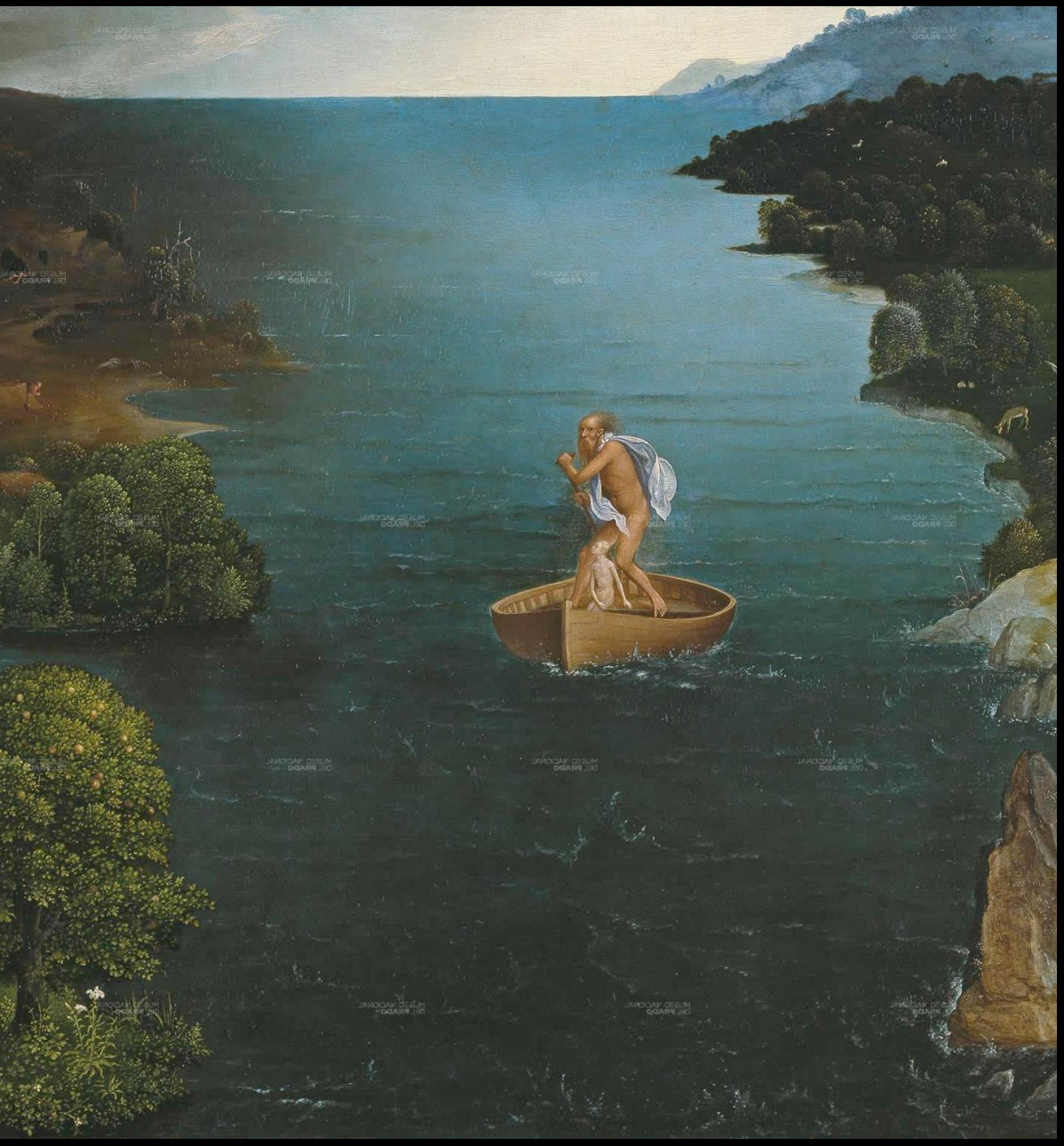
Virgin Lands of Invention

LIFE IN PATENT ECOSYSTEMS

PABLO ZAPATERO



Virgin Lands of Invention

Virgin Lands of Invention. Life in Patent Ecosystems

Pablo Zapatero

EDITORIAL DYKINSON

2014

Para Julia y Elías

Primera edición 2013, primera reimpresión 2014

Venta: Editorial Dykinson
c/ Meléndez Valdés, 61 – 28015 Madrid
Tlf. (+34) 91 544 28 46
E-mail: info@dykinson.com
http://www.dykinson.com

Preimpresión: TallerOnce
Diseño: Chano del Río
Motivo de cubierta: El paso de la laguna Estigia, de Joachim Patinir

ISBN: 978-84-9031-770-9

Depósito Legal: M-35786-2013

Versión electrónica disponible en e-Archivo
http://hdl.handle.net/10016/18197

CONTENTS

1

THE IP WORLD

1. Decoding

Exclusive rights regimes (e.g. patents) are just one of a larger mix of available public policy tools to spur scientific and technological innovation. At present, innovation ecosystems have become more sophisticated and are now built on more internationalized, collaborative, open innovation models. However, the importance of non-patent based innovation is often downplayed in order to frame patent systems as the driving force behind innovation.

Nowadays, our legal infrastructures for innovation are entrenched within the mantra of proprietary knowledge. Under this flagship, mainstream public politics and policy are ratcheting up standards of proprietary knowledge and *market exclusivity* (monopoly).

From a legal perspective, patents are government-sponsored exclusive rights dealing with a unique commodity: knowledge. The exclusive rights regimes in which these are embedded are designed to remove the general authority to act on given information, by locating that authority in the hands of a given private agent (patent-holder).

In principle, inventors secure remuneration for their work through patents. The argument behind this government-sponsored private retribution is that the exclusive rights-based innovation of patent systems increases the inventors' incentive to pursue inventions.

However, by designing the system in this way, patents systems do not respond to unmet public demands, but instead to the ability to pay. Patents embed vertical control over the use of information in things and activities; read goods and services, respectively.

Nowadays, the physical property of any traded good yields to the intangible property. In this regard, in accordance with article 51 of the 1996 WTO Agreement on Trade related Aspects of Intellectual Property Rights (TRIPS), non-IP complying assets in 159 state jurisdictions can be physically destroyed

by courts in *at least* those cases of trademark counterfeiting or copyright piracy on a commercial scale.[1] Hence:

– The intangible is given precedence over the thing (or 'physical carrier')
– The property of the intangible is given precedence over the propriety of the thing
– The proprietor of intangibles is given precedence over the proprietor of the thing

The meaning of this structural change of paradigm over property cannot be underestimated.

Patents entail the artificial creation of scarcity by radical state intervention.[2] In this regard, the conceptual nature of abstract objects (or incorporeal rights) created by intellectual property is particularly challenging.[3]

As Cohen explained in 1927, whatever technical definition of property we prefer, we must recognize that a property right is a relation not between an owner and a thing, but between the owner and other individuals in reference to things: a right is always held against one or more individuals.[4]

Patent ecosystems grant government-sponsored legal monopolies and, as such, are non-market mechanisms. Currently, global markets lack common rules regarding fair, reasonable, and non-discriminatory (FRAND) terms for the use of patents under automatic mandatory licensing. In short, any possible negotiation over the granting of a voluntary license under these non-market mechanisms is conventionally considered to be under the pervasive and expansive freedom of contract. Thus, patent-holders appropriate knowledge and trade it or not (voluntary licensing), whatever the impact on innovation, by clearing prices aside from market-based mechanisms.

In addition, the mechanisms through which governments grant compulsory licenses (CL) are generally stochastic and discretionary, as well as time-consuming and hazardous.

The patent system is itself an idea and, as such, an invention of the mind. Arguably, however, it is probably not the best of ideas, as it legalize le

1 See Section 4 of Part III on enforcement in TRIPS agreement (article 51 and accompanying legal footnote 14) and section 2 in chapter 8 below.

2 See S. Picciotto & D. Campbell, 'Whose Molecule Is It Anyway? Private and Social Perspectives on Intellectual Property', *New perspectives on property law, obligations and restitution,* (Cavendish 2003) at 280.

3 See P. Drahos, *A Philosophy of Intellectual Property* (Aldershot 1996) (chapters 2 and 7).

4 See M. Cohen, '"Property and Sovereignty"' 13 *Cornell Law Quaterly* 8 (1927): 12.

a world-scale mechanism, which not only inhibits the free dissemination of inventions for the promised lands of 'free for all' tomorrow, but grants monopolistic dominion over world markets, and thus trade.

In any case, the patents gospel in Western societies has spread and ritualized incrementally, constructing a system for appropriation over intangibles which began centuries ago. During the last two centuries, patent ecosystems have regularly been perfected in domestic and international venues; until a minimum common denominator was created by multilateral international law, in the final quarter of the 20th Century.

The opening decades of the new millennium have witnessed an unprecedented acceleration of initiatives for the ratcheting up of IP standards and enforcement through a wide variety of world regulatory networks.

The social impact of patents should not be underestimated. Once inventors are granted a patent, this legal device essentially becomes a knowledge monopoly, allowing the patent holder full control over the registered invention in related goods and services. From then on, the holder has the exclusive right to decide how, when and under what terms the invention is to be marketed (quantity, price etc) in any given domestic territory in which the patent has been obtained.

Profits as pay-back from 'invention' (whatever we decide inventiveness is) are boundless, as long as these are extracted during the patent's term of protection (generally, a minimum 20 year period). This legal infrastructure of innovation (patents as time-limited propertization of inventions) potentially embraces the whole world, as inventors can file as many patent applications as possible, in almost as many jurisdictions as there are on earth.[5]

Provided that the patent application complies with increasingly standardized patent laws, the global patent game pays for those who know how to play the system, combining it with other IP assets (notably, trademarks and trade secrets).

The feasibility of obtaining world-scale profits from a given invention is only counterbalanced by the so-called doctrine of international exhaustion of IP. In this regard, imports are normally an infringement of the rights of the patent holders, excepting when a country applies the doctrine in its territory.[6]

---

5 159 Members (and 25 observers) of WTO as of December 2013.

6 See F. Abbott, 'First Report (Final 1997) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel importation', 1 *Journal of International Economic Law* 4 (1998): 607–636 and M. Pugatch. *The In-*

Importation without the authorization of the patent-holder is called 'parallel importation', or also 'parallel trade'. However, such practices are not common, as a result of industry and inter-state peer pressure.

In the brave new world of IP global politics, any infringement of a patent granted to a foreigner by a patent office is enforceable in domestic courts (from 1 to at least 159 jurisdictions). Technically, this implies that a global company may decide to protect an IP asset throughout practically the entire world, which amounts to a tremendous amount of government-sponsored power.

In any case, in pure economic terms, less than 50 societies are of potential interest for patent-holders (mainly OCDE + E7 economies),[7] as consumer purchasing power and/or government procurement programmes in these societies are not adapted to their business model, which is oriented towards the wealthy societies.

Needless to say, the architects and major players of patent systems are currently global companies, as they have the resources for regulatory capture (architects), and subsequent patent enforcement (players) in multiple jurisdictions of the world.

Are these corporate inventions? They are in legal terms. Notwithstanding the thousands of individual inventors searching for golden inventions, the patent game is controlled by hard core repeat players; that is to say, the large patent-holding corporations. Nowadays, the inventions devised by those multitudes of brilliant individuals are activities performed under contract and, as such, labour output.

The real individual contribution by those scientists working within corporate research departments and centres of major global firms (the physical creators of inventions) is regulated by employer-employee relationships. Notwithstanding the fact that innovation is intellectually and physically performed by individuals (not legal persons), 'invention by contract' makes the legal term 'inventor' an empty shell, likely to be occupied and thus appropriated by legal proxies of capital-holders operating through the corporate form and structure.

As a result, the vast majority of patents currently enforceable in do-

---

tellectual Property Debate: Perspectives from Law, Economics and Political Economy (Edward Elgar 2006), pp. 180–181.

7 The so-called E7 emerging economies are China, India, Brazil, Russia, Mexico, Indonesia and Turkey.

mestic courts are held by corporations.[8] In fact, exclusive rights over inventions and other proprietary knowledge assets are increasingly concentrated in strong IP portfolios through strategic buying and selling, mergers and acquisitions added to corporate programs of patent productivity.

2. 'Intangibles'

Proprietary innovation is the master-value of the patent system paradigm, as patents are structurally based on the propertization of intangibles, thus commodifying ideas by translating them into the language of property.

The patent-based approach towards innovation is currently framed by a knowledge trade-off. The narrative was brilliantly portrayed half a century ago by Joan Robinson, coining the so-called 'paradox of patents'. From then on, the patents game has been explained as a supposedly inevitable trade-off: 'by slowing down the diffusion of technical progress, patents ensure that there will be more progress to diffuse'.[9]

Basically, mainstream frameworks and portraits of patents excuse the foreclosure of access to existing knowledge as an inconvenient side-payment for breakthrough technological innovation: in the absence of such power rules, society is said to face underproduction of inventive activity.[10] In short, patents are conventionally pictured as a sort of social contract (between society and inventors) in which available knowledge tomorrow is exchanged for restricted knowledge today.

Unfortunately, this narrative has at least one relatively big question mark: to quote the centuries-old axiom, knowledge is power. In this regard, the *government-sponsored* power granted to patent-holders over information and knowledge combined to build an invention is strong private power; or more precisely, *legal monopoly power*, having a strong effect on the functioning of markets and states, and thus society.

---

8 See C. Fisk, 'Removing the 'Fuel of interest' from the 'fire of the genius': law and employee-inventor, 1830–1930', 65 *University of Chicago Law Review* 4 (1998): 1127–1198. On the move to include corporations as inventors see also J. Boyle, *Shamans, Software, and Spleens: Law and the construction of the information society* (Harvard UP 1996).

9 J. Robinson, *The Accumulation of Capital* (Macmillan 1956), p. 87.

10 See K. Arrow, 'Economic Welfare and the Allocation of Resources for Invention', *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton University Press 1962), pp. 609–626.

Technically, once a patent is granted, a legal monopoly over the invention is set up, since any (tradable) good and service containing traces of that proprietary knowledge operates under private control, and is thus enforceable, for a fixed period of time. The incentives in playing regulatory capture of such a power rule regime should not be taken for granted.

Nowadays, large corporations increasingly pursue profit-maximizing strategies by using ownership links and contracts exercising power over knowledge. The government-sponsored appropriation of knowledge further maximizes their exercise of (private) power, expanding long-term accumulation of capital through the corporate form and structure. Thus, we should not be so naïve in the general discourse of proprietary innovation.

The interdependence phenomenon coined as 'globalization' is commonly understood to be an historical phase in the evolution of market capitalism, whose development is essentially technological in nature.[11] As the fine global policy practitioners emphasize, globalization is nothing if not the worldwide technology-driven spread of capitalism –a process which has been unfolding, in fits and starts, for three hundred years.[12]

Traditional political thinking, and thus the ideological frame of mainstream policymakers (whether left or right), are challenged by these global transformative forces. For most informed observers, the policy space and momentum to substitute (read 'provide an alternative'), re-engineer (read 'mediation'), or counterbalance (read 'resistance') global capitalism is weak, at best.

However, there are plenty of people doing powerful things under a new non-proprietary information paradigm. In any case, the fact is that we all live in uneasy and perplexing times.

Capital holders concentrate power through corporate proxies, while public power is generally diminishing, and often adapting its capacity to transform societies to the special interests of the former. Given this state of affairs, current regulatory captures transforming science into proprietary knowledge come as no great surprise. After all, the ratcheting up of IP standards (legal monopoly on information) is an optimum policy for profit maximizing through corporate proxies, as societies increasingly trade in knowledge-intensive goods and services.

---

11 P. Lamy, *Globalization and trade opening can promote human rights,* WTO | *Speeches and statements* (5 June 2009).

12 P. Lamy, *The need for 'unity in our global diversity',* WTO | *Speeches and statements* (14 June 2011).

People are not legal persons. Our social nature moves us to explore, understand, and collectively transform the fruits of our endeavors into tools that improve our life within community. In this regard, it is fair to sustain that inventions are essentially collective endeavors,[13] and a natural by-product of inter-individual collaboration (cumulative innovation) that has been advancing relentlessly, in fits and starts, since our ancestors shared caves.

Thus, the public-good nature of information should reasonably be translated into policy measures.[14] There are multiple ways for financing knowledge public goods.[15] Prizes and auctions are, for example, alternative ways of rewarding breakthrough inventiveness and thus also breakthrough inventions and innovation.[16]

Informed observers and A2K (Access to Knowledge) advocates are making quantum leaps in analysing as well as practicing non-proprietary alternatives to patent systems and other IP vehicles for spurring innovation. Against the background of public-goods theories, these people build a strong case arguing that exclusive right regimes for information lead to inefficiency (underuse of information) from both a consumption and production perspective.

The information-commons paradigm has strong transformative power. It is reasonable to suppose that the exclusion of those willing to afford the social cost of using information (individual time and efforts) will inhibit innovation. Those excluded cannot do socially useful things with proprietary information, thus leading to underuse by non-property holders or license have-nots.

---

13 R. Allen, 'Collective invention', 4 *Journal of Economic Behavior & Organization* (1983): 1–24 and A. Nuvolari, "Collective invention during the British Industrial Revolution", 28 *Cambridge Journal of Economics* 3 (2004): 347–363.

14 Y. Benkler, 'The Idea of Access to Knowledge and the Information Commons: Long-Term Trends and Basic Elements'*, Access to Knowledge in the age of Intellectual Property* (Zed Books 2010), p. 219.

15 On financing public goods see J. Love & T. Hubbard, 'Paying for Public Goods', *Code: Collaborative Ownership and the Digital Economy* (MIT Press 2005) at 207–229 and T. Hubbard &. J. Love. 'A New Trade Framework for Global Healthcare R&D' 2 *PloS Biology* 2 (2004): E52. For comments see D. Baker, *Financing Drug Research: What Are the Issues?* (Center for Economic and Policy Research 2004).

16 For prizes in innovation see B. Wright, 'The economics of invention incentives: Patents, prizes, and research contracts", 73 *American Economic Review* (1983): 691–707 and S. Shavell & T. Van Ypersele. 'Rewards versus intellectual property rights' 44 *Journal of Law and Economics* (2001): 525–547. For auctions see, in particular, M. Kremer, 'Patent buyouts: a mechanism for encouraging innovation' 113 *Quarterly Journal of Economics* 4 (1998): 1137–1167.

Exclusive rights regimes reduce innovation and externalize social costs by reducing productive consumption of information goods.[17] In this sense, the 'invention' of government-sponsored intangible rights raises some issues deserving care. In this regard, critics make a case for sustaining that the right global infrastructure for innovation, collaboration and flow of knowledge and ideas among 'innovation players' are comparatively more powerful incentives for breakthrough innovation (which arguably is where social progress stands) than exclusive rights regimes.

Alternatively, for advocates of the information-commons paradigm, non-commercial, non-proprietary, individual and peer production encapsulate a transformative policy vision of its own: shifting from the current production model based on private means of production and the commodifying of labor (enclosed in proprietary knowledge) ...to open models based on social means of production, non-proprietary knowledge and open information infrastructures.

These inspiring currents of practice and thought could always sustitute, reform or at least counterbalance the hyper protection and enforcement of IP. However, the patent system and related IP vehicles somehow appear to be locked-in. Decision-making in this area is constrained by stringent international commitments. Therefore, rebalancing exclusive rights regimes and other public values is a key issue for all, whether living in Asia, Europe, Africa or America. Jagdish Bhagwati bluntly but clearly depicted the challenge produced by the TRIPS agreement:

> Few believe that the optimum IPR is zero; and so do few believe that it extends as high as the 20-year patent rule that was forced into the World Trade Organization (WTO) by the business lobbies![18]

Not only are such terms highly questionable for their insufficient deliberation, but different types of inventions would also reasonably require different

---

17 See M. Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' 3 *Harvard Law Review* 111(1998): 621–88; S. Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law', 5 *Journal of Economic Perspectives* 1 (1991): 29–41 and R. Merges & R. Nelson, 'On the Complex Economics of Patent Scope', 90 *Columbia Law Review* 4 (1990): 839–916.

18 J. Bhagwati, 'Economic Freedom: Prosperity and Social Markets (Key Note Speech)', *Economic Conference on Economic Freedom and Development*, Tokyo (June 17-18, 1999).

terms of protection.[19] Last but not least, and notwithstanding the rules in place, there is no one universally optimum level of protection for all states.[20]

Therefore, the stakes in global patent politics are high. On one hand, technology-importing countries generally argue for more IP flexibility and mandatory technology transfer. On the other hand, technology-exporting countries not only argue for the opposite but for ratcheting up IP standards; the former are often in the group of developing countries (leaving aside emerging economies), and the latter in that of developed countries.

There are no conclusive evidence that exclusive rights are capable of leading to higher levels of breakthrough innovation than nonproprietary alternatives. In this regard, the public-goods nature of information advocates caution, and thus keeping IP regimes reduced to the minimum. Minimized exclusive rights regimes increase social efficiency, by giving more individuals a chance to innovate (cumulative innovation).

However, setting up alternatives to patent systems is difficult. A complex legal infrastructure regulating patents is already in place in both domestic and international law. As mentioned above, the international patent system is locked-in, as there is enormous public and private investment in its development, too many vested interests, and too many people working within.

In any case, history is never linear. In fact, the famous controversy over patents between 1850 and 1875 almost put the cause of patents under the wheels of *laissez faire* and free trade;[21] thus, such critical events also suggest that policy room is not fixed but fluid, and can always be worked out in order to reengineer the international patent system.

3. A matrix

Arguably we should not frame the issue around a 'yes' or 'no' to patent systems but instead focus on what is missing, what needs to be replaced or fixed. Any reform of the international patent system requires a balance between appro-

19 See W. D. Nordhaus, *Invention, Growth and Welfare* (MIT Press 1969) (particularly chapter 5), and F. M. Scherer, "Nordhaus' Theory of Optimal Patent Life: A geometric reinterpretation', 62 *American Economic Review* (1972): 422–427.

20 See P. Drahos, '"IP World"-Made by TNC Inc', *Access to Knowledge in the age of Intellectual Property* (Zed Books 2010), p. 199.

21 F. Machlup & E. Penrose, 'The patent controversy in the nineteenth century', 1 *Journal of Economic History* 10 (1950): 1–29.

priation of knowledge (monopoly) and diffusion of knowledge (free-riding) and there are probably some cost-effective solutions for obtaining a proper balance.

Following Meir Pugatch, the measurement levels for all IP protection can be geometrically portrayed as a three-dimensional matrix: a first dimension (the X axis) of the *scope of protection* (e.g. how widely is market exclusivity granted), a second dimension (the Y axis) on the *strength of exclusivity/degree of monopoly* granted (e.g. how difficult are CL to obtain) and a third dimension (Z axis) on the *periods of protection*.[22]

The content of this taxonomy has to be more seriously deliberated by society at large. In this sense, for example, the standard of real inventiveness should simply be very high, in order to reengineer the patent system towards breakthrough invention, not innovative techno-trinkets. In this regard, inventions should pass meaningful standards of patentability (effective application of the tests of patentability in the public interest), and should be linked through penalties to full disclosure of know-how, as this permits the invention to be worked once the patent has expired.[23]

Reasonably, patents should not be granted easily. The overarching presumption of patentability means that doubts over patentability are often weighted by patent offices in favor of the patent applicant.[24] As Llewelyn explains, although patents are said to reward inventors contributing to the public good, neither contribution nor public good is currently acting as the driving force behind the grant of such rights.[25]

The reward of inventiveness lies at the heart of the grant of a patent. However, the functioning of the patent system currently rewards those who invest in the patent process itself. Thus, nowadays, the presence of breakthrough inventiveness in patent systems is at a minimum.

Defining what inventive step means (the standard of inventiveness to be set) is not easy. However, imposing a global standard of genuine creative

---

22 M. Pugatch, 'The international regulation of IPRs in a TRIPS and TRIPS plus world' 6 *Journal of World Investment and Trade* 3 (2005):430–465.

23 P. Drahos, with J. Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002), p. 206.

24 For public-private regulatory partnerships in patent offices see P. Drahos, *The Global Governance of Knowledge: Patent Offices and their clients* (Cambridge University Press 2010).

25 M. Llewelyn, 'Schrodinger's Cat: An Observation on Modern Patent Law' *Death of Patents* op. cit., p. 12.

inventiveness is a priority, as the expansion of patent monopoly has created an incentive to invest in the patent itself, rather than in inventiveness.[26] As a result, it is increasingly fair to say that not only is the validity of all these patents undermined but that of the patent system itself.

Notwithstanding these and other alternatives, public rulemaking is steadily pushing for upward ratcheting of IP through a wide variety of (multilateral, regional, bilateral or unilateral) initiatives. For this reason, the safeguards available in patent law are to be seriously considered.

In this regard, current patent limits and exceptions (in both domestic and international law) offer significant policy space to readapt patent ecosystems to the needs of knowledge-based societies, without recourse to major reforms. Hence, they are a powerful avenue to explore for balancing innovation and diffusion, as some policies in developing countries have shown.

In fact, some governments are timidly reconsidering assumptions over the proper functioning of exclusive rights regimes. As a result, patent-restricting decisions to protect innovation and/or development in technological areas are beginning to take place. These interventions (notably through compulsory licenses and mandatory cross-licensing) rely on antitrust warfare. Policy initiatives in this area generally focus on limiting IP protection to secure innovation and market efficiency in critical technological areas (e.g. essential technological standards) but also on access to technology by have-nots (e.g. exorbitant prices), among other objetives.

The power of competition law and policy should not be taken for granted. Notably, for example, some current interventions in the area of communications technologies use out-of-court mandatory guidance to develop a dynamic balance of rights and obligations both (A) between individual patent-holders (e.g. Samsung *vs* Apple), and also (B) among groups of patent-holders in critical areas (e.g. essential technological standards).

Also interestingly mobile communications and internet technologies are increasingly withholding patent protection. In fact, the current stage of technological development in this sector would have been severely inhibited if patent-holders had generally prevented others from using those inventions.

Thus, the evolution of this highly innovative sector suggests that public authorities can contribute to spurring innovation through a policy mix, based on softening (government-sponsored) exclusive right regimes, and se-

26 P. Drahos, 'Death of the Patent System - Introduction', *Death of Patents* (Lawtext Pub Ltd 2005), p. 9.

curing (government-sponsored) open architecture and joint development in the long-term.

This approach is being increasingly pursued in recent times. As a result, for example, antitrust authorities from key technology-exporting powers, such as the European Union and the United States, have up-scaled their surveillance over private negotiations and decisions regarding voluntary licensing of technology, and are now intervening in 'licensing transactions' related to essential patents on communication technologies. This policy trend aims at securing voluntary licenses for essential technologies through proactive public intervention.

Civil society has a contribution to make in this area. In this regard, legal incentives for private antitrust actions against anticompetitive behavior in the IP world (treble damages, etc) should be enhanced in order to give more room to cause-lawyering and watchdog litigation against IP-based anti-competitive behavior.

Last but not least, the intensive use of technology in advanced societies would suggest a reform of the international patent system to implement an automatic (and cheap to license) global mandatory regime for essential technological inventions. There is a strong case for applying a flat fee equation-based license regarding payments for the use of patents without the need for authorization.

Interestingly, the European Union currently provides for mandatory compulsory cross licensing of both patents and sui generis plant variety protection in sensitive cases: those involving follow-on innovations entailing significant technological progress of considerable general interest.[27] This experience proves that there is some policy space for downward ratcheting of propietary-knowledge.

In short, the establishment of non-exclusive rights regimes should be more seriously considered. Reasonably, as explained below, automatic licensing based on *compensatory liability regimes*[28] would be an easy to implement alternative for avoiding the increasing social costs of IP-based *excludability / exclusivity* in critical scientific and technological areas.

---

27 See *Council Regulation (EC) No 2100/94 on Community plant variety rights* (27 July 1994) and *Directive 98/44/EC on biotechnological inventions* (6 July 1998).

28 See S. Picciotto & D. Campbell, 'Whose Molecule Is It Anyway? op. cit at 280 and J. Reichman, 'Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation', *Expanding the Boundaries of Intellectual Property. Innovation Policy for the Information Society* (Oxford University Press 2001), pp. 23–53.

4. Index

The current pages explore global IP policy developments in the area of life-sciences. To encapsulate its content, the book first explores the main patterns and trends of the global ratcheting up of IP standards (chapters 2 to 4), and goes on to explain some feasible pragmatic market-driven changes to make it work for the public interest (chapters 5 and 6). Subsequently, these pages explore the variety of ways in which the proprietary paradigm of knowledge (the IP paradigm) relates to science (chapter 7), and society (chapter 8) to finally wrap-up with some conclusions (chapter 9).

Specifically, the second chapter enters the current world policy battles on pharmaceutical patent protection, and the games of the so-called global forum shift in IP standard-setting.

The globalization of IP law was subject to a strategic forum shift from the World Intellectual Property Organization (WIPO) to the multilateral trading regime. IP was incorporated in the 8th round of GATT multilateral trade negotiations (MTN), beginning in 1986 and giving rise to the TRIPS agreement on 1 January 1996.

However, this historical treaty-based device, producing top-down standardization, was drafted according to the terms of developed countries and their patent-holding and copyright constituencies, and thus did not take due account of its possible social effects on low-earning individuals, notably, but not only, in developing countries. As a result, developed and developing countries have, for more than a decade been involved in a rather tense re-regulatory process aimed at securing legal 'flexibilities' with respect to these rules. In this regard, the historical Declaration on public health and access to medicines at the launch of the Doha Development Round (2001) functioned as a legitimizing world policy framework for the quest to improve access to affordable medicines in developing societies.[29]

The third chapter explains how trade in generics is a priority policy for both low-income individuals and health authorities in the developing world, as trade is margin cutting, and thus the most effective way of purchasing affordable medicines (read through global markets) when developing countries lack the manufacturing capacity to produce medicines under compulsory license.

However, developed countries are strategically undermining the sus-

29 See WT/MIN (01)/Dec/2, Doha WTO Ministerial 2001: *Declaration on the TRIPS Agreements and Public Health* (20 November 2001).

tainability of production and distribution of generics for both domestic consumption and export through a wide variety of global initiatives. In this regard, the brave new world of increasing TRIPS+ schemes promoted by developed countries suggest legal ceilings should be established against extra IP protection and enforcement in life-sciences.

The next chapter navigates the current segmentation of patent protection in the so-called 'world markets', and analyzes the traditional trade policy solution for enhancing access to medicines in the developing world. This policy change, taking trade back home to the multilateral system, could certainly out- compete the burdensome and strikingly ineffective *state-driven* mechanism designed in 2003 to facilitate access to generics in developing countries that lack manufacturing capacity: the WTO 2003 Decision on the so-called paragraph 6 issue of the 2001 Doha Declaration.

Alternatively, *market-driven* solutions need to be deployed. The multilateral trading system could improve access to affordable generic medicines in low-income countries by concentrating on what it does best, namely, promoting world trade in brand-name and non-brand name drugs, and thus market formation on a global scale.

The fifth chapter explains the power of competition as a TRIPS-compatible vehicle for accessing medicines in the developing world. In this regard, there is a critical legal tension between the market-building approach to development of the multilateral trading regime, based on free trade and its comparative advantages, and the monopoly rights inoculated in this regime through IP linkage to trade.

Arguably, the business of mainstream antitrust law and policy in developed countries is increasingly focused on price-based consumer welfare maximization under the limited rationale of dynamic oligopoly regulation.

The point to make here, ironically, is that this pervasive approach towards antitrust in advanced economies (focusing on prices and price-based consumer welfare) could seriously improve access to medicines in the developing world through antitrust enforcement cooperation, particularly if carrying out regular coordinated inter-state investigations on global anti-competitive licensing practices.

Interestingly, some authorities from developing countries have taken the smart route of antitrust law and policy by threatening with the issuance of compulsory license-based consent decrees in order to down-price critical therapeutic brand-name drugs in their territories.

Reasonably, antitrust authorities from developed countries could certainly help to enforce down pricing policies through current schemes of antitrust enforcement cooperation, by simply following the dictates of consumer welfare maximization, and thus taking IP-based anticompetitive behaviour seriously (e.g: exorbitant prices).

The sixth chapter deals with the tense issue of what should be done, when and where, from the policy angle of inter-agency competence. In this regard, it recalls that health and economic agencies share competence, not only across the board of IP domestic policymaking but also international policymaking.

In principle, IP is *related to trade* as long as trade and IP are also *related to health*. In this sense, increased policy deference between health and economic agencies would be highly advisable from a purely rational angle. If this were the case, policy coherence could be increased and, by extension, higher levels of legitimacy could be reached in this socially sensitive area of world policy making.

Thus, the chapter argues that specialized domestic agencies (e.g. health and economy ministers), as well as the global institutions in which these separately participate (e.g. WHO, WIPO, WTO, etc), should embrace upstream engagement in global policymaking. In this respect, there is an evident case for equal involvement of health ministers in any global negotiation dealing with health-related IP protection.

The seventh chapter generally explores the structural tensions between scientific innovation and knowledge appropriation in a world in which the profit-maximizing corporate proxies of capital-holders increasingly use the so-called 'IP asssets' as devices to discipline if not annull markets and competition.

In order to do that, the chapter approaches the issue of propietary-knowledge under the prism of institutional stake holders such as WIPO and WHO high level scientific committes. Finally, it explores the potential impact of the extreme IP paradigm on the functioning of the advanced academic and scientific institutions.

Following that, chapter eight argues that IP functions a sort of super-asset, which is not only highly liquid but fully enforceable worldwide; thus, a highly tradable world property in its own rights. In addition, the chapter suggests that many hub-and-spokes global licensing schemes annul market and competition-mechanisms and thus operate anticompetitive arrangements.

Finally, the wrap-up chapter poses some open reflexions and conclusions, and basically argues for mitigating the current extreme IP paradigm.In this regard, the international patent system is probably here to stay for some years to come. Transforming the game is not an easy task, as path dependence and vested interests are in place. Thus, while we work for strong policy upgrades in the interest of everyone, it would be reasonable not to neglect policy-second bests; in the meantime, these could at least secure some degree of knowledge ecology in the functioning of patent ecosystems.

Conceptually, on one hand, the granting of government-sponsored proprietary rights over knowledge diverges not only from the very public-goods nature of information but also from the cooperative side of human nature.

On the other hand, for centuries, government-sponsored monopolies have proved to be an extremely well trodden path, providing both a corridor and a revolving door for special interests in colluding against the general interest.

Thus, any exclusive rights regime must be addressed with consummate caution. In this regard, whatever the government-sponsored IP optimum is said to be now and then (read *legal scope*, *strength*, and *period* of protection), public decision-making regarding the propertization of knowledge should proceed with greater care.

Access to affordable medicines is one of the most qualified examples of the social challenges produced by proprietary knowledge, as patents ultimately deal with human life and death. The following pages focus on such issues, in order to explore their social implications. In this regard, patent systems should be socially sustainable.

2

CHESS-BOARD POLITICS

1. Trading on IP

The transition from government to governance, as Picciotto explains, means a lack of a clear hierarchy of norms, a blurring of distinctions between hard and soft law, and a fragmentation of public functions entailing a resurgence of technocracy.[1] In this context, the globalization of intellectual property standards exacerbates the historical tensions that characterise patent and health protection.[2] Private interest and public values are in increasing conflict,[3] while developed and developing countries continuously shift fora, battling to ratchet IP protection up or down.[4]

These regulatory fluxes produced the first critical forum shift to the benefit of IP constituencies during the Uruguay Round. This shift is already part of modern world history, as it officially inaugurated a relentless and se-

---

1 For an historical analysis through the prism of law and legal creativity see S. Picciotto, *Regulating Global Corporate Capitalism* (Cambridge University Press 2011) as well as 'International Transformations of the Capitalist State', 43 *Antipode* 1 (2011): 87–107.

2 See G. Gereffi, *The Pharmaceutical Industry and Dependency in the Third World* (Princeton University Press 1983), J. Braithwaite, *Corporate crime in the pharmaceutical industry* (Routledge & Kegan Paul 1984), M. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Brookings Institution Press 1998), P. Drahos & J. Braithwaite, *Information Feudalism: who owns the knowledge economy* (Earthscan 2002), S. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003), P. Drahos, *The Global Governance of Knowledge*: Patent Offices and their clients (Cambridge University Press 2010).

3 See S. Picciotto, 'Defending the public interest in TRIPS and the WTO' *Global intellectual property rights: Knowledge, access and development* (Palgrave Macmillan / Oxfam 2002), pp. 224–243.

4 P. Drahos, 'Four lessons for developing countries from the trade negotiations over access to medicines' 28 *Liverpool Law Review* (2007): 33.

rious game of global 'chessboard politics' on the protection, limits and exceptions to knowledge-based monopoly rights.[5]

At the beginning of the 1980s, parties to the Paris Convention for the Protection of Industrial Property, the oldest convention providing protection for patented inventions outside domestic laws, applied the rules of non-discrimination and national treatment to patents and patent applications but retained country autonomy in substantive criteria such as the patentability or non-patentability of pharmaceuticals.[6]

In the 1980s and early 1990s, a Diplomatic Conference held under the auspices of WIPO attempted to revise the Convention. However, developing and developed countries could not agree on critical issues such as compulsory licenses (CL).[7] In fact, attempts by developing countries to upgrade its CL provisions (article 5A) brought the Conference to an end.[8]

The failure of this Conference persuaded IP constituencies to promote a forum shift to the next round of GATT multilateral trade negotiations (MTN). By the time of the launch of the Uruguay Round (1986), 49 of the 98 members of the Paris Convention excluded patent protection for pharmaceutical products.[9] In essence, US IP constituencies shifted their strategy from the IP to the trade regime and pushed the United Trade Representative (USTR) to follow suit as a final effect of the crises facing the WIPO in its dealings with the US, when WIPO became a forum for criticism of copyright and patents in the 1960s and 70s.

The move to the multilateral trading system also aimed to benefit from the comparative institutional advantages of the new dispute settle-

---

5 K. Alter & S. Meunier, 'The International Politics of Regime Complexity', 7 *Perspectives on Politics* (2009): 13–24.

6 See *Paris Convention for the Protection of Industrial Property, March 20, 1883, as revised at Stockholm (1967), 21 UST 1583, 828 UNTS 305.*

7 See e.g. J.H, Reichman & C, Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, UNCTAD/ICTSD-Project on IPRs and Sustainable Development, Issue Paper No. 5 (2003).

8 Compulsory licensing is as old as patent law. For the historical origins of the patent system see, in particular, I. Mgbeoji, 'The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization' 5 *Journal of History of International Law* (2003): 403–422.

9 See *Existence, scope and form of generally internationally accepted and applied Standards/Norms for the Protection of Intellectual Property-Note prepared by the International Bureau of WIPO* (15 September 1988). MTN.GNG/NG11/W/24/Rev.1.

ment mechanism that was being negotiated in the Uruguay Round (e.g. binding multilateral jurisdiction and authorization of sanctions/suspension of concessions).[10]

Interestingly, the ministers represented in WIPO reacted with celerity, launching negotiations to produce a (WIPO) dispute settlement treaty, but the initiative was derailed.[11] As a result, trade-related IP rights are now part of a 'WTO covered agreement' and thus enforceable through its binding dispute settlement mechanism.[12]

Wanted or not, WIPO had to learn to 'share' its original competences with WTO, and nowadays provides legal advice and technical assistance on TRIPS implementation in accordance with their cooperation agreement of 1995.[13] Therefore, a pure jurisdictional reallocation or 'forum shifting' has taken place in the area of global IP protection.

As a result, new global standards for IP protection were established under the TRIPS agreement. Thus, ministers of trade and finance managed to inoculate IP protection within the multilateral trading system by using a strategic association of ideas: 'trade-relatedness'.

Obviously, the 'trade-relatedness' invention opens up a world of possibilities for global policy formation in all areas, and thus also to multiple jurisdictional reallocations,[14] as almost everything is interrelated, in some way or another.

---

10 For the negotiating history see J. Ross & J. Wasserman, 'Trade-Related Aspects of Intellectual Property Rights', *The GATT Uruguay Round: A Negotiating History (1986-1992)*, Volume II (Kluwer Law and Taxation Publishers 1993) at 2241–2313 and D. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet and Maxwell 1998).

11 See *WIPO Proposed Treaty on the Settlement of Disputes between States in the Field of Intellectual Property*, WO/GA/XXI/2 (30 April 1997) and *Background information document*, WO/GA/XXI/3 (30 April 1997).

12 For the first studies on the *forum-shifting paradigm* see J. Braithwaite & P. Drahos, *Global Business Regulation* (Cambridge University Press 2000) at 564–571 and L. Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking', 29 *Yale Journal of International Law* 1 (2004): 1–83.

13 For a detailed overview see WIPO Annual Reports, available at http://www.wipo.int.

14 See chapter 6.

2. TRIPS lens

The TRIPS agreement is a revolution in the history of IP protection.[15] Having been designed to establish minimum protection standards for trade-related IP, this treaty applies a top-down approach towards harmonization.[16] Basically, it is the most far-reaching and comprehensive legal regime ever to be concluded in the intellectual property area.[17] However, the TRIPS provisions do not establish 'IP-related' public health protection with similar sensitivity. Consequently, this agreement has been in need of strategic re-engineering from the very first day that it entered into force in 1996.

Developing countries 'agreed' to negotiate the TRIPS agreement during the Uruguay Round in exchange for trade concessions on textiles and agricultural products, and under the pressure of US trade unilateralism.[18] The agreement was in fact negotiated in the shadow of unilateral trade sanctions pursued by the so-called USTR diplomacy.[19]

GATT Contracting Parties such as Brazil, India, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and the former Yugoslavia were among the most active GATT Contracting Parties opposing IP lawmaking in the Uruguay Round, arguing that the multilateral trade system was primarily concerned with trade in goods and not property rights in intangibles.[20]

---

15 C. Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press 2008), p. 1.

16 P. Stephan, "Institutions and Elites: Property, Contract, the State, and Rights in Information in the Global Economy", 10 *Cardozo Journal of International Law and Comparative Law* (2002): 305–306.

17 C. Correa & A.Yusuf, *Intellectual Property and International Trade: the TRIPS Agreement* (Kluwer Law International 1998), p. xvii.

18 See K. Watal, *Intellectual Property Rights in the WTO and Developing countries*, Oxford University Press, 2001 and R. Okediji, 'Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement', 17 *Emory International Law Review* 2 (2003): 819–918.

19 The Omnibus Trade and Competitiveness Act in 1988 amended section 301 of the US Trade Act of 1974 and required USTR to identify inadequate domestic IP protection and unilaterally enforce market access. See, particularly, M. Ryan, 'The Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking', 19 *University of Pennsylvania Journal of International Economic Law* (1998): 558–559.

