations in the US and Australia, the EUTR effectively contributes to 'the stepwise construction of a broader transnational forest governance regime' (Overdest and Zeitlin, 2016: 6).[16]

In addition to using DDSs, the EUTR establishes a third way for operators to exercise due diligence, notably by creating a 'green lane' for products licensed under a FLEGT VPA system or under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).[17] The EUTR reasons that since 'under the FLEGT licensing scheme only timber harvested in accordance with the relevant national legislation and timber products derived from such timber are exported into the Union'. Therefore, FLEGT licensed timber is to be considered to have been harvested legally (EUTR, 2010 (9)). In addition to creating a general market incentive to curb illegal logging, the EUTR explicitly complements and promotes VPAs by banning any timber from VPA countries that is not FLEGT licensed, while providing 'green lane' access to the EU market, meaning EUTR due diligence requirements do not apply. The EUTR therefore grants a significant market advantage to FLEGT licensed timber compared to non-licensed timber since it imposes significant additional costs on firms from non-VPA countries. This direct link between the AP's demand side measures, operationalized through the EUTR, and the supply side, through the VPAs, is considered as a potentially very strong incentive for timber producing countries to take part in the in the FLEGT regime (TEREA et al., 2016: 54).

Overdest and Zeitlin argue in this regard that the EUTR can be seen as the FLEGT regime's 'penalty default', since it disincentives actors to circumvent the new legality regime while offering an attractive alternative to participating countries in the form of easy access to the EU market. Indeed, the adoption of the EUTR, arguably in combination with other international initiatives like the 2008 US Lacey Act[18], triggered a significant rise in interest for VPAs as the period between 2008-2010,

[16] In 2012, Australia adopted the Illegal Logging Prohibition Act, which makes it illegal for operators to place illegally sourced wood on the market and requires them to exercise due diligence to avoid doing so. For more information on the Act, see: http://www.euflegt.efi.int/australian-illegal-logging-prohibition-act-2012. The US Lacey Act is described below in fn. 16.

[17] CITES is an inter-governmental agreement that has been in force since 1975 and aims to ensure that international trade in tropical wild animals and plant species does not endanger their survival. As such, any imports or exports of animal and plant species covered by CITES should be authorized through a licensing system and governments party to the Convention are expected to identify both Management and Scientific Authorities, respectively to monitor and advise that licensing system. For more information on the species covered under CITES and the details of its licensing scheme, see: https://cites.org/eng/disc/what.php

[18] In 2008, in reaction to the momentum created by the EU FLEGT AP as well as for domestic economic considerations, the US amended its Lacey Act – which previously only dealt with trade in illegal wildlife products - expanding its scope in order to criminalise the import, trade or handling of any timber products harvested in violation of the domestic legislation of the country of origin. The US thus became the first country in the world to ban illegal wood-based products, though, in comparison, the EUTR is much more stringent when it comes to demanding a proactive approach to due diligence from its operators. For a comprehensive assessment of the Lacey Act and its impact on illegal logging and the related trade, see: Momii (2014).

when both the EUTR and the Lacey Act were taking shape, witnessed an exceptional surge of countries entering into VPA negotiations (Overdest and Zeitlin, 2014: 11).

(2) State of play

Like concluding and operationalising VPAs, the implementation of the EUTR has been slow. First, the EU provided a two-and-half year time frame between the adoption of the Regulation in 2010 and its entry into force in March 2013, to allow business and EU MSs to adjust their operations to the EUTR requirements. Second, and despite this preparation phase, the implementation of the EUTR so far has been highly uneven and inconsistent. As is often the case with EU policy implementation, MSs perceived as front-runners in a particular policy field act as pace-setters when it comes to outlining EU policy-making in that particular area and are more likely to design EU policies similar to their own, effectively minimising the associated 'translation costs' to the domestic level. Latecomers on the other hand, often face a severe backlog to implement EU policy-setting and may lack the expertise, staff power, technology and general resources required to adequately confirm with new EU legislation (Jonsson et al., 2015: 23-24).

In the case of the EUTR, such differences between front-runners and latecomers have resulted in unfair competition between MSs, inconsistent market requirements for the private sector in timber exporting countries, and, ultimately, a real risk for VPAs to lose their value and credibility as a market access system. Particularly challenging issues include the (rather lengthy) MS procedures to designate 'competent authorities' to implement the EUTR and, once designated, competent authorities generally face severe capacity constraints in terms of staff, resources and training, although here as well there is considerable variation across the MSs. Other challenges so far included the rather slow, cumbersome and inconsistent process of approving MOs, the demanding and costly nature of due diligence systems and the difficulties encountered by EU operators, particularly SMEs, in developing and operating their own due diligence mechanisms. Although the Commission did provide guidance to companies on the EUTR implementation, such guidance came rather late (six months after the EUTR came into force) and some considered it insufficient and unclear (TEREA et al., 2016: 56-57).

As a result of these implementation difficulties, the degree of implementation and enforcement of EUTR varies significantly between EU MS and outstanding challenges are still abound. Whereas all 28 MSs were obliged to implement and enforce the EUTR provisions as of 3 March 2013, by July 2013, 18 still reported problems. In order to promote a swift implementation, the Commission organized official meetings with private sector representatives, competent authorities and civil society, in order to sensitize and inform them about the EUTRs implications for their respective stakeholder constituencies. In combination with a 'score board' on the Commission's website, which compares compliance across the MSs, the Commission's implementation guidance seems to have been successful since, by early 2016, 27 MSs had designated competent authorities in place to monitor compliance of operators and 24 MSs had issued legislative or non-legislative acts defining the nature and severity of penalties in case of infringement with EUTR obligations. 13 MSs enacted new laws to enforce the EUTR or revised existing national legislation to make direct reference to the EUTR (COM 2016b: 11-13).

While more work remains to be done and many stakeholders have raised concerns about the need for harmonization and improved coordination among the MSs, the EUTR seems to have already

generated considerable impact in controlling illegal timber on the EU market. The 2016 evaluation of the EUTR notes in this regard that operators have started to 'progressively require suppliers to provide evidence on the legality of the products prior to their delivery to the EU market and favour third-party verified or certified suppliers as a risk mitigation tool'. In doing so, the Regulation seems to have encouraged more responsible sourcing policies, demonstrating the EUTR's potential to change operators' market behaviour (COM, 2016b: 18; TEREA et al., 2016: 58).

Overall however, the delayed and uneven implementation of the EUTR, in combination with the cumbersome operationalisation of TLASs in VPA countries and the subsequent lack of FLEGT licenses so far, has raised considerable concerns about a possibly waning momentum for FLEGT. The idea is that the delays encountered could negatively affect domestic support for legality verification in VPA countries. In the absence of a functioning EUTR, as a backstop or penalty default to encourage timber countries to negotiate and implement a VPA, local producers and EU-based operators may turn to other solutions, like private certification, to meet the EUTR's due diligence requirements. This, in turn, could diminish incentives for local timber producers and their governments, to invest in the implementation of a national timber legality assurance regime. Moreover, such developments would punish those firms who actively participated in VPA multi-stakeholder processes to define and enact a workable national legality standard in the understanding that this would eventually pay off through preferential EU market access. Overdest and Zeitlin (2014) rightfully argue in this regard that, ironically, it is the EU's 'all or nothing' approach to licensing that is part of the problem, in the sense that it fails to reward VPA countries for incremental performance improvements through gradual or selective market access (Overdest and Zeitlin, 2014: 13-14). It is worth stressing however, that progress on implementing FLEGT has been slow because, it is not simply imposed top-down. This is true in particular for VPAs, but the EUTR as well has been a consultative learning-process, involving broad stakeholder engagement, which by definition is a complex and time-consuming undertaking. Many stakeholders however, have argued that this consultative process in and by itself has been an exceptionally rewarding and enriching experience for all involved, and has already resulted in greater transparency and accountability in many of the VPA countries and has generated more inclusive policy making in general (Jeffree, 2015: 48-49; Interviews August 2016).

C. FLEGT in Ghana

Formal negotiations between the EU and Ghana began in March 2007 and on 3 September 2008, Ghana became the first country to successfully agree upon a VPA. Ghana thus offers an interesting case-study to assess stakeholders' perceptions regarding the scope for human rights protection and poverty reduction under FLEGT, not only given its role as a front-runner in both negotiating a VPA and developing fair and effective governance reforms in forest management, but also as an exemplary case for consensual multi-stakeholder decision making, Ghana has been a crucial experience, which, to a large extent shaped how the FLEGT community went about developing the VPA process in other countries (interview August 2016).

1. Ghana country context

a) Setting the scene: governance and human rights context

After independence in 1957, the Ghanaian constitution established a parliamentary monarchy. One of the leaders at the forefront of the Pan-African decolonisation movement, Dr. Kwame Nkrumah became the country's first Prime Minister and later. when Ghana became a republic in 1960, its first

president (Quashigah 2013).[19] While the new constitution established a multi-party democracy, Ghana soon descended into a de facto one party state and in 1964 President Nkrumah introduced a constitutional amendment which made himself president for life and his Convention People's Party (CPP), the only legally recognised party (Quashigah, 2013). Nkrumah and his CPP were soon to be overthrown in 1966 however, when a military coup forced him into exile. The coup was followed by interludes of short-lived democratic constitutional dispensations under the Second (1969-72) and Third (1979-81) Republics, interspersed by four more coups by the military. These periods of military rule were 'marked by gross human rights violations' (Abdulai 2009: 1) and Ghana finally returned to democratic governance in 1993 after the adoption of a liberal constitution in 1992, 'which established a unitary presidential system of government, based on multi-party democracy' (Nyarko, 2016: 96).

The current Constitution establishes a democracy based on the supremacy of constitutional law (1992 Constitution: article 1) and empowers the Supreme Court to review any legislation or acts of omissions of the other branches of government, enabling it to strike down any unconstitutional policy-making (1992 Constitution: article 2). The state is primarily managed through a central government with a decentralised local government, which exercises limited administrative, fiscal and political powers (Hoffman BD and Metzroth, 2010). The Constitution also dedicates a chapter to 'fundamental human rights and freedoms' (1992 Constitution: chapter 5), consisting of a comprehensive list of civil and political rights and some social, economic and cultural rights (Nyarko, 2016). The Constitution further also mandates the state to enact laws for the 'protection and promotion of all other basic human rights and freedoms, including the rights of the disabled, the aged, children and other vulnerable groups in the development process' (1992 Constitution: Article 37(2)(b)). Finally, other rights, notably those protected under 'treaties, conventions, international or regional accords, norms and usages' (Adjei-Ampofo v. Attorney General) including 'provisions of international human rights instruments (and practice under them) or from the national human rights legislation and practice of other states'(Ghana Lotto Operators Association and Others v. National Lottery Authority), can also be legally enforced in Ghana if a claimant can show that they are rights 'inherent to a democracy'.

Since the 1992 Constitution, Ghana has held 6 multiparty elections with peaceful transfers of power from one government to the other. The National Democratic Congress (NDC) won two successive elections in 1992 and 1996 but we defeated in the December 2000 general elections and handed over power to the New Patriotic Party (NPP) in January 2001. The NPP would go on to rule for 8 years after winning the 2004 elections. The NDC returned to power in 2009 after defeating the NPP in the December 2008 general elections. Political liberalization has increased, enabling the emergence of an active civil society and an independent media to scrutinize governmental accountability (Abdulai: 2009:2). The CSO landscape has changed over the past three decades, the most significant change being the dominance of formal CSOs (NGOs) and the 'loss of mass mobilisational politics' within the civil society space (Star-Ghana, 2013). Whilst liberal democracy has enabled the formalization of CSOs, the proliferation of policy making fora as a result of a shift from political to technocratic decision making has resulted in CSOs spreading thin. This coupled with

limited funding and capacity in some cases and lack of information has resulted in limited participation of CSOs in policy making (Star-Ghana, 2013).

Overall, Ghana has thus made significant progress in institutionalising 'multiparty democratic governance within the framework of the 1992 Constitution' (Abdulai, 2009) and is generally regarded as a well administered country, particularly in comparison to other African countries, and has been described as 'a beacon of hope' on the continent for its track record on good governance and respect for human rights (Sithole, 2012).

Despite such praise, democratic governance in Ghana is still a work in progress with many deficits at both the higher and lower levels of domestic governance (Abdulai 2009). At the national level, political power is highly centralised in the executive branch of government (Ayee et al., 2010), and many scholars have argued that the presidential office wields excessive power over state institutions, a situation which is deemed to be detrimental to democratic consolidation and the protection of human rights (Abdulai, 2009: 7). Constitutional checks and balances remain fragile (Ayee et al., 2010), with parliamentary activity often reduced to 'rubberstamping' the executive decision-making. A clear manifestation of executive dominance is the vast appointment powers entrusted in the President by the Constitution (Abdulai, 2009: 7). The Constitution further also establishes many independent institutions to support the democratisation process, including the Commission on Human Rights and Administrative Justice (CHRAJ), which is mandated to address human rights violations and corruption, the National Media Commission (NMC), mandated to insulate the media from state control, promote the independence of the media and responsible journalism, the National Commission on Civic Education (NCCE) to provide civic education to citizens, and the electoral Commission to organise periodic, free, and fair elections (Abdulai 2009: 7).

Executive dominance however, has adversely affected the effective functioning of these independent institutions, meant to provide checks and balances against potential abuses or interferences from the executive branch (Abdulai 2009: 7). In addition to budgetary dependence, the heads and senior staff of these institutions are generally appointed by the president, creating a 'gratitude effect' (Gyimah-Boadi and Asamoah, 2001). Political patronage thus continues to be a problem. Abdulai (2009: 8) particularly cites the relationship between executive and national human rights and anti-corruption institutions such as CHRAJ and the Economic and Organised Crimes office (formerly Serious Fraud Office) to illustrate the implications of executive dominance on democratic consolidation and the enjoyment of human rights. Whilst CHRAJ is empowered by the Constitution to investigate reports of corruption and human rights violations, its effectiveness is affected by executive hegemony. First, whilst CHRAJ has the power to investigate allegations of corruption, only the Minister of Justice and the Attorney General can decide on whether to prosecute alleged offenders based on recommendations of CHRAJ. This essentially means that the Minister of Justice and the Attorney General can conveniently ignore the recommendations of CHRAJ especially where sitting government officials are involved (Abdulai, 2009: 8). Secondly, CHRAJ lacks financial independence as its annual budget has to be approved by the Minister of Finance, a situation that has led a former Commission of CHRAJ to remark that 'the independence of the Commission can only be fully realised if its budget is submitted directly to Parliament for vetting and approval' (Abdulai, 2009: 8; OSIWA and IDEG 2007:132).

Limited access to information further hinders efforts to hold government officials accountable. Although the Constitution guarantees the right to information 'subject to such qualifications and laws as are necessary in a democratic society' (Constitution of Ghana 1992: Article 21(1)(f)), no law has been enacted to give effect to this provision, leaving officials with almost complete discretion to decide what types of information they make public. A study conducted by the Open Society Justice Initiative (OSJI) in 2006 revealed that, only 9% of the requests for information to a variety of government agencies received a satisfying response (OSJI, 2006: 74). Again, the executive monopoly over official information often results in 'the denial of access by citizens to critical data that is necessary to hold government to account and to keep executive abuses in check' (Abdulai, 2009: 8). As such, CSOs have increasingly started to litigate against the government, in order to gain access to certain information. In the most recent attempt, the Human Rights Division of the High Court in Accra ruled that the government cannot rely on its own failure to enact legislation on access to information as a basis for denying the Constitutional right to information held by government agencies. The Court therefore ordered the relevant government agencies to supply the information requested (*Lolan Kow Sagoe-Moses and others v. The Honourable Minister and Attorney Genera*l, Suit No. HR 0027/2015).

b) Ghana's forestry sector

Forestry constitutes an important, albeit decreasing and largely informal, part of Ghana's economy (Ramcilovic-Suominen, Gritten and Saastamoinen, 2010). In 2000, the sector accounted for 11% of the country's export earnings (Marfo, Adam, and Darko-Obiri, 2009), good for 6% of Ghana's GDP. Currently however, the sector's contribution to the national GDP has decreased to 2.3% in 2015 (Ghana Statistical Service, 2015) and Illegal logging by far outweighs formal timber harvesting. While the latter focusses almost exclusively on export markets and employs about 90.000 people, the informal sector provides for the domestic market and employs 130,000 people directly, most of whom working in illegal chainsaw operations (Oduro et al., 2012). As such, illegal logging accounts for an estimated 70% of the timber harvested in Ghana each year (Birikorang et al., 2001; Hansen and Treue, 2008; Ramcilovic-Suominen et al., 2010). As a result, Ghana has lost about 78% of its tropical forest over the last century (Repetto, 1990; Ramcilovic-Suominen et al., 2010). Recent studies have shown that Ghana's forests are heavily over-harvested for timber, with an estimated annual harvest of between 3.3 and 3.7million m^3 between 1996 and 2005, against an annual allowable harvest of 1.0 million m^3 (Hansen and Treue, 2008; Ramcilovic-Suominen et al., 2010). The current allowable cut is 2.0 million m^3 consisting of 0.5 million m^3 from forest reserves and 1.5 million m^3 from off-reserve areas[20] (Bamfo, 2005). Current harvest levels however, are estimated between 3.7 million m^3 and 6 million m^3 (Hansen et al., 2012). Forests nonetheless continue to constitute a crucial element in the livelihoods of many rural communities and in the general rural economy of Ghana (Appiah et al., 2009). About 14% of the Ghanaian population live in forest fringe communities who depend directly on the forest for 35% of their livelihoods (Mayers et al., 2008), while 78% of households nationwide, rely on wood fuels for their primary energy consumption (EcoEcon 2015).

Ghanaian forestry policy is outlined by the Ministry of Lands and Natural Resources (MLNR), while it is the mandate of the national Forestry Commission (FC) to implement and enforce that policy

[20] On-reserve timber refers to timber harvested from designated forest reserves. Any other timber not harvested within a designated forest reserve is categorized as off-reserve.

(EcoEcon 2015: 22-23). [21] The FC contains five operational divisions and a limited number of regional centres in addition to its headquarters in Accra. The five operational divisions are i) the Wildlife Division (WD), responsible for implementing government policy on wildlife; ii) a Forest Services Division (FSD), responsible for implementing policy on safeguarding the forest 'through protection, management and development of forest resource'; iii) the Timber Industry Development Division (TIDD), which is in charge of implementing government policy on maximum utilisation of timber and wood resources through the regulation of timber trade and by providing market intelligence; iv) the Resource Management and Support Centre (FMSC), which provides technical and advisory support for the effective implementation of forest and wildlife policy; and finally v) the FC Training Centre (FCTC), which provides courses and training sessions for forestry and wildlife professionals (EcoEcon 2015: 23-28). The FC is a centralised entity based in Accra, and as such its local level operational units report directly to headquarters, a way of working described by civil society as a 'command and control' approach which limits the participation of other relevant stakeholders in forest governance (Forest Watch Ghana, 2010).

Forest policy is also strongly influenced by commercial interests, while donors, politicians, bureaucrats and land owners (traditional authorities) play significant roles as well. NGOs play diverse roles in advocacy for human rights, forest conservation and sustainability but their strength in influencing forest policy has traditionally been rather weak. In recent years, the influence of NGOs in influencing forest policy has considerably improved however especially when they cooperate as a coalition such as FWG (Marfo and Mckeown, 2013: 26).

In the past, several attempts have been made to reform the forestry sector and to improve resource governance more generally, e.g. a ban on chainsaw operations and attempts to reform the fiscal regime, have had limited success due to a general resistance to reform among Ghana's political and economic elites. This is because the forest governance regime has served the entrenched interests of political and economic elites who benefit from the exploitation of timber in Ghana. This elite has with considerable success resisted any attempts at forest sector reform which could threaten their favourable position (Lund et al., 2012: 117). For instance, the state has continued the use of administrative permits even though legislation provides for competitive bidding procedures. This is associated with a practice of industry patronage that safeguards the interest of industry (Forest Watch Ghana, 2010). Hansen and Lund (2011) also report that timber taxation has remained low in Ghana because politicians wield discretionary control over logging rights which they allocate through 'patron–client networks' in exchange for political support.

In sum, Ghana's forestry regime has historically served the entrenched interests of an economic and political elite which subsequently and with considerable success, has resisted any progressive reform attempts that could affect their beneficial position. The effectiveness of FLEGT in Ghana thus depends on the extent to which it can accommodate and address such barriers to change in the political economy of the country's forestry sector. At the time the VPA with Ghana was being negotiated, the EU accounted for 60% of the country's timber exports (TIDD 2008). By 2010 however, this had reduced to about 25% (Lund et al. 2012: 117). The FLEGT-VPA between the EU

[21] The legal framework regulating timber harvesting is based on the Constitution, the Forestry Commission Act, 1997 (Act 571), the Timber Resources Management Act (Act 547) and its Regulations, including Legal instruments (LI) 1649 and 1721, and the Forest and Wildlife Policy of 2012 (As above).

and Ghana nonethelss remains an important instrument in safeguarding the forestry resources of Ghana as well as to bring about better governance to the sector if effectively implemented.

2. The EU-Ghana VPA

Upon signing and ratifying the agreement by both sides, respectively in November 2009 and March 2010, Ghana not only became the first country to conclude a VPA with the EU, it was also the only country to do so before the EUTR was officially adopted by the European Council in November 2010. Ghana's interests to get involved in FLEGT diverged considerably depending on the stakeholder group concerned. For timber trade associations and logging firms operating in the formal sector, market access obviously constituted a major consideration to join a VPA with the EU. Particularly since, at the time, Ghana exported over 60% of its total timber exports, in both volume and value, to the EU. For the Ghanaian government as well, market incentive undeniably played a major role, while other considerations within government and among some of its implementing agencies, included donor support for forest related initiatives, as well as using the VPA to finish what they perceived as incomplete governance reforms in the sector (interviews VPA consultant, FC officials and CSO representatives, 8-12 and 19 August 2016).

For Ghana's civil society in particular, the latter arguably constituted the primary incentive to support the VPA process. Ghana had signed on to the African Forest Law Enforcement and Governance (AFLEG) mechanism in Yaoundé in 2003, the African outcome of the regional FLEG process initiated by the WB in Bali in 2001 (see above), and while some initial discussions on forest governance were ongoing, AFLEG did not result in any concrete initiatives and the state of play of governance in the forest sector remained largely unchallenged. The VPA process was therefore welcomed as 'another vehicle to push forest governance in Ghana forward […] with the condition that the process would involve complete stakeholder participation at every stage'. Indeed, civil society in Ghana saw the VPA as an opportunity to address some of the underlying causes of illegal logging, notably by ensuring 'empowered participation of stakeholders, effective monitoring of legality compliance and reform of forest policy and law' (CSO Ghana, 2015:1; Arts and Beeko, 2010: 223, Interviews civil society 9 August, 2016).

a) Negotiating phase: process and outcome

Official negotiations between the EU and Ghana were preceded by a series of bilateral consultations between the different stakeholder groups and an independent consultant appointed by the EU to coordinate the VPA. These bilateral consultations ultimately informed an informal technical workshop between the EU and a group of forestry sector stakeholders in Accra in May 2005. The pre-negotiation phase identified two common objectives among all stakeholders involved, notably to make the VPA an instrument to develop and regulate the domestic market; and ii) to ensure that the VPA, over time, could be used as an instrument that would contribute toward sustainable forest management. Both of these ambitions effectively went beyond the EU's legality focus for the export market, and particularly the inclusion of the domestic market came as a bit of a surprise to the EU, who initially reacted lukewarm to the idea out of fears that it would make the whole process needlessly complicated (Interview August 2016). Official negotiations between the EU FLEGT Delegation and the Government of Ghana then began with a meeting in March 2007, at which civil society participants were invited to share their positions on governance reform, community rights and participation (Ansah, 2010: 3).

