

“Branded or Generic,” the Legal Analysis and Strategic Management of Pharmaceutical Patent Disputes—The Taiwan Model

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Abstract

Because of intensive research and innovation in pharmaceutical industries, legal disputes and strategic management of intellectual property (IP) has become increasingly critical between competing pharmaceutical manufacturers. From specialized IP jurisdiction, industrial capacity and pharmaceutical market prospective, Taiwan is an appropriate research model for industries to elucidate patent disputes between branded and generic pharmaceutical companies. After analyzing recent pharmaceutical patent decisions held in the IP Court of Taiwan, and comparing them with China Patent Act and the U.S. patent laws and precedents, a three-stage model was developed to categorize pharmaceutical patent disputes between global branded and local generic companies. First, in the preparation stage, either branded or generic companies apply different legal strategies to extend or exempt of patent exclusivity respectively. Second, in the injunction stage, this article demonstrates why specialized IP jurisdiction, financial burden for countersecurity and abuse of IP rights affect generics to stay in the market. Third, in the litigation stage, This article illustrates how indirect infringement protection, validity of patents, and physicians' defense play the crucial roles of patent litigations in Greater China area. Finally, to integrate the strategic considerations and commercial effects of these legal battles, this patent dispute model in pharmaceuticals provides a useful guideline and some suggestions for both generic and branded companies that intend to develop or sustain their pharmaceutical business in Asia or globally.

Keywords: Patent, infringement, pharmaceuticals, branded, generic

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I. Introduction

In recent years, the legal strategies and intellectual property (IP) managements has become increasingly critical in many industries. For example, in September 2013, Microsoft and Nokia announced that they had agreed on a transaction worth EUR 5.44 billion. Microsoft not only purchased Nokia's Devices and Services business for EUR 3.79 billion, but, more importantly, also paid EUR 1.65 billion to license Nokia's patents.¹ Additionally, Google purchased Motorola Mobility for US \$12.5 billion in 2011, and announced that "Motorola Mobility's patent portfolio will help protect the Android ecosystem."² Although Google subsequently sold Motorola Mobility to Lenovo for US \$2.91 billion in January 2014, Google still retains the vast majority of Motorola's patents.³

As for pharmaceuticals, in 2013, the Supreme Court of the United States in *FTC v. Actavis Inc.* considered whether it is presumed to be lawful for branded manufacturers to use reverse-payment settlements to keep generic competitors out of the pharmaceutical market for some period of time prior expiration of drug patents.⁴ The consideration of legal strategies and IP managements in pharmaceuticals should be also crucial and should include anti-competitive issues because of the healthcare rights and public policy.⁵

Taiwan is an appropriate research area for pharmaceutical industries to elucidate IP disputes between branded and generic pharmaceutical companies. From a legal perspective, similarly to the U.S. Court of Appeals for the Federal Circuit, Taiwan established the Intellectual Property Court (hereinafter, "IP Court") with specific jurisdictions for IP-related disputes. From an industrial perspective, Taiwan and the United States have well-recognized manufacturing capacities and are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as the PIC/S), which only four

¹ See Microsoft News Center, *Microsoft to Acquire Nokia's Devices & Services Business, License Nokia's Patents and Mapping Services*, Sept. 03, 2013, <http://www.microsoft.com/en-us/news/press/2013/sep13/09-02announcementpr.aspx> (last visited Aug. 1, 2014).

² Google, *Facts about Google's Acquisition of Motorola*, <http://www.google.com/press/motorola/> (last visited Aug. 1, 2014).

³ See Larry Page, *Lenovo to Acquire Motorola Mobility*, OFFICIAL BLOG, Jan. 29, 2014, <http://googleblog.blogspot.tw/2014/01/lenovo-to-acquire-motorola-mobility.html> (last visited Aug. 1, 2014).

⁴ See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

⁵ See, e.g., Daniel A. Crane, *Actavis, the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions*, 15 MINN. J. L. SCI. & TECH. 51 (2014); William W. Fisher III & Felix Oberholzer-Gee, *Strategic Management of Intellectual Property: An Integrated Approach*, 55(4) CALIFORNIA MANAGEMENT REVIEW 157 (2013).