20 J. Bradley, 'Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations', 23 *Stanford Journal of International Law* (1987): 8.

However, their initial resistance for a narrower interpretation of the mandate for the Uruguay Round negotiations on this issue (Ministerial Declaration of 1986) broke down in 1988, with the second amendment of the Section 301 of the US Trade Act of 1974, the so-called Special 301.

Entering into operation in 1989, Special 301 granted USTR the authority to apply unilateral trade sanctions against countries providing 'insufficient' protection of intellectual property. Indicatively, 5 of the 10 countries in the hard line group which was against incorporating IP protection in the negotiations were listed for bilateral attention in the first USTR announcement of Special 301 country targets. Countries such as Argentina or Egypt were placed on the Watch List, while both Brazil and India, the leading opponents of the US agenda were placed on the Priority Watch List, Special 301 most serious country-category (USTR's annual Special 301 IPR Reports).[21]

As a result, the original legal framework of WTO law today contains an agreement on trade-related IP protection. However, almost a decade since it entered into force, there is growing criticism among developing countries as they have to live with the 'burden' of stringent IP standards, while developed countries have not equally honoured their trade commitments (lowering tariffs and subsidies on agriculture and textiles).[22]

Last, but not least, the TRIPS agreement is producing some unforeseen adverse effects on the policies of the developing world.[23] As Drahos explains, both developed and developing countries alike were generally in ignorance about its likely effects on information markets:[24] in addition, most importer nations did not have a clear understanding of their interests and, as this Australian recalls, were not in the room when the critical technical details were settled.[25]

---

21 F. Abbott, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', 22 *Vanderbilt Journal of Transnational Law* (1989): 689 and 708–709.

22 See *Integrating intellectual property rights and development policy*: Report the Commission on Intellectual Property Rights (2003), p. 8.

23 On the perverse distributional effects of TRIPS patent protection with regards to pharmaceuticals see, in particular, E. Benvenisti & G. Downs, '*Distributive Politics and International Institutions: The Case of Drugs',* 36 *Case Western Reserve Journal of International Law* (2004): 21–52.

24 P. Drahos, "Developing Countries and International Intellectual Property Standard-setting", *Study Paper 008 of the Commission on Intellectual Property Rights* (United Kingdom 2001), p. 13.

25 See P. Drahos & J. Braithwaite, *Information* op. cit at 190–191 and F. Scherer, 'A Note on Global Welfare in Pharmaceutical Patenting', 27 *World Economy* (2004).

The information revolution has reduced production costs, significantly raising the (legal) value of knowledge. In theory, TRIPS rules were precisely designed to promote the legal protection of these knowledge-production processes; in practice, however, the rules do not facilitate access to medicines in the developing world, among others issues.

In any case, finding a proper balance between patents and health is not itself an easy task, as interests and values are seriously at odds in this disputed area of global politics.[26]

Conventional thinking on patents argues that effective patent protection is a prerequisite for technological innovation, and thus also a lever for economic development generally.[27] According to this view, IP friendly environments promote foreign direct investment (FDI) and technology transfer (e.g. foreign technology licensing, and joint ventures).[28] Conversely, critical thinking argues that less burdensome public mechanisms could alternatively obtain similar outcomes without incurring the social burdens of patent systems.

Interestingly, numbers provided by the industry itself tend to bear this out. For example, the figure provided by the US pharmaceutical industry itself in its 2011 industry profile reached $ 67.4 billion on Global R&D by all private companies in 2010.[29] For that same year, the estimate on global sales by industry-friendly IMS Health Market Prognosis reached $ 856 billion.[30]

But leaving aside those figures, there is also a strong point to make that the price we pay for patents nowadays is unrelated to the price of discovery and development. This is not only a question of price that the consumer can afford but also the price paid by under developed societies. Access to afforda-

---

26 On the two main schools alternatively suggesting a conflict (primacy of human rights) or co-existence (need for a balance) of human rights with IP monopoly rights see L. Helfer, 'Human Rights and Intellectual Property Rights; Conflict or Co-existence?', 5 *Minnesota Intellectual Property Review* (2003).

27 For the first global reports on the interaction between IP, technology transfer and FDI see *Economic Arguments for Protecting Intellectual Property Effectively* (OCDE 1989) and *Intellectual Property Rights and Foreign Direct Investment* (United Nations Department of Economic and Social Development 1993).

28 *See* e.g. *Creativity, Innovation and Economic Growth in the 21st Century: An Affirmative Case of Intellectual Property Rights,* Business and Industry Advisory Committee to the OECD 2004.

29 See *2011 PhRMA industry profile,* p. 2.

30 See 'Total Unaudited and Audited Global Pharmaceutical Market: 2003–2010', *IMS Health Market Prognosis* (March 2011).

ble medicines in any given society has a significantly more positive impact on development than high standards of pharmaceutical patent protection and enforcement.[31]

Notwithstanding the dilemmas raised by the patent and health relationship, a variety of authoritative diagnostics reveal that a more nuanced balance between public health (rights of citizens/patients) and private property (rights of patent holders/corporations) is needed, particularly (but not exclusively) regarding access to affordable medicines in the developing world.[32]

3. Flexibility

Small groups tend to be more adept than the general public at organizing the ways in which they pursue their interests, as their transaction costs are lower.[33] As a result of that, developed countries over-protected the interests of their industries in TRIPS agreement.

The drafting of the TRIPS agreement was basically a trade diplomat driven-process permeated by the latter.[34] Indeed, its very existence (and a good deal of its substance) owes much to the global firms that guided the USTR strategy during the Uruguay Round negotiations with a generously staffed team of business advisors and IP experts.[35]

---

31 See B. Wright, 'The economics of invention incentives' and S. Shavell & T. Van Ypersele. 'Rewards versus intellectual property rights', M. Kremer, 'Patent buyouts: a mechanism for encouraging innovation' op. cit, J. Love, *From TRIPS to RIPS: A Better Trade Framework to Support Innovation in Medical Technologies,* Paper presented at Agence Nationale de Recherches sur le Sida, University of the Mediterranean (Marseille 2003) and T. Hubbard & J. Love, 'A New Trade Framework for Global Healthcare R&D' *Plos Biology* 2: 147–150.

32 For scientific and deliberative commissions on the issue see, in particular, *Public Health, Innovation and Intellectual Property Rights,* Final Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (WHO 2006) and *Integrating intellectual property rights and development policy,* Report the UK Commission on Intellectual Property Rights (2003).

33 M. Olson, *The logic of collective action: public goods and the theory of groups* (Harvard University Press 1965), pp. 22–36.

34 See P. Drahos & J. Braithwaite, *Information* op. cit (chapters 8 and 9).

35 In the words of Sell: "it was not merely their relative economic power that led to their ultimate success, but their command on IP expertise, their ideas, their information, and their framing skills (translating complex issues into political discourse". See S. Sell, *Private Power* op. cit., p. 4.

In essence, the USTR acted as a proxy for the technology and pharmaceutical industry (through the US Advisory Committee on Trade and Policy Negotiation) and the EU representatives as well as other developed countries followed suit.[36]

The TRIPS agreement is a regulatory by-product of global corporate capitalism.[37] Its drafting was seriously and strongly influenced by a precisely circumscribed coalition of private technology exporters, namely, the twelve companies that originally founded the Intellectual Property Committee (IPC) in 1986 in order to mobilise support for the adventure.[38][39] In the bold words of Susan Sell, a dozen corporations managed to make public law for the world.[40]

The capacity of developing countries to influence outcomes was limited by US unilateralism but also as a result of the scant exposure of some developing country negotiators to the arcane technicalities of western (read also US-style) intellectual property law.[41] Thus, a model of IP protection which originated in the developed world has been transplanted to the developing world through the tools of international law.[42]

In consequence, flexibility is required. The way the TRIPS agreement approached development is based merely on transitional periods and is therefore too simplistic. The balancing of patent protection and health protection was envisioned as an issue to be approached by buying time, instead of adapting its implementation to the changing levels of development of WTO Members (phase-ins) and linking technology transfer to compliance.

Generally, WTO members had to implement the TRIPS Agreement at the end of the 1995–2000 transition periods. In addition, an extra term was granted until 1 January 2005 in the area of pharmaceutical product patents for certain developing WTO Members. In consequence, these were allowed to

---

36 For an insightful business case study on the participation of Pfizer in the development of international trade law see M. Sontoro & L. Paine, 'Pfizer: Protecting Intellectual Property in a Global Marketplace', *Harvard Business School,* Case study No. 9-392-073 (1992).

37 See S. Picciotto, *Regulating global corporate* op. cit, P. Drahos & J. Braithwaite. *Information* op. cit and J. Braithwaite & P. Drahos, *Global business* op. cit.

38 For the whole process of this regulatory 'private-public partnership' see in particular P. Drahos & J. Braithwaite, *Information* op. cit.

39 See G. Dutfield, *Intellectual Property Rights and the life science industries: A Twentieth Century History,* (Ashgate 2003).

40 See S. Sell, *Private Power* op. cit., p. 96.

41 P. Drahos, 'Developing Countries and International Intellectual' op. cit., p. 13

42 See S. Tully, *Corporations and International lawmaking* (Martinus Nijhoff 2007).

delay product patent protection in areas not protected by their legal systems at the time that the agreement entered into force (TRIPS Article 65.4). Developing countries (less than twenty developing countries including India and Brazil) were required to accept patent applications from 1995 onwards (the so-called patent 'mailbox') and began to assess them in 2005.

Finally, a third transition period covering patent protection of pharmaceuticals and exclusive marketing rights was granted to provide Least Developed Countries (LDCs) with a longer phase-out to comply with TRIPS obligations. As a result, LDCs enjoyed a temporary waiver originally expiring on 1 January 2006 that has been further extended to 1 January 2016 through a Decision of TRIPS Council in 2002.[43]

However, transitional periods are inevitably incapable of regulating the complexities of pharmaceutical patent protection in the developing world. As mentioned above, transitional periods are unconditional, merely based on granting developing countries time (phase-outs) to implement the given rules. Consequently, they are not easily adapted to the changing realities of developing countries and are thus particularly inefficient in regulatory terms.

As a direct result, WTO Members are currently involved, and have been almost since the entry into force of the agreement, in a regulatory learning process to re-engineer the TRIPS disciplines in order to address the health realities of developing countries.[44] In fact, the problem became a public relations disaster for the new WTO in 2000, immediately following its first and failed Round of negotiations (the so-called Millennium Round, derailed in 1999), and prior to beginning a second attempt (the Doha Development Round, initiated in 2001).

At the beginning of a new decade, century and millennium, health advocates and public health representatives managed to effectively question the state of affairs of pharmaceutical patent protection in the developing world and blamed TRIPS rules in part for the difficulties that developing countries were facing in gaining access to affordable medicines.

With the WTO's legitimacy being questioned prior to a new negotiating

---

43 See IP/C/25 *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*, Decision of the Council for TRIPS of 27 June 2002, Council for TRIPS (1 July 2002).

44 For a proposal for making WTO law more pro-development friendly by linking IP compliance to economic factors see T. Cottier, 'From progressive liberalization to progressive regulation in WTO law', 9 *Journal of International Economic Law* 4 (2006): 779–821.

round, finding a solution was considered an institutional priority by the WTO Secretariat and most, if not all, WTO Members. The world trading system was under pressure to deliver consensus-based solutions on this highly sensitive issue, and thus also had a major opportunity to demonstrate its 'flexible' legal culture in the beginning of the Doha Development Round.[45]

Thus, trade ministers concentrated on negotiating some collective (re)interpretations to extend the scope within TRIPS agreement for pursuing public health policies in developing countries. In this regard, the TRIPS Council had the complex task of developing a consensus-based formula (read acceptable for all) for reinterpreting TRIPS obligations on this issue.[46]

In practice, WTO Members collectively entered into a complex re-regulatory learning process which continues today. This sign of the times is clearly captured in their reaction, in April 2001, to the settlement of a famous domestic lawsuit against the South African Medicines and Related Substances Control Amendment Act. Interestingly, the settlement of this lawsuit brought by the South African Pharmaceutical Industry Association and several affiliated companies, merited an unprecedented welcome from the WTO Director-General himself. Even the Press Release takes advantage of the event as proof of the flexible nature of WTO law:

> The settlement *shows* that the WTO agreements, such as TRIPS, contain the necessary flexibility to meet the health needs of developing countries *and can be used as a basis for resolving difficult issues* concerning access to essential drugs.[47]

However, arriving at a new legal balance with regard to health-related patent protection was never going to be easy. In this respect, the African Group, Brazil and India took the lead inside WTO corridors and meeting rooms, while social activists were effectively voicing the issue in the global media.

The pressures of developing countries against any substantial policy change with regard to patents and health were critical; but the anthrax cases in the United States, and the subsequent intention of the US administration

---

45 See R. Gold & J. Morin, 'Consensus-seeking, distrust and rhetorical entrapment: The WTO Decision on access to medicines' 16 *European Journal of International Relations* 4 (2010): 563–587 (578).

46 See C. Ehlermann & L. Ehring, 'Decision-making in the world trade organization', 8 *Journal of International Economic Law* 1 (2005): 64.

47 See WTO News: Speeches—DG Mike Moore. *Moore welcomes news of settlement of South Africa drug lawsuit,* Geneva (19 April 2001).

to issue a compulsory license for Cipro (a Bayer antibiotic), secured some policy momentum to upgrade the legal *status quo*.

In June 2001, TRIPS Council had its first special meeting on access to medicines, requested by the African Group. That was also the same month that the US withdrew its WTO complaint against Brazil's pharmaceutical policies, thus conveying a change in attitude and suggesting a willingness to adapt TRIPS rules to the health realities of the developing world.[48]

The rationalization of TRIPS rules began in a 7-hour session of that special meeting, with interventions from over 40 delegations.[49] In that session, trade representatives developed some (first) common interpretations on TRIPS inner 'flexibility'.

For the WTO Director-General, TRIPS rules 'strikes a carefully-negotiated balance' between providing IP protection and 'the flexibility to ensure that treatment reach the world's poorest and most vulnerable people'. Pursuant to this, the TRIPS Council 'reinforced' the security that WTO Members 'can use' the available 'flexibility' in the agreement. Furthermore, should any improvements be needed, as 'nothing is perfect', these improvements could be negotiated in the Doha Round.[50]

Hence, access to medicines was on board the so-called Doha 'Development Round' in the Ministerial Conference of Qatar. In fact, the Ministerial Declaration opening the Round had already underlined the critical importance of making a pro-health implementation and interpretation 'by promoting both access to existing medicines and the creation of new medicines' (paragraph 17).

The Doha Declaration on public health and access to medicines, adopted in November 2001, was certainly a milestone in the whole process of reengineering the TRIPS agreement. In the words of the current WTO DG, at the High-Level Symposium on Global Health Diplomacy, held in 2011 to mark the Declaration's 10th anniversary, '*this historic instrument has reinforced health policy choices worldwide*'.[51]

---

48 See *Brazil Measures Affecting Patent Protection*, WTO Doc WT/DS199/3 (January 9, 2001).

49 See the working paper submitted by the African Group and 17 developing countries. IP/C/W/296, *TRIPS and Public Health* (June 29, 2001).

50 See WTO News: Speeches—DG Mike Moore. *Moore: Countries must feel secure that they can use TRIP´s flexibility* (20 June 2001).

51 See WTO News: *10-year-old WTO Declaration has reinforced health policy choices, Lamy tells symposium* (23 November 2011).

The key idea underlying the Declaration is formal recognition that the TRIPS agreement provides for 'flexibilities' to secure state regulatory autonomy in the patents and health policy area. The flexibilities of TRIPS rules recognized in the 2001 Declaration are to be found and developed through the interpretative prism of the objectives and principles of the agreement:

– Article 7 (objectives): '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*'.
– Article 8 (Principles): '[Members may adopt] *measures necessary* to protect public health and nutrition, and to promote the public interest *in sectors of vital importance to their socio-economic* and technological *development*, provided that such measures are consistent with the provisions of this Agreement'.

Interestingly, Paragraph 5 of the 2001 Declaration itself expressly recalls how flexibility needs to be built upon those provisions: '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*'.

The Declaration determines that the TRIPS agreement 'does not and should not prevent members *from taking measures to protect public health*'.[52] In this sense, the agreement 'can and should be *interpreted* and *implemented* in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all' (paragraph 4). Its provisions also refer to a right to use those rules, 'for this purpose' and '*to the full*'.

The legality of *compulsory licensing* is thus secured under this legal rationale. The term was not regulated as such in TRIPS agreement but as 'other use without authorization of the right holder' in the title of article 31.[53] In any case, the right to grant compulsory licenses was made clearer than under ar-

52 See WT/MIN (01)/Dec/2, Doha WTO Ministerial 2001: *Declaration on the TRIPS Agreements and Public Health* (20 November 2001), paragraph 4.

53 For a history of article 31 see also R. Gold & D, Lam, 'Balancing Trade in Patents: public non-commercial use and compulsory licensing', 6 *Journal of World Intellectual Property* (2003): 5–32.

ticle 5A of the Paris Convention,[54] and was thus reworded in broader terms to avoid misinterpretations:

> Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[55]

Legal exceptions based on health crises were, in addition, formally recognized: '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 national emergency or other circumstances of extreme urgency' (paragraph 5.c).

To sum up, the 2001 Doha Declaration facilitates pro-health implementation, providing for extra (TRIPS compatible) policy space based on re-regulation and flexible interpretations. Certainly, the reach of 'TRIPS flexibility' depends on the political will of those who can authoritatively interpret and waive TRIPS rules through WTO decision making-processes. As even well-known IP critics recognize, in any case, the Declaration has critically increased and reinforced the legality of TRIPS flexibilities on health-related areas.[56]

4. Reregulation

The Declaration confirms that WTO Members have the 'right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'. In addition, it also mandated the TRIPS Council to make additional efforts in some areas, and particularly with regard to the so-called 'Paragraph 6 issue' of the 2001 Doha Declaration[57]: TRIPS Article

54 The right of governments to grant CL on virtually any ground (including public interest, abuse or anticompetitive conduct, or for noncommercial government use, among others) was incorporated in TRIPS agreement thanks to the fortitude and analytical skills of the Indian delegation. See J. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options', *Journal of Law Medicine* (2009): 248.

55 See paragraph 5.b.

56 See J. Love, 'What the 2001 Doha Declaration Changed?, *Knowledge Ecology International* (16 September 2011).

57 See WT/MIN(01)/Dec/1, Doha WTO Ministerial 2001: *Ministerial Declaration* (20 November 2001) paragraph 17.

31 recognizes the legality of granting CL to order generics but also determines that 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'.

As a result, the provision not only prevented developing countries with no manufacturing capacity (which was most of them) to import generics from countries in which the patented drug was produced. It also limited production to an unspecified volume, by using the expression 'predominantly'.

The wording of the paragraph 6 issue was precisely framed under the policy pressure of the new pro-development Doha Round: 'to find an *expeditious solution* to this problem before the end of 2002.

The 'solution' was reached with the so-called 'Motta text' (named after Perez Motta, the former Chairman of the TRIPS Council) in December 2002,[58] and was finally adopted on 30 August 2003 through a WTO General Council Decision –interestingly, not a TRIPS Council Decision– on the implementation of paragraph 6 of the Doha Declaration.[59] In the words of Supachai Panitchpakdi, Director-General of the WTO at that time, the 'final piece of the jigsaw" had fallen into place with this Decision; proving 'once and for all' that WTO 'can handle humanitarian as well as trade concerns'.[60]

In essence, the Decision waives article 31(f) requiring production under CL to be 'predominantly' for the domestic market. The object of this waiver is reasonable, as it is simply an unachievable requirement for developing WTO members that lack manufacturing capacity.[61] As mentioned above, these inevitably have to be supplied by global generics markets. In order to provide this, the *waiver* creates a member-driven mechanism allowing the import and export of generics on a case-by-case, drug-by-drug, country-by-country basis. The regulatory structure of this member-driven (paradoxically not

58 See in particular F. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', 99 *American Journal of International Law* 2 (2005): 317–358 and see D. Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health: A Solution to the Access to essential medicines problem?', 7 *Journal of International Economic Law* 1 (2004): 73–107.

59 See WT/L/540, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, Decision of the General Council of 30 August 2003 (1 September 2003).

60 See WTO News: 2003 Press Releases, Press/350/Rev.1, *Decision removes final patent obstacle to cheap drug imports* (30 August 2003).

61 In fact, former WTO Director, Supachai Panitchpakdi, described the Decision as 'an historic agreement.' See WTO News: 2003 Press Releases (9 September 2003).

market-driven) mechanism is based on a notification procedure for both importing and exporting countries planning to trade in generics.[62]

The Decision, pre-negotiated by the United States, India, Brazil, South Africa and Kenya, basically helped WTO Members to keep the ongoing Doha negotiating process on track at the Cancun Ministerial Conference (September 2003). The negotiated instrument aims with questionable success to strike a balance between potential importers of generics (mainly in Africa, Asia and America), potential exporters (such as India and Brazil), and technology-exporting countries.[63]

The 2003 Decision also establishes that WTO Members may notify their intention not to use the system as importers, or to use it only in a limited way. Practically all OECD countries have issued such notifications, under pressure from their patent-holding industries. Thus, the instrument includes a list of developed countries who will formally refrain from importing generic medicines, as well as a list of countries that will commit to importing generic drugs only in cases of extreme urgency or national emergency.

The Decision is accompanied by a separate statement of the General Council chairperson ensuring that it would not provide a backdoor for commercial use of those generics, by re-entering non-exempted markets. The statement expresses several 'shared understandings' regarding the Decision and the way it has to be interpreted and implemented:

(1) the system has to be used 'in good faith', undertaking not to pursue 'industrial or commercial objectives';
(2) all reasonable measures should be taken to prevent *market diversion* (re-exports);
(3) issues arising from the Decision have to be solved expeditiously and amicably and finally;
(4) notifications should include information from the Member on the ways and means it has employed to conclude that there is insufficient manufacturing capacity in the sector.

The chairperson also attaches to his separate statement a short list of guidelines (selected 'best practices' from producers) to reduce and minimize product diversion (anti-diversion measures) and thus to ensure market segmentation.[64]

---

62 See <http://www.wto.org/english/tratop_e/TRIPS_e/public_health_notif_export_e.htm>.

63 For a comment see generally F. Abbott, 'The WTO Medicines Decision' op. cit 317–358 and D. Matthews, 'WTO Decision on Implementation' op. cit., pp. 73–107.

64 These schemes built on the previous experience of anti-diversion business practices by companies like Novartis, Merck, Pfizer and others, differentiating regular

Interestingly, the 2003 Decision is an interim *waiver* to be applied until the TRIPS agreement is amended.[65] As a result, the General Council adopted a Protocol of Amendment in 2005.[66] Open to acceptance by WTO Members before 1 December 2007, this protocol contains an extremely elaborate (: bad) article 31bis to be incorporated as an Annex to the TRIPS agreement if accepted by two thirds of WTO Members.[67]

By the time this book was completed, less than 50 WTO Members[68] had accepted the Amendment including the United States (17 December 2005) and the European Communities (20 November 2007).[69]

Interestingly, a new Decision of WTO Members in 21 December 2007 finally established an unlimited extension to the waiver, probably taking into due consideration the obvious difficulty of ratification by WTO Members: 'The period [...] shall be extended until 31 December 2009 *or such later date as may be decided* by the Ministerial Conference'.[70] In short, the self-evident political difficulties to ratify the Protocol suggest that it is unlikely to enter into force, at least in the near future.[71]

Its wording is, in any case, overly burdensome.[72] In fact, African countries, Brazil and India strongly opposed the provisions contained in the amendment itself without much success. Basically, the amendment trans-

---

products from products supplied through discounted pricing or donor policies. See WT/GC/M/82, *General Council Chairperson´s Statement* (13 November 2003).

65 See *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Decision of 30 August 2003,* WT/L/540 (29, august 2003).

66 For a detailed legal study on available policy options see F. Abbott, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on public health', 9 *QUNO Paper n.9* (2002).

67 See WT/L/641, *Amendment of the TRIPS Agreement* (8 December 2005).

68 See <http://www.wto.org/english/tratop_e//TRIPS_e/amendment_e.htm>.

69 See SGS7/166652, *Instrument of Acceptance, Council of the European Union* (Brussels, 19/11/2007).

70 See WT/L/711, *Amendment of the TRIPS Agreement-Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement* (21 December 2007).

71 See *European Parliament Resolution on the TRIPS Agreement and access to medicines,* B6-0288/2007 (9 July 2007), paragraph K.7, the study commissioned by its Committee on International Trade as well as *European Parliament Debates* CRE 11/07/2007–18 (7 July 2007) and PV 11/07/2007–18 (7 July 2007).

72 See V. Bradford & K. Lee, 'TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?' 3 *Globalization and Health* (2007): 3.

forms into treaty law the (non-functioning) member-driven mechanism created by the 2003 Decision. In this regard, it is reasonable to suggest that it is not cost-efficient to allocate significant public resources to that ratification.

Developing countries without pharmaceutical manufacturing capacity have legal and legitimate expectations of accessing generics through global markets. In this regard, market mechanisms tend to function better when strong vested interests are involved. A member-driven mechanism such as the paragraph 6 mechanism (requiring a double compulsory licence from both the importing and exporting country to trade in generics) is inefficient vis-à-vis market mechanisms.

In this regard, this member-driven mechanism is not only dependent on the unnecessary bureaucratic processes of public decision-making in both the potentially exporting and importing countries, but it is also highly exposed to the pharmaceutical brand-name industry pressures against the CL which are required to make it function.

Hence, it not difficult to conclude why the mechanism has only been used once since its 2003 inception,[73] involving a generics transaction between Rwanda and Canada (260000 packs) of an HIV/AIDS combination therapy (TRIAvir) manufactured by Canadian Apotex Inc.[74] In consequence, it is easy to understand why developing countries are pressing to renegotiate.

---

73 See IP/N/9/RWA/1, *Council for Trade-Related Aspects of Intellectual Property Rights - Notification under paragraph 2(a) of the Decision of 30 August 2003*–Rwanda (19 July 2007) and IP/N/10/CAN/1, *Council for Trade-Related Aspects of Intellectual Property Rights–Notification under Paragraph 2(c) of the Decision of 30 August 2003* – Canada (5 October 2007), respectively.

74 On this transaction see in particular C. Cotter, 'The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries', 5 *Loyola University of Chicago International Law Review* (2008): 177 y 185-86, J. Cohen-Kohler, L. Esmail & A. Perez Cosio, 'Canada's implementation of the Paragraph 6 Decision: is it sustainable public policy?', 3 *Globalization and Health* (2007):12 and H. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines', 11 *ASIL Insight 28* (December 10, 2007).

3

EXPANDING PROPERTIES

1. States as proxies

Many developing countries have scant manufacturing capacity or none at all, and are thus supplied with generics by global markets. For this reason, patents within middle-income developing countries with manufacturing capacity are of the most critical concern. In essence, sustainable generic production in the latter is a prerequisite for exporting those medicines to the former.

In recent decades, an efficient generic drug industry has burgeoned in developing countries such as South Africa, Thailand, India, and Brazil has also become a key source of global generic production and distribution. Manufacturers such as Cipla (India) or Cristalia (Brazil), for example, have long-standing experience in producing quality drugs for export to developing countries where there is no patent, or where the patent has expired or, less frequently, the patent is under compulsory license (CL), or government use. As a result, a wide variety of cheap generic medicines are competing today in generics markets.

However, patents are becoming more widespread as a result of the TRIPS agreement, as well as other TRIPS+ initiatives and this has restricted generic competition for newer patented drugs.[1] Brazil, for example, passed Decree n^{0} 1355 reintroducing patents, after a 30-year vacuum, as early as 30 December 1994, and India amended its Patent Act in March 2005 on similar lines.[2]

---

1 B. Waning, M. Kyle and E. Diedrichsen, L. Soucy & J. Hochstadt *et al,* 'Intervening in global markets to improve access to HIV/AIDS treatment: an analysis of international policies and the dynamics of global antiretroviral medicines markets', 6 *Globalization and Health* (2010): 13.

2 Before this, interestingly, both a WTO *panel* and Appellate Body decision had ruled against India for not taking the required steps to prepare its compliance with TRIPS agreements in 2005 (transitional obligations). See WT/DS79/R *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (August 24, 1998) and WT/

Patent protection of new drugs in these countries adversely affects access to second and third treatments in developing countries. The cost structure for drugs in developing countries is bound to be severely affected if the generic manufacturers in these countries operate under increasingly strong patent regimes and smaller scale operations. For this reason, it is critical to ensure that generic industries compete in the global markets and thus, upscale their operations.

Obviously, the pharmaceutical industry is not particularly supportive of the export-oriented production of generics in the developing world. Lobbies such as IIIA (International Intellectual Property Alliance) or US PhRMA (Pharmaceutical Research and Manufacturers of America) are in fact targeting the sources of generic production and distribution.

As a result, developing countries with export-oriented generic production are under pressure from aggressive IPs+ domestic lobbying and litigation. These strategies deployed by the industry are complemented by technology exporting countries acting as proxies to negotiate (bilateral and regional) TRIPS+ treaties.[3]

In short, some developing countries are bargaining away the existing health-related TRIPS flexibilities in exchange for more expedient market access, in order to obtain (or not to lose) concessions elsewhere (foreign aid withdrawal, refusal to transfer technology, etc), or to avoid becoming a target for unilateral action.[4] In addition, no country is interested nowadays in suffering the inconvenience of being subject to a corporate campaign depicting it as a piracy-lenient country.

As a result, TRIPS flexibilities remain untested in many developing countries. Public policies in developing countries are subject to carrots and sticks from developed countries.[5] Thus, ministries other than health ministers tend to be reluctant to support critical health policies such as pharmaceutical compulsory licensing (CL). It is noteworthy, for example, that the first CL granted by India to a generic producer was issued as late as 2012. The

---

DS50/AB/R *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (December 19, 1997), respectively.

3 See V. Bradford & K. Lee, 'TRIPS, the Doha declaration' op. cit., p. 3.

4 See, in particular, P. Drahos & J. Braithwaite, *Information* op. cit., pp. 187–197 (chapter 12).

5 E. Hoen, 'Public Health and International Law. TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha', 27 *Chicago Journal of International Law* (2002): 32–33.

decision authorizes Natco until 2020 to manufacture a patented anti-cancer drug from Bayer for the domestic market.

The USTR (United States Trade Representative) and the EU DG Trade are critical players in this brave game of ratcheting up IP standards, in which some bilateral diplomatic signals are sent each time an initiative to issue a compulsory license is underway in a developing country.[6]

The USTR's Special 301 epitomizes the race for stringent global patent standards, sharply contrasting with the leniency shown towards IP generally in the United States during the period of its trade power formation. As Picciotto recalls, the United States is appointing itself as the main global policeman of IP rights but paradoxically it refused copyright protection for foreign works until 1891, and did not even join the Berne Convention until 1987, just when it finally placed IP on the regulatory agenda of the Uruguay Round; certainly, 'the late converts may be the most fervent apostles'.[7]

In fact, the functioning of Special 301 targets accelerated TRIPS implementation singling out the rules and policies of other countries that the United States deems objectionable, irrespective of whether or not they are TRIPS compatible. Thus, the mechanism often pushes countries to go beyond their TRIPS obligations:

> In the US, TNCs continue to monitor these agreements through the US Trade Representative advisory committee called IFAC-3 (Industry Functional Advisory Committee-3), made up of 20 members drawn from Industry Sector Advisory Committes and 20 from private-sector" working across all US IP-related trade initiatives.[8]

In the words of Charlene Barshefsky, former USTR, the instrument is much more than an in-depth review of public policies of other countries: it provides 'a direct route to press countries to improve their IP [rights] practices'.[9]

Unfortunately, the EU has followed suit in respect of this strategy by replicating some of its critical elements in its own IP enforcement strategy,

---

6 See generally F. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements'. *Occasional Paper N. 14*, Quaker United Nations Office, 2004.

7 See S. Picciotto. 'Defending the public interest in TRIPS and the WTO' op. cit., p. 226.

8 See P. Drahos, '"IP World"-Made by TNC Inc' op. cit., p. 208.

9 See 'USTR Announces Results of Special 301 Annual Review', Press Release 97-37 (April 30 1997).

adopted in 2005. The EU strategy on IP enforcement outside European borders, currently under revision, functions with a similar rationale: conducting broad surveys on IP rights enforcement, which are used to update the list of 'priority countries' and acting accordingly.[10]

2. Upward ratcheting

In addition, an extra tool for promoting stronger global IP protection is the negotiation of clone treaties based on TRIPS+ schemes.[11] These instruments inhibit the implementation of health-related TRIPS flexibilities in developing countries, and are thus basically producing international re-regulation through the back door.

Recent US FTAs, for example, prevent or undermine the ability to implement TRIPS flexibilities by requiring the adoption of measures such as patent term extensions, data exclusivity, linkage of patents with registration, restrictions on compulsory licensing, restrictions on or elimination of parallel imports and border enforcement requirements, among others.[12] The EU also follows the US lead on these practices by promoting its own bilateral TRIPS+ treaties. A recent example is the controversial EU-India FTA originally planned for signature by the end of 2012 but which is still under consideration.

The higher standards of protection in TRIPS+ schemes delay or restrict, by their very nature, trade in generics and thus generic competition.[13] In essence, through these bilateral and regional treaties, developing countries 'are being made to agree' to a ratcheting up of IP standards.[14] By strengthen-

10 See *Strategy for the enforcement of intellectual property rights in third countries,* Official Journal of the European Union, C129, Volume 48 (26 May 2005) at 3.

11 US bilateral treaty-making on IP did not begun but intensified after TRIPS. In this regard, see P. Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property', 4 *The Journal of World Intellectual Property* (2001): 807–808.

12 See generally K. Gopakumar & S. Smith, 'IPR provisions in FTAs: Implications for access to medicines', *Intellectual property and access to medicines: papers and perspectives* (World Health Organization 2010) and also *Access to Generic medicines and 'TRIPS plus' provisions,* European Generics Association, Position Paper (November 2007).

13 See C. Correa, 'Implications of bilateral free trade agreements on access to medicines', 84 *Bulletin of the World Health Organization* (2006): 402.

14 See P. Drahos, 'Developing Countries and' op. cit., p. 21.

ing, broadening and lengthening monopolies on medicines generally, their provisions are bound to create a chilling effect on generic market entry and thus they erode the consolidation of a global market for generics.

It is important to underline that these treaties are not health+, or human rights+, but IP+ schemes. The contents of some of the new obligations are illustrative in this regard: (a) extending patent terms beyond the 20 years required by TRIPS agreement, (b) requiring new export and burdensome procedures for generics, (c) restricting conditions for compulsory licenses to be issued, (d) delaying approval and registration of generics by providing original manufacturers with exclusive rights on pharmaceutical test data, (e) requiring regulatory authorities to pursue a policing role on patent enforcement, among others.[15]

Inevitably, the restricted rationality of these TRIPS+ treaties undermines the flexibilities provided by TRIPS rules and the 2001 Doha Declaration on TRIPS agreement and Public Health.[16] In theory, WTO law and policies formally recognized some major TRIPS flexibilities with regard to access to medicines. In practice, however, pharmaceutical lobbying is taking those rights away by using states as proxies to promote stringent global standards in other fora.

A significant example of the present state of affairs is the new IP enforcement trends treating generics as counterfeit ('counterfeit drugs'). In this regard, TRIPS article 61 mandates Member States to establish severe criminal penalties in order to deter counterfeiting; as some counterfeit drugs may pose a threat to public health, this provision is often used to combat counterfeit medicines.

However, the zeal of some patent-holders goes beyond what is reasonable. In this regard, these IP+ enforcement trends have already allowed the seizure of generic medicines transiting through European ports to Africa and Latin America on the basis of the EU Customs Regulation 1383/2003. The first cases include several million doses of generics detained in transit at Rot-

15 See S. Sell, 'TRIPS-Plus Free Trade Agreements and Access to Medicines', 28 *Liverpool Law Review* (2007): 56–57 and F. Abbott, 'A new dominant Trade Species emerges: is bilateralism a threat?', 10 *Journal of International Economic Law* (2007): 571–583.

16 The United Nations Development Report of 1999 already referred openly to the 'relentless march of intellectual property rights" and underline that this process "needs to be stopped and questioned'. See *UNDP Human Development Report 1999* (Oxford University Press 1999), p. 73.

terdam in December 2008 (Losartan, an anti-hypertension drug), Frankfurt in May 2009 (Amoxicillin) and in Paris in October 2009 (Clopidogrel, a blood thinner).

As a result, Brazil and India filed a WTO complaint against the EU in May 2010, recently settled,[17] on the legal grounds of GATT article V (freedom of transit) and the 2001 Doha Declaration.[18]

In addition, TRIPS+ treaties such as the Anti-Counterfeiting Trade Agreement (ACTA) also contain measures confusing generics with counterfeit medicines.[19] Despite its name, this ('trade-related') IP enforcement treaty targets border and internal enforcement of IP infringements. ACTA provisions formally exclude patents from border measures and, in fact, contain safeguards on access to health.

However, ACTA also include civil trademark infringement with strong penalties, to name just one qualified regulatory feature. As a result, customs officials could initiate a seizure and even destruction of an allegedly infringing product under its provisions, in order to protect the interests of the rights holder of a commercial trademark.

Generally, these IP enforcement trends are in themselves strong disincentives for those companies eager to trade in generics at global scale, and thus for the consolidation and development of a global market for generics to the benefit of patients in developing countries.

The drive towards stronger IP enforcement is thus of particular concern. Something is going wrong in global IP politics when IP advocates, such as the former President of the International Anti-Counterfeiting Coalition, Timothy Trainer, with no hesitation whatsoever, makes this formal statement: 'ACTA is an initiative that allows governments to voluntarily commit themselves to whatever TRIPS+ standards are agreed'.[20]

---

17 See B. Mercurio, 'Seizing' pharmaceuticals in transit: analysing the WTO dispute that wasn´t', 61 *International and Comparative Law Quarterly* (2012): 389-426 and B. Baker, 'Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough', *Northeastern University School of Law Research Paper No. 81-2012* (January 1, 2012).

18 See WTO/DS408, *European Union and a Member State-Seizure of Generic Drugs in Transit* - Requests for consultations, India (11 May 2010) and see WTO/DS409, *European Union and a Member State-Seizure of Generic Drugs in Transit* - Requests for consultations, Brazil (12 May 2010).

19 See K. Outterson & R. Smith. 'Counterfeit Drugs: The Good, the Bad and the Ugly', 15 *Albany Law Journal of Science & Technology* (2006): 525.

20 See T. Trainer, 'Intellectual Property Enforcement: A Reality Gap (Insufficient

The statement certainly suggests that, for some actors, global IP protection is nowadays a sort of Wild West in terms of international legislation.

Interestingly, the European Parliament has recently rejected ACTA under its Lisbon Treaty power to reject international agreements: for the first time after the entry into force of the Lisbon Treaty, EU MPs have exercised here this power: 478 votes against, 39 in favor, and 165 abstentions.[21]

The current state of affairs has to be seriously considered from a purely legal perspective. Pro-health TRIPS flexibilities cannot reasonably be interpreted as a floor but rather as a ceiling of pharmaceutical patent protection. In this sense, it is reasonable to argue that any TRIPS+ regime with regard to pharmaceutical patent protection is WTO-illegal. Not only does the TRIPS agreement contain major flexibilities with regard to public health but WTO Members have agreed to adopt the 2001 Doha Declaration on TRIPS agreement and public health.

In any basic notion of global equity or justice, it is not legally reasonable to put forward the argument that what WTO Members have agreed on multilaterally, with regard to public health, can be undone in other fora by ratcheting up mere monopoly rights.

Pro-health flexibilities operate as legal *benefits* granted to all WTO Members. These flexibilities contained in WTO primary rules (TRIPS agreement) have in fact been confirmed in WTO secondary rules through multilateral decision-making (2001 Doha Declaration).

As Correa recalls, implementation of the 2001 Doha Declaration should not be regarded as a matter of political choice if article 26 of the Vienna Convention on the Law of the Treaties is taken into due consideration: the Declaration creates international obligations which should be complied with in good faith by all WTO Members.[22]

In this sense, good faith is a key principle of international law and thus

---

Assistance, Ineffective Implementation?', 8 *John Marshall Law School Review of Intellectual Property Law* (2008): 74.

21 See *European Parliament legislative resolution of 4 July 2012 on the draft Council Decision on the conclusion of the Anti-Counterfeiting Trade Agreement* (4 July 2012).

22 C. Correa, *Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (World Health Organization 2004), p. 8.

of treaties:[23] 'every treaty in force is binding upon the parties to it and must be performed by them in good faith' (article 26).

In addition, article 31 of VCLT clearly determines that treaties 'shall be interpreted in good faith'. Thus, applying TRIPS rules and the health-related 2001 Doha Declaration in accordance with the VCLT reasonably imposes certain limitations on WTO members. A contrary application may constitute an abuse or rights.[24]

TRIPS+ schemes with regard to pharmaceuticals technically infringe WTO law by producing an *annulment or denial of WTO benefits*. These TRIPS+ schemes are to be read by their own nature as TRIPS-Minus with regard to the balance of benefits and concessions resulting from WTO law: a body of law historically made up of a series of complex trade-offs (e.g. more market access in exchange for patent standards).

In consequence, TRIPS+ schemes invalidate the flexibilities provided by the TRIPS agreement and, as such, could be challenged as WTO non-compatible under the WTO Dispute Settlement Body (DSB).[25] In fact, any WTO Member may request a panel if any measures from other Members (including treaties) is denying or annulling those benefits.[26] As a result, the negotiation or implementation of TRIPS+ schemes by WTO Members (treaties *external to* WTO) could nullify or impair benefits deriving from WTO law.

The compatibility of these schemes could be challenged not only by IP *violation complaints* but also by the so-called *non-violation* complaints, provided the present moratorium on the latter is finally lifted.[27] However, developing countries are probably those who would benefit most from the lifting

---

23 See generally J. Connor, *Good Faith in International Law* (Dartmouth Publishing 1991).

24 For abuse of rights as a ceiling to patent protection see in particular M. Temmerman, 'The Legal Notion of Abuse of Patent Rights' *NCCR Trade Regulation Working Paper No 2011/23* (May 2011), pp. 5–10.

25 F. Abbott, 'The WTO Medicines Decision' op. cit., p. 357.

26 In fact, the DSU standing is very open, and in practice close to an *actio popularis*. See P. Kuijper, 'The Law of GATT as Special Field of International Law. Ignorance, further refinement or self-contained system of international law?', 25 *Netherland Yearbook of International Law* (1994): 239–241.