Whereas both the FLEGT AP and the Council conclusions approving its adoption were explicit about the need to ensure broad stakeholder participation in any discussions with interested countries – an objective which was later incorporated into the Commission's negotiating mandate – the Ghanaian government initially did not favour the direct involvement of CSO in the negotiation processes. Negotiations were led by a Negotiation Team, a Steering Committee, a VPA Secretariat located within the FC, and four Working Groups (Lesniewska and McDermott, 2014: 20). It was only after both local and European NGOs, led by FERN and Global Witness threatened to pursue legal action and engaged the media, that the Ghanaian government felt pressured to open up the process to greater civil society involvement. Due to the wide variety among CSOs, a VPA Contact Group (CG) was created, facilitated and hosted by Forest Watch Ghana (FWG) - a local NGO platform bringing together over 40 NGOs and individuals working on forest issues and the rights of poor forest users. The GC offered a broader CSO platform, including timber traders and their unions, traditional authorities, local forest forums[22], members of FWG, to elect two representatives to formally serve on the Steering Committee and unofficially join the Ghanaian Negotiation Team to provide technical support. In addition to the Steering Committee and the bilateral negotiations, the GC was also represented in four (and chairing two) working groups, respectively dealing with i) Legality Definition/Standards; ii) the Verification and Licensing Scheme; iii) a Domestic Market Regulation; and iv) Timber Industry Restructuring. The output of these working groups then fed into a Policy Committee, which was mandated to synthesise and report their work, here as well the CG was represented. (Adeleke and Karmona, 2008: 1-3).

The involvement of local CSOs at various level of the VPA's preparatory and negotiation phase was supported by European NGOs, notably Global Witness and FERN. The latter in particular reportedly provided capacity support at arms-length, allowing civil society in Ghana to be a real voice without pushing its own agenda. It was said that FERN understood very well the need for domestic CSOs to be informed and to understand the issues at stake – but without getting involved themselves. As such, FERN helped domestic CSO to take ownership of the process in a manner that would guarantee sustainable engagement in the VPA (Interviews August, 2016). FERN and Global Witness furthermore also informed local communities and national stakeholders about the aims and processes of FLEGT and the VPA in particular, while the International Union for the Conservation of Nature (IUCN) and the UN Food and Agriculture Organisation (FAO) also funded a number of community consultations that fed into the VPA process (Ansah, 2010: 3).

Increased CSO input into the VPA negotiations considerably reshaped and broadened the forest governance discourse in Ghana, effectively triggering a shift in focus from mere timber production to broader governance and sustainability issues, which in turn resulted in significant reforms of the domestic legal framework. Indeed, the first step in Ghana's VPA process was to arrive at a broadly supported definition of 'legal timber' and while the EU formulated general principles for timber legality, it was up to the VPA country to specify these at the national level through an inclusive governance process. Since the legality definition was to be drawn from the existing laws covering the different aspects of timber legality, rigorous multi-stakeholder deliberations soon identified multiple shortcomings and incoherencies in the existing legal framework and indicated the lack of a clear overarching governance vision for the sector (Ansah, 2010: 5). Beeko and Arts argue in this regard that, through rigorous multi-stakeholder deliberations, Ghana developed a legality standard which

[22] Cf. infra.

provided a new, holistic governance vision for the sector, indicating a shift in focus from timber to the multiple uses, benefits and impacts of the forests and from law enforcement to law effectiveness in order to ensure that the legality standard adopted under the VPA would be an implementable one, meeting the aspirations of good governance in the sector. In sum, it is fair to say that, as a result of the VPA development process, the traditional forest sector was opened up, changing the policy space to allow new actors to significantly reshape the governance discourse in the sector (Beeko and Arts, 2010: 224-225; Wiersum and Elands, 2013: 16).

As a result, Annex II of the EU-Ghana VPA, not only provides a set of jointly agreed legality definitions, but also includes provisions for future 'forest policy and legislative reform aspiration[s]'. As such, Ghana explicitly 'recognises that the provisions in the existing law […] need to undergo significant reforms to be able to address existing inadequacies as well [as to] respond to emerging issues in the sector that bothers on the principles of good governance'. This reform process would follow a two tier approach, notably i) changes to areas that would not require extensive legal reform processes would be introduced through subsidiary legislation within one year from the VPAs adoption; while ii) more substantial changes requiring broad consultations, expert advice and political reflection were expected to take between three and five years. Among the latter areas requiring a consultative reform process, Annex II indicates issues 'pertaining to e.g. good governance, stakeholder participation, benefit sharing, etc.' (EU-Ghana VPA, Annex II, 22-23).

Beyond legal and policy reforms, Art. 15 of the VPA indicates the need for supplemental measures, notably to address 'the root causes and drivers of illegal logging […]. Particularly with regard to tackling the challenges of growing domestic demand and the need to retool industry to remain competitive' (EU-Ghana VPA, Art 15(1)). Annexes IX therefore identifies the particular areas where the VPA implementation process would require supportive measures. Apart from capacity building of the government agencies and non-state actors tasked with implementing and/or monitoring the LAS (see below), the development of the domestic wood market features high in this regard, including the promotion of alternative livelihoods for people currently involved in illegal forest activities (EU-Ghana VPA, Annex IX).

In order to help domestic stakeholders to establish the legality of traded wood, the EU-Ghana VPA commits to developing a Legality Assurance System (LAS) based on the legality definition described in Annex II of the Agreement, and covering all wood harvested or processed (thus including wood imports) in the country. As part of the LAS implementing architecture, the VPA commits to develop a Wood Tracking System (WTS) to monitor and report on timber legality at a series of critical control points at different locations within the chain of custody, from pre-harvest inventory data gathering to the licensing for export. The WTS would thus gather information at different points of the supply chain, then process the data gathered and automatically reconcile it with the data gathered at previous check points in order to identify any errors or irregularities that might pop up. To monitor the WTS, the LAS also establishes a Timber Validation Department (TVD), an independent unit based within the FC's headquarters in Accra, mandated to gather and verify the data generated from the WTS along the entire process chain of wood products destined for both export and for the domestic market. In doing so, the TVD is also responsible to check whether the procedures provided under the legality definition have been complied with and, if need be, to report on any infractions or make recommendations to the Ministry of Land and Natural Resources (MLNR) to improve the system. Under the new set-up created by the LAS, the Forest Service Division (FSD) will continue to regulate

and manage the control interventions between pre-harvest surveys and the moment the logs are transported, while the Timber Industry Development Division (TIDD) will function as the designated authority to issue FLEGT permits. Even though all domestic timber production and processing will be go through the LAS, only timber destined for the EU market will be issued with FLEGT licenses, while timber for other export markets will receive export permits (Ansah, 2010: 5; EU-Ghana VPA, Annex V: 33-34 and 50-51). Finally, it is worth noting that, whereas the TVD does not have the mandate to arrest or prosecute offenders, it does have teeth in the sense that it can refuse or withdraw traders' export licenses if they fail to comply with the LAS's requirements (Interview TVD, 11 August 2016).

To ensure the independence and credibility of the TVD, the LAS also provides in the establishment of a Timber Validation Committee (TVC) to exercise oversight over the functioning of the TVD. To ensure sufficient independence from the FC and the TVD, the TVC will consist of a variety of different stakeholders, including high-ranking officials from the Judiciary, Policy, customs, the MLNR, civil society, the timber industry, as well as the Chief Executive of the FC and the Director of the TVD. Both the TVD and the TVC however report to the MLNR through the FC (EU-Ghana VPA, Annex V: 51).

A limited number of interviewees from civil society however remained critical about the decision to house the TVD, as an independent auditing unit to control the forest sector's compliance with the VPA's legality standards, within the FC. It was noted that illegal forest practices were intrinsically linked to corruption at various levels within both the private and public sector, often including FC officials, particularly at the district and local level. While the WTS was generally welcomed as a good step in the right direction, one correspondent from a forest conservation NGO argued that 'all it really does is adding checkpoints, which means that when someone is cheating the system, more people will know about it, and therefore more people will need to be paid off'. The WTS currently being piloted is a centrally monitored electronical system, which means that 'when things don't add up, the WTS will identify them and, contrary to the previous paper-based system, they cannot be erased'. Since both the FSD and the TIDD are located within the FC, this implies that, when irregularities were to arise, this would mean that the TVD would have to audit its own colleagues (Interview environmental NGO representative, 9 August 2016). Other respondents however stressed that it was precisely out of recognition of this problem that a multi-stakeholder oversight mechanism like the TVC was created to function as a watchdog and a complaints mechanism to monitor the TVD's independence. The TVC was thus created, precisely because the FC understood the need for an external auditor that could guarantee the TVD's credibility independent of possible turnover in staff (Interviews civil society and FC officials in Accra, and VPA consultant, 8-12 and 19 August 2016).

In addition to the TVD and the TVC, the VPA also calls for the appointment of an Independent Monitor (IM), responsible to audit and assess the overall effectiveness and implementation of the LAS, notably by conducting field investigations to assess the work of the relevant regulatory forest agencies at various levels, including through cross-checks with information from the competent authorities on the EU (MS) side. As such, the Independent Monitor is expected to identify and document systemic failures or instances of non-compliance, and to assess whether corrective measures have been recommended and implemented by the relevant agencies to address these. The IM is to report on its findings to every six months during the first year of the VPA, shifting to annual intervals afterward (EU-Ghana VPA: Annex VI). In the short term, independent monitoring

has been outsourced to a foreign company, Scientific Certification Systems Global (contracted in May 2014), though with an office in Ghana, which was part of its ToR, in order to ensure capacity is built in-country for a local actor to take over that role in the medium-to-long term (Interview CSO Accra and VPA consultant, 9 and 19 August 2016 respectively).

Finally, the VPA also establishes a Joint Monitoring and Review Mechanisms (JMRM), an EU-Ghana oversight body which monitors and reviews the VPA's general implementation and progress made. The JMRM consists of representatives of the Ghanaian government, led by the minister of the MLNR, and an EU representation, led by the Head of the EU Delegation to Ghana. The JMRM meets at least once a year and its records of discussions are made public. Its particular responsibilities include reviewing reports from the IM, assessing the social, economic and environmental impact of the VPA, resolve any possible conflicts that may arise among the stakeholders involved, and ultimately, to recommend the date upon which the FLEGT licensing scheme should become fully operational (EU-Ghana VPA, Art. 19). Whereas the joint monitoring bodies in other VPA countries are simply called Joint Implementation Committees, Ghana insisted on a title that would reflect the shared, but differentiated responsibilities, where 'each would do its own thing', the EU managing things on their side, e.g. rolling out the EUTR, while Ghana would implement the domestic VPA process, notably the LAS. The operational dynamics of the JMRM developed in a similar manner in the sense that the EU would encourage the different Ghanaian stakeholders to try to resolve any issues arising from the implementation process amongst themselves, involving civil society to come to a broadly supported solution, before taking it to the JMRM. The Ghanaian government as well now reportedly prefers solving things in a consensual manner internally. As a result, the EU's involvement when it comes to reconciling domestic differences has been limited overall and ownership of the VPA process has been entirely on the Ghanaian side – which brings us to the implementation phase of the EU-Ghana VPA (Interviews civil society Accra and VPA consultant, 8-12 and 19 August 2016).

b) Implementation phase: state of play and outstanding challenges

Based on the VPA's suggested two tier track, allowing more fundamental legal and policy reforms to be carried out while the LAS would already be operational, Ghana initially estimated to start exporting FLEGT licensed timber by the end of 2010 (Ansah, 2010: 5). A variety of both circumstantial. technical and political challenges and discrepancies however considerably delayed the operationalisation of the LAS, and some thorny issues remain unsolved to date. Below, we provide an overview of some of the main topical challenges that have so far characterized the VPA's implementation process – though some issues, notably those considering livelihoods impacts and the reorientation of the domestic market, have deliberately been left out to be dealt with in the following chapter.

Process-wise, many interviewees and observers noted a loss of momentum shortly after the adoption of the VPA in 2008. A lesson learned for future VPAs in this regard, was the need for formal arrangements between the EU and the Ghanaian government to discuss and monitor progress against the VPA in the time between the agreement and its ratification almost two years later. The lack of such formal mechanisms created somewhat of an institutional vacuum and almost no progress was made between 2008 and 2011. Moreover, 2008 was an election year for Ghana, which resulted in an almost complete overhaul in the relevant ministries and at the top of the FC (Interview civil society representative, 9 August 2016). To make matters worse, the key negotiators from both

the FC and FWG also moved on to other positions, leading to a significant loss in both technical and political knowhow among the domestic drivers in the process. Finally, since the fundamentals of the EUTR were still being discussed within the EU, Ghana's private sector did not experience any incentive, nor sense of urgency, to take an interest in the VPA process. Following the ratification of the VPA in March 2010, and the adoption of the EUTR in November that same year, a broad coalition of private and public actors reinvigorated the VPA process in Ghana (Groen, 2013; Overdest and Zeitlin, 2016: 33).

Institutionally, it is the VPA Secretariat within the FC who coordinates the implementation of the VPA, including the same people who previously participated in the negotiation phase and were later involved in setting up the TVD. In addition, civil society and the FC jointly established a Multi-Stakeholder Implementation Committee (MSIC), which brings together representatives of the VPA secretariat several relevant ministries and government agencies, as well as a member of parliament, a traditional authority and representatives of civil society and the private sector (civil society interview 9 August 2016; EFI FLEGT Facility website).[23]Throughout the implementation phase, civil society has been represented in both the JMRM and the MSIC, effectively ensuring a formal process for CSOs to engage in the VPA implementation process, allowing them to raise concerns about unresolved issues concerning forest governance or the development of the LAS in the presence of the EU Delegation, 'thereby putting pressure on the Ghanaian authorities to address them as a condition for moving forward towards FLEGT licensing' (Overdest and Zeitlin, 2016: 51).

Content-wise, the first obstacle to overcome was the development of an effective and functional WTS, as the backbone of the entire LAS architecture. While an international software company specialised in supply chain management was contracted and a pilot of an electronic WTS was initiated as soon as 2009, the system developed by the first company soon showed considerable shortcomings. The envisioned WTS was intended to provide an electronic system that could track timber and provide a wide variety of information regarding its geographical location, species, volume and size, and this across the entire chain of custody. As such, field staff would be able to introduce basic data which would then be transmitted and processed at a central database, managed by the FC. This database could then not only be used to identify irregularities in terms of legality verification, but also to inform forest management and to provide information on financial flows and trade statistics. The pilot WTS however failed to produce all these types of information and suffered from a number of fundamental flaws in its design, operationalisation and ease of use (Gyimah, 2012: 33-35). These flaws eventually led the decision not to upscale the ongoing pilot and to launch a new tender in 2012, this time with the requirement to enable the WTS to be used for both legality verification, as well as for broader forest management and industry purposes. The failure of the first WTS pilot had cost the process over two years of delay, particularly since 'we had to start again from scratch', as one correspondent noted (Interview CSO representative, 9 August 2016).

A new WTS however has been developed in close cooperation with the FC and a number of large timber exporting firms in order to ensure its functionality and, unlike the earlier pilot, the new system will produce information that is useful for legality verification, industry-and trade statistics, and forest (inventory) management. Based on real-time automated data reconciliation, the WTS will be able to automatically identify any inconsistencies or discrepancies between the data entered at

[23] http://www.euflegt.efi.int/national-vpa-implementation-structures

different check points throughout the supply chain, making it much harder to cheat or falsify, since that would involve elaborate coordination among more people, at different stages of the supply chain (Overdest and Zeitlin, 2016: 52-53). While the WTS is still not operational due to persistent problems of power outages and connectivity, the system has been through the final stages of testing to ensure a flawless and reliable usage, and is expected to be operational soon (Interview TVD, 11 August 2016). Ghana recently presented its WTS to Tanzania as an example of effective electronic wood tracking, indeed the new WTS is 30% faster than the previous paper-based system and is able to process more data, from different types of input. Whereas the development of the new WTS has been rather successful and has generated broad interest and enthusiasm among various stakeholders, Ghana's ambition to change to an electronical system was initially received with quite a bit of criticism as questions were raised why Ghana would need 'such a fancy system', arguing that a paper-based system could have been established much faster (Interview EFI FLEGT, 23 August 2016). Various stakeholders argued in this regard that the current WTS was very much an essential element of Ghana's vision for forest governance and that both the MLNR and a number of people within the FC had used the VPA process in a very politically savvy manner, essentially as a means to gain visibility and political support within government to push true a long-standing reformist agenda, including the use of a comprehensive, electronical WTS (Interview VPA consultant and EFI FLEGT Facility, 19 and 23 August, 2016). From a functional point of view, the digitalisation of the WTS in Ghana has already helped accelerate the FC's endeavours to update its forest management plans. Indeed, Since the VPA legality definition requires all forest reserves supplying FLEGT-licensed wood to have an accurate forest sustainability management plan, the FC has been pressured to fast track the review its management plans since most of them had not been updated since the 1960s Overdest and Zeitlin, 2016: 57-58).

While the delays encountered during the development of a functional WTS were of a predominantly technical nature, most of the other obstacles encountered throughout the VPA implementation process have been of a fundamentally political nature and often touched upon deeply entrenched issues of political economy. Below, we discuss two of those longstanding problems, notably the conversion of concession leases to Timber Utilization Contracts (TUC) and the abuse of administrative permits, both issue result from a tradition of lacking or incomplete enforcement of the legal felling regime.

Ghanaian law identifies three types of felling permits: i) Timber Utilisation Contracts (TUCs), written contracts issued by the MLNR minister and ratified by the national parliament, which grant harvesting rights based on a competitive bidding process; ii) Salvage permits, which are permits signed by the FC to literally 'salvage' trees from development, e.g. due to large construction or infrastructure works. Salvage Felling Permits (SFP) need to be accompanied by their application and an inspection report from the FSD; iii) Timber Utilisation Permits (TUPs) are small scale permits intended for community or social purposes, signed by the FC for a defined number of trees. As such, commercial, export-oriented logging generally requires a TUC, whereas SFPs and TUPs are intended for limited numbers of trees, under defined circumstances. Under the legality definition of the EU-Ghana VPA, only TUCs and SFPs are considered as legal felling permits since TUPs are reserved exclusively for community and/or social purposes and cannot be sold or exported. A Certificate of Purchase (CoP) is not a felling permit but proves legal ownership of a load of seized or abandoned timber and constitute a third legal source of ownership under the VPA legality definition (ClientEarth, 2013a: 1-6).

TUCs are granted by the minister of the MLNR, on behalf of the President, and – since they concern natural resource rights - require parliamentary ratification. The application procedures for accessing a TUC, as well as additional conditions concerning royalties and incentives, are outlined in some detail in the 1998 Timber Resource Management Act (TRMA). The latter was amended in 2003, making it compulsory for any TUC to be based on a competitive, two-stage bidding process, a pre-evaluation phase and the actual bidding. The bidding procedure itself is thus open only to companies who pre-qualified during the evaluation phase and the company who offers to pay the highest annual Timber Rights Fees (TRF) is awarded the TUC. TRFs were introduced to generate more revenues from natural resource exploitation and were supposed to mainly benefit local communities living in TUC areas, even though funds first go to the national government. The winner of the TUC then receives a Notice of Grant, specifying a number of additional conditions, including the conclusion of a Social Responsibility Agreement (SRA) with local communities (see below), upon which the actual right to harvest timber in the defined area ultimately depends (ClientEarth, 2013b: 14).

The legal framework described above, notably the TRMA and its 2003 amendment on competitive bidding, was hardly enforced in practice however. First, before the enactment of the TRMA in 1998, concessional leases had been granted to logging firms and under the new law such leases would have to be converted into TUCs. Such conversion of leases to TUCs never happened, the TRMA was thus never enforced in that regard. The VPA, which takes domestic legislation including the TRMA as its legal base, however requires enforcement of conversion as a condition to issue FLEGT licenses. Since pre-1998 concession leases do not qualify under the VPA's legality standards, logging firms would not be able to export timber to the EU market without conversing their old leases to TUCs. The Ghanaian timber industry however strongly opposes such conversion, notably since it would involve paying years of overdue TRFs. and they consider this was not part of the original (concessional) agreements. Converting old leases into TUCs, often linked to paying considerable amounts of outstanding TRFs, has been a long-standing issue between the government and the timber industry. Whereas initially, Ghana's Attorney General argued that concession holders would indeed have to pay the backlog in TRFs, going back to the year the TRMA entered into force, a second opinion from a new Attorney-General demanded TRFs to be paid only from the point of conversion to TUC onwards. The discussion on whether and how concession holders should pay TRFs upon conversion is still ongoing but have moved into the direction of a one-off payment. At the moment of writing, a (non-public) legislative draft had been submitted to parliament at the end of July 2016, presenting legislation aimed at resolving both the issue of conversion and the use of special permits (see below) (Interviews EU Delegation, DOLTA, NGOs and TVD, 8-12 August 2016).

A second major issue of contention arising from the lack of enforcement of the TRMA concerns the abuse of a legal loophole created in 2002, allowing minister of Land and Natural Resources to issue 'administrative permits'. Indeed, because the TUC regime initially encountered flaws, e.g. incorrect forest inventories leading some companies to overbid, the government decided to add a subsection to Section 20 of the TRMA, introducing a new type of 'administrative' or 'special' timber permits: 'The expression "timber utilization contract" shall apply with the modifications that are necessary, to a certificate of purchase, a permit or any other authorization for timber rights approved by the Minister on the recommendation of the Commission' (LI547, S.2 (2)).

