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석사학위 논문

Development in the Age of IP

조선대학교 대학원

법학과

Nikolaus Trapani

IP시대에서의 발전

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Abstract

Development in the Age of IP

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Economic and social development are closely tied to progress in innovation, as history illustrates clearly. Inventions such as the steam engine changed the course of human history in a matter of decades. This innovative surge has only increased in pace over time, though not equally for all nations. Currently, attempts to stimulate innovation and spur development though the standardization of intellectual property rights across the globe may be having the effect of furthering the gap between developed and developing nations. This paper examines the theoretical, philosophical and economic underpinnings of one aspect of intellectual property(IP), namely patents, and attempts to explain the effect of patent regimes on the developing world. It begins by examining the patent system's effect on innovation and the effect of innovation on development in the closed system of a single state. It then examines how IP behaves when broadened to a system of interconnected but competitive states. The following sections look at the development-specific aspects of the two major international IP regimes, The World Intellectual Property Organization(WIPO) and and the WTO's Trade Related aspects of Intellectual Property (TRIPs).

The penultimate section concerns itself with how developing states negotiate for their best interests in the face of the economic and political clout of the developed world. Known as regime shifting, developing states can use horizontal movement along various IP and non-IP regimes to create favorable conditions for negotiation elsewhere. This process is made possible by the recent proliferation of regimes in multiple issue areas such as health and human rights. The so-called regime complexity which arises, where an abundance of rules exist across multiple venues, allows states to choose their battlegrounds under the most favorable conditions.

[We] would be foolish if we studied world politics in search of beauty or lasting truth. Beauty is absent because much that we observe is horrible, and many of the issues that we study involve dilemmas whose contemplation no sane person would find pleasing.

-Robert O. Keohane, 1988

1.Introduction

Current popular understandings of the role of patents in encouraging innovation vastly overstate the empirical evidence in support of it. And while there exists data to suggest that intellectual property rights do have positive effects, those that espouse these positive effects to promote their agenda rarely acknowledge how contextually specific they are. When patent protections are extended trans-nationally by the standards of the developed world, there is significant literature to suggest that it can be detrimental to the development of some low-income countries.

Even when allowing for the idea that strict and broad patent protection may promote innovation, one study suggests that strict enforcement of Western – often synonymous with developed – levels of IP rights in the developing world has little effect on innovation in the developed world (Park, 2011). To restate, by and large, innovation in the developed world is solely effected by policies and legislation in the developed world. We may infer from this that low levels of patent protection in developing states have little impact on innovation overall and while the first line of defense against any call for reduction of patent protection is that it will harm innovation, the actual harm is to profit, potential and not actual. In spite of this, there is a continued effort to extend universalized patent protection standards to all states under the banner of the promotion of innovation.

Through strict patent regimes the potential for profit is high, however the significant and costly impact of this on many developing nations in terms of money and lives is immediate and real. The cost of creating new IP legislation, the enforcement of such legislation and the ensuing impacts on health caused by increases in both licensing and consumer prices means that the human and economic costs incurred are significant. The developed world's attempts to maximize the profit of

their knowledge industries are not fully compatible with the developing world's need to address public health issues and crises. Apologists often point to the built in flexibilities in TRIPs and the Doha declaration's clarification on state's rights to determine and implement public health strategies. Though these do represent a hard-earned improvement when compared to the ideal protections of the developed world's industries, they fail to make the process easy or efficient, only possible. For some, this is the equivalent of an obstacle course to the emergency room; utterly inappropriate and life-threatening.

The structural aspects of international forums and domestic legislation of members of the developed world such as the US, EC and Japan tend to favor stronger states. As Daniel Gervais points out, high income countries have available to them agents who specialize in multiple relevant fields such as both IP and international negotiation, while low and middle income states must choose from a smaller pool of personnel, which in the case of TRIPs negotiations meant individuals whose specialty was negotiating, with a conspicuous absence of knowledge of the topic of IP (2005). Having already established a floor for IP protections under suboptimal conditions, one often employed strategy of smaller states to deal with hegemonic forces in the international arena is regime shifting.

Regime shifting is the practice by states of relocating the "rulemaking processes to international venues whose mandates and priorities favor their concerns and interests." This is made possible by the increasing number of international rule setting and standard setting bodies, also known as regime complexity (Helfer, 2009). This complexity can be seen in the area of international intellectual property where both the WIPO and the WTO have mandates as rule making bodies. Where issue areas overlap, such as pharmaceutical patents and public health, it is possible for states to address specific needs in forums such as the WHO which are more hospitable to their needs. This paper will look at recent trends and practices in regime shifting in regards to public health; more specifically pharmaceutical patents, the proliferation of intellectual property standards set by and most appropriate for developed countries, and the effect of these on public health in developing countries and least developed countries (LDCs).

1.1 The Path to Modernity

Technological development has been glacial up until relatively recently. A number of factors have influenced this sudden sprint of innovation. According to Kremer, population itself seems to spur technological innovation, due to the non-rivalry of technology (1993). That is to say, given that a person's ability to invent is independent of population size, the diffusion of technology as an intangible good will find innovation on a greater scale in larger populations (ibid). In addition, it is known that research productivity increases as a product of both income and human capital (Nehru, Dhareshwar & DEC, 1994.). Thus, while the population of Europe between the years 500 and 1500 essentially did not increase, neither did the per capita GDP, resulting in a millennium of technological stagnation (Galor and Weil, 1999). This understanding of technological change has impacted modernity, in all its guises, in a drastic way.

In the modern era, income and technological disparities between states vary immensely, in stark contrast to the aforementioned millennium (Maddison, 2001). Though technology itself is inherently non-rivalrous, it is not impervious to the machinations of institutions. Modern attempts to manage and stimulate innovation, namely the Intellectual Property(IP) regimes of developed states, introduce a legal device which creates a rivalry, ostensibly to reward innovation. This rivalry – referred to as an intellectual monopoly by Boldrin and Levine (2009) – grants exclusivity to the innovator in order that he or she may use the artificial scarcity to reap the rewards of their intellectual labor. This however seems to be a solution for a problem which may not exist; as Boldrin and Levine point out, there is little empirical evidence that intellectual monopolies do anything but promote intellectual monopolies (2009, 2012). Furthermore the current atmosphere which promotes the necessity of patent rights also creates an exclusivity not just among innovators, but between nations. And, as all things are not equal, creates winners and losers among those nations. The rules of this game are often set by the most powerful states and it is their experience which informs their decision making.

The path dependence¹ which the developed world suffers from makes it seem a forgone conclusion that the intellectual property regimes it supports are not only necessary but advantageous. However, if we consider Boldrin and Levine's conclusion that older stagnant industries tend to use the IP system to freeze out new competition, it becomes evident that the patent system in its current

¹ In other words, the available decisions in the present being limited in scope by decisions made in the past.

incarnation behaves exactly as a monopoly is predicted to; eliminating competition (and possibly dampening innovation) at a cost to overall welfare (ibid).

The clear benefit of monopoly power over ideas is not lost on governments seeking to increase the welfare of their own state. However, the non-rivalrous nature of technology means that absent the appropriate domestic legislation, so-called intellectual property enters into the commons. This commons, which would be essential to the economic and intellectual growth of developing nations, poses a problem for developed nations who seek to maintain their monopoly on their intellectual labor. So how do developed nations cope with the threat of this loss of control?