Asian countries have qualified for.⁶ From a market perspective, Taiwan shares its culture with China, forms part of an integrated supply chain, and has become the appropriate touchstone for global pharmaceutical companies to explore the booming pharmaceutical markets in the Greater China.⁷

Thus, by systemically analyzing pharmaceutical patent decisions held in the Taiwanese IP Court, and comparing them with U.S. patent laws and precedents, this article develops a three-staged model to categorize pharmaceutical patent disputes between branded and generic companies. In the first preparation stage, we demonstrate how pharmaceutical companies apply legal strategies to exempt or extend patent protection. Second, in the injunction stage, this article analyzes how specialized IP jurisdiction, financial burden for countersecurity, and abuse of IP rights affect generics to stay in the market. Third, in the litigation stage, this article illustrates why indirect infringement protection, validity of patents, and physicians' defense play the crucial roles in Greater China area. Finally, this paper provides pragmatic suggestions for generic or branded companies to apply this three-staged model to develop or sustain their pharmaceutical business in Asia or globally.

II. Preparation Stage:

In pharmaceuticals, the exclusivity effect of patent terms can be strategically modified. Prior expiration of drug patents, generic manufacturers can use the research exemption from patent infringement and to obtain drug approvals as soon as possible. Conversely, branded manufacturers submit numerous types of "evergreening" patent application for soon-to-expire patents to extend the core patent protection as long as possible.⁸

A. Research Exemptions for Generic Companies

To ensure drug safety and efficacy, under U.S. FDA regulations, all drugs must undergo clinical trials to obtain New Drug Approval (hereinafter, "NDA") or Abbreviated NDA (hereinafter, "ANDA"). This administrative filing process can require several months to years. Therefore, generic company must conduct clinical trials for filing ANDA applications to enable generics market entry immediately following the branded patent expiration.

⁶ See, e.g., Pharmaceutical Inspection Co-operation Scheme homepage, PIC/S, <http://www.picscheme.org/pics.php> (last visited Aug. 1, 2014), Members & Partners, <http://www.picscheme.org/members.php> (last visited Aug. 1, 2014).

⁷ See Mei-Hsin Wang, *Recent Patent Litigation on Pharmaceuticals in Great China*, 2 NTUT J. OF INTELL. PROP. L. & MGMT. 58, 68 (2013).

⁸ See Su-Hua Lee, *A Study on Pharmaceutical Patents: Some Observations from Evergreening Patent of Pharmaceutical Sector in Taiwan*, 41 NTU L.J. 647, 667 (2012).

However, conducting drug research or trials prior to patent expiration can result in patent infringement.

In the United States, the Federal Circuit in *Roche Prods. v. Bolar Pharm.* previously ruled that the experiments performed by the generic company, Bolar, had a commercial purpose and, therefore, violated Roche's patent rights.⁹ However, in consideration of the positive effect of such drugs on human health, the U.S. Congress subsequently passed the Hatch-Waxman Act in 1984. This act exempted parties involved in pharmaceutical R&D experiments that are pursuant to FDA regulations from infringement (also known as the FDA safe-harbor exemption).¹⁰ The Federal Circuit consequently upheld this research exemption in many famous cases.¹¹ In the case of *Merck KGaA v. Integra Lifesciences I, Ltd.*, the Supreme Court construed the FDA safe-harbor provision and held unanimously that the Hatch-Waxman Act can exempt all uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use, or distribution of drugs from infringement.¹² The similar research exceptions are also ensured by EC Directives in EU and by Article 30 of the TRIPs Agreement in WTO.¹³

In Taiwan, the research exemption provision can be also applied to experiments or clinical trials.¹⁴ In *Eli Lilly v. TTY Biopharm*, Eli Lilly (Lilly),

⁹ See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861, 863 (Fed. Cir. 1984).

¹⁰ See 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.").

¹¹ See also *Intermediacs, Inc. v. Ventriex Co., Inc.* 991 F.2d 808 (Fed. Cir. 1993); *Eli Lilly Sc Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F. 3d 1226 (Fed. Cir. 2003).

¹² See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

¹³ In the European Union, equivalent exemptions are allowed under EC Directives 2004/28/EC and 2004/27/EC. Additionally, Article 30 of the TRIPs Agreement provides, "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