27 The moratorium is being extended from one ministerial conference to the other, the latest being the extension from the 2013 Bali Ministerial Conference (3-6 December 2013) to the ministerial meeting to hold in 2015. For the extension see WT/L/842, *TRIPS non-violation and situation complaints, Decision of 17 December 2011* (19 December 2011).

of the moratorium, as they have more technical resources to invest in speculative legal claims.[28]

In any case, the substantive rules are already in place (TRIPS flexibilities) to be properly adjudicated as violation complaints. This generous standing has been part of the legal *acquis* of the multilateral trading system almost since GATT was originally conceived.[29]

Arguably, some health ministers would see a legal case here, irrespective of whether or not they represent a developing country. However, they are not on board the WTO ship. In practice, ministers of trade are those responsible for the final decision on whether or not to file WTO complaints. Those who govern WTO are trade ministers, not health ministers.

The balance between rights and obligations resulting from the trade-offs negotiated in the Uruguay Round should be honoured. Promoting stringent patent standards for pharmaceuticals outside WTO, once these rules are in place, is playing against the traditional rules and inner functioning of the world trading system. In fact, it is also playing above those rules (playing a *meta-game*) against the interest of WTO itself as a global institution responsible for progressive trade liberalization.

In this regard, there is a strong case for a legal ceiling on health-related patent protection in the benefit of the developing world. In fact, it could probably be critical to the success of the ongoing Doha Development Round…

The WTO constituency should recall that the 2001 Declaration on Public Health (read Doha) helped to keep on track the first post-GATT Round of negotiations (read WTO), after the (globally broadcasted) 1999 Millennium Round derailment (read Seattle).

In this sense, the existence (or non-existence) of *international legal ceilings* for the global ratcheting up of patent protection is a structurally critical *trade* issue deserving serious legal consideration by the WTO regime.

---

28 Non-violation complaints allow WTO Members to challenge a measure in WTO dispute settlement procedures that is not infringing WTO law, but nullifying or impairing the trade benefits that its members could have reasonably expected to obtain. See F. Abbott, 'Non-violation nullification or Impairment Actions under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder', 11 *QUNO Occasional Paper* (2003).

29 For its critical evolution compare J. Jackson, *World Trade and the Law of GATT. A Legal Analysis of the General Agreement on Tariffs and Trade* (The Boobs-Merrills Company Inc 1969) at 163–189 and J. Jackson, *Restructuring the GATT System* (New York Council on Foreign Relations Press 1990) at 65 and, in particular, J. Jackson, 'The WTO Dispute Settlement Understanding: Misunderstandings on the Nature of Legal Obligation', 91 *American Journal of International Law* (1997): 60.

In short, the TRIPS rules, together with the 2001 Declaration on Public Health, should reasonably be interpreted as a legal ceiling against stronger IP protection in health-related areas, but also as a legal floor to promote the consolidation of a global brand-name and non-brand-name market to the benefit of developing countries.[30]

3. Uneasy captures

However, vested interests are involved. Nowadays, modern patent systems have created high returns on revenues, assets and shareholders' equity over decades, making the pharmaceutical industry annually ranked as among the most profitable industries in the world. These revenues are highly concentrated in the markets of developed countries.

Thus, the CEOs' and shareholders' expectations on high future returns from investments in this area (R&D and marketing) have been fuelled by their private-public partnerships with trade representatives negotiating new global IP standards.

In practice, this phenomenon has produced a 'global money illusion' on exponential increases of corporate profits. As a result, brand-name companies are involved in aggressive strategies to secure worldwide monopoly rents,[31] and are not open to other profitable but alternative wealth-enhancing strategies.

In this regard, brand-name companies could easily obtain profits at least comparable to those of generic producers (profiting from off-patent medicines in developing countries) by selling their brand-name products to larger numbers of poor people at *very* low prices:[32] *price-based competition* is the word.

That was in fact the rationale of the government of Thailand, when it officially suggested a shift of pricing strategies based on 'low-volume, high margin returns' to 'high-volume, low margin returns'.[33]

---

30 See chapters 4 and 5.

31 See particularly, S. Picciotto, 'Private rights vs public interests in the TRIPS agreement: the access to medicines dispute', *Proceedings of the annual conference of the American society of international law* (2003), p. 167.

32 J. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions' op. cit., pp. 247–263.

33 See *Facts and Evidence on the 10 Burning Issues Related to the Government*

However, brand-name companies are less focused on price-based competition and more on derailing generic companies from global markets through the ratcheting up of global IP standards.

In consequence, international legislation is perceived as a second level playing field for policy formation, as it is often more effective than merely lobbying domestic legislators. For corporations operating in multiple state jurisdictions, it is more efficient to lobby collectively for international legislation (which is binding in at least two or more state jurisdictions) than for domestic legislation (binding in one state jurisdiction).

Last but not least, as Correa bluntly recalls with regard to US bilateralism, by creating protection standards higher than those applied domestically, the pharmaceutical industry may be able to force an amendment of US domestic laws 'in ways simpler and less costly than through lobbying in Congress'.[34]

The point applies to most developed countries. These modern rent-seeking strategies are amplifying socially wasteful public law on a multi-state scale. Nowadays, as a result, some international rules are almost by-products of corporate regulatory captures.

The enhanced and increasing leverage of special interest groups on global decision making has critical consequences. These processes, which are currently shaping global politics cannot be understood or explained through a simple and traditional state-centric approach to international rule-making.[35] Therefore, traditional approaches need to be revisited, to combat or avoid the capture of public international law by special interest.

In this regard, it is also reasonable to argue that the pharmaceutical business model itself requires a structural transformation. In fact, the WHO Commission on Intellectual Property Rights, Innovation and Health (CIPIH) has already made some clear recommendations on this issue:

> Companies should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low income developing countries, they should avoid filing patents, or enforcing them in ways that might inhibit access. Compa-

Use of Patents on Three Patented Essential Drugs in Thailand, Ministry of Public Health and National Health Security Office, Thailand (February 2007).

34 C. Correa, 'Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines' 36 *Case Western Reserve Journal of International Law* (2004): 93.

35 See K. Alter & S. Meunier, 'The International Politics of Regime Complexity' op. cit., pp. 13–24.

nies are also encouraged to grant voluntary licenses in developing countries, where this will facilitate greater access to medicines, and to accompany this with technology transfer activities.

In addition, the CIPIH has also clearly stated that 'companies should not lobby government for more stringent standards than those contained in TRIPS agreement'.[36]

These are critical ideas. However, the socially wasteful rent-seeking strategies of the industry in developing countries cannot be inhibited through mere (voluntary) initiatives of corporate social responsibility (CSR), but by reforming legal institutions.

The reason is simple: these companies are run by publicly inefficient incentives structures, and not by unethical persons who could be convinced to act (read manage) differently. In essence, these companies do what they do because their CEOs are tied too tightly to the mast of profit maximization, as a direct result of the incentives structure in modern corporate law (the corporate form itself) and financial markets.

4. The window openers

Nowadays, global policymaking occurs through nodes of closely connected actors in a diversity of networks.[37] In the world of "nodal governance", both public interest and private interest coalitions battle in multiple fora, without equal footing, to regulate public issues such as access to medicines.[38]

Fortunately, transnational advocacy networks have an essential role to play here,[39] as direct result of the growing research and legally-oriented function of NGOs in global politics.[40] As Shaffer suggests, developing countries

---

36 See *Public Health, Innovation* op. cit., p. 181 (paragraph 4.16).

37 P. Drahos, 'Intellectual Property and Pharmaceutical Markets: a Nodal Governance Approach', 77 *Temple Law Review* (2004): 401–424.

38 See S. Burris, P. Drahos & C. Shearing, 'Nodal Governance', 30 *Australian Journal of Legal Philosophy* (2005): 30–58.

39 On the use of law for empowering and legitimating transnational advocacy networks see K. Sikkink, 'Transnational Advocacy Networks and the Social Construction of Legal Rules' *Global Prescriptions: The Production, Exportation, and Importation of a New Legal Orthodoxy* (The University of Michigan Press 2002), pp. 37–64.

40 See generally M. Keck & K. Sikkink, *Activists Beyond Borders: Advocacy Networks in International Politics*, (Cornell University Press 1998).

could critically enhance their prospects of success with regard to access to medicines if they worked together with US and European constituencies such as NGOs.[41]

In fact, global campaigns had a major impact on the WTO decision-making processes leading to the 2001 Doha Declaration.[42] The policy momentum would certainly not have been reached without global campaigns such as the so-called *PMA case* in South Africa.[43]

These and other events provided the window of opportunity for developing countries and civil society to obtain the first special session of the TRIPS Council to discuss health-related TRIPS issues in April 2001. The rest, including the 2001 Doha Declaration, is already part of contemporary world history.[44]

The 2001 Doha Declaration on public health is, as Drahos refers to it, 'a case of a weak coalition making a gain that an observer would not have predicted given the power resources of the US-led coalition'.[45]

In the brave new world of TRIPS+ schemes, however, developing countries/NGOs coalitions are forced to take action in multiple battlefields almost daily: the ongoing cycle of action and reaction with regard to global IP standard setting takes place in a wide variety of fora.[46]

Since the early 1980s, advocates seeking to ratchet up IP protection have shifted fora both vertically and horizontally to achieve their goals. They have shifted vertically, from multilateral to regional to bilateral levels, and they have shifted horizontally across diverse international organizations.[47]

---

41 G. Shaffer, 'Recognizing public goods in WTO Dispute Settlement: Who participates? Who Decides? The case of TRIPS and pharmaceutical patent protection', 7 *Journal of International Economic Law* (2004): 479–80.

42 See, for example, R. Mayne, 'The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective', *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan (2002) at 244–259.

43 See *The Pharmaceutical Manufacturers' Association of South Africa and Others v. The President of the Republic of South Africa and Others,* Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division).

44 On the impact of events such as the PMA case see S. Sell, 'TRIPS and the Access to Medicines Campaign', 20 *Wisconsin International Law Journal* (2001–2002)*:* 511.

45 P. Drahos, 'Four lessons for' op. cit., pp. 11–39.

46 See F. Abbott, 'The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health', *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge 2006), p. 31.

47 See S. Sell, 'Cat and Mouse: Forum shifting in the battle over intellectual property rules and enforcement', Paper presented the *International Studies Association Montreal* (March 16-19th, 2011).

As Sell suggests, international politics are far messier than is generally assumed.[48] In fact, the game is never over, as all actors involved continuously cycle through fora to find one at a moment in time where their power will be optimized.[49]

In the words of Chorev, institutions have interactive effects in any given policy space:[50] as a result, the repositioning of one piece in one of those institutions (e.g. adoption of a rule) may result in the repositioning of pieces in other institutions. This phenomenon has been also defined as 'chessboard politics'.[51]

Securing pro-health global law and policy is directly dependent on the relative efficiency of the strategies deployed by developing countries/NGOs coalitions.

Sell employs an illustrative 'cat and mouse' metaphor to explain the arena in which public interest coalitions struggle for success today: in the 1980s, IP advocates (the 'cat') made the first move moving 'trade-related' intellectual property from WIPO into the GATT regime. However, once the developing countries/NGOs coalition (the 'mouse') mobilized in the WTO, IP advocates (the 'cat') moved again to TRIPS+ bilateral and regional treaties, the Anti-counterfeiting Trade Agreement (ACTA) or a Substantive Patent Law Treaty (SPLT).

The 'mouse' is nowadays definitely trying to chase the 'cat' out of the WTO.[52] The ongoing global battles over generic medicines are currently taking place on multiple fronts, both in and outside the WTO. Given this scenario, public interest coalitions need to adopt a longitudinal, broad perspective of multiple moving parts on global IP negotiations.[53] Otherwise, as Drahos suggests, these coalitions risk winning battles (2001 Doha Declaration) yet finally losing the war.[54]

---

48 S. Sell, 'Cat and Mouse' op. cit., p. 31.

49 P. Drahos, 'Four lessons' op. cit., p. 33.

50 N. Chorev, 'Political and Institutional Maneuvers in International Trade Negotiations: The United States and the Doha Development Round', *Strategic Arena Switching in International Trade Negotiations* (Ashgate 2007), pp. 33–34.

51 K. Alter & S. Meunier, 'The International Politics of Regime Complexity' op. cit.

52 S. Sell, 'Cat and Mouse' op. cit., p. 30.

53 P. Drahos, 'Four lessons' op. cit., at 35–37.

54 P. Drahos, 'Winning Battles, Losing the War: Lessons for the Weak from the Negotiations over the Doha Declaration on TRIPS and Public Health', paper presented at *Trade Negotiation and Developing Countries: The Doha Round, International Workshop*, Griffith University (August 12-13, 2005).

In this sense, as resources are limited on their side, it would be reasonable to argue that public interest coalitions should consider forming a coalition to veto the continuous ratcheting up of IP standards.[55] A veto coalition on TRIPS+ schemes should certainly fight the major battle in the corridors of the William Rappard building in Geneva, speaking the language of WTO law and TRIPS flexibilities.

Interestingly, in May 2006, ten South American Ministers of Health (Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela) adopted *the Declaration of Ministers of South America over Intellectual Property, Access to Medicines, and Public Health* to establish a united position against TRIPS+ schemes.

In this regard, an efficient and reasonable strategy for the developing countries/NGOs coalition –in order to avoid battling continuously on every front– would be to obtain a formal WTO Declaration confirming that TRIPS flexibilities constitute a legal ceiling with regard to pharmaceutical protection in the developing world.

Promoting a new Declaration on TRIPS as a legal ceiling for pharmaceutical patent protection would be a major move, complementing the historic 2001 Doha Declaration on Public Health. In addition, such a critical initiative could provide some extra leverage towards a necessary Development Round.

55 See P. Drahos & J. Braithwaite, *Information* op. cit at 204–205 and 208–209.

4

NON-MARKET ECONOMICS

1. Red taping

The 2003 Decision was created to constitute an 'expeditious solution' for 'WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector' who faced difficulties in 'making effective use of compulsory licensing under the TRIPS Agreement'. However, it is fair to say that it is a complete failure.

There is only one successful compulsory licence under the 2003 Decision to date, involving a generics transaction between Rwanda (Notification of intent to import on 17 July 2007)[1] and Canada (Notification of intent to export on 4 October 2007)[2] of 260000 packs of TRIAvir (an HIV/AIDS combination therapy), manufactured by Apotex Inc.

In addition, transaction between India and Nepal was withdrawn in the very first stages of the paragraph 6 mechanism. In September 2007, an Indian generic manufacturer applied in India for a compulsory license for three medicines to be exported to Nepal but decided to withdraw the request in India as the Nepal authorities had not granted the compulsory licence to import the medicines, nor had the TRIPS Council been notified of its intention to import under the paragraph 6 mechanism.

Leaving aside the reasons why this single (and thus unique) transaction took four years to proceed, it is easy to understand why developing countries have increased their pressure against the present *statu quo* with regard to trade in generics.

---

1 IP/N/9/RWA/1, *Council for Trade-Related Aspects of Intellectual Property Rights–Notification under paragraph 2(a) of the Decision of 30 August 2003* – Rwanda (19 July 2007).

2 IP/N/10/CAN/1, *Council for Trade-Related Aspects of Intellectual Property Rights – Notification under Paragraph 2(c) of the Decision of 30 August 2003* – Canada (5 October 2007). The information on the shipment (quantities and distinguishing features) is posted on the licensee's website pursuant to paragraph 2(c) and 2(b) (iii) of the Decision of 30 August 2003. See also <www.apotex.com/apotriavir/abouttriavir.asp>.

Developed countries are not eager to admit that the mechanism does not function properly, as this would reasonably open the door for reform initiatives with a more pro-trade rationale.

However, developing countries strongly demand a proper fact determination in this regard,[3] and call for real-life experiences to be seriously analysed in the Annual Reviews of the mechanism by the TRIPS Council.[4]

Developed countries act like the emperor in his new clothes, and buy time in the meantime to also promote TRIP+ schemes in other fora. It is hard to see how this will not lead to major tensions in the mid-term. It is noteworthy that Annual Reviews of paragraph 6 mechanism contain an agenda item with the illustrative title 'Any alternatives to the use of Paragraph 6 System'.

There are some explanations for the failure to use the 2003 Decision. The very fact that it is member-driven is a critical factor in its failure to function: generic companies are directly excluded from the possibility of using the mechanism to trade in generics, since any global transaction requires a dual authorisation (from both importing and exporting countries) for it to operate.

In short, having been designed in WTO, the mechanism certainly suffers a paradoxical anti-market and anti-trade approach. In essence, the procedure compartmentalizes transactions on a case-by-case, drug-by-drug and country-by-country basis through a dual compulsory licensing scheme.[5]

As a result, notifications under this scheme require issues to be determined in advance, such as to whom will the license be extended, what volume, at what royalty rate, and on what grounds.

In addition, advance notifications to the TRIPS Council of the intention to use the procedure leave those developing countries willing to import generics under CL open to pre-emptive political pressures. Thus, a strong political barrier is effectively raised against weak developing countries at the outset.

The devil is certainly in the details: notifications must specify the names and expected quantities of the product needed over a specific period of time,

---

3 For the Annual Review of 2012 see IP/C/63 *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health— Report to the General Council* (26 November 2012).

4 See e.g. IP/C/61 *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Report to the General Council* (18 November 2011), paragraph 56 (Indian Delegation intervention).

5 F. Abbott & J. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 10 *Journal of International Economic Law* 4 (2007): 921–987.

the royalty rate that will be paid, and outline the evidence for the lack of or insufficient manufacturing capacity.

Consequently, there is no automaticity in it but stronger procedural market segmentation to what already existed before the 2003 Decision. Thus, the attainment of the economies of scale required to stimulate global generic production and competition are inhibited and by extension, so are the inner virtues of international trade.

Market-driven mechanisms are part of the solution, not the problem. In this regard, generics manufacturers are dependent on sufficiently large production to achieve economies of scale: high-volume, low margin returns.

In order to apply for an export-oriented compulsory licence (CL) under the current procedure, generics companies have to perceive that making use of it will not only be economically viable but also profitable. In this sense, it is highly unlikely that the paragraph 6 mechanism will ever provide sufficient economic incentives for generic companies, since authorizations are granted drug order by drug order and only upon request by the public authorities of another country.

There are also critical obstacles in place such as, to name one key example, the condition to produce only the amounts needed to satisfy the requirements of licensees as notified to the TRIPS Council. As Abbott and Reichman explain, the procedure is saddled with unnecessary administrative hurdles that make the export of generic versions of patented drugs neither simple nor expeditious.[6]

It is also important to underline that TRIPS article 31(h) requires adequate remuneration be paid to the patent holder. However, the 2003 Decision states that it is the exporting country that is required to remunerate or compensate the patent holder.[7] In practice, requiring the exporting country to compensate the patent holder adds yet another hindrance.

Obviously, the governments of developed countries have no incentive to promote the export of generic products by their industries when they bear the burden of paying the fee. Certainly, alternative solutions could easily have been designed.[8]

---

6 F. Abbott & J. Reichman, 'The Doha Round's Public Health Legacy', op. cit., p. 932.

7 For an analysis on remuneration and its problems see in particular D. Cahoy, 'Confronting Myths and Myopia on the Road from Doha', 42 *Georgia Law Review* (2007): 150.

8 D. Cahoy, 'Confronting Myths' op. cit., pp. 148–53.

For many, the procedure is designed to make it difficult for countries to issue compulsory licences and to hinder the functioning of domestic procedures. In the words of Stiglitz, 'if [trade advocates] wanted developing countries to have access to essential drugs, they should have allowed automatic licences for all drugs except those that are not essential'[9]. Certainly, the black letter law produces difficulties that could easily have been avoided.

Last but not least, the 'implementation game' is also a difficult one.[10] Potential exporting countries such as Canada, India, Norway, China and the European Union itself have already adopted legislation to implement the Decision in order to enable the production and export of generic medicines under compulsory licences.[11]

However, some of these domestic regulations have added more administrative requirements and thus could further hamper use of the Decision. Interestingly, while Canada's Access to Medicines Regime (CAMR) passed in 2004 contains 200 articles, India's implementing legislation consists of a scant 3 paragraphs.[12]

CAMR was the first enabling legislation for the production and export of generic medicines under compulsory licences to developing countries lacking manufacturing capacity.[13] For many, this domestic legislation is considered to be fraught with deficiencies and epitomises the flaws of the implementation game.[14] However, it is also true that the first and only successful compulsory licence under the 2003 Decision to date involved a generics transaction from Canada.

Developing and developed countries radically differ in their explanations for why the mechanism is not being used.

---

9 J. Stiglitz, 'Trade agreements and health in developing countries', 373 *The Lancet* (January 31 2009): 365.

10 See C. Deere, *The Implementation Game*, op. cit.

11 E. Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers 2009), pp. 36–37.

12 See E. Ng & J. Kohler, 'Finding flaws: the limitations of compulsory licensing for improving access to medicines: an international comparison' 16 *Health Law Journal* (2008): 166.

13 R. Elliot, 'Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceutical for export', 1 *International Journal of Intellectual Property Management* 1 (2006): 94–112.

14 See, in particular, C. Cotter, 'The Implications of Rwanda's' op. cit at 177 and 185-86; J. Cohen-Kohler, L. Smail & A. Perez Cosio, 'Canada's implementation of the Paragraph 6 Decision: is it sustainable public policy?', 3 *Globalization and Health* (2007):12 and H. Hestermeyer, 'Canadian-made Drugs for Rwanda' op. cit.

On 27 October 2010, for example, Canada delivered three interventions related to the review of the mechanism in the WTO TRIPS Council. For Canada, CAMR worked efficiently, effectively and in a timely fashion: the length of time needed to export to Rwanda was not caused by the paragraph 6 mechanism, but instead by other factors. Canadian representatives explained that the mechanism is a member-driven process; as such, it only applies to instances where countries seek a generic version of the patented drug.

In this sense, once the eligible importing country (Rwanda) had notified the WTO of its intention to import under the mechanism, the CAMR process (starting with a request for voluntary licences and ending with a CL granted) was completed in just over two months. For Canada, in short, the delays incurred in Apotex's export of medicines to Rwanda were 'separate' from CAMR.

In this regard, Canada recalled that it took 3.5 years for Apotex to develop the drug, identify a recipient country, secure a supply contract, manufacture the drug and export it. Thus, under this rationale, Canada underlines that it is not a company (Apotex) but rather a country (Rwanda) which is required to use the mechanism in order for it to become operational.

Indeed, this is certainly the case. The major structural flaw of the mechanism is that its functioning depends on the political will of Member States.

Alternatively, the 2003 Decision would have been more efficiently designed if the inner economic rationale of free trade had been taken into serious consideration, instead of creating extra market segmentation and barriers to trade; that is to say, maximizing access to medicines through world market formation.

2. Drug pipelines

In any case, the 2001 Doha Declaration (not the 2003 Decision) has critically transformed the original *status quo* in which developing countries and pharmaceutical companies now negotiate their deals.

In this sense, the 2001 Declaration has critically promoted the negotiation of voluntary licences between patent holding companies and their generic manufacturing counterparts under the threat (by generic companies) of

a request for a compulsory licence, or the threat (by public authorities) of the issuance of a compulsory license.[15]

In addition, the 2001 Declaration as well as the WTO general discourse on TRIPS flexibilities is also used by health authorities in developing countries as leverage in their price negotiations vis-à-vis patent holders. In practice, the Declaration functions as a bargaining chip for governments to alternatively negotiate brand-name price reductions subject to issue of a compulsory license.

Currently, the use of compulsory licensing is limited. In fact, as Attaran recalls, no generic medicines, or practically none, have been manufactured this way in the 90s.[16] However, things are gradually changing. Beneath the surface, in the words of Reichman, health Ministries quietly began to use the threat of compulsory licences to rein in the prices of selected medicines, particularly AIDS drugs. As these negotiated deals are often kept secret, the surface calm appears more assured than it really is.[17]

Interestingly, an authoritative case study on the use of TRIPS flexibilities, for the treatment of AIDS between 2004 and 2008, documented 65 formal statements by developing countries authorizing the procurement, import and use of generic medicines.[18] In addition, as Hoen et alia recall in a later study, 26 out of 32 LDCs authorized generics imports with express reference to paragraph 7 of the 2001 Declaration (delaying the granting and enforcing of patents on medicines until 2016).[19]

Therefore, it is reasonable to conclude that the 2001 Declaration, as well as the institutional discourse on flexibilities, has been of great use for the reinforcement of both the legality and legitimacy of public health policies based on measures such as CL on pharmaceuticals. The health ministry from Brazil, for example, has been among the most successful in using compulsory licensing threats to obtain major concessions from brand-name companies.

---

15 See J. Reichman & C. Hasenzahl, 'Non-voluntary Licensing of Patented Inventions', 5 *ICTSD/UNCTAD Issue Papers* (2003).

16 See A. Attaran, *'Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution', 2 Emory International Law Review* 17 (2003*): 743–780.*

17 J. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions' op. cit., pp. 249–250.

18 E. Hoen, *The Global Politics* op. cit., pp. 59–60.

19 E. Hoen, J. Berger, A. Calmy & S. Moon, 'Driving a decade of change: HIV/AIDs, patents and access to medicines for all', 14 *Journal of International Aids society* 15 (2011): 1–12.

In short, governments make companies negotiate price reductions under the threat of issuing a CL but also generic companies directly negotiate voluntary licences with patent-holding companies under the threat of requesting a CL. Interestingly, these negotiations are pursued without the need to use the paragraph 6 mechanism.

However, it is important to underline that not all developing countries could obtain similar success by pursuing these strategies. Inevitably, as the procedure of 2003 Decision to import generics under CL is not functioning, CL threats by developing countries are only credible when they are backed by a burgeoning local generics industry (read India, China and Brazil).

In consequence, as Benvenisti and Downs suggest, price breaks under CL threats should be considered more as isolated victories, materially important in the short term but 'institutionally irrelevant in the long term'.[20] In this sense, the only real victory is the availability of cheap quality drugs in developing countries as a result of a thriving global market pushing prices down globally. That is, *global price-based competition*.

The procedure contained in the 2003 Decision does not provide the required result. Fortunately, the 2003 Decision is not the only legal vehicle to facilitating access to medicines in the developing world. The TRIPS agreement permits major flexibilities to balance public health and legal monopoly rights (patents) other than importing generics under CL by developing countries lacking production capacity.

In this regard, WTO Members are allowed to adopt complementary measures that may facilitate access to medicines, as set out in articles 7 and 8 of the TRIPS agreement, and explicitly recognized by the 2001 Declaration.[21] However, the existence of enabling legislation, as mentioned above, is critical in this respect. Suitable legal provisions should be enacted beforehand in order to use these and other TRIPS flexibilities in domestic law and policies. As WTO rules and acts are not self-executing, it is essential that adequate provisions be enacted in domestic laws in order to enable developing countries to make use of flexibilities.

As Musungu recalls, the major problems here are a 'widespread lack of clarity about the options available, coupled with the lack of local legal and

20 *See* E. Benvenisti & G. Downs, '*Distributive Politics*' op. cit.

21 See generally C. Correa, 'Intellectual property rights and public health: the general context and main TRIPS compliant flexibilities', *Intellectual property and access to medicines: papers and perspectives* (World Health Organization 2010).

technical expertise for incorporating and implementing TRIPS flexibilities in national law and policy'.[22]

With regard to CL in particular, it is crucial to establish straightforward, simple and clear decision-making processes as well as domestic provisions which will avoid its suspension as a result of an appeal by the patent holder.[23]

In addition, domestic royalty rates are also an issue of concern as there are no general binding rules on the matter. Voluntary licence rates generally set royalty rates from 4 to 5 percent.[24] In turn, the WHO-UNDP Remuneration Guidelines for Non-Voluntary Use of Patents on Medical Technologies suggest royalties from 0 to 6 percent of the price charged by the generic competitor.[25]

In practice, the lack of clear-cut guidelines results in developing countries authorising CL with rather different royalty rates these days. Precise legal criteria on this issue would be of major importance. Predictability in setting the remuneration or compensation required by Article 31(h) is an imperative for improved functioning of generic markets.

To summarise, developing countries have to adopt adequate legislation for making the most of TRIPS flexibilities. This is particularly relevant for export-oriented generics producers. In this regard, it is useful to recall that, before 1996, developing countries with exporting generics manufacturers such as India, Brazil, South Africa, Singapore and China engaged in a robust trade in generics. Thus, many 'pre-TRIPS' drugs entered the market in generics-manufacturing countries, and are still produced and exported as generics.[26]

As a direct result, many developing countries are nowadays importing generic medicines from these export-oriented producers. However, new developed drugs are likely to be patented in multiple jurisdictions today and to

---

22 S. Musungu & C. Oh, *The use of flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?* (WHO 2006), pp. 119–120.

23 In addition, when compensation is appealed, it would also be useful to place the onus on patent holders to disclose the economic data to justify claims of inadequate royalty rate in order to discourage unjustified claims from patent holders. See S. Musungu & C. Oh, *The use of flexibilities* op. cit., p. 67.

24 P. Mayharduk & S. Rimmington, 'Compulsory Licenses: A tool to improve global access to the HPV vaccine', 35 *American Journal of Law & Medicine* (2009): 323–350.

25 *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies,* WHO-UNDP, 2005.

26 E. Hoen, *The Global Politics* op. cit., p. 36–37.

be subject to at least 7300 days (20 years) of patent protection in all WTO Members, but LDCs (until 2016).

Obviously, the rationale of patent protection requires granting patent holders exclusive rights to produce and sell their products and thus, inevitably, restrict access to newly discovered medicines.[27] In consequence, as transitional periods end, the sources of new generics from these export-oriented producers are in danger of drying up, and thus blocking the global pipelines of generic drugs for developing countries.[28]

Developed countries and brand-name pharmaceutical industries tend to concentrate their pressure on patent protection and enforcement in emerging economies and middle-income developing countries. In this regard, not only their potential shares of the pharmaceutical market, but also their capacity to export generics, make these countries targets for the private-public partnerships backing a extreme IP paradigm (TRIPS+ treaties, etc).[29]

Therefore, strong patent protection and enforcement for new pharmaceuticals in these countries risks blocking the sources of export-oriented generic production. In essence, if these sources are impaired, not only will emerging economies and middle-income developing countries have less generics suppliers for both old and new medicines, but so will LDCs in general.[30]

3. Unworking solutions

Nowadays, alternative legal grounds are beginning to be considered by developing countries in order to avoid taking the path of the paragraph 6 mechanism and the related provision in TRIPS article 31.[31] For many experts and

27 See generally, F. Scherer & J. Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Countries' *Commission on Macroeconomics and Health,* Working Paper n.WG4:1, Geneva (WHO 2001) and M. Mrazek, 'Pharmaceutical Pricing in the Developing World: Issues of Access to Medicines', 2 *Expert Rev Pharmacoeconomics Outcomes Research* 1 (2002): 43–50.

28 C. Correa, *Implementation of the WTO* op. cit.

29 Although these economies only represent today approx 5% of the global pharmaceutical market, the opportunity to increase pharmaceutical sales in emerging economies is rising fast as the size of their markets is growing. The GDP of E7 economies is expected to triple by 2020, compared to only a 40% increase in the G7 countries (Price Waterhouse Coopers 2007).

30 E. Hoen, *The Global Politics* op. cit., p. 62.

31 The use of the exceptions clause of article 30 is not foreclosed by the 2003

informed observers, article 30 (*exceptions to rights conferred*) still remains an alternative option with regard to compulsory licensing generally.[32]

This is certainly a more effective policy approach. In fact, the issue is already under consideration in the implementation measures of the WIPO Development Agenda. The WIPO Standing Committee on the Law of Patents (SCP) considers 'Exceptions and Limitations to Patent Rights' as an agenda item since 2008.

In June of that year, the SCP asked the WIPO Secretariat to establish preliminary studies on 'exceptions from patentable subject matter and limitations to the rights, inter alia research exemption and compulsory licenses'. Interestingly, in 2010, Brazil proposed setting up a working programme in order to hold a wide-ranging and sustained debate on this issue with a view to drawing up a WIPO manual of exceptions and limitations.[33]

However, tensions run high. For example, delegates at the 18th session of the WIPO Standing Committee of the Law of Patents (SCP) between 21 and 25 of May 2012 were unable to reach agreement on the committee's future work programme, as a result of the strongly diverse opinions regarding work on agenda items such as patents and health, exceptions and limitations to patent rights, quality of patents and technology transfer.

Positions between Group B (industrialised countries) –particularly United States and EU– and developing countries were irreconcilable when a joint proposal on this future programme was tabled by the African Group and the Development Agenda Group.

The balance between exclusivity (monopoly rights) and public interest is generally considered to be provided through the subtle interplay of articles 30 and 31. Thus, it is through this interplay that TRIPS-consistent policy options are conventionally defined nowadays, as article 30 details substantive criteria for exceptions to exclusivity, and article 31 contains a list of procedural requirements to limit that exclusivity.

However, article 44 also potentially provides further flexibility with re-

---

Decision. See C. Garrison, *Exceptions to Patent Rights in Developing Countries*, UNCTAD-ICTSD Issue Paper 17 (2006).

32 The (restrictive) interpretation of Article 30 by the panel in the *Canada-Generics* case is not legally relevant as adopted prior to 2001 Doha Declaration, which placed Article 30 in a new interpretative framework. See *Canada — Patent Protection of Pharmaceutical Products*, WT/DS114/R (17 March 2000).

33 See SCP/14/7, *Proposal from Brazil, Standing Committee on the Law of Patents*, Fourteenth Session, Geneva, (January 20, 2010).

gard to permanent injunctions. In this regard, compulsory licences granted under Part III of the TRIPS (enforcement), and therefore those based on article 44 (injunctions), are subject to a different regime from that of the compulsory licences granted under the procedures of Part II (standards), as the former are not subject to the restrictions existing for article 30 and 31.

Interestingly, US judicial practices regarding CL permanent injunctions are already considered by developing countries as potential new alternatives for extending policy space with regard to export-oriented pharmaceutical CL.

As a result, in the chessboard politics of global IP standards, the African Group/DAG made a strategic move in 2011 by requesting that the International Bureau of WIPO 'organise a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44'[34]

In fact, several US cases regarding CL injunctions with export-oriented elements are tracked by developing countries as a result of a landmark US Supreme Court judgment on CL in 2006: *eBay Inc. v. MercExchange*.[35] In this high-profile case, in which MercExchange requested that the Court grant a permanent injunction, the Supreme Court held that the plaintiff had to satisfy a *4-factor Test* based on equity before a court could issue a permanent injunction in respect of compulsory licences.

For the court, this 4-factor test for permanent injunctions is necessary on the grounds of principles of equity, namely criteria such as (1) having suffered an irreparable injury, (2) inadequate legal remedies (e.g. compensation) being unable to compensate the injury, (3) balancing the 'hardships between the plaintiff and defendant', and (4) not disserving the public interest.

Following this judgment on the issuance of compulsory licences, there have been several such cases in the United States.[36] Thus, for example, in the case of *Edwards Lifesciences v. CoreValve* in 2011, a compulsory licence was granted in the US for manufacturing an export-oriented medical device to treat aortic valve stenosis, without being affected by the restrictions of TRIPS

34 See SCP/16/7, *Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group* (May 18, 2011).

35 See *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

36 See A. Mace, 'TRIPS, EBay, and denials of Injunctive Relief: is article 31 compliance everything?', 10 *Columbia Science and Technology Law Review* (2009): 233-266 and Ch. Cotropia, 'Compulsory Licensing Under TRIPS and the Supreme Court of the United States' Decision in *eBay v. MercExchange', Comparative Patent Law: A Handbook of Contemporary Research* (Edward Elgar 2008), pp. 557–583.

article 31 on exports under a compulsory licence and the paragraph 6 mechanism.[37]

The African Group/DAG, and particularly India, are already benchmarking those judicial experiences in order to obtain further policy space for their export-oriented generic industries outside the paragraph 6 mechanism.[38]

This policy approach is more useful for health policy formation than focusing on article 31(f) and the unpromising paragraph 6 mechanism. It is reasonable to argue that, since TRIPS agreement entered into force, enough time and efforts have been dedicated to article 31(f) by developing country health and trade officials, NGOs, and A2K advocates. Any cost-effect analysis would suggest finding a more simple and automatic procedure to avoid the ongoing and exhausting allocation of resources to the multiple (global and domestic) battles related to this issue.

The high transaction cost involved in the paragraph 6 mechanism is clearly described by Sell: 'even when single battles are won with regard to a specific medicine needed by any given country, the whole process must then be wound up and started over again for the next drug in the next country, with all the legal, economic, and political costs to be repeated'. The resulting 'patchwork quilt of territorial measures and countermeasures', as she recalls, increases the transaction costs of all the stakeholders while not appreciably stabilising access to essential medicines for citizens in poor countries as a whole.[39]

Political science literature offers insights on why the 'solution' contained in the 2003 Decision was made. For Gold and Morin, for example, NGOs and developing countries became trapped in consensus-seeking rhetoric, making it preferable for all parties involved to agree on adopting a flawed mechanism, and thus save face in a particular momentum. Thus, the process of rhetorical action led to adopting an *unworking agreement* in the sense of an arrangement made of 'sham standards', permitting a claim to the *de jure*

---

37 See *Edwards Lifesciences* v. *CoreValve, Inc. and Medtronic CoreValve, LLC*, No. 2011-1215, -1257, Fed. Cir. (2011).

38 See Doc IP/C/M/67, *Council for Trade-Related Aspects of Intellectual Property Rights - Minutes of meeting*, 24 - 25 October and 17 November 2011 (15 February 2012), paragraphs 221–223.

39 S. Sell, 'From Forum-Shifters to Shape-Shifters: Rulemaking and Enforcement in Intellectual Property', *International Studies Association Meeting*, New York City (February 15-19 2009), p. 87.

existence of a mechanism and relieving pressures for the continuation of the debate as previously framed.[40]

Certainly, by rendering the 2003 Decision unworkable, developed countries and IP industries obtained a public relations (PR) success without the need to incur the foreseeable reputational losses associated with insisting on restricting, for example, its coverage to a limited number of products and/or diseases. In this regard, the Decision certainly provided for a 'media-visible solution' to a highly 'sensitive issue'; the 'theatre policy dimension', as Robert Hudec would have said.[41]

For Hoen, according to this line of reasoning, the Decision is a textbook example of a compromise with little practical use: 'at the end of the day, the objective was to reach an agreement –any agreement– without regard to the effectiveness of the compromise'.[42]

The WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) had already predicted these problems and in fact recommended that the effectiveness of the Decision needed to be kept under review 'and appropriate changes considered to achieve a *workable solution*, if necessary'.[43]

Interestingly, generic producers kept a very low profile during the 2003 Decision negotiations. Shadlen sheds light on this issue, as her interviewees working with the generics industry explained their preference for dedicating efforts to other policy issues, as they considered the whole procedure to be a predictable failure.[44]

For some authors, the 2003 Decision closed the door on further contention over the legitimacy of the TRIPS agreement. In the words of Pugatch, IP owners had learned the lesson of PR mistakes with regard to access to medicines in the past,[45] and thus adopted a proactive, rather than defensive, strategy.

---

40 See E. Gold & J. Morin, 'Consensus-seeking, distrust' op. cit.

41 See R. Hudec, 'International Economic Law: the political theater dimension', 17 *Journal of International Economic Law* (1996): 9–15.

42 E. Hoen, *The Global Politics* op. cit., pp. 36–37 and p. 38.

43 See *CIPIH Recommendation 4.15*: 120.

44 K. Shadlen, 'The political economy of AIDs treatment: Intellectual property and the transformation of generic supply', 51 *International Studies Quarterly* 3 (2007): 576–577.

45 Particularly, the legal challenge (February 1998) in the running up to the Doha WTO Ministerial Conference by 39 drug companies against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act of 1997 violated TRIPS and the South African Constitution.

For the industry, it was politically necessary to conclude negotiations in a manner that would be perceived as beneficial to developing countries. On the other hand, by signing the 2003 Decision, developing countries were essentially declaring that TRIPS rules "no longer obstruct efforts to promote public health'.[46]

4. The way out

Thus, the 2003 Decision does not facilitate access to generic medicines in developing countries lacking manufacturing capacity. The underlying master-value of the Decision is clear, in that it is compatible with WTO to import and export generics to developing countries without sufficient pharmaceutical manufacturing capacity under certain conditions. However, its regulatory structure compartmentalizes transactions on a case-by-case, drug-by-drug and country-by-country basis through a (member-driven) double compulsory licensing scheme.[47]

As mentioned, the Annual Reviews of the mechanism by the TRIPS Council already contain an agenda item under the illustrative title 'Any alternatives to the use of Paragraph 6 System to achieve the objective of access to medicines'.[48] In this regard, there are several policy options linked to trade that could seriously contribute to reducing prices of essential medicines in the developing world. This is the case of pooled procurement, among others.

Pooled procurement reduces the transaction costs among participating countries, creates greater buying power, and offer suppliers incentives to invest in generics production. In addition, it also offers incentives to the originating firms to become 'low bidders', as developing countries pooling their procurement can produce economies of scale which will facilitate exporters'

46 M. Pugatch, 'Political economy of intellectual property policy-making — an observation from a realistic (and slightly cynical) perspective' 7 *The Journal of World Investment & Trade* 2 (2006): 270–271.

47 F. Abbott & J. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 10 *Journal of International Economic Law* 4 (2007): 921–987.

48 See e.g. the intervention of the Indian delegation in IP/C/61 *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Report to the General Council* (18 November 2011), paragraph 56.

long-term planning under supply contracts offered by a centralized procurement authority.

The two decades of experience of the Pharmaceutical Procurement Service of the Organization of Eastern Caribbean States (OECS/PPS) are among the best practices of inter-state pooled procurement. In fact, the OECS/PPS has successfully used pooled procurement to steadily and significantly reduce the price of pharmaceuticals and medical supplies for its nine Ministries of Health since its establishment in 1986.

As Jerome Reichman suggests, pooling procurement (by coordinating the potential use of compulsory licences) can generate economies of scale and scope to entice even the pharmaceutical companies that originated the product to 'play ball' with them.

The carrot dangled in this scenario is the possibility for the originator company to exercise its exclusive rights (including trademarks) over a suitably large area that would make it worthwhile, even at discount prices;[49]again, high-volumes, low-margins.

In addition, these measures could eliminate the high transaction costs of uncoordinated legal action by developing countries: as Abbott and Reichman recall, action by single states on a case-by-case approach will remain vulnerable to strong legal and economic pressures by right holders, in the form of 'defensive actions to choke off critical sources of supply'.[50]

Reichman has also put forward an interesting new idea by suggesting the creation of loose trade agreements between developing countries (as long as they involve at least an LDC) to establish a regional pharmaceutical supply centre in one LDC member country (exempted from patent protections until 2016) and to re-export generics drugs imported under double compulsory licenses throughout the entire group of Members.