It may seem surprising (though it shouldn't) that in an age where trade liberalization has become the de facto ideology, there is a significant effort to export the concept of intellectual monopoly. When we consider Gervais' assertion that trade liberalization is merely a means to the promotion of economic growth (2005), it makes sense that stronger patent protection will help to achieve that end when intellectual objects are viewed as property. However, allowing that economic growth is the noble end which it is purported to be, and that the non-rivalrousness of intellectual objects allows them to be enjoyed without detriment by multiple parties, and further, that access to these intellectual objects is vital to further innovation, and thus economic growth, we can begin to see that while Gervais might be correct, he fails to explain for who and subsequently why.

In spite of (or perhaps due to) the current trade climate, several agreements exist which regulate the movement of knowledge. The oldest, in its current incarnation known as the WIPO (World Intellectual Property Organization), exists as a specialized UN agency to promote the standardization of the processes of IP registration and regulation. The more recent TRIPS (Trade Related Aspects of Intellectual Property) is an annex agreement to the GATT 94 trade agreement, itself an updated version of GATT 47, developed in the post war era in order to liberalize trade among all nations. TRIPS lays out minimum protections while allowing each member state to develop their own legislation in order to achieve such ends. These two agreements provide separate though often complimentary functions.

Ultimately, however, the strength and novelty of the two agreements fail to effectively address the fact that all things are not equal between states, a persistent and self-perpetuating issue. The decision of the Northern Atlantic states to go mercantile when other states still relied on the power of the state alone to create wealth resulted in a massive economic gulf between nations which persists to this day (Diamond, 1997). This gulf has allowed some states to flourish at the cost of the

development of others through the extraction of primary resources and the suppression of domestic industry. The current use of IP rights and its (perhaps not cynical) proliferation continues this trend. The effects on developing nations might be described as lethal. The regulation of IP impacts health, education, income and human rights. For example, in countries which prosper economically, the cost of medicine relative to income is low, and the availability of universal education means that the welfare losses of IP enforcement can be absorbed without devastating impact. Unsurprisingly, least developed countries (LDCs), due to a lack of industry and education, cannot compete. The relative high costs of medication, the lack of education and infrastructure, both physical and social, continue a cycle of poverty and underdevelopment which is not easily remedied without external cooperation.

1.2 Regime Shifting

There are multiple issue areas where patents and development meet, such as human rights, plant genetic resources, bio-diversity and public health (Helfer, 2004). This paper will be limited to the last of these, public health. Though the patent system is contentious, both sides of the argument agree that pharmaceuticals are a special case. Due to the significant costs of both research and testing, as well as the length of time it takes to bring products to market, the pharmaceutical industry offers a best case scenario for the defense of patents.

This paper will take an instrumentalist approach to the discussion of patents and development. That is to say that it views public health as a defensible goal towards which other institutions should be developed. This is convenient on the grounds that the normative value of other industries, such as entertainment or IT is debatable, making the case for or against patents quite malleable. However the primacy of health and life is, under normal circumstances, immutable and enshrined in various constitutions and agreements across the globe.

Thus, while the forces of money and political hegemony may work towards the goal of monopolizing intellectual objects for profit and structural leverage, other institutions exist who do not share these goals. Inter-governmental organizations (IGOs) and non-governmental organizations (NGOs) exist to organize around issue areas. The World Health Organization is one such organization, the objective of which is laid out in article 1 of its constitution, stating “The objective of the

World Health Organization [...] shall be the attainment by all peoples of the highest possible level of health.”²

Another such organization, The World Intellectual Property Organization (WIPO), states its objectives as “(i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization, (ii) to ensure administrative cooperation among the Unions.”³ Both of the WHO and WIPO are specialized agencies of the United Nations, ostensibly binding them to the UN charter itself and to its preamble, which sets out common humanitarian goals. This fact may speak to the humanistic elements of the two organizations, though certainly the former more than the latter.

The WTO, another such international institution, is not bound by this association. Its stated purpose is much more technocratic, centering around the need to liberalize trade. Membership in all of these organizations is voluntary, but while the two UN agencies enjoy wide participation, the WTO offers significant structural and economic advantages as well as the network effect which makes both non-membership and exit difficult. These advantages, such as strict enforceability, a well developed dispute settlement body (DSB) and open access to foreign markets make the WTO an attractive organization. However, the drawback which will be discussed later in this paper is the binding nature of all of the WTO treaties, and their interdependence, which means that infractions against the Trade Related Aspects of Intellectual Property (TRIPs) annex can result in punitive trade restrictions in physical goods, generally the lifeblood of developing nations. The effects on public health, as we shall see, can be detrimental.

2 http://www.who.int/governance/eb/who_constitution_en.pdf , accessed 12/11/02

3 http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html#article_1 , accessed 12/11/02

2. Literature Review

2.1 The real value of IP

It would be a mistake to take as a given that strict universal IP rights are beneficial. Indeed, this paper will argue that the application of intellectual property rights in a one size fits all fashion is often detrimental. In this section, we will discuss both the theoretical benefits of IP rights and the theoretical detriments. Significant literature exists on both sides as to the efficacy of intellectual monopoly in fostering innovation. Before we enter into that discussion, it is worth examining the various facets of IP. Critics such as Richard Stallman of the Free Software Foundation, suggest that the term Intellectual Property is itself misleading. By bundling the concepts of copyright, patent and trademark together, the subsequent conflation serves to reinforce the idea of intellectual property as a property right and belies each type of IP's unique historical and philosophical underpinnings.⁴ However, for the purposes of this paper, the term IP will be used to reference the package of intellectual property laws as it exists currently and the term intellectual objects will be used as a value neutral reference to the subject matter of IP rights.

There are several types of IP, ranging in subject matter and controversy. The least contentious being Trademarks. These devices legally protect the branding, identity and point of origin of goods and services, in order to prevent passing-off. The heading trademark can also include geographic indicators and trade dress (such as the shape of a bottle). For obvious reasons this is advantageous to both producer and consumer, signifying reputation be it good or bad. The duration of a Trademarks generally can be extended *ad infinitum*.

Copyright, as the names suggests, finds its origins in the right to copy. However, this has evolved over time to also protect performance, distribution and related rights as well as moral rights. The subject matter of copyright is "original works of authorship" such as books, music, and performance. Unlike trademarks, copyright is a time limited monopoly, which in many jurisdictions extends 70 years past the life of the author before entering into the public domain. Copyright, like patents, has undergone significant change in the past century. Not only has the duration of a copy-

⁴ <http://www.gnu.org/philosophy/not-ipr.xhtml> , accessed 12/10/10

rights term been extended multiple times but related and neighboring rights have increased as well. In addition, the subject matter of copyright has expanded. For example, copyright has been expanded to include software as a “literary work” (May and Sell, 2006). This trend of protecting more and not less has also been evident in the patent system.

Patents protect a design or a process of production (in other words an invention). Unlike the previously mentioned forms of IP, the justification for patenting is to give incentives for technological innovation as well as to diffuse that technology by allowing skilled practitioners of the art to recreate the invention (Bessen, 2004). Unlike copyright, the subject of the patent must be novel, non-obvious and in many cases, producible. The thinking goes, inventors will be more likely to invest in research and development when they are guaranteed the right to exclusive exploitation of that invention. The government grants this monopoly right in exchange for full disclosure of the invention’s details, allowing anyone skilled in the relevant field to reproduce it. Patentable subject matter is by nature a fundamental component of development, being solely concerned with technological innovation. Like copyright, patents have undergone significant development, with extensions to duration and subject matter. One type of subject matter which is of critical importance to public health is that of chemical processes, specifically pharmaceuticals.⁵

The above information is not necessarily new to the layman. IP reliant industries have made a significant effort to inculcate society with “values” which equate intellectual property with real property. The rest of this section will discuss the literature on the value of IP to society and its theoretical and real effects.