¹⁴ The previous Patent Act of Taiwan exempted noncommercial behaviors or acts to exploit the invention for research, teaching, or experimental purposes. However, as in the *Bolar* case, whether clinical trials performed by generics prior to branded patent expiration constitute "noncommercial behavior," as outlined in the Patent Act, remains unclear. In 2005, the Pharmaceutical Affairs Act of Taiwan was amended as stating, "The patent right of the new drug shall not be applicable to research, teaching, or testing prior to the application for registration by the pharmaceutical firms." This act clearly exempted pharmaceutical firms from infringements related to researching, teaching, or testing drugs prior to the application for ANDA registration. Subsequently, pharmaceutical legal disputes shifted from the

the patent holder for the anticancer drug Gemcitabine, claimed that the clinical trials of generic Gemcitabine injection conducted by TTY Biopharm (TTY) violated Lilly's Taiwan patent No 66262, 110476, and 109978. TTY claimed that its attempt to improve the Gemcitabine formulation was in compliance with the "research, teaching, or testing" condition, as described in the Pharmaceutical Affairs Act of Taiwan. TTY further argued that improving the formulation from Lilly's "freeze-drying lyophilization powder" to TTY's "soluble injection" required highly advanced techniques, thus meeting the requirements of the research exemption provision. However, the courts decided that improving the Gemcitabine formulation did not meet the "research, teaching, or testing" requirement, and thus ruled that TTY had infringed on Lilly's patent rights and must pay NT\$ 2 million in compensation.¹⁵

This Gemcitabine dispute also involved related actions in China because TTY's active pharmaceutical ingredient (API) of Gemcitabine was primarily manufactured by a Chinese pharmaceutical company, Hansoh Pharmaceutical. Lilly filed litigations against Hansoh in 2001 at the People High Court in JianSu Province, but finally failed in 2010.¹⁶ The People Supreme Court favored Hansoh Pharmaceutical and ruled that Lilly should pay a total 162,810 RMB.¹⁷

This Gemcitabine dispute provides several salient facts. First, because the pharmaceutical supply chain is integrated throughout the Greater China area, patent holders must consider possible differences in pharmaceutical statutes and judicial systems between China and Taiwan. In 2013, the Patent Act of Taiwan newly amended and integrated the research exemption provision of the Pharmaceutical Affairs Act, and the scope and standards of pharmaceutical research exemption are now more clearly defined.¹⁸ However, the Patent Law of the People's Republic of China simply states that any person can be exempt from patent infringement under the condition

concern of whether clinical trials constituted "commercial behavior" to that of whether these clinical trials constituted "research, teaching, or testing."

¹⁵ See *Eli Lilly v. TTY*, Taiwan High Court, 94 Zei-Sun Zi no. 26 (2006), *rev'd* by Taiwan Supreme Court, 96 Tai-Sun Zi no. 1710 (2007).

¹⁶ See JianSu People High Court, 2001 Su-Min-San-Chu Zi no.1 (2002).

¹⁷ See People Supreme Court, 2009 Min-San-Zun Zi no. 6; *see also* Wang, *supra* note 7, at 60-61.

¹⁸ In Taiwan, Article 59 of the Patent Act states, "The effects of an invention patent right shall not extend to the following circumstances: ... 2.) necessary acts to exploit the invention for research or experimental purpose(s)." Article 60 states, "The effects of the patent right shall not extend to research and trials, including their practical requirements, necessary for obtaining registration and market approval of drugs under the Pharmaceutical Affairs Act or obtaining market approval of pharmaceuticals from a foreign country."

of using the relevant patent for the purpose of scientific research and experimentation.¹⁹ Therefore, the scope of the research exemption in China may allow some leeway for judicial construction.

Second, although the Taiwanese generic company TTY lost the intermediate judicial decision, this case eventually ended in a settlement.²⁰ TTY was allowed to manufacture and sell its generic Gemcitabine in Taiwan, and its API was provided by Lilly's approved suppliers. This reconciliation demonstrated that patent litigations hinge on business interests rather than legal justice.

B. Evergreening Patents for Branded Companies

On the other hand, branded companies attempt to “evergreen” their patent life by filing multiple subsidiary patents prior to the core patent expiration.²¹ Strategies to extend the life of a pharmaceutical patent include modifying formulations, designing new administration routes, switching chirality or enantiomers, finding novel uses or indications, combining existing drugs, and metabolizing materials.²²

In Taiwan, for example, Merck Sharp & Dohme (MSD) had extended the core patent life of Alendroid acid, a drug for osteoporosis, by modifying the dosage from once per day to once per week.²³ AstraZeneca extended the core patent life of Esomeprazole, a blockbuster drug to treat peptic ulcers, by converting the omeprazole's optical isomers.²⁴ The patent extension of pioglitazone, another blockbuster drug produced by Takeda to treat diabetes, was achieved by drug combination and active metabolite patents.²⁵

¹⁹ Patent Law of the People's Republic of China art. 69 (“The following shall not be deemed to be patent right infringement: ... (4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation.”).