Based on this rather vague legal basis, special permits allowed ministers to issue timber harvesting rights in their own personal capacity, without competitive bidding or parliamentary oversight. Whereas CSOs have always criticized administrative permits as arbitrary an insufficiently transparent, pointing to the risks of corruption and patronage, the government and the FC on the other hand would argue that special permits were appropriate for off-reserve areas, which were deemed too small to justify competitive tendering procedures, and in some cases a necessary tool to enable an accelerated permitting process to prevent illegal logging (Overdest and Zeitlin, 2016: 58). Research by Lund et al. (2011), however shows that between the enactment of competitive bidding in April 2003 and 2005, only six out 50 long-term felling permits had been allocated through competitive bidding, whilst the remaining 44 had been granted administratively – as had all other long-term contracts before. Moreover, of the 124 TUPs –destined for community and social purposes- in place in 2005, all had been granted to timber firms instead of community groups. Likewise, all 448 salvation permits, covering on average 23 km^2, as well had been allocated to firms through special permitting. Lund et al. argue that the widespread misuse of the respective timber felling regimes, in combination with questionable taxing rates, arguably suggest that timber rights were allocated 'in return for payments and/or political support, e.g. in connection with election campaigns' (Lund et al., 2011: 3)

Respondents were keen to note in this regard that, within government, the use and abuse of special permits had been a long-standing issue of contest as some LNR ministers had agreed with NGOs and promised to stop issuing such permits (notably in 2013), while a new minister had continued the practice, based on their legality under the TRMA, regardless of the VPAs legality stipulations (Interviews civil society, 9 August 2016). Indeed, one of civil society's biggest successes during the VPA's negotiation phase was to recognise only TUCs, SFPs and CoPs as legal sources of timber under the legality definition, effectively ensuring that timber harvested on the basis of other, 'special' permits could not be legally exported to the EU (ClientEarth, 2013a: 4). In order to find a way for the special permits regime to 'fit' into the VPAs legality definition, the JMRM convened a multi-stakeholder working group, facilitated by Client Earth, which developed a set of guidelines that make the special permits regime conform to the VPA's legality definition, essentially by depoliticising the permitting process in a transparent and accountable way. Following a period of protracted discussions within governments as well as among civil society, the MLNR has now decided to integrate these guidelines into a legally enforceable Legal Instrument (LI). The legitimization of special permits through the new regulations would introduce a new element into the legality definition, notably of legal sources, and therefore the Ghanaian government will need to inform the EU of its intent to add administrative permitting to the legality definition (Interviews EUD, TVD, civil society, 8-12 August 2016).

D. Legality, sustainability and human rights

Over the years, critical observers have identified a number of particular risks associated both with FLEGT's (exclusive) focus on legality verification as a means to enhance forest governance, as well as with the way the FLEGT regulations currently entrust the definition of legality to national legislation in the VPA countries. The two sections below respectively first outline these concerns in a general, theoretical manner and then discuss them in the particular context of the VPA experience so far in Ghana.

1. Theoretical framework

Illegal and unstainable forest practices, and the political economies sustaining them, not only have serious implications for climate change and biodiversity, they also perpetuate corruption, undermine the livelihoods of vulnerable communities and fuel social conflict (Hoare, 2015: viii).[24] Indeed, while generally presented as a predominantly environmental issue, illegal logging and unsustainable forest practices are associated with a variety of social issues and affect a broad range of human rights, particularly those defined in the 1966 International Covenant on Social and Economic Rights (ICESCR), the International Covenant on Civil and Political Rights (ICCPR), as well as the International Labour Organisation (ILO) conventions on Indigenous peoples (No. 169) and those relating to occupational health and safety (No. 155). A growing number of local and international NGOs have picked up on these issues and have raised international attention about a number of specific cases of human rights violations in the context of failing forest governance.[25] Moreover, the logging and timber industry suffers from an infamous reputation when it comes to applying industry standards and protecting its workers from occupational health and safety hazards. As such, the ILO has documented a series of particularly gruesome violations of fundamental rights in forestry work, including the use of child labour, debt bondage and forced labour. Since forest areas are often situated in remote, isolated regions, the communities living there are often more vulnerable to violations of human and labour rights, while their chances of formally redressing any injustices that may occur, e.g. through sector law enforcement, trade union representation or community networks, are more limited (ILO, 2001: 21).

Developed in the context of the Asian and African FLEG meetings organised by the World Bank in 2001 and 2003, FLEGT takes a similar approach in the sense that it focuses exclusively on the question of legality, deliberatively leaving wider and more complex issues concerning sustainability outside the scope of the programme. The 2003 Action Plan however notes that 'the EU's wider objective is to encourage sustainable forest management' and that, for many countries, 'legislation is based on the premise of sustainable forest management'. As such, FLEGT's focus on legality verification is presented as a first, key step toward more sustainable forest management, notably through law enforcement (COM, 2003: 5). Indeed, at least at the policy level, the documents and regulations outlining the structures and ambitions of FLEGT at large are explicitly aimed at addressing the three pillars of sustainability, including social (sustainability) issues and the related human rights. Most notably, the 2003 EU FLEGT Action Plan recognises the social and human rights issues associated with illegal logging, and acknowledges the need (and the challenge) to ensure that 'actions to address illegal logging, particularly enhanced law enforcement, do not target weak groups, such as the rural poor, while leaving powerful players unscathed'. The Action Plan further recognises that existing forest governance systems generally tend to promote large-scale logging operations, often limiting the chances of small- and medium-sized local operations, as well as community networks, to access forest resources. Such inequity, according to the AP, not only creates resentment and/or conflict, it also forces local people, who depend on forest resources to sustain in their livelihoods, to operate illegally in the informal economy (COM, 2003: 6).

[24] For an overview of human rights concerns associated with illegal and/or unsustainable forest practice, as well as reports on various global human rights violations within the sector, please see The Forest Peoples Programme: http://www.forestpeoples.org/background/about-forest-peoples-programme

[25] For a number of examples, please see: EIA, 2014; Greenpeace India, 2012; HRW, 2009; HRW 2013; CIFR, 2008.

In a similar vein, the Council Conclusions adopting the FLEGT AP in 2003 acknowledged that 'forest law enforcement, governance and trade needs to be addressed within the framework of sustainable development, sustainable forest management and poverty reduction, as well as social equity and national sovereignty' (EC, 2003, Art. 6). The Conclusions further urged the Commission and the MSs to engage in 'a political dialogue with key target countries to instigate forest sector governance reforms', paying specific attention to, *inter alia* i) strengthening land tenure and access rights, especially for marginalised, rural and indigenous peoples; ii) strengthening effective participation of all stakeholders, notably non-state actors and, again, indigenous peoples, both in policy-making and implementation; iii) increasing transparency in association with forest exploitation; and finally iv) reducing corruption in the sector (EC, 2003: Art. 9).

When it comes to defining what constitutes legal timber however, FLEGT maintains a rather ambiguous approach between policy guidelines and legal requirements, leaving ample discretion for partner countries to set their own standards of legality definition. On the policy side, a 2007 FLEGT Briefing Note issued by the Commission states that, since the long-term aim of the FLEGT AP is to promote sustainable forest management, any definition of legal timber should therefore 'incorporate laws that address the three pillars of sustainability – i.e., those aimed at economic, environmental and social objectives'. Further according to the Briefing Note, such laws 'are likely to include' legislation concerning i) the granting and compliance with timber harvest rights; ii) requirements regarding forest management, including relevant environmental, labour and community welfare legislation; iii) requirements concerning taxes as well as import and export duties, royalties and fees directly related to timber harvesting and trade; iv) respect for tenure or usage rights to land and resources; and v) compliance with trade and export procedures (COM, 2007b: 1).

On the legal side, the 2010 EUTR defines 'legally harvested timber' as timber harvested in accordance with the applicable legislation in the country of origin, while 'applicable legislation' covers the domestic rules and regulations in force regarding i) rights to harvest timber within legally gazetted boundaries; ii) payments and duties for timber harvesting; iii) environmental and forest legislation, including forest management and biodiversity conservation; iv) third parties' legal rights concerning use and tenure, notably when affected by timber harvesting; and v) trade and customs, as far as the forest sector is concerned that is (EP and EC, 2010: Art. 2). Finally, whereas the EUTR preamble notes that 'relevant international conventions to which that country is party, should be the basis for defining what constitutes illegal logging', the operational part of the Regulation makes no mention of what conventions should be considered as 'relevant' in this regard, or how such international agreements should be integrated into the legality definition under a LAS or DDS (PE and EC, 2010: Art 14; Buhmann and Nathan, 2012: 63). In sum, in terms of legal requirements, VPA countries are free to choose what 'relevant' national and international laws and agreements are to be complied with in order for timber to be considered legal.

From a human rights and sustainability perspective, widespread concerns have been voiced about FLEGT's focus on legality verification and how this is entrusted to national legislative processes within the VPA partner countries. First of all, legality verification in and by itself has been criticised for its tendency to lead to legal formalism, which in turn could undermine different forms of legal

pluralism, which evolved over time allowing local users and smallholder producers to operate under locally negotiated rules (Nathan et al., 2014: 3). Essentially, the argument here is that the replacement of informal or customary governance systems, e.g. with regard to land usage or tree tenure, with formalised, western legal systems could negatively affect small-scale operators as well as the livelihoods of local communities in general. As such, the emphasis on legality as a means to improve forest governance is subject to broader contestation, beyond just FLEGT, particularly among CSOs working with local communities. The 'T' in FLEGT adds an additional point of pressure, in the sense that the market incentive provided by the EUTR is believed to encourage participating governments to (rapidly) conform with a standardisation of its legal framework. Lesniewska and McDermott (2014) argue in this regard that 'international trade favours the formalisation and standardisation of rules and procedures, coupled with third-party verification as the means to achieve global transparency and transform local products into fully equivalent and exchangeable commodities', while 'there is ample evidence across both industry- and CSO-led processes that standardisation and third-party verification have created disproportionate market barriers for small-scale and community or indigenous production systems' Lesniewska and McDermott, 2014: 18);. In sum, FLEGT's use of market incentive and legality verification risks encouraging governance approaches and legal reforms which, deliberately or not, favour large-scale international business interests over the interests and livelihoods of local communities. This may particularly be the case when the process is hasted and when considerable economic interests are at stake, as well in countries or sectors where civil society and vulnerable communities are not being heard. FLEGT however also provides incentives which are not tied to market uptake, notably in the form of EU funding and technical support to operationalise the VPA, which could therefore create the political space for a reform process that is more oriented toward appeasing domestic and local needs, particularly since such EU support is linked to multi-stakeholder participation in rule-making (Lesniewska and McDermott, 2014: 18; Buhmann and Nathan, 2012: 73). As noted above, the 2003 FLEGT AP shows an awareness of these risks and aims to ensure that increased law enforcement does not target weak groups, 'while leaving powerful players unscathed' (COM, 2003: 6).

Secondly, along with concerns over the dominance of a western interpretation of legal formalism and standardisation, and the effects that could have on local communities and small forest operators, questions have been raised about whether a focus on legality verification risks reducing the emphasis on (social) sustainability and human rights. While both the EUTR and the VPAs are presented as measures to promote sustainable forest management, their focus is on legality verification and legality in itself does not equate or promote sustainability, quite the contrary, legal formalisation often risks maintaining current unsustainable practices. Buhmann and Nathan argue in this regard that, '[i]ncreased international competition among timber growing or processing states to supply to markets that require legality based on national law may lead to lowering the bar rather than raising it' (Buhmann and Nathan, 2012: 77). Also, whereas leaving the definition of legality to domestic processes in VPA countries arguably strengthens national ownership of the VPA process, it also makes the scope for integrating stakeholders' interests, such as human rights and concerns about working conditions, susceptible to local dynamics of political economy, particularly with regard to whether or not there is sufficient political space for civil society engagement (Ibid, 77-78). Again, the Commission is aware that FLEGT's focus on legality falls short of providing a solution to all issues of unsustainable forest practices, yet argues that, since there is no doubt that illegal timber and the trade therein undermine efforts towards sustainable forest management, legality

verification is to be seen as a means to address the most destructive forest practices in the short term, while paving the way for a more comprehensive approach toward sustainability (COM, 2004:1).

A final major concern relates to the substance of the legality definition, more specifically to the fact that this is largely left to the discretion of national processes. Indeed, since legality is defined as conformity with national laws, concerns have been raised that VPAs might prioritise national laws over international and customary laws which could have guaranteed a better or more comprehensive recognition of the human rights and livelihoods of local communities and forestry workers (TEREA, 2016: 142). From a human rights perspective especially, the integration of international human rights standards and core labour conventions in VPA legality definition could arguably improve the social sustainability of FLEGT. A group of international human rights and environmental NGOs, have demanded concrete steps in this regard, to bring about 'a broader, more comprehensive conception of illegality which includes compliance with international human rights and environmental laws', notably by making sure that the priorities under the EU's Action Plan on Human Rights and Democracy (2015-2019) are explicitly integrated and mainstreamed into the implementation of the FLEGT AP, including through the introduction of international human rights law as an element of legality in VPAs and TLASs (Greenpeace et al., 2016: 2-6), based on the argument that

> Illegal logging is not only confined to direct contraventions of existing (often inconsistent) national laws. It also relates to non-compliance with international human rights and environmental law standards which in many cases have direct application in national legal systems, but have not been properly integrated into national laws (Ibid, 2016: 1).

The 2016 Independent Evaluation of the FLEGT AP raises the following, additional argument in this regard:

> 'by entrusting definition of legality to national legislation in producer countries, the EU may not live up to its own international commitments. In the absence of an international law on forests, reference to the national laws for both EUTR and VPA has resulted from the fundamental principle of national sovereignty of the producing country in FLEGT. While this is a key value in the FLEGT approach, which contributes to national ownership, sustainability and more effective enforcement of FLEGT at local level, it also creates potential deficiencies, especially with regards to human rights and protection of indigenous communities' (TEREA, 2016: 11).

2. The Ghana experience: scope for human rights protection and poverty reduction

As discussed in the section above, FLEGT's design scheme – notably the provisions stipulating the requirements for legality definition – leave ample space for national governments and domestic stakeholders to define the countours of what constitutes domestic timber in the country-context at hand, including in how far the legality definition takes into account broader sustainability and human rights considerations and how this impacts the lives and livelihoods of local forest communities.

In order to provide a comprehensive assessment of how this process has played out in Ghana so far, we take a dual approach. First, at a procedural level, we look into the multistakeholder political processes that are central to the negotiation and the implementation of each VPA process since these decide to what extent civil society and local communities are involved and empowered, both in terms of contributing to the decision-making and in terms of monitoring the implementation process. Forests, like all natural resources, are contested issues, subject to highly political decisions about their use and management. Whether or not the VPA creates the political space for civil society and local community to have a say in their exploitation thus potentially makes a big difference, e.g. in terms of how business interests are alligned with the needs and interests of domestic and local actors. Second, at a more 'substantive level', notably when it comes to legislative reforms, we look into the rules and policies in place, their distributive implications on access rights to forest resources, and how legal formalisation and enhanced law enforcement affect the livelihoods of forest fringe communities.

a) Procedural rights: civil society and community involvement

Buhmann and Nathan (2012) argue that, 'from the perspective of the EU, the main human rights element which the FLEGT scheme is seen to contribute towards is related to public participation in public governance' (Buhmann and Nathan, 2012: 72). Indeed, the right to participation in public affairs is a human right, recognised notably under art. 25 of the ICCPR. In the context of FLEGT however, participation in public decision- and rule-making is presented, not as a human right in itself, but rather as a means to contribute to good forest governance. Notably, the Commission believes that the multi-stakeholder process of negotiating and implementing VPAs will have a positive bearing in terms of rendering adequate recognition of the rights of local communities and indigenous peoples, reducing corruption and greater transparency and accountability, including a national mechanism for consultation on forest governance (Proforest, 2014: 5; In: Buhmann and Nathan, 2012: 73).

Generally speaking, examples from various VPA countries have shown that CSO and community participation and engagement in VPA processes has been one of the key success stories of the FLEGT AP (Bollen and Ozinga, 2013: 5; TEREA, 2016: 124-125). In Ghana as well, the VPA process has been hailed by domestic CSOs as 'transformational in the sense that it has opened up the space for continued dialogue in the forest sector, allowing civil society to engage and bring novel ideas to government led discussions' (Civil Society Ghana, 2015: 6). Respondents noted that, whereas before relations with the government and the FC were often cold or even confrontational, the VPA – and the EU's emphasis on consensual decision-making – had marked an incremental improvement in the level of trust and engagement between civil society and government. Such increased involvement in policy-making has been a steep learning-curve for both government and civil society, though the latter has proved its value and expertise, and while disagreements still exist, experience has shown there are more points of joint interest than points of divergence (Interviews with civil society, 9 August 2016).

The VPA process in Ghana is believed to have significantly improved the technical expertise understanding of forestry issues among domestic civil society organisations, enabling them to play an effective role at various stages of the VPA, particularly throughout the development of the LAS, including in a mock audit of the legality matrix. Without the suppurt provided through various training and capacity building initiative funded by the EU, the FAO and DfID, CSOs would not have

been able to effectively engage in more technical aspects of the VPA, e.g. in quality management systems and audits of chain-of-custody systems for forest products. As a result of this enhanced capacity, CSOs have not only been aksed by the FC to be involved in several projects under the VPAs implementation, the VPA process and the capacity support it rendered also created an opportunity for different types of civil socieyt organisations to come together and discuss governance issues well beyond VPA, which greatly contributed to the level of 'social captial' in the forestry sector (Adeleke and Karmona, 2008: 4; Civil Society Ghana, 2015: 3).

Besides CSO involvement, the legality matrix in the EU-Ghana VPA also requires continuous community involvement in order to ensure that forest fringe communities receive the benefits and access rights they are entitled to. Unfortunetly, the marked improvements in terms of CSO involvement and capacity support at the national level have not immediately been extended to the inclusion of local forest fringe communities, both in the negotiating and implemenation phase. This is a general observation, but holds true for the Ghanaian experience as well (TEREA, 2016: 125). Empowerment and involvement of local communities is important however, since VPA processes at the national leval can only be resilient if local communities buy in to the process and participate in its monitoring and implimentation on the ground. As a result, direct involvement of local communities in the VPA's implementation process is key to ensure that the systems and regulations in place i) do not have a harmful impact on the people concerned, and ii) are relevant and enjoy traction on the ground (Ozinga and Leal, 2010: 1; Lartey et al., 2013: 40-42). In Ghana, respondents voiced mixed oppinions about whether local communities had been sufficiently involved in the VPA process, though the general narrative whas that local communities had not been adequately represented in the negotiating process, which arguably excluded them from key legal reforms, whereas the implementation phase has witnessed some improvements in community representation (interviews civil society, 8-12 August 2016; Lesniewska and McDermott, 2014: 20).

Indeed, local communities in Ghana did not enjoy direct representation in the bodies involved in the VPA negotiations, but were represented indirectly through the VPA contact group and the NGO coalition FWG. Both the contact group and FWG consulted local communities, primarily through so-called Forest Forums (FF), which are multi-stakeholder dialogue and deliberation platforms on forest governance issues, organised at community-, district-, zonal- and national level – as a bottom up process, the lower-levels feed into the discussion and the decision making at the higher levels. FFs constituted the only place where local forest communities and user groups could discuss the VPA negotiations. In terms of frequency of assembly, Community FFs are supposed to assemble at least three times a year, whereas at the District level they do so a biannual basis, while Zonal and National FFs only meet once a year. In reality however, they meet when sufficient resources are available and unfortunately, during the VPA negotiations, only a few district-level FFs were operational, wich significantly limited the participation of communities from other districts. In terms of oprating, FWG facilitates both Community and District FFs and organises community outreach programmes, while the VPA contact group also included FF representatives in its coalition. As such, both FWG and the VPA contact group, both directly involved in the VPA negotiations, regularly interacted with local communities and their representatives. Through the respective feedback mechanisms of both the FWG and the contact group, community groups were, in theory, able to receive updates about the VPA negotiation process. In practice however, this rarely happened due to a lack of time and resources (Léger, 2014: 6). In cases where such information did reach the community, it proved challenging to introduce their feedback into the negotiation process since, in most cases information

was shared either through briefing papers and community radios, which generally did not allow community memebrs to react, let alone to influence the process (Mensah, 2013: 52). Whereas the feedback and information sharing mechanisms between local communities and their representatives at the nationa level have since not changed fundamentally, the implementation of the VPA in Ghana did release funds for the CSO-members of FWG and the contact group, in turn allowing for more regular community consultations (Léger, 2014: 6-7).

As such, the community representation through FFs improved throughout the implemenation phase and, since 2011, funding from DfID and the EU has allowed civic response to organise National FF meetings every year. This has significantly increased the ability of local communities to raise their concerns and interests at the national level. In addition, and sourced with similar funding, various awaraness raising efforts by different civil society organisations have resulted in an improved appreciation of forest laws and rights among local communities, allowing them to hold forestry officials and timber companies accountable .[26] In a similar vein, interviewees noted that, local communities have become increasingly aware that the provions under the VPAs legality definition grant them certain rights, yet overall, the lack of information in this regard remains problematic and many communities remain in the dark about their redistributive rights (interviews with civil society and private sector representatives, 9 and 12 August, 2016).

3. Substantive rights: legislative reforms

VPAs are broadly acknowledged for their potential impact on legislative reform. First, they encourage (potential) partner countries to assess and revise their legislative framework on forest governance, especially where legislation is outdated, incoherent or contested. Secondly, while maintaining the pre-eminence of national legislation, VPA processes steer reform processes to make the national legislation compatible with the spirit of the FLEGT AP, which includes explicit notions of sustainability and 'equitable and just solutions' to ensure governance reforms and enhanced law enforcement 'do not have an adverse impact on people' (COM, 2003: 3). The 2016 independent evaluation of the AP however notes that in most VPA countries 'the main work on legal reform remains to be done' and 'issues regarding land allocations, old permits/licenses and land right' are still pertinent (TEREA, 2016: 115). Moreover, the general consensus, 'cross-VPA' is that the legislative processes in VPA countries have so far yielded little progress in securing 'substantive rights', despite significant progress when it comes to 'procedural' rights like CSO involvement. As argued by Duffield and Richards (2014), the main advances made under VPA processes have been made in terms of procedural rights, notably in the form of improved transparency, consultation, monitoring and accountability, rather than in terms of substantive rights. Whereas the former arguably constitute a vital pre-condition for the latter, progress on legal reforms has overall been limited and whether VPAs will effectively contribute to more just and equitable forest governance structures thus remains to be seen (Duffield and Richards, 2014: 2).

In Ghana, the key legal reforms with a direct bearing on the rights and livelihoods of local forest communities, have focused on two interlinked issues, notably a reorientation of the domestic timber market, away from illegal chain-saw-milling (CSM), and a better observance of the Social Responsibility Agreements between companies and communities.

[26] Examples include communities like Dench in the Bodi District, Obengkrom and Wassa Akuampim in Prestea Huni Valley District, all in the Western Region (Civil Society Ghana, 2015: 2).

Even though *strictu sensu* it was not necessary in order to comply with the VPA/EUTR requirements, a progressive coalition of domestic actors used FLEGT as a vehicle to address the domestic market's dependence on illegal CSM. As a result, the inclusion of the domestic market in the VPA process effectively forced the Ghanaian government to reconcile a dual objective, ensuring future domestic needs can be met in a legal manner, whilst securing revenues from wood exports. Whereas the VPA was 'used', as a 'convenient instrument to reinforce overriding national interest for reforms', especially considering the detrimental impact CSM had on Ghana's forest resources, the VPA process did provide the legislative legitimacy and political momentum to take the process forward, not in the least through EU support to civil society members of the reformist coalition (Marfo and McKeown, 2013: 28).