In the western paradigm, the support for IP is vocal and well funded. The reasons are obvious; IP vests persons or entities with a monopoly power over ideas which when exploited properly can lead to financial gain far beyond that available under perfect competition (or even normal competition). Lobby groups such as Motion Picture Association of America (MPAA) and the Recording Industry Association of America (RIAA), who represent copyright reliant industries have a significant interest in not only effecting legislation but winning over the consumer mind towards their way of thinking. Other such groups exist for various other industries, such as The Pharmaceutical Research and Manufacturers of American (PhRMA) and The European Federation of Pharmaceutical

⁵ In many countries, such as South Korea up until the early 1980s, pharmaceuticals were not a patentable subject matter. As is discussed later, after strong pressure from the US using its infamous “Super 301” law, South Korea expanded its patent system to include chemical and pharmaceutical processes.

Industries and Associations (EFPIA). According to the pro-IP side, the need for strong IP protection is twofold. First, strong IP gives incentive for innovators to create new and novel ideas, by guaranteeing them exclusive rights and thus financial reward for their efforts. Secondly, the theft of IP costs the US economy dearly in terms of lost profits. Thus, optimal protection and strong enforcement of IP rights will be a net gain for the country as a whole as well as its industry.

Regardless of the above arguments, each side of the debate has real reasons for seeking change in the IP system. Firms seeking to maximize profits and consumers seeking to maximize utility both have valid cause to be interested in the debate. However, formulating a Pareto efficient modification to IP law, that is to say a change which will leave neither side worse off than it had been, requires there to be a baseline understanding of the goal. There are currently two goals to IP law: to stimulate innovation thereby increasing the net welfare of the public, and to increase the profitability of invention.

There is ample philosophical justification for intellectual property. However, there is little empirical evidence that those justifications are relevant. Short of philosophy, common sense may also sufficiently justify IP. As Edwin Hettinger points out, it seems intuitive that a person should own the fruits of their labor (2011). The “I made it, it’s mine” line of reasoning may be the most powerful argument among the masses, as everyone can sympathize. Hettinger also however offers a more solid justification for IP: Markets can not operate without well-defined property rights. Should we accept that intellectual objects are in fact property, then this argument should suffice as an instrumentalist justification as to why intellectual objects require IP rights. And yet intellectual objects do not operate the same as real property. As has already been mentioned, such objects are non-rivalrous and are the product of generations of previous thought and development. In other words, they are not the single work of a lone author/inventor who will be deprived of his right to possess his work by it being possessed by another person. Though we may seek to apply Lockean principles of property in order to suit this reality, so too may we apply the Lockean proviso in order to refute it.⁶

2.2 Patents and Innovation in The Domestic Market

As mentioned above, the two main supports of IP rights are legal and economic. Legal justifica-

⁶ “...at least where there is enough, and as good, left in common for others”

tions are inherently normative and thus, for the purposes of this paper, dangerously relativistic when the scope of the issue is international. However, the economic/policy driven approach is empirical in nature, and thus we may find more solid evidence either for or against patent protection.

Petra Moser's study of two twentieth century World's Fair exhibitions provides some interesting insights. Her findings indicate that the introduction of patents does not increase innovation but rather has an effect on steering innovation towards certain industries. In the absence of patent protection, innovation was concentrated where alternative methods of protecting intellectual objects were possible, such as secrecy (Moser, 2003). More relevant to this topic, the developmental level of a particular industry seemed to have an impact on whether patent protection had any effect. For example, she suggests that when mechanization of the manufacture of scientific instruments was possible, those countries with patent systems innovated in that sector, while those without patent systems saw innovative growth in sectors where trade secrecy was adequate for protection, such as food and agriculture (ibid).

The implication is that patent protection does not necessarily encourage innovative activity, but rather encourages certain sectors of activity in regions where those activities are possible. However, other regions, lacking either the technological progress or patent protection will still innovate. We can thus conclude (at least from this study) that patent protection is not necessary for innovation, but possibly beneficial for innovation in certain sectors. Given that low-income countries' economies depend significantly on agriculture and primary resource export, we may also conclude that the patent protection which may benefit certain technological sectors will provide little in the way of encouragement to innovation in these countries, where trade secrecy will do.

Multiple studies conducted have reached similar conclusions, the need for patent protection in developing countries is nil as they tend to be consumers and not producers of technology (Chaudhuri 2007, Maskus, 2000). Like Moser, they conclude that a certain level of developmental achievement is necessary for patent protection to be beneficial. Otherwise it tends to be an expensive yet needless exercise. For larger economies which are further along in the development process, such as India, the patent protection of developed economies where TRIPS had little effect was more important than the post-TRIPS legislative environment of their own countries, presumably due to their export driven growth (Chaudhuri, 2007).

Accepting the above, that a patent system is effective in steering innovation, and that the level of development dictates which industries may be present in any given country, there arrives a

corollary finding; That the direction of R&D (and thus innovation) also changes with the economic progress of a country. A phenomenon which has appeared recently in economic literature, the productivity paradox, describes the trend over the past 40 (now 50) years where investment in R&D has continued to climb in advanced industrial nations, while economic growth has hardly done so at all. Ivo De Loo and Luc Soete posit that this is due to R&D efforts shifting from real innovation towards product differentiation(1999). We may conclude from this that shifts in IP policy in the advanced economies, while suited to their particular situation, will not translate well in less developed economies, but rather introduce non-beneficial static inefficiencies.

On the micro and macro level (be it national and international, sector and nation or product and market) one large issue continues to rear its head. Patent legislation generally does not take into account variations in subject matter. While pharmaceutical industry and the software industry have vastly different inputs when compared to each other, the patent system has little in the way of accommodation for the life cycle of each industries products.

2.3 Patents and The Pharmaceutical Industry

The pharmaceutical industry offers a unique case through which to examine the patent system.⁷ As mentioned earlier, the research, development and testing of new drugs is lengthy and expensive. The most expensive part being the testing phase, which carries the burden of extra industry-specific regulation. According to Boldrin and Levine, the most expensive aspect of this process is actually the testing of new compounds (2009). In addition to these expenses, it has been argued that the cost of imitation is low, making protection necessary to prevent free-riding from competition.

In the US, pharmaceuticals have always been patentable as chemical products have always been patentable (ibid). Currently the US recognizes two forms of chemical patents, process patents and chemical formula patents however many countries do not recognize patents on chemical formulas, only on processes of producing them(ibid). Current patent systems in the developed world (and according to TRIPs stipulations, which will be addressed later) offer a 20 year term. The European Patent Office (EPO) grants extensions for delays from regulatory approval. US law also recognizes

⁷ This section borrows largely from Boldrin and Levine

that because of regulatory hurdles, extensions should be granted on the length of patents on pharmaceuticals.⁸

Developing countries such as Brazil and China have historically had lax regulation on the patenting of pharmaceuticals. This is slowly changing. The TRIPs agreement stipulates minimums for the patenting of pharmaceuticals, though it also attempts to make concessions for developing countries and LDCs in recognition of significant public health issues in these countries (See Article 31 of the TRIPs agreement). Another large source of pressure to tighten patent regulations regarding chemicals and pharmaceuticals is large multinational corporations. As discussed below, countries like South Korea experienced significant pressure from both the US government and foreign multinational corporations. Italy as well bowed to pressure from outside forces (in other words, Multinational Firms) to institute a patent system for pharmaceuticals. Citing a study by Scherer and Weisburst, Boldrin and Levine discuss the effects of the newly introduced pharmaceutical patents on Italy. In their words,

[...A] thriving pharmaceutical industry had existed in Italy for more than a century, in the complete absence of patents. That is point one. Point two is that neither the size, nor the innovative output, nor the economic performances of that industry have improved, to any measurable extent, during the thirty years since patents were adopted. Every indicator one can look at suggests that, if anything, the Italian pharmaceutical industry was hurt, not helped, by the adoption of patents, and every expert that has looked the matter has reached this same conclusion (Boldrin and Levine, 2008 p. 252).