²⁰ See the settlement announcement of Lily and TTY, http://www.tty.com.tw/news/show_news.php?subaction=showfull&id=1287113572&archive=&template=Custom (last visited Aug. 1, 2014).

²¹ See Lee, *supra* note 8

²² See Himanshu Gupta, Suresh Kumar, Saroj Kumar Roy, & R. S. Gaud, *Patent Protection Strategies*, 2(1) J. PHARM. BIOALLIED SCI. 2 (2010); see also Richard Li-dar Wang & Pei-Chen Huang, *Patent Protection of Pharmacologically Active Metabolites: Theoretical and Technological Analysis on the Jurisprudence of Four Regions*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 493 (2013).

²³ See Taiwan Patent no. 226833 (Pharmaceutical Composition for Inhibiting Bone Resorption).

²⁴ See Taiwan Patent no. 11446 (Omeprazole and its Alkaline Salts with High Optically Purity, their Pharmaceutical Compositions, Process for Preparation Including their Intermediates and Application in Pharmaceuticals).

²⁵ See, e.g., Taiwan Patent no. 135500 (Pharmaceutical Composition for Prophylaxis and Treatment of Diabetes); Taiwan Patent no. 63119 (Thiazolidinedione Derivative, Production

1. Aventis Pharma S.A. v. TTY Biopharm

The case of *Aventis Pharma S.A. v. TTY Biopharm*, heard in the Taiwanese IP Court, can demonstrate how evergreening patents extended the protection period by using a modified formulation.²⁶ The API of Taxotere®, a cancer treatment drug produced by Aventis, was docetaxel trihydrate; however, Tyxan®, a generic injection produced by TTY, also used docetaxel as its API after 2008. Because the patent protection period for the docetaxel compound expired in 2007, Aventis used several methods to extend the drug patent for Taxotere®. For example, in 1992, Aventis filed for a Taiwanese patent No. 197394 for an improved formulation.²⁷ This '394 patent successfully extended protection of the original docetaxel patent from 2007 to 2012. In addition, in 1993, Aventis applied for another Taiwanese patent No. 76742 for a modified formula containing a surfactant and water solution.²⁸ This '742 patent also extended patent protection to November 2013, and provided the basis for litigation against TTY in 2008.²⁹ On the other hand, TTY successfully invented around and preemptively obtained another patent for a three-part injectable formulation.³⁰ TTY finally won this litigation.³¹

2. Takeda Pharma v. China Chemical & Pharmaceutical Co.

The case of *Takeda Pharma v. China Chemical & Pharmaceutical Co. (CCPC)* is another example to show how evergreening patent extended patent protection by drug combination and active metabolites.³² Takeda's blockbuster diabetes drug, Actos®, which used pioglitazone hydrochloride as the API, and the basic patent for pioglitazone (Taiwanese patent No. 26611) expired in 1994. Therefore, Takeda filed for Taiwanese patent No. 135500 by

and Use Thereof).

²⁶ See *Aventis Pharma S.A. v. TTY Biopharm*, Taiwan IP Court, 98 Min-Kan-Su Xi no. 95 (2010).

²⁷ See Taiwan Patent no. 197394 (Compositions Suitable for the Production of Injectable Perfusion). The details of the patent primarily indicated that because of the low solubility of taxane, surfactants and ethanol were added for injection use.

²⁸ See Taiwan Patent no. 76742 (Two-Part Injectable Composition Comprising a Taxane Derivative in a Surface Active Agent and an Additive to Prevent Gelling on Dilution).

²⁹ See *Aventis Pharma S.A. v. TTY Biopharm*, *supra* note 26.

³⁰ See Taiwan Patent no. 321471 (Three-Part Injectable Composition Comprising Docetaxel in a Surface Active Agent and an Additive to Prevent Gelling on Dilution And Diluents). The patent was granted because this formulation can reduce aggregation phenomenon and facilitate nursing clinical preparation.

³¹ See *Aventis Pharma S.A. v. TTY Biopharm*, Taiwan IP Court, 98 Min-Kan-Su Xi no. 95 (2009).

