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Inside Analysis From Pillsbury Winthrop Shaw Pittman LLP: The Asian Equation of Patents and Drugs – Key Factors in Balancing Innovation Cost Recovery and Drug Affordability (Part 1 of 2)

By Leslie A. Platt, Brian Jelinek, Hean Koo, Vladimir Chechik and Mary Ellen Ash

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The past few years have born witness to a struggle between broad access to life-saving medicines and the intellectual property rights of the biopharmaceutical firms producing them. Increasingly, there has been a trend by multiple countries to wield the power of compulsory licensing to effectively nationalize patent rights granted to biopharmaceutical firms in the name of public interest. The unpredictable application of compulsory licensing around the globe has created uncertainty in assessing the business environment for biopharmaceutical firms operating in these regions.

Although many considerations affect the balance required to support both drug innovation and affordability, the challenges that confront biopharmaceutical firms in Asia and throughout the world are illuminated by several new developments in IP. These include recent patent decisions by the United States Supreme Court, which directly impact the U.S. market and many of the world's largest biopharmaceutical firms.[1] Additionally, implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) throughout Asia, and particularly in India and Thailand, is establishing global precedents for compulsory licensing of pharmaceuticals. In establishing these trends, it is important that we understand the long-term implications and effects of current policy on drug innovation, access and affordability.

Calls For Compulsory Licensing In The U.S.

IP protection in the United States is relatively developed, stable and predictable in comparison to much of the rest of the world. The pharmaceutical industry in the United States has been accorded equivalent IP protection as that available in other industries and areas of technological innovation, something which is not universally true throughout the world. Respect for IP rights has contributed to creating an environment where pharmaceutical firms, investors and stakeholders feel secure in investing substantial funds to research and develop new drugs that improve public health and welfare.

For instance, patents have enabled pharmaceutical firms to determine, establish and give notice of their inventive contributions to the marketplace. Patents encapsulate discovery and innovation into assets having tangible value that incentivize pharmaceutical firms to invent, invest and develop improvements and breakthroughs in technology. Furthermore, patents encourage pharmaceutical firms to be trailblazers, rather than followers, by benefiting the first who discover, disclose and patent their inventions.

Using patents, innovative pharmaceutical firms have been able to generate revenue by licensing later market entrants, thus quantifying the value of intellectual capital incorporated within manufactured products. In addition, pharmaceutical firms have been able to receive damages in the event that their patents were infringed by others and were traditionally granted permanent injunctions restricting further activity by the infringer.

However, a recent decision by the U.S. Supreme Court may cause concern for pharmaceutical firms because the interpretation of the conditions necessary for the application of an injunction for patent infringement has changed. Permanent injunctions were to be granted only when a rigorous four-part test was met. U.S. courts, however, rarely applied this test after finding patent infringement and issued injunctions nearly automatically. In 2006 the Supreme Court ruled in *eBay v. MercExchange* that ignoring the four-part test for permanent injunctions in patent cases was inconsistent with the law.[2] Accordingly, it was found that courts must apply the four-part test when determining whether to grant a permanent injunction to a patent holder. [3]

As a result, courts may consider alternative remedies for patent infringement that are less desirable for patent holders. For example, after *eBay,* a permanent injunction was not automatically granted in *Paice LLC v. Toyota Motor Corp.*,

even though patent infringement was found by the Court of Appeals for the Federal Circuit, the highest U.S. patent court. [4] Instead, the CAFC ordered the infringer to pay an ongoing royalty, which the court deemed "reasonable" in light of the circumstances. [5] These cases suggest that patent rights may be balanced against other considerations, and that patents may not exclude infringers from practicing a patented invention absolutely.

Other instances in which the ability of a patent holder to exclude infringers is reduced arises in the context of compulsory licensing, when a government forces an IP right holder to grant use of the IP to another entity. Compulsory licensing is generally disfavored in the United States; however, other mechanisms exist by which public interest may be favored at the expense of IP rights. Some of these mechanisms are *per se* compulsory licensing, while others amount to *de facto* compulsory licensing because of their effects.