This somewhat shocking conclusion must however be tempered by the fact that while Italy had no pharmaceutical patent protection, it did enjoy the ability to use the research and knowledge available to them through other countries which did have such protection. The lesson here is that in a globalized world, it is difficult to judge the effects of a particular patent system in a vacuum. However, there is a more important conclusion to be drawn. That is, the absence of such a patent system does not seem to coincide with a complete lack of innovation or even an environment inhospitable to innovation. Quite to the contrary, available data suggests that after the institution of pharmaceutical patents, Italy's contribution to the list of new active chemical compounds actually decreased (ibid).

⁸ See the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act (S.1538)

2.4 Section 301 of the US Trade Act

A study done in 1996 by Sumner La Croix and Akihiko Kawaura examined the effect of the sudden introduction of strict patent laws by the pharmaceutical industry of South Korea. The reformed Patent Act of 1982 specifically excluded, among other things “medicines or processes for the manufacture of medicine by mixing two or more medicines” as patentable subject matter. In 1985, The USTR, at the behest of then president Reagan initiated an investigation into South Korean trade practices under US Trade Act section 301 (also known as super 301), with the implicit threat of trade sanctions.

The US Trade Act sections 301-310 are US domestic legislation which allow the US Trade Representative (USTR) to determine,

under section 304(a)(1) that (A) the rights of the United States under any trade agreement are being denied” or “(B) an act, policy or practice of a foreign country – (i) violates, or is inconsistent with, the provisions of, or otherwise denies benefits to the United States under, any trade agreement, or (ii) is unjustifiable and burdens or restricts United States commerce.”⁹

The findings of such an inquiry, which could be initiated by the USTR under its own discretion, or by a complainant among national industries, may result in the USTR taking retaliatory action against said nation, to either redress an imbalance or force the elimination of “such act, policy or practice”¹⁰

La Croix and Kawaura imply that due to the 301 investigation, in just over a year, Korea’s legislature passed a revised Patent Act which “extended product patents protection to new chemical and pharmaceutical products as well as to any new uses arising from these products.”(1996)

The results of La Croix and Kawaura’s inquiry are most startling. They estimate that the pharmaceutical sector lost approximately 74% of its value on the Korean stock market relative to the

⁹ See 19 USC § 2411, This is the current text, though the act has been amended multiple times. This section remains largely unchanged. However Subsec. (a)(2)(A) was amended to update the language from referencing GATT to referencing the current WTO DSB

¹⁰ Section 301(a), 19 U.S.C. §2411(a).

market portfolio over a one year period following the announcement of the introduction of more strict patent laws.

This stands in very stark contrast to the experience of Japan. According to a previous study by the same authors using the same methodology they found that Japan experienced a 25% gain over a two month period (ibid). It is claimed that the main difference is that Japan's pharmaceutical industry was largely in favor of the change, perhaps signaling a level of maturity in the industry where the introduction of patents would be beneficial. The Korean experience however was seemingly initiated under duress, resulting in significant static losses.

Super 301 (as that section of the US Trade Act is known) is a tool which allows the US to leverage its economic clout to not only retaliate against nations which do not conform to US trade practices and expectations, but also to use the specter of retaliation to influence foreign states policy and legislation. It has been challenged several times in the WTO Dispute Settlement Body to no avail (for example, see WT/DS152/R 22 December 1999¹¹)

3. International Regimes and Intellectual Property

The previous section discussed the effects of patents in general and pharmaceutical patents in particular on domestic markets. As mentioned, it is increasingly difficult to judge the effects of IP on domestic markets in the current globalized economy. This section will discuss the effects of IP in such an environment and specifically its impact on developing and least-developed countries.

IP is now a standard part of trade agreements the world over (Fink and Maskus, 2005). Now, more than ever before, IP is located in all areas of trade in one form or another, and consequently the importance of protecting these rights has taken center stage in international negotiations. However, the increase in intellectual property protection is anathema to the current push for an otherwise liberalized international trade environment, and thus controversial (Chadhuri 2003, Branstetter et al, 2006). Controversy or no, IP rights are a reality in international trade. The many forums that serve as arbitrators of international IP rights such as the TRIPs agreement and the WIPO are

11 <http://www.worldtradelaw.net/reports/wtopanels/us-section301%28panel%29.pdf> accessed 12/10/26

a product of international dynamics between developed and developing countries in addition to domestic industries' push for stronger and broader IP right enforcement.

However, the proliferation of forums and the changing contexts of international relations have allowed developing countries and least developed countries (LDCs) to develop their own strategies to negotiate these inhospitable terrains, for example regional integration, resource nationalization, South-South trade, and increasing budgets for health and education (James, 2008)¹². Moreover, the change in status of an organization (such as the WIPO's accession as a UN specialized agency) can see a shift in priorities which may offer more assistance towards those nations who are losing out on the IP game internationally.

3.1 Regimes

Because there is no globally recognized central power, the international stage is essentially anarchic. In this environment the unequal power of states allows some to leverage their power to the detriment of others. However, in recent years, there has been an explosion of international forums which attempt to give a central focus to international issue areas (Drezner, 2007). Given the unequal distribution of power across states, Drezner's assertion that these "focal points" promote rules-based outcome over power-based outcomes is worth keeping in mind (2007). These rules-based outcomes come with reduced transaction costs making international forums attractive means to effect international change for most parties.

As with the arbitrariness of power distribution across states, forums too are not equal. Their relative efficacy is intrinsically tied to their structural composition as well as their members, the most obvious example being the comparison between the United Nations and its predecessor The League of Nations. The conspicuous absence of the United States from the League not only limited its effective power, but also speaks to its structural incompatibility with that government. And while the UN can boast near universal membership, the League's limited membership and frequent inabil-

¹² http://www.alternet.org/story/95799/impasse%3A_are_we_nearing_the_end_of_the_corporate_globalization_era/ Accessed 12/10/8

ity to reach any consensus rendered it mostly impotent. Modern institutions still vary in efficacy as well, though perhaps the lessons of the past have allowed them to be more lasting.

Helfer identifies three components of a regime; the substantive, the institutional and relational aspects. He defines the substantive as the rules and norms, the institutional as the structure and the relational as the common thread, or the issue area at which all parties meet (2004). While this is an extreme oversimplification of his description, it is still helpful in seeing how regimes can vary. A significant change in any of these aspects can create a profoundly different type of institution. The comparison between the WIPO and the WTO is apt here. Relationally the WIPO and the WTO have a commonality, but the addition of materials and services in the WTO portfolio as well as its strong enforcement mechanisms means that it is significantly more effective and difficult to exit.

The anarchic nature of the international stage suggests that the most powerful actors can choose to act unilaterally, allowing them full freedom of movement. However, according to contractual institutionalism, there are at least three reasons for states both powerful and weak to be party to international institutions. First is the ability of these institutions to create a cost/benefit situation, where a party's cooperation provides either positive or negative incentives. Reputation also plays a large role, as it can effect the benefits of future exchanges by establishing an actor as credible or not. Finally, information garnered from participation can give a level of certainty about the credibility of other actors' commitment (Johnston, 2001). These factors are complimentary to the rule-based outcomes mentioned earlier and suggest that on some level, international institutions offer a level of predictability which both powerful and weak states can take advantage of.