³² See *Takeda Pharma v. CCPC*, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009).

introducing a combination therapy that added an insulin-secreting stimulator to pioglitazone, extending patent protection to June 11, 2016.³³ Moreover, because the human body biochemically metabolizes pioglitazone hydrochloride into a thiazolidinedione derivative, Takeda further applied for Taiwanese patent No 63119 for the natural metabolites, extending patent protection to April 10, 2012.³⁴

These two pioglitazone evergreening patents, the combination and metabolite patents, provided grounds for the litigation filed against another two generic manufactures in Taiwan, CCCP and Genovate. Details of the subsequent patent litigations are described in the section III B 2.

According to an investigation reported by the U.S. Federal Trade Commission, 75% of generic manufacturers have been sued by original patent holders, and evergreening of patents was a major reason for litigation.³⁵ Similar situations have been observed in Taiwan. The aforementioned cases held in the Taiwanese IP Court demonstrate a practical model for branded manufacturers to continuously attack generics by evergreening patents, and for the generics to defend themselves by invent-around patents.

III. Injunction Stage

Remedies in patent infringement primarily include monetary compensation and equitable relief. Preliminary injunctions, in equity, are critical in legal and business strategy.³⁶ If a branded company argues that a generic's behavior has resulted in material harm or imminent danger, after providing a security, they can be granted a preliminary injunction to prevent the generic from manufacturing and selling the infringing products, or force them to destroy the products. The unfair use of preliminary injunction will also induce some anti-competitive issues. In Greater China area, the Code of

³³ See Taiwan Patent no. 135500 (Pharmaceutical Composition for Prophylaxis and Treatment of Diabetes).

³⁴ See Taiwan Patent no. 63119 (Thiazolidinedione Derivative, Production and Use Thereof).

³⁵ See Federal Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, <http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study> (last visited Aug. 1, 2014).

³⁶ In the U.S., the plaintiff seeking the preliminary injunction must fulfill all four requirements (1) that there is a substantial likelihood of success on the merits of the case, (2) that the plaintiff faces a substantial threat of irreparable damage or injury if the injunction is not granted, (3) that the balance of harms weighs in favor of the plaintiff seeking the preliminary injunction, and (4) that the grant of an injunction would serve the public interest.

Civil Procedure of Taiwan and the Patent Law of the People's Republic of China also includes similar injunction provisions.³⁷

To clearly indicate the legal and commercial effect of preliminary injunctions on legal strategy and IP management, this paper presents two preliminary injunctions related to the same Takeda “blockbuster” diabetes drug, Actos®, which resulted in two dramatically distinct effects.

A. Takeda v. Genovate Biotechnology

In the first case, Genovate had applied ANDA of Vippar® for pioglitazone, the same API of Takeda's Actos®, and received a qualification notice from Taiwan's pharmaceutical authority. However, Takeda promptly claimed that Genovate had violated Takeda's patent for pioglitazone combination therapy, and requested a preliminary injunction.³⁸ Takeda was granted the preliminary injunction after providing a security of approximately New Taiwan Dollars (NTD) 43 million (approximately US\$ 1.4 million).³⁹ The district court then issued an injunction order to suspend the final ANDA approval. However, Takeda lost the final decision four years later.⁴⁰

Genovate subsequently filed a law suit against Takeda under unfair competition and abuse of rights for a market delay.⁴¹ Takeda argued that, as a patent holder, no abuse of IP rights occurred because the motion of the preliminary injunction constituted an exercise of legal rights according to civil procedures. However, the IP Court ruled that inappropriate behavior such as the abuse of rights or the breach of good faith, resulting in a negative effect on trading order, must be subject to compensation for unfair competition. Because the motion of preliminary injunction filed by Takeda

³⁷ In Taiwan, the preliminary injunction was codified as the “injunction maintaining a temporary status quo.” See Article 538 of Taiwan Code of Civil Procedure art. 538 (“Where necessary for purposes of preventing material harm or imminent danger or other similar circumstances, an application may be made for an injunction maintaining a temporary status quo with regard to the legal relation in dispute.”). In China, Article 66 of The Patent Law of the People's Republic of China provided, “If the patentee or interested party has evidence to prove that another person is committing or is about to commit a patent infringement, which, unless being checked in time, may cause irreparable harm to his lawful rights and interests, he may, before taking legal action, file an application to request that the people's court order to have such act ceased. When filing such an application, the applicant shall provide guarantee.”

³⁸ See Taiwan Patent no. 135500 (Pharmaceutical Composition for Prophylaxis and Treatment of Diabetes).

³⁹ See *Takeda v. Genovate*, Taichung District Court, 93 Tsai-Chuan no. 3340 (2004).

⁴⁰ See *Takeda v. Genovate*, Taiwan Supreme Court, 98 Tai-Sun Zi no. 367 (2009).