Chainsaw milling, the use of motor-operated chainsaws to cut and saw logs into lumber, became a wide-spread means of producing timber in the early 1980s in Ghana. The practice however soon became associated with excessive and indiscriminate felling, which led a proliferation of regulatory regimes at various levels of governance. Largely due to this incoherent, decentralised regulatory framework, the sector expanded further and appeared to lack any form of public oversight since the rules in place were systematically abused by both operators, forestry officials and local government officials. By the late 1990s, the problem had become so extensive, rapidly depleting forest resources in an unsustainable manner, that, after a comprehensive policy review, the government saw it best to ban CSM altogether (Marfo and Mckeown, 2013: 26). The criminalisation of the sector under the 1998 TRMA was not followed by a drastic crackdown on the activity however, and by the early 2000s CSM had become a real problem and an industry in its own right. The sector is believed to employ some 130 000 people, provides livelihood support to about 650 000 people and accounts for no less than 84% of the timber supply to the domestic market. The informal sector constitutes an important source of livelihood support for forest communities, many of which are involved in CSM operations or permit illegal chainsaw operators to fell and saw trees on their farms in return for a share of the profits. Meanwhile, several attempts to enforce the ban have failed, particularly because the conventional sawmill industry is predominantly export-oriented and is unable to supply the domestic demand by legal means. Indeed, while legislation requires all wood-processing firms in Ghana to secure 20% of their production for the domestic market, this is not enforced effectively and, even if it were, it would not suffice to meet domestic demands (Hansen and Treue, 2008; Marfo and McKeown, 2013: 26). In addition, high levels of rural unemployment, weak law enforcement and corrupt practices among forestry officials constitute additional reasons for the sector's continuous growth (Marfo, 2010: vii-xi; interviews DOLTA and civil society organisations: 9 August, 2016).

In sum, Ghana's forest governance regime has created a situation in which the domestic demand for timber is supplied by the informal sector, largely based on illegal CSM operations. Due to its inclusion under the VPA however, and arguably also in continuation of previous reform initiatives, Ghana has taken a number of concrete steps to reform its domestic timber sector. Finding ways to legally source the operations of the suppliers to the domestic market is one of the key outstanding challenges ahead in this regard. As a first step, a new public procurement policy has been issued, which obliges contractors involved in public construction projects to use only legally sourced timber, and be able to demonstrate this. The new policy is believed to contribute to curbing corruption by eliminating the gap between contractual and actual prices. Moreover, public procurement was estimated to constitute roughly half of the domestic demand for timber. Legalizing that line of

demand therefore potentially represents cutting down one of the main drivers for illegal CSM (Overdest and Zeitlin, 2016: 56).

In order to address the root causes of illegal CSM however, respondents stressed the need to allow CSM operators and local communities to link up with legal supply chains and to provide adequate incentives for long-term alternative livelihoods. One way to do so is to design tendering procedures for harvesting concessions which are specifically tailored to the needs and capacities of small- and medium-sized local operators. Civil society representatives expressed concern in this regard since government tendering procedures for concesssions are better suited for large, formal, export-oriented companies, than for smallholder chainsaw operators. One respondent noted in this regard that 'as usual, when a 1-size fits all template is applied to governance reform, it is tailored to the needs and interests of the large actors and as a result, smallholders are crowded out'. While the tendering issue is currently being addressed (partly) in the draft L.I mentioned above (concerning the reform of special permits), loopholes would still allow for bigger companies to downgrade and access smaller-scale concessions, while smallholders do not get preferential access to smaller concession contracts. Indeed, the current proposal offers no preferential treatment for those who are supplying timber for the domestic markets and even though the policy refers explicitly to small scale producers, it does not exclude big firms biding for these contracts. As such, bigger, export-oriented companies are believed to continue to overrun the contracts, leaving small scale producers little option other than to resort to illegal timber (interviews DOLTA and civil society, 9 August 2016).

Some initial steps have been taken to encourage illegal chain-saw operators to integrate themselvels as artisinal millers into legal supply chains to the domestic market. Back in 2008, Tropenbos International (TBI), with support from the EU, establihed a multi-stakeholder dialogue process to create a platform to discuss the development of alternatives for illegal CSM. Through these discussion, the concept of 'artisinal milling' was identified as a potential alternative to CSM, both in terms of supplying the domestic market, as well as in terms of providing an alternative livelihood to CSM operators and the communities depending on them. Basically, TBI –with financial support from the EU- has helped artisinal millers, former chainsaw operators that is, to link up with large forest concession holders and to provide timber for their mills, effectively producing for the domestic market. As a pilot, this system has so far been applied with success to five artisanal milling groups in the country, yet, questions remain whether expanding the use of artisinal milling could potentially meet domestic timber demands. Additional challenges are to be taken into account as well, including elite capture of the concept, abuse of the system, corruption and, importantly, depleting forest resources (TBI, 2015:1). Finally, it was noted by interviewees that, in order for people to reconsider their first source of livelihood, 'it's all a matter of incentives, and as long as CSM remains illegal, no standards apply, there's a guaranteed market, all while illegal wood is free' (interview with civil society representative, 9 August, 2015. Reorienting the domestic market away from illegal CSM thus remains one of the key oustanding challenges under the implementation of the VPA, and one with a considerable bearing on the livelihoods of vulnerable forest communities currently relying on the sector.

A second major issue when it comes to securing the rights and livelihoods of local communities revolves around the observance of Social Rights Agreements (SRA). As described abover, the TMRA requires winning contenders for a TUC, upon receiving a Notice of Grant, to conclude a SRA with local communities before gaining the actual right to start harvesting timber in the allocated

concession area (ClientEarth, 2013b: 14). Local communities are defined by the FC by their geographical location, notably by their vicinity to a forest reserve. As such, only communities located within a distance of 5 Km from a forest can benefit from an SRA with an operator who wants to harvest timber in that forest (Lartey et al. 2013: 41). Under an SRA, timber contractors negotiate an agreement regarding the provision of specific social facilities and amenities, valued at a maximum of 5% of the value of the stumpage fees, to the local inhabitants of the proposed logging area in both on- and off-reserves. In theory, SRAs thus allowed forest communities to profit from timber harvesting. Historically however, these SRAs have been poorly implemented and many communities were not sufficiently aware of their rights to such compensation (Interviews with civil society organisations 8-12 August, 2016)

In addition to SRAs, revenues from concessions rent and stumpage fees are considered as stool land revenues and are therefore required to be shared with the i) the Office of the Administrator of Stool Lands (OASL) (10%), and the remaining part between District Assemblies (55%), Stools (25%) and traditional councils (20%), all of which are supposed to use these revenues for the development of infrastructure and social amenities of their respective consistencies. Multiple interviewees, as well as Hansen and Lund (2011) argue that the distribution of these revenues is highly discretionary and rarely trickles down to the community level (interviews logging firm and civil society representatives, 9 and 12 August 2016; Hansen and Lund, 2011: 634-637).

Since very little public revenue from forest exploitation ever reaches the local level, arguably implies that the main, direct contribution of timber harvesting to the livelihoods of local forest communities depends on how SRAs are negotiated and observed. Moreover, adequate SRA implementation is not only necessary to ensure that local communities receive their fair share in benefits from timber revenues, ill-defined SRAs and/or outright abuses have in the past resulted in conflicts between local communities and timber companies and a mutual lack of trust still prevails. Sometimes this has resulted in forest communities getting payed off by illegal CSM operators to harvest on the legal concession areas of the companies who agreed to an SRA with the said community. Conversely, a correct and well-defined SRA can arguably help mobilise the cooperation of local people in terms of preventing such illegal CSM (Interviews civil society and logging firm, 9 and 12 August 2016).

The legality definition of the VPA's TLAS in Ghana makes FLEGT licensing conditional upon both the negotiation of a SRA and upon its correct observance. The VPA process has therefore reignited the discussion on the implementation of SRAs and a number of concrete steps were taken to improve their enforcement. Notably, after a 2014 field test of the TLAS revealed a lack of procedures when it came to establishing whether or not an SRA had been appropriately observed, the FC, in consultation with three NGOs involved in the VPA implementation process, developed a 'compliance checklist' which has now been integrated into the revised legality verification protocols for the TVD and the independent auditor (Interview civil society representative, 9 August 2016). The checklist includes practical questions such was whether communities were given relevant information, e.g. regarding the type and amount of compensation they were entitled to, and whether the timber company had delivered upon those obligations under the SRA (Overdest and Zeitlin, 2016: 55-56). Various interviewees noted that the inclusion of an SRA checklist into the TLAS, effectively making FLEGT licensing conditional upon their implementation, had been one of the main achievements of the VPA for local communities so far in Ghana. Finally, the sustainability manager of one of Ghana's largest timber companies noted that various companies had now begun to educate forest

communities about their rights and responsibilities under SRAs, as well as to educate them to hold their district assemblies accountable in terms of using timber revenues to their benefit (timber company representative, 12 August, 2016).

E. Concluding remarks

Over the years, critical observers have identified a number of particular risks associated both with FLEGT's (exclusive) focus on legality verification as a means to enhance forest governance, as well as with the way the FLEGT regulations currently entrust the definition of legality to national legislation in the VPA countries.

Indeed, FLEGT's design scheme, notably the provisions stipulating what constitutes legal timber, leave ample space for national governments and domestic stakeholders to define the contours of a national legality definition in the country-context at hand, including in how far the legality definition takes into account broader sustainability and human rights considerations and how this impacts the lives and livelihoods of local forest communities. As such, this case-study looked into how this has played out in the particular VPA experience of Ghana. We do so by taking a dual approach, first we discussed rights of a procedural nature, notably whether the multistakeholder political processes central to the negotiation and the implementation of each VPA process were sufficiently inclusive to civil society and, particularly, to local forest communities. Secondly, at the level of substantive rights, notably when it comes to legislative reforms, we look into the rules and policies in place, their distributive implications on access rights to forest resources, and how legal formalisation and enhanced law enforcement affect the livelihoods of forest fringe communities.

Along with other observers, the analysis captured in this case-study finds that indeed, the main advances made under the VPA process in Ghana have, so far, been accomplished at the level of procedural rights, notably in the form of improved transparency, consultation, monitoring and accountability, rather than in terms of substantive rights, for example in the form of redistributive or access rights, although here as well, credible legislative and regulatory measures have been taken to address these, more complex, issues in the medium- to long-term.

In terms of multi-stakeholder involvement, the Ghana VPA has been hailed by domestic CSOs as 'transformational' in terms of opening the political space in policy-making, as well as in terms of improving the capacity of domestic non-state actors to take part in forestry issues that previously would have been 'too technical' for non experts to get involved. At the level of community involvement as well, the VPA process, and the funding that came with it to local NGOs is believed to have significantly contributed to the involvement, albeit still indirect, of local forest communities in national policy processes. More remains to be done to develop a genuine and effective bottom-up approach however. Recognising and strengthening the sub-structures which currently facility community deliberations, e.g. the Forest Forums, therefore merits further support.

In terms of substantive rights, our analysis focused on two particular issues of concern in the Ghanaian context, the reorientation of the domestic market, away from illegal and unsustainable chain saw practices, and the observation of Social Responsibility Agreements between local communities and the timber companies operating in their vicinity. Both issues are of deeply complex nature and it will take time before tangible changes in the livelihoods of forest communities are noticeable. Yet both issues have benefited from a reinvigoration induced by the legal justification

and political momentum triggered by the VPA. For SRAs especially, the legality approach of FLEGT has contributed greatly to addressing the issues, although challenges remain widespread as irregularities in the implementation of the SRAs persist. Reforming the domestic market arguably constitutes the greatest challenges for the VPA in Ghana, both generally speaking as well as from a rights and livelihoods perspective. A new public procurement policy and pilot trails with artisanal milling show promising commitment however, to enable illegal chainsaw operators into the formal sector to supply legal timber to the domestic market. Further tailoring the tendering procedures for forest concessions to the needs of smallholder operators or local cooperatives however remains important as well in this regard.

At a more general level, across the VPAs in place so far, we find that Ghana is doing reasonably well to outline its interpretation of timber legality along the lines set out in the 2003 FLEGT AP, notably in terms of providing 'equitable and just solutions' to local communities, with due attention for (social) sustainability and human rights issues. However, as noted in the AP's recent evaluation 'the integration of human rights in VPAs is diverse, as the experimentalist design of FLEGT allows for tailor-made approaches and adaptation to local needs'. Such discretion arguably contributes to national ownership, yet also creates space for potential deficiencies, 'especially with regards to human rights and protection of indigenous communities' (TEREA, 2016:11). As such, we recommend integrating and mainstreaming human rights standards, notably from international commitments, as well as from the EU's own human rights strategy, into the legality requirements for VPA countries. In addition, such human rights provisions could then be made part of the regular progress discussions at the level of the Joint Implementation Committees. Such comprehensive expansion of the legality definition would however require a phased, rather than an all-or-nothing approach, granting incremental benefits corresponding with the progress made, including on the relevant human rights issues.

III. The human rights aspects of intellectual property clauses in EU free trade agreements – The case of access to medicines in EU-India negotiations

A. Introduction: Intellectual property rights and their international protection

According to the World Intellectual Property Organization (WIPO), intellectual property (IP) 'refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce'.[27] Intellectual property has gradually been protected by a number of legal instruments which allow IP owners (authors, inventors, etc.) to enjoy the benefit of their creations and inventions.

Two types of intellectual property can be distinguished according to the protection it receives: copyright and related rights, and industrial rights.[28] WIPO describes these two categories as follows:

> Industrial property takes a range of forms. These include patents to protect inventions, and industrial designs, which are aesthetic creations determining the appearance of industrial products. Industrial property also covers trademarks, service marks, layout-designs of integrated circuits, commercial names and designations, as well as geographical indications, and protection against unfair competition.[29]

Whereas

> Copyright relates to artistic creations, such as books, music, paintings and sculptures, films and technology-based works such as computer programs and electronic databases. In most European languages other than English, copyright is known as author's rights. The expression copyright refers to the main act which, in respect of literary and artistic creations, may be made only by the author or with his authorization. That act is the making of copies of the work. The expression author's rights refers to the creator of the artistic work, its author. It thus underlines the fact, recognized in most laws, that the author has certain specific rights in his creation which only he can exercise (such as the right to prevent a distorted reproduction). Other rights (such as the right to make copies) can be exercised by other persons, for example, a publisher who has obtained a license from the author.

The IP protection afforded to its owner is generally designated under the terms 'intellectual property rights' (IPR) and derive from the IP mechanisms described above. These IPR are of course present in domestic legislations, but given the fact that such creations of the mind had a vocation to travel across borders to be shared and traded, a number of international treaties have progressively been adopted since the end of the 19th century, so as to establish a common baseline of IP protection regardless of where intellectual creations were located. The most important among these treaties include

[27] See http://www.wipo.int/about-ip/en/

[28] Robin Ramcharan, *International Intellectual Property Law and Human Security* (TMC Asser Press 2013) 46.

[29] World Intellectual Property Organization, 'Understanding copyright and related rights', online http://www.wipo.int/edocs/pubdocs/en/intproperty/909/wipo_pub_909.pdf, 4.

- The Paris Convention for the Protection of Industrial Property of 1883;
- The Berne Convention for the Protection of Literary and Artistic Works of 1886, amended in 1979;
- The Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations of 1961.

The European Union itself, has competence to harmonise intellectual property rights as part of the construction of the internal market. Article 118 TFEU provides in that

> In the context of the establishment and functioning of the internal market, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.
>
> The Council, acting in accordance with a special legislative procedure, shall by means of regulations establish language arrangements for the European intellectual property rights. The Council shall act unanimously after consulting the European Parliament.

However, the most important IP-related treaty was probably adopted within the ambit of the World Trade Organization (WTO). It is the Agreement on Trade-Related Aspects of Intellectual Property Rights (1994), in short the 'TRIPS Agreement' or simply 'TRIPS', which provides for a basic level of protection of the different types of intellectual property, and was adopted by all WTO members. We will see, however, that under TRIPS, States are free to adopt legislations providing for more or better protection of IP, or to agree such more protective terms in bilateral treaties, which the EU has consistently been trying to achieve throughout its network of trade agreements.

The multilateral legal framework of intellectual property protection, as well as its bilateral appendices, has been the object of an intense debate concerning its impact on human rights, whether positive and/or negative. In the following pages, we will seek to review how the international trade law and governance framework for IPR is affecting human rights, with a focus on the right to health and access to medicines. We will see whether the EU is or is not able to ensure that the human right to health is not negatively impacted by the intellectual property provisions contained by the trade agreements which it negotiates with key partners

The first part of this chapter will provide a broad introduction to the links between the international law of IP and the human right to health – more in particular access to medicines. The EU policy in this regard will also be analyzed. The second part of this chapter will be dedicated to a case-study of the differences of approach between the EU and India on these subjects, and how these differences affect the negotiations of the free trade agreement which the two entities are currently negotiating.

B. The international legal framework for protecting intellectual property rights through trade

As indicated above, the most important treaty establishing a baseline for IP protection is TRIPS. In this section we will shortly analyse the contents of this treaty so as to better understand how it can affect the human right to health.

Articles 1 and 2 of TRIPS refer to the three international conventions above, and states that it does not derogate from them. It gives effect to the Paris Convention (Art. 2 TRIPS) and the Berne Convention (Art. 9 TRIPS). TRIPS therefore legislates partly by reference to other agreements, thereby reinforcing their harmonising character, a practice which is also used in other WTO agreements such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[30]

Some authors have remarked that it might be surprising that a WTO agreement would be endorsing and supporting rules which are outright barriers to trade by making it more difficult for commercial goods to be traded internationally, but indeed the WTO is only intent on promoting *fair* trade and therefore does not condone, for instance, the liberalisation of trade in counterfeit goods.[31]

TRIPS then goes on, like every WTO Agreement, to provide for national treatment (NT) and most favoured nation (MFN) treatment (Arts. 3 and 4).

Then come the stated objectives of TRIPS (Art. 7), which are worded as follows:

> 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.

This provision already underlines the entire philosophy of TRIPS, which is to seek to resolve the tension between protecting the interests of rights holders and the interests of the users and beneficiaries of IP-protected items (see *infra*). And indeed, Art. 8 TRIPS contains safeguards against overly detrimental effects on the public interest and abuse of rights by the rights holders. Although the TRIPS Agreement contains provisions regarding all types of IPRs listed above, in the following paragraphs, we will only review the case of patents, and more in particular how the TRIPS Agreement introduces so-called 'flexibilities' in order to ensure such balance.

'Patents' are described by the TRIPS Agreement as protections for 'inventions' (whether products or processes) which 'involve an inventive step' and are 'capable of industrial application' (Art. 27 1. TRIPS). Patents require to apply for them with competent national or international institutions, and when granted, give an exclusive right to the patent holder on the 'making, using, offering for sale, selling or importing' the patented products or the products derived from the patented process (Art. 28). The duration of a patent is set to 20 years (Art. 33).

As indicated above, TRIPS is a 'minimum rights' agreement which leaves much leeway to states to legislate the modalities of the protection, notably in order to reach an appropriate balance between

[30] See analogically Agreement on the Application of Sanitary and Phytosanitary Measures (1994), Art. 3.
[31] Andreas F Lowenfeld, *International Economic Law* (Oxford University Press 2002) 101.

protection of patent holders and end-users of products. This flexibility is particularly acute in relation to the supply of pharmaceutical products, which can be limited by decisions of the patent holder on marketing in certain countries, or on pricing. Such flexibilities include, for instance, the possibility to exclude inventions from patentability if necessary for human, animal or plant life of health; or diagnostic, therapeutic and surgical methods for the treatment of humans and animals (Art. 27 2 and 3). Likewise, a country may grant what has been called 'compulsory licenses'. Compulsory licenses allow a country to grant licenses to produce a patented product without the consent of the patent holder, under strict conditions, including:

- The country in question must have sought to obtain authorisation from the patent holder under normal commercial terms (except in case of a national emergency or other circumstances of extreme urgency, in which case only a notification is sufficient) (Art. 31 b);
- The compulsory licence must be limited to the time necessary for the purpose for which it was granted (Art. 31 c);
- The products under compulsory licence must be 'predominantly for the supply of the domestic market', i.e. they may not be exported (Art. 31 f);
- The right holder must be paid adequate remuneration taking into account the economic value of the authorisation (Art. 31 h);
- The decisions relating to the authorisation and the compensation must be amenable to independent judicial review (Art. 31 i and j).

As we shall see below, these 'flexibilities' are particularly relevant to the protection of the right to health through the guaranteeing of access to medicines by states.

One of the additional innovations of TRIPS is to provide for 'enforcement' of IPR, and enjoin members to put in place judicial mechanisms allowing rights holders to seek such enforcement (Arts. 41 ff.). TRIPS also lists a number of additional mechanisms which can be activated by the states to enforce IPR such as criminal procedures (mandatory for trademarks and copyright, optional for patents, Art. 61); seizure by customs authorities (Arts. 51 ff.); or provisional measures to prevent the sale of counterfeit goods (Art. 50).

Finally, and this can also be included in the list of 'flexibilities', developing and least developed countries were granted extensions to implement their obligations under TRIPS, which entered into force on 1 January 1995. In practice:

- As per Art. 65 2 and 3, Developing countries and countries transitioning from a planned economy had until 1 January 2000 to apply most of TRIPS' provisions. NT and MFN clauses had to be applied immediately;
- As per Art. 66, least developed countries (LDCs) were given until 1 January 2006 to apply the agreement. This grace period was then extended until 1 July 2013, and then until 2021.[32]
- LDCs were given until 2016[33] to apply the agreement to pharmaceutical products. On 6 November 2015, this term was extended until 2033;[34]

[32] Council for Trade-Related Aspects of Intellectual Property Rights, 'Extension of the transition period under article 66.1 for least developed country members', 12 June 2013, WTO Doc. No. IP/C/64.
[33] WTO Ministerial Conference, 'Declaration in the TRIPS Agreement and Public Health, 20 November 2001, WTO Doc. No. WT/MIN(01)/DEC/2.

- As per Art. 65 4. of TRIPS, if developing countries did not provide IPR protection to certain technological products on the date of the entry into force of TRIPS, they did not have to do so before 1 January 2005. For pharmaceuticals and agricultural chemicals, these countries however had the obligation to allow patent applications as from the date of entry into force of TRIPS, even if the decision would only be made in 2005 (Art. 70 8.). A number of countries, including India, availed themselves of this provision.[35]

C. The interplay between TRIPS and human rights

1. IPR and human rights in general

As we have seen above in the structure and logic of the TRIPS agreement, it is clear that IPR and some human rights like the right to health are in tension. However, as remarked by some authors, intellectual property law and human rights law have tended to develop largely autonomously, as IP and human rights lawyers seldom engaged each other until recently.[36]

Beyond the question of impacts, one way in which IPR and human rights law directly intersect is through the reference to intellectual creations in foundational human rights texts. Art. 27 of the Universal Declaration of Human Rights (UDHR) reads:

> (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
>
> (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Likewise, Art. 15 1. of the International Covenant on Economic, Social and Cultural Rights (ICESCR) provides:

> The States Parties to the present Covenant recognize the right of everyone:
>
> (a) To take part in cultural life;
>
> (b) To enjoy the benefits of scientific progress and its applications;
>
> (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Again here, the tension between IPR and human rights is visible, as these two articles declare the right of everyone 'to enjoy the benefits of scientific progress and its application'; whereas at the same time insist that the authors of such progress must have their 'moral and material interests' protected, suggesting that they should be remunerated for their creations.