Such schemes could probably give producers sufficient scale to justify the investment in producing generics for export to these countries, and even setting up production in one of these countries. In this sense, such an initiative could also be an opportunity to help developing countries build regional manufacturing. In this regard, health ministers could offer incentives to patent holders to set up a regional factory, supervise production quality, and supply the member states from that facility.

---

49 J. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions' op. cit., p. 258.

50 F. Abott & J. Reichman, 'The Doha Round's Public Health Legacy' op. cit., p. 973.

The scheme would also amplify the bargaining power vis-à-vis the industry, as it would allow health ministers, acting jointly, to hold their bundle of compulsory licenses and go to the original patent holder and offer the possibility of supplying the entire regional market, if the required drugs were offered at affordable prices.

Taking this road instead of issuing individual CL also cancels out the risks of playing alone against the global pharmaceutical industry. In this respect, under pooled schemes, it would be more difficult to threaten a developing country successfully with domestic lawsuits.

Interestingly, the German Development Agency was among the first to recall that the LDCs transition period (until 2016) was a major window of opportunity for focusing on technology transfer to establish export-oriented generic pharmaceutical production bases in key LDCs and trade in generics with other LDCs. In fact, the German agency is actually very active in supporting local production of pharmaceuticals in countries such as Bangladesh, Cameroon, Ethiopia, Kenya and Tanzania.[51]

However, this window of opportunity as well as that referred to by Reichman is due to be phased-out if WTO members fail to agree on adopting new extensions to this transitional period.[52]

In any case, even counting on the possibility of an extra transitional period, it would be reasonable not to leave access to medicines at affordable prices in the developing world to member-driven mechanisms but to trade and traders. In this regard, a critical element for the solution to access to affordable medicines in the developing world is more global trade: the same global trade that has silently managed to make electronic devices, food, cars, clothing, etc, affordable in our societies since the inception of GATT in 1947 and the following eight Rounds of trade negotiations.

Creating and developing a thriving global market for generics is certainly a more efficient policy option than adding extra market segmentation to the traditional market segmentation for patents. In this regard, the 2003 Decision's double-CL scheme was unreasonable. In this line of reasoning, it is also critical to underline that all the trade involved in world economic growth

51 See *Investment in Pharmaceutical Production in the Least Developed Countries: A Guide for Policy Makers and Investment Promotion Agencies* (United Nations 2011), p. 13.

52 See WTO/L/845 *Decision on the Transition Period for Least-developed countries under Article 66.1 of the TRIPS Agreement adopted by the Eighth Ministerial Conference on 17 December 2011* (19 December).

during last half century was neutral towards domestic IP protection until TRIPS agreement entered into force (1996).

The historic Doha Declaration on access to medicines can open the doors for a pro-trade WTO policy decision aiming to facilitate access to medicines in developing countries. In this regard, WTO has a historical opportunity to confront its critics and handle humanitarian concerns by going for the core of its activity (world trade and market formation) and not for what has been made "*related to*" IP through the TRIPS agreement.

More than a decade since the inception of the 2001 Declaration, it is reasonable to suggest that humanitarian concerns in this area could be more efficiently managed by embracing trade, not through extra market segmentation and a member-driven mechanism at odds with the historical inner economic logic and rationale of the world trade system. In this regard, it is obvious that the member-driven mechanism adopted so far in the 2003 Decision does not prove effective for improving access to medicines in the developing world.

Member-driven solutions are at odds with world trade, and market-driven solutions should thus be explored. In this respect, WTO Members could make a better contribution to the provision of access to generic medicines in developing countries by leaving aside bureaucratic controls and market segmentation to concentrate on what the world trade system does best, namely promoting market formation on a global scale.

For any market to function properly, prices must be affordable for potential buyers. However, the purchasing capacity of brand-name medicines by most patients in developing countries is extremely low at best, and their public authorities do not still have capacity to deliver. In consequence, global trade in generics may be the only option to have a major impact on prices and thus on affordable medicines in these countries.

By fostering price-based competition through increasing potential generic suppliers both from developed and developing countries, the price of both generic and patented medicines can be significantly brought down in developing countries. In this regard, it is not market failure but market success what strongly suggests strengthening global trade in generics both in and for the developing world.

Beginning at the launch of the Doha Development Round (2001), WTO Members have been involved in an open re-regulatory process to facilitate pro-health pharmaceutical policies in the developing world. However, the measures taken so far have not proved sufficiently effective.

Alternatively, (TRIPS compatible) market-driven solutions have to be explored. Promoting public health in developing countries through trade requires not only ensuring zero tariffs on health products (medicines, active ingredients and medical products) but facilitating world trade flows of generics under automatic mandatory licensing. Nowadays, the former is improving but the latter is not.

With regard to the former, there is a trend within the WTO regime toward tariff reduction on medicines, active ingredients and medical products. Notwithstanding these improvements, some LDCs, developing countries and transition economies still maintain high tariff rates on health products.[53] In consequence, pro-health endeavors are required to further reduce tariffs in those countries.

With regard to the latter, world trade flows in health products under compulsory license towards developing countries are almost non-existent. Although developing countries such as India and Brazil have increased their participation in world trade in health products in recent decades, the key players are still a small group of developed countries strongly opposing the adoption of any rule and policy facilitating world trade in pharmaceutical products under compulsory licensing.[54]

Fortunately, competition authorities in developing countries can play a major role here by issuing compulsory licenses not only to produce but also to import generics in order to tackle critical antitrust issues such as, particularly, exorbitant or excessive pricing.

In addition, the potential for increasing flexibility (read adaptability) of WTO law through Declarations and waivers is underestimated. In fact, all studies of WTO practices on waivers tend to stress their potential.[55] In this

53 The study updates data and extends the universe of health products, going beyond the three health products taken as a sample by Olcay and Laing in their study for the WHO CIPRIH (2005). See respectively M. Helble, *More Trade for Better Health, International Trade and Tariffs on Health Products*, Staff Working Paper ERSD-2012-17, WTO Economic Research and Statistical Division (18 October 2012) and M. Olcay & R. Laing, *Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?*", Study prepared for the Commission on Intellectual Property Rights, Innovation and Public Health (World Health Organization 2005).

54 For empirical data see, in particular, M. Helbler, *More Trade for Better Health,* op. cit., pp. 11–13.

55 In this regard, the typology offered by Feichtner (individual exceptions, general exceptions and rule-making instruments) and her reflections on this issue are particularly clear. See I. Feichtner, *The Law and Politics of WTO Waivers: Stability and*

regard, WTO structures offer significant regulatory capacity to reconsider (re-regulate) TRIPS disciplines in this and other areas; provided there is sufficient social pressure, and thus political will among its Members.

Flexibility in Public International Law (Cambridge International Trade and Economic Law 2011).

5

PRICE-BASED COMPETITION

1. Maximizing generics

Intellectual property rights are legal instruments designed to grant private control over inventions, information and ideas.[1] Prior to the entry into force of WTO law and its Annex 1C TRIPS Agreement, international intellectual property had a limited influence on the capacity of developing countries to regulate public health. However, for more than a decade, WTO members have been involved in a regulatory learning process to rebalance patent and health protection in the TRIPS Agreement.[2]

Obviously, the core right conferred with a patent is the 'right' to exclude others from profiting from an invention: patents are legal monopolies created to secure a (temporary) *exclusion of competitors* with regard to a given invention. In this regard, the competition provisions in TRIPS agreement may play a critical role towards the *inclusion of competitors* and thus the promotion of global generics competition and market formation generally.

And here, the WTO formal recognition that TRIPS rules are flexible offers major policy space. In this sense, trade ministers could collectively make a considerable contribution to access to medicines by promoting global generic competition and, particularly, pro-generics domestic regulation and policies in the developing world.

There is a case for stronger competition law and policy in the brave new world of knowledge monopolies, and particularly in the life-science industries . Global competition issues have a major impact on prices, and pricing is certainly a key factor in access to affordable medicines.

For any market to function properly, prices must be affordable for po-

---

1 P. Drahos & J. Braithwaite, *Information* op. cit.

2 See generally S. Picciotto, 'Defending the Public Interest in TRIPS and the WTO', *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave and Oxfam 2002).

tential buyers. However, as recalled above, the purchasing capacity of brand name medicines by most patients and/or public procurement authorities in developing countries tends to be very low at best.

Certainly, cost is not the sole factor impacting access to medicines in the developing world, but it must be resolved first. Thus, generic drugs are critical to ensuring a steady stream of affordable medicines by bringing prices down to the marginal production cost, plus a sustainable royalty: a truly efficient drug market might offer, not the lowest prices *per se,* but the lowest prices possible while at the same time ensuring innovation.[3]

Sustainable prices for medicines in the developing world can be more easily constructed if more volumes are involved, and this can only be done through global trade in generics. By fostering (price) competition through the existence of a multiplicity of potential generic suppliers, both from developed and developing countries, the price of generic and patented medicines can be brought down. Thus, in order to effectively lower prices, a thriving global generics market requires promoting market formation, and pro-generics competition law and policies.

Policy measures taken in this direction could certainly help in advancing (or unblocking) the agenda of the Doha Round. In this regard, it is not market failure but market success what strongly suggests strengthening generic competition both in and for the developing world.

2. Pro-health antitrust

Nowadays, a variety of private and public practices are using IP protection in order to inhibit global market formation, and therefore global competition. However, competition and intellectual property are inevitably required to converge in the medium term.[4]

---

3 B. Waning, M. Kyle & E. Diedrichsen *et al,* 'Intervening in global markets' op. cit., p. 17.

4 See generally, G. Ghidini, *Intellectual Property and Competition Law: The Innovation Nexus* (Edward Elgar 2006) at 99–118 (chapter 5), E. Fox, 'Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?', *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press 2005) and, particularly, N. Gallini & M. Trebilcock, 'Competition policy and intellectual property rights' *Competition policy and intellectual property rights in the knowledge-based economy* (University of Calgary Press 1998), pp. 17–61.

Any unrestrained freedom to exploit knowledge monopolies, and subsequent monopoly pricing, produces deadweight losses (losses occurring when potential consumers cannot afford to buy a product), and it thus requires more antitrust policymaking and enforcement. In this regard, access to affordable medicines in developing countries is a major example requiring incorporating pro-competitive TRIPS flexibility into their antitrust enforcement policies.[5]

Domestic competition laws and policies are strongly instrumental in any pro-development reading of TRIPS agreement.[6] In fact, according to article 40 of TRIPS (Section 8: *control of anti-competitive practices in contractual licenses*), countries have full regulatory autonomy to define what may be deemed anti-competitive conduct.

Thus, not only practices such as applying excessively broad patents to block research, 'sham litigation', 'patent clusters', 'evergreening' and others can be scrutinised by competition authorities in developing countries. Also excessive pricing itself, or the refusals to negotiate voluntary licences blocking the access of generic competitors to essential facilities, among others, are anti-competitive practices which require the competition authorities to take decisions (such as the issuance of compulsory licences), in order to secure affordable prices for essential drugs.

In the past two decades, developing countries have begun to generally adopt competition law and policies as a structural element of their development strategies. These laws and policies are increasingly perceived as instrumental in promoting and protecting welfare creation in areas such as intellectual property.[7] As a result, some developing countries have begun to explore pro-competition readings of pharmaceutical protection in order to gain access to medicines at affordable prices.

There is no doubt that enforcing competition law and policy could be

---

5 For a pre-TRIPS history of the impact of pharmaceutical corporate practices on the health care systems of developing countries see G. Gereffi, *The Pharmaceutical Industry and Dependency* op. cit.

6 T. Avafia, J. Berger & T. Hartzenberg, 'The ability of select sub-Saharan African countries to utilize TRIPS Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries', *Trade Law Center for Southern South Africa (TRALAC) Working Paper No. 12* Stellenbosch (2006), p. 52.

7 J. Drexl, 'The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights', *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press 2005), pp. 709–725.

particularly helpful in this regard. It is true that addressing pharmaceutical anticompetitive practices requires complex economic analysis, skilled regulators, as well as sophisticated administrative and judicial processes.[8]

However, the benefits clearly outweigh the costs. In terms of comparative law and policy, competition authorities enjoy a more pro-active role and more independent investigative powers than patent authorities for pursuing cases which are in the public interest.

In fact, cases can be pursued on the simple basis of third party complaints. Conversely, patent law normally tends to rely on directly interested parties who are often reluctant to dedicate time and resources to costly and complicated litigation against large patent-holding corporations.

Patent licensing procedures and competition law procedures differ from each other in key issues. In particular, the inquiry by the competition authorities is public and focuses on the legality or illegality of a given practice. Last, but not least, competition laws are punitive!

In consequence, it is self-evident that competition commissions may play a critical role in access to affordable medicines in developing countries through pro-competitive compulsory licensing (CL).

These actions are WTO compatible, as TRIPS article 31(k) provides for efficient policy space to grant pro-competitive CL, by waiving the need for a previous negotiation with patent holders and leaving the possibility of granting royalty free licences. In this sense, a finding of anti-competitive conduct under article 31(k) would exempt WTO Members from negotiations with the patent holder, and even from the TRIPS requirement to limit CL predominantly for the supply of the domestic market. In addition, remuneration may also become marginal in such cases, given the punitive elements of remedying anticompetitive practices.[9]

Hence, some competition authorities from the developing world are beginning to tackle excessive pricing of pharmaceuticals and showing an example to others.

In this regard, the South African Competition Commission was among the first competition authorities in the developing world to use the stated purposes of its competition rules with a pro-generics rationale in mind: Section

8 J. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions' op. cit at 253 and E. Fox, 'Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?', *International Public Goods and Transfer of Technology under a Globalised Intellectual Property Regime* (Cambridge University Press 2005), pp. 758–769.

9 J. Reichman, 'Compulsory Licensing of Patented' op. cit., p. 253.

2 of the Competition Act states that its purpose is to promote and maintain competition in order 'to promote the efficiency, adaptability and development of the economy', 'to provide consumers with competitive prices and product choices' and 'to advance the social and economic welfare of South Africans'.

Section 8 in turn determines that it is prohibited for a dominant firm 'to charge an excessive price to the detriment of consumers [and to] refuse to give a competitor access to an essential facility when it is economically feasible to do so'.

To date, one of the most successful uses of competition law regarding generics was a complaint brought before this competition commission against GlaxoSmithKline and Boehringer Ingelheim in 2002, and an agreement obtained from Bristol-Myers Squibb by an NGO, under the threat of an antitrust complaint to the commission in 2005.

Both cases are based on abuse of dominance, and focus extensively on excessive pricing with regard to pharmaceutical products for the treatment of HIV infection and AIDS-related diseases. In both cases, interesting insights are provided with regard to the use of competition law and policy in the pharmaceutical area.[10]

In *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, the complainants bluntly alleged that the prices that GSK and BI were charging for their products were responsible for the premature, predictable and avoidable loss of human lives.

The Commission determined that GSK and BI engaged in restrictive practices that violated the Competition Act of 1998's prohibitions against excessive pricing (section 8(a)), denying a competitor access to essential facilities (section 8(b)) and exclusionary acts with an anticompetitive effect outweighing technological, efficiency or other pro-competitive gains (section 8(c).

The Competition Commission referred their refusal to license generic manufacturers to the competition tribunal for a ruling, and requested the tribunal 'to make an order authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty'.

---

10 J. Berger, *Advancing public health by other means: using competition policy to increase access to essential medicines*. Bellagio Series on Development and Intellectual Property Policy: Policy Options for Assuring Affordable Access to Essential Medicines (ICTSD 2004).

In addition, a penalty of 10% of the annual turnover of the respondents' ARVs was recommended for each year that they were found to have violated the Competition Act. In the following months, the companies agreed to negotiate voluntary licences with generic companies to avoid not only a legal precedent, but a PR disaster.[11] The agreement allowed generic products still under patent to be available for the first time in South Africa.

In the latter case, TAC (Treatment Action Campaign) advocates also threatened BMS to file a complaint in the shadow of the previous case, aiming to open access to key first line AIDS medicine patents. For TAC, BMS was charging excessive prices for an off-patent product under a *de facto* monopoly which was already being marketed at substantially lower prices in countries such as Brazil, among others. Before any formal decision by the Commission, BMS agreed to settle the issue by offering a price cut of approximately 80%.

In short, some first pro-generics experiences are already available in the competition enforcement policies of the developing world.

It should also be recalled that countries such as the United States already make strategic use of compulsory licensing to remedy anti-competitive practices. The US administration is in fact exemplary in this regard, as it has long been particularly active in granting compulsory licences to correct anti-competitive practices.

Paradoxically, this administration has used compulsory licensing decrees in antitrust law and policies as a remedy in more than 100 case settlements including pharmaceutical cases involving meprobamate, synthetic steroids, the antibiotics tetracycline and griseofulvin, and basic biotechnology patents, as Frederic Scherer explains.[12]

In fact, the US administration has not been alone in making use of pro-competition CL in the field of pharmaceutical protection. The Italian Competition Authority, for example, has already granted several compulsory licences under article 31(k) between 2005 and 2007. On 21 June 2005, this regulatory agency granted a compulsory license against Merck for its refusal to license an antibiotic (Imipenem Cilastatin) and on 8 February 2006 against GSK for its refusal to negotiate with Fabbrica Italiana Sintetici SpA a voluntary license for the manufacture of an active ingredient (Sumatriptan Succinate) to produce a migraine drug.

---

11 T. Avafia, J. Berger & T. Hartzenberg, 'The ability of ' op. cit., p. 27–32.

12 See F. Scherer, *Competition policy, domestic and international* (Elgar Publishing 2000), p. 352.

Also, on 21 March 2007, the Italian Competition Authority authorized 3 CLs for the active ingredient (Finasteride) of a product used to treat prostatic hypertrophy, prostate cancer and baldness. The three of these compulsory licences involved exports to other European countries.[13]

The UE Commission is also taking more responsibility on IP-related competition policy in the field of generic drugs. In January 2008, DG Competition launched a sector inquiry (under Article 17 of Regulation 1/2003) on the pharmaceutical sector to examine the reasons why fewer new medicines are brought to market and why generic entry seems to be delayed in many cases.

Reacting to the findings of the final report (8 July 2009)[14], the Commission has intensified its scrutiny of the pharmaceutical sector, including monitoring of settlements between originator and generic drug companies. Several investigations into pharmaceutical company practices have been conducted and are in progress as a result of this inquiry. Additionally, between 2010 and 2011, the Commission launched two Reports on the monitoring of problematic pharma patent settlements.[15]

As a result, it is reasonable to suggest that competition authorities in developing countries should seriously benchmark these pro-generics developments in the competition policies of developed countries in order to obtain negotiating leverage regarding their own policies. This is particularly the case with regard to the major export-oriented generic producers from the developing world.

Also, the empowering legal language of competition should not be underestimated in its promotion of pro-health policies in the developing world. In this sense, competition rules and policies allow not only competition authorities but health ministers to take a more vigilant and proactive role with regard to lawmaking and policymaking in patents and public health areas.

With this objective in mind, it is important for developing countries not only to strengthen their institutional capacity with regard to competition law

---

13 See IP/C/61 *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Report to the General Council* (18 November 2011), paragraphs 51–54.

14 See *European Commission Communication* and *Technical Annex- Commission Staff Working Document* (8 July 2009).

15 See *DG Competition-1st Report on the Monitoring of Patent Settlements* (July 2010) and *DG Competition-2nd Report on the Monitoring of Patent Settlements* (July 2011).

and policy but global institutions such as the WHO, WIPO and UNDP also need to incorporate competition issues in their agendas.

Nowadays, developing common ground for pro-development competition law and policy in the IP area is a major global policy issue. Fortunately, WIPO has already granted itself a promising mandate on Intellectual Property and Competition Policy. At the 2007 General Assembly, WIPO Member States adopted 45 recommendations for immediate implementation under the Development Agenda.

As a result, Recommendation 7 (Cluster A: Technical Assistance and Capacity Building) urges promoting *measures that will help countries deal with intellectual property-related anti-competitive practices, by providing technical cooperation to developing countries, especially LDCs, at their request, in order to better understand the interface between IPRs and competition policies*.

Added to this, Recommendation 23 (Cluster B: Norm-setting, flexibilities, public policy and public domain) underlines the importance of pro-competitive licensing practices: *to consider how to better promote pro-competitive intellectual property licensing practices, particularly with a view to fostering creativity, innovation and the transfer and dissemination of technology to interested countries, in particular developing countries and LDCs*.

Finally, Recommendation 32 (Cluster C: Technology Transfer, Information and Communication Technologies (ICT) and Access to Knowledge) refers to systemic exchanges with regard to policy formation in this area: *to have within WIPO opportunity for exchange of national and regional experiences and information on the links between IPRs and competition policies*.

Interestingly, the former WTO Director General Pascal Lamy was also clearly aware of the need to develop common ground in this area. For this pragmatic practitioner of globalization, the prospects for success of domestic competition policies and the WTO are 'profoundly inter-linked'.

According to Lamy, the relationship is "a delicate and subtle one", begging critical questions that cannot be answered by any organization acting in isolation but through joint reflection and deliberation by organizations such as WIPO, the OECD, UNCTAD, the International Competition Network (ICN) and the WTO, in addition to national competition agencies with experience in this field.[16]

16 See P. Lamy, 'Strong competition policies key to a dynamic and healthy market economy', WTO| *Speeches and statements* (16 February 2012).

Hence, it is be reasonable to assume that pro-competitive TRIPS flexibilities should be developed in collaboration with other international institutions.

3. Generics competition

Competition is perhaps 'the most powerful policy instrument for bringing down drug prices for off-patent drugs', in the WHO's own words. The final report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was already stressing in 2006 how generic competition played a significant role in pushing down the prices of off-patent products.

For CIPIH, developing countries should adopt pro-competitive measures for preventing or remedying anti-competitive practices related to the use of pharmaceutical patents.[17] Thus, the commission recommends that developing countries should 'generally promote policies that support greater competition between generics, whether branded or not'.[18]

Their proposal is precisely framed: 'competition is *in the last instance* the key tool to drive prices down and improve access to medicines'.[19] For CIPIH, in consequence, '*governments and concerned international organizations* should promote *new purchasing mechanisms* to stimulate the supply of affordable new products and to enhance the number of suppliers in order to provide a more competitive environment'. Under this rationale, the Commission reaffirms '*avoiding or dismantling unjustified barriers to the entry of generics'* as 'a *major responsibility of governments*'.[20]

In fact, in reaction to its authoritative diagnosis, a Global Strategy and Plan of Action on public health, innovation and IP was adopted in May 2008 by the World Health Assembly. Element 6 of the Global strategy, under the title *Improving delivery and access,* signals TRIPS-consistent generic competition as a critical instrument to improve availability and affordability of health products, 'through the development of national legislation and/or policies that encourage generic production and entry'.[21]

---

17 See 'Recommendation 4.23' and 'Recommendation 4.25' in *Public Health, Innovation and Intellectual Property Rights*, CIPIH Final Report (WHO 2006).

18 See 'Recommendation 4.24'.

19 See CIPIH Final Report, op. cit., p. 112.

20 See CIPIH Final Report, op. cit., p. 128 and p. 181.

21 See *Global Strategy and Plan of action on public health, innovation and in-*

For many, global welfare could be improved if developing countries were generally allowed to free ride on pharmaceutical innovation under certain conditions.[22] Notwithstanding that the current international patent system produces difficulties for going down this route, they are not insurmountable. TRIPS rules still provide for very significant flexibility for combating world anti-competitive conduct in the pharmaceutical patent area, both on a domestic and global scale.[23]

At the present time, several provisions in the TRIPS framework allow for developing flexible pro-competition policies in one way or another (e.g. articles 6, 7, 8, 30, 31, 40 and 44). In addition, as Berger underlines, 'there is sufficient disagreement between and within developed countries on the relationship between competition policy and intellectual property to provide significant space within which to manoeuvre'.[24] This lack of consensus certainly allows an important window of opportunity to develop (TRIPS compatible) pro-generics policies.

The TRIPS agreement offers powerful policy space for promoting global pro-generics competition. The principles of the agreement itself, contained in article 8.2, expressly establish that *appropriate measures* may be needed 'to prevent the abuse of intellectual property rights by right holders or the resort to practices *which unreasonably restrain trade*'.

Added to this, article 40.2 recognizes pro-competition limitations of IP rights generally: '[n]othing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market'.

In short, TRIPS principles contained in article 8.2 (measures to prevent unreasonable trade restrictions) and pro-competition provisions contained in article 40.2 (measures to prevent the abuse of IP rights having an adverse effect on competition) open a window of opportunity for promoting domestic and global public policies towards greater generic competition.

In fact, antitrust remedies are obviously not covered by the 2003 Decision and thus are exempted from the paragraph 6 mechanism. Therefore,

---

tellectual property, Sixty-First World Health Assembly, Agenda item 11.6 (24 May 2008).

22 F. Scherer, 'A Note on Global Welfare in Pharmaceutical Patenting', 27 *World Economy* (2004) 7: 1141.

23 See chapter 8.

24 J. Berger, *Advancing public health by other means* op. cit., p. 4.

developing countries enjoy enough leeway to determine what pharmaceutical patent-related conduct constitutes anti-competitive behaviour in the TRIPS agreement and how to correct it. Indeed, these articles offer them ample 'wiggle room' to implement policies favouring the public interest in free competition.[25]

TRIPS article 31(k) allows CL to correct anti-competitive practices of a patent holder. As a result, compulsory licensing is a promising TRIPS-compatible policy option to combat anti-competitive behaviour in the global pharmaceutical sector. In this sense, the general rules on CL contained in article 31(f) do not apply to those CL granted to remedy or correct anti-competitive behaviour. Thus, public authorities are exempted prior to negotiation with the patent-holder and can even refuse to provide for compensation to the patent-holder.

In addition, there are also some additional pro-competition policy tools that could seriously contribute to price-based competition and thus lead to significant price reductions for essential medicines in the developing world. These are not only the pooled procurement above mentioned but, in particular, the cases of automatic mandatory licensing and patent pooling.

In automatic mandatory licensing, any company can use the patented invention, provided it complies with the legal requirements (drug quality standards, required royalties, etc). In order to achieve this, governments have to leave patents open to all qualified applicants.[26]

As a result, this type of licence allows multiple firms to enter the market, and thus expand competition. In addition, governments are prevented from selecting one provider only as there will be more than one available. Breach of contract and failure to deliver can also be easily remedied, with no need to issue a new licence.

Patent pooling is also a promising initiative. A patent pool is created when patent rights, held by different owners are brought together (pooled) and made available on a non-exclusive basis to pharmaceutical manufacturers through voluntary licences by paying royalties to the pool.

Firms that are contemplating producing and marketing generics can access these 'one stop shop" facilities and make use of the covered patents.[27]

---

25 J. Reichman, 'From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement', 29 *New York University Journal of International Law and Politics* (1996): 28.

26 See chapter 9.4.

27 E. Hoen, *The Global Politics of* op. cit., pp. 90–91.

The idea was first launched by James Love from Knowledge Ecology International, after studying the US airplane patent pool established in 1917 by the US Government to overcome patent barriers to the mass production of airplanes for the military.[28]

UNITAID, a mechanism originally designed for the purchase of medicines (and financed by a tax on airline tickets), evolved to operate along these lines and established a Medicines Patent Pool for HIV drugs that became operational in 2010.[29]

These licences, available for producing low-cost generics, are designed to cover as many developing countries as possible, in order to both maximize public health protection and to ensure economies of scale in generic drug production.

Interestingly, patent pooling is not frowned upon by developing countries. In the post-Doha scenario, developing countries and large pharmaceutical industries prefer to promote any sort of public and/or private initiatives based on voluntary licensing rather than lowering their guard and accepting a generalized issuance of pro-health CL. The US administration, for example, is already publicly supporting patent pooling as an alternative voluntary model.

These private-public initiatives should not be underestimated, as the experiences of generic producing countries illustrate that making effective use of CLs issued by governments is not always easy, as patent offices often grant patents not sufficiently disclosed. Given the lack of sufficient disclosure, the poor quality of many patents may mean an unreasonably long time for developing countries to develop and produce a given invention, if there is no voluntary collaboration by the patent-holder.

In a submission to the WIPO Standing Committee on the Law of Patents (SCP) in 2010, Brazil illustrated this problem with its own experience with the CL granted for an antiretroviral drug (Efaviretz) in May 2007: it took the Oswaldo Cruz Foundation almost two years to develop and produce the drug.[30]

Technology transfer programs should obviously be given more weight

28 See D. Serafino, 'Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures', *KEI Research Notes* (6, 4 June 2007), pp. 15–16.

29 See J. Bermudez & E. Hohen, 'The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good', 4 *Open AIDS Journal* (2010): 37–40.

30 See SCP/14/17, *Exceptions and Limitations to Patents Rights, Brazil Proposal*, paragraph 15–16 (15 January 2010).

in trade negotiations, as developing countries without pharmaceutical manufacturing capacity should not be dependent on foreign supply forever.

Transfer of technology programs (investing in plant and equipment, and upgrading systems for compliance with OECD GMP quality standards) are of critical importance for securing local pharmaceutical production in developing countries. Ironically, however, they have been reclaiming the development of effective global disciplines to facilitate technology transfer for half a century now.

The TRIPS article 7 itself reads 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'.

Article 66.2 also has relevant provisions on this issue: 'Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'.

How should these provisions be read from the legal perspective of TRIPS flexibility? Certainly, promoting world-class pharmaceutical production in developing countries would facilitate major global generic competition. The existence of more export-oriented pharmaceutical industries in (and for) developing countries would reduce pharmaceutical prices in the developing world.

However, developed countries and their industries are generally somewhat reluctant to pave the way for this to happen. In fact, Special and Differential treatment for developing countries under TRIPS rules is not based on any particular commitment with regard to technology transfer but merely on transitional periods.

Following a Decision at the Doha Ministerial Conference in 2001, the WTO established a mechanism for ensuring the monitoring and full implementation of the above mentioned obligations. This mechanism was set up by a Council Decision in 2003, detailing the information to be supplied by developed countries on how their domestic technology transfer incentives are functioning in practice.[31]

31 See IP/C/28 *Council for Trade-Related Aspects of Intellectual Property Rights*

Under this mechanism, developed countries have to provide detailed reports every third year and in the intervening years provide updates. However, the scope and depth of the technology transfer is purely voluntary.[32] In this regard, technology transfer for domestic and global exports between LDC and developed countries should be renegotiated and enforced.

4. Sealing legal ceilings

The domestic markets of many developing countries are not considered by the patent-holding pharmaceutical industry to be sufficiently profitable to file patent applications in their jurisdictions. However, these markets still need to be supplied with imported generics, as they have scant domestic manufacturing capacity or none at all.

For this reason, patents in middle-income developing countries with pharmaceutical manufacturing capacity are of critical concern. Sustainable generic production in these countries is a prerequisite in order to export those medicines to other developing countries.

In recent decades, as above mentioned, an efficient generic drug industry has burgeoned in developing countries such as South Africa, Thailand, India, and Brazil has become a key source of global generic production and distribution. Manufacturers such as Cipla (India) or Cristalia (Brazil), for example, have long standing experience in producing quality drugs for export to developing countries where there is no patent, or where the patent has expired or where, less frequently, it is under compulsory licence or government use. As a result, a wide variety of cheap generic medicines are competing today in the global generics markets.

However, patents are becoming more widespread and this is restricting generic competition for newer patented drugs.[33] As already mentioned, Brazil passed Decree no. 1355 reintroducing patents after a 30-year vacuum in December 1994, and India amended its Patent Act in March 2005 on similar lines.

Just before this, interestingly, both a WTO *panel* and Appellate Body decision had ruled against India for not taking the required steps to prepare

- *Implementation of Article 66.2 of the TRIPS Agreement - Decision of the Council for TRIPS* (19 February 2003).

32 For the reports see WTO Docs IP/C/W/*.

33 B. Waning, M. Kyle, E. Diedrichsen, L. Soucy & J. Hochstadt *et al,* 'Intervening in global markets' op. cit., p. 13.

its compliance with TRIPS agreements in 2005 (transitional obligations). The case, filed by the United States in 1997 claimed, among other issues, India's non-compliance with TRIPS article 70.8 (providing for means to file patent applications, etc) and article 70.9 (granting exclusive marketing rights to products subject to patent application in other WTO Members).[34]

Patent protection of new drugs in these countries adversely affects access to second and third treatments in developing countries that lack manufacturing capacity. If the generic manufacturers in these countries have stronger patent regimes and smaller scale operations, there will be an adverse impact on the cost structure for drugs in developing countries.

In this regard, international antitrust enforcement between developing countries –perhaps together with antitrust agencies of some developed countries– can be instrumental in ensuring that generic industries successfully upscale global price-based competition.

Obviously, the pharmaceutical industry is not supportive of export-oriented generics production in the developing world, and thus of global generics competition. As above mentioned, lobbies such as IIIA (International Intellectual Property Alliance) or US PhRMA (Pharmaceutical Research and Manufacturers of America) are, in fact, targeting the sources of generic production. Not surprisingly, developing countries that produce and/or import generics are under pressure from aggressive TRIPS+ lobbying and litigation. These strategies are complemented by developed countries negotiating TRIPS+ treaties as well as GSP benefits in exchange of stringent IP obligations.[35]

Thus, some developing countries are bargaining away their TRIPS flexibilities in favour of trade concessions elsewhere, or in exchange for more expedient market access. Any developing country reliant on trade with powerful trading partners is inevitably reluctant to use TRIPS flexibilities, as there is a rational concern of being targeted by (direct and indirect) sanctions in other policy areas. In addition, as above mentioned, no country is interested in suffering the inconvenience of being subjected to a campaign depicting it as a piracy-lenient country. As a result, TRIPS flexibilities remain untested in many developing countries.

---

34 See WT/DS79/R *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (August 24, 1998) and WT/DS50/AB/R *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (December 19, 1997), respectively.

35 See V. Bradford & K. Lee, 'TRIPS, the Doha Declaration' op. cit.

The restricted rationality of the TRIPS+ initiatives under negotiation undermines the 2001 Doha Declaration as well as the TRIPS flexibilities with regard to health protection. To avoid such an impact, for example, the WHO Regional Office for the Eastern Mediterranean has surprisingly managed to publish a *Policy Guide on Public health related TRIPS-plus provisions in bilateral trade agreements*.[36]

The trend of key global institutions questioning the *status quo* is, in any case, steady since the United Nations Development Programme begun referring openly in its Report of 1999 to the 'relentless march of intellectual property rights', stating that this process 'needs to be stopped and questioned'[37]

In essence, WTO law and policies have formally recognized the right of developing countries to import/export generics under certain conditions while, in practice, pharmaceutical lobbying is taking those rights away by using proxy states to advance stronger global standards to those contained in TRIPS itself.

Therefore, the existence of *legal ceilings* with regard to IP protection is certainly a critical issue deserving global consideration. Arguably, TRIPS+ treaties that invalidate TRIPS flexibilities are TRIPS-Minus with regard to trade concessions and benefits in WTO law, and thus should be legally interpreted as WTO non-compatible.

In conclusion, the TRIPS rules, together with the 2001 Doha Declaration should reasonably be taken as a world legal ceiling for stronger IP protection as well as an international legal foundation for antitrust authorities promoting world market formation and thus global generics competition.

In this last regard, TRIPS articles 40 and 31(k) together with the 2001 Declaration are critical legal instruments for consolidating a thriving global generics market to benefit patients from developing countries.

---

36 See *Public health related TRIPS-plus provisions in bilateral trade agreements: A Policy Guide for negotiators and implementers in the WHO Eastern Mediterranean Region* (WHO and ICTSD 2010).

37 See *UNDP Human Development Report 1999* (Oxford University Press 1999), p. 73.

6

WORLD POLICY COHERENCE

1. Relatedness

Finding a proper balance between patents and health through inter-agency cooperation is not an easy task. Certainly, in this structurally disputed area of international law and global politics, values and (public and private) interests seriously conflict.[1] In any case, it is reasonable to contend that more nuanced balances between public health (rights of citizens-patients) and private property (rights of patent holders-corporations) should be considered.

The prime example of the imbalances resulting from multilateral trade-related IP protection is the difficulties experienced by developing countries in importing generics under TRIPS rules.

Ironically, in order to solve the problem, the 2003 Decision has erected a extremely burdensome procedure. In essence, the Decision compartmentalises transactions on a case-by-case, drug-by-drug and country-by-country basis through a dual compulsory licensing scheme. Thus, the rules of the game are based on a procedure reinforcing world-scale '*market' segmentation*.

As a result, the inner virtues of world trade are thus inhibited, as well as the attainment of the economies of scale required to stimulate generic production and competition. Thus, the functioning of this mechanism depends on political will; and large corporations can always derail political will at both the supply and demand side in any given generics transaction.

Having been designed in the rooms and corridors of the world trading regime (i.e. the WTO), the solution suffers from a paradoxical anti-market and anti-trade approach. Reasonably, a different solution would have been reached if trade ministers had allowed health ministers and other agencies sit at negotiating table.

---

1 See in particular L. Helfer, 'Human Rights and Intellectual Property Rights, op. cit., p. 47.

Trade ministers tend to have more leverage vis-à-vis health ministers (as well as other domestic agencies). As a direct result, there are multiple *health-related* IP treaties administered by the latter... but no *trade-related* IP treaties administered by the former.

The TRIPS agreement itself formalizes this state of affairs in which trade ministers have expanded their power to negotiate treaties by using a strategic association of ideas; not for nothing does TRIP stands for Agreement on Intellectual Property Rights *related to Trade*.

Obviously, the invention of 'trade-relatedness' opens up a world of possibilities for global policy formation in all areas. In that case, is not almost everything related to everything else? The health and trade area is no exception.

Is the trade in generics a trade policy or a health policy? Or more precisely, is the trade in generics a policy dependent on ministers of trade and finance, and their global institutions such as the WTO? Or is it a policy dependent on ministers of health and, consequently, global institutions such as the WHO?

Patent protection is both a trade-related and a health-related policy issue. Therefore, there is clear case for increasing inter-agency coordination in these critical areas of public policymaking.

This controversial state of affairs could have been avoided if trade negotiators had been more open to other public policy expertise. At the present time, the issue of trade in generics epitomizes the current global tensions where human rights and monopoly rights intersect.[2]

Reasonably, more balanced solutions could have been developed if technical guidance and assistance from the United Nations agencies specializing in health protection (WHO) and human rights (UN Human Rights regime) had been requested by trade negotiators.[3]

This is a global policy area in which not only WTO but the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the United Nations Human Rights Regime have concurrent authorities and mandates. However, these other global institutions were not consulted

2 See L. Helfer & G. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2011), p. 90.

3 On health and international health law as global public goods see, in particular, L. Chen, T. Evans & R. Cass, 'Health as a Global Public Good', *Global Public Goods: International Cooperation in the 21st Century* (United Nations Development Programme 1999), pp. 284–305.

when the TRIPS agreement was being drafted, nor were they invited to participate in the design of a solution to the paragraph 6 issue.[4]

2. Chairs at the table

Developing consensus-based public policies in this and other health-related global policy areas would certainly benefit from a more inclusive approach in this regard. In any case, it is not only a question of pragmatism and legitimacy, but of pure international legality, as each of these concurring international regimes share complementary responsibilities and overlapping authority in this area.

For its part, WIPO is responsible for administering a group of IP treaties under its institutional umbrella. However, the emergence of WTO has *de facto* limited its competence. When the Uruguay Round (1986-1994) gave rise to the WTO, incorporating 'Trade-Related Intellectual Property Rights' under its jurisdiction, part of the global IP agenda was moved beyond the WIPO structure. Irrespective of its own wishes, WIPO has learnt to 'share' its original competence with WTO and nowadays provides legal advice and technical assistance on TRIPS implementation in accordance with their co-operation agreement of 1995.[5]

On the health side, the WHO is the mandated global institution primarily responsible for world health strategy. Its constitution envisages a regulatory regime designed to promote the attainment of 'the highest possible level of health' (Preamble). In consequence, it grants the WHO powers to adopt conventions (article 19), binding regulations (article 21), and recommendations (article 23) as well as to monitor national health legislation (article 63). As such, and paraphrasing Taylor, it is the only international regime that brings together the institutional mandate, legal authority, and public health expertise for the codification of treaties that principally address global public health concerns.[6]

---

4 See generally H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2007) and L. Helfer & G. Austin, *Human Rights* op. cit.

5 For detailed overviews see WIPO Annual Reports, available at http://www.wipo.int. With regard to TRIPS flexibilities see, in particular, *Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels*, WIPO Secretariat, Part I (2010) and Part II (2011).

6 A. Taylor, 'Governing the Globalization of Public Health', *Journal of law, medicine and ethics* (2004): 507.

In addition, the UN human rights regime has the primary responsibility for promoting and protecting the right to health on a global scale, as determined in article 25.1 of the Universal Declaration of Human Rights (1948). In addition, the International Covenant on Economic, Social and Cultural Rights (ICESCR) establishes the human right to 'the highest attainable standard of health' (article 12.1) and thus its various bodies also have competence and authority over these complex issues.

Reasonably, in consequence, these multilateral institutions should also participate in both global policymaking and rulemaking with regard to access to medicines.

In fact, their authoritative interpretations in this area deserve some legal deference. Examples of this are the WHO Global Strategy and plan of action on public health, innovation and intellectual property adopted in May 2008 which should provide a major reference for WTO in its search for TRIPS flexibilities.

Prior to that, on 24 May 1999 the World Health Assembly had unanimously adopted a resolution on Revised Drug Strategy, requesting the WHO to intensify its activities in six areas: national drug policies, pharmaceuticals and trade agreements, drug information and drug promotion, drug quality, drug donations and partnerships.[7]

However, the *statu quo* tips the scale in favour of the WTO regime because the WIPO, the WHO and the UN Human Rights regimes lack a compliance structure (or 'teeth') as efficient as WTO's (e.g. binding dispute settlement and subsequent authorization to suspend trade concessions) when it comes to obtaining compliance with their respective legal interpretations on these issues.[8] In essence, their comparative legal leverage is dependent on institutional design.[9]

Given this imbalanced state of affairs, some pre-emptive initiatives are required in order to at least mitigate potential legal friction or conflicts between these regimes. In this regard, global policy coherence in this area can only reasonably be obtained through deeper upstream inter-institutional co-

---

7 See *World Health Assembly Resolution* EB103/1999/R1, Revised Drug Strategy (24 May 1999).

8 M. Montaña y Mora, 'A GATT with Teeth: Law Wins Over Politics in the Resolution of International Trade Disputes', 31 *Columbia Journal of Transnational Law* 1 (1993): 103–180.