⁴¹ See *Genovate v. Takeda*, Taiwan IP Court, 99 Min-Kung-Sun no. 3 (2010), *aff.* by Taiwan Supreme Court, 101 Tai-Sun Zi no. 235 (2012).

was based on a flawed expert report, Takeda had either grossly negligent or knowingly attempted to take advantage of the injunction proceedings, and had, therefore, engaged in unfair competition. The IP Court finally ruled that Takeda was liable for NT\$50 million (approximately US\$1.6 million) in compensation for this anticompetitive behavior.⁴²

B. Takeda v. CCPC

In the second case, CCPC had obtained ANDA for pioglitazone and Takeda also filed for a preliminary injunction. Conversely, after CCPC provided a countersecurity of approximately NT \$140 million (approximately US \$4.5 million), the preliminary injunction was revoked.⁴³ CCPC promptly entered the market and began to sell their generic drug. Although the final court ruling of this case was identical to that of *Takeda v. Genovate* (i.e., that no violation of Takeda's patent rights had occurred), the business implications of the two cases differed dramatically.

These two different injunctions, concerning the same drug of pioglitazone, provide at least two lessons as follows. First, from a strategic perspective, if a small generic company cannot afford to pay a full countersecurity in a timely manner, it can be prohibited from manufacturing and selling the product, or required to destroy the products. However, because countersecurity may range around millions of U.S. dollars, they are unaffordable for small-scale generics. Even if small generic companies finally win such lawsuits, as in *Takeda v. Genovate*, they suffer a delay in bringing the product to market. Therefore, motions for preliminary injunctions filed by patent holders can either apply capital pressure on small generics or keep them out of the market.

Second, from a legal perspective, because the time allowed for courts to review motions of injunction relief is extremely short and because determining pharmaceutical patent infringement requires specialized knowledge, courts are limited in their ability to reach sound judgments. Therefore, patent holders can take advantage of filing a motion of injunction against generics, or use the prolonged litigation process to maintain a market monopoly. The specialized IP court systems, which established in some countries, plays a critical role in making timely decisions to prevent the possible unfair use of preliminary injunctions.⁴⁴

⁴² See *Genovate v. Takeda*, Taiwan IP Court, 99 Min-Kung-Sun no. 3 (2010); see also Announcement by Genovate on Aug 16, 2012, <http://mops.twse.com.tw/mops/web/t05st01> (last visited Aug. 1, 2014).

⁴³ See *Takeda v. CCPC*, Taiwan High Court, Kang-Geng-1 no. 3 (2008).

⁴⁴ Currently, at least nine countries or areas worldwide have established a specialized IP court, including Germany, the United Kingdom, the United States, Japan, South Korea, Singapore, Thailand, Taiwan, and the European Union.

III. Litigation Stage

Following a preliminary injunction, a court considers whether a patent is valid, whether the product in question infringes on the patent, whether any defense of infringement exists, and how to calculate damages for compensation. In the following section, cases held in the Taiwanese IP Court are used to discuss the differences of patent systems between Taiwan and the United States regarding the validity of evergreening patents, enforcement of indirect infringement, and physicians' defense against infringement.

A. Patent Validity

In pharmaceuticals, the opinions concerning patent validity showed extremely diverse in different jurisdictions. For the example of pharmaceutical metabolite patents, the active metabolites are produced by natural biological reaction of the human body after drugs intake. In the U.S., in *Schering Corp v Geneva Pharms., Inc*, the Federal Circuit applied the "inherent anticipation doctrine" to invalidate the metabolite patent concerning an antihistamine substance because the physiologically produced metabolite could be anticipated by pre-metabolite compound, and its novelty had been lost.⁴⁵ In India, under the "product of nature" doctrine, the 2005 Patents (Amendment) Act recognizes the active metabolite as a "new type of known substance," and thus considers metabolite invention as merely discovery without patentability.⁴⁶ However, in Taiwan, the IP Court did not invalidate the active metabolite patent, but ruled that no infringement had occurred because human body physically metabolizes generic drugs *in vivo* should be not constitute "exploiting" the metabolite patent for infringement liability.⁴⁷

Besides, to challenge the validity of a patent, two legal strategies, either arguing in IP court for invalidation or in IP Office for revocation, are commonly used.⁴⁸ In Taiwan, Alendroid acid, a drug for osteoporosis or

⁴⁵ See *Schering Corp v. Geneva Pharms., Inc.* 339 F.3d 1373 (Fed. Cir. 2003); see also Wang & Huang, *supra* note 22, at 497-501.