Many of these mechanisms have been tested in the context of broader access to medicines in the United States, and include "march-in rights" and "government takings." For example, drugs developed with the assistance of U.S. government funding have caused debate about the right of the U.S. government to "march-in" and acquire rights to those drugs. In particular, the Bayh-Dole Act of 1980 grants patent and other IP rights to researchers for inventions that are developed using government funds. [6] In exchange, the U.S. government may request the patent holder to license the patent rights to another party under certain circumstances. [7] In the event that the patent holder refuses, the U.S. government may exercise "march-in rights" by itself granting the license to another party. [8]

The Bayh-Dole Act was lauded for providing an incentive to bring basic research to the marketplace. In addition, proponents advocated that using Bayh-Dole would reduce drug prices by allowing competitors to manufacture generic versions of the patented drug in limited circumstances. However, the National Institutes of Health, which funds most of the U.S. government's biomedical research, has been reluctant to exercise the "march-in" provisions of the Bayh-Dole Act.

In support of this policy, the NIH cited its goal of stimulating research and encouraging the private sector to bring technology innovations to market. [9] For example, the cancer drug ***Taxol*** (paclitaxel) yielded worldwide sales of $9 billion for Bristol-Myers Squibb through 2002. [10] The NIH contributed $484 million to produce Taxol, but received only $35 million in licensing fees because its principal focus was to get the drug on the market rather than to generate revenue from drug licensing or to recoup grant funds.

More recently, the NIH has refused to exercise its "march-in rights" to make the drugs ***Norvir*** (ritonavir) and ***Xalatan*** (latanoprost) more available and affordable. In particular, the NIH found no grounds to resort to such an "extraordinary remedy" to lower prices. [11] [12] Although the NIH does not consider price control a sufficient reason for the NIH to exercise the "march-in" provisions of Bayh-Dole, the U.S. government will continue to be pressured to use the Bayh-Dole Act to make drugs more available and affordable, particularly during national public health crises.

For example, the U.S. government was pressed to intervene during the anthrax attacks of 2001. [13] At the time, the U.S. government had only enough ***Cipro*** (ciprofloxacin), the preferred antibiotic to treat anthrax, for two million people. [14] Furthermore, a one-month supply of Bayer's patented Cipro was $350, whereas generic versions of the same drug were only $10 in other countries. [15] Although Cipro did not fall under the provisions of Bayh-Dole, interventionists advocated using government use powers to force greater availability and cost reductions. [16] For instance, Canada had already issued a compulsory license for Cipro in reaction to these events.

The U.S. government ultimately elected to renegotiate the prices charged by Bayer for Cipro, while respecting Bayer's patent rights. [17] Although the U.S. government did not implement compulsory licensing, as had Canada, Bayer lowered prices for Cipro under the threat of such action. It is difficult to predict the magnitude of public health crisis that would cause the U.S. government to discount IP rights to the extent of issuing compulsory licenses. However, the Cipro case is evidence that even in the United States, IP rights may be balanced against public interest during crises.

Challenges and TRIPS

The challenges that confront governments balancing IP rights and public health are even more pronounced in developing countries that struggle to meet greater public health needs with fewer resources. These challenges are reflected in the policy debates surrounding TRIPS.

More than a decade has passed since TRIPS was negotiated during the establishment of the World Trade Organization in 1994. [18] In this time, TRIPS has become a topic of intense disagreement between those who believe that IP rights foster innovation in the development of vital, new medicines, and those who believe that IP rights create an artificial price barrier preventing access to medicines currently marketed. Several trends are emerging as developing countries

use the provisions of TRIPS to adapt the protection accorded to IP rights to their own needs, particularly with regard to pharmaceuticals.