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[34] Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the transition period under article 66.1 of the TRIPS Agreement for least developed country members for certain obligations with respect to pharmaceutical products', 6 November 2015, WTO Doc. No. IP/C/73.

[35] World Trade Organization, 'TRIPS and pharmaceutical patents', Fact Sheet, September 2006, online https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf.

[36] Laurence R Helfer and Graeme Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2011) 31.

Many commentators have made sense of this tension by stating that the interest of the public in sharing the benefits of scientific progress had to be accompanied with incentives for inventors to make that progress in the first place.[37] However, although some aspects of IPR in these provisions resonate with human rights, such as the right to property or the dignity of being compensated for one's work and enjoy an adequate standard of living, many have also challenged interpretations of such rights as giving rise to 'exclusivity' in the benefits of intellectual creations and generally a human right to all economic proceeds of such creations.[38]

And indeed, the UN Committee on Economic, Social and Cultural Rights, in General Comment No. 17,[39] has denied that Art. 15 1 (c) of the ICECSR was meant to elevate all IPR protections to the rank of human rights by pointing to differences between the two categories:

- Human rights are 'fundamental as they are inherent to the human person as such', whereas IPR are 'of a temporary nature and can be revoked, licensed or assigned to someone else' (paras. 1 and 2);
- Whereas Art. 15 1 (c) 'safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments.' (para. 2).

The General Comment goes on to clarify that the protection of the 'moral and material interests' must be 'effective', but that such protection 'need not necessarily reflect the level and means of protection found in present copyright, patent and other intellectual property regimes' (para. 10). However, the General Comment does not exclude that IPR may be an appropriate means to afford such protection 'provided that these standards do not unjustifiably limit the enjoyment by others of their rights under the Covenant.' (para. 11).

This last sentence brings us back to the question of the tensions and conflicts which can exist between IPR and (other) human rights. Many authors have criticised the fact that TRIPS was designed in such a way as to represent 'the standard', while the rest, including human rights such as the human right to health or to food, was the exception.[40] Logically, given the 'fundamental

[37] Rochelle Cooper Dreyfuss, 'Patents and Human Rights: Where Is the Paradox?' in Willem Grosheide (ed), *Intellectual property and human rights : a paradox* (Edward Elgar 2010) 75 and UN Committee on Economic, Social and Cultural Rights, 'The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 5, paragraph 1 (c) of the Covenant), General Comment No. 17 (2005), 12 January 2006, UN Doc. E/C.12/GC/17, para. 4.

[38] Klaus D Beiter, 'The Right to Property and the Protection of Interests in Intellectual Property : A Human Rights Perspective on the European Court of Human Rights' Decision in Anheuser-Busch Inc. v. Portugal' (2008) 39 IIC : International review of industrial property and copyright law 714.

[39] UN Committee on Economic, Social and Cultural Rights, 'The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 5, paragraph 1 (c) of the Covenant), General Comment No. 17 (2005), 12 January 2006, UN Doc. E/C.12/GC/17.

[40] On the human right to health, see Sarah Joseph, *Blame It on the WTO? : A Human Rights Critique* (Oxford University Press 2011) 216. Concerning the right to food, see Olivier De Schutter, 'Seed policies and the right to food: enhancing agrobiodiversity and encouraging innovation', Report of the Special Rapporteur on the Right to Food, 23 July 2009, UN Doc. No. A/64/170.

character of human rights', it is argued that it should be the other way around, and that satisfaction of human rights should always precede compliance with IPR.[41]

In the following pages, we will briefly examine how this tension has played out in practice between TRIPS and the human right to health, more in particular concerning access to medicines.

2. IPR and access to medicines

a) The human right to health and access to medicines

What is generally dubbed the 'right to health' is in full the 'right to enjoy the highest attainable standard of physical and mental health', and is protected under Art. 12 of the ICESCR. The Committee on Economic, Social and Cultural Rights has issued a General Comment on the right to health,[42] which specifies that the right to health should not interpreted as the fact that one has a right to good health, as 'States [cannot] provide protection against every possible cause of human ill health.' Rather, the content of the right to health corresponds to the 'enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.' (para. 9.)

The General Comment further makes it clear that States are responsible under this provision to ensure access to medicines as they must 'control the marketing of medical equipment and medicines by third parties' (para 35) and 'protect consumers and workers from practices detrimental to health, e.g. by employers and manufacturers of medicines or food' (para. 51). Then Special Rapporteur Paul Hunt summarised in a 2006 report the obligations of States regarding access to medicines as follows:

> 47. States not only have a duty to ensure that existing medicines are available within their borders, they also have a responsibility to take reasonable measures to ensure that much-needed new medicines are developed and thereby become available.
>
> 48. In addition to being available, medicines must also be accessible. Accessibility has four dimensions. First, medicines must be accessible in all parts of the country […]. Second, medicines must be economically accessible (i.e. affordable) to all, including those living in poverty […]. Third, medicines must be accessible without discrimination on any of the prohibited grounds, such as sex, race, ethnicity and socio-economic status […]. Fourth, reliable information about medicines must be accessible to patients and health professionals so they can take well-informed decisions and use medicines safely.[43]

Sadly, this high threshold for access to medicines is far from being reached, and that many in the world, particularly the developing world, are largely without access to live-saving medicines. Former UN Special Rapporteur on the Right to Health, Anand Grover, made the following dire assessment in 2011:

[41] Lisa Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2011) 14 The Journal of World Intellectual Property 155.
[42] UN Committee on Economic, Social and Cultural Rights, 'The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights), General Comment No. 14 (2000), 11 August 2000, UN Doc. No. E/C.12/2000/4.
[43] Paul Hunt, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', 13 September 2006, UN Doc. No. A/61/338, 13.

> Despite recent progress, massive inequalities remained in access to medicines around the world, as nearly 2 billion people (or one third of the world's population) lack such access. Furthermore, more than 100 million people fall into poverty annually because of high health-care costs. In low- and middle-income countries, 50 to 90 per cent of the cost of medicines is paid by the patient, even though medicines account for 20 to 60 per cent of the health-care budget. The median coverage of health insurance is 35 per cent in Latin America, 10 per cent in Asia, and less than 8 per cent in Africa. Furthermore, only 5.2 of the 15 million persons living with HIV receive antiretroviral treatment.[44]

One of the causes for such lack of access to medicines in the poorer regions of the world has long been thought to be the current international legal regime on IPR. Below we briefly analyze this debate.

b) IPR and access to medicines: a conflict?

As indicated above, the underlying principle of IPR is to give exclusive rights to the IP owner on the use, sale and proceeds of its inventions, thereby giving him or her a monopoly over the marketing of these inventions. For pharmaceuticals, this means in practice that a patent holder is free to apply the price they choose for their drug, and is of course incentivised to make as much profit from a discovery before competition is allowed to enter the market and to bring prices down. IPR therefore *de facto* result in price inflation.[45] Pharmaceutical companies and in general, defenders of the IP protection system argue that such price inflation is necessary for firms to recoup the investments they made in research and development (R&D), and to provide them with incentives to enter into research in the first place by guaranteeing them a return in case R&D efforts yield a positive result. However, both the actual level of R&D spent by companies and the actual incentive effect of IPR to enter into useful R&D are increasingly being challenged.[46] In fact, it has been argued that this system only incentivised pharmaceutical firms to research diseases which are mostly prevalent in wealthy parts of the world such as diabetes, obesity or cholesterol excess.[47] Availability of medicines in less affluent parts of the world might therefore be put in jeopardy if cures to local diseases are not being researched, but even when they are, the pricing policies of pharmaceutical companies may make these drugs simply unaffordable in developing countries. HIV/AIDS is a case in point, as Sarah Joseph writes:

> For example, the costs of patented drugs which combat the HIV virus are enormous. A month's worth of Atripla, an anti- HIV drug, costs US$1,300 a month. Such prices are only affordable in industrialized countries due to government benefits, which are not available in the developing world. Clearly, it is impossible for most people in the developing world, where most HIV cases arise, to pay such prices. The result is a health divide: HIV remains a death sentence for most sufferers in the developing world whereas it can be managed for many years by sufferers in the developed world who have access to alleviating medication.[48]

[44] UN Human Rights Council, 'Expert consultation on access to medicines as a fundamental component of the right to health', 16 March 2011, UN Doc. No. A/HRC/17/43.
[45] Joseph, *supra* n. 41, 217.
[46] Ibid 231.; Ramcharan, *supra* n. 29 118.
[47] Helfer and Austin, *supra* n. 37, 140.
[48] Joseph, *supra* n. 41, 217.

The solution to these pricing problems has been to produce 'generic' medicines, i.e. 'copies' of the drugs which can then be marketed at significantly lower prices in developing countries. Taking again the example of HIV/AIDS, Anand Grover noted that, in 2001, at the peak of the HIV/AIDS epidemic in Africa, generic antiretrovirals were able to reduce the yearly price of treatment per person from $15,000 to $400.[49]

Beyond the problem of pecuniary access to medicines, IPR have also been argued to stand in the way of human rights progress in several other manners. For example, IPR and the obstacles they place on access to medicines in developing countries are considered to run counter to development dynamics as this monopoly confiscates the incentives to create and innovate and locates R&D capacity firmly in the west.[50] For example, India, which has been nicknamed 'the pharmacy of the developing world' due to its sizeable pharmaceutical industry, has mostly been manufacturing generic drugs rather than engineered new products through R&D of its own.[51]

As a response to what seemed like a problematic relationship, the Sub-Commission on Human Rights of the UN Economic and Social Council used the following forceful terms in 2000:

> 2. Declares […] that since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other;
>
> 3. Reminds all Governments of the primacy of human rights obligations over economic policies and agreements; […]
>
> 8. Requests the World Trade Organization, in general, and the Council on TRIPS during its ongoing review of the TRIPS Agreement, in particular, to take fully into account the existing State obligations under international human rights instruments.[52]

In the following section we will see how TRIPS has sought to adapt to respond to these challenges and criticisms.

c) TRIPS flexibilities and access to medicines

As indicated above, there are 'flexibilities' in TRIPS, which allow, for instance, developing countries to delay patenting pharmaceutical products, and to grant 'compulsory licenses' to domestic manufacturers with a view to supplying the local market with medicines. TRIPS was therefore written with the idea that some sort of balance was to be achieved between IPR and other public interests, but given notably the numbers on access to medicines given above, one cannot fail to conclude that that balance was not achieved. Reasons for this failure were on the one hand that

[49] UN Human Rights Council, 'Expert consultation on access to medicines as a fundamental component of the right to health', 16 March 2011, UN Doc. No. A/HRC/17/43, 8.
[50] Lowenfeld, *supra* n. 32, 106.
[51] Joseph, *supra* n. 40, 233-234.
[52] UN Economic and Social Council, Sub-Commission on Human Rights, 'Intellectual property rights and human rights', Resolution 2000/7, online https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/E-CN_4-SUB_2-RES-2000-7_Eng.pdf.

awareness of the possibilities offered by the TRIPS flexibilities, and on the other hand that, even if they made use of these flexibilities many countries lacked the industrial infrastructure to actually produce drugs irrespective of whether they were protected by a patent or not.[53] Let us indeed recall that, under Art. 31 f of TRIPS, drugs produced under a compulsory licence have to be destined primarily to the domestic market, therefore preventing one developing country from producing massive amounts of medicines and to export them in others.

WTO members therefore took a number of steps to ease the conditions placed on the use of these flexibilities. First of all, shortly following the Sub-Committee's 2000 resolution, the WTO Ministerial Conference adopted, on 14 November 2001, the so-called 'Doha Declaration on the TRIPS agreement and public health'.[54] The Doha Declaration explicitly recognised the 'concerns about [IPR] effects on prices' (para. 3), and recalled that TRIPS '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.' (para. 3) The declaration then goes on to restate and clarify what these flexibilities consist of:

> a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
>
> b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
>
> d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4. (para 5)

This restatement of existing law was of course insufficient, and therefore the declaration also took two concrete measures:

- As per para. 7, it extended the waiver to apply the provisions related to patents (and the protection of clinical trial data) for LDCs until 2016. This waiver has been extended until 2033 by the TRIPS Council on 6 November 2015.[55]
- In para. 6, the Ministerial Conference recognises the fact that compulsory licenses are of little help to developing countries which do not have industrial capacity and instructs the TRIPS Council to come up shortly with 'an expeditious solution'.

[53] UN Human Rights Council, 'Expert consultation on access to medicines as a fundamental component of the right to health', 16 March 2011, UN Doc. No. A/HRC/17/43, 13.

[54] WTO Ministerial Conference, 'Declaration in the TRIPS Agreement and Public Health, 20 November 2001, WTO Doc. No. WT/MIN(01)/DEC/2.

[55] Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the transition period under article 66.1 of the TRIPS Agreement for least developed country members for certain obligations with respect to pharmaceutical products', 6 November 2015, WTO Doc. No. IP/C/73.

On 30 August 2003, the WTO General Council adopted a decision[56] which contained three additional waivers with respect to Art. 31 f of TRIPS:

> Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.
>
> Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.
>
> Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.[57]

This mechanism therefore allows drugs produced under compulsory license in one country to be exported where they are needed, under the condition however that countries using this mechanism 'take reasonable measures, within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system'. (para. 4). This responds to the concern of pharmaceutical companies that generic medicines re-exported into western markets would undercut the market share of their patented drugs. To reassure them further, 23 rich countries declared from the outset that they would not be making use of this system, joined by others later.[58]

So far, it appears that this mechanism has not been extensively used for several reasons. First, other waivers such as the one which applied to developing countries until 2005 did in any event not oblige them to comply with Art. 31. Second, this mechanism apparently involves a lot of red tape for importers, as it notably requires to notify the TRIPS Council of names and quantities of drugs needed, etc. (para. 2), which may have discouraged a number of countries to participate. Finally, corporations, who were always wary of the system of compulsory licenses, began to adopt policies of 'differential pricing', selling their products at a cheaper cost in poorer countries to ensure better accessibility and by the same token render the system of compulsory licenses moot.[59]

Even though it seems that a number of mechanisms have been put in place to ensure that application of the baseline IPR protections contained in TRIPS was not to the detriment of access to medicines, additional concerns have started to emerge, linked to bilateral policies of a number of countries or regional blocs.

First of all, a number of experts have lamented the fact that some developing countries, in particular emerging countries whose markets are becoming large enough to represent a stake for western

[56] WTO General Council, 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health', Decision of the General Council of 30 August 2003, WTO Doc. No. WT/L/540 and Corr.1, 1 September 2003

[57] World Trade Organization, 'TRIPS and pharmaceutical patents', Fact Sheet, September 2006, online https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf, 6.

[58] *Id.*

[59] Joseph, *supra* n. 40, 226-228.

firms, have experienced 'pressures' from developed countries, regions or corporations not to take advantage of TRIPS flexibilities. These pressures have been well documented and notably involved, the US and the EU against Vietnam in 2006-2007.[60]

Second of all, developed countries and blocs like the EU have started negotiating wide networks of bilateral FTAs, which typically include provisions related to IPR and in many instances seek to go beyond the protections included in TRIPS ('TRIPS-plus', such as extension of the validity of patents); or to add new protections not included in TRIPS ('TRIPS-extra', such as the obligation to grant exclusivity to clinical trial data submitted as part of a patent application).[61] To the extent that these provisions render more difficult the attainment by States of the highest standard of health for the affected populations, these provisions would constitute violations of Art. 12 ICESCR. General Comment No. 14 in this regard makes clear that is a violation of the right to health 'the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organisations and other entities, such as multinational corporations.' (para 50)

Given that the EU is particularly active in negotiating FTAs including IP chapters, and given that the EU has firmly committed to ensure that all its policies, including its trade policy, complied with, and promoted human rights (Art. 2, 21 TEU; Art. 207 TFEU), it is interesting to survey in the next section how EU FTAs relate to IPR and access to medicine, before moving to a concrete examination of how the EU and India seek to reach a balance on these questions in their current FTA negotiations.

D. EU Free Trade Agreements, Intellectual Property and Access to Medicine

1. The EU and IPR

The EU is a staunch defender of IPR and firmly believes that innovation and progress require a strong IPR regime.[62] It is determined to work in order to improve the multilateral IPR regime,[63] to track down violations, as demonstrated by the recent creation of the EU Observatory on Infringements of Intellectual Property Rights,[64] and to litigate them where possible. For instance, out of 34 WTO disputes which concerned TRIPS, the EU was a claimant seven times, two of which specifically concerned pharmaceuticals, against India[65] and Canada.[66] India and Argentina then subsequently

[60] *Id.*, 230.
[61] Mario Cimoli and others, *Intellectual Property Rights : Legal and Economic Challenges for Development* (Oxford University Press 2014) 443. And Peter K Yu, 'The International Enclosure Movement' (2007) 82 Indiana Law Journal 827, 867–868.
[62] European Commission, 'Positive aspects of IP Rights', 2009, online http://trade.ec.europa.eu/doclib/docs/2009/january/tradoc_142108.pdf.
[63] European Commission, 'Trade for All – Towards a more sustainable trade and investment policy', 2015, online http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153846.pdf, 28.
[64] See https://euipo.europa.eu/ohimportal/en/web/observatory/home.
[65] Panel Report, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Complaint by the European Communities and their member States, WT/DS79/R, adopted 22 September 1998, DSR 1998:VI, p. 2661.
[66] Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, p. 2289.

incepted consultations regarding the seizure of drugs transiting through the EU on suspicion of counterfeiting.[67]

Therefore, whereas the EU is fully supportive of the multilateral IPR regime, it also recognises that it contains some weaknesses and therefore has come up with a strategy of its own to 'for the protection and enforcement of intellectual property rights in third countries.'[68] This strategy notably makes the following diagnosis:

> While [developing countries'] relationship with IP is changing from imitation to creation, counterfeiting, piracy, IP theft and other forms of IP misappropriation are still widespread. There is a huge drive by developing countries to continue their impressive economic growth and move up the value chain by mastering or gaining access to foreign technology, through legitimate competition or, by some actors, illegitimate means. Therefore, it is not sufficient just for the EU to get its IPR policy right–we must also strive to enhance protection and enforcement of IP abroad, in particular among our key trading partners.[69]

One of the EU's objectives is therefore to improve enforcement of IPR in developing countries. Beyond developing countries, the EU is also pursuing the objective of bringing the IPR rules applicable to EU businesses and creators abroad as close as possible to those which are in force within the EU, thereby pursuing a form of harmonisation effort which will, it is hoped, 'create further business opportunities and markets, thus leading to new jobs and economic growth.'[70]

2. EU FTAs IPR provisions and access to medicines

The EU is therefore implementing a policy of improving IPR protection in its bilateral relations with trade partners which by its own admission seeks to both improve enforcement of existing multilateral standards and add to these standards by trying to bring them up to EU domestic level. Aware of the debates that are ongoing regarding the possible impact of IPR on the public interest and human rights – which notably led to the failure of the Anti-Counterfeiting Treaty Act, or ACTA – and recalling its commitment to human rights in external policies, the EU claims that the IPR provisions it includes in FTAs are 'compliant with the Charter of Fundamental Rights',[71] which in its Art. 35 provides that 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.' The EU must therefore take into account the impact of IPR provisions in its FTAs on the right to health during negotiations and upon signing. In this regard, the review we had conducted, in Deliverable 9.2, of all Sustainability Impact Assessments completed by

[67] See respectively https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm and https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm.
[68] European Commission, 'Trade, growth and intellectual property -- Strategy for the protection and enforcement of intellectual property rights in third countries', 1 July 2014, COM(2014)389final.
[69] *Id.*, 4.
[70] European Commission, 'Protection of Intellectual Property in Free Trade Agreements', online http://trade.ec.europa.eu/doclib/docs/2012/november/tradoc_150081.pdf, 1.
[71] *Id.*

the EU in respects of its trade agreements does not indicate that impact of IPR policies on the right to health has to date been a fixture in these assessments.[72]

However, the EU is undoubtedly aware of the tension, as the recent 'Trade for all' communication states that it will 'continue promoting an ambitious global health agenda and better access to medicines in poor countries, including through a permanent waiver for least developed countries (LDCs) for pharmaceutical products under the WTO Agreement on Trade-Related Aspects of IPRs (TRIPs).'[73] In negotiating FTAs, the EU therefore claims to apply a differentiated policy according to the level of development of the partner at hand, aiming for stringent increases in IPR with developed partners, whereas very modest provisions are concluded with poor countries:

> We take as a reference the existing EU legislation, and calibrate our level of ambition to the partner country's level of development. For least-developed countries and poorer developing countries, a more limited set of IPR provisions may be considered.
>
> Recently concluded negotiations on trade agreements by the European Union have successfully integrated chapters on IP protection and enforcement. The most recent, those with countries in the Eastern Partnership (e.g. Georgia, Moldova, Ukraine) achieved significant regulatory standards as per the EU acquis. Others contain substantial improvements on TRIPS (e.g. Canada, Republic of Korea, Singapore) while others are also notable for improving beyond minimum international standards (e.g. Central America, Colombia, Peru).[74]

And indeed, a rapid survey of recent FTAs concluded by the EU with different types of partners evidences a downward curve: the EU-Korea FTA[75] contains significant advances, such as an unconditional extension of patent terms to make up for the time spent obtaining a marketing authorisation for up to five years (Art. 10.35), or the prohibition, for at least five years, to use clinical trial data submitted for the first time by an applicant for the purpose of obtaining a second marketing authorisation for a pharmaceutical product (thereby forcing, for instance, a generics manufacturer, to produce new data for essentially the same drug) (Art. 10.36). The Korea FTA also contains a lengthy enforcement chapter providing great detail as to the criminal penalties associated with copyright or trademark infringement, and confer wide-ranging powers to customs and other authorities to seize and confiscate counterfeit goods of their own motion (Arts. 10.54 ff).

On the contrary, the EU-Colombia/Peru FTA[76] contains language which expressly seeks to balance IPR and access to medicines. Art. 197 which contains the general principles of the IP chapter opens as follows:

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[72] See Nicolás Brando, Nicolas Hachez, Brecht Lein, and Axel Marx, 'The impact of EU trade and development policies on human rights', (2015) FRAME Deliverable 9.2, available at http://www.fp7-frame.eu/wp-content/uploads/2016/08/Deliverable-9.2.pdf, annex II.

[73] European Commission, 'Trade for All – Towards a more sustainable trade and investment policy', 2015, online http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153846.pdf, 14.