9 See P. Zapatero, 'Modern international law and the advent of Special Legal Systems', 23 *Arizona Journal of International and Comparative Law* 1 (2005): 55–75.

ordination.[10] Thus, deeper coordination is a critical policy option to find a better balance between the diverse rules and policies of these global institutions.

Hence, policy design and implementation regarding access to essential medicines in developing countries should reasonably be coordinated among the WHO, WTO as well as UN human rights regime and WIPO.[11]

Interestingly, the former Director-General of WTO himself suggested this approach while in charge of the EU DG Trade in relation to health and trade issues: 'when there's too much mistrust in the game then you have to call a third party, and the WHO is a trusted party'.[12]

The pragmatic Lamy has certainly been not only a practitioner but also an advocate of major global inter-institutional coherence.[13] In fact, he has seriously toyed with the idea of coherence as a potential general principle of international law: 'this is, in my view, the place and role of the WTO and its legal order in the international legal order: a catalyst for international mutual respect towards international coherence and even for increased global governance'.[14]

For the former WTO DG, 'the effectivity and legitimacy of the WTO depends on how it relates to norms of other legal systems and on the nature and quality of its relationships with other international organizations'.[15]

In fact, he acted in consequence, as WTO Director-General, by promoting *practical cooperation to ensure policy coherence,* in collaboration with WHO DG Margaret Chan and WIPO DG Francis Gurry.

The idea of closer work between WTO, WHO and WIPO was first pursued by the three Director Generals following the 2001 Doha Declaration, particularly focusing on capacity building and technical assistance to help developing countries using IP flexibilities in the pharmaceutical area through a series of annual, Geneva-based workshops.

---

10 See P. Zapatero, 'Searching for coherence in global economic policymaking', 24 *Pennsylvania State International Law Review* (2006): 595–627.

11 For a World Bank-sponsored Guide on the paragraph 6 mechanism, see F. Abbott & P. van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* (World Bank 2005).

12 See 'European Voice: Lamy access-to-medicine plan under fire', Press Clips-Médecins sans Frontières (17 January, 2003).

13 P. Lamy, *Towards World Democracy* (Policy Network 2004).

14 P. Lamy, 'The Place of the WTO and its Law in the International Legal Order', 17 *European Journal of International Law* 5 (2007): 982 and 984, respectively.

15 P. Lamy, 'The Place of the WTO', op. cit., p. 977.

Interestingly, on 14 July of 2009, in a panel with the theme 'Strengthening Multilateral Cooperation on Intellectual Property and Public Health' in a WIPO conference, Pascal Lamy and Margaret Chan were making the point that 'the whole is greater than the sum of its parts', and thus reinforced the need for major partnership, dialogue and policy coherence: "within our distinct mandates, we can each bring our own areas of expertise and work towards stronger, more broadly based and effective outcomes'. [16]

The first joint symposium on pricing and procurement policies, held in 2010, is an example of pragmatic initiatives with this vision in mind.[17] This particular event was designed to bring together their concurrent areas of expertise and collective data resources and know-how, as a basis for policymaking.

Concentrating on gathering sources of technical information and pooling practical experiences, this technical symposium was driven to move technical cooperation beyond the boundaries of formal overviews of treaty standards to real information exchanges on policy choices and practical experience in their implementation.[18]

In the words of the (then) WTO DG, 'the idea was not to engage in policy discussions or legal debate, but rather, it was a chance for us to look at how we could collaborate more closely and more effectively to provide a stronger, more coherent and more accessible information base for policy debate'.[19]

Also interestingly, the former Chairperson of the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH),[20] Ruth Dreifuss, closed the last panel discussion under the title *Taking Stock and Defining Future Needs*...

This trilateral cooperative program is a promising ongoing tool for upgrading coherence.

All three Director-Generals publicly refer to the 'cooperative program

16 P. Lamy. 'Urging multilateral cooperation to advance public health "in the real world"', WTO | *Speeches and statements* (14 July 2009).

17 See 'WHO, WIPO, WTO join forces to put access-to-medicines under the microscope', WTO | *2010 News items* (16 July 2010).

18 See *Creating Synergies between Intellectual Property Rights and Public Health*, Joint technical Symposium by WHO, WIPO and WTO (16 July 2010).

19 See 'TRIPS Symposium tackles how to know whether a medicine is patented', WTO | *2011 News items* (18 February 2011).

20 See *Public Health, Innovation and Intellectual Property Rights: Final Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health* (WHO 2006).

of the three Secretariats' as well as expressly underlining the importance of exchanges on practical experience and ideas for future cooperation and planning.[21]

In short, the three secretariats decided to foster a better understanding of the link between public health and intellectual property policies, and to enhance a mutually supportive implementation of their policies, by strengthening their cooperation with regard to the critical interface that is intellectual property and public health.

As a result, the three institutions began to work together more closely, in order to mutually assist each to fulfil its own mandate more effectively, to provide cross-support initiatives, to avoid duplication of their efforts and, ultimately, to use their limited resources more efficiently (e.g. technical assistance).

Thus, their trilateral program concentrated on coordinating technical cooperation and capacity building, promoting mutual participation in their respective activities, and pooling and sharing data resources to inform such technical cooperation.

An interesting output of this policy approach is a joint study by the WHO, WIPO and WTO Secretariats on access to medicines and innovation released in 2013.[22] This trilateral study is among the first of its kind,[23] and illustrates how such a simple thing as collective research initiatives can be a building block for the convergence of policy visions in critical areas.

Interestingly, the increasing tensions in this area are so enormous that even common inter-institutional documents such as this may help in contributing to framing the world policy issues in the best balanced light. In fact, at the famously derailed 18th session of the WIPO SCP (21-25 May 2012) mentioned above, the US Delegate warned other delegates against duplicating work, holding that the imminent publication of this joint study should reasonably predate any further work at the SCP (!)

Hence, the WHO, WIPO and WTO Secretariats can make a contribution to world policy coherence regarding access to medicines by enhancing and incrementally upgrading their trilateral program on technical cooperation.

---

21 See *Creating Synergies,* op. cit.

22 See *Promoting Access and Medical Innovation: Intersection Between Public Health, Intellectual Property and Trade* (WHO-WTO-WIPO 2013).

23 Before this trilateral initiative, a 171 pages bilateral joint study was produced in 2002 by the WHO and the WTO Secretariats. See *WTO Agreements & Public Health: a Joint Study by the WHO and the WTO Secretariat* (WHO-WTO 2002).

In this regard, the 2001 WTO Doha Declaration, the 2007 WIPO Development Agenda[24] and the 2008 WHO Global Strategy and Plan of Action[25] constitute in their own terms the concept framework for their joint initiatives. Arguably, the intertwining of these three instruments could provide promising building bricks for developing more policy synergies regarding access to medicines in the long term.

3. A key legal issue

There is an increasingly complex scheme of shared and complementary competences, functions and jurisdictions across the board of global institutional architecture. The intertwining of patent and health is a perfect example of the need to build new interfaces between international regimes.[26]

It would be reasonable to assume that administration of the increasing number of multi-jurisdictional issues dealt with through international regimes needs to shift the paradigm. Improving coherence requires upstream inter-institutional coordination (consultation, dialogue and diplomacy); particularly, in the absence of jurisdictional *fora* to solve possible conflicts and frictions among international regimes and their sets of rules and policies (e.g. WHO and WTO).

Inevitably, international regimes with shared competence will be required to converge in one way or another. As we live in a world of interdependent global jurisdictions, coherence requires inclusive inter-institutional approaches: international regimes have common interests, overlapping mandates, and complementary functions.

The interdependence of mandates, competence, and functions between these international regimes encourages inter-institutional coordination on a more profound level. At the present time, this can lead to several conflicts:

---

24 See *World Intellectual Property Organization Development Agenda,* Assemblies of the Member States of WIPO (General Assembly), Forty-Third Series of Meetings, Res A/43/16 (2007).

25 See *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, World Health Assembly 61st, Res WHA61.21 (2008).

26 For the first wave of UN human rights reports in this regard see, in particular, *Report of the High Commissioner on the impact of the TRIPS Agreement on human rights* UN Doc E/CN.4/Sub.2/2001/13 (27 June 2001) and *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health Report,* Special Rapporteur, E/CN.4/2003/58 (13 February 2003).

(1) Horizontal conflicts between the rules of their constitutive treaties (*A—B*);

(2) Horizontal conflicts between acts adopted by these regimes (*a—b*); and

(3) Conflicts between a constitutive treaty and an act adopted by other regime (*A—b* or *a—B*).[27]

In this regard, inclusive horizontal coordination among international regimes is the most feasible tool for increasing legal coherence (absence of antinomies) in current rule-based global governance. Needless to say, world policy coherence regarding access to medicines in the developing world would benefit from such an approach.

However, ministries and agencies with competence in economic areas have increased their policy leverage vis-à-vis other non-economic branches of government through the strategic use of the international regimes they manage and develop. As a direct result, non-economic agencies have been removed from developing "consensus".

Economic globalization is not a deregulatory but a reregulatory process in which certain social values are given preference over others. The international patent system analysed in these pages is a simple but critical example.

Hence, the modern architecture of global governance comprises a set of coexisting regimes. Thus, increased coordination and upstream engagement between these 'constituencies' can certainly help to promote coherence in the long term. Pascal Lamy explains with great clarity the challenge ahead in relation to the health and IP area:

> IP has moved to the centre of cross-cutting debates that defy traditional boundaries between separate policy domains, and between distinct areas of technical expertise. Coherence, cooperation and practical dialogue within the international system is indispensable, if we are to address these fundamental policy questions in a sustainable manner. [28]

As the WHO Commission on Intellectual Property and Health (CIPIH) also recommends, governments should ensure that health ministries are prop-

---

27 For an interesting case discussing the interaction between adjustment programs and WTO law see Appellate Body Report, *Argentina-Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items,* WT/DS56/AB/R (27 March 1998). Commenting on this case see also D. Siegel, 'Legal Aspects of the IMF/WTO Relationship: The IMF's Articles of Agreement and the WTO Agreements', *Current Developments in Monetary and Financial Law*, Volume 3 (International Monetary Fund 2005), pp. 572–576.

28 See P. Lamy. *'Urging multilateral cooperation'* op. cit.

erly represented in trade negotiations.[29] A more inclusive approach in international economic policymaking is required; and access to medicines is a critical example in this regard: as mentioned, a more balanced outcome with regard to IP protection would have certainly been delivered during the Uruguay Round negotiations if these had also involved some *external* trade-offs with health agencies, instead of mere *internal* trade-offs between trade agencies.

But there are also other critical issues to reconsider. In fact, paragraph 19 of the Doha Declaration instructs the TRIPS Council to pursue a work program which will cover new issues such as (1) the review of paragraph b of article 27.3, (2) the review of the implementation of the TRIPS agreement under article 71.1 and the work pursuant to paragraph 12 of the Declaration, as well as (3) the study of the relationship between the TRIPS agreement and the Convention on Biological Diversity.

In addition, complex issues of public international law are raised. For example, legal frictions between norms and/or acts from different international regimes tend to be solved or avoided applying the customary rules of treaty interpretation. However, these customary rules expressed in the Vienna Convention of the Law of the Treaties (VCLT) do not provide for neutral solutions. In practice, in the use of interpretation criteria as a method for integrating external norms in the functioning of specialized dispute settlement mechanisms (e.g. WTO dispute settlement system) these norms (e.g. WHO norms) take a 'backseat' in that interpretation.

Under section *c* of VCLT article 31.3, the operation of interpretation requires *taking into account* 'any relevant rules of international law applicable in the relations between the parties'. Therefore, interpretation is focused *on* a given norm and only takes "into account" those other norms, 'together with the *context'* of the latter. Thus, the two norms in tension (or direct conflict) are not interpreted together, nor are they given similar weight in the operation of interpretation: in practice, one is subordinate to the other. Obviously, this has clear implications for the outcome of the interpretation.

Alternatively, when interpretation cannot provide a solution, as a result of a contradiction between A and B (antinomy/conflict of rules), general rules on conflict of treaties apply (*lex posterior, lex specialis* and clauses of conflict). However, these rules cannot solve conflicts in every case; not only because they occasionally come up against cases of conflicts with no solution (e.g. later general treaty provisions vs. prior special treaty provisions with

29 See 'Recommendation 4.21', CIPIH Final Report, op. cit.p. 126.

both contradicting clauses of conflict or no clauses of conflict) but also because modern international regimes tend to operate in relative cultural isolation, as self-contained legal systems.

The TRIPS agreement is under the self-contained jurisdiction of the WTO. In essence, the applicable rules of the WTO dispute settlement mechanism are the covered WTO agreements (read WTO law). In consequence, this mechanism adjudicates (compulsory jurisdiction) and enforces TRIPS obligations (authorization to suspend concessions) but, for example, not human rights provisions. In this sense, the TRIPS agreement only incorporates by reference provisions from pre-existing treaties in the field of intellectual property (the Rome, Paris and Berne Conventions), but not international health law or human rights law.

Being unable to apply international human rights law and health law on an equal footing to WTO law, the WTO dispute settlement mechanism faces some challenges in order to properly balance competing public goods in this area.

Therefore, WIPO, WHO or the UN Human Rights regime could always develop legal interpretations conflicting with those of WTO. In practice, nothing precludes these regimes from developing their own 'unilateral' legal position on any issue (e.g access to medicines in developing contries).

This situation poses a considerable challenge to the international community, as world policy interdependence is pervasive. Clearly, low inter-institutional cooperation in areas of shared competences among these international regimes (ie. access to medicines in the developing countries) could produce global policy tensions. Recommendation 14 of the WIPO Development Agenda is illustrative in this regard:

> Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement.

Obviously, the legal issues arising from this type of inter-institutional coordination cannot be managed with traditional legal tools. New methods have to be explored as there is no such a thing as a neutral world forum for adjudicating conflicts or frictions between these bodies of international law.

Thus, it would be reasonable for diverse specialized agencies (whether trade, health or other related areas of government) to work closely together

to develop concerted legal policies at a global scale in sensitive areas. In this regard, more formal contacts and regulatory dialogue are required in order to foster inter-institutional coordination between these regimes.

Reasonably, article 31.f of TRIPS as well as the so-called paragraph 6 mechanism designed to solve its problems, are already a textbook case study of how not to manage global policymaking. Having access to the trade-related expertise of other ministers (health ministers) as well as of the global institutions in which they operate (WHO) could have avoided WTO Members getting trapped both in the biased drafting of article 31.f of TRIPS as well as the subsequent controversial (e.g. malfunctioning) paragraph 6 'solution'.

Non-communicable diseases (NCDs) could also be another case study of how not to manage global policymaking. As is widely acknowledged among world health experts, non-communicable diseases (chronic diseases or Type I diseases) are rapidly increasing in developing countries.[30]

As a result, some developing countries are beginning to issue compulsory licenses (CL) for these diseases (e.g. Thailand´s CL orders for treatments for cardiovascular disease and cancers).[31]

However, many trade representatives from developed countries are not eager to interpret the term 'essential medicine' contained in the 2001 Doha Declaration on TRIPS and health Policy as covering generic versions for non-communicable diseases able to export.

Reasonably, these and other sensitive issues could be better tackled by deepening upstream engagement with other specialized regimes which have concurrent competence in the field, such as the WHO.

In short, there is a wide variety of cases in which such collaboration and coordination would be highly advisable from both a legal and policymaking perspective.

Currently, the WHO is the global specialized agency bringing together the mandate, legal authority, and public expertise on issues of global public health.[32] Thus, the WHO could improve the solutions devised within the world trade regime on health-related issues.

The WHO is the legally mandated global institution responsible for

30 See e.g. G. Alberti, 'Non communicable diseases: Tomorrow´s pandemics', 79 *Bulletin of the World Health Organisation* 10 (2001): 907.

31 E. Hoen, *The Global Politics of Pharmaceutical Monopoly* op. cit., p. xvi.

32 See A. Taylor, 'Governing the Globalization of Public Health', 32 *Journal of law, medicine and ethics* 2 (2004): 507.

world health strategies.[33] Improving coherence in global policymaking requires its expertise to fertilize the WTO regime. Hence, regarding access to medicines in developing countries, the world trading system should grant legal deference to WHO determinations on critical issues such as the following, among others:

(1) *What* constitutes a 'public health crisis' or a 'health emergency',
(2) *Which* are 'essential medicines', etc.

Thus, it is reasonable to argue in favour of paying due legal deference to WHO health-related fact determination inside WTO procedures.

The WTO Dispute Settlement Understanding (DSU) already contains several provisions referring to fact determination. Ironically, however, the only global institution which is expressly granted relevance with regard to fact determination pursuant to the DSU is the International Monetary Fund (IMF), in the field of balance of payments.[34]

Paying due legal deference to the WHO inside the world trade regime could make a positive contribution to the functioning of the WTO regime and, by extension, to the coherence of global policy making.

The WHO constituency is well aware of it and, in fact, already claims more deference from the WTO. In fact, the WHO Resolution on the Revised Drug Strategy in 1996 already request that the WHO 'report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO'. Interestingly, the Resolution also mandated the compilation of a 'WHO Guide' containing Recommendations concerning TRIPS implementation.[35]

In a globalizing world, treaty interpretation of highly sensitive areas requires some form of multi-institutional collaboration. In this regard, the

---

33 Surprisingly, it has not been very active on international law-making in the past. Taylor attributes to WHO's organizational culture its traditional conservatism on the use of legal institutions for promoting health. See A. Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health', 18 *American Journal of Law and Medicine* 4 (1992): 301–346.

34 See F. Roessler, 'The relationship between the World Trade Order and the International Monetary Fund', *The Legal Structure, Functions and Limits of the World Trade Order: A Collection of Essays* (Cameron May 2000), pp. 157–159.

35 See, respectively, *Revised Drug Strategy Resolution: WHO Assembly Resolution,* WHA 49.14, (1996) and G. Velasquez & P. Boulet. *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement* (WHO 1999).

interpretation of TRIPS provisions cannot be an isolated and exclusive competence of WTO bodies in those cases in which competence and authority is shared with other international regimes. From a purely technical standpoint, these regimes have concurring jurisdiction over the *same subject-matters*.[36] Thus, only collectively negotiated interpretations in those highly sensitive issues could reasonably secure the coherence of both global governance and international law.

For example, it would be reasonable to argue that the WHO could help in developing a flexible interpretation of the TRIPS rules with regard to NCDs, as these diseases are becoming increasingly prominent in global health governance.

In fact, a first WHO global ministerial conference on healthy lifestyles and non-communicable disease control was held in Moscow on 28-29 April 2011 and a UN High-level Meeting of the General Assembly on NCDs on 19-20 September of that same year have already set the ball rolling.

As mentioned, the WHO institutional bodies always have the possibility of providing their own policy guidance over WTO rules. Interestingly, for example, the WHO Regional Office for the Eastern Mediterranean published a *Policy Guide on Public health related TRIPS-plus provisions in bilateral trade agreements* on his own in 2010;[37] and the WHO published a Policy Brief in 2011 on how countries can use TRIPS flexibilities to improve access to HIV/AIDS treatment together with UNDP and UNAIDS.[38]

The ministers of health are already suggesting that the scant deference paid to the rulemaking processes led by trade ministers in health-related areas is not reasonable, and not even legitimate.

This is particularly the case in the area of TRIPS+ schemes. As already mentioned, 10 South American Ministers of Health adopted *the Declaration of Ministers of South America over Intellectual Property, Access to Medicines, and Public Health* in May 2006 to establish a united position against TRIPS+ schemes negotiated by their cabinet colleagues.

---

36 See P. Zapatero, 'Modern international law' op. cit.

37 See *Public health related TRIPS-plus provisions in bilateral trade agreements: A Policy Guide for negotiators and implementers in the WHO Eastern Mediterranean Region* (WHO & ICTSD 2010).

38 See *Using TRIPS flexibilities to improve access to HIV treatment*, UNAIDS, WHO and UNDP Policy Brief (13 September 2011).

4. Individual rights

Certainly, a similar diagnosis also applies to the UN human rights regime. In this regard, the Committee on Economic, Social and Cultural Rights has developed some authoritative interpretations on the right to health contained in the ICESCR (article 12.1) over the years. As a result, the main authoritative interpretation of the human right to health is contained in its General Comment no.14 (adopted by ECOSOC on May 2000, Session 22th):[39] this highly structured instrument builds upon the experience gained by the committee in examining reports from state parties and is expressly designed to assist the states on the implementation of the Covenant.

General Comment no.14 contains a well-organized regulatory structure: (a) normative content (part I), (b) obligations of state parties (part II), (c) violations (part III), (d) national implementation (part IV) and (e) obligations of non-state actors (part v). This authoritative instrument is made up of "interrelated and essential elements" that depend on diverse conditions: (a) availability; (b) accessibility (non-discrimination, physical accessibility, and affordability and information accessibility); (c) acceptability and (d) quality (paragraph 12). In accordance to its provisions, international right to health imposes three types of obligations on states parties: *Obligations to respect* (non-state interference); *Obligations to protect* (prevention of interference by third parties) and *Obligations to fulfil* (facilitation, provision and promotion).[40]

These obligations also correlate with three forms of infringement codified in the Covenant: (a) violations of the obligation to respect, (b) violations of the obligation to protect and (c) violations of the obligation to fulfil (Part III).

Finally, state compliance is dependent on 6 'core obligations' and 5 'obligations of comparative priority'. The 'core obligations' require ensuring the satisfaction of, at least, 'minimum essential levels of the rights' specified in both the Covenant and the General Comment no.14. These obligations are complemented by 5 additional *obligations of comparable priority* (paragraph 43-45).

---

39 See 'The right to the highest attainable standard of health', *General Comment No.14,* UN Doc E/C.12/2000/4 (4 July 2000).

40 See *General Comments No.12* & *No.13* ('to facilitate' and 'to provide') and *General Comment no.14* ('to promote').

In consequence, it is reasonable to argue that *core obligations* on the right to health (paragraph 43) should have some legal relevance in WTO law and procedures. In this regard, some of the *general* core obligations are "*to ensure* the right of access to health [...] goods and services on a non discriminatory basis, especially for vulnerable groups" (subparagraph a) and "*to ensure* the equitable distribution of all health [...] goods and services" (subparagraph e).

In addition, the *specific* core obligations insist on the need '*to provide* essential drugs', as defined under the WHO Action program on essential drugs (subparagraph d); reasonably, such provision should be legally relevant for TRIPS implementation purposes.

In a similar vein, some *obligations of comparable priority* (paragraph 44) are arguably also required to have some legal relevance inside WTO law and procedures: '*to provide* immunization against the major infectious diseases occurring in the community' (subparagraph b) and '*to make measures* to prevent, treat and control epidemic and endemic diseases' (subparagraph c).

Interestingly, General Comment no.14 already takes the interdependence of treaties into consideration with regard to article 12.1 of the covenant. Thus, this instrument determines that states parties should ensure that the right to health is given '*due attention* in international agreements' and, to that end, should consider 'the development of further legal instruments' (paragraph 39).

Accordingly, states parties should take steps to ensure that other international agreements '*do not adversely impact upon* the right to health': states have an obligation '*to ensure that their actions* as members of international organizations *take due account of* the right to health' (paragraph 39).

On the other hand, the General Comment also adds that international organizations, UN specialized agencies, subsidiary organs and programmes '*should cooperate* effectively' with states parties to implement the right to health at the national level, 'with due respect to their individual mandates' (paragraph 64).

Last but not least, article 22 of the covenant states that ECOSOC may 'bring to the attention' of other UN organisations and bodies 'any matters' arising out of the reports referred to in the covenant which may assist such bodies in 'deciding, each within its field of competence, on the advisability of *international measures likely to contribute to the effective progressive implementation* of the [covenant]'.

Therefore, there is a simple but critical question to answer: how are these rules rebalancing the TRIPS agreement in relation to effective access to affordable medicines in developing countries? Unfortunately, the answer is self-evident.

7

SHOULDERS OF GIANTS *INC*

1. Pathologies

A decade ago, not a single developed country was spending more than 10% of its health budget on medicines. However, nowadays, national expenditure estimates on pharmaceuticals are increasing faster than GDP in all developed countries.

Our health authorities are devoting an increasingly high percentage of their health spending to drugs. Currently, the percentage of GDP devoted to this budget line is around 12% in USA, 15% in Germany, 22% in Spain, 16% in France and 17% in Canada, for example. As a result, needless to say, fewer resources are available for other valuable public purposes.

Added to this, individuals without universal health coverage also pay more for their drugs in pharmacies, or through private insurers as the latter are raising contributions and/or reducing coverage benefits.

Unfortunately, these issues are not easy to tackle for strong reasons. As mentioned above, for decades, modern patents systems have created exorbitant returns on revenues, assets and shareholders' equity, thus the pharmaceutical industries are annually ranked as among the most profitable industries of the world.

Notwithstanding the fact that these revenues are highly concentrated in the markets of developed countries, the international patent system has severely fuelled shareholders' expectations on high (and increasing) returns from investments on pharmaceutical innovation and marketing.

In essence, the international patent system has produced a 'global money illusion' of exponential increases of corporate profits, as corporations are legal proxies of capital-holders that raise the bar to obtain those expected profits.

As a result, patent-holding companies in the pharmaceutical area (and other IP-based industries) invest part of their earnings on securing and ex-

panding the worldwide monopoly rent exacted from the international patent system.[1]

For the WHO CIPIH, 'companies should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low income developing countries, they should avoid filing patents or enforcing them in ways that might inhibit access'. Interestingly, the commission also made a recommendation concerning and concerned with regulatory capture:

> Companies should not lobby governments for more stringent standards than those contained in TRIPS agreement.

Last but not least, the CIPIH encouraged companies 'to grant voluntary licences in developing countries, where this will facilitate greater access to medicines, and to accompany this with technology transfer activities'.[2]

However, these socially wasteful income-seeking strategies of IP companies cannot easily be inhibited through initiatives of corporate social responsibility (CSR). Patent-holding companies are not run by unethical persons but by socially non-efficient structures of incentives.

In short, pharmaceutical companies are tied too tight to the mast of profit maximization by (1) modern corporate law, (2) the corporate form itself and, last but not least, (3) the mantra of shareholder value, which lies at the core of financial markets.

Beneath the surface of branded wonder drugs of east and west, accumulation of capital by those who have it (capital-holders) is the structure of incentives that make pharmaceuticals perform in that way. These companies are simply an efficient proxy of such phenomenon.

Therefore, there is no room for naivety regarding global rulemaking politics in our brave new world of expert regulatory networks. Nowadays, considering treaties as 'public goods' per se equates to pop internationalism, as these are sometimes negotiated under corporate advice, and thus pursuing policies with restricted rationalities.

The long term impact of some of these instruments should not be underestimated, as the reform of their provisions leads to high transactional

---

1 See, particularly, S. Picciotto, 'Private rights vs public interests in the TRIPS agreement: the access to medicines dispute', *Proceedings of the annual conference of the American society of international law* (2003) at 167.

2 See CIPIH Final Report op. cit at 181 (paragraph 4.16).

costs once these are in force. In sum, once a given IP treaty enters into force, its rules are here to stay, in principle, for decades to come.

Treaties involve high transaction costs. They are rather like old seagoing galleons, requiring too much effort and resources to build and sail them. However, once launched, there is no easy route to reconstructing them or simply getting them out of the water.

Hence, if IP treaties end up serving the public interest badly, a lock-in phenomenon raises the costs for suspending, reforming or getting rid of these rigid regulatory structures.

Achieving more balanced treaty outcomes in the IP area requires transparency in negotiations, open consultations with all stakeholders, and non-economic domestic agencies and branches of government (e.g. culture, science, health, etc) coming to the negotiating table. Last but not least, it is also advisable to pursue a more committed parliamentary participation in these processes.

Nowadays, the IP foreign policy of developed countries in all treaty-making fora and venues basically perpetuates the legal competitive advantage of large patent-holding companies, by protecting and promoting their knowledge monopolies multi-jurisdictionally.

These corporate-driven policies not only block the functioning of markets and competition but also economic development of technology-importing countries.[3] As a result, strong policy tensions are pervasive in all IP and IP-related global fora.[4]

The Standing Committee of the Law of Patents (SCP) of the World Intellectual Property Organization (WIPO) is a particularly illustrative example. Resulting from the new structure of incentives erected by the TRIPS agreement, differences between the so-called Development Agenda Group and Group B (industrialized countries) are increasingly difficult to bridge on such critical agenda items as 'quality of patents', 'patent and health', 'exceptions and limitations to patent rights', or 'technology transfer', among others.

On the other hand, some traditional pathologies of patent systems with regard to R&D have been exacerbated. In principle, patent systems provide incentives for getting involved in innovation, by granting government-sponsored legal monopolies over inventions for specific periods.

---

3 See chapter 8.

4 See *Joint Proposal by the African Group and the Development Agenda Group SCP Work Program on Patents and Health*, SCP/16/7 (16-20 May 2011).

However, the international patent system raises some puzzling tensions in the process of turning scientific ideas into proprietary inventions in life-sciences. These are some adverse effects of modern patent ecosystems in life-sciences:

(1) increasing distortions of the research agenda (research bias),
(2) disincentives to pursuing scientific research on non-patentable processes,
(3) incentives to researching patentable products and services with little or no gain,[5]
(4) wasted research into duplicate products and services (copycat or "me-too" products and services),[6]
(5) disclosing information required to obtain patent approval and increasing secrecy in scientific research,
(6) secrecy and concealment of negative research findings and unwelcome results,
(7) misleading public opinion for economic gain by using questionable research outcomes or biased findings and
(8) hard core spending on marketing.

Arguably, patent-based research is inconsistent with the disinterested scientific pursuit of truth, but also with full disclosure and open access to scientific outcomes.[7] For many, in this regard, IP-based profit-oriented research blurs the very foundations of science which, on its own terms, is open and co-operative. Last but not least, it inhibits or limits the spread of critical academic research on issues that are structurally important for big patent-holders.

Under current patent systems, 'competitors' have also strong incentives to create new, different and better inventions, either by making improvements or, alternatively, by creating an entirely new equivalent product, and thus 'inventing around' patents.

As a result, 'patent races' among competing firms are common; the first prize is patenting a 'breakthrough drug'; but there are some other gains too: the so-called 'me-too drug' above referred also pays off.

Thus, for example, the allocation of research resources to extend market control beyond the life of original patented drugs ('ever greening') diverts

5 See P. Trouiller, P. Olliaro, E. Torreele, J. Orbinski, R. Laing & N. Ford, 'Drug development for neglected diseases: a deficient market and a public health policy failure'. 359 *The Lancet* 9324 (2002): 2188–2194.

6 D. Weatherall, 'Problems for Biomedical Research at the Academia-Industrial Interface', 9 *Science and Engineering Ethics* (2003): 43–48 and D. Packham & M. Tasker, 'Industry and the Academy–a Faustian Contract?' 11 *Industry and Higher Education* 2 (1997): 85–90.

7 See in particular P. Suber, *Open Access* (MIT Press 2012).

scarce productive resources towards cumulative patents, which are generally socially inefficient.[8]

However, patent systems are 100% blind to this weak (or even lack of) inventiveness when it comes to granting protection to 'invention'. As a result, many new drugs entering the market are equivalent to existing ones in terms of their chemical structures and therapeutic effects. Last but not least, all patented inventions are worked out by propertizing public scientific innovation resulting from very long-term public-funded research.

2. Life and Death

Obviously, these phenomena disrupt the inner logic of current public law incentives (read legal monopolies) targeting breakthrough innovation. Society should not to put all its eggs in the basket of exclusive right regimes in order to deliver breakthrough inventions.[9] Fortunately, as long as modern patents exist, there will also be alternative incentives to spur innovation; and here, there is still wiggle room to enter into major explorations.

The critics basically argue that less burdensome mechanisms could obtain equivalent outcomes without incurring in the social burdens of modern patent systems. In consequence, many innovation experts are aiming to transform IP ecosystems for optimizing innovation through more effectively tailored rewards. In this regard, an increasing variety of policy substitutes and/or supplements to patent systems are already available.

However, the transaction costs of obtaining legal reforms in this frontline of knowledge-based capitalism have sky-rocketed, as the world is already covered by a thick membrane of rules and institutions inhibiting replace-

8 Any non-sponsored estimates of drug's industry research budgets are rather striking when compared with their domestic sales and profits. See e.g D.W. Light & J. Lexchin, 'Will Lower Drug Prices Jeopardize Research? A Policy Fact Sheet', 4 *The American Journal of Bioethics* 1 (2004): W3–W6. For independent measurements of the contribution to R&D by the US pharmaceutical industry, see in particular, *Research and Development in Industry: 2000* (National Science Foundation 2003). For a global comparison see P. Barral, *20 Years of Pharmaceutical Research Results throughout the World: 1975-1994* (Rhone-Poulenc Rorer Foundation 1996).

9 See E. Von Hippel, *Democratizing innovation* (2005), Y. Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (Yale University Press 2006) and C. Doctorov, *Makers* (2009).

ment. In short, patent ecosystems are nowadays at the core of the matrix of global power-politics.

In any case, there are alternatives available. The current debate over patents in this regard is focused on how to fine-tune patent systems in order to win them back for public interest and thus as long-term (legal) innovation infrastructure.

However, there are also a number of innovation policy tools available which can be promoted irrespective of future policy evolution regarding this debate. The main tools consist of 'push mechanisms' to subsidize R&D costs (e.g. grants, equity participation, tax credits) and 'pull mechanisms', paying for the R&D output (e.g. advance purchase, prizes).[10]

The WIPO Development Agenda is one of the venues in which reforms are being discussed. Part of these initiatives build upon the global policy experiences in the health area over the last decade; one of them being the Global Forum for Health Research, founded in 1997 and convened annually to address the 10/90 Gap in Health Research.

In addition, WHO has made some serious improvements in health research systems analysis, and its Advisory Committee on Health Research has already identified a number of priority global research initiatives.[11] Finally, the International Conference on Health Research for Development (Bangkok 2000) made health research visible at the core of the UN Development Agenda; and some developments are in the offing.

Also importantly, the high-level WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) delivered a widely recognized report in 2006 proposing some policy guidelines, including recommendations regarding alternative mechanisms to promote innovation. In this influential global report, for the first time in history, *innovation* was linked to *access*.

The report's definition of the term 'innovation' was defined as including 'delivery' (access to results of innovation), and not only the standard 'discovery' and 'development'. Last but not least, for the CIPIH, patents tend to be only effective legal incentives for R&D projects addressing diseases in wealthy societies:

Where the market has very limited purchasing power, as is the case for diseases affecting

10 C. Correa. 'Fostering R&D and promoting access to medicines' op. cit.

11 See *World Report on Knowledge for better health: Strengthening Health Systems* (WHO 2004).

millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market…For developing countries where the demand is weak – not the need — there is little incentive to develop new or modified interventions appropriate to the disease burden and conditions of the country.[12]

All in all, for the most authoritative commission in last decades, patents are considered to be only effective for *profitable markets*…

As an immediate result of these and other critical findings and determinations, a World Health Assembly Resolution mandated the WHO in 2007 to encourage exploration on new incentive mechanisms.[13]

In short, the international patent system is unsuccessful in developing targeted medicines for diseases affecting those countries lacking substantial markets, as a logical outcome of non-affordability: patent-centred innovation is market-driven and thus highly dependent on the relative size of the targeted market.

In this regard, it is already out of question that the international patent system set up in 1996 does not provide the proper incentives for R&D on prevailing diseases which primarily affect the population of developing countries (neglected diseases).

Patents systems do not stimulate R&D in situations where the average buyer of a potential product, whether individual consumer or public authority, lacks sufficient purchasing power to pay for the expected profits margins required by the business model of the brand-name pharmaceutical industry.

Thus, the structural incentive of earning patent-protected profits only promotes innovation in diseases of those societies where the monopoly prices of brand-name medicines are affordable by strong public health systems (read procurement programmes) or, alternatively, a significant middle-class population.

Hence, the combination of patents systems with large corporations carrying out R&D in profit-maximizing mode (read shareholder value) does only contribute to innovation in wealthy markets.

The industry simply allocates most resources to the development of medicines that primarily affect wealthy societies. In technical term, the system does not provide for incentives regarding R&D on *neglected diseases* and *very neglected diseases*. Diseases prevailing in developing countries are sci-

12 See *CIPIH Final Report* op. cit., p. 34 and p. 36.

13 See *Resolution WHA 60.30 on Public Health, innovation and intellectual property* (23 May 2007).

entifically indexed as Type II (*neglected diseases*) and Type III diseases (*very neglected diseases).*

In this regard, on the one hand, Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries (e.g. HIV/AIDS and tuberculosis); on the other, Type III diseases are those that overwhelmingly or exclusively occur in developing countries, such as African sleeping sickness (Trypanosomiasis), or African river blindness (Onchocerciasis).[14] In essence, the lack of demand makes patent protection relatively relevant for Type II and relatively irrelevant for Type III diseases.[15]

Thus, the international patent system fails to promote pharmaceutical innovation for neglected diseases primarily affecting the poor, such as malaria, tuberculosis, meningococcal meningitis, trachoma (Chlamydia trachomatis), Kala-azar (visceral leishmaniasis), Chagas' disease (American trypanosomiasis) or sleeping sickness (African trypanosomiasis).

Notwithstanding that basic research is being done on some of these diseases, patent-based business preferences are inhibiting both preclinical research and the entry of drug projects in the clinical development process.

However, the problem goes far beyond having more new medicines in the pipeline, or bringing unprofitable abandoned drugs back into production: a portion of the medicines targeted at diseases causing mortality in developing countries is becoming increasingly ineffective.

The catch phrase encapsulating the challenge is the so-called '10-90 gap': 10 percent of global health research resources are targeted at combating the most severe diseases affecting 90 percent of the world´s health problems.[16]

Whether those are the exact numbers or not, there is a critical gap, thus proving that the mere globalization of patent systems has not precisely promoted R&D benefiting all the peoples of the world.[17]

---

14 See CIPIH Final Report, op. cit., pp. 28–29.

15 See C. Correa, 'Fostering R&D and promoting access to medicines', *New ICTSD Series on New Opportunities through Innovation* (2007).

16 Notwithstanding that the disease burden differs across countries, the 10/90 gap is a useful concept for drawing attention to the fact that few resources are spent on diseases affecting the societies of developing countries. See '10/90 Reports on Health Research', *Global Forum for Health Research Fatal Side Effects: Medicine Patents Under the Microscope* (Oxfam 2000).

17 For the estimates which gave birth to this catchphrase see *Health Research:*

3. IP for π

On similar grounds, there are reasons for carefully rebalancing the international patent system in order to promote open science.[18] For centuries, the free flow of information was the hallmark of science. The human quest for science is based on openness[19] and collaboration,[20] in which scientists learn from their peers, in a networked process structurally based on collective cross-pollination and open imitation (scientific openness and collaboration).

Inventors are not foreign to this ongoing social practice and, as a result, extensively borrow from the ideas and information produced by others; we all advance by drawing on pre-existing knowledge. Newton writing to Hooke in 1676 is always agreeable to read and always helpful in framing the problem; 'if I have seen further it is by standing on the shoulders of giants'.[21]

However, it is not easy to imagine ourselves standing on the shoulders of a scientific industrial complex, at least in order to see further. Probably we would not stand on its shoulders but under its feet. Proprietary-scientific knowledge is a serious game.

Traditionally, the reward of peer reputation among scientists was directly related to the diffusion of knowledge, and thus endeavors were pollinated through communication of scientific research in journals, conferences, dialogues and conversations. That vision is thus at odds with the secrecy-based appropriation and commercialization of scientific knowledge through patent filing.

Public universities have been major incubators of innovation in last centuries. In fact, the educational systems establishing the infrastructures that created modern science –in which patent-holding companies profit nowadays– were set up by the taxpaying public. Added to this, public investment funded most of the basic research for key technologies predating the global revolution in proprietary knowledge.

Essential Link to Equity in Development (Commission on Health Research for Development 1990).

18 See *Keeping science open: the effects of intellectual property policy on the conduct of science*, Royal Society (14th April 2003).

19 P. David, 'Common Agency Contracting and the emergence of "open science" institutions', 88 *American Economic Review* 2 (1998): 17.

20 R. Merton, *Sociology of Science* (University of Chicago Press 1973).

21 R. Merton, *On the shoulders of giants: A Shandean Postcript* (Free Press 1965).

However, intellectual property is deconstructing scientific innovation, by reversing the inner incentive structures of universities. In this regard, the old university ideal –that purporting knowledge as the common heritage of humankind– is currently undergoing a transformation.[22]

The expansion of patent culture within universities, together with the scarce public resources available to them, are pushing for managerial strategies rewarding university-originated patents, and thus for patent positions in applied science.

Thus, the emerging model softly replicates the profit-oriented culture of corporate research departments and centers around the world.

Patents and royalties do not yet represent a major source of university revenue generally, but public funding is in decline and not expected to recover at any time soon. Thus, the academic institutions are embracing patent-based strategies for obtaining alternative sources of revenue.

By playing the patent game, universities emulate corporations. However, by emulating these for-profit organizations, universities are turning public goods into private ones. Like it or not, universities playing this game are recycling public information into proprietary knowledge; and by doing so, their scientists inevitably swap priorities from publishing in scientific journals (open/commons) to patent journals (proprietary/appropriation). [23]

A clear example on the impact of patent-based academic entrepreneurship is the 1980 Bayh-Dole Act, allowing US universities to own patents in inventions developed with federal funds.[24]

Originally, patents obtained with federal funds were transferred to the funding agencies, or simply entered the public domain. However, the Bayh-Dole Act accelerated the expansion of patent culture among academic scientists and institutions in the United States, by offering them a promised land of extra earnings and funding (royalties).

Certainly, university income obtained from the licensing of IP in publicly funded technology (e.g. biotech) has expanded in some top US institutions; although the rest is not profiting equally and, in fact, now face difficulties using proprietary biotech research tools. Thus, the 'best practices' of

---

22 For a critic see S. Zolla-Pazner, 'The Professor, the University, and Industry', 268 *Scientific American* 3 (1994): 120.

23 P. Drahos, *Information* op. cit., p. 42.

24 See, in particular, H. Markel, 'Patents, Profits, and the American People —The Bayh–Dole Act of 1980', 369 *New England Journal of Medicine* (2013): 794–796.

some top universities (e.g. Ivy League) are a false retribution-model for those others lacking their old corporate roots, ties and resources.

The entrepreneurial twists and turns of academic science mean that universities join and foster patent races by managing proprietary knowledge generated by their scholars along private sector lines.