On the other hand, Haggard and Simmons suggest that regimes themselves may alter state preferences by changing, in their word, reality (1987). Moreover, an additional level of complexity is present when internal political issues subvert a states ability to participate in these international institutions (ibid). This last point was clearly demonstrated by the United States' push to develop the WTO to include an intellectual property annex in spite of the existence of the WIPO. According to May and Sell (and mentioned briefly by Helfer), this quasi- exit from the WIPO was the product of lobbying from a group known as the International Property Committee. This group was composed of content industry members who recognized early on the great potential for international trade in knowledge and information related goods as well as the great potential for theft (2006).

There is unfortunately little consensus in the literature on the dynamics of international regimes, possibly due to the multiple levels of complexity involved and the wide array of actors and

motivations. However, The proliferation of international forums and institutions is considered by many to be a positive phenomenon. Through these institutions and their rule-based outcomes, peaceful and often mutually agreeable results can be had. However, and perhaps obviously, even within these institutional frameworks power still grants advantages. The most relevant to the current topic being that an ever thickening institutional complex requires significant knowledge and resources to take advantage of. While larger, more powerful states have ample human capital, low income states will struggle to fully participate (Drezner, 2009).

3.2 International Intellectual Property Institutions

International intellectual property is governed by a number of bodies, the foremost being the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Each of these bodies has a number of treaties in its purview; for example the WTO oversees the GATT 1994 in addition to the Trade Related aspects of Intellectual Property agreement. Its dispute settlement body is also responsible for arbitrating trade issues between member states. The WIPO on the other hand, is a specialized agency of the United Nations and oversees such instruments as the Paris and Berne Convention, as well as the Copyright treaty (WCT), Performances and Phonograms Treaty (WPPT), Patent Law Treaty (PLT) among others.

Besides these two bodies, there are a number of other instruments at work to regulate the trade of IP related goods. By far, the most stringent are the so-called “TRIPs plus” regional or free trade agreements. These treaties build upon the original TRIPs standards and add stricter measures, often because the measures in the TRIPs agreement are considered by some states to be too relaxed. In addition to these bodies and instruments, other forums which are not exclusively about Intellectual Property have been used as leverage by smaller economies in a process called Regime Shifting, which will be discussed in the next section. This section, however, will look at the WTO and WIPO as arbiters of international IPR and discuss the measures added in TRIPs plus agreements.

3.2.1 The WIPO

The World Intellectual Property Organization is the result of more than a century of international IP law. Both the Berne and Paris conventions were signed in the 19th century and were initially managed by the United International Bureaux for the Protection of Intellectual Property (Better known as BIRPI). Over the last century, the organization moved from its home in Berne to Geneva to be closer to other international law making bodies such as the UN and in 1967 became the WIPO. In 1974, WIPO officially became a specialized agency of the UN.

The role of WIPO has shifted over the past century as well, often in response to other entities which shared its issue space; chiefly the TRIPs agreement. It has also seen a change in organizational culture from its inclusion in the UN, whose mission is humanitarian in nature.

Currently, as mentioned above, the WIPO oversees several treaties regarding intellectual property. Those directly concerned with patents include the Paris Convention, the Patent Cooperation Treaty (PCT), the Patent Law Treaty, the Strasbourg Agreement and the Budapest Treaty.

The Paris Convention for the Protection of Industrial Property is the prime WIPO treaty regarding industrial property which “shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.”¹³ Compared to the TRIPs agreement, the Paris Convention is relatively toothless. It offers little in the way of specifics, but rather a structural environment for member countries to offer reciprocal benefits. There are two significant differences between the Paris Convention and TRIPs. Article 2 grants national treatment among members though is silent on matters such as subject matter and duration of patents. Article 28 allows that members may bring disputes to the international court of justice. TRIPs on the other hand mandates most favored nation status for all nations while at the same time creating minimum standards (in effect creating a global standard). The WTO Dispute Settlement Body is not only rigorous but binding, meaning that members are obliged to settle disputes within the WTO and are bound by the findings of the DSB.

The Patent Cooperation Treaty of 1970 is a compliment to the Paris convention. It allows for the simultaneous filing of patent applications across a multitude of member states of which there

¹³ Paris Convention, Art. 1 Sec. 2

are currently 146. While no “international patent” actually exists, the filing of the so-called PCT application fixes the date of application across all member states. The PCT is also silent on patentable subject matter, leaving that up to individual states.

The Budapest Treaty is concerned solely with the creation and recognition of international authorities for the deposit of microorganisms while the Strasbourg Agreement is an agreement among various European states meant to streamline and unify the patent process in Europe. The Strasbourg Agreement is a substantive law treaty which seeks to harmonize patent laws across states and is distinct from the European Patent Convention which created a Europe-wide patent authority.

Though TRIPS seems to have eclipsed the WIPO as the international IP go-to organization, in fact, both institutions have become part of what Helfer calls a “bimodal intellectual property regime”(2004). Being part of the UN system, the WIPO tends to operate in a consultative capacity, offering technical assistance to developing countries, as well as managing existing IP treaties, while TRIPS “emphasized implementation, enforcement and dispute settlement”(ibid), the latter being one of the most troublesome weaknesses of the WIPO. And while developed states tend to have more control over TRIPS proceedings thanks to their immense economic clout, the institutional composition which gives a single vote to each member of WIPO allows it to be a forum where soft law which is more friendly towards lower income states can be made.

3.2.2 TRIPS

The Trade Related Aspects of Intellectual Property Rights or TRIPS is the product of the Uruguay round of WTO negotiations. It was in part the product of US dissatisfaction with the WIPO's level of protection and enforcement of intellectual property (Cordray, 1994) as well as the above mentioned pressure from the IPC and its partner organizations in other developed countries. Because each member of the WIPO has equal voting power, developing countries had been successful at blocking US attempts at raising the level of IP protections, motivating the US to shift forums to achieve its goals. As already mentioned, there are two major differences which separate TRIPS from the WIPO agreements. Firstly, TRIPS provides minimum protections which all parties to the treaty must provide (see below chart). Secondly, TRIPS departs from WIPO's national treatment towards

Most Favored Nation treatment (MFN), in other words in place of providing foreign nationals with the same level of protection it provides its own nationals, a party to the treaty must provide “any advantage, favor, privilege or immunity granted by a party to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other GATT parties” (Cordray, 1995).

Perhaps the most significant difference – and not coincidentally most relevant to this paper – are the dispute and enforcement mechanisms in place in each. WIPO members who are party to the Paris and Berne agreements are allowed to settle disputes in the International Court of Justice (ICJ), however parties are also allowed to declare itself not bound by the ICJ (Berne, A33 S2, Paris, A33 S2). Besides the obvious problem with being able to not recognize the ICJ, Cordray also points out that those who do recognize the ICJ would scarcely be inclined to use it, as such a suit might be seen as ‘unfriendly’ (1995, quoting Joos and Moufang). Conversely, the WTO dispute settlement system is an “inventive admixture of conciliation, negotiation and adjudication...” (Cassese, 2005) with an effective enforcement regime.

The WTO encompasses a number of aspects of trade beyond intellectual property, including goods and services. The Dispute Settlement Body (DSU) has jurisdiction over all of these aspects and in certain cases sanctions retaliatory measures by the injured party. The combination of these two aspects means that reaping the benefits of the WTO’s trade regime means also acquiescing to its other annexes, including TRIPs. For low-income countries, both exit and non-compliance are thus difficult and non-entry means losing out on access to larger markets. For high income states such as the US, there existed a trade off. While able to link intellectual property to trade in goods had its obvious advantages, entering into a multilateral agreement was necessary to close the Uruguay round and put behind it the aggressive unilateralism it had displayed in the previous decade (Helfer, 2004).