⁴⁶ See Section 3 of the India Patents (Amendment) Act of 2005 (Act No. 15 of 2005) ("(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or Explanation.-For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."), <http://www.wipo.int/wipolex/en/details.jsp?id=2407> (last visited Aug. 1, 2014).

⁴⁷ See *Takeda v. CCPC*, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009); see also Wang & Huang, *Supra* note 22.

⁴⁸ For patent litigation, the invalidation rate in the Taiwanese IP Court is as high as 60%.

Paget's disease, clearly demonstrates the effects of these two patent-validity strategies on pharmaceutical patent disputes. In the case of *MSD v. Novartis Taiwan*, MSD argued that the generic drug Alendronate (Sandoz 70-mg) sold by Novartis Taiwan violated its Taiwanese No 226833 patent and filed a motion for injunction and a plea for compensation.⁴⁹ This '833 patent was evergreened to extend MSD's core patent life of Alendroid acid by modifying the oral dosage from 10mg daily to 70mg weekly, which can enhance patient compliance and reduce gastric complications. The Taiwanese IP Court ruled that MSD's patent was invalid based on the grounds of "obviousness" for dosage modification.⁵⁰ In addition, another local generic manufacturer filed a request with the Taiwanese IP Office for the invalidation of this patent based on Article 71 of the Patent Act, and this patent was subsequently revoked in 2011.⁵¹

B. Indirect Infringement

From the perspective of patent protection, the different IP enforcement systems will produce various industrial impacts. In the United States, the patent enforcement systems include not only direct infringement provisions (35 U.S.C. § 271 (a)), but also indirect infringement provisions (35 U.S.C. § 271 (b), (c)). By contrast, the Patent Act of Taiwan and the Patent Law of the People's Republic of China provide only direct infringement provisions; the provisions for indirect infringement are not expressly codified.⁵² Therefore, in the Greater China area, patent enforcement must be supplemented by the tort concept of joint and several liability according to the Civil Code in Taiwan and Tort Law in China.⁵³ This difference greatly affects IP

See American Chamber of Commerce in Taipei, ISSUES-Chinese, <http://www.amcham.com.tw/topics-archive/topics-archive-2012/vol-42-no-07/3625-issues-chinese-449> (last visited Aug. 1, 2014).

⁴⁹ See Taiwan Patent no. I226833 (Pharmaceutical Composition for Inhibiting Bone Resorption).

⁵⁰ See, e.g., *MSD v. Novartis*, Taiwan IP Court, 99 Min-Kan-Su Zi no. 149 (2011); 100 Min-Kan-Sun no. 21 (2012).

⁵¹ See Taiwan IP Office Decision, Zh-Kan 3(4) 02021 no. 10020498200 Regarding Patent no. 226833, revoked on June, 13, 2011; see also <http://alveice.blogspot.tw/2011/07/merck-alendronate-fosamax.html> (in Chinese) (last visited Aug. 1, 2014).

⁵² See Chapter VII of Protection of Patent Rights, Patent Law of the People's Republic of China, http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html (last visited Aug. 1, 2014).

⁵³ See Taiwan Civil Code art. 185, para. 1 ("If several persons have wrongfully damaged the rights of another jointly, they are jointly liable for the injury arising therefrom."), para. 2 ("Instigators and accomplices are deemed to be joint tortfeasors."); Tort Law of the People's Republic of China art. 8 ("Where two or more persons jointly commit a tort, causing harm to

management and the litigation strategies adopted.

In Taiwan, *Takeda v. CCPC* is an apt example for indirect infringement.⁵⁴ Takeda manufactured and sold the diabetes drug Actos®, with the API of pioglitazone, which basic patents expired in 1994. Takeda filed an action against CCPC's pioglitazone-based generic Glitos®, claiming infringement of two evergreening patents for pioglitazone. These two patents were an active metabolites patent (the '119 Patent) and a drug combination patent (the '500 Patent), which also described in this article of section II B (2).⁵⁵

First, for the infringement of active metabolites patent, Takeda argued that when any patient took and metabolized the generic Glitos® into active metabolites, the patient directly infringed Takeda's active metabolite patent; the manufacturer CCPC was thus considered as an accomplice or contributory infringer.