[74] European Commission, 'Trade, growth and intellectual property -- Strategy for the protection and enforcement of intellectual property rights in third countries', 1 July 2014, COM(2014)389final, 15.

[75] Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part, signed 06/10/2010.

[76] Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, signed 26 June 2012.

> 1. Having regard to the provisions of this Title, each Party may, in formulating or amending its laws and regulations, make use of the exceptions and flexibilities permitted by the multilateral intellectual property agreements, particularly when adopting measures necessary to protect public health and nutrition, and to guarantee access to medicines.
>
> 2. The Parties recognise 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.

The substantive provisions are more low key than the ones to be found in the Korea FTA. For instance, patent extension due to administrative backlog is not foreseen, but parties commit to use their 'best efforts to process the corresponding application expeditiously with a view to avoiding unreasonable delays' (Art. 230 3.). Data exclusivity shall 'normally' be granted for five years and only for pharmaceuticals containing 'new chemical entities' (Art. 231 2.). Concerning enforcement, advances are limited, as for instance there are no provisions regarding further criminalisation of IP infringement.

Concerning the poorer countries, as indicated, the EU does not currently pursue substantial advances in IP protection – in any event no TRIPS-plus provisions[77] – but rather works through capacity building and awareness-raising. An examination of recently concluded (interim) Economic Partnership Agreements (EPAs) indeed reveals that provisions concerning IP are rather commitments to keep negotiating further terms on those issues.[78] An exception is the Cariforum EPA, which contains a fully-fledged IP chapter which obliges party to accede to new patent-related treaties, and in that sense can be characterised as TRIPS-plus.[79]

This differentiation of requirements is a welcome policy but its benefits in terms of access to medicines and the right to health should be relativised in a number of ways. First of all, concerning emerging countries, the EU's initial demands are always exorbitant, and it is only after stiff resistance from the partners that more reasonable provisions are agreed. It was for instance stated that the EU's initial demands in respect of the EU-Colombia/Peru FTA 'centred almost exclusively on the interests of the rights holders' and 'washed away flexibilities set forth in the [TRIPS] Agreement.' In short, '[t]he provisions did little to advance the public interest.'[80]

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[77] James Thuo Gathii, *African Regional Trade Agreements as Legal Regimes* (Cambridge University Press 2011) 410.

[78] See e.g. Economic Partnership Agreement between the European Union and its Member States, of the one part, and the SADC EPA States, of the other part, which contains a 'rendez-vous clause' covering intellectual property at Art. 53. See also Art. 16 6. of the Interim EPA with the Southern African Development Community, which states: 'The Parties may consider entering into negotiations on the protection of IPRs in future, and the SADC EPA (not yet into force) States have as their ambition, and will endeavour, to negotiate as a collective. Should negotiations be launched, the EU will consider including provisions on cooperation and special and differential treatment.'

[79] Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part, signed 15 October 2008, Art. 147.

[80] Xavier Seuba, Juan Fernando García, 'Intellectual Property and Public Health in the EU-CAN FTA' 14 Bridges, 16 September 2010, online http://www.ictsd.org/bridges-news/bridges/news/intellectual-property-and-public-health-in-the-eu-can-fta.

Likewise, the inclusion of IPR commitments in 'goods-only' EPAs has been described as 'undue pressure' by some analysts, as IPR were not concerned by the WTO waiver concerning the Cotonou Agreement and therefore did not have to be concerned with its expiry and the negotiation of EPAs. The parties could therefore have taken all their time to consider whether and in what terms to negotiate an agreement on IPR, but it seems that the EU took advantage of the fact that ACP countries were under time pressure to conclude the EPAs.[81] Likewise, capacity-building and cooperation programmes have been found in the past to have led some developing countries to implement early the provisions of TRIPS, therefore not taking advantage of the transitional grace periods which had been afforded to them.[82]

We may therefore entertain some doubts as to whether or not the EU's approach to IPR in FTAs is or is not sensitive to the issues of the right to health and access to medicines. To be fair, the EU is quite active in beyond-trade settings on these issues, and notably has put in place a so-called 'health-in-all-policy' which consists in support notably for global health organisations and initiatives such as contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria; support for low- and middle-income countries' public health systems; support for R&D of medicines needed by low-and middle-income countries[83] The EU has also adopted legislations to encourage tiered pricing by pharmaceutical companies,[84] and to encourage the exportation of patented medicines to countries experiencing health crises.[85]

In the following sections, we will evaluate, through a practical case-study, how concrete FTA negotiations between the EU and India are currently playing out, and how widely diverging points of view concerning IPR might be reconciled in that context.

E. The right to health and access to medicines in the EU-India FTA

1. EU-India Trade Relations and the Negotiation of FTA

The formal bilateral diplomatic relationship between India and the European Union (EU) were established during 1960s. Since then that bond had grown closer in recent times with both sides regarding themselves as "natural allies in a wide range of global issues".[86] This relationship took more formal shape with the conclusion of a Cooperation Agreement in 1973, followed later by the

[81] Dalindyebo Shabalala, 'Intellectual Property in European Union Economic Partnership Agreements with the African, Caribbean and Pacific Countries: What way Forward after the Cariforum EPA and the interim EPAs?', Centre for Internatioanl Environmental Law, April 2008, online http://www.ciel.org/Publications/Oxfam_TechnicalBrief_5May08.pdf, 3.

[82] Joseph, *supra* n. 40, 229.

[83] European Commission, 'Access to Medicines: EU global health actions for low- and middle-income countries Fact sheet', April 2016, online http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154443.pdf.

[84] Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, *OJ* L 135, 3.6.2003, p. 5–11

[85] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, *OJ* L 157, 9.6.2006, p. 1–7

[86] For an overview of India and European Union Relations see http://www.mea.gov.in/Portal/ForeignRelation/India-EU_Relations_Website_Brief_-July_16__2015.pdf <accessed on 3 September 2016>; Also see High Level Trade Group. `Report of the EU-India High Level Trade Group to the EU-India Summit', (2006) http://trade.ec.europa.eu/doclib//docs/2006/september/tradeoc_130306.pdf

1994 Cooperation Agreement.[87] Further, both decided to elevate this relationship to a strategic partnership in 2004.[88] The EU identified India as its strategic partner considering its growing economic strength and increasing stature on the international scene.[89] According to one view these strategic partnerships had become one of the key features of European foreign policy as a way for the EU to assert itself while allowing emerging powers like India to build up their status as global players.[90] India, on its part, shaped its relationship with the EU taking into account some of its key interests which had been broadly classified as (a) safeguarding of its territorial integrity, economic and trade interests, nurturing its civilizational heritage and enhancing its strategic space; (b) creating conditions in its immediate neighborhood so as to facilitate channelising large part of its resources to health, education, environment and other vital social areas; and (c) developing its international political relationships to extend its interests in ever widening concentric circles, thus enabling it to fully harness its political, economic and technical resources.[91]

The EU regarded India as an important trade partner and also as an emerging global economic power with sizable and growing market of more than one billion people. The trade between both India and the EU had touched over 75 billion Euros in 2016.[92] More importantly, the trade between both of them had been growing exponentially covering several sectors.[93] The EU had been one of India's largest trade partners in recent years. It was, therefore, logical that both sides regarded as necessary and feasible to upgrade their relationship to a strategic level.

Despite this, according to some analysts, the strategic partnership between the two had not been taking off to a new level due to several systemic and complex reasons.[94] However, there were other viewpoints referring to the EU as a source of investment for India and a major destination of overseas acquisition for many Indian companies.[95] Even at the political level, both India and the EU

[87] This was preceded by a Joint Political Statement of 1993 and later in 1994 the conclusion of Cooperation Agreement which replaced Cooperation Agreement signed on 17 December 1973 and 23 June 1981

[88] European Commission, `An EU-India Strategic Partnership', (2004), Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee (COM (2004) 430; also see Gulshan Sachdeva, `India-EU Economic Ties: Strengthening the Core of the Strategic Partnership' in L. Peral and V Sakhuja (eds.), *The EU and India Partnership: Time to Go Strategic?* (EUISS and ICWA, 2012), 54; also see Gulshan Sachedeva, `EU-China and EU-India: A Tale of Two Strategic Partnerships' Strategic Analysis, 2014, vol.38, No. 4, 427 http://dx.doi.org/10.1080/09700161.2014.918415. <accessed on 3 September 2016>

[89] For The India-EU Strategic Partnership: Joint Action Plan, see http://commerce.nic.in/trade/India_EU_jap.pdf <accessed on 3 September 2016>

[90] See Jan Wouters, Idesbald Goddeeris, Bregt Natens Filip Ciortuz, `Some Critical Issues in EU-India Free Trade Agreement Negotiations', Working Paper No. 102 – February 2013, Leuven Centre for Global Governance Studies, KU Leuven 2

[91] See Bhaswati Mukherjee, *India and the European Union: Future Perspectives* http://www.mea.gov.in/in-focus-article.htm?24797/India+and+the+European+Union+Future+Perspectives <accessed 3 September 2016>

[92] For an account on India and EU Bilateral Trade Relations as discussed within the industrial associations see http://www.ficci-ineupf.com/trade.html <accessed on 3 September 2016>.

[93] For volume of trade and other details between India and EU see http://ec.europa.eu/trade/policy/countries-and-regions/countries/india/ <accessed on 3 September 2016>

[94] See Stephen Keukeleire and Bas Hooijmaaijers, `EU-India relations and multilateral governance: Where is the `strategic partnership'? https://lirias.kuleuven.be/bitstream/123456789/389027/1/EU-India.pdf. <accessed on 3 September 2016>

[95] Acquisition, for example, of Jaguar and Land Rover, Corus by TATAs and Schoneweiss & Co Gmbh now part of Mahindra and Mahindra, an Indian company. Besides these, there were several Information Technology-related companies that had been on a regular basis acquiring interests in several of the EU companies. See Saurabh Kumar, `The Political Economy of EU-India FTA', Briefing Paper No. 10/2013, CUTS International

had been coordinating their positions on many global issues and the potentials for the revitalisation of the strategic partnership continued to exist.[96] However, both sides had been in constant dialogue to overcome some of these bottlenecks. The 13th Summit between the EU and India which took place in Brussels on 30 March 2016 reconfirmed its commitment to give new momentum to the bilateral relationship endorsing the EU-India Agenda for Action 2020 as a common roadmap to jointly guide and strengthen the India-EU strategic partnership in the next five years.[97] Both sides had also decided to reengage in discussion on how to further the EU-India Broad-based Trade and Investment Agreement (BTIA) negotiations.[98]

India-EU Summit held periodically at the highest level had been to a considerable extent successful to ease some of these bottlenecks. The dialogue had been initiated and continued in areas such as energy, cyber security, research and innovation, environment, investment and several others. The list of subjects addressed in the Joint Summit held between India and the EU contained several topics, including that needed convergence at the global level. The Joint Statement issued on completion of this Summit could be a good indicator of trust and accommodation to arrive at consensus on certain policy goals. Some of these issues in the Joint Statement had included, though indirectly, references to human rights issues. The first efforts towards such summits began between India and the EU in 1993 with a Joint Political Statement, followed by a Joint Cooperation Agreement on Partnership and Development in 1994.[99] All these agreements and the joint political statements, *inter alia,* included provisions seeking "respect for Human Rights and democratic principles" as the basis for the cooperation between them and that it constituted an "essential element in the Agreement." The Preamble to the 1994 Agreement also spoke about the "…need to support Indian efforts for economic development, especially improving the living conditions of the poor." It also spoke about the protection of environment; linkages between environment and development, both at the global and local level. One of the highlights of these interactions between both sides, as narrated above, included taking existing bilateral relations, in particular trade relations to a new level through the negotiation of a comprehensive bilateral trade and investment agreement.

The negotiation of this bilateral trade and investment agreement which was otherwise termed as `free trade agreement' (FTA) was based on the recommendation rendered by a High Level Trade Group in October 2006 expecting it to be finalised in the next three years.[100] However, even after a

http://www.cuts-citee.org/pdf/Briefing_Paper13-The_Political_Economy_of_EU-India_FTA.pdf <accessed on 4 September 2016>

[96] Gulshan Sachdeva, `Evaluation of the EU-India strategic partnership and the potentials for its revitalisation, Directorate-General for External Policies, Policy Department, European Parliament, June 2015 http://www.europarl.europa.eu/RegData/etudes/STUD/2015/534987/EXPO_STU(2015)534987_EN.pdf <accessed on 4 September 2016>

[97] EU-India Summit: A new momentum for the EU-India Strategic Partnership, European Commission, Press Release, http://europa.eu/rapid/press-release_IP-16-1142_en.htm <accessed on 4 September 2016>

[98] Ibid.

[99] Reference should be made to the 1973 and 1981 Agreement between India and the EU which governed their formal relationships.

[100] This was launched pursuant to EU-India High Level Trade Group meeting in October 2006. See for EU-India Joint Action Plan: Implementation Report, http://www.mea.gov.in/bilateral-documents.htm?dtl/6347/EUIndia+Joint+Action+Plan+Implementation+Report <accessed on 3 September 2016>. Also see Report of the EU-India High Level Trade Group to the EU-India Summit, 13th October 2006, http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_130306.pdf; Also see paragraph 5 of the Joint Statement issued at the EU-India Summit: Helsinki, 13 October 2006 which stated "The rapidly growing flows

decade, with sixteen rounds of consultations, both sides were still attempting to fill the gaps that existed in the negotiations that related to several trade and non-trade issues such as to improve market access for goods and services, government procurement, issues relating to Geographical Indications and sustainable development.[101] Some analysts pointed out that the EU had been particularly active in seeking the so called "deep" integration FTAs to push their agenda of trade expansion and investment opportunities for their multinational companies, going beyond trade liberalisation to secure market openings in service sectors like banking and insurance, retail trade, business services, including legal and accountancy; government procurement, increased protection of intellectual property rights (IPRs) in geographical indications, data exclusivity in the drugs and pharmaceuticals sector that go beyond the Agreement of Trade-related Aspects of IPRs (TRIPs) negotiated within the ambit of the Uruguay Round of Negotiations within the World Trade Organization (WTO).[102] The EU was, however, prepared to take into account several other factors while negotiating on IPRs. The European Commissioner for Trade, for instance, had stated that though the EU had desired that the IPR chapters should as far as possible offer identical levels of intellectual property rights protection to that existing in the EU they were prepared to take into account the levels of development of the countries concerned and adapt their level of ambitions.[103]

2. Trade and Human Rights Nexus in the FTA Negotiations

The broader India and EU relationship based on the strategic partnership was to be guided by the promotion of human rights and with the harmonisation of their respective positions in all major multilateral forums. European Parliament through its resolutions specifically sought to link FTA negotiations with human rights issues.[104] In this, the EU had been mandated by the Lisbon Treaty to treat human rights as a key factor and the Treaty itself had brought about significant changes in the way the EU looked at human rights issues not only within its Member States but also with its

of two-way trade and investment between the EU and India reflect the strengthening of bilateral ties. Leaders on both sides encouraged an expansion and deepening of trade and investment linkages. Recognising that stronger economic engagement is mutually advantageous and would buttress the Strategic Partnership, the leaders decided to advance their bilateral trade relations. The Summit welcomed the work done by the High Level Trade Group and endorsed the case made for a future broad-based bilateral trade and investment agreement. The Summit agreed that both sides move towards negotiations for such an agreement. http://eeas.europa.eu/delegations/india/documents/eu_india/021_eu_india_res_7th_summit1_en.pdf <accessed on 3 September 2016

[101] India enjoyed trade preferences with EU under the Generalized Scheme of Preferences. However, this position is changing. *India-Quantitative Restriction case* before the WTO dispute settlement panel in early 2000 debated some of these issues in greater detail between India and the EU. See *India-Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products,* WTO, DS96, 18 July 1997, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds96_e.htm; Also see *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries,* WTO, DS 246 27 January 2003 https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds246_e.htm.

[102] Suman Modwel and Surendra Singh, `The EU-India FTA Negotiations: Leading to an Agreement or Disagreement?' *Observer Research Foundation,* February 2012, http://www.orfonline.org/research/the-eu-india-fta-negotiations-leading-to-an-agreement-or-disagreement/ <accessed on 3 September 2016> also see

[103] Address by Karen De Gucht, European Commissioner for Trade on `International Trade and Intellectual Property Rights,' 7 September 2011, Brussels, http://trade.ec.europa.eu/doclib/docs/2011/september/tradoc_148192.pdf <accessed on 30 August 2016>

[104] European Parliament, `Resolution of 26 March 2009 on an *EU-India Free Trade Agreement*', (2009) 2008/2135(INI), 43

external relations with other States.[105] One of the key elements of the Treaty for the EU was to place human rights at the centre of its relations with all third countries, including its strategic partners.[106]

For India, its Constitution mandated pursuance of its human rights norms both in its internal and external relations.[107] Human rights were in-built into its Constitutional framework and these rights were inalienable.[108] However, it would be difficult to find a direct relationship between trade and human rights within the context of Indian Constitutional scheme. This was done through various legal and policy formulations. There were several dimensions to the linkage of trade and human rights within the context of FTAs negotiations.[109] In the present study the scope of the examination of this linkage would be limited to IPRs.

a) Access to Medicines

Insistence on inclusion of TRIPs-plus provisions in the FTA negotiations by the EU generated wide spread debate on the issue of access to medicines.[110] The TRIPs-plus provisions generally meant and included those standards that complement and go beyond the standards of TRIPs Agreement and other relevant IP treaties. These standards, *inter alia*, included those provisions relating to public health and access to medicines such as data exclusivity, patent term extension and limitations of grounds of compulsory license. It had been contended that these FTA norms on IPRs would restrict India's capability to produce cheaper version of the generic medicines and in the process would affect the global supply of and access to medicines. However, some experts argued that the FTA negotiations usually stemmed from trade-offs in other areas that were important to India such as transfer of technology, geographical indications and opening of services sector, specifically Mode 4

[105] Nicolas Hachez, `Essential Elements' Clauses in EU Trade Agreements Making Trade Work in a way that helps Human Rights?' Working Paper No. 158, April 2015, Leuven Centre for Global Governance, KU Leuven.

[106] Article 21 (1) of the Lisbon Treaty provided "The Union's action on the international scene shall be guided by the principles which have inspired its own creation, development and enlargement, and which it seeks to advance in the wider world: democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity and respect for the principles of the United Nations Charter and international law." The European Economic and Social Committee explicitly supported this and sought to human rights with the FTA negotiations. See European Economic and Social Committee, `Opinion of the European Economic and Social Committee on the Role of Civil Society in the Free Trade Agreement Between the EU and India', (2011) REX/316 CESE 1612/2011, 4-5.

[107] Part XIII of the Indian Constitution relating to Trade, Commerce and Intercourse within the Territory of India provided for broader framework for internal trade relations. Article 301 of this Part provided "Subject to the other provisions of the Part, trade and commerce and intercourse throughout the territory of India shall be free." Reference should also be made to Article 51 of the Indian Constitution (in Part IV of the Directive Principles of State Policy) which, *inter alia*, provided, "The State shall endeavour to (a) promote international peace and security; (b) maintain just and honourable relations between nations; (c) foster respect for international law and treaty obligations in the dealings of organized peoples with one another; and (d) encourage settlement of international disputes by arbitration.

[108] Part III of the Indian Constitution guaranteed certain basic human rights, such as right to life, freedom of free speech and expression, right to pursue one's faith and religion and several others. These were termed as `fundamental rights' and any violation of these rights could be directly justiciable in the higher courts.

[109] Daniel Acquah, `Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a Need to Rebalance?' *International Review of Intellectual Property and Competition Law,* May 2014, Vol. 45, Issue 3, 256-286; Henning Gross Ruse-Khan, `Protecting Intellectual Property under BITs, FTAs and TRIPs: Conflicting Regimes for Mutual Coherence', *Max Planck Institute for Intellectual Property and Competition Law,* Research Paper No. 11-02, http://SSRN.com/abstract=1757724.

[110] Carlos M. Correa, `Negotiations of a Freed Trade Agreement European Union –India: Will India Accept TRIPs-plus Protection?' Oxfam, June 2009, 1.

of GATS.[111] It would be crucial for India known as the `pharmacy of the developing world' as to how far it would go to reconcile its position.[112] Several civil society groups had been actively campaigning against such possibilities within the proposed FTA.[113]

However, in order to understand this, reference should be made to the changing nature of Indian pharmaceutical industry and its healthcare provisions. The Indian pharmaceutical industry remained import-dependent till mid 1970s.[114] With the introduction of a new patent law in 1972 and Drug Price Control Order (DPCO), 1970 the nature of the Indian pharmaceutical industry changed. It had been further pointed out that increasing public sector focus on pharmaceutical industry and policies that sought to regulate the conduct of big pharmaceutical companies led to the growth of small and medium scale domestic Indian firms and established India as a dominant supplier of pharmaceutical drugs across the world.[115] On the legal front, absence of product patents and allowing only the process patents in the field of pharmaceutical drugs resulted in the creation of new generic companies. These generic companies soon developed capabilities to produce these generic drugs with very low production costs.[116]

[111]According some such trade-offs would lead to better relations for India with EU and other developed countries. It could also attract more foreign direct investment and lead towards a more willingness to enable access to these products in regulated markets of the "west". Tereza De Castro, `EU-India TRIPs-plus Agreement: A Real Threat for the Developing World?' http://www.ces.upol.cz/wp-content/uploads/2014/12/ces1_11_castro.pdf <accessed on 28 August 2016>; Sidonie Descheemaeker, `India, Pharmacy of the Developing World: IP, Trade and the Access to Medicine', https://www.law.kuleuven.be/jura/art/49n3/descheemaeker.pdf <accessed on 29 August 2016>

[112] Ibid.