Articles 7 of the TRIPs annex lay out general principles which require that the promotion of intellectual property protection shall “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.” while article 8.1 allows for domestic legislation to include measures which protect public health and welfare and 8.2 allows for appropriate measures to prevent abuse by rights holder which “unreasonably restrain trade or adversely affect the international transfer of

technology.”¹⁴ Article 8 also stipulates that measures taken must be consistent with the provisions of the TRIPs agreement. In spite of these provisions, significant controversy exists regarding the TRIPs agreement, sometimes referred to as a North-South debate.

The substantive provisions of the TRIPs agreement for “Patentable Subject Matter” outlined in Articles 27 through 34 seem to establish standards for IPRs protection that can hardly be deemed minimal. To the contrary, it has been commented that during negotiations, developed countries got “95% of what they wanted” (Sell, 2010 p.448). But, as Sell points out, TRIPs was just the beginning (ibid). Rather than a ceiling, the negotiations had set a floor for minimum standards which would then be added to in more strict bilateral agreements (Morin, 2009).

The effects of TRIPs on low-income countries varies. According to Danielle Tully, because the costs of innovation are much higher for low-income countries, the sudden introduction of strict IPRs as mandated by TRIPs would do little to foster innovation (2003). In addition, the expense of reform would be significant. Due to this, developing countries were initially given until 2001 to implement legislation, while LDCs were given until 2006 (this has since been extended to 2013 and 2016 respectively). Other concessions for developing countries include a requirement in article 67 that developed countries...

...shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

However, possibly due to the qualification “mutually agreed terms”, Tully states it is not clear if the TRIPs agreement has actually fostered any technological transfer for the benefit of developing countries.

14 [http:// www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm) accessed 12/10/22

3.2.3 TRIPs-plus

TRIPs-plus refers to provisions included in bilateral treaties and agreements which go beyond the levels of the original TRIPs agreement. The text of the TRIPs agreement specifically mentions this practice in Article 1.1 where “Members may, but shall not be obliged to, implement in their law more extensive protection that is required by this Agreement”. Peter Drahos further defines a TRIPs-plus agreement as one which eliminates options which are built in as flexibilities in the TRIPs agreement for the benefit of developing and least developed countries.

By far the largest instigator of bilateral treaties in the US. Through an amendment to the Trade Act of 1974, it altered the aforementioned Section 301 to specifically protect US intellectual property interests by linking IP protection to duty free trading privileges granted to developing countries. . A further device, the so-called “Special 301” allowed the USTR to identify countries which did offer acceptable protection to US IP interests and if identified, put them on a watch list or recommend retaliation.

The US usually uses model treaties to reduce the cost of negotiation. One such model is the Bilateral Investment Treaty (BIT). BITs usually include MFN and national treatment clause though they do not include specific IP provisions but rather relies on existing standards set out by, for example, TRIPs. BITs define IP as a type of investment which requires protection in the foreign market, and one stipulation is the commitment that laws be implemented which protect these investments. For developing and least developed countries, this may mean implementation ahead of the TRIPs mandated schedule. In addition, according to Drahos, these agreements include language which, for example, make the compulsory licensing of a “covered investment” such as an exclusive license grounds for legal action (1995). Drahos also suggests that BITs are used as a “carrot” to coerce countries to sign Bilateral Intellectual Property Agreements (BIPs). In his example the US-Nicaragua BIP included the requirement that Nicaragua the International Union for the Protection of New Varieties of Plants (ibid) which among other things harmonizes breeder’s rights among members (Jördens, 2005).¹⁵

The US also uses other trade agreements to shoehorn in IP related stipulations, such as the US-Panama Trade Promotion Agreement of 2011. This too contains provisions for prerequisite

¹⁵ The US has similar agreements with UPOV stipulations with Singapore, Lao, Turkey, Jordan and Vietnam, to name a few (See Lindstrom, 2010).

international agreements such as the a number of WIPO treaties and the UPOV, as well as 32 pages of other provisions regarding all manner of intellectual property.

Of course, waiting behind the wings of all of these agreements is the specter of Super 301.

4. Regime Shifting

In a working paper for the WHO, Carlos Correa identified two objectives for developing patent law in developing countries. It should be designed to serve all groups in society, and it should be responsive to health policy objectives and to the needs of the poor (2000).

It is in this context that the societal benefit aspect of intellectual property rights should be given more than the usual lip service it receives. Even Boldrin and Levine admit that under current conditions, the Pharmaceutical Industry is one of the few industries where the up front costs of R&D will discourage firms from innovating (2012). Yet patent protection also allows firms to charge far above marginal costs in both the short and medium term while the patent is valid. Barring any largess on the part of pharmaceutical companies, this translates into a lack of access to necessary medicines in low and middle-income areas.

While developed countries a century ago enjoyed a rapid increase in incomes, resulting in improved sanitary conditions and nutrition, there is no such quick change on the horizon for most developing countries. This rapid increase in welfare resulted in significant decreases in death rates for the developed world. However currently medical technology must make up that lag in countries where welfare is generally low (Kremer, 2002). The WHO estimates the deaths caused worldwide in 1999 by AIDS/HIV, Tuberculosis and Malaria to be 5,428,000. Of this, 4,616,000 (85%) were in Africa and South East Asia. While these statistics are grave, it is encouraging to know the WHO reports that deaths from AIDS/HIV related causes has dropped significantly, most likely due to a massive increase in the amount of people in low and middle income countries receiving anti-retroviral therapy from approximately 300,000 in 2002 to 6,650,000 in 2010. This speaks quite clearly to the effectiveness and dire necessity of making these drugs available.¹⁶

According to the WHO, spending on pharmaceuticals represents between 25 to 66% of the total public and private health spending of developing countries while in developed countries, that number is below 20%.¹⁷ A reoccurring conclusion that comes up in the research of both patent advocates and critics is the benefit of stringent patent protection in the pharmaceutical industry, though the understood level of benefit varies depending on the bent of the particular commentator.

¹⁶ See http://www.who.int/hiv/pub/progress_report2011/en/index.html

¹⁷ http://www.who.int/medicines/services/essmedicines_def/en/index.html accessed 12/10/12

Does this conclusion hold for developing countries as well?

In 2006, the Thai Ministry of Public Health (MPH) issued a compulsory license for efavirenz, an anti-retroviral drug used to combat HIV. This license allowed Thailand to import the drug from India where the drug is not patented even while Merck held the patent in Thailand. Thailand's unilateral issuing of the compulsory license had a rather controversial effect, particularly as it did so without consultation with Merck (Steinbrook, 2007). The Thai MPH asserted that countries "have a right to issue a safeguard measure to protect public health, especially for universal access to essential medications using compulsory licensing on the patent of pharmaceutical products." (As quoted in Steinbrook, 2007).

Brazil has itself begun production of its own generic versions of efavirenz though in the Brazilian case, they were able to negotiate price discounts and voluntary licenses for local manufacture (ibid). The policies in both Brazil and Thailand are that of free medicine for HIV patients, so it may be no surprise that both of these countries seek to minimize costs when importing or producing the drug.¹⁸ Along with the lowered cost of drugs, a significant decline in related costs was seen as AIDS-related hospitalizations decreased by 80 percent (Okie, 2006). 't Hoen puts the figure at a savings of \$472 million US dollars over two years.