The rationale is evident. On one side, these institutions aim to increase licensing revenue to fill the vacuum of shrinking public funds. On the other, taking strategic patent positions is a rational decision to improve the bargaining position (read offer/sell proprietary knowledge) in the negotiations of research contracts, grants and long-term agreements with for-profit funders.

However, the payoff involved is not a free meal for all. In order to play the game more effectively, some universities are already conditioning staff promotion on obtaining patent applications and/or corporate research grants.

Thus, as the structure of incentives within universities changes, researchers become less motivated to explore research areas where there are no patent payoffs: that is to say, researchers have less incentive to pursue projects which do not promise commercial profits.

Needless to say, many of those are basic science projects. Also interestingly, most of what is currently patented by the public sector is applied science, and it generally flows to the private sector via licensing.

4. Sponsorship

Profit maximizing organizations embracing and expanding the global patent game, if possible, is something to be expected. On the contrary, universities replicating patent-based corporate behavior regarding science is not at all to be expected, and thus is a phenomenon of concern.[25] In this regard, public-public partnerships (ppps) in science should be carefully regulated in the general interest.

Not surprisingly, the profit calculations that companies commonly make on the payoffs of basic research are already present in academic research, as academic research moves down the ladder of applied science in order to adapt itself to the patent game (narrow subjects and quick payoffs).

25 See Anonymous, 'Is the University-Industrial Complex Out of Control?' 409 *Nature* 119 (11 January 2001).

In this regard, the scientists giving preference to projects with commercial value tend to focus on producing those innovations corporations could be interested in buying (patenting) and selling (licensing). Obviously, these are not the breakthrough inventions that patent systems were reasonably thought to work for.[26]

On the other hand, curiosity and independent exploration are how some of the most unpredictable yet beneficial results of science are discovered. In principle, universities and academic researchers had different missions and incentives to those of directly controlled corporate research centers and researchers. However, and paraphrasing Drahos and Braithwaite, in a meeting of two research tribes, the public and the private, the public adopted the mores (the patent mores) of the private.[27]

Company profit maximization is the essential legal structure of incentives embedded in modern corporate form and structure. Thus, it is hardly surprising that the appropriation of knowledge goes beyond scientific inventions to also enter, through copyright, scientific diffusion itself. In this regard, paradoxically, universities are currently paying royalties to access the publications of their own scientists.

In fact, at the end of the day, academic institutions pay significant license fees to publishers for publicly funded research which is written, edited and reviewed by their employees. Today, these items of knowledge are displayed in fee-based proprietary databases and journals. As a result, scientists make copies of their articles under permission of collective rights organizations (CROs) exercising delegated enforcement power by public law and publishers.[28]

As public funding for universities declines, so heads and chairs feel the need to offer all type of services to profit-making organizations. By doing so, universities may compromise scientific principles,[29] as the quest for proprietary knowledge within universities –and the concomitant rise of corporate-sponsored university funding– may block freedom of scientific enquiry in some areas, and also critical scientific debate and questioning.

---

26 On the changing degree of inventiveness in scientific patent-based research see, in particular, D Hicks, T Breitzman, D Olivastro & K Hamilton, 'The Changing Composition of Innovative Activity in the US – A Portrait Based on Patent Analysis', 30 *Research Policy* (2001).

27 P. Drahos & J. Braithwaite, *Information* op. cit., p. 165.

28 S. Picciotto & D. Campbell. 'Whose Molecule Is It Anyway? op. cit., p. 280

29 See, generally, T. Veblen, *The higher learning in America: Memorandum on the conduct of universities by business men* (B.W Buebsch 1918).

On one hand, universities dependent on corporate funding facilitate the private sector's setting public research agendas; on the other, unwelcome research outcomes can be inhibited or silenced. Reasonably, the communication of negative evidences and findings related to activities, products, goods, policies from corporate sponsors and funders seriously inhibits the regular flow of university finance. Putting it bluntly, this type of communication implies the non-renewal of corporate research contracts and grants at best; and legal actions for breach of non-disclosure clauses in research contracts and agreements at worst, provided that information was sensitive for the company interest.

Adding to that, critical academic voices related to corporate practices can be silenced or mitigated from within by managerial and peer pressure. Thus, academic freedom is likely to suffer.

Corporate funding of universities is not focused on obtaining philanthropic charm: corporate IP owners still depend heavily on the public sector and the public domain to sustain and expand profits and market share. Hence, companies forge links with universities because they are dependent on public science in all fields of technology, including pharmaceuticals and biotech.

Universities supply facilities and low-wage researchers, and corporations supply funding; as a result, patent-holding corporations expand or sustain their competitive advantage and market-share by managing to redirect part of the publicly funded resources of basic science. Thus, the knowledge obtained from public-funded research under contract or grant is generally channeled to corporate patent portfolios, which is later charged again to the general public by the patent-holder or the patent licensee.

Obviously, universities obtain some extra funding in the process (x amount). However, by compromising science, universities end up captured within the proprietary maze of knowledge-based capitalism.

The appropriation logic is almost unbeatable: on one side, once public science has identified an opportunity at the taxpayer's expense, corporations claim the whole fruit of that knowledge as private property; on the other, their patent-based partnerships offer some part of that fruit (IP) to universities (retribution).

Therefore, in one way or another, patent-based partnerships between universities and corporations recycle public knowledge for private reward.

Finally, commercialization of knowledge produced by university re-

search has a non-egalitarian effect: by rewarding scholars for obtaining patents, research projects are redirected to prioritize the needs of those who have resources to pay for the IP bonus; thus not research on neglected diseases, for example.

Hence, and regarding pharmaceuticals, scientific research is channeled towards the health needs of wealthy societies and individuals, not on the needs of have-nots, following the same pattern of corporate research centers.

Scientific behavior changes when scientists become patent oriented. In this regard, some researchers who worked openly have moved to for-profit research in secrecy, as the free flow of information is a major threat to profitable opportunities. The prospect of a new scientific paradigm based on research contracts papered with clauses of confidentiality is dispiriting.

8

SUPER-ASSETS

1. Legal monopolists

The practice and theory of information goods helps to conceptually frame the challenge of a strong global IP paradigm. Information goods are 'non-rivalrous'; that is, the fact that one person uses them does not restrict others from using them as well. All the costs incurred in producing such goods are allocated to making the first copy; the development of these goods involves high initial 'sunk costs' but the 'marginal cost' of producing subsequent units is minimal;in fact it is close to zero.[1] In short, additional revenue from exploitation is close to gross profit.

Patents are 'propertized' information goods. Their rationale is conventionally framed by explaining that they provide inventors with sufficient incentives to invest time and resources on innovation. Thus, a patent confers government-granted monopoly rights over an invention for a fixed period of time, by giving its holder control over the legal conditions of the invention to be produced and distributed (commercial exploitation) in goods and services.

As innovation involves a high ratio of fixed to variable costs, the larger the market for the invention, the likelier it is that fixed costs will be recouped. However, under the international patent system perfected in 1996, protection is available in all jurisdictions in which the patent has been granted.

Consequently, the patent-holder may decide on whatever fits her plans, whether to market inventions directly, to license them in some or all domestic territories (right to exploit invention), or even to leave the patent unworked.

Thus, until patent protection ends, an 'orderly marketplace' of sequential windows of exploitation are produced on a global-scale either directly, through ownership, and/or indirectly, through vertical contract, all governed

1 For the canonical explanation see K. Arrow, 'Economic Welfare and the Allocation of' op. cit at 609–626. For an analysis within A2K theory see Y. Benkler, *The Wealth of Networks* op. cit.

by the patent-holder. During that period, the patent-holder is allowed to control the commercial conditions both for accessing the invention (read royalties for licensees) and the goods and services built on that invention (read monopoly price for consumers).

Patent-holders, particularly large companies, can play out their 'property' across multiple jurisdictions, maximizing global returns from their inventions, by subdividing territories in potentially unlimited 'windows'; 'territories' rather than 'markets', as the goods and services that are distributed using IP are controlled through the government-granted legal monopoly of patents.

From a capital-maximizing perspective –namely that which is embedded in the corporate form and structure–, the patent game is based on the exploitation of a monopoly by supplying or authorizing the supply of patent-based goods and services in its country of origin as well as any other foreign territories.

Hence, the business practice is based on subdividing or segregating territories into 'windows' of exploitation. However, by running this 'orderly marketplace', the plurality of domestic territories contributes to the invention's potential total payout beyond any reasonable expectations.

In this regard, patent-based innovation would result in lower social costs (e.g. life-or-death products and services) if these inventions entered the global public domain, once the innovation (R&D) costs are amortized, and a premium has been obtained during the period of protection. However, the incentives structure of the international patent system currently fails to decouple world-scale patent-based profits and innovation costs on unconvincing grounds.

Patents entail the artificial creation of scarcity by radical state intervention.[2] From centuries, the objects of property become capital through contract. Property law constitutes the objects of property, and contract enables the exchange of those objects.[3] The protection of both property and contract promotes economic development.[4] However, once propriety and contract are assured, capital-holders have moved ahead, expanding the sphere of security and thus that of what can be 'propertized' and contracted.[5]

---

2 See S. Picciotto & D. Campbell, 'Whose Molecule Is It Anyway?'op. cit.

3 J. Braithwaite & P. Drahos, *Global business* op. cit., p. 54.

4 D. North, *Institutions, Institutional Change and Economic Performance* (Cambridge University Press 1990).

5 J. Braithwaite & P. Drahos, *Global business* op. cit., p. 46.

In this regard, the most important expansion of property is the invention of intangible rights, as these translate what emerges from human minds into property. Evidently, the idea of owning something that we cannot see or touch (e.g. ideas) transposes a significantly transformative idea to law. Hence, these property rights in intangibles have become an increasingly powerful body of law, permeating social life and subjected to strong pressures for continuous ratcheting up of standards.

Not surprisingly, the internationalization of IP is sometimes depicted as the foundation for a new form of capitalism: this 'new' capitalism focuses on the control of abstract objects (intangible assets), as the owners of this intangible property can reach into the material world, through IP-based things (goods) and activities (services), and thus control vital resources.[6]

This critical process has resulted in the paroxysm that is patents. Irrespective of the term used to define its philosophical core (appropriation or propertization), its legal nature is that of a government-sponsored monopoly and, in consequence, a quite visible hand in economic terms. As a result, the impregnation of proprietary *cells* with globally-traded goods and services currently allows optimal accumulation of capital.

Paradoxically, for mainstream observers, these knowledge monopolies do not challenge the inner functioning of markets and competition: thus, public authorities can nurture monopoly and the market-economy all together, within a 'coherent' economic policy vision for the entire world.

Economics professionals are among those doing their best to solve this paradox. Certainly, economists still have the idea of efficiency for somehow rationalizing the possibility of monopolizing knowledge and ideas,[7] irrespective of their definition of efficiency. However, as ideas and knowledge are inherent to human nature, it is not easy to bridge knowledge propertization with economic efficiency. [8]

Through the lens of profit maximization, knowledge appears to be the ideal object of propertization, since it is non-rivalrous in supply. As Braithwaite and Drahos recalls, the same knowledge can be endlessly recycled to many generations, each one having to pay for use or access.[9]

---

6 J. Braithwaite & P. Drahos, *Global business* op. cit., p. 57.

7 M. Eisner, *Antitrust and the Triumph of Economics. Institutions, Expertise and Policy Change* (University of North Carolina Press 1991).

8 For the classic argument that technology requires monopolies see J. Schumpeter, *Capitalism, socialism and democracy* (Harper 1950) (chapter 8).

9 P. Drahos & J. Braithwaite, *Information* op. cit., p. 216.

Hence, sustained pressure towards the ratcheting up of propertization makes sense for the purely rational economic actors; that is to say, proxy vehicles (corporations) remotely-controlled through capital-markets.

To paraphrase Drahos, TNC's unity on the IP front is based on the *deep ideology* of hyper-effective IP protection, not on the specific rules; as this enables them all to invest in turning knowledge from public good into a private good, and then set the terms of access accordingly.[10]

Thus, the increasing accumulation of capital by the net beneficiaries (capital-holders acting through corporate proxy) allows them to ratchet up global standards by investing some surplus on manufacturing official consent (regulatory capture).

Patents are public legal devices that both lock up knowledge and monopolize economy: in the world of public ideas that´s a two-for-one in the long run for those who have capital, and arguably a strike out for the have-nots. In short, and again, the current expanding patent system is an ideal legal vehicle for maximizing profits through the patent-holding corporate form and structure.

In principle, it is not easy to devise a more efficient way of legally concentrating power over knowledge, society, market and competition in fewer –thus increasingly visible– private hands.

For mainstream thinking in this area in any case, the patent system may be equated with 'progress', whatever that is deemed to be, as long as the patent-holders keep delivering some type of innovation; currently, not necessarily breakthrough innovation.

However, the granting to individuals of dominion over land and things conveys some type of *imperium* over others.[11] Reasonably, granting dominion over ideas conveys the greatest *imperium* of all, particularly if the intermediate incumbent is a 'nonhuman legal person'; in other words, an artificial profit-maximizer.

As profit maximizing is the explicit functional nature of the corporate form, it is reasonable to be cautious when granting corporations proprietary control over knowledge and ideas.

In short, and notwithstanding some –although not so many– breakthrough inventions, proprietary knowledge is not the best platform for *seeing further*.

---

10 P. Drahos, '"IP World"-Made by TNC Inc' op. cit., p. 211.

11 M. Cohen, 'Property and Sovereignty' op. cit.

2. Monopoly traders

There are currently several millions of patents in force around the world, and a further host of unexamined applications still pending. Their ownership and commercial exploitation is dominated by large companies incorporated in a small group of countries, and this has been the case since the first robust statistical data was made available in the 70s.[12]

Reasonably, as Machlup argued half a century ago, 'no economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss to society'.[13]

In any case, however, patents do create wealth for net exporters of patent-based goods and services. Thus, there is transfer of wealth through the current international patent system by anulling the functioning of market-based price mechanisms for the given proprietary technology.

As there may be no legally allowed competitors for that (invention-based) product or service, society cannot benefit from the market-mechanism. Thus, the individual consumer cannot benefit from competition in markets. As a result, there is a double prize for the patent-holder, entering a world level-playing field of unexisting markets in relation to the particular invention, and thus a level-playing field characterized by the absence of competition.

Hence, the proprietor of an invention may decide that a corporation, SME, self-employed, employed, unemployed or a nonproductive individual should pay these or those royalties for gaining access to the given invention. Alternatively, she may simply exclude some, but not others, or even fail to allow access to knowledge to anyone. Thus, considerable power is granted by an official document.

Without necessarily delving into the etymology of 'royalty' just to make a point, market and competition are at odds or in strong tension with this government-sponsored structure of incentives.

---

12 See *The Role of the Patent System in the Transfer of Technology to Developing Countries,* (UNCTAD 1975) op. cit., p. 38–39.

13 See F. Machlup, *An Economic Review of the Patent System, Study of the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary*, United States Senate, 85th Congress, Second Session, Study No. 15 (1958) at 79 and B. Hindley, *The Economic Theory of Patents, Copyrights, and Registered Industrial Designs: Background Study to the Report on Intellectual and Industrial Property* (Economic Council of Canada 1971).

The architecture of the international patent system is built on modules; thus, virtually an infinite *combination* of IP rights-based contracting modes is available for the patent-holder to construct in multiple jurisdictions, as long as the invention commercially pays off. In other words, the patent-holder is both a private regulator and controlling authority, until the patent term expires.

However, the patent-holder may manage to obtain some extended play: for example, by not disclosing all the relevant information in the registered patent, by playing the card of data exclusivity, or by simply obtaining extra tranches of protection by promoting legal reform to extend patent *scope*, *strength* and *term*.

The patent-holder acts as the global controlling authority over the fine intangible *monopoly-asset*: the IP code. As far as privilege is concerned, infringers are outside the law; and their infringing goods can be disposed of outside the channels of commerce or, where constitutionally possible, destroyed.

In this regard, the TRIPS agreement regulates enforcement procedures for enabling right holders to prevent, in cooperation with customs administrations, the release of infringing imports into free circulation. These provisions are covered by Section 4 of its Part III on enforcement.

Thus, TRIPS article 44 requires that the judicial authorities be empowered to order injunctions, including the possibility of preventing imported infringing goods from entering the domestic market. In addition, as mentioned above, article 46 also requires WTO Members to grant courts the authority to order infringing goods to be disposed of outside the channels of commerce or, 'unless this would be contrary to existing constitutional requirements, destroyed'.

On the other hand, according to TRIPS article 51 (and accompanying specifications of its footnote 14), the goods subject to border enforcement procedures *must include at least* trademark counterfeiting or copyright piracy on a commercial scale for importation and exportation. In addition, according to article 61, the infringements of patent-related IP rights are open to criminal proceedings, and thus possibly to imprisonment and/or monetary fines in 159 jurisdictions. Last but not least, again, 'in appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods'.

The propertization logic of the international patent system, as a public legal device, is so autonomy-enhancing for corporations –its major players–

vis-à-vis society and economy alike that many large IP owners are currently involved in playing *meta-games* with IP rulemaking: that is to say, changing the public rules of the game while playing them. TRIPS+ rules are an egregious example.[14]

Understandably, any company holding a large portfolio of these power-assets will be eager to allocate resources for ensuring that this legal ecosystem does not only continue its 'business as usual' but expands legal protection of intangible assets.

By manufacturing legal monopolies in almost all state jurisdictions, the international patent system is a rent-transferring machine operating on a global scale. Subsequently, legal linkage (combination) to the world trade regime transforms incumbent (patent-holders) in *trading monopolists*. Hence, a great deal of power is concentrated in the hands of the large repeat players.

The magic ring of IP law grants powerful qualities to the products and services based on proprietary technologies. The very existence and trading of these products and services depend on the IP owner's authorization. As a result, nowadays, technology-driven companies heavily invest in proprietary knowledge in order to avoid seeing their products and services enter price-based competition, as the IP rights lock-in profit increases by skipping marginal revenue: no market, no competition.

Thus, firms use IP intensively to exclude markets as social mechanisms in which companies 'compete' by selling the best quality good at the lowest price possible.

A patent confers an exclusive right on its owner over the making and distribution of goods and services. Thus, this legal device grants the discretionary power to authorize the trading of those goods and services by anchoring them to a monopoly right. Hence, in practical terms, patent licenses are *trading licenses*; and those who control the granting of those voluntary licenses are *trading monopolists* in respect of that invention.

Thus, by the very nature of the patent form, the legally-protected monopolist decides who is allowed to trade, and on what conditions; and the legal monopoly can be registered in the patent offices of multiple jurisdictions.

Given this scenario, licensing policies and royalty-setting practices are thus critical issues for all, as they define the chance and opportunity for others to produce, distribute, consume or trade a given IP-based good or service.

14 See chapter 3.

In short, the patent transforms its holder into the gatekeeper of every state territory in which the patent is granted.

This legal device gives the holder power to (1) work out the patent herself, (2) grant exclusive licensing agreements, or even (3) allow license-based competition between fairly treated licensees; in any case, power to act at will over the invention. Thus, access to trading in and from each state jurisdiction that grants the patent is determined on purely private grounds and conditions.

The invention protected by patent and related IP assets is multi-jurisdictionally propertized, and therefore, a private issue regulated through chance and opportunity at the patent-holder's behest.

In granting the patent-holder legal control over all those processes, the noun describing the actual phenomenon is not 'market power': there is no market and competition in sight, as the holder legally opens or forecloses a variety of segmented and vertically controlled territories for the given invention under patent.

Patent rights lock up access to knowledge, allowing companies to have a common-and-control position on invention-based goods and services. Thus, once a large company obtains a critical breakthrough patent, a vertical infrastructure can be developed around it by suppliers and distributors, organizing world production and distribution through hub-and-spokes schemes based on licensing.

Somehow, these legal schemes are thus a form of 'knowledge sovereignty' at will. Thus, it is no accident that patent management is governed by increasingly sophisticated practices and technicalities in the realm of expert legal communities.[15]

In the brave new world of patent wars, companies collecting strong IP portfolios improve their capacity to legally block other patent-based competitors in any given domestic society (legal claims, related injunctions, etc).

Thus, information disclosure is not a priority for filing companies. Going through the instructions disclosed on patents rarely permits key scientific and technological inventions to be reproduced, as patent applications contain deliberately incomplete and misleading data; or they have also been very broadly designed and drafted, in order to maximize coverage of sciences and

15 For clever detailed analysis of this phenomenon see S. Picciotto, *Regulating* opt.cit. For a complete study on politics, patent offices and experts see P. Drahos, *The Global* opt.cit.

technologies. Hence, the registration itself is often useless without access to undisclosed know-how.

On the other hand, the mixture of technicality and calculated ambiguities that legal experts insert into their designs potentially turns them into hard core warfare: in this regard, patent walls erected over some technological domains frequently deter competitors and researchers from entering the arena.

As corporate research departments are managed according to productivity criteria (read patent quotas), the contestability (legal validity) of patents is currently 'downgrading'. However, testing validity in court requires money; and consequently, testing validity in a thick patent bundle or the entangled patents governing a key technology, requires significant amounts of money. Thus, doubtful privileges remain unchallenged, crowding the lands of invention with legal minefields.

The major repeat players play the system best. For them, filing and acquiring patents is not only a means of capitalizing each financial quarter, as it also provides a legal armor to secure a level-playing field for intercompany negotiation over proprietary technology (cross-licensing deals). Thus, by maintaining a strong patent portfolio the chances of neutralizing potential suits (mutual legal deterrence) are increased, while also securing some bargaining power to solve IP-related conflicts between big and small players.

As a result, tech companies protect themselves from patent-holding predators (the so-called patent trolls) by obtaining as many patents as possible in emerging technologies. Additionally, obtaining a license over other proprietary technologies in good conditions may require proprietary technology exchange. Hence, here again the game gives larger players the advantage, if not actually excluding other contenders.

Not surprising, the task of patent offices in governing these power-games in the public interest is not an easy one, as patent offices are generally overburdened by stockpiles of patent applications. In addition, many applications are packed with hyper-technicalities, indeterminate terms and some catch-in ideas for the invention. Thus, officials are often overwhelmed by their task of legal quality control.

Last but least, their work is obviously subject to litigation on appeal. In this regard, major players take patent offices to court more often than not, not only in order to obtain individual key patents but also for tightly marking judicial precedents over criteria of inventiveness, patentability, etc. Thus, large

repeat players do their best to fine-tune this clockwork system by working their way up the judicial ladder.

Patent officials do their best, despite the current state of affairs. However, the patent productivity policy structurally entrenched in the ir activities forces them to adopt, like it or not, simple corporate-friendly positions, and thus to abandon their role as watchdog seeking and ensuring inventiveness.

In this regard, patent offices have structural incentives to grant as many patents as possible, and thus to make as few inquiries as possible on inventiveness, disclosure requirements, or validity of scope.

Globalization requires reconsidering some traditional frameworks of both administrative and international law.[16] Deterring regulatory capture requires the Patent Offices to improve the deliberative quality of their administration.[17] In this sense, achieving an efficient balance in intellectual property rights requires representation, transparency and non-domination combined with institutionalized opportunities for thoughtful deliberation.[18]

3. Combinations

The most challenging characteristic of current IP intercompany arrangements is that these are often vertically structured around world hub-and-spokes exclusive licensing schemes. Thus, they are sometimes not uniquely based on old-school horizontal cross-licensing between global oligopolists but also on multi-jurisdictional exclusive licensing of domestic corporations.

Hence, some brief notes on the history of international cartels are required before entering into these IP-based global contractual practices. In this way, the TRIPS rules promoted by some large pharmaceutical companies and other IP companies can be contextualized, along with the resulting reinforcement of these practices.[19]

During the first part of the 20th century, the big pharmaceutical industries obtained the 'know-how' from the chemical industries (cartel as tech-

16 See in particular A. Aman, '*Globalization, Democracy, and the Need for a New Administrative Law*', 49 *UCLA law review* (2002): 1687–1716 and A. Aman, *The Democracy deficit: taming Globalization through law reform* (NYU Press 2004).

17 See generally I. Ayres & J. Braithwaite, *Responsive regulation: transforming the deregulation debate* (Oxford University Press 1992) (and chapter 3 in particular).

18 See in particular P. Drahos. *The Global Governance of Knowledge* op. cit.

19 See generally S. Picciotto. *Regulating* op. cit. (chapters 4 and 9).

nique or method of industrial organization), who had the dubious honor of globalizing price fixing for one of the first time in contemporary history. It is not incidental that they were also responsible for the German chemical industrial complex.[20]

To make a long story short, the first patent-based global chemical cartels of the early 20th century became a 'business model' for entire industries. During the 20s and 30s, as a result, 35 out of the 52 US antitrust proceedings against international cartels involved patent exchange agreements.[21] By 1939, cartels were active in industries that accounted for 42% of world trade.[22] Many of these cartels were based on cross-licensing and patent pools.[23]

In this context, for the chemical corporate pioneers, moving to the pharmaceutical sector was a natural move to make, as chemicals compounds and chemical processes are instrumental for synthesizing drugs. This inter-sector pollination (or contamination) was critical for the evolution and development of business models in entire industries.

Prior to World War 2, companies were already using patents for processes, as well as copyright and trademarks, to protect drug inventions both in Germany and the USA, as the patentability of chemical compounds was still prohibited. Thus, between the two World Wars, IP began to be used strategically as a means of structuring and enforcing cartels on a variety of industry sectors.[24]

In a moment in which the market-economy was still taking form conceptually –Sherman Act only dated back 1890–, IP allowed them to upgrade their autonomy in the economy. In particular, IP sidelined two key weaknesses in traditional cartel activity; namely, (1) the illegality of such schemes and (2) free-rider problems (cheating) by cartel members.

The discovery of antibiotics –notably penicillin in 1928– changed the landscape, by leading to the era of wonder drugs, after the War, and thus to expectation of exponential profits.

Incidentally, the discovery of antibiotics –being substances natural-

---

20 F. Steckel, 'Cartelization of the German Chemical Industry 1918–1925', 19 *Journal European Economics History* 2 (1990): 329–352.

21 See G. Stocking & M. Watkins, *Cartels in Action* (Twentieth Century Fund 1947), p. 293.

22 See W. Wells, *Antitrust and the Formation of the Postwar World* (Columbia University Press 2003) at 25.

23 See S. Picciotto. *Regulating* op. cit. (p. 397).

24 See G. Stocking & M. Watkins, *Cartels in Action* op. cit., p. 4.

ly occurring in nature– was non-patentable. Even in Germany, it was only possible to obtain protection for chemical processes, not for chemical compounds. Hence, meta-game through legal subtlety had to overcome non-patentability in the US.

Thus, patent lawyers and officials came to the rescue: as long as some significant process was transforming nature, substances isolated and purified by discovery were patentable. The argument went through and, as result, a first antibiotic cartel held prices stable in the US during the 50s.[25]

After World War 2, the pharmaceutical industry had multiplied profits through the discovery and patenting of broad-spectrum antibiotics.[26] By that time, only large corporations had the scale and scope to exploit the potential of emerging technologies through patents.[27] The extra earnings gained through combining the payoff from patent reform (on patentability) and the anti-competitive know-how from the older chemical cartels allowed the industry to globally expand these anti-market business practices and culture.[28]

By cartelizing production and distribution of pharmaceuticals around IP assets, in a relatively short period, a small group of German, Swiss, British and American companies globalized pharmaceutical business on IP cartel grounds. Those legal schemes (cartel + IP) anesthetized state and markets for two decades.

However, in some years, the global expansion of this inter-corporate business model would begin to face the structural challenge of a blossoming generic manufacturing industry in developing countries.

In particular, the Indian model of generic production (granting patents on processes but not on products) was giving birth to a highly competitive industry, able to deliver quality and cheap drugs. By reinvesting profits on cheaper (patentable) processes to make drugs, the technical capabilities of the industry boomed (reverse-engineering, etc).

Partly as a result of that, pharmaceutical companies begun recruiting

---

25 P. Drahos & J. Braithwaite, *Information* op. cit (chapter 2).

26 On the US innovation public policies and occupied Germany see J. Gimbel, *Science, Technology, and Reparations: Exploitation and Plunder in postwar Germany* (Stanford University Press 1990).

27 See generally A. Chandler, Jr, *Scale and Scope: The Dynamics of Industrial Capitalism* (Belknap Press 1990).

28 On pharmaceutical practices in developing countries see G. Gereffi, *The Pharmaceutical Industry and Dependency* op. cit. and J. Braithwaite, *Corporate Crime* op. cit (chapter 5).

collaborators among the IP related industrial sector at the outset of the project for creating a new global IP regime within the multilateral trading system; thus the TRIPS agreement erosed, as centerpiece of the current extreme IP paradigm.

The equation of patent-based profit maximization is formed by two related variables. On one hand, the patent-holder exercises a government-sponsored monopoly, and thus the right of contracting out its exploitation through license in exchange for capital (royalties). On the other hand, the licensee has an agency relationship with the patent-holder to exact monopoly rents on the given domestic jurisdiction, or jurisdictions. By obtaining that license, the licensee is authorized to perform some activities over IP-based goods and services under the terms contained in the arrangement (agency contract or agreement).

This second variable (the licensee) is as significant as the first (the licensor) with regard to the impact of IP on the functioning of domestic and global markets. By obtaining powerful legal rights from these licenses, licensees are among the winners of the current international patent system.

In practice, the capital-holder who obtains a license (licensee) from a patent-holder (licensor) exacts *dominion* from the proprietary code within any given good or service. On top of that, government-sponsored *dominion* is enforceable in all territories granting the patent, and that can technically account for 1 to 159 jurisdictions.

Therefore, in those cases in which the IP owner implements an exclusive license policy, there will be one licensee in each domestic jurisdiction. Thus, the group of international exclusive licensees may range from a relatively minor group of incumbents, depending on how many jurisdictions have registered the patent; again from one up to 159 licensees.

An exclusive licensing arrangement is an agency contract working out a price for that territory, and preventing anyone other than the agent from importing any product or service built on proprietary technology. This also seriously applies for other agents that have been licensed with the same proprietary technology in foreign territories.

As a result, by obtaining a domestically-enforceable monopoly right in each given jurisdiction, this transnational elite of exclusive licensees may form a vertically operated anticompetitive arrangement, with the licensor at the apex.

Obviously, licensees tend to inhibit non-license based parallel impor-

tation, by taking to court exporting licensees from other countries, and thus preventing imported infringing goods from entering into domestic distribution channels. Added to this, notably, the legal conflicts, tensions and relationships between these global licensees are ultimately governed by the patent-holder licensor, and thus they may obtain formal or informal mediation (alternative dispute settlement) from this ruling global IP owner.

Arguably this does not have so much to do with the idea of competition. As far as we are concerned, the hard core example of exclusive rights is also particularly disquieting when essential technological innovations are involved, such as i.e. essential medicines. In these cases, closed and vertical distribution models involving the very few is thus open to question.

Exclusive license-based arrangements are welfare-reducing. There are multiple complex cases within the current international patent system which would suggest reconsideration of the extreme IP approach to licensing. For example, even as individuals we are increasingly licensed by global companies to gain access to new essential technologies. In principle, therefore, in a global business model, based on non-exclusive licensing, the number of potential licensees would range from 1 to all of us as potential end-users.

Notwithstanding that an *essential universal license* would be difficult to both implement and manage, and perhaps in the interim would be transferred by states to the public domain through CLs, the point to make is that the current system and thus patent offices would remain structurally neutral in the face of such possible development.

As has been explained, the patent-holder has the power to segment or partition access to a given invention in all territories in which a legal monopoly right has been granted. As a result of that decision, a small transnational group of capital-holders acquiring a piece of *paper monopoly* through contract have –at the end of a chain in an *n* number of fiduciary forms– a full range of segmented and closed territories (state jurisdictions) from which to obtain rents.

These licensees produce and distribute the proprietary-knowledge of others through nonmarket and noncompetitive drives; those of a legal monopolist trading on IP. Thus, these agents are allowed to export the goods and services based on that proprietary technology as long as such activity is allowed in the terms of the licensing contract.

The economic driving force on both sides of the contractual relationship is based on nonmarket and noncompetition-driven criteria. Interesting-

ly, this driving force is not built on comparative advantage but on government-sponsored ownership and contract over territorially-operated proprietary knowledge.

Hence, analysis on the contract-side is highly illustrative in this regard. The licensor and exclusive licensees agree on terms and are thus part of a globally integrated distribution network of the given IP asset.

Reasonably, the largest licensors are not supposed to operate as some sort of revived 'merchant company' cooperating with licensees to set up a 'shipping conference' on 'IP freights'; although sometimes this appear to be the case.

In any case, and leaving aside analysis on the pathologies of hard core global licensing, the IP rights holder and those licensees obtaining the production and distribution rights over the 'intellectual technology' gain enormous (sometimes exorbitant) power over society, the market and competitors in general.

In essence, the contracting of a government-granted privilege over a *meme* or a knowledge *cell* in a given territory allows the exclusive licensee to control any 'IP-pollinated' goods and services, and thus its physical materialization and presence in that territory.

Thus, the patent-holder technically controls the world legal ecosystem for the given invention, as she or he is allowed to exercise monopolistic control over production and distribution of goods and services based on that pro-proprietary technology in any given territory.

Therefore, those inter-company contractual relationships constitute a second-level delegation of a government-granted monopoly allowing them to structurally exclude non-licensed competitors.

Unfortunately, when these hub-and-spokes contractual arrangements affect essential technologies, this legal monopoly-based leverage can put highly competitive and market-efficient companies out of business.

To summarize, the original monopoly source distorts the global functioning of the market-economy mechanism through world vertical control over multi-state production and distribution. Therefore, provided there is a critical proprietary technology at stake, deep and stable licensing bonds produce maximum capital accumulation for the incumbents of this world legal game.

Obviously, such a legal relation is detrimental to the competitiveness of non-licensed players. Needless to say, these could be more competitive pro-

ducing and distributing those goods and services but licensors do not allow them to prove it.

Reasonably, no government-granted monopoly should produce such a negative impact on inter-company competition. Putting competitive companies out of business as a result of IP licensing is not the wisest of ideas. Inevitably, these exclusive licensing schemes are collectively wealth-reducing, as they allow inter-corporate cooperation to secure safety-rents and thus keep the incumbents outside margin-based competition.

Designed by seasoned lawyers, many of these contractual mechanics could be technically framed as machinations devised to fix prices, in the technical sense of a price-fixing conspiracy of the Sherman Act. However, these world legal schemes are not automatically illegal as the international patent system, in principle, protects property (patents) and contracts (licensing) in all jurisdictions:

> Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.[29]

A long-nurtured legitimizing legal chain protects the legality of these IP-based world transactions. That legal chain is the age old entanglement of property and contract.

By combining the power-laws of property, contract and IP-linked world trade, capital-holders have obtained a global ground breaking legal device for accumulating capital. From an intellectual perspective, the sophistication of this elaborate piece of legal clockwork is remarkable. Thus, new lawyers entering large firms and legal boutiques as IP code-programmers will continue their playback on this great design for quite some time to come, perhaps with slight upgrades now and then. The power-rule was written a while ago.

Today, patents rights and concomitant license agreements have grown up as a restriction over market-based prices, production, distribution and, obviously, trade.

As a result, public authorities should consider reforming the rules of the game regarding IP propertization and contracting. In this sense, any effective global antitrust policy in this area should reasonably start horizontally, by establishing *international automatic mandatory licensing* in all business

29 See TRIPS article 27.2.

sectors considered to be essential for society (e.g. pharmaceuticals, communications technologies, etc).

For centuries, capitalism has advanced through property and contract. As mentioned, property is the position, contract the move; going forward relentlessly in a series of feedback moves. In this regard, the *property-contract* 'move' makes IP (patents, know-how, trade secrets and trademarks) an optimum legal device to expand both individual and collective corporate autonomy in any given business sector through anti-competitive contractual practices.

In essence, IP facilitates the combination of two vehicles that irregularly maximize capital-holders' autonomy through the legal forms of property and contract: public law-based monopolies (patent as property) and private law-based arrangements (licensing as contract).

As a result, moving into intellectual property makes incredible sense for capital-holders as rational economic actors. By combining patent rights and subsequent license arrangements, their corporate proxies increase the capacity for circumventing antitrust laws.

More often than not, both antitrust authorities and tribunals tend to leniently interpret these practices as mere exercises of property and contract. This is particularly the case with most global exclusive licensing frameworks. As they comprise ownership and contract, public authorities find them difficult to break up.

In this regard, world patent-sharing agreements may obtain an equivalent anti-competitive effect to the old-school of commodity cartels: that of controlling production, setting prices and dividing up territories. However, the IP game permits *reframing*, by moving from the legal label of anti-competitive machinations to that of pure and neutral exercise of property rights.

As a result, the extreme IP paradigm and its legal infrastructures solved the historical dual weakness of old-school commodity cartels: unenforceable legal action against free-riding and cheating. Noncompliance with the terms of the arrangement by a contracting party can now be framed by another contracting parties as a simple infringement of IP, and thus be adjudicated in domestic courts or private international arbitration.

In essence, public players tend to have difficulties acting against property-based contractual relationships, and thus to reframe those transactions as anti-competitive practices. As a result, the move to a strong IP paradigm facilitates global second-generation cartels, which are more difficult to scan and bust.

Public authorities tend to intervene with relative unease on private arrangements based on property and contract. The difficulties multiply when the phenomenon internationalizes. The subtle legal line between 'international cartel' and a mere disposal of property through contract plays to the advantage of legal technicians and corporate clients knowing the trade.

Interestingly, international cartels are the only area in which antitrust authorities have a shared commitment of coordinating their domestic enforcement policies. Arguably, international cartels are the only easy thing to agree on between competition agencies from both developed and developing countries for some time to come: for antitrust experts and practitioners global cartelists are the contemporary pirates of the global market-economy in the making.

In this regard, antitrust representatives and officials share a common culture and understanding on this critical issue. In fact, the most successful annual workshops within the inter-agency regulatory framework of the International Competition Network (ICN)[30] are those on international cartel-busting. Therefore, there is some critical policy space to explore there.

As far as general arguments are concerned, that goes for both *vertical* (e.g. exclusive licensing) and *horizontal* (e.g. cross-licensing) global arrangements based on IP.

4. The origins

Reasonably, the current business model of global pharmaceutical industries has to be portrayed within the perimeter of this type of legal combinations. But before addressing the model, however, it is important to take a brief look at the evolution of classical cartels, in order to contextualize where we all come from and thus where we stand at present.

As Kronstein explains, these 'private alliances of enterprises' operating behind the windbreak of state power remove a market from the ordinary eco-

30 See M. Djelic & T.Kleiner, 'The international competition network: Moving towards transnational governance', *Transnational Governance: Institutional Dynamics of Regulation* (Cambridge University Press 2006) at 287–307, W. Kovacic & H. Hollman, 'The International Competition Network: Its Past, Current and Future Role' 20 *Minnesota Journal of International Law* (2011): 274-323 and W. Kovacic, H. Hollman & A. Robertson 'Building Global Antitrust Standards: The ICN's Practicable Approach', *Research Handbook on International Competition Law* (Edward Elgar 2012), pp. 89–109.

nomic order and subject it to their own making.[31] In this regard, cartels are ideal for explaining what the market-economy is not about. For that reason, it would be helpful to look back a little further. Thus, describing its long evolution facilitates our understanding of the present time, as well as possible future developments.[32]

Interestingly, since the final quarter of 19th century and beyond, there was a wide-spread perception among industrialists, policymakers and the economic professions alike that cartelization was an optimum tool for avoiding overproduction and related crises in the mass-manufacturing industrial economy.

However, these cooperative anti-market arrangements also attracted increasing popular criticism in that quarter, due to their impact on prices. Thus, the Sherman Act of 1890 was adopted as a catalyst for reducing corporate practices in line with what would later be called 'market economy'.

Not incidentally, by that time, the market economy was an ongoing conceptual endeavor, thus originally also thought to be a sole national endeavor. Economic nationalism characterized that era, as at the time, economic globalism was only a political idea which was beginning to be connected for the first time, in positive terms, to world trade.

Hence, the highly cartelized economy of the 19th century was subsequently subjected to a shaky restart. In line with the winds of popular opposition to concentration in key sectors of the US economy through trusts, the 1890 Sherman Act catalyzed social disaffection and translated it into a new power-law. The power-law gave rise to an overarching prohibition framing the nascent market economy and its comparative law and politics:

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.

That provision is a minimum common denominator in building a close-to-customary world-consensus on the proper functioning of modern-market economies; no more, and no less.

In fact, quite significantly, this is one of the very few areas, along with anti-bribery, in which comparative law and politics of the market-economy

31 See H. Kronstein, *The Law of International Cartels* (Cornell University Press 1972), p. 4.

32 See in particular S. Picciotto, *Regulating global* op. cit (chapter 4).

find some traces of criminal law and enforcement in white-collar corporate activity.

The 1890 Sherman Act did frame intercompany cooperation in radically negative legal terms, as the new legitimizing framework for the US economy (read market > competition > *efficiency*) was impossible to reconcile with large inter-corporate cooperation such as cartelization (read no market > no competition > *inefficiency*).

The power-idea was called *market economy* and thus its power-law was focused on the *law of the land;* thus, the land referred to in the constitution of the United States of America, no other. Hence, international cartels were not framed in negative terms either by economists, politicians or judges alike, as long as these had no effect on the US (ie. domestic prices). Therefore, the gate of international cartelization still remained open. In fact, the Webb-Pomerene Act of 1918 legalized export cartels on these delicate economic policy lines.

These particular policy developments within a US market economy in the making would later have serious consequences for the global industry's move to IP cartelization in decades to come.

In principle, as cartels are distorting instruments (*dominium*) for a market economy, corporations would not be able to enjoy new entries and attempts at this lethal *combination*. In order to allow the nurturing of a renovated economic paradigm, cartels became the new pirates within the conceptual framework of those who were legally constructing the new market economy paradigm.[33] Hence, the Sherman Act was partly responsible for solving that potential structural problem, by prohibiting intercompany cooperation.

However, by acting tough in busting domestic intercompany arrangements (particularly Samuel Dodd's trusts), the century-old Sherman Act indirectly promoted oligopoly formation. As long as companies were legally prohibited to agree on prices or production through contract, property could come to the rescue.

As Picciotto explains, competition law, although born from a populist impulse to restrict oligopolistic economic power, largely became a means of legitimating it.[34]

---

33 For global anti-cartel US and EU actions (citric acid, lysine and vitamins conspiracies) see, in particular, J.M.Connor, *Global Price Fixing* (Springer 2007).

34 See S. Picciotto. *Regulating* op. cit., p. 109.

The Act indirectly transformed the entire US industrial landscape by offering large corporations a great upward shift (concentration), frequently referred to as 'consolidation' in corporate American English, as both a legitimate and legal business strategy in the market economy.