[113] Letter from MSF to the Indian Prime Minister regarding access to medicines and the EU-India FTA, Geneva, 14 March 2013, http://www.msfaccess.org/content/letter-msf-indian-prime-minister-regarding-access-medicines-and-eu-india-fta. <accessed on 25 August 2016>; Letter to Karel de Gucht, Commissioner of Trade, European Commission, by OXFAM International and Health Action International "Safeguarding access to medicines in the last stage of free trade agreement negotiations with India", http://haieurope.org/wp-content/uploads/2014/02/Oxfam-HAI-Europe-letter-on-EU-India-FTA-negotiations.pdf <accessed on 25 August 2016>; In a letter dated 14 May 2013 to the Minister of Commerce and Industry 38 Civil Society Organisations under the banner of Forum Against FTAs, sought to critically evaluate the gains from the EU-India FTA, https://www.scribd.com/document/141449334/Letter-on-EU-India-FTA-by-Civil-Society-Organizations-from-India-to-their-Minister-of-Commerce-and-Industry <accessed on 25 August 2016>

[114]Nearly 70 per cent and above patents are obtained in India by the foreign companies. See *Annual Report, 2014-15*, Intellectual Property India, The Office of the Controller General of Patent, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce and Industry http://ipindia.gov.in/cgpdtm/AnnualReport_English_2014_2015.pdf <accessed on 1 September 2016>

[115]*Annual Report, 2014-2015*, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, http://pharmaceuticals.gov.in/sites/default/files/AnnualReport201415.pdf <accessed on 1 September 2016>

[116] In 2013 the Indian pharmaceutical industry was the `third largest in the world in terms of volume' estimated to be worth $ 10 billion. There were over 10000 units, either small, medium or unorganized, engaged in the production of drugs and pharmaceuticals. However, some have argued that there were more than 23000 units extending direct employment to 500,000 people and indirect employment to 1.9 million people. Among these only about 23 per cent produced bulk drugs and the others were engaged in the manufacturing of formulations. It had also been pointed out that the Indian pharmaceutical industry had a very skewed distribution with top ten manufacturers accounting for almost 37 percent of market share. The production of patented drugs, it should be noted, had only 1 percent of the market share. See Rakesh Basant and Shuchi Srnivasan, `Intellectual Property Protection in India and Implications for Health Innovation: Emerging Perspectives' Working Paper no. 2015-04-01, April 2015, Indian Institute of Management, Ahmadabad, India. http://www.iimahd.ernet.in/assets/snippets/workingpaperpdf/12875275012015-04-01.pdf <accessed on 1

The advent of the TRIPs regime necessitated several legal and policy changes within India. The Indian intellectual property laws, in particular its patent laws were amended in three stages incorporating TRIPs obligations.[117] These changes also necessitated the Indian pharmaceutical and other IP-related companies to adjust to the new post-TRIPs situations.[118] Some analysts had argued that the prices of the pharmaceutical products would go up during India's post-TRIPs implementation phase.[119] There were others who argued otherwise.[120] However, there had been marginal increase in the prices of drugs and medicines in certain sectors. With the introduction of product patent regime, it was anticipated that the Indian generic industry would lose its sheen and might not be able to sustain the production and supply of cheap medicines.[121]

India, while amending its laws, introduced a provision according to which a mere discovery of a new form of known substance which did not result in the enhancement of the known efficacy of that substance would not be patentable. It also provided that the mere discovery of any new property or new use for a known substance or mere use of a known process would not be patentable unless such process would result in a new product or employ one new reactant.[122] It had been argued in

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September 2016> Also see Report of the Working Group on Drugs and Food Regulations, The 12th Five Year Plan, Panning Commission of India http://planningcommission.gov.in/aboutus/committee/wrkgrp12/health/WG_4drugs.pdf ; also see for a detailed account of how India is adjusting to the post-TRIPs regime, Prabodh Malhotra, *Impact of TRIPs in India: An Access to Medicines Perspective,* (2010) Plagrave/Macmillan, 58; also see Padmashree Gehl Sampanth, `Economic Aspects of Access to Medicines after 2005: Product Patent and Emerging Firm Strategies in the Indian Pharmaceutical Industry,' Institute for New Technologies (INTECH), United Nations University, http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf <accessed on 1 September 2016>

[117] Indian Patent Law was amended three times to give effect to TRIPs obligations. The first amendment took place in 1999 to incorporate provisions relating to `Exclusive Marketing Rights' and `Mail-Box' provisions in Article 70 (8) and (9) of the TRIPS Agreement. The second set of amendments took place in 2002 and followed by 2005 amendments wherein the Indian law adhered to the product patent regime. For an account on the Indian amendments and its impact on access to medicines see K.M. Gopakumar, `Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPs Patent Regime', *The Law and Development Review,* Vol.3, No.2 (2010) https://ideas.repec.org/a/bpj/lawdev/v3y2010i2n11.html <accessed on 30 August 2016>

[118] Prabodh Malhotra, *Supra* note 31, 57-78.

[119] Biswajit Dhar and Niranjan Rao, `Transfer of Technology for Successful Integration into the Global Economy: A Case Study of the Pharmaceutical Industry in India', UNCTAD/ITE/IPC/2003/6, 87-133, http://unctad.org/en/docs/iteipc20036_en.pdf <accessed on 29 August 2016>; also see Sudhip Chaudhuri, *WTO India's Pharmaceutical Industry: Patent Protection, TRIPs and Developing Countries* (New Delhi: Oxford University Press: 2006).

[120] Reji K. Joseph, *India's Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges,* Discussion Paper no. 159 (New Delhi: Research Information System for Developing Countries: 2009) *http://www.ris.org.in/images/RIS_images/pdf/dp159_pap.pdf* <accessed on 28 August 2016>

[121] There was a significant impact on the nature and working of the pharmaceutical industry within India with introduction of product patent regime in 2005 pursuant to amendments to the Indian Patent Act, 1972 to give effect to the India's TRIPs obligations. For detailed study on this aspect see *Effects of New Patent Regime on Consumers and Producers of Drugs/Medicines in India,* August 2010. http://wtocentre.iift.ac.in/UNCTAD/09.pdf <accessed on 26 August 2016>

[122] Section 3 of the Indian Patent Act provided for `what are not patents'. Section 3(d) provided that the patents that are "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. *Explanation.*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers,

India that this provision was necessary to place check on the abuse of patent monopoly and attempts to extend such monopoly on mere discovery of new forms of use of the drug.[123] The legal validity and the consistency of this provision with the TRIPs obligations were challenged before the Indian courts.[124] The Indian Patent Law also provided for two levels for the opposition proceedings under its law before a patent is finally granted, namely, pre-grant and post-grant opposition.[125] Both these provisions had been criticised as being inconsistent with India's TRIPs obligations.[126] India, however, did not agree and continued to maintain that its amended patent law had been consistent with its TRIPs obligations.[127]

b) Data Exclusivity

There were also concerns with regard to provisions on data exclusivity. The EU had argued that the data generated for the development and marketing of a new medicine based on extensive research

complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy; also see William J. Bennett, `Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India', *Washington University Global Studies Law Review,* vol.13, no.3 (2014) http://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1500&context=law_globalstudies <accessed on 30 August 2016>

[123] This was known as `evergreening' of patents or `patent layering'; for the Indian account and its larger impact on access to medicines see Rajarshi Banerjee, `The Success of, and Response to, India's Law against Patent Layering', *Harvard International Law Journal*, vol. 54, May 2013, 204. Also available at http://www.harvardilj.org/wp-content/uploads/2013/06/Banerjee-to-Publish.pdf ; also see *2016, Special 301 Report*, Office of the United States Trade Representative, April, 2016 https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf ; Aditya Kant, `Section 3 (d): `New' Indian Perspective', *Journal of Intellectual Property Rights,'* vol.14, 2009, 385 *http://nopr.niscair.res.in/bitstream/123456789/6057/1/JIPR%2014(5)%20385-396.pdf;* Shalini Arora and Rekha Chaturvedi, `Section 3 (d): Implications and Key Concerns For Pharmaceutical Sector', *Journal of Intellectual Property Rights,* Vol. 21, January 2016, 16 http://nopr.niscair.res.in/bitstream/123456789/34013/1/JIPR%2021(1)%2016-26.pdf

[124]Indian Supreme Court dealt with the case of patenting of drug namely, `Glevec'. Some other form of this drug known as `Imatinib' had been patented in 1993. The Indian Patent Office refused to grant patent to the modified version of this drug invoking Section 3 (d) of Patent Act. Against this decision of the Patent Office Novartis which held the patent initially took the case to the High Court of Madras and later appealed to the Indian Supreme Court which also rejected its claim. This decision has been regarded as an authoritative interpretation of the Section 3 (d) of the Indian Patent Act. This case generated huge debate in India. Even the Cancer Patients Aid Association also contested the case along with the generic firm NATCO Pharma Limited which sought the licence to manufacture this drug. *Novartis AG v. Union of India* 1 April 2013, http://supremecourtofindia.nic.in/outtoday/patent.pdf ; Following this Supreme Court case , the Indian Intellectual Property Appellate Board (IPAB) interpreted and applied Section 3 (d) in two other cases, namely, *Fresenius Kabi Oncology Ltd v. Glaxo Group Ltd* (No.1), Order (No. 161 of 2013), 27 July 2013 and *Fresenius Kabi Oncology Ltd v. Glaxo Group Ltd (No.2*) Order (No. 162 of 2013), 27 July 2013.

[125] Section 25 of the Indian Patent Act provided for the two-stage opposition; once before the grant of patent grant and thereafter after the grant of patent. Both these opposition proceedings could be proceeded upon based on the same grounds. This kind of opposition at two levels and at different times on similar grounds had been criticized for delaying the patent grant. See Indian Statement before the World Intellectual Property Organization (WIPO) justifying the pre-grant and post-grant opposition proceedings in its Patent Law, http://pmindiaun.org/pages.php?id=1154 <accessed on 26 August 2016>

[126] Rakesh Basant, *Supra note* 31, 8

[127]Note on India's Intellectual Property Rights' Regime, Embassy of India, Washington D.C. https://www.indianembassy.org/messages.php?id=12 <accessed on 9 September 2016>; also see Biswajit Dhar and K. M. Gopakumar, `Effects of Product Patents on Indian Pharmaceutical Industry', http://wtocentre.iift.ac.in/Papers/3.pdf <accessed on 9 September 2016.

and test required to be adequately protected.[128] The EU, during FTA negotiations, noted that it would be important to take into account the fact that the development and marketing of a new medicine required the originator to conduct extensive research and testing.[129] The process of generation of these data, the EU further pointed out, would take more than ten years to complete and would have high value in terms of utility.[130] the EU's position was that considering these aspects an adequate data exclusivity provision should be provided for as required by Article 39 (3) of the TRIPs Agreement.[131] the EU had been demanding in its FTA negotiations with India that the generic manufacturers should conduct their own clinical trials to get marketing approval or should wait till a specified exclusivity period gets elapsed before a generic product was to be approved. This period was to be fixed at ten years. This measure, it had been pointed out, would create exclusivity for medicines separate from patents and would also apply to those pharmaceutical products that were off-patent. This demand by the EU, if conceded, had been regarded as having a devastating effect on the Indian pharmaceutical industry. The effect of such inclusion on data exclusivity in FTA negotiations with countries like Columbia, Peru and others had also been referred to.[132]

India had been consistently exploring the options that were available to it to put in place an appropriate data exclusivity regime.[133] Before a new drug was introduced into a market the

[128] These data were generated as required by the law through rigorous clinical and field trials before introducing and marketing any new medicine or agro-chemical product. The Drugs and Cosmetics Act, 1940 continued to be the primary legislation within India to regulate this aspect of data generated through clinical and field trials. EU had provided protection for data supplied in support of marketing authorization for medicines since 1987. According to its Directive 65/65 amended by Directive 87/21/EEC it established a minimum six years of data exclusivity for the originator's test data and ten years exclusively for high technology products, biotechnology products and new chemical entities. See Council Directive 87/21 EEC of 22 December 1986 amending Directive 65/65 EEC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31987L0021:EN:HTML. <accessed on 30 August 2016>

[129] European Commission, Access to Medicines, http://trade.ec.europa.eu/doclib/docs/2013/april/tradoc_150989.pdf

[130] In the United States and Europe generally innovator firms had complete and perpetual control over the clinical trial data. In other words, these firms had the exclusivity over these data for perpetuity. This discouraged generic firms from undertaking any of their clinical trial as it would have taken long time to conduct such trials and involved huge financial outlay. In order to encourage generic pharmaceutical firms US Congress enacted the Drug Price Competition and Patent Term Restoration Act (also known as Hatch-Waxman Act) in 1984. See http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec355.htm

[131] Ibid. Article 39.3 of the TRIPs Agreement provides "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosures, except, where necessary, protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

[132] The EU-India Free Trade Agreement and Access to Medicines, http://www.twn.my/title2/resurgence/2012/259/cover04.htm <accessed on 8 September 2016>

[133] Initially, the Indian Government funded a major study to understand and identify the suitable mode of protection for test data taking into account the interest of Indian industry, in particular pharmaceutical industry. N.S.Gopalakrishan, *Study of Test Data Protection in India,* School of Legal Studies, Cochin University of Science and Technology (CUSAT: 2005). This study did not support data exclusivity as the only mode to protect test data against unfair commercial use and treated data exclusivity requirement as a TRIPs-plus approach and not binding WTO Member States. Also see Position Paper on *Regulatory Data Protection – A Building Block for Pharmaceutical R & D,* Organization of Pharmaceutical Producers of India (2008) https://www.indiaoppi.com/sites/default/files/PDF%20files/Regulatory%20DATA%20PROTECTION%20-%20OPPI%20Position%20Paper.pdf <accessed on 8 September 2016>

pharmaceutical company introducing the drug should submit clinical test data to the relevant national drug regulatory authority to prove and ensure the drug's safety and efficacy. In several countries such fresh clinical test data need not be submitted if there was already such clinical trial had taken place and that the pharmaceutical company just had to show that what it was introducing was only a bioequivalent to the medicine of the originator company. While this would allow the generic medicines to enter the market quickly, it would otherwise affect commercial interests of the originator company who would have otherwise invested lot of time and resources in conducting these trials. Some had argued that TRIPs did not require countries to provide data exclusivity as it only required them to protect such data against `unfair commercial use' if it was a `new chemical entity' and involved a `considerable effort.'[134]

The Indian position on data exclusivity, some had argued, appeared to be ambivalent and inconsistent.[135] It was shaped, initially, on the basis of the Inter-Ministerial Committee constituted by the Indian Government.[136] This Committee examined the feasibility of applying separately data exclusivity requirements for three distinct industrial sectors, namely, agro-chemical, pharmaceutical and traditional medicine industry. For each of these sectors it provided separate regulatory framework. It supported full-fledged `data exclusivity' regime for agro-chemical sector. For the pharmaceutical sector it only suggested a `non-disclosure or confidentiality' regime. Lastly, for the traditional medicine sector it recommended a `confidentiality' regime as well; however, with the constitution of a regulator who could still decide on the data and information to grant approvals for generics.[137]

Some had further argued that this ambivalent Indian position with regard to the application of `data exclusivity' to all sectors, including the pharmaceutical sector would be to provide an incentive for clinical trials in India and an effective `free-ride' off the regulatory data that pharmaceutical companies were bound to generate for the prosperous markets of Europe and North America.[138] However, it would be doubtful as to whether such clinical trials data could be used to validate drugs in an entirely different socio-economic-genetic context. Data exclusivity, therefore, was one of the main issues. India was apprehensive about the implications of Registration, Evaluation, Authorisation and Restriction of Chemicals Substances (REACH) framework on their market access for chemicals, dyes, etc. in the EU.[139] Under these regulations, each and every chemical to be imported to the EU

[134] *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,* Human Rights Council, A/HRC/11/12, 31 March 2009, 24 also see *Intellectual Property Rights and Access to Medicines: A South-East Asia perspective on global issues,* World Health Organization (WHO), Regional Office for South-East Asia, (2008) 27.

[135] T. Prashant Reddy, `The Data Exclusivity Debate in India: Time for a Rethinking', *The Indian Journal of Law and Technology,* Vol. (2014), 8.

[136] *Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement,* Department of Chemicals and Petro-chemicals, Ministry of Chemicals and Fertilizers, Government of India (2007), http://chemicals.nic.in/sites/default/files/DPBooklet.pdf

[137] The data exclusivity issue was taken up later by a Committee of the Indian Parliament which recommended against any such protection, see *Report on Patents & Trade Marks System in India*, Department-related Parliamentary Standing Committee on Commerce, *Rajyasabha*, Parliament of India (2008) http://www.ip-watch.org/weblog/wp-content/uploads/2015/03/Parliamentry-Committee-on-Commerce-88th-Report-on-Patent-and-TM-System-in-India.pdf

[138] Prashant Reddy, *Supra note* 50, 25.

[139] According to a study by Oxfam International with regard to the effect of *US-Jordan FTA* on data exclusivity showed that it resulted in significant delays to the introduction of generic competition for 79 percent of

had to be registered in advance and the cost of this registration was very high.[140] This cost was prohibitive for small and medium exporters of India and would make products of large producers also uncompetitive in the EU market.[141]

The data exclusivity issue within India is still unresolved. There is no concrete domestic legislation on this aspect as of now, although the Government is proposing to introduce a separate bill only for the pesticides.[142]

c) Patent term Extension

TRIPs Agreement provided for a patent term of twenty years. The EU had been contending that it had become difficult for pharmaceutical firms to get the full term on account of various procedural hurdles, particularly in the processing of marketing approval applications. It argued for longer patent term to compensate drug innovators for long delays during patent life in obtaining marketing approval and other necessary clearances. The EU had noted that on account of these delays pharmaceutical products were made available in the market several years after the patent application had been filed. In addition to data exclusivity clause, this patent term extension would be appropriate to provide the right holder effective patent protection.

India had been arguing that such extension of patent life could significantly impact the ability of its population to access medicines and might also pose a burden for its national health budgets.[143] It had been estimated that the three-year patent extension provision in the US-South Korea FTA would cost US$ 504.5 billion and a four-year extension would cost US$ 722.5 billion, consequently placing heavy burden on national health systems.[144] The draft proposal in the EU-India FTA had proposed additional five year term to compensate for the time required for the marketing approval of medicinal product. This provision was modeled on the basis of`supplementary protection certificate' applied in the European context. The grant of such certificates, it had been pointed out, would in practice extend the monopoly conferred by a patent and delay the entry of generic competition

medicines. This led to price increases of between two and ten-fold for key medicines to treat cardiovascular diseases and cancer. The study estimated that the availability of generic equivalents would have reduced Jordan expenditures on medicines between $6.3 million and $22 million during 2002 and 2006. Oxfam, `All Costs, No Benefits: How the US-Jordan FTA affects access to medicines', *Oxfam International Briefing Paper No. 102,* (2007), http://policy-practice.oxfam.org.uk/publications/all-costs-no-benefits-how-trips-plus-intellectual-property-rules-in-the-us-jord.114080 <accessed on 30 August 2016> ; also see Saurabh Kumar, `The Political Economy of EU-India FTA,' *Briefing Paper No. 10/2013,* CUTS International,

[140] For an account on the EU and US positions on data exclusivity and other technical details see Gargi Chakrabarti, `Need of Data Exclusivity: Impact on Access to Medicines,' *Journal of Intellectual Property Rights,* Vol.19, September 2014, 325-336.

[141] India had been seeking data secure status for its information technology sector to increase its outsourcing business capacity in Europe. Because of its lack of data secure status, India currently had no access to intellectual property or other sensitive information, such as patient records required for telemedicine from EU countries. As per the existing EU law, outsourcing business with countries that were not data secure had to fulfill strict requirements which restricted EU companies to carry out business with India.

[142]It had been proposed by the Government of India to introduce a Pesticides (Amendment) Bill in the Parliament which would provide for data exclusivity period of five years for the agro-chemicals. *Data Exclusivity back on the table for India*, http://spicyip.com/2015/03/data-exclusivity-back-on-the-table-for-india.html <accessed on 8 September 2016>

[143] Report of the Special Rapporteur, *Supra Note* 49, 23.

[144] Ibid, 24.

which otherwise would have reduced the prices increasing thereby the affordability of the pharmaceutical products.[145]

The EU, however, had pointed out that during its discussion in the FTA negotiations, that it would not press on this issue of supplementary protection of patents[146] if the process of marketing approval application in India was not a major concern. The EU had noted that market authorisations in India were handled in an expeditious manner and therefore, this issue should not become a hurdle in the FTA negotiations.[147]

d) Compulsory Licensing (CL)

The EU had pointed out that adoption of compulsory licensing in industrial sectors would affect the flow of technology from overseas to India.[148] However, the EU was not against issuance of CL by using the flexibilities that existed within the TRIPs Agreement.[149] It also confirmed that in case of conflict between data exclusivity rules and compulsory licensing, the latter would override the former.[150]

This had become particularly contentious not only within the context of FTA negotiations, but also with the adoption of the India's National Intellectual Property Rights Policy[151] and also its National Manufacturing Policy (NMP).[152] Under these policies, particularly under the NMP an option was provided to entities such as the Technology Acquisition and Development Fund to approach the Government for issuance of compulsory license for the technology which was not being provided by the patent holder at reasonable rates or was not being `worked in India' to meet the domestic demand in a satisfactory manner. Indian Government kept the options to issue compulsory licenses for green technologies that had been patented. One other important issue that was of a major

[145] Carlos M. Correa, `Negotiation of a Free Trade Agreement European Union-India: Will India accept TRIPs-Plus Protection?' *Oxfam*, *Deutschland* e. V. June 2009, 10; also see Juan Bacalski, `Mexico's Pharmaceutical patent Dilemma and the Lesson of India', http://arizonajournal.org/wp-content/uploads/2015/11/BacalskiNote.pdf <accessed on 8 September 2016>

[146] EU has detailed provisions on the `Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products,'https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en <accessed on 8 September 2016>

[147] *EU-India FTA negotiations and access to medicines: Questions and Answers* http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf <accessed on 30 August 2016>; Legal developments within EU had been closely monitored by the Indian pharmaceutical industry, see Omkar Joshi and Archna Roy, `Supplementary Protection Certificates Provisions for Pharmaceutical and Biotechnological Products in Europe: An Era after *Medeva* and *Gerogetown* Decisions,' *Journal of Intellectual Property Rights,* Vol.19, November 2014, 378-386 http://nopr.niscair.res.in/bitstream/123456789/30050/3/JIPR%2019(6)%20378-386.pdf <accessed on 8 September 2016>

[148] Arun S, `Compulsory licensing in manufacturing may slow down investments: EU', *The Hindu,* 5 February 2016 (New Delhi) http://www.thehindu.com/business/compulsory-licensing-in-manufacturing-may-slow-investments-eu/article8194418.ece <accessed on 3 September 2016> ;

[149] EU-India Questions and Answers, *Supra* note 62.

[150] Ibid.

[151] For the complete text of the National Intellectual Property Rights Policy, see http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf <accessed on 10 September 2016>

[152] For the text of the NMP and other details of India's Make-in-India Policy see http://www.makeinindia.com/policy/national-manufacturing <accessed on 10 September 2016>

concern for India related to the effective use of a compulsory license, particularly in the context of data exclusivity provisions proposed to be negotiated within the FTA.[153]

The Indian Patent Office issued the first compulsory license under its amended Patent Law in 2012 in the case of *Natco v. Bayer.*[154] In this case, Natco, an Indian generic drug manufacturer, had initially requested for a license from Bayer to manufacture and sell the drug `Nexaver' used for kidney cancer at a cheaper price. Bayer did not agree. The case was decided on the basis of three issues that were part of the Chapter XVI of the Indian Patent Law. The issues were: (a) whether the reasonable requirements of the public with respect to the patented invention had been satisfied? (b) whether the patented invention was available to the public at a reasonably affordable price? (c) whether the patented invention had been worked in the territory of India?[155]

The Controller in his decision held that the Bayer though had manufacturing facilities in India failed to produce the patented drug in Indian even after four years from the date of the grant of the patent. The case was appealed to the Indian Intellectual Property Appellate Board (IPAB). The IPAB while upholding the decision of the Controller of Patents increased the royalty amount from 6 percent to 7 percent and also noted that the working of a patented invention was not necessarily restricted to local manufacturing within India and that, in certain cases, importation might equally constitute working of a patented invention.[156] There had been another application for a compulsory license before the Indian Patent office which was not accepted on certain procedural grounds.[157]

India had been attempting to reconcile its Patent Law with the developments that were taking place at several forums including TRIPs.[158] The EU-India FTA negotiation was another area where India had to reconcile its position on compulsory licensing. One such attempt appeared to be done with the formulation of a National Intellectual Property Rights Policy.