To quote Susan Sell, "While many countries believed that they were negotiating a ceiling on intellectual property rules, they quickly discovered that they actually had negotiated only a floor." (2010). In 16 years since the advent of TRIPS, the explosions of bilateral, multilateral and regional trade agreements which include TRIPS+ type language, this has proven to be truer and truer. The binding nature of TRIPS and its attachment to the larger WTO agreement meant that participating nations would suffer the immediate welfare loss of instituting restrictive IP laws though would also gain in the short and long term by the open access to developed nations' markets in tangible goods (Helfer, 2004). However, as mentioned earlier, the nature of strict international IP standards means that developing nations would likely remain in a permanent state of development. The inability to develop native advanced industries translates into a continued reliance on the export of primary and monoculture goods while exporting money in order to pay for licensing and goods which can not be produced locally.

It is thus understandable that TRIPS regret has developed into a concerted effort to renegoti-

¹⁸ While in the US in 2006, a year supply of Sustiva (its branded name) cost about \$6,000, in least developed and middle income countries, that price was \$277 (Steinbrook, 2007).

ate the status quo. But given the binding nature of the WTO and the otherwise strong theoretical benefits of the GATT 94 agreement, how can LDCs and developing nations have their cake and eat it too? In other words, if the disadvantage of leaving the WTO is roughly equal to the disadvantage of remaining, what options are left for countries of insufficient economic clout to effect a beneficial change?

As Deborah James, the Director of International Programs for the Center for Economic and Policy Research explains, given the failure of the WTO during the Doha round to address the issues of developing nations, “some governments are increasingly experimenting with alternative policies, such as regional integration, resource nationalization, South-South trade, and increasing budgets for health and education, which are delivering growth and prosperity far more effectively.”¹⁹

Several additional methods are being employed by the developing world to gain access to intellectual property based growth. The world’s “policy arena” has expanded both horizontally and vertically. While the vertical expansion which introduces new more compulsory forums such as the WTO itself favors the developed world, horizontal expansion into forums which focus on different issue areas allows developed nations to expand their access to IP (Sell, 2011). In the example, we will see how other institutions such as the WHO allow developing nations to re-frame the issues in non-corporate terms.

4.1 The Regimes

Realist theory suggests that powerful hegemons can tailor regimes to their needs. And as we have seen so far, the ability of larger states to shift at whim from one manner of coercion to another, or from one venue to another is fairly fluid. In the US example, dissatisfaction with the WIPO among other things gave rise to the development of the TRIPs agreement. By using the institutional legitimacy of the WTO, the US is then able to negotiate bilateral treaties with IP sections under the guise of international norms. All while keeping its finger on the button in case Super 301 is needed. This fluidity is one which few states enjoy. However, the norms which these regimes create are also binding upon powerful states. The fact that regimes are expensive to create and existing regimes represent a significant investment themselves makes them sticky, or as Daniel Drezner refers to it, high

¹⁹ *Supra* 17

viscosity(2009). High viscosity regimes are difficult to exit, even for hegemonic states. Accordingly, Helfer states that while regimes tend to reflect existing power distributions at their inception, over time the institutional dynamics of the regime itself take over (2004).

4.1.1 The WHO

The WHO has undergone significant change over the course of its existence, and perhaps most relevant to this paper is its attempt at resurgence after decades of tarnished reputation and mismanagement (Brown, Cuento and Fee, 2006). As mentioned before, the change in status of an organization can have a significant impact on its institutional focus. The WIPO ceding ground to the WTO had put it in a position to redefine itself as a support organization. Similarly, the WHO had for some time been eclipsed by the World Bank. The World Bank had attempted to use its significant financial resources to promote a privatized health system among countries with which it dealt while the WHO began losing funding and prestige due several missteps. In naming Gro Harlem Brundtland, a former physician and prime minister of Norway as head of the WHO in 1998, the organization was attempting to restore its credibility. Recent interest in global health threats, including HIV/AIDS, as well as Brundtland's interest in transforming the WHO into an organization able to "monitor and influence other actors on the global scene"(ibid) might have created exactly the right institutional environment for developing states to attempt to influence the WTO.

In 1996, the 49th World Health Assembly released the Revised Drug Strategy (WHA49.14). One provision requested the Director-General "to 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 the collaboration between WTO and WHO". Several developing countries and NGOs took advantage of this shift in institutional priorities. Pressure from Brazil, South Africa and Zimbabwe along with the likes of Oxfam and Medecins sans Frontières put pressure on the WHO to look into the issue of TRIPs. In 1996 the WHO commenced its review of TRIPs and its effects on public health. Though the language of the resulting report was moderate, the US and several European countries sought unsuccessfully to suppress it (Helfer, 2004).

Since 1977, the WHO has published and updated lists of essential medicines (EML). These lists are developed based on disease prevalence, efficacy and safety and cost-effectiveness. According to

the WHO's own website, these lists are not meant to be a global standard, but are "led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity."²⁰ An Oxfam research report reveals that at the 1999 WTO ministerial conference in Seattle, the "Like-minded Group" composed of 12 developing countries proposed that the list of essential medicines published by the WHO be included in the list of TRIPS exceptions to patentability.²¹ After the breakdown of the talks, the concerns were move to the WTO general council special sessions but were unable to find purchase.

4.1.2 The WIPO Development Agenda

In 2004, in preparation for the coming WIPO General Assembly meeting, Argentina and Brazil began circulating a proposal which became known as the Development Agenda. Soon, 11 other countries joined Brazil and Argentina as co-sponsors and numerous NGOs offered their support. The Development Agenda's goal was to focus the WIPO on development issues, issues to which it had done little so far to address. As an organ of the UN, WIPO is obliged to assist in the transference of technology to developing countries, in order to help them achieve their objectives. However, the backers of the Development Agenda claim that rather than that, WIPO serves more the interests of a small group of developed nations and their national corporations (May, 2007). The development agenda's gist was simple. It asked that the WIPO realign its goals with that of its parent organization, the UN, and begin assisting in the transfer of technology, engagement in civil society, an amendment to the convention which established the WIPO to explicitly include a development dimension, various seminars and working groups to address development related issues among other things. In 2007, the WIPO finally adopted a set of 45 points as its official development agenda.²² The central

20 http://www.who.int/medicines/services/essmedicines_def/en/index.html, accessed 12/11/06

21 Art. 27.3(b)

22 Perhaps not coincidentally, around that same time the US and its developed world partners began work on the Anti Counterfeiting Trade Agreement, which in spite of the name effects issues far beyond counterfeiting. Included in the draft of the agreement were provisions which allowed the ex-officio seizure and destruction of IP rights infringing goods at trans-shipment points. This type of legislation (in this instance, EC Council regulation 1383) had previously been involved in a number of incidents including of the return of a shipment of generic medicines from India to Brazil as it waited in a trans-shipment port in the Netherlands in 2008. For a general overview and some reactions to this issue see <http://www.ip-watch.org/2009/03/06/alarm-escalates-over-delayed-generic-drug-shipments-as-action-sought/>

idea behind the development agenda is that developing and least developed nations are not all alike and it rejects the one size fits all ethos of previous agendas (de Beer, 2009).

4.1.3 The Doha Declaration

10 years later, after the institution of the TRIPs agreement, a number of obvious cracks appeared. For one, article 31 of the TRIPs agreement regarding “Other Use Without Authorization Of The Rights Holder”, lays down the terms by which compulsory licenses may be issued. Art 31(f) state “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”, thereby eliminating the possibility that nations with poor or no native pharmaceutical industry will have access to generic medicines. This and other issues, such as the growing HIV/AIDS epidemic as well as that raised by South Africa’s Medicines and Related Substance Control Amendment Act of 1997²³ sparked an organized backlash (Wakely, 2011). Recognizing the humanitarian and political necessity of addressing the issue of intellectual property and public health, then-US president Clinton announced a change in US policy and issued an Executive Order on Access to HIV/AIDS Pharmaceuticals and Medical Technologies (‘t Hoen, 2003).