IP rights are important within the pharmaceutical industry due to the high fixed costs incurred to develop, test and receive regulatory approval for new drugs, and to offset expenses incurred to develop prospective drugs that ultimately fail for lack of efficacy or safety. [19] For instance, patent rights allow firms to recover their investment costs by providing a period of time during which competitors can be excluded from making or selling their patented drugs. [20]

IP rights are particularly important to pharmaceutical firms which develop new drugs, because generic copies typically can be marketed more quickly and less expensively than the name-brand drug. [21] This is partly because drugs are relatively easy to reverse-engineer and it is often unnecessary to repeat extensive clinical trials and regulatory approval processes for generic drugs. [22] Rather, firms often receive regulatory approval for generic drugs by showing that they are bioequivalent to approved drugs. [23] India, for example, has founded its pharmaceutical industry largely on its expertise in reverse engineering drugs patented in foreign countries, and is currently one of the world's largest suppliers of generic drugs. [24]

TRIPS is significant because it introduced IP rights into the multilateral trading system for the first time. [25] By tying IP rights to trade, and by linking these to the dispute resolution provisions of the WTO, an effective mechanism was created to enforce IP rights internationally. [26] In addition, TRIPS has resulted in increased harmonization of the protection given to IP rights as countries have amended their laws to conform with TRIPS.

TRIPS requires all WTO countries to implement and enforce minimum standards of IP protection, including patents, trade secrets, trademarks and copyrights. [27] For example, under TRIPS, patent protection must be available for inventions in all fields of technology (which includes pharmaceuticals) for at least 20 years. [28] Prior to TRIPS, the duration of patent protection in many countries was fewer than 20 years, and 40 countries lacked patent protection for pharmaceutical products. [29] India, in particular, is notable because its longest patent term was 14 years [30] and it specifically excluded patents on pharmaceutical products (although India did provide pharmaceutical *method* patents having a term of seven years). [31]

TRIPS has been challenged on the grounds that it benefits developed countries at the expense of poorer developing countries. In particular, developing countries tend to produce fewer research-and-development (R&D)-intensive products than they consume. [32] As a result, during the formation of TRIPS and the WTO developing countries negotiated for greater access to the agricultural and textile markets of developed countries in exchange for greater IP rights. [33]

Some have argued, however, that greater protection for IP rights results in higher prices for new medicines. Additionally, greater IP rights will not necessarily increase R&D expenditures on diseases prevalent in developing countries, such as malaria, due to the low purchasing power of developing countries and the low incidence of these diseases in developed countries. [34]

Impact of the Doha Declaration

In order to address the concerns of developing countries, the WTO issued the Doha Declaration in 2001. [35] The Doha Declaration explicitly reaffirmed the right of countries to use the provisions of TRIPS to address public health issues. In particular, the Doha Declaration acknowledged the right of countries to determine rules for the exhaustion of IP rights [36] that commonly specify that a patent holder's rights are "exhausted" once the patented product is sold. [37] This enables countries to import drugs sold by the patent holder in another country, without the consent of the patent holder, in a practice known as parallel importation. [38] Accordingly, if a patented drug is sold at a lower price in one country, another country may import the drug at the lower price rather than purchase the drug directly from the patent holder at the higher price. [39]

However, although parallel importation may provide a country with lower-priced sources to purchase patented drugs, it also may inhibit the ability of a patent holder to implement differential pricing across markets. [40] Differential pricing allows a patent holder to provide drugs at prices adjusted for the purchasing power of different countries and enables the patent holder to charge poorer countries less than developed countries. [41] The ability of pharmaceutical firms to use differential pricing to subsidize poorer countries with less-expensive drugs by charging wealthier countries more can be counteracted by parallel importation if the lower-priced drugs are diverted from poorer markets to wealthier markets. [42]

The Doha Declaration also emphasized that countries have a right to promote access to medicines for all [43] and

specifically highlighted the HIV/AIDS, tuberculosis and malaria epidemics affecting many developing countries. [44] Accordingly, the Doha Declaration states that countries may grant compulsory licenses and have the freedom to determine the grounds upon which these licenses are granted. [45] Furthermore, each country may determine for itself what constitutes a national emergency or circumstances of extreme urgency which may necessitate a compulsory license. [46]

It was also recognized that practical challenges confront the effective use of compulsory licensing by countries that lack the capacity to produce pharmaceuticals domestically. [47] According to TRIPS, a country can only issue a compulsory license "predominantly for the supply of the domestic market … ." [48] As a result, it was uncertain whether a country could produce patented drugs for export to a country that had issued a compulsory license but lacked the ability to produce the drug for its own needs.