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[153] Chapter XVI of the Indian Patent Act provides for provisions relating to compulsory licenses. Indian Patent Act in section 84 clearly provides that patents are not granted for just enjoying monopoly. It also has a public interest concern. Patent grant of a specific subject matter, in particular pharmaceutical products should take into account the `reasonable requirements of the market' and accordingly `local working' of the patented products should be encouraged. At the same time, patent law also should take into account the factor of `affordability' of the population in accessing to the medicines. For an overview see Gopakumar G. Nair and Andreya Fernandes, `Patent Policies and Provisions Relating to Pharmaceuticals in India,' *Journal of Intellectual Property Rights,* Vol.19, January 2014, 7-17, http://nopr.niscair.res.in/bitstream/123456789/26503/1/JIPR%2019(1)%207-17.pdf

[154] *Natco v. Bayer,* Compulsory Licence Application No. 1 of 2011, decision of the Indian Controller of Patents (9 March 2012) www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf

[155] Article 84 (1) of the Indian Patent Act contained these three grounds.

[156] *Bayer v. Union of India & Others,* OA/35/2012/PT/MUM, decision of the Indian Intellectual Property Appellate Board (4 March 2013).

[157] *BDR Pharmaceuticals International Ltd. v. Bristol Myers Squibb Company,* CL No. 1 of 2013, decision of the Indian Controller of Patents (29 October 2013); also see Emmanuel Kolawole Oke, `Exploring the flexibilities in TRIPs: lessons from India's pharmaceutical patent law,' *Commonwealth Law Bulletin,* Vol. 41, No. 1, 82-106.

[158] India had been working towards reconciling some of its position on issuance of compulsory license in the context of TRIPs, generally to have a look at the official Indian position see *Discussion Paper on Compulsory Licensing*, Ministry of Commerce and Industry, Government of India, www.dipp.nic.in/English/Discuss_paper/CL_DraftDiscussion_02September2011.doc <accessed on 11 September 2016> also see Savita Gautam and Meghna Dasgupta, `Compulsory Licensing: India's Maiden Experience', ARTNet Working Paper Series No. 137, November 2013, Bangkok, ESCAP http://www.unescap.org/sites/default/files/AWP%20No.%20137.pdf <accessed on 10 September 2016>

3. Indian IP Policy and Its Impact on Access to Medicines

India adopted for the first time a new National Intellectual Property Rights Policy[159] (`new IP Policy' hereinafter) to spur creativity and to stimulate innovation.[160] It had also been claimed that the new Policy would lay down the roadmap for the future of IPRs in India.[161] The all-encompassing IPR Policy, according to Government of India, would not only ensure protection of public interest, but would also promote an environment to build up an IP ecosystem.[162] The new IP Policy was truly `all-encompassing' as it dealt with all aspects of IP in seven different areas such as (a) awareness: outreach and promotion; (b) generation; (c) legal and legislative framework; (d) administration and management; (e) commercialisation of IP; (f) enforcement and adjudication; and (f) human capital development.

The Policy was essentially an inward-looking instrument that addressed primarily the domestic concerns towards building up of an IP-culture. There were some references to international dimensions of the IP as well in the form of India's obligations under various treaties and international agreements relating to IP. Some had argued that the entire new IP policy was adopted to consider and accommodate the concerns of the US and the EU has regarding the formulation and implementation of Indian IP laws in recent times.[163] For instance, though there were several references to the protection `public interest' of various stake holders, the primary focus of the new Policy was to protect the interests of the right holders.[164] The new Policy, like in the TRIPs Preamble, recognised IP as private rights. For that reason, it argued that these rights must be enforced by the right holders. Further, a close reading of the new IP Policy appeared to be emphasising on the development of IP culture within India. It wanted everyone to be aware of IP, its role and importance in the national development.[165] In the same breadth it also sought to balance IPRs system to "enhance socio-economic and cultural development" and "focus on enhancing access to

[159] For the text of the National Intellectual Property Rights Policy adopted by the Government of India in May 2016 see http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf

[160] Message by the Indian Minster for Commerce & Industry on the adoption and approval of the National IPR Policy by the Government of India.

[161] Ibid.

[162] Message by the Secretary, Department of Industrial Policy & Promotion, Ministry of Commerce & Industry upon adoption and approval of the new National IP Policy.

[163] According to one view "One of the unstated reasons for putting together the policy is to ease pressures from the US to deliver on IP awareness, service orientation of the Patent Office and IP generation." see K.M.Gopakumar, `Why New IPR Policy Is Inadequate: Pressure from the US Is Unstated Reason,' *Economic & Political Weekly,* 21 May 2016, http://www.epw.in/journal/2016/21/commentary/why-new-ipr-policy-inadequate.html; Dinesh Abrol, `The Wrong Incentive: The National Intellectual Property Rights Policy Must Be Opposed,' *Economic & Political Weekly,* 11 June 2016, http://www.epw.in/journal/2016/24/commentary/wrong-incentive.html

[164] Ibid.

[165] The Vision Statement hoped for "An India where creativity and innovation are stimulated by Intellectual Property for the benefit of all; an India where intellectual property promotes advancement in science and technology, arts and culture, traditional knowledge and biodiversity resources; an India where knowledge is the main driver of development, and knowledge owned is transformed into knowledge shared." ; For an account on other substantive problems with the IP Policy see Shamnad Basheer, `An IP policy with no innovation,' The Hindu, 17 May 2016 http://www.thehindu.com/opinion/op-ed/intellectual-property-an-ip-policy-with-no-innovation/article8607910.ece; Achal Prabhala and Sudhir Krishnaswamy, `Patently a missed opportunity', The Hindu, 25 May 2016, http://www.thehindu.com/opinion/op-ed/national-intellectual-property-rights-policy-patently-a-missed-opportunity/article8641600.ece

healthcare, food security and environmental protection, among other sectors of vital social, economic and technological importance.[166]

There was still a larger question as to how all these policy goals translated into a larger issue of providing effectively `right to health' to its marginal sections of the population and also give them `access to medicines' while retaining the salience of the Indian generic industry in supporting these twin objectives. The new IP Policy, somehow, appeared to dodge these twin objectives. It also did not sufficiently link these decades-old objectives of the Indian IP system with the changing perception of the larger world on IP protection. However, the new policy had proposed strict measures for treating `generic' medicines as `counterfeit' or `spurious'. At the same time, the Policy had suggested that stringent action be taken against any misbranded, adulterated and spurious drugs. It did not say as to how this to be implemented or undertaken.

Overall, policy was about creating awareness and a vibrant IP culture among the people. It also laid down emphasis on the protection of traditional knowledge and such related areas. Some have criticised the new policy as repeating *ad nauseam* the various platitudinous phrases around intellectual property.[167] Some have expressed apprehension that the new policy opens the door for changes in the existing laws in the form of `updating and improving' or `removing anomalies.'[168] Eventually, it has been argued, that these changes would lead to India accepting TRIPs-plus provisions. However, there were no such indications. India, on the other hand, is committed to the 2001 Doha Declaration on TRIPs and Public Health. Some civil society activists have argued that the new policy has overemphasis on IP enforcement. They have also pointed out that the new policy did not address the gaps that innovators faced in the bio-medical field. The developed world would not be interested in developing medicines that are important for the developing world such as for example, malaria and other similar diseases. The policy, some have argued, does not create an atmosphere where Indian companies could develop such medicines. While some argued for more innovation component in the new policy, others suggested that this would not help the Indian generic industry.

This Indian initiative has been noted and welcomed by the EU and US. Both have hoped that the policy would take India towards more globally acceptable IP protection and enforcement. The Policy, however, does not outline any proposal to change the existing Indian IP laws.

4. India-EU Divergence Analysis of the case of `counterfeit' medicines from the point of view of TRIPs and Human Rights

There is a divergence of views between India and the EU with regard to the issue of counterfeit medicines.[169] The EU regards the manufacturing and selling of counterfeit medicines as an offence as it could be a serious health hazard. The EU treats counterfeit medicines as spurious drugs with

[166] Mission Statement of the new IP Policy

[167] Shamnad Basheer, *Supra note* 80.

[168] Gopakumar, *Supra note* 78.

[169] EU negotiated an Anti-Counterfeiting Trade Agreement (ACTA) along with US, Mexico, Japan, Australia, Canada, Morocco, New Zealand, Singapore and South Korea from 2007 to 2010 in 11 rounds. However, in July 2012, EU Parliament in a Plenary Session rejected the Proposal for a Council Decision on the joining of the ACTA. There were several contentious issues before the EU Parliament. For an account on this see Duncan Matthews and Petra Zikovska, `The Rise and Fall of the Anti-Counterfeit Trading Agreement: Lessons for the European Union, *IIC-International Review of Intellectual Property and Competition,* September 2013, Vol.44, 626-655 http://link.springer.com/article/10.1007/s40319-013-0081-y. <accessed on 20 September 2016>

serious implications for the health of its population. The EU also regards production of counterfeit medicines as violation of existing IPR norms as embodied in the TRIPs Agreement and EU Customs were empowered to detain goods suspected of infringing IPRs under its regulations. Immediate problems arose on account of some of the Indian pharmaceutical cargo that was on transit to some South American countries were detained at some European ports on the suspicion that they were violating or infringing the European IP laws.[170]

India was concerned about such a treatment to its pharmaceutical products on the ground that they were counterfeits.[171] India had argued that these were generic medicines produced legally within India and now being exported to other countries.[172] India, on the other hand, treated counterfeit medicines as part of its generic pharmaceutical industry and that not all counterfeit medicines should be categorised as spurious.[173] Several Indian and global civil society organisations working in the field of healthcare consider Indian generic manufacturing capability as one of the key factors in providing accessibility and affordability to the cheap medicines to the vulnerable sections of the society.[174]

[170] The European Customs seized at least 19 generic medicine shipments from India and Brazil in transit through EU to developing countries in 2008 and 2009. The EU's Director-General, Competition, in its 2009 `Pharmaceutical Sector Inquiry', reported that the IP enforcement measures were often abused by originator companies to delay generic entry of a large number of medicines. See EC (2009) `Executive Summary of the Pharmaceutical Sector Inquiry Report,' http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf.

[171]Rama Lakshmi, `India's market in generic drugs also leads to counterfeiting,' 11 September 2010, *The Washington Post,* http://www.washingtonpost.com/wp-dyn/content/article/2010/09/10/AR2010091003435.html <accessed on 21 September 2016>; also see Gardiner Harris, `Medicines Made in India Set Off Safety Worries' 14 February 2014, *The New York Times,* http://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries.html?_r=0 <accessed on 23 September 2016>

[172] India brought up this issue before the Council of TRIPs of the WTO seeking information from the EU with regard to the basis for drug seizure. See Minutes of the TRIPs Council Meeting held on 8-9 June, 2009, *WTO,* IP/C/M/60.

[173] The Indian Drugs and Cosmetics Act, 1940 in Section 17, 17A and 17B refers to spurious drugs as `misbranded', `adulterated' and `spurious'. It does not mention the term `counterfeit', `substandard' or `falsified drugs'. In India, the term `counterfeit' is used in the context of Trademark as "willful trademark infringement" to be consistent with the TRIPs Agreement. See Article 51 of the TRIPs Agreement which in a footnote defines the "counterfeit trademark goods" which essentially deals with the labelling and packaging. In India, if a legal manufacturer `willfully chooses to label its product with someone else's trademark, only then the product is deemed to be a counterfeit (as a category of spurious drug); See generally, Maulik Chokshi, Rahul Mongia and Vasudha Wattal, `Drug Quality and Safety Issues in India,' Working Paper 310, September 2015, *Indian Council for Research on International Economic Relations,* http://icrier.org/pdf/Working_Paper_310.pdf*;* Also see `The Conundrum of Poor Quality Drugs in India', *Financial Express* 26 October 2015, http://www.financialexpress.com/fe-columnist/the-conundrum-of-poor-quality-drugs-in-india/156676/ <accessed on 21 September 2016>

[174] *Trading Away Access to Medicines – Revisited: How the European Union trade agenda continues to undermine access to medicines,* 29 September 2014, Health Action International Europe (HAI) and OXFAM https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf ; also see *The Truth Behind the Spin: How the Europe-India Free Trade Agreement Will Harm Access to Medicines,* 4 November 2010, *Medecins san frontiers (MSF),* http://www.doctorswithoutborders.org/news-stories/briefing-document/truth-behind-spin-how-europe-india-free-trade-agreement-will-harm

This divergence issue should be seen in the context of impact TRIPs Agreement possibly has on the access to medicines issues. The discourse on the relationship between TRIPs and human rights, *inter alia*, is essentially about access to medicine issues. The impact of the TRIPs Agreement on the availability of the medicines to the vulnerable sections of the society at an affordable price is the key to this discourse. This aspect has been examined in several studies since the inception of the TRIPs agreement itself.[175] This discourse, in fact, precedes the conclusion of the TRIPs Agreement within the framework of WTO. During WTO negotiations on TRIPs several of the developing countries, including India were apprehensive of the possible impact this agreement could have had on the accessibility of the medicines. The computation and quantification of the impact was trifle difficult to arrive at that point of time. With the passage time, several studies and scholars started realising the increasing impact of the TRIPs obligations that resulted in the amendment and reformulation of national laws and policies that had direct bearing on the accessibility issues concerning medicines.

The human rights discourse on TRIPs in various dimensions has continued till the present day through various national and international legal and institutional mechanisms. The TRIPs Agreement created in no uncertain normative terms obligations on large number of its Member States. India in 1995, when the TRIPS Agreement entered into force, was no exception. It also carefully worked out the ways to do it as well through various legal and procedural mechanisms. These implementation obligations created by the TRIPs had been carefully crafted by providing transitional periods and certain kinds of in-built exceptions to the developing countries. Less-developed countries were excluded from these TRIPs implementation obligations. The Indian IP laws in general terms though were more or less consistent with the TRIPs obligations, certain of the patent-related obligations as incorporated in its domestic patent law were regarded as inconsistent.

India, however, is critical of the EU's increasing IP enforcement standards. This aspect of increasing enforcement of IP against so called `counterfeit' goods, especially pharmaceutical products, are being negotiated within the framework of India-EU FTA. India views this as a possible way to curb its generic manufacturers from trading legitimately in the pharmaceutical products that are already in the public domain. This, it is being pointed out, would increase not only litigation, but also would impact availability of affordable medicine. Some have argued that the scaled up enforcement provisions could expand the monopoly power of the IP right holders. This, it is being further argued, would undermine the balance that existed between IP protection and the public health.

F. Conclusions

This chapter has given an overview of the tensions which exist between IPR and human rights, more in particular the human right to health and its corollary, access to medicines. We have reviewed the various ways in which conflict could happen, and how these tensions have polarized the debate between developed countries, which are staunch promoters of IPR, and developing or least developed countries, for whom the most pressing issue is to allow their populations to attain the

[175] *Access to Medicines in the context of Right to Health,* United Nations, Human Rights, Office of the High Commissioner, http://www.ohchr.org/Documents/Issues/SForum/SForum2015/OHCHR_2015-Access_medicines_EN_WEB.pdf ; For an overview on innovation and related issues see *United Nations Secretary General's High-Level Panel on Access to Medicines: Promoting Innovations and Access to Health Technologies,* 14 September 2016, United Nations, https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf

highest possible level of health, even if this means producing and marketing medicines which are protected by IPR in the west.

We have seen that the multilateral IPR regime embodied by TRIPS and the WTO was under pressure to resolve this tension, and had implemented a number of flexibilities to allow countries subject to particular health needs and who cannot afford IPR-protected medicines at western price to still ensure access to these drugs. We have seen that not only these flexibilities were gathering relative success and that the objective universal access to medicines was still very distant. A worrying trend in this regard are the policies of developed trading blocs such as the EU which consist in inserting in FTAs with developed and developing countries chapters on IPR which undermine the TRIPS flexibilities and thereby access to medicines. We have seen, notably, that the EU, whereas it officially pursues differentiated policies according to the level of development of its trade partners, still had a tendency to place exorbitant demands at the outset of negotiations which if accepted would be detrimental to the right to health. The current and very protracted EU-India FTA negotiations are a case in point of such situation in which the EU seeks to negotiate additional commitments from India, and in which India, as 'the pharmacy of the developing world', is fiercely resisting the EU's demands.[176] There are several key issues in the EU-India FTA on which the gap could not be breached. Some of these issues have already been referred to in the present study. The primary scope of this study is to examine the EU-India FTA in the context of access to medicine issues. This has been examined in the broader context of IPRs and Human Rights with specific focus on the TRIPs Agreement.

While primarily focusing on India, the study has attempted to outline its position on some of the contentious IP-related issues such as (a) the nature of pharmaceutical sector in India; (b) access to medicine issues; (d) compulsory licensing; (c) patent-term protection; and (d) data exclusivity, (e) the new Indian IP policy and others. In the final analysis an attempt has been made to outline the divergences that exist between the EU and India within the context of FTA negotiations on the issue of `counterfeit' medicines. Each of the above mentioned topics have been posing complex set of questions.

Beginning with the study of the nature and context of the pharmaceutical industry in India, it is clear that this industry has been constantly in a state of flux. This is particularly true when one examines the kind of pressures that have brought in on India and other similarly placed countries to adhere to the stronger IP norms. As is well-known, the growth of the chemical and pharmaceutical industry is closely linked to the level of IP protection. The EU has been arguing that the level of IP protection in India is weak and that it needs an upgrade to make it more consistent with the global requirements. The production of generic medicines at a reasonably affordable price determines the scope and work of the Indian Pharmaceutical sector. The obligations that have been created pursuant to TRIPs Agreement changed all this for India and to be consistent with TRIPs India has amended its patent law thrice. India has also introduced or brought into force several new IP-related legislations such as, for example, Geographical Indications Act, Plant Variety Protection and Farmers Rights Act.

[176] Jan Wouters, Idesbald Goddeeris, Bregt Natens and Filip Ciortuz, Some critical issues in the EU-India free trade agreement negotiations', *Leuven Centre for Global Governance Studies Working Paper No. 102,* August 2013, online http://ghum.kuleuven.be/ggs/publications/working_papers/new_series/wp101-110/wp102-wouters-goddeeris-natens.pdf/, 10-12.

On the issue of data exclusivity India appears to be ambivalent. While India is ready to grant such data exclusivity protection to agro-chemicals, it is not ready to grant such similar rights to the pharmaceutical sector. India also has created a separate regime for its traditional medicines regime with regard to data exclusivity. As of now, there are three different strands in the protection mechanism of the data exclusivity. As regards the patent term extension and compulsory licensing, India is ready to be TRIPs complaint. It does not want to go beyond its TRIPs obligations. The EU has clearly denied that it had been insisting on any kind of TRIPS-plus obligations, despite its reservations to some of the provisions of the Indian patent law, such as Section 3D (which does not provide patent protection for the new use of a chemical entity whose properties are known) and the issuance of compulsory licensing. The first such compulsory license was issued by the Indian Patent Office in the case of *Natco v. Bayer* during 2011-2012. This case was followed by another case on Section 3D pursued by the European pharmaceutical company Novartis.

The new IP policy of India has made an attempt to bring in several layers of arguments for the effective working of the IP in India. As is clear, this policy is essentially about developing an IP-culture in India. However, it has been argued that this IP policy took shape in response to and to accommodate to an extent the US and EU interests. There are also some references in this wide-ranging policy to negotiate and become party to IP conventions. This policy appears to dwell less on innovation, but has brought in many `campaign' kinds of ideas and notations. As identified in the study, this policy is essentially an inward-looking policy.

In the final analysis, the study briefly looks at the divergence of normative perception that exists between India and EU with regard to the issue of `counterfeit' medicines. This issue has been examined the larger context of TRIPs and human rights. This relationship, the study further argues, is essentially about the `access to medicines.' The issue of `counterfeit' poses several practical problems for India in terms of its generic pharmaceutical products' seizure in Europe. The Indian law does not define `counterfeit' broadly to include all kinds patent infringements and enforcements. In fact, there is no law on the subject of `counterfeits' in India in the sense it has been perceived within the EU context.

Despite the existence of several divergences in the EU-India trade relations specifically in the context of IPRs, the gap appears to be narrowing down. This is clear from the EU's stand point that it has been insisting only on IPR commitments that are within the realm of TRIPs and not beyond that. Though India is not ready to accept any TRIPs-plus obligations, the TRIPS-only obligations should be able to take the talks forward. The new Indian IP policy opens up many such options in a more informal setting and it should be possible for both countries to achieve some middle ground.

IV. General concluding remarks

To recall, the objective of this deliverable was to assess whether EU trade policies in the field of forestry and intellectual property were acting as 'forces for good global governance' against the erosion of basic rights such as the right to food, to health, or to housing. The two case-studies – on FLEGT in Ghana and on IPR in the EU-India FTA negotiations – have yielded quite different results, which are probably due to the very different contexts of the two case-studies.

FLEGT and the system of VPAs based are characterized by their voluntary character and the deference they show towards domestic legislation, up to the point that the focus on human rights may give way to mere legality verification. The outcomes of the system, though it is still quite young and more reliable data will only be available in a few years, are mixed, and its effectiveness as a driver of good governance specifically for human rights is not clear. The most obvious human rights benefits which our case-study uncovered had to do with so-called procedural rights, namely participation rights in the system, whereas the impact on substantive rights will only emerge after the new forestry legislations promoted by the scheme will have produced some effects.

The conclusion which may be suggested based on the case-study on FLEGT in Ghana is that such a unilateral trade policy seeking to leverage human rights in a sector in which the EU does not have a direct stake may raise doubts as to its effectiveness in countering the erosion of basic rights, owing to a number of factors.

The inclusion of IPR in EU FTAs is in turn characterized by its binding character, and by its distrust of the legal frameworks of EU partner countries. IPR chapters are aimed to ratchet up the level of IPR protection which EU IP owners will enjoy abroad. The direct stake which the EU has in this ratcheting up of standards plays a large role in how the EU views its role as a 'force for good global governance' for human rights, and these interests may make the EU lose sight of the balance to achieved between IPR and human rights, as was demonstrated through our study on the protection of pharmaceutical patents and access to medicines: the EU is attempting to use trade agreements to improve the former in ways which are likely to hurt the latter.

The (unsurprising) conclusion which may be suggested in this regard is that the EU may at times risk undermining human rights protection when it pursues its trade policies with too little regard for the balance which must be achieved between its direct interests and the protection of human rights. In the case of access to medicines which we have presented, this lack of balance is only countervailed by the fierce resistance of partner countries such as India, and to other activities which the EU is conducting in non-trade areas to the effect of ensuring protection of the right to health despite the undermining effects of IPR.

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