Thus, corporate integration took place on a large scale in the US through primitive forms of what we call today 'mergers and acquisitions'. As a result, by the first decades of the 20th century, large corporations already pervaded most sectors of the US market economy, and would soon begin to export an oligopolized model of market economy beyond its borders.

The structure of incentives embedded in the 31 words voted by US Congress when passing article 1 of the Sherman Act, indirectly contributed to industrial concentration, as capital-holders moved to this new game.

In technical terms, companies would be allowed to consolidate as long as they maximized consumer welfare (in the current legal sense of higher quality and lower prices). However, according to this bargain, advanced societies have incrementally oligopolized their market economies; and arguably, 'as long as' may not last forever.

The market structure of increasing sectors in advanced market economies is currently oligopolistic. Monopoly was precluded as a capital-enhancing vehicle, but oligopoly was allowed. Thus, this limit to capital accumulation (or profit maximization) through higher-level market concentration could only be circumvented by expanding business activity to other jurisdictions. In essence, controlling shareholders could raise the bar by playing the multi-jurisdictional game through their corporate proxies.

It is no accident that this multi-jurisdictional game was often based on cartels, as international cartelization was still a viable legal device organizing business activity. As mentioned, the Webb-Pomerene Act legalized global cartels originated or joined by US companies, as long as they did not have a negative effect on the US market-economy in the making.[35]

Only by the end of 30s, did the US antitrust authorities begin paying some attention to the distorting impact of international cartels on domestic economies. The change in public attitude under the Roosevelt administration was brought about, right after World War 2, by the US Antitrust Division led by the forceful Assistant Attorney General Thurman Arnold,[36] when this

35 See E. Hawley, *The New Deal and the problem of monopoly: a study in economic ambivalence* (Princeton University Press1966).

36 See T. Arnold, *The folcklore of capitalism* (Beard Books 2000).

agency began to pursue anti-global cartel enforcement actions having effects on the US market economy.[37]

Inevitably, antitrust enforcement actions and their concomitant consent decrees increased the cost of global cartelizing from the 40s, so US companies began searching for new legal schemes to maximize corporate autonomy in the interest of capital-holders; and there goes the move to IP.

In any case, global companies did not only move to IP as a concomitant result of the activities of the US Antitrust Division, but also because agreeing to a productivity quota or a fixed price between two or more autonomous companies is always *iuris et de iure* invalid under antitrust law (read plainly illegal). Thus, free-riding and cheating between cartelists was not judicially enforceable. As a result, the legal clockwork mechanics of cartels had to be finely tuned to correct this limited incentives structure within the cartel form itself.

In sum, in order to nurture a more autonomy-enhancing vehicle, the public-private legal Rubicon between market-based competition and property based-contracting had to be crossed; not an easy task in technical legal terms.

Thus, US chemical industries and their American Chemical Association began to consider that optimum corporate autonomy for all incumbents was better obtained by moving cooperative activities to IP.

Cooperation and monopoly appear to be an oxymoron, but they are not, as even the oligopolists have to agree with somebody on something; thus, better to choose who you agree with than indulging in infighting and leaving public authorities to enter the quarrel.

Hence, it was not incidental that the first attempts were to benchmark the German chemical industrial complex. In fact, the key expert in that trade, and a highly influential individual in devising and developing a new legal culture of corporate patents was Edwin Prindle, former high rank patent official and chief of the Patent Committee of the American Chemical Association.[38] Interestingly, the inner power-logic of patents within the modern intercompany monopoly-games is beautifully explained by this legal entrepreneur himself:

---

37 For the prosecution of world cartels during World War 2 and after see generally W. Wells, *Antitrust and* op. cit.

38 See E. Prindle, 'The marvelous performance of the American patent system', 10 *Journal of the Patent Office Society* (1927–28): 255 and 258.

Patents are the best and most effective means of controlling competition. They occasionally give absolute command of the market, enabling their owner to name the price without regard to cost of production. . . The power which a patentee has to dictate the conditions under which his monopoly may be exercised has been used to form trade agreements throughout practically entire industries, and if the purpose of the combination is primarily to secure benefit from the patent monopoly, the combination is legitimate. Under such *combinations* there can be effective agreements as to prices maintained.[39]

The only legal flaw in his entire argumentation is that trade agreements were supposed to be inter-state agreements. Thus, the critical distinction between public and private law is wiped out.

Certainly, that is exactly what is currently happening. In this regard, and notwithstanding any compromising interpretation, the terms of trade legalized by the current international patent system structurally promote monopoly-based inter-corporate agreements.

As a result of this natural by-product of the current extreme IP paradigm, capital-holders maximize autonomy vis-à-vis public authorities and society at large, through a tactical legal merger of intra-corporate and inter-corporate decision making (read property and contract, respectively) based on government-sponsored legal monopolies (read IP).

In this sense, these advanced schemes are highly performing legal vehicles for profit maximization through mixing corporate proxies. Hence, the boards and CEOs of some global IP companies (including pharmaceutical corporations) play out these strategies through variable combinations of contract and property so that shareholders maximize profits.

Arguably, this phenomenon has left public representatives out of things for some years. As the 8th round of GATT multilateral trade negotiations proceeded, from 1986 to 1994, and the Berlin Wall came down right in the middle of it (1989), it is not hard to see why people thought non-market economy capitalism was the only economic system remaining.

However, and sidelining determinism, the market economy and the social state were and are still in existence. In this regard, the international patent system could have been written with a rather different rationale such as that of *automatic mandatory licensing*, for example.

Therefore, there is work to do in breathing new power into the combined social infrastructures of states and markets, by making them work better together. Reasonably, market economies and social states are critical in-

39 See D. Noble, *America by Design* op. cit., p. 89.

frastructures for globalizing a better world; and are thus a combined common good.

Fortunately, the voices of those who valued the social state are present here and there in TRIPS; and equally fortunately, the voices of those who valued the market economy are everywhere in the GATT of 1994. For that reason, antitrust authorities still have the legal opportunity to amplify TRIPS inner flexibilities through article 40 and other antitrust related provisions of this agreement.

In any case, an easy way for balancing extreme IP can be found not only in international antitrust law –particularly the old international law regarding cartels– but within the pro-trade technicalities of the GATT of 1994. Arguably, the current semi-constitutional functions of the WTO agreement allow the 2001 Doha Declaration to rebalance some TRIPS rules (thus IP) in relation to GATT rules (thus trade). In this regard, there are interpretative margins in the WTO regime, not only for mitigating extreme IP but for considering TRIPS as what it should be: a world legal ceiling with regard to health.[40]

5. World properties

Patents are certainly part of modern legal infrastructures of innovation. However, the current functioning of the international patent system has transformed them into global vehicles which keep prices up and competitors out.

While innovation is not an easy quality to measure, steady prices are, and that should be a warning for those who think that markets and competition are good inventions to be harvested in the public realm.

Doing business as well as trying to get into business (potential entrants) in an IP world is becoming difficult for non-large players (economic diversity).

Under the current international patent system, there is no such a thing as a 'global market' or 'global markets'. Segmentation is the word: when every product and service with the *imprimatur* of IP code is controlled by the IP owner, the term `market´ does not apply to the transaction.

We are dealing here with monopoly-privilege, legal enforcement, thus

40 See chapter 5.4.

courts, thus public law, thus jurisdiction, thus territory, and thus sovereignty: this is to say segmentation of 159 territories in which 158 potential monopoly privileges can be granted to one foreign IP owner. In short, the whole international patent system runs on legal monopoly code.

Hence, by holding patents in multiple territories, companies have the enforceable prerogative to decide over the import or export of any good or service produced under their patent. Thus, the unique authorized 'free trader' is the monopolist, as she is allowed to manage a world hub-and-spokes device, placing goods and services under the rules of property (patent) and contract (license).

In short, the genius of trade and traders –the traditional and centuries-old merchants and trading entrepreneurs– is inhibited in the name of the so-called 'value-added' proprietary-knowledge. To a great extent, the global interdependence in all past millennia of the analog era was a by-product of people moving things around the world, from one market-community to another. From January 1st 1996, the linkage of trade and IP equals to *private* trade conditionality. In this sense, IP transactions across the world are based on a form of private *trade conditionality*.

Understandably, the historical tensions over patents and trade are centuries old, and they recur for good reason. Historically, the patent originated as a means of circumventing guild control of innovation.[41] By doing so, however, patents became *monopoly privileges*, having a bearing on social and economic fundamentals.[42]

In England, the policy battles between the English parliament and the Crown at the beginning of the 17th century over 'letters patent' was an expression of the severe social questioning regarding privilege-based monopolies in commerce and trade. As many of these monopolies had nothing to do with the protection of inventions, the *Statute of Monopolies* (25 May 1624) only left in place the protection of the latter.[43]

Interestingly, the next English social movement questioning patents

41 See S. Picciotto, Whose Molecule is it anyway? op. cit and F. Frager, 'A history of intellectual property from 1545 to 1787', 26 *Journal of the Patent Office Society* (1944): 711–760.

42 E. Penrose, *The Economics of International Patent System* (John Hopkins University Press 1951), p. 2.

43 A. Christie & Ch. Dent, '"Generally inconvenient": the 1624 *Statute of Monopolies* as political compromise', Intellectual Property Research Institute of Australia, *Working Paper No. 4/10* (June 2010).

as government-sponsored legal devices for promoting invention focused on their adverse effect on free trade and laissez-faire,[44] during the 19th century.[45]

For centuries, national treatment (NT) regarding patent protection (read reciprocity) has been an issue in inter-state relations. The extent to which a state granted patent rights to foreigners was not fixed, as a public policy issue, and was even conditioned on occasion; thus, for example, requiring the patent to be worked in the jurisdiction.

Until the final decade of the last century, states bargained around the legal recognition of the rights of foreign patent holders through bilateral inter-state negotiations. Hence, NT has been historically bargained over through bilateral relations.

As a result, IP-based protectionism has been used indistinctly by developed and developing countries alike throughout history. Thus, this form of protectionism is not circumscribed to developing countries.

At the time of the first (German) global chemical industries, for example, the United Kingdom reformed its patent law in 1919 to exclude patentability of chemical compounds (while leaving chemical processes patentable): the objective was to create incentives for its domestic industry to invent processes for competing with the large German chemical industries. The exclusion was applied between 1919 and 1954.[46]

On the development side, the 1970 Patent Act of India granting protection to process patents, but not to product patents, was adopted with the aim of developing pharmaceutical local production, and thus to provide sufficient incentives for domestic companies to invest in (patentable) cheaper processes for making drugs. Those companies honored the 'cheap drugs for patentable processes' deal.

However, under the current international patent system, the old IP-based protectionism has been replaced: nowadays, trade in goods and servic-

---

44 F. Machlup & E. Penrose, 'The patent controversy in the nineteenth century' op. cit.

45 For the history of English patent laws see C. MacLeod, *Inventing the Industrial Revolution: The English Patent System 1660-1800* (Cambridge University Press 1988) and H. Dutton, *The Patent System and Inventive Activity during the Industrial Revolution 1750-1852* (Manchester University Press 1984).

46 J. Murmann & R. Landau, 'On the making of competitive advantage: the development of the chemical industries of Britain and Germany Since 1850' *Chemical and Long-term economic growth: insights from the chemical industry* (1998), pp. 27–70.

es built on a proprietary technology generally are multi-jurisdictionally regulated by monopoly traders, as world trade of goods and services using that technology depends on how the patent holder defines the licensing terms. Hence, the patent-holder will set the terms of trade (yes or no and in what conditions).

As a result, things (goods) and activities (services) chained to the invisible IP traces cannot be traded freely by other entrepreneurs (parallel importation), as infringement of the *terms of trade* is enforced in the name of the IP owner through both private policing and custom inspections.

IP also operates in world trade as a form of structural-PPM. Clearly, non-discrimination regarding PPM (Process and Production Methods) of imported goods is the backbone of world trade. The multilateral trading system was underpinned by the fact that none of its participants would question the product and process methods (PPMs) of imported goods (read environmental and labor standards), in order to maximize world trade.

That was both the explicit and implicit deal. By building on that, and notwithstanding its critics, the multilateral trading system considerably contributed to world economic development for half a century. Thus, the multilateral trading system moved ahead under a structural trade-off based on importing and exporting goods without discriminating on PPM grounds, except for prison labor.[47]

As the GATT of 1947 included developing countries among its 23 founding Contracting Parties, the deal ensured that developed countries would not condition market access on compliance with process and production methods. In exchange, developing countries would open up their economies. Hence, trade was neutral towards PPMs.

However, a *form* of global PPMs has been incorporated in the world trade system by linking IP to trade and subsequently interpreting TRIPs provisions through the prism of extreme IP.

Thus, this prism could be lessened by surgically rebalancing IP and trade in essential areas of technology (ie. world trade in pharmaceuticals). This could be done through WTO Members' Ministerial Decisions (WTO article IX:1), or even authoritative interpretations (WTO article IX:2).

In this regard, the article IX of the WTO (*Decision-Making*) has already proved (read 2001 Doha Declaration on TRIPS and public health) that it is the honorable heir of 1947 GATT article XXV (*Joint Action of the Contracting*

47 See section (e) in article XX of GATT.

Parties); a power-rule that made possible for the GATT regime to blossom in complicated times (read failure to ratify the Havana Charter).

The WTO article IX is extremely powerful not only for rebalancing IP and trade to the benefit of wealth-enhancing global pharmaceuticals market (both generics and brand-name drugs) but also for restating the institutional leadership of the world trade regime itself in the post-TRIPS scenario.

The functioning of the current international patent system suggests making reforms. Currently, as long as a patent has been granted in any given territories, the flow of trade in goods or services building on that invention is legally controlled by the will of those holding the official patent document. The customs enforce this control over trade with the help of private agents providing IP policing services and enforcement for large IP producers and distributors.

Hence, the terms of international trade are structurally reframed both by and through IP law; all issues related to market are controlled by the IP owner: *market access* and *market exit,* or more precisely, *market entry* and market *reentry*.

Interestingly, in the traditional non-IP conditioned global trade, there was basically one commonly used word: 'market access', as the rest was basically free will. That is to say, international free movement of goods.

In the past, the import-export-import-export and *n* trade moves were simply the *open nature* of the trading opportunity: the value of *openness*; this is exactly what Pascal Lamy tried to put back on the global governance radar, by coining 'trade in value-added', and then quantifying it with the help of OECD.[48]

Conversely, the rules of trade in goods and services based on IP are those of licensing arrangements. No other traders than the *licensees* are allowed to enter the transaction.

Those are the actual terms of trade; and they are all under the legally enforceable control of the IP owner. Hence, IP-related trade is a radically different 'trade' than that which gave rise to the so-called world trading system.[49]

Therefore, traditional images of trade vanish; the image of trade understood as entrepreneurs acquiring things in one place on earth and selling them in another dissapears. The term 'trade', conventionally described as *ac-*

48 See *OECD-WTO: Statistics on Trade in Value Added* (OCDE, 1 January 2013).

49 R. Gardner, *Sterling-Dollar Diplomacy* (Clarendon Press 1956) at 31 and J. Jackson, *World Trade and the Law of GATT* op. cit.

tivity of buying and selling, or exchanging, goods and/or services between people or countries by the Cambridge English Dictionary, does not describe this new type of trade in IP-based goods and services.

As long as there are non-authorized traces of proprietary technology in a given good, the IP owner can interfere with the free movement of that good or service; no matter how many tariffs and non-tariffs barriers have been pulled down in the last half a century of GATT negotiating rounds. There will be no trade.

The new trade barriers are all private, high and hard. As long as we climb the ladder of proprietary technologies and thus IP-based goods and services, less and less of the old trade will move things and activities across borders.

We all know that free trade has winners and losers within the workforces of the open market economies of the world. In a balance, it was basically agreed that international trade was a pragmatic wealth-enhancing option,[50] particularly looking back to the autarchies leading to recent Second World War.

However, the free traders of late 80s got a Trojan horse on board, on the last big wave of all past GATT MTN: the Uruguay Round. Quite surprisingly, the board reached the shore in the spring of 15 April of 1994, and there was thus a happy ending at the Ministerial Meeting of Marrakech.

Thus, the TRIPS agreement entering into force on 1 January of 1995 soon began transforming world trade by linking IP compliance to trade. The text is, in its own terms, a magnificent regulatory capture by a relatively small group of corporations. Through that capture, the IP constituency and some key developed countries inhibited the wealth-enhancing mechanics of free trade in exchange for expanding world IP monopolies.

The great fabric of world trade is in trouble for many reasons, but also in part as a result of this Faustian bargain entered into by the trade representatives of developed countries with their IP constituencies. In fact, nowadays, by undoing the long walk of the old-school GATT diplomacy, these trade representatives are currently packaging and marketing bilateral trade-related deals door-to-door.[51]

---

50 J. Viner "Conflicts of Principle in Drafting a Trade Charter", 25 *Foreign Affairs* (1947): 612–628.

51 For current prospects see, in particular, D. Gantz, *Liberalizing international trade after Doha: multilateral, regional, and unilateral initiatives* (Cambridge University Press 2013).

Arguably, in the IP area, as long as developed countries embrace the special interest of the strong IP hard-liners, developing countries will not easily follow. Last but not least, the E7 economies have increasing economic and political leverage to step-off by offering alternative models in their bilateral and regional trade deals.

Nowadays, large IP owners have absolute legal control over the movement across borders of IP goods and services. Not surprisingly, the old world trading system is somehow upside down; this is not to say that it was an ideal system, but the linkage of IP to trade is troubling. The case of access to medicines in the developing world analysed in previous pages is a clear example.

While antitrust authorities of developed countries are paying increased attention to IP-originated battles on high technology standard setting, they do little to promote price-based world competition in order to facilitate access to essential technologies in the developing world (e.g. access to medicines). In this regard, IP restraints world market interoperability in similar ways to the manner in which it distorts communication interoperability in world technological standard setting.

After all, the two fields (world trade and technology standards) are captured by the very same *intellectual legal technology*; 'Intellectual property': a legal technology in its own terms and indeed a fine invention of the mind.

Economic interdependence requires world interoperability. However, a critical legal infrastructure of interoperability for a world-market economy has been thwarted by the advent of the international patent system.

Developed countries are shooting themselves in the foot by pushing for an extreme IP paradigm that does not recover workforces or taxation but unplugs the welfare-enhancing economics of world trade.

Reasonably, the current model does not help advanced economies to recover from deindustrialization, nor does it facilitate trade-based growth in developing and least-developing economies. However, it certainly benefits the shareholders of the so-called 'knowledge-based companies' that are promoting this proprietary-knowledge model for the world economy.

Interestingly, those IP-intensive companies are structurally characterized by having very scarce workforces and a low tax-paying performance compared to the industrial sector as a whole. It is no surprise that, they also have the highest earnings.

Making world trade channels dependent on IP compliance is a good deal for the shareholding individuals controlling IP-based corporate proxies.

However, it is also a bad deal for the have-nots and middle classes in the developing and developed world.

Virtually all economics textbooks explain why monopolies are socially inefficient. With IP hyper-protection in the offing, the explanatory frame for a global market-economy in the making blurs. Arguably, something is missing in our so-called 'knowledge-based societies' when information and knowledge are transformed into world legal monopolies.

Over the last century, markets, competition and efficiency have provided a framework for explaining, and imagining our world, but two of these three pillars are now being eroded in entire key economic sectors, if not actually wiped out, purely as a result of international IP enforcement. Hence, we are leaving efficiency, whatever info-econometrics deems that to be, to its own devices.[52]

Lately, trade ministers from developing countries have been pushing the fast-forward IP button. In the meantime, antitrust authorities reduce some distortions here and there in this area while Parliaments face the hurdle of seeing technocratic regulatory networks run right through them, both domestically and globally.[53]

Therefore, a highly technical legal issue such as the so-called paragraph 6 issue epitomizes the imbalance of the global IP paradigm. In this regard, the ongoing governance of access to affordable medicines in the developing world by our state and market elites illustrates a policy misjudgment.

Free trade is part of the solution for access to drugs in the developing world. However, by linking IP to trade, the leverage of global trade, competition and markets to push prices down have been legally annulled.

It is reasonable to assume that a more meaningful paradigm is needed. Bringing back meaning to IP requires not only efficient public-sponsored rules and institutions on licensing, but also free trade, stronger markets and competition.

---

52 For an assesment on the global dissemination of economic expertise see Y. Dezalay & B. Garth. 'National Usages for a "Global Science: the dissemination of New Economic Paradigms as a Strategy for the Reproduction of Governing Elites', *Global Science and national sovereignty: studies in historical sociology of science* (Routledge 2009), pp. 143–167.

53 See generally, S. Picciotto, *Regulating* op. cit.

9

CAPITAL LEGAL GAMES

1. Terms of Trade

For centuries, capitalism has advanced through property and contract. As mentioned above, property is the position, contract the move; going forward relentlessly in a series of feedback moves.

Public authority in stable societies currently exercises its power over some contractual relationships, by establishing *ex ante* limits in public law, and thus annulling contracts *ex post* through judicial review, or correcting them through regulatory agency proceedings (e.g. antitrust consent decrees).

Except within the structural context of social crises, public authorities do not normally involve themselves in matters of extensive property accumulation. Consequently, property often comes to the rescue of private individuals as a legal safe haven within which to build autonomy, particularly when public policies reduce contractual autonomy.

Naturally, as capital is power, the new forms of *private* power exercised through capital tend to gradually self-legalize; and *public* power follows suit, in order to catch up with it, re-regulating to recover collective control over those new forms. Thus, a variety of appropriation rituals are endlessly seen to shore up social life, propertizing activities and things through the assembly of new legally enforceable vehicles and forms.

The mechanics are simple: in order to maximize autonomy, capital-holders invest in autonomy-enhancing legal vehicles to prevent public power from interfering in accumulation, and thus make regular moves to remain outside the confines of public law, by keeping one legal step ahead.

Using autonomy-enhancing legal vehicles, capital-holders induce hands-off public policies (or pro-capital-holder policies) regarding accumulation. Thus, the backbone of the political community is anaesthetized with regular doses of corporate legal creativity in the benefit of capital-holders; when the effect wears off, the public authorities react, and the game goes

on, but the capital-holder is ahead of the community´s next catching up manoeuvre.

This is how the old *property-contract* move functions regarding the inter-play between contemporary public authorities and capital-holders. Needless to say, those moves have been consented to and later validated by public power.

Inventions of the mind are limitless. The inventions of the legal mind are also limitless. Thus, by 'proprietizing' knowledge and ideas, an extended game play is obtained in the age-old cat-and-mouse game between public authorities and the capital-holding individuals.

The representative of the corporation makes a legal point in the name of the shareholders: IP is ours; the corporate form is the proprietor of all intellectual output of its employees; those were the terms of contract with our scientists and authors.

That legal standpoint is certainly correct since today's advanced societies have accepted that the labour force can be traded as a commodity. However, intellectual propriety was originally a government-sponsored privilege granted to both the actual individual inventor and author, not to corporations.

In principle, scientists and the artists have for centuries represented the mind and spirit of society. Arguably, these people are the heirs of those who first painted images in caves, transmitting shared symbols and ideas inter-generationally, thus laying the foundations of our first communities.[1] Thus, it would reasonable to be argued that the industrial appropriation of human genius by corporate proxies is too excessive.

The transfer of invention to a large, globally-operated corporation allows capital-holding individuals to appropriate the most essential human creations. From there, IP becomes a world commodity, which corporations trade at will, through globally operated oligopolies in the hands of controlling shareholders.

However, by appropriating the very 'essence' of those who push the boundaries of the social system, allowing it to dream (artists) and see further (scientists), something radical is taking place.

Interestingly, the current IP measures basically align the two critical legal codes (patents and copyright) within standard generational time frames (20–30 years):

1 See http://whc.unesco.org/en/list/310.

– Patent: 7300 days (20 years)
– Copyright: 18250 days (50 years)

In a way, developed countries and IP constituencies have done the job of a non-existent international bureau of IP weights and measures by establishing these time frames. In any case, the legal term '*at least'* (and also *'no less'*) in the TRIPS table of IP 'weights and measures' is a power-term of its own, as it implies that IP time frames are not still universally fixed, and thus can be bargained up. [2]

As mentioned in previous pages, some private and public high level technicians still perceive TRIPS, not as an international legal ceiling, but as a floor. As a result, for these extreme IP advocates, those very time-limits or any other issue within the scope, strength and length of IP is not fixed, and thus they are counting on multiple and unremitting negotiations to come (i.e: the so-called TRIPS+ treaties).[3]

Following the demise of the non-democratic (and totalitarian) regimes of the 20th century, the global consensus held that no monopoly could be a good thing. Most of us continue to consider that the extreme accumulation of power in the hands of a few individuals (whether public or private) is bad for society; in essence, because there is no reining in or balancing of those individuals' wishes, and therefore neither is there any constraint on what emerges from their minds and spirits.

Reasonably, one important question which requires serious attention is why we are giving 7300 days of monopoly protection to scientific inventions. After all, no scientific data-driven deliberative process has taken place.

The world standard of IP time frames was decided rather liberally by 159 state representatives, who simply assumed that 7300 days was an appropriate time frame; a figure reached by adding 1095 days to the 1861-1994 patent terms in the United States.

Interestingly, the intangible proprietary code indexed in the IP portfolios of modern corporations comprises liquid and tradable assets, which are increasingly fit for standardized measurement, indexing and trading. Added to this, IP assets themselves are also a tradable commodity, the value of which is publicly disclosed through mandatory financial information anchored to company shares.

---

2 See chapter 3.

3 On IP legal ceilings see chapter 5.4.

In the past, most of a company's value was its monetary, tangible and fixed assets. Nowadays, these assets are to a great extent replaced in importance by patented technology, trademarks, copyrights, trade secrets and other intangible 'assets'. In this regard, IP intangible assets have become the dominant assets in many global corporations. Thus, these IP 'assets' are increasingly moving at the core of corporate market value, and that intangible value is reflected in their stock prices.

Beginning in the mid 90s, IP assets moved to the core of the 'competitive advantage' of companies.[4]As a result, the trading of IP based-company shares transforms the patent issue into a (financial) market issue. In consequence, capital markets ironically come to legitimize these legal monopolies.

Again, the K-10 and 10-Q like forms of the world securities markets do index and measure IP for the world-marketing of industrially produced proprietary technologies. In this regard, the productivity performance of industrialized proprietary intangibles provides critical *material information* for financial markets.

The so-called 'IP assets' thus have a bearing on capitalization of non-IP productive sectors. In consequence, a call-effect makes many publicly-owned companies shift their business model, or elements thereof, to IP mode. Thus IP mode promotes further IP mode in the current stage of IP inflation. Hence, measuring the extent to which IP impacts on world economic productivity is an issue which demands serious economic analysis and social consideration.

Inevitably, investor expectations of financial performance of IP companies increased as soon as the world trading regime began conditioning trade to compliance with global IP standards, and IP owners were thus able to vertically enforce standardized IP in 159 potential jurisdictions of the world. As explained above, the linkage of the international patent system (TRIPS) with the original legal infrastructures of world trade (GATT) produces incredible incentives for capital-holders to aggressively move their investment to IP stock and trading.

Ironically, as information is what allows developed capital markets to work efficiently, the above mentioned new financial *materiality* automatically shifted the economic preferences of capital-holders (and their institutional

4 R. Parr, *Royalty Rates for Licensing Intellectual Property* (John Williams & Sons 2007), p. 22.

vehicles) trading in securities markets. Thus, the TRIPS agreement produced two basic transformations on the critical world regimes of trade and finance:

(1) As for *world trade*, the IP linkage adapted world trade to *monopoly trading*, as the world market was suddenly partitioned or segmented along the lines of domestic IP rights. (2) As for *financial markets*, the IP linkage transformed these multi-jurisdictional legal monopolies into new tradable *world properties* and thus these markets further increased capitalization of both IP sectors and companies.

Hence, financial markets re-embedded these monopoly assets into a market-mechanism and thus somehow 'certified' them as market-driven assets. Nowadays, both systems (world trade and financial markets) are technically trading on these new intangible assets.

Therefore, the combined structure of incentives within (1) the international patent system, (2) IP conditioned world trade, and (3) world capital markets are transforming our economic and social ecosystems by producing a new global property. There is no great dark hand behind this transformation, but the simple result of handing control over our lives to these legal speculative forms of global corporate capitalism.[5]

These forms differ in two essential ways from traditional tangible properties. On one hand, this is a *global* property of limitless production. On the other hand, nowadays, the standardized IP minting presses of the world (Patent Offices) are monopoly-making machines, managed according to productivity inputs.

Needless to say, proprietary knowledge is the contemporary optimum form of property, as not only can it be limitlessly produced, but also easily distributed through world contractual relationships.

2. Oligopoly decoding

Capitalism is not the natural driving force of market and states. The mechanics of states and those of markets are the inner mechanics of *advanced societies,* and they function under an opposite logic. Currently, markets and states are collectively institutionalized virtues. On the contrary, capitalism is an aggregation of individual faults. The measure of capitalism is a measure of individual accumulated power vis-à-vis society at large.

The inner principles and ideals within states and markets are socially

5 See generally, S. Picciotto, *Regulating* op. cit.

valuable for people in inter-generational terms. We may not 'love' them, but we know that it is right that they are in place, so that society basically functions for all in our everyday lives.

As the principles and ideals within states and markets are socially perceived as valuable for all, their loose prescriptions rooted in the commons tend to be voluntarily and collectively enforced by citizens themselves in their interpersonal relationships. States and markets are both the basic legal infrastructures of society, private and public:

Markets and states are generally honored social codes, rooted in a long collective history whose principles and ideals are complementary, but at the same time distinct; and thus, they are required to be continuously balanced through deliberative processes.

Rationally speaking, that is what is lacking, globally. Societies based on any form of social state and market economy are socially and economically efficient.

On one hand, the basic principles and ideals of contemporary states are democracy and human rights, which provide (in multiple forms) the safety nets of education, health care and social security, as a means of producing social cohesion and thus social efficiency. On the other, the basic principles and ideals of contemporary markets are competition and freedom of movement of persons, goods and services (people, things and activities), as means for producing economic efficiency.

State and market elites (high level public officials and corporate managers) should reasonably work together to find ways of enforcing these ideals and principles, both domestically and worldwide.

Perhaps we can develop a common ground for building a better world, by leaving both the moralist utopia and the apology of realpolitik out of the practices of international law.[6] However, in order to do that, we have to be result-oriented and stick to specifics. In other words, and to paraphrase Sol Picciotto, the challenge is to design international institutions and rules which can help to ensure that the increasing international contacts, flow and opportunities empower ordinary people.[7]

The markets and states in advanced societies defeated the totalitari-

---

6 See M. Koskenniemi, *From Apology to Utopia; The Structure of International Legal Argument* (Lakimiesliiton Kustannus 1989).

7 S. Picciotto. 'What rules for the global economy', *Regulating international business: beyond liberalization* (MacMillan 1999), p. 5.

an conception of social and individual life such as communism, and could certainly do the same with capitalism. However, winning over capitalism requires expanding effective markets and states to the international; thus making these social mechanisms work for all the peoples of the world.

On the contrary, domestic and world oligopolies are capital-cumulative driven, and thus structurally anti-market and anti-state. Corporate capitalism is deeply rooted in oligopoly and monopoly *culture* as vehicles of capital accumulation, often merging private and public decisionmaking (eg: public-private regulatory partnerships) in the benefit of the wealthy few.

Oligopolies (weak market, weak competition) and monopolies (no market, no competition) are both the main trades of large individual capital-holders, with a differential performance on accumulation rates. English dictionaries tend to have entries both for the noun 'monopoly' and the action of transforming markets and competition into monopolies (ie 'to monopolize'). They also have an entry for oligopoly as a state of limited competition, in which a market is shared by a small number of producers or sellers.

However, interestingly, there is no entry for the actions leading to transform markets and competition into a weak-market economy. Following the usage of written language, oligopolization is placed in brackets when writing in non-technical fields. Thus, even today it is still not a standard current term for something that precisely defines corporate globalization in multiple sectors.

The people of Pompeii did not initially react sensibly at the smoke pouring down the hill. They did not know what was going on as they had no understanding of the implications of that smoke. World oligopolization is a smoke column signaling, in a way, an artificial eruption.

Reasonably, a deliberative process regarding oligopolization should take place. Those domestic corporations that succeed in oligopolizing in a given business sector are those who are first in the line in global capital accumulation. Having reached the position of oligopoly in that sector, most of these companies (particularly if they are publicly traded) move on together to the following second level playing field:

a) domestic diversification, as a way of circumventing domestic antitrust, and

b) peer-pressure on domestic authorities to facilitate the globalization of their domestic oligopolies.

Monopolization is a black letter illegal term in all jurisdictions of the

world[8]. Thus, publicly traded corporations throughout the world (read profit-maximizing corporations) increase their size and leverage on state and markets by bargaining around that crucial domestic legal prohibition.

By doing so, these legal proxies remotelly-controlled by controlling shareholders are expanding to a global market-economy still in the making, and thus governed by weak international antitrust enforcement.

As mentioned, a *meta-game* consists of changing the rules, while the game is actually being played. Thus, those controlling share-holders and corporate echelons who make the Faustian bargain of cheating to get more, tend to become involved in capital-intensive legal creativity and aggressive regulatory capture.[9]

In this regard, it is easier and safer to cheat by reframing things as something different, through law reform. The case of IP is paramount, for the reasons explored in the foregoing pages.

Those individuals playing meta-game with state and market regulation always release disruptive power; this not only has an adverse effect on the regulated business sector of their special interest, but it often transforms economic and social fundamentals.

By changing economic fundamentals, these individuals go beyond touching a core business: they touch all core businesses and sectors of economy and society. By changing social fundamentals, these people not only stick their hands into others' pockets; their fingers touch the lives of everyone.

However, traditional monopoly cannot be obtained through market-based competition because it is plainly illegal. Therefore, reaching the monopoly 'premium' (as the final stage of capital accumulation) is only possible by playing the illegitimate game of re-engineering the legal system at large. Therefore, the transformative dimension of the meta-game produced by linking IP to trade (contrary to the advice of the old GATT diplomacy) is not easy to match in comparative legal terms. A more autonomy-enhancing vehicle than IP is conceptually difficult to dream up. Basically, everything that can be inoculated with traces of IP can be monopolistically traded worldwide.

---

8 See chapter 8.3.

9 For the classic example of legal creativity in this regard see, in particular, M. van Ittersum, *Profits and Principle: Hugo Grotius, natural rights theories and the rise of Dutch power in the East Indies, 1595-1615*, Brill Studies in Intellectual History (Brill 2006).

Obviously, some of the companies that managed to make IP trade-conditioned and worldwide-enforceable were already oligopolies in their domestic markets prior to 1996. However, by using states as proxies to structurally transform intellectual property – and thus the so-called international patent system–, these companies transform themselves into world *legal monopolists*.

The resulting long-term disruptions in the social fabric go beyond technology. Extreme IP disrupts markets, competition, states, society, economy, science, art, and thus the individual and social life of each one of us.

3. Into extreme IP

Extreme IP is a world redistributive system based on the propertization of knowledge in all areas of social life. Extreme IP allows the shareholders of corporate proxies operating multi-jurisdictionally to industrially appropriate knowledge, capital and thus common wealth.

As a result of international legal reengineering (TRIPS rules), multiple global companies nowadays trade in legal monopoly code, and thus have vertically organized the global distribution of all their IP assets. The roller coaster advances by converting a combination of vehicles, institutions and processes into a new IP paradigm.

This paradigm will increase the current high disparities in global wealth distribution. Upward (or down-top) redistribution is widening inequality in real-time within south and north and between south and north; and south and north are everywhere.

From a perspective of social and economic world-policy, the issue can be framed as a simple question: to what extent are poor societies to be allowed to free-ride on the proprietary inventions of large patent-holding companies? The answer is as much as possible.

Poor societies should be allowed to free-ride to the greatest extent, if social development is a priority for the practitioners of global governance. Reasonably, poor societies should be helped to build up and strengthen their own domestic markets and states, based on a generous free-riding ticket for scientific innovation, together with redistribution from the wealthy societies of both West and East.

For almost half a century pre-TRIPS GATT law managed to reduce

trade tariffs to almost irrelevant levels. By doing so, world wealth was increased and redistributed to developing countries. Inevitably, it is distorting to see how those world trade tariffs have been now replaced by world license-fees.

Furthermore, it is unfair to force their societies to play by the rules, when many in wealthy societies played without any rules during the first stages of their industrial development.[10] Obviously, these and other such 'appropriations' can certainly be tracked far back in our long history: cumulative innovation has been the game, and it is based on several millennia of free-riding social imitation.

In this regard, from a purely developmental angle, it is difficult to question that free access to affordable medicines has a stronger positive impact on development than securing high standards of patent protection and enforcement of pharmaceuticals; if people die of AIDs there will be no development whatsoever. For this reason, developing countries should free ride on innovation, extensively, by conditioning degrees of patent protection to measurable stages and degrees of development.

However, the issue does not only affect developing societies and their citizens. In this regard, the citizens of wealthy societies should not deceive themselves by playing solitaire on this issue, as any improvement to their quality of life based on IP will be directly dependent on the evolution of their purchasing power.

On the other hand, the productivity of these industries consists of propertizing intangibles in order to exercise legal monopolies. Thus, these companies tend to keep IP rights and outsource global production and distribution, so there is not much workforce around these industries in their countries of incorporation.

In addition, profits from their intangibles are easily and ritually shifted to low tax jurisdictions. In this regard, transfer pricing problems are pervasive,[11] as the intangibility of their assets facilitates movement of income through tax havens and offshore financial centers of the world.[12] Therefore, the mantra of protecting innovation through IP for the good of society should

10 D. Ben-Atar, *Trade Secrets*: *Intellectual Piracy and the Origins of American Industrial Power* (Yale University Press 2004).

11 See S. Picciotto, *International Business Taxation* (Quorum Books 1992).

12 See J. Sharman, *Havens in a Storm: The Struggle for Global Tax Regulation* (Cornell University Press 2006).

also stick to measurable economic and social results in both developing and developed societies.

The 'knowledge-based society' is certainly a very catchy term encapsulating the greatest tautology on earth: knowledge is the essence of the aggregated us. Society is the cumulation of many inter-generational endeavors aiming at offering a good life for all. For it be so, there has to be an opportunity to keep on moving ahead, rubbing sticks to make fire and progressing to the starship.

In this regard, it would be reasonable for our upward-collective mobility to be as information commons-oriented as possible. After all, human society differs from a primate society in terms of structural collective innovation and inter-generational knowledge-sharing. This is precisely what is being inhibited by the current extreme IP paradigm.

We have invented an innovation model based on reprocessing and repackaging centuries of scientific research output as propriety-knowledge (read propertizing the information and intellectual commons) to trade on it through top-down license-based legal relationships.

An increasing corpus of critical analysis has already highlighted the risks to society of pursuing the extreme IP paradigm to nowhere.

The first TRIPS corporate raiders did not probably expect to create a global transformation of 'intangible productivity' in entire world industries. However, the move to extreme IP is no longer the mere move *of* global companies in the proprietary-technology sector, as businesses from many other sectors are also moving to extreme IP.

This structure of incentives is now embedded across the board of multiple business sectors to the benefit of those capital-intensive companies able to invest in pipelines, marketing and lobbying to exact fixable rents through autonomous price setting.

Free price systems were said to be an essential part of the market-economy. However, now goods or services have been somehow *i-podded*; they are *Made of IP* and thus no longer *Made in*. As a result, world patent-holders determine mandatory prices worldwide for proprietary technologies.

Meta-gaming is a relentless re-engineering of the social fabric, allowing large capital-holders to bargain upwards within the infrastructures of society at large. Thus, the power of these large capital-holders to do good or bad is incommensurate within any previous measure of ancient and modern power, including those individuals at the head of old dynastic Empires. The rea-

son is self-evident, namely the proxy corporate form and structure operating globally; one of the most beautifully perfected organizational machines in the whole history of mankind; able to exert influence, and thus change for good or bad, over the two hemispheres.

In this regard, corporations are somehow like the unmanned systems of capital-holders: large capital-holders use proxy corporations to 'play' capital accumulation through them, with no responsibility whatsoever, as if doing things 'through' these new Leviathans were pure digital game playing; which it is not. Extreme IP has to be read in this light, as a move in the interest of those capital-holders who are remote-controlling IP-based corporations.

4. Virgin lands

The systemic alternative to global corporate capitalism is a well-proven legal infrastructure with two main drivers: states and markets, or market and states. In this regard, the professionals working within each of these realms share common and complementary values.

Market-economy mechanisms –such as competition and efficiency– and social-state mechanisms –such as democracy and human rights– cross-pollinate each other by introducing checks and balances in the social fabric, thus preventing a large concentration of power in the hands of any individual.

The debates on the coherence of global economic governance and international law are a basic expression of the need to build states and markets in a coherent global policy framework; somehow, part of that original project got lost in translation, beginning with the two systems of San Francisco, and Bretton Woods.[13]

The legal technological infrastructures of societies are markets and states. After all, these two organizational forms are the natural heirs of the ancestral shelter and barter exchange, respectively, and thus provide the inner legal foundations for any past and present human community. Nowadays, we need somehow to bring them together globally, in order to prevent large capital-holders from aggressive bargaining within markets and states worldwide.

Extreme IP is one of those by-products. In this context, current phar-

13 P. Zapatero, *Searching for coherence in global economic* op. cit.

maceuticals legal protection is merely an example or an extremely unreasonable legal situation produced by those individuals who will economically benefit from it, namely the controlling shareholders of major global companies.

Access to medicines in the developing world requires constructing a thriving competitive global market trading in both generics and brand-name drugs. However, in order to do that, both states and markets have to deliver: the former, by building health infraestructures and a global pharmaceutical marketplace targeting the enforcement of right to health, and the latter by engaging in margin-cutting competition to deliver the cheapest essential drugs possible in that marketplace.

In recent decades, competitive industries from some developing countries such as Brazil and notably India, efficiently developed generic copies of drugs and distributed them at marginal cost prices in their local markets, but also exported them to others.

Before the pre-TRIPS era, these countries did free-ride on patent protection in order to provide incentives for local entrepreneurs to join and invest in the sector. Thus, generic industries became progressively more efficient in reverse-engineering technologies, and thus managed to copy complex pharmaceutical inventions, without the need to rely on the traditionally incomplete data disclosure of the kind registered in patent offices. As a result, a highly competitive generic industry blossomed and now provides access to affordable drugs for millions of people.