TRIPS was amended in 2005 to address this situation. [49] Currently, the WTO provides that a country may produce, without the authorization of the IP right holder, a drug for export to a country in quantities limited to the amount necessary to meet the needs of the importing country in cases where the importing country lacks the capacity to manufacture the drug. [50] As with compulsory licensing generally under TRIPS, the IP right holder must be paid adequate remuneration taking into account the value of the compulsory license to the importing country. [51] Furthermore, the drugs must be clearly marked, presumably in order to mitigate diversion and parallel importation of the drugs to wealthier countries. [52]

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[40] *Id.*

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Although many considerations affect the balance required to support both drug innovation and affordability, the challenges that confront biopharmaceutical firms in Asia and throughout the world are illuminated by several new developments in IP. These include recent patent decisions by the United States Supreme Court, which directly impact the U.S. market and many of the world's largest biopharmaceutical firms. Additionally, implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights throughout Asia, and particularly in India and Thailand, is establishing global precedents for compulsory licensing of pharmaceuticals. In establishing these trends, it is important that we understand the long-term implications and effects of current policy on drug innovation, access and affordability.

India and TRIPS

With regard to TRIPS, India has been an advocate of the rights of governments to ensure affordable medicines and to use the provisions of TRIPS whenever IP rights inhibit access to medicines.[1] For example, the emergence of the H5N1 strain of influenza (bird flu) caused concerns that the first line medication, Roche's ***Tamiflu*** (oseltamivir), would be unaffordable and unavailable in sufficient quantities to prevent a pandemic.[2] Indian pharmaceutical firms experienced in reverse-engineering patented drugs sought compulsory licenses for Tamiflu for use in India and for export.[3] Cipla, India's third largest pharmaceutical firm, indicated that "right or wrong" it would start making a generic version of Tamiflu[4] despite Roche's indication that it intended to remain the sole manufacturer.[5]

The Indian Cabinet in 2005 considered issuing compulsory licenses to Indian generic drug firms, including Ranbaxy, Cipla, and Hetero Drugs, allowing them to produce Tamiflu for the domestic market and for export.[6] Although a compulsory license for Tamiflu was not granted, the mere threat of issuing a compulsory license can pressure a pharmaceutical firm to acquiesce to government demands.[7] Not coincidentally, Roche announced shortly thereafter it had granted a sub-license to Indian firm Hetero Drugs for the production of Tamiflu.[8] In addition, Ranbaxy and Cipla began producing Tamiflu without licenses from Roche.[9]

More recently, Natco Pharma has applied for a compulsory license for export from India to Nepal of Pfizer's renal cancer drug ***Sutent*** (sunitinib) and Roche's lung cancer drug ***Tarceva*** (erlotinib).[10]Roche also has filed a patent infringement suit against Cipla, which began marketing Tarceva in India in late 2007.[11] The final outcome of these cases is pending.

Given the legislative history of Indian patent law, it is clear that pharmaceutical firms have faced an uphill battle in protecting their IP rights.[12] However, India appears to be at a crossroads between its past and its future. As India's pharmaceutical industry matures, it is increasingly moving from a reliance on development research such as reverse-engineering and manufacturing to more intensive discovery *research*.[13] Accordingly, India may place greater emphasis on IP rights as India's pharmaceutical industry creates more new drugs.[14]

Thailand and TRIPS

Thailand has tested the limits of TRIPS perhaps more than any other country. In 2006 and 2007, Thailand issued compulsory licenses for Merck's ***Sustiva*** (efavirenz) for treating HIV/AIDS, Abbott's ***Kaletra*** (lopinavir/ritonavir) also for treating HIV/AIDS, and Sanofi-Aventis' anticoagulant ***Plavix*** (clopidogrel) for treating heart disease.[15] Thailand has been criticized for its implementation of these compulsory licenses even though TRIPS and the Doha Declaration affirm that each country may determine the grounds for granting compulsory licenses and what constitutes national emergencies or circumstances of extreme urgency.[16]