Public debate continued and two years later at the Fourth Ministerial Conference of the WTO in Doha, Qatar, saw the first time intellectual property was discussed in the context of public health (ibid). In September of 2011, the African Group along with nineteen other members presented a comprehensive draft text for a ministerial declaration. The draft reaffirmed members rights to address public health issues as well as sought to clarify various provisions on compulsory licensing, parallel import and production for export of pharmaceuticals. The spirit of the declaration is captured in Paragraph 4, ultimately the product of negotiations between the US and Brazil, which reads,

We agree that the TRIPS Agreement does not and should not prevent Members from taking

23 Article 15C was amended to allow the Health Minister to “prescribe conditions for the supply more affordable medicines... to protect the health of the public” though generic substitution and parallel importation. Suits were filed by both native and international pharmaceutical organizations as well governments such as the EU and the US. Effective public protest caused great embarrassment for then American vice-president Al Gore which removed the government backing for the pharmaceutical companies. Also, significantly, the legislation was based on a draft legal text supplied by the WIPO (‘t Hoen, 2003). For a more detailed look, see “Wakely, Jenny European Intellectual Property Review, 2011, 33(5), 299-309” and the text of the legislation available at http://www.chr.up.ac.za/undp/domestic/docs/legislation_54.pdf

measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that 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.

The declaration also granted the extension to LDCs for the implementation of the TRIPS agreement to 2016.

Paragraph 6 of the Declaration specifically addresses the issues faced by countries with little or no manufacturing capability vis-a-vis TRIPS prohibition against the exportation of compulsory licensed drugs (Art. 31(f)). It instructs the Council for TRIPS to find an "expeditious solution to this problem and to report to the General Council before the end of 2002." The result of this was an interim waiver released in August 2003.

The "August 2003 Decision" posed its own problems. Though it granted developing countries the ability to waive Art. 31(f) restrictions on importing medicines and other pharmaceutical products necessary for addressing public health issues. It also allows any WTO member to export to any eligible importing member. Unfortunately, safeguards are built into the waiver which require importing countries to notify the Council for TRIPS. Exporting countries as well must submit notice. This requirement has drawn criticism as it can be time consuming and result in the loss of lives (Wakely, 2011). Other criticisms center around the requirement that drugs may only be produced for export in the requested quantities, limiting the economies of scale which allow for cost-effectiveness (ibid). By 2011, only Canada and Ghana had successfully take advantage of the 2003 decision. India has faced significant issues attempting to export medicines under the decision due to its own poorly drafted legislation (ibid).

4.2 Conclusion

It has been 16 years since the WHO took on the issue of intellectual property and public health. The above vignettes into the institutional workings of three inter-governmental institutions is by no means an exhaustive list of the back and forth of IP and public health. Rather it is illustrative of a growing trend. Where formerly international regimes focused solely on their area of competence, there is growing recognition that issue areas do not exist in a vacuum. Currently, the WHO and the

WTO continue to publish joint reports on the effects of TRIPs on public health. The WIPO, as mentioned above has taken advantage of its usurpation by the WTO to redefine its role in international law making. It seems fair to conclude that regime dynamics include at least one other actor, which is the regime itself. Unfortunately, because some regimes continue to have significantly more clout than others, the rapid change that may save lives is yet to come. The change from island forums to archipelagos of issue areas signals a new level of complexity. It remains to be seen how this thicket of regimes will effect the overall dynamic of international law making.

5. Discussion

Unfortunately developing countries are not the only ones shifting regimes. While these lower income states have been pursuing horizontal (in Helfer's words) or longitudinal (in Sell's) shifting, the US and other more powerful actors have been putting their economic and human capital to good use by shifting vertically. Recent attempts have been numerous and it seems clear that when the these high income states lose a battle in one arena, they begin attempting to build another. ACTA, as mentioned before is one such instance, but it has not stopped there. Bilateral trade negotiations have not stopped, and until as recently as 2011, the US has negotiated several new treaties including UPOV stipulations. Not only has there been renewed interest in the WIPO's deliberations over the Substantive Patent Law Treaty (SPLT), but a new forum is developing in fits and starts called the Trans-Pacific Partnership Agreement (TPP). Like ACTA, it has been negotiated in secrecy though a draft of the agreement has been leaked. According to the draft, it may include DMCA like provisions which protect digital rights management as a copyright. Sell also suggests that TPP will be essentially a multilateral TRIPs -plus agreement, the negotiations of which are guided by an "industry wish-list"(2011). Similar to the KORUS FTA, the TPP would limit the ability of governments to use what is called reference pricing on pharmaceuticals, essentially a method of keeping drug prices down by charging at the lowest priced comparable medicine. Interestingly, this would roll back legislation in the US itself as reference pricing is used in at least in the state of Massachusetts(i-bid), which may be the exact strategy the US pharmaceutical industry is pursuing.

What has been discussed in this paper is a very specific and admittedly narrow part of the world's intellectual property system. It should not be assumed that any of the positive or negative aspects mentioned carry over into other areas of intellectual property. Copyright, for example, generally carries with it fair use exceptions and while there are those that seek to chip away at these exceptions (particularly in the IT and digital sectors) there is significant vested interest even from within that opposes doing so.

This issue is part of the heart of the matter. As Boldrin and Levine point out,

... there are many players in the patent game but that "consumers" are not among them. On the side of the potential patentees there are individual inventors, corporate inventors and patent trolls[...]. On the other side is the patent office that issues patents, the patent lawyers who file and litigate patents, and the courts where the litigation takes place. The rules of the game are established

– although only in part – by the executive and legislative branches of government, and in so far as the interests of the general public are concerned, it is these players who represent them. Since patenting is a technical subject about which few voters know anything with clarity – and hardly any are likely to have a detailed empirical knowledge of the consequences of patent systems – the interests of voters are not well represented at all, but rather the competing interests of the other players. This is exactly the same phenomenon that Stigler [1971] and other public choice theorists argue to have given rise to regulatory capture in other spheres of government regulation. Hence to understand why the patent system is the way it is, we need to understand the motivation and incentives of the relevant players (2012).

This brings up one more salient point. While state governments may be the only bodies representing consumer interest, like forums, the dynamics of state and interstate economics is ever in flux. Where as in decades past, least developed countries could rely on relatively strong partners to help champion their causes, as these larger developing nations continue to develop, their economic interests begin to shift.

During the cold war India and Brazil played a large role in the coalition of developing countries known as the G77 (Drahos, 2002). However, Drahos notes, that coalition has significantly weakened in the recent past, partially due to some Indian's belief that "India has something to gain from parts of the intellectual property regime"(ibid). The IP maximalist agenda is unfortunately self perpetuating, creating winners with the means to freeze out competition. Without the continuing efforts of smaller developed countries, it seems likely that power will continue to be concentrated among the few.

Like so many other fields, intellectual property is institutionally entrenched. Industries, governments and experts all have invested significant time and money to mold IP rights to their benefit. It is beyond the scope of this paper to suggest that IP should simply be tossed away. And even by most critics reckoning, to do so with abandon would be foolish. Again path dependence dictates that our options going forward are limited by the choices made in the past. This paper does not suggest, as do Boldrin and Levine that "intellectual property is an unnecessary evil"(2009), as that is beyond its scope. Rather, the implication of this paper which has been shown in numerous studies, actual situations and the poor health and untimely demise of the unnamed many is that it is crucial to understand that the dynamics of intellectual property on the national level do not apply on a global scale and to pursue a course of universalization is not only economically inefficient, but inhumane.

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