However, this move to generic production and distribution challenged the profit-making expectations of global brand-name companies and thus posed a threat for their bottom line. The challenge was not so much to divert potential profits from those local markets, as not that many developing countries enjoy significant manufacturing capacity. The challenge was the formation itself of a world pharmaceutical market, as monopoly rights are at odds with market-structures.

As a result, the industries fought back the formation of global market-structures in their sectors by packaging a new discourse around promoting scientific innovation and protecting their 'technology-exporting societies' from 'pirates'.

With regard to generics, that meant giving a battering to global distribution of generic products and thus world trade in generics, by capturing a critical hub of international trade law (read WTO TRIPS agreement). However, by doing so, the IP crusades touched social and economic fundamentals.

Boards and CEOs are basically proxies of controlling shareholders, operating through quarterly earnings and phone calls. Thus, the boards of directors and CEOs of major brand-name pharmaceutical companies perceived that the profitability of their business would be at risk if the cheaper-for-all generic drugs business model expanded its reach and clout to affluent societies.

Thus, the US pharmaceutical industry and some other industries, such as entertainment, software and others, pursued an historical quest to standardize world patent protection, and related IP forms, through multilateral hard-law; and surprisingly they managed it!

In order for them to obtain word-scale fixed rents on their monopoly products, patent products and processes also needed to be protected world-scale. The IP agenda of these global corporations during the GATT Uruguay Round focused on (1) upgrading the legal qualities and level of protection of the IP forms and (2) controlling world trade flows on goods and services produced under proprietary knowledge and thus avoiding unauthorized trade transactions.

World generics competition was thus inhibited by obtaining two basic legal outcomes: (1) domestic standardized mandatory protection or both product and process patents, and (2) protection of other instrumental IP forms (e.g. trademarks and trade secrets).

By succeeding, not only world trade in goods and services based on imitation or copy was precluded: the worldwide access to their proprietary technologies would be determined by the licensor and the licensee (thus property and contract). Hence, IP goods and services using proprietary technologies could be vertically distributed worldwide through hub-and-spokes pipelines.

As a result, nowadays, large patent-holding companies *compete for legal monopoly* on new inventions and, once they have obtained the patent, a wide variety of companies *compete for a license*, worldwide. The resulting legal scheme mixes all autonomy-enhancing tools (legal monopoly, anticompetitive arrangements and oligopoly) into one killer compound, for eliminating markets and thus precluding price-based competition.

That state of affairs is unreasonable. In any case, and sticking to the global poor, developing countries should not be required to pay back the cost of innovation in developed countries, as the social cost of patent protection in these societies is not correlated to that innovation.

In this regard, it is unreasonable to demand rents from developing countries if social and economic development is still an important world policy issue. The investment in drug innovation is already recouped with a generous premium in the wealthy markets of the developed world, in part thanks to public funding of health-care and health-related pharmaceutical research.

Developing countries without manufacturing capacity rely on world generics markets to access essential generic drugs but also to bargain with brand-name pharmaceutical companies to obtain the best prices. Their market structure requires pricing drugs very close to the marginal cost of production. However, those companies targeting the global poor as consumers have to outcompete others on very low margins, combined with large outputs. Only the brave (producer, distributor and trader) survive in such markets.

In this regard, the pharmaceutical industry has still not adapted its business model to the reality of our world of global poverty. On the contrary, it pursues an unrealistic business model, by means of domestic and world law reform. In essence, large brand-name companies have managed to block key global sources of generics through legal linkage of trade to IP. As a result, world trade flows in generics under compulsory licensing are not common.

The 2001 Doha Declaration on access to medicines already allows developing countries to play ball with TRIPS flexibilities and win more matches in this global policy area.[14] However, it will not be easy.

Reasonably, large brand-name companies could have obtained a less socially distorting global regime by simply obtaining a *global flat fee license* (GFFLs) for health-technologies. In this regard, a GDP-based GFFL on access to proprietary-technology would certainly have had a positive effect on developing countries.

After all, drug sales data reveals uniformity in the fraction of domestic's GDPs spent on health care R&D, regardless of population's per capita income. Thus, some informed observers and experts are already proposing that countries be released from the IP obligations in the health area, once that GDP fraction is reached.[15]

However, instead of adapting to the diversity of markets and demands, the global pharmaceutical industry pushed for the negotiation of TRIPS

14 J. Love, 'What the 2001 Doha Declaration Changed?, *Knowledge Ecology International* (16 September 2011).

15 See J. Love & T. Hubbard, 'Paying for Public Goods", *Code: Collaborative Ownership and the Digital Economy* (MIT Press 2005): 207–229.

agreement as well as for other TRIPS+ schemes.[16] Needless to say within these complex networks, corporate free-riding and capture often blur the public interest.[17]

Inevitably, any weak commitment among high ranking state and market elites towards the principles and ideals of markets and states reinforces the leverage of large capital-holders on their day-to-day operational decisions. In this regard, it is reasonable to assume that common good-oriented solutions would be easier to develop by taking the core ideals of the market-economy and the social-state as the starting point (together in same weight) of any policy design.

The corporate proxies of large capital-holders are 100% coherent, and have increasing resources at their disposal in order to wrap economic determinism in technical discourses on so-called economic freedom, economic efficiency, big is good, knowledge-based competition, extreme IP, etc.

Unfortunately, the current loopholes in our global policy framework produce a somewhat indulgent attitude among the state and market elites towards capital-holders. As a result, the essential battles over ideas are being partly replaced by technical (but not-principle driven) collaboration between these technocracies. By doing so, some of these experts are eroding the common values of their professions: that is to say, the principles and ideals embedded within the market and the state.

Sometimes, some of these state and market professionals mistake technocracy for neutrality. However, technicalities and techniques are never neutral, as they always operate on assumptions. Paradoxically, a gross manifestation of this phenomenon is how public-private partnerships rule domestic and international economic regulation. The TRIPS agreement analysed in these pages is a paramount example, as it is already hard entrenched world law.

The global chess-board politics of the pharmaceutical industry in this regard, and the casual way it deals with life and death –still without sufficient commitment– is a clear example in itself of how the incentive structures of capitalism play 'winner takes all' games for large capital-holders at the expense of states and markets and, thus, at the expense of us all.

IP itself is an invention; that is to say intellectual legal technology. The real paradox of patents is, in this regard, inventing proprietary inventions.

Patents are government-sponsored legal monopolies disciplining mar-

16 See above (chapter 3).

17 See generally S. Picciotto, *Regulating* op. cit.

kets. As such, patents provide a powerful tool for limiting competition, by segmenting / partitioning world's jurisdictions and thus annulling markets and inhibiting competition. IP is often used by global companies nowadays '*to exclude markets'* from functioning. By doing so, firms intensively use that IP '*not to compete in markets'*.

By linking IP to trade, a global structural change was devised in global industrial organization. The impregnation of proprietary *cells* with globally-traded goods and services currently allows optimal accumulation of capital through the corporate form and structure. As a result, big industries are pipelining 'intangible productivity' towards the monopoly-granting machines of Patent Offices.

In fact, the logic of intangible propertization appears to be relentless as IP expansion to the biotechnology sector strongly suggests, for example. Exclusive rights regimes for intangibles always offer great new meta-games to invent. Thus, evidently, the reach of patents over biotechnology is far greater than those based on chemical technologies, and thus creates a radically different level-playing field for world propertization of both natural and human life.

As a result, in recent decades patent-focused biotech has become a critical field for propertizing the human environment (seeds, plants, animal varieties, living organisms and genes) as well as our own nature (human genes), and thus the very ecosystem of human life.

Propertization of intangibles is limitless in conquering things and activities, even life itself. Thus, in keeping with our inventive nature, intellectual propertization games are up-scaling to run deep and high.

Nowadays, current discussions over patents focus on how to fine-tune the international patent system in order to win it back for public interest and thus provide a viable (legal) innovation infrastructure for the world.

Law and lawyers play a key part in creating the concepts and institutional forms of capitalism.[18] Extreme IP is one of those concepts and institutional forms. As these pages attempt to explain, the extreme version of cur-

18 See S. Picciotto, *Regulating corporate capitalism* (Oxford University Press 2010), generally, and also Y. Dezalay, 'Between the State, Law, and the Market: The Social and Professional Stakes in the Construction and Definition of a Regulatory Arena', *International Regulatory Competition and Coordination* (Clarendon Press 1996) at 59–87 and Y. Dezalay & B. Garth, 'Law, Lawyers, and Empire ', *The Cambridge History of Law in America. The Twentieth Century and After (1920-)* (Cambridge University Press 2008), pp. 718–758.

rent IP exclusive rights regimes produces severe social costs and is thus a bad world policy option.

Automatic licensing based on compensatory liability regimes (*compensatory liability regimes*) would be an easy alternative for avoiding the social costs of government-sponsored *artificial excludability / exclusivity* in critical scientific and technological areas.[19] Both developing and developed societies alike would benefit from that less-invasive approach to IP protection.

Moving from excludability / exclusivity to *remuneration rights* could correct the socially distorting effects of extreme IP regarding technological and scientific proprietary-knowledge.[20] As explained by David Campbell and Sol Picciotto, the simple solution would be to recast IP as 'rights to compensation' rather than 'rights to exclude', and thus opt for automatic licensing: 'This would mean essentially that users would have an automatic license, although the innovator would be entitled to appropriate compensation, rather than a right to exclude backed by the potential of injunctions and swingeing damages'.[21]

There is a strong case to make for global *automatic mandatory licensing* based on FRAND terms in all technological and scientific areas.[22] Public authorities, and particularly antitrust authorities, can and should contribute to promoting innovation through a policy mix, based on long-term mitigation of exclusive rights regimes, and long-term securing of open architectures.

The *intensive natural use* of science and technology by our species suggests that the international patent system should be adapted to an easy-and-cheap-to-license mandatory approach to patents: human collective upward mobility is based on science and technology, and thus should reasonably be kept as information commons-oriented as possible.

After all, society for humans differs from a society for primates in terms of structural collective innovation and inter-generational knowledge-sharing; and this is precisely what the current extreme IP paradigm is inhibiting. Hence, there is a strong case for reregulating or recalibrating exclusive rights regimes through the prism of science.

---

19 See generally S. Picciotto & D. Campbell, Whose Molecule is it anyway? op. cit.

20 J. Reichman, 'Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation', *Expanding the Boundaries of Intellectual Property. Innovation Policy for the Information Society* (Oxford University Press 2001), pp. 23–53.

21 See S. Picciotto, *Regulating* op. cit (chapter 9, section 4) and S. Picciotto & D. Campbell, *Whose Molecule is it anyway?* op. cit, p. 301.

22 FRAND: *fair, reasonable, and non-discriminatory*.

Incentiving innovation would advise public authorities to do things right, rather than arbitrarily. Reasonably, we should treat the actual structure of incentives as an issue with which the scientific community should be involved, so that states can deliver mandatory basic *equations* for IP weights and measures in the short-term.

In this regard, a basic equation is needed to calculate automatic mandatory licensing rates for at least essential scientific and technological inventions. Constructing and enforcing a flat fee equation would avoid the high transaction costs incurred by all companies when dealing with global proprietary-knowledge. That equation could be easily added as a third section to article 27 or a WTO General Council Decision, by stating as follows, for example:

> The WTO Members shall upgrade on a biannual basis a list of automatic compulsory licenses for essential scientific and technological inventions through formal consultation with the WIPO, the ITU and the WHO. The right holder of any of these essential patents will be remunerated with a fair and reasonable royalty based on the following equation: [...]. [23]

Alternatively, such regulatory solution could also be pursued through international cooperation by antitrust authorities without the need to add any provision to TRIPS, as such antitrust policy is TRIPS compatible. In this regard, the antitrust authorities from the country of origin of the patent holder could issue permanent consent decrees if these patent holders do not automatically facilitate FRAND licensing based on that equation.

In short, the IP-based innovation infrastructures should move towards *mandatory automatic licenses* in order to reduce transaction costs in global innovation markets, and thus to pursue the common good.

In this regard, it should be reasonable not only to release LDCs and the developing countries from their IP pharmaceutical obligations –as long as they are underdeveloped– but to seriously promote long-term technology transfer towards these societies.

In the meantime, the TRIPS rules, together with the 2001 Doha Declaration should reasonably be taken as a world legal ceiling for stronger IP protection as well as the international legal foundation to promote global market formation (instead of world market segmentation) both in generics and brand-name pharmaceuticals.

To sum up these pages, the world legal infrastructures for innovation

23 See TRIPS article 27 (*Rights conferred*).

should be upgraded by pursuing world-market formation, automatic mandatory licensing schemes in all essential scientific and technological sectors, as well as strong cooperation on antitrust enforcement against anticompetitive world inter-company arrangements in the IP area.

Extreme IP is not a good path for society to obtain social and economic progress. People are knowledgeable; as a group, we will keep that condition as long as we primarily feed our minds and spirits through non-proprietary, open access, open source and, thus, the knowledge and information commons.

The painting on the cover of this book hangs in El Prado; one of the most comprehensive and complete European art galleries. *Crossing the Styx* is the title of this piece by the Flemish painter Joachim Patinir. Dated 1520, the painting eloquently depicts the passing from life to death; there we have Charon taking us to the other side.

Access to essential medicines should not be a problem for anybody: its real-world costs are life-costs, and as death suggests, life is incommensurate. Drugs are science, and the product of science should be available to everyone.

10

BIBLIOGRAPHY

A. Aman, '*Globalization, Democracy, and the Need for a New Administrative Law*', 49 *UCLA law review* (2002): 1687–1716

A. Aman, *The Democracy deficit: taming Globalization through law reform* (NYU Press 2004)

Anonymous, 'Is the University-Industrial Complex Out of Control?', 409 *Nature* 6817 (1 January 2001)

I. Ayres & J. Braithwaite, *Responsive regulation: transforming the deregulation debate* (Oxford University Press)

F. M. Abbott. 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', 22 *Vanderbilt Journal of Transnational Law* (1989), pp. 689–745

F. Abbott, 'First Report (Final 1997) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel importation', 1 *Journal of International Economic Law* 4 (1998): 607–636

F. Abbott, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on public health', 9 *QUNO Paper* (2002)

F. Abbott, 'Non-violation nullification or Impairment Actions under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder' 11 *QUNO Occasional Papers* (2003)

F. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' 14 *QUNO Occasional Papers* (2004)

F. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', 99 *American Journal of International Law* 2 (2005): 317–358

F. Abbott & J. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 10 *Journal of International Economic Law* 4 (2007): 921–987

F. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', 99 *American Journal of International Law* 2 (2005): 317–358

F. Abbott & P. van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* (World Bank 2005)

F. Abbott, 'The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health', *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge 2006), pp. 27–40

F. Abbott, 'A new dominant Trade Species emerges: is bilateralism a threat?', 10 *Journal of International Economic Law* (2007): 571–583

R. Allen, 'Collective invention', 4 *Journal of Economic Behavior & Organization* (1983): 1–24

A. Attaran, 'Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution', 2 *Emory International Law Review* 17 (2003): 743–780

G. Alberti, 'Non communicable diseases: Tomorrow´s pandemics', 79 *Bulletin of the World Health Organisation* 10 (2001): 907

K. Alter & S. Meunier, 'The International Politics of Regime Complexity', 7 *Perspectives on Politics* (2009): 13–70

K. Arrow, 'Economic Welfare and the Allocation of Resources for Invention', *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton University Press 1962), pp. 609–626

T. Arnold, *The folcklore of capitalism* (Beard Books 2000)

T. Avafia, J. Berger & T. Hartzenberg, 'The ability of select sub-Saharan African countries to utilize TRIPS Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries', 12 *TRALAC Working Papers* (2006)

B. Baker, 'Settlement of India/EU WTO Dispute re Seizures of In-Tran-

sit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough', 81 *Northeastern University School of Law Research Papers* (January 1, 2012)

D. Baker, *Financing Drug Research: What Are the Issues?* (Center for Economic and Policy Research 2004)

P. Barral, *20 Years of Pharmaceutical Research Results throughout the World: 1975-1994* (Rhone-Poulenc Rorer Foundation 1996)

D. Ben-Atar, *Trade Secrets*: *Intellectual Piracy and the Origins of American Industrial Power* (Yale University Press 2004)

Y. Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (Yale University Press 2006)

Y. Benkler, 'The Idea of Access to Knowledge and the Information Commons: Long-Term Trends and Basic Elements', Access to Knowledge in the age of Intellectual Property (Zed Books 2010), pp. 217–237

E. Benvenisti & W. Downs, '*Distributive Politics and International Institutions: The Case of Drugs',* 36 *Case Western Reserve Journal of International Law* (2004): 21–52

J. Berger, *Advancing public health by other means: using competition policy to increase access to essential medicines,* Bellagio Series on Development and Intellectual Property Policy: Policy Options for Assuring Affordable Access to Essential Medicines (ICTSD 2004)

J. Bermudez & E. Hohen, 'The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good', 4 *Open AIDS Journal* (2010): 37–40

J. Bhagwati, 'Economic Freedom: Prosperity and Social Markets (Key Note Speech)', *Economic Conference on Economic Freedom and Development*, Tokyo (June 17-18, 1999)

J. Boyle, *Shamans, Software, and Spleens: Law and the construction of the information society* (Harvard University Press 1996)

V. Bradford & K. Lee, 'TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?' 3 *Globalization and Health* (2007): 3

A. Bradley, 'Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations', 23 *Stanford Journal of International Law* (1987): 57–87

J. Braithwaite, *Corporate crime in the pharmaceutical industry* (Routledge & Kegan Paul 1984)

J. Braithwaite & P. Drahos, *Global Business Regulation* (Cambridge University Press 2000)

S. Burris, P. Drahos &. C. Shearing 'Nodal Governance', 30 *Australian Journal of Legal Philosophy* (2005): 30–58

D. Candland, *Feral children & clever animals: reflections on human nature* (Oxford University Press 1993)

D. Cahoy, 'Confronting Myths and Myopia on the Road from Doha', 42 *Georgia Law Review* (2007): 131–192

A. Christie & Ch. Dent, '"Generally inconvenient": the 1624 *Statute of Monopolies* as political compromise', Intellectual Property Research Institute of Australia, *Working Paper No. 4/10* (June 2010)

M. Cohen, '"Property and Sovereignty"' 13 *Cornell Law Quaterly* 8 (1927): 11–14

J. Cohen-Kohler, L. Esmail & A. Perez Cosio, 'Canada's implementation of the Paragraph 6 Decision: is it sustainable public policy?', 12 Globalization and Health 3 (2007): 1–16

J. Connor, *Global Price Fixing* (Springer 2007)

C. Correa & A. Yusuf, *Intellectual Property and International Trade: the TRIPS Agreement* (Kluwer Law International 1998)

C. Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health*' (World Health Organization 2004)

C. Correa, 'Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines' 36 *Case Western Reserve Journal of International Law* (2004): 79–94

C. Correa, 'Implications of bilateral free trade agreements on access to medicines', 84 *Bulletin of the World Health Organization* (2006): 399–404

C. Correa, 'Fostering R&D and promoting access to medicines', *New ICTSD Series on New Opportunities through Innovation* (2007)

C. Correa, 'Intellectual property rights and public health: the general context and main TRIPS compliant flexibilities', *Intellectual property and ac-*

cess to medicines: papers and perspectives (World Health Organization 2010)

Ch. Cotropia, 'Compulsory Licensing Under TRIPS and the Supreme Court of the United States' Decision in *eBay v. MercExchange', Comparative Patent Law: A Handbook of Contemporary Research* (Edward Elgar 2008), pp. 557–583

C. Cotter, 'The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries'*,* 5 *Loyola University of Chicago International Law Review* (2008): 177–189

T. Cottier, 'From progressive liberalization to progressive regulation in WTO law', 9 *Journal of International Economic Law* 4 (2006): 779–821

A. Chandler, Jr, *Scale and Scope: The Dynamics of Industrial Capitalism* (Belknap Press 1990)

L. Chen, T. Evans & R. Cass, 'Health as a Global Public Good', *Global Public Goods: International Cooperation in the 21st Century* (United Nations Development Programme 1999), pp. 284–305

N. Chorev, 'Political and Institutional Maneuvers in International Trade Negotiations: The United States and the Doha Development Round', *Strategic Arena Switching in International Trade Negotiations* (Ashgate 2007), pp. 33–34

P. David, 'Clio and the Economic Organization of Science: Common Agency Contracting and the emergence of "open science" institutions', 88 *American Economic Review* 2 (1998): 15–21

C. Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press 2008)

Y. Dezalay, 'Between the State, Law, and the Market: The Social and Professional Stakes in the Construction and Definition of a Regulatory Arena', *International Regulatory Competition and Coordination* (Clarendon Press 1996), pp. 59–87

Y. Dezalay & B. Garth, 'Law, Lawyers, and Empire ', *The Cambridge History of Law in America. The Twentieth Century and After (1920-)* (Cambridge University Press 2008) , pp. 718–758.

Y. Dezalay & B. Garth, 'National Usages for a "Global Science: the dissemina-

tion of New Economic Paradigms as a Strategy for the Reproduction of Governing Elites', *Global Science and national sovereignty: studies in historical sociology of science* (Routledge 2009), pp. 143–167

W. Diebold, *The End of the ITO*, 16 *Essays in International Finance* (Princeton 1952)

M. Djelic & T.Kleiner, 'The international competition network: Moving towards transnational governance', *Transnational Governance: Institutional Dynamics of Regulation* (Cambridge University Press 2006) , pp. 287–307

C. Doctorov, *Makers* (2009)

H. Dutton, *The Patent System and Inventive Activity during the Industrial Revolution 1750-1852* (Manchester University Press 1984)

G. Dutfield, *Intellectual Property Rights and the life science industries: A Twentieth Century History* (Ashgate 2003)

P. Drahos, *A Philosophy of Intellectual Property* (Aldershot 1996)

P. Drahos, 'Developing Countries and International Intellectual Property Standard-setting', UK Commission on Intellectual Property Rights, *Study Paper 8* (2001)

Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property', 4 *The Journal of World Intellectual Property* (2001): 991–808

P. Drahos with J. Braithwaite, *Information Feudalism: Who Owns the Knowledge* (Earthscan 2002)

P. Drahos, 'Intellectual Property and Pharmaceutical Markets: a Nodal Governance Approach', 77 *Temple Law Review* (2004): 401–424

P. Drahos, 'Winning Battles, Losing the War: Lessons for the Weak from the Negotiations over the Doha Declaration on TRIPS and Public Health', paper presented at *Trade Negotiation and Developing Countries: The Doha Round, International Workshop*, Griffith University (August 12-13, 2005)

P. Drahos, 'Death of the Patent System - Introduction', *Death of Patents* (Lawtext Pub Ltd 2005), pp. 1–11

P. Drahos, 'Four lessons for developing countries from the trade negotiations over access to medicines' 28 *Liverpool Law Review* (2007): 11-39

P. Drahos, *The Global Governance of Knowledge: Patent Offices and their clients* (Cambridge University Press 2010)

P. Drahos, '"IP World"-Made by TNC Inc', *Access to Knowledge in the age of Intellectual Property* (Zed Books 2010), , pp. 197–215

J. Drexl, 'The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights', *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press 2005), , pp. 709–725

C. Ehlermann & L. Ehring, 'Decision-making in the world trade organization', 8 *Journal of International Economic Law* 1 (2005): 51–75

M. Eisner, *Antitrust and the Triumph of Economics. Institutions, Expertise and Policy Change* (University of North Carolina Press 1991)

R. Elliot, 'Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceutical for export', 1 *International Journal of Intellectual Property Management* 1 (2006): 94–112

I. Feichtner, *The Law and Politics of WTO Waivers: Stability and Flexibility in Public International Law* (Cambridge International Trade and Economic Law 2011)

C. Fisk, 'Removing the 'Fuel of interest' from the 'fire of the genius': law and employee-inventor, 1830-1930', 65 *University of Chicago Law Review* 4 (1998): 1127–1198

E. Fox, 'Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?', *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press 2005), pp. 758–769

F. Frager, 'A history of intellectual property from 1545 to 1787', 26 *Journal of the Patent Office Society* (1944): 711–760

D. Gantz, *Liberalizing international trade after Doha: multilateral, regional, and unilateral initiatives* (Cambridge University Press 2013)

N. Gallini & M. Trebilcock, 'Competition policy and intellectual property rights' *Competition policy and intellectual property rights in the knowledge-based economy* (University of Calgary Press 1998), pp. 17–61

R. Gardner, *Sterling-Dollar Diplomacy* (Clarendon Press 1956)

G. Gereffi, *The Pharmaceutical Industry and Dependency in the Third World* (Princeton University Press 1983)

D. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet and Maxwell 1998)

G. Ghidini, *Intellectual Property and Competition Law: The Innovation Nexus* (Edward Elgar 2006)

J. Gimbel, *Science, Technology, and Reparations: Exploitation and Plunder in postwar Germany* (Stanford University Press 1990)

R. Gold & D, Lam, 'Balancing Trade in Patents: public non-commercial use and compulsory licensing', 6 *Journal of World Intellectual Property* (2003): 5–32

R. Gold & J. Morin, 'Consensus-seeking, distrust and rhetorical entrapment: The WTO decision on access to medicines' 16 *European Journal of International Relations* 4 (2010): 563–587

K. Gopakumar & and Smith, 'IPR provisions in FTAs: Implications for access to medicines', *Intellectual property and access to medicines: papers and perspectives* (World Health Organization 2010), pp. 141–150

E. Hawley, *The New Deal and the problem of monopoly: a study in economic ambivalence* (Princeton University Press1966)

L. Helfer, 'Human Rights and Intellectual Property Rights; Conflict or Co-existence?', 5 *Minnesota Intellectual Property Review* (2003): 167–179

L. Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking', 29 *Yale Journal of International Law* 1 (2004): 1–83

L. Helfer & G. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2011)

M. Helble, *More Trade for Better Health, International Trade and Tariffs on Health Products*, Staff Working Paper ERSD-2012-17, WTO Economic Research and Statistical Division (18 October 2012)

A. Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' 3 *Harvard Law Review* 111(1998): 621–688

H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2007)

H. Hestermeyer, 'Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines', 11 *ASIL Insight 28* (December 10, 2007)

D. Hicks, T Breitzman, D Olivastro & K Hamilton, 'The Changing Composition of Innovative Activity in the US – A Portrait Based on Patent Analysis', 30 *Research Policy* (2001): 681–703

B. Hindley, *The Economic Theory of Patents, Copyrights, and Registered Industrial Designs: Background Study to the Report on Intellectual and Industrial Property* (Economic Council of Canada 1971)

E. Hoen, 'Public Health and International Law. TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha', 27 *Chicago Journal of International Law* (2002): 27–46

E. Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers 2009)

E. Hoen, J. Berger, A. Calmy & S. Moon, 'Driving a decade of change: HIV/AIDs, patents and access to medicines for all', 14 *Journal of International Aids society* 15 (2011): 1–12

D. Hounshell & J. Kenly Smith, *Science and corporate strategy: Dupont R&D 1902-1980* (Cambridge University Press 1988)

T. Hubbard &. J. Love. 'A New Trade Framework for Global Healthcare R&D' 2 *PloS Biology* 2 (2004): 147–150

R. Hudec, 'International Economic Law: the political theater dimension', 17 *Journal of International Economic Law* (1996): 9–15

D. Hull, *Science as process* (University of Chicago Press 1988)

J. Jackson, *World Trade and the Law of GATT. A Legal Analysis of the General Agreement on Tariffs and Trade* (The Boobs-Merrills Company 1969)

J. Jackson, *Restructuring the GATT System* (New York Council on Foreign Relations Press 1990)

J. Jackson, 'The WTO Dispute Settlement Understanding: Misunderstandings on the Nature of Legal Obligation', 91 *American Journal of International Law* (1997): 69–74

M. Keck & K. Sikkink, *Activists Beyond Borders: Advocacy Networks in International Politics*, (Cornell University Press 1998)

M. Koskenniemi, *From Apology to Utopia; The Structure of International Legal Argument* (Lakimiesliiton Kustannus 1989)

W. Kovacic & H. Hollman, 'The International Competition Network: Its Past, Current and Future Role' 20 *Minnesota Journal of International Law* (2011): 274–323

W. Kovacic, H. Hollman & A. Robertson, 'Building Global Antitrust Standards: The ICN's Practicable Approach', *Research Handbook on International Competition Law* (Edward Elgar 2012), pp. 89–109

M. Kremer, 'Patent Buyouts: A Mechanism for Encouraging Innovation', 113 *Quarterly Journal of Economics* 4 (1998): 1137-1167

See H. Kronstein, *The Law of International Cartels* (Cornell University Press 1972)

P. Kuijper, 'The Law of GATT as Special Field of International Law. Ignorance, further refinement or self-contained system of international law?', 25 *Netherland Yearbook of International Law* (1994): 239–241

P. Lamy, *Towards World Democracy* (Policy Network 2004)

P. Lamy, 'The Place of the WTO and its Law in the International Legal Order', 17 *European Journal of International Law* 5 (2007): 969–984

P. Lamy, *Globalization and trade opening can promote human rights,* WTO || *Speeches and statements* (5 June 2009)

P. Lamy. 'Urging multilateral cooperation to advance public health "in the real world"', WTO || *Speeches and statements* (14 July 2009)

P. Lamy, *The need for 'unity in our global diversity',* WTO || *Speeches and statements* (14 June 2011)

P. Lamy, 'Strong competition policies key to a dynamic and healthy market economy', WTO || *Speeches and statements* (16 February 2012)

R. Landes. 'Consumer choice as the ultimate goal of antitrust', 62 University of Pittsburg Law Review (2000-2001): 503-526.

D. Light & J. Lexchin, 'Will Lower Drug Prices Jeopardize Research? A Policy Fact Sheet', 4 *The American Journal of Bioethics* 1 (2004): W3-W6

J. Love, *From TRIPS to RIPS: A Better Trade Framework to Support Innova-*

tion in Medical Technologies, Paper presented at Agence Nationale de Recherches sur le Sida, University of the Mediterranean (Marseille 2003)

J. Love & T. Hubbard, 'Paying for Public Goods", *Code: Collaborative Ownership and the Digital Economy* (MIT Press 2005): 207–229

J. Love, 'What the 2001 Doha Declaration Changed?, *Knowledge Ecology International* (16 September 2011)

M. Llewelyn, 'Schrodinger's Cat: An Observation on Modern Patent Law', *Death of Patents* (LawNext 2005), pp. 11–66

A. Mace, 'TRIPS, EBay, and denials of Injunctive Relief: is article 31 compliance everything?', 10 *Columbia Science and Technology Law Review* (2009): 233–266

F. Machlup & E. Penrose, 'The patent controversy in the nineteenth century', 1 *Journal of Economic History* 10 (1950): 1–29

F. Machlup, *An Economic Review of the Patent System, Study of the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary*, United States Senate, 85th Congress, Second Session, Study No. 15 (1958)

C. MacLeod, *Inventing the Industrial Revolution: The English Patent System 1660-1800* (Cambridge University Press 1988)

H. Markel, 'Patents, Profits, and the American People—The Bayh–Dole Act of 1980', 369 *New England Journal of Medicine* (2013): 794–796

D. Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health: A Solution to the Access to essential medicines problem?', 7 *Journal of International Economic Law* 1 (2004): 73–107

P. Mayharduk & S. Rimmington, 'Compulsory Licenses: A tool to improve global access to the HPV vaccine', 35 *American Journal of Law & Medicine* (2009): 323–350

R. Mayne, 'The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective', *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002), pp. 244–259

B. Mercurio, 'Seizing' pharmaceuticals in transit: analysing the WTO dispute that wasn´t', 61 *International and Comparative Law Quarterly* (2012): 389–426

R. Merges & R. Nelson, 'On the Complex Economics of Patent Scope', 90 *Columbia Law Review* 4 (1990): 839–916

R. Merton, *On the shoulders of giants: A Shandean Postcript* (Free Press 1965)

R. Merton, *Sociology of Science* (University of Chicago Press 1973)

I. Mgbeoji, I. "The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization" 5 *Journal of History of International Law* (2003): 403–422

M. Montaña y Mora, 'A GATT with Teeth: Law Wins Over Politics in the Resolution of International Trade Disputes', 31 *Columbia Journal of Transnational Law* 1 (1993): 103–180

M. Mrazek, 'Pharmaceutical Pricing in the Developing World: Issues of Access to Medicines', 2 *Expert Rev Pharmacoeconomics Outcomes Research* 1 (2002): 43–50

J. Murmann & R. Landau, 'On the making of competitive advantage: the development of the chemical industries of Britain and Germany Since 1850' *Chemical and Long-term economic growth: insights from the chemical industry* (1998), pp. 27–70

S. Musungu & C. Oh, *The use of flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?* (WHO 2006)

D. Noble, *America by Design* (Oxford University Press 1979)

D. North, *Institutions, Institutional Change and Economic Performance* (Cambridge University Press 1990)

E. Ng & J. Kohler, 'Finding flaws: the limitations of compulsory licensing for improving access to medicines-An international comparison' 16 *Health Law Journal* (2008): 143-172

W. D. Nordhaus, *Invention, Growth and Welfare* (MIT Press 1969)

A. Nuvolari, "Collective invention during the British Industrial Revolution", 28 *Cambridge Journal of Economics* (2004) 3: 347–363

J. O'Connor, *Good Faith in International Law* (Dartmouth Publishing 1991)

M. Olcay & R. Laing, 'Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?', *Study prepared for the Commission on Intellectual Property Rights, Innovation and Public Health* (World Health Organization 2005)

M. Olson, *The logic of collective action: public goods and the theory of groups* (Harvard University Press 1965)

K. Outterson & R. Smith, 'Counterfeit Drugs: The Good, the Bad and the Ugly', 15 *Albany Law Journal of Science & Technology* (2006): 525–543

D. Packham & M. Tasker. 'Industry and the Academy–a Faustian Contract?' 11 *Industry and Higher Education* 2 (1997): 85-90

R. Palan, *The offshore world: sovereign markets, virtual places, and nomad millionaires* (Cornell University Press 2003)

R. Parr, *Royalty Rates for Licensing Intellectual Property* (John Williams & Sons 2007)

E. Penrose, *The Economics of International Patent System* (John Hopkins University Press 1951)

S. Picciotto, 'What rules for the global economy', *Regulating international business: beyond liberalization* (MacMillan 1999), pp. 1–28

S. Picciotto, 'Defending the Public Interest in TRIPS and the WTO', *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave and Oxfam 2002), pp. 224–243

S. Picciotto, 'Private rights vs public interests in the TRIPS agreement: the access to medicines dispute', 97 *Proceedings of the annual conference of the American society of international law* (2003): 167–172

S. Picciotto & D. Campbell, 'Whose Molecule Is It Anyway? *Private and Social Perspectives on Intellectual Property',* New perspectives on property law, obligations and restitution (Cavendish 2003), pp. 279–303

S. Picciotto, *Regulating global corporate capitalism* (Oxford University Press 2011)

S. Picciotto, 'International Transformations of the Capitalist State', 43 *Antipode* 1 (2011): 87–107

S. Picciotto, *Towards Unitary Taxation of Transnational Corporations* (Tax Justice Network 2012)

E. Prindle, 'The marvelous performance of the American patent system', 10 *Journal of the Patent Office Society* (1927–28) at 255–258

M. Pugatch, 'The international regulation of IPRs in a TRIPS and TRIPS plus world.' 6 *Journal of World Investment and Trade* 3 (2005):430–465

M. Pugatch, 'Political economy of intellectual property policy-making — an observation from a realistic (and slightly cynical) perspective' 7 *The Journal of World Investment & Trade* 2 (2006): 257–274

M. Pugatch. *The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy* (Edward Elgar 2006)

J. Reichman, 'From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement', 29 *New York University Journal of International Law and Politics* (1996): 12–93

J. Reichman, 'Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation', *Expanding the Boundaries of Intellectual Property. Innovation Policy for the Information Society* (Oxford University Press 2001), pp. 23–53

J. Reichman & C. Hasenzahl, 'Non-voluntary Licensing of Patented Inventions', 5 *ICTSD/UNCTAD Issue Papers* (2003)

J. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options', 37 *Journal of Law Medicine* (2009): 247–263

J. Robinson, *The Accumulation of Capital* (Macmillan 1956)

F. Roessler, 'The relationship between the World Trade Order and the International Monetary Fund', *The Legal Structure, Functions and Limits of the World Trade Order: A Collection of Essays* (Cameron May 2000), pp. 157–181

J. Ross & J.A. Wasserman, 'Trade-Related Aspects of Intellectual Property Rights', *The GATT Uruguay Round: A Negotiating History (1986-1992)*, Volume II (Kluwer Law and Taxation Publishers 1993), pp. 2241–2313

M. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Brookings Institution Press 1998)

M. Ryan, 'The Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking', 19 *University of Pennsylvania Journal of International Economic Law* 2 (1998): 535-586

F. Scherer, "Nordhaus' Theory of Optimal Patent Life: A geometric reinterpretation', 62 *American Economic Review* (1972): 422–427

F. Scherer, *Competition policy, domestic and international* (Elgar Publishing 2000)

F. Scherer & J. Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Countries' *Commission on Macroeconomics and Health,* Working Paper n.WG4:1, Geneva (WHO 2001)

F. Scherer, 'A Note on Global Welfare in Pharmaceutical Patenting', 27 *World Economy* 7 (2004): 1127–1142.

J. Schumpeter, *Capitalism, socialism and democracy* (Harper 1950)

S. Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law', 5 *Journal of Economic Perspectives* 1 (1991): 29–41

S. Sell, 'TRIPS and the Access to Medicines Campaign', 20 *Wisconsin International Law Journal* (2001–2002): 481–522

S. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003)

S. Sell, 'TRIPS-Plus Free Trade Agreements and Access to Medicines' 28 *Liverpool Law Review* (2007): 41–72

S. Sell, 'From Forum-Shifters to Shape-Shifters: Rulemaking and Enforcement in Intellectual Property', *International Studies Association Meeting*, New York City (February 15-19, 2009)

S. Sell, 'Cat and Mouse: Forum shifting in the battle over intellectual property rules and enforcement', Paper presented the *International Studies Association Montreal* (March 16-19th, 2011)

D. Serafino, 'Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures', *KEI Research Notes* (6, 4 June 2007)

K. Shadlen, 'The political economy of AIDs treatment: Intellectual property and the transformation of generic supply', 51 *International Studies Quarterly* 3 (2007): 559–581

G. Shaffer, 'Recognizing public goods in WTO Dispute Settlement: Who participates? Who Decides? The case of TRIPS and pharmaceutical patent protection', 7 *Journal of International Economic Law* (2004): 459–482

J. Sharman, *Havens in a Storm: The Struggle for Global Tax Regulation* (Cornell University Press 2006)

S. Shavell & T. van Ypersele, 'Rewards versus intellectual property rights' 44 *Journal of Law and Economics* (2001): 525–547

D. Siegel, 'Legal Aspects of the IMF/WTO Relationship: The IMF's Articles of Agreement and the WTO Agreements', *Current Developments in Monetary and Financial Law*, Volume 3 (International Monetary Fund 2005), pp. 873–941

K. Sikkink, 'Transnational Advocacy Networks and the Social Construction of Legal Rules' *Global Prescriptions: The Production, Exportation, and Importation of a New Legal Orthodoxy* (The University of Michigan Press 2002), pp. 37–64

M. Sontoro & L. Paine, 'Pfizer: Protecting Intellectual Property in a Global Marketplace', *Harvard Business School,* Case study No. 9-392-073 (1992)

F. Steckel, 'Cartelization of the German Chemical Industry 1918-1925', 19 *Journal European Economics History* 2 (1990): 329–352

P. Stephan, 'Institutions and Elites: Property, Contract, the State, and Rights in Information in the Global Economy', 10 *Cardozo Journal of International Law and Comparative Law* (2002): 305–318

J. Stiglitz, "Trade agreements and health in developing countries", 373 *The Lancet,* January 31 (2009): 363–365

G. Stocking & M. Watkins, *Cartels in Action* (Twentieth Century Fund 1947)

P. Suber, *Open Access* (MIT Press 2012)

A. Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health', 18 *American Journal of Law and Medicine* 4 (1992): 301–346

A. Taylor, 'Governing the Globalization of Public Health', 32 *Journal of law, medicine and ethics* 2 (2004): 500–508

M. Temmerman, 'The Legal Notion of Abuse of Patent Rights' *NCCR Trade Regulation Working Paper No 2011/23* (May 2011)

T. Trainer, 'Intellectual Property Enforcement: A Reality Gap (Insufficient Assistance, Ineffective Implementation?', 8 *John Marshall Law School Review of Intellectual Property Law* (2008): 47–79

P. Trouiller, P. Olliaro, E. Torreele, J. Orbinski, R. Laing & N. Ford, 'Drug development for neglected diseases: a deficient market and a public health policy failure'. 359 *The Lancet* 9324 (2002): 2188–2194

S. Tully, *Corporations and International lawmaking* (Martinus Nijhoff 2007)

M. van Ittersum, *Profits and Principle: Hugo Grotius, natural rights theories and the rise of Dutch power in the East Indies, 1595-1615*, Brill Studies in Intellectual History (Brill 2006)

T. Veblen, *The higher learning in America: Memorandum on the conduct of universities by business men* (B.W Buebsch 1918)

J. Viner "Conflicts of Principle in Drafting a Trade Charter", 25 *Foreign Affairs* (1947): 612–628

E. Von Hippel, *Democratizing innovation* (MIT Press 2005)

B. Waning, M. Kyle, E. Diedrichsen, L. Soucy & J. Hochstadt *et al,* 'Intervening in global markets to improve access to HIV/AIDS treatment: an analysis of international policies and the dynamics of global antiretroviral medicines markets', 6 *Globalization and Health* (2010): 9

K. Watal, *Intellectual Property Rights in the WTO and Developing countries*, Oxford University Press, 2001 and R. Okediji, 'Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement', 17 *Emory International Law Review* 2 (2003): 819–918

D. Weatherall, 'Problems for Biomedical Research at the Academia-Industrial Interface', 9 *Science and Engineering Ethics* (2003): 43–48

W. Wells, *Antitrust and the Formation of the Postwar World* (Columbia University Press 2003)

A.Wilcox, *A Charter for World Trade* (Arno Press 1972)

B. Wright, 'The economics of invention incentives: Patents, prizes, and research contracts", 73 *American Economic Review* (1983): 691–707

P. Zapatero, 'Modern international law and the advent of special legal systems', 23 *Arizona Journal of International and Comparative Law* 1 (2005): 55–75

P. Zapatero, 'Searching for coherence in global economic policymaking', 24 *Pennsylvania State International Law Review* (2006): 595–627

S. Zolla-Pazner, 'The Professor, the University, and Industry', 268 *Scientific American* 3 (1994): 72–77