Some have argued that Thailand did not represent a clear "national emergency or other circumstances of extreme urgency."[17]HIV/AIDS, tuberculosis and malaria epidemics, which predominantly impact the most impoverished countries in the world, were specifically addressed by the Doha Declaration. However, Thailand was not suffering from an epidemic.[18] Furthermore, it was questioned if the treatment of heart disease constituted a national emergency or circumstances of extreme urgency necessitating the compulsory licensing of Plavix.[19]

Some have portrayed the compulsory licensing not as a contest between poor-country sick and rich-world drug companies, but rather as the rise of middle-income countries and the generics pharmaceutical industry.[20] Thailand is a relatively developed nation which ranks 34 out of 181 nations by nominal GDP[21] and had foreign exchange reserves of close to $60 billion.[22] Yet, Thailand has made extensive use of the compulsory licensing provisions of TRIPS and the Doha Declaration primarily intended to address the needs of the poorest countries exhibiting the most extreme public health conditions.

Ultimately, pharmaceutical firms are concerned that the use of compulsory licensing[23] may become a *de facto* method of price control.[24] In particular, pharmaceutical firms have a reduced ability to negotiate compensation under the threat of a compulsory license, especially after their drugs effectively have been expropriated by issuance of a compulsory license.[25] Further, price reductions achieved under threat of a compulsory license may negatively impact the prices pharmaceutical firms may receive in other markets and reduce drug innovation as investment in the pharmaceutical sector becomes relatively less attractive.[26]

Although TRIPS requires that the right holder be paid adequate remuneration[27] in the event that a pharmaceutical firm is subject to a compulsory license, it may be difficult for a firm to receive what it believes is fair compensation. For example, in the cases of Sustiva, Kaletra and Plavix, the affected firms received a 0.5 percent royalty.[28] Although different models can be used to determine royalty rates, the guidelines established by the United Nations Development Programme set a royalty rate range of 2 percent to 6 percent.[29]

A second accepted model, based on the rank of the importing country in the United Nations Human Development Index, established royalty rates on a sliding scale of 0.02 percent to 4 percent. According to this approach, Thailand would be assessed a royalty rate of 2.259 percent.[30] Under either royalty model, the royalty paid to the affected pharmaceutical firms would have been at least four times higher.

In protest of Thailand's compulsory licensing, Abbott removed seven new drugs from the registration process in Thailand. Included was its newest AIDS drug, ***Aluvia*** (lopinavir/ritonavir), which does not require refrigeration, an important improvement over Kaletra because many Thais do not have refrigerators. Under intense international pressure, however, Abbott offered to sell Aluvia in Thailand and reduced the price of Kaletra below that of generic versions.[31]

Thereafter, Thailand further recommended compulsory licenses for four cancer drugs that had been targeted due to their expense. These included Novartis' leukemia drug ***Glivec/Gleevec*** (imatinib) and breast cancer drug ***Femara*** (letrozole), Sanofi-Aventis's lung cancer drug ***Taxotere*** (docetaxel), and Roche's lung cancer drug Tarceva.[32] In an effort to protect its breast cancer drug Femara, Novartis offered free supplies of Glivec (imatinib) if Thailand would not subject Femara to compulsory licensing.[33] Nevertheless, Thailand subsequently imposed compulsory licenses on Femara, Taxotere and Tarceva.[34]

Achieving a Proper Balance?

It is not clear where and how compulsory licensing will be implemented in Asia and around the world in the future. Compulsory licensing, in some respects, enables countries to revert to the state of IP rights that existed prior to TRIPS. For example, Thailand illustrates a regression to less protection of IP rights due to the compulsory licensing of drugs unrelated to restraining epidemics and its relative affluence as a developing country. However, the maturation of the Indian pharmaceutical industry may be evidence of a fundamental shift toward greater investment in drug discovery and IP protection in other developing countries. Regardless, the search for the optimum balance between cost recovery of innovation and drug affordability will continue.

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