Second, for the infringement of drug combination patent, Takeda argued that when any physician prescribed drugs that combined generic Glitos® and other drugs to treat diabetes, the physician violated Takeda's combination patent as the direct infringer and CCPC violated the patent as a accomplice or contributory infringer. In addition, CCPC was also a instigator to induce physicians to infringe on Takeda's combination patent by labeling Glitos® in such a way of drug combination therapy.⁵⁶

The Taiwanese IP Court ruled that the generic of CCPC neither directly violated Takeda's metabolite and combination patents, nor constituted joint liability or indirect infringement.⁵⁷

Concerning the active metabolite patent, the IP Court did not invalidate patent validity, but ruled that the claimed metabolite of pioglitazone which unconsciously converted by human body was not construed as the consequence of human control behavior or commercial sales. Therefore, the patient did not "exploiting" the metabolite patent and no infringement had occurred.⁵⁸ CCPC was thus not considered as an accomplice or contributory infringer.

Concerning the combination patent, the IP Court further explained that physicians prescribe drug combination therapy to treat diabetes based on their own professional knowledge and under individual patient's condition.

another person, they shall be liable jointly and severally.”), art. 9 (“One who abets or assists another person in committing a tort shall be liable jointly and severally with the tortfeasor.”).

⁵⁴ See *Takeda v. CCPC*, Taiwan IP Court, 97 Min-Kan-Sun no 20. (2009).

⁵⁵ See, e.g., Taiwan Patent no. 135500 (Pharmaceutical Composition for Prophylaxis And Treatment of Diabetes); Taiwan Patent no. 63119 (Thiazolidinedione Derivative, Production and Use Thereof).

⁵⁶ See *Takeda v. CCPC*, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009).

⁵⁷ See *id.*

⁵⁸ See also Wang & Huang, *supra* note 22, at 505-07.

Therefore, CCPC labeled the generic for combination therapy should not construed as either an instigators or accomplice under the tort laws. In addition, the second instance of Taiwanese IP Court clearly construed that no provisions for indirect infringements, such as contributory infringement and induced infringement, are codified in the Patent Act of Taiwan.⁵⁹

C. Physicians' Defense against Infringement

In the U.S., under 35 USC § 287(c)(1), patent systems protect medical practitioners and healthcare entities from possible infringement when performing medical activities.⁶⁰ In Taiwan, the exemption scope of physician's defense is much narrower than that of defense in the U.S. physicians can be only exempted from infringement when they prescribe combination prescriptions by Article 61 of the Taiwanese Patent Act.⁶¹ In *Takeda v. CCPC*, because the Taiwanese IP Court directly ruled that physicians who prescribed combination therapies did not infringe Takeda's combination patents, the court did not further apply this provision of physician's defense against infringement.

From a strategic perspective, in addition to this physician defense, even when medical institutions or physicians actually engage in direct infringement of patent rights through the procurement or prescription of generic drugs, brand-name manufacturers are disinclined to press legal charges against these healthcare providers to avoid threatening their business relationship.

VI. Conclusion

From the perspective of IP management, the outcome of litigation is not the only or primary objective. Empirical results have revealed that more than 80% of patent litigations end in settlements.⁶² When patent holders file litigation, not only are they required to pay huge litigation costs, but they risk

⁵⁹ See *Takeda v. CCPC*, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009).

⁶⁰ See 35 U.S.C. § 287(c)(1) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271 (a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.").

⁶¹ See Patent Act of Taiwan art. 61 ("The effects of the patent right for the invention of medicines to be manufactured by mixing two or more medicines or for the invention of a process thereof shall not extend to the preparing of medicines in accordance with a prescription from a physician, or the medicines so prepared.").

⁶² See Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237, 262-264 (2006).

their patents being declared invalid, especially in Taiwanese IP Court.⁶³ Even when non-practicing entities file repeated litigation, the real goal is to receive settlements, rather than determining whether particular products constitute patent right infringement.⁶⁴ The legal strategies and IP managements designed for competing pharmaceutical manufacturers should also hinge on substantial business interests rather than merely legal justice.

By comparing the patent laws and precedents concerning pharmaceutical disputes heard in Taiwan and in the U.S., this article develops a three-staged model for pharmaceutical patent disputes. This dispute model can demonstrate useful guidelines and provide pragmatic suggestions for both local generic and global branded companies. First, for the extension of patent exclusivity, generic companies should pay more attention to search out and invent around the evergreening patents hidden by branded companies, because no compulsory patent disclosure, like the Orange-Book listing in the U.S., are required in Greater China area. Second, for the out-of-market effects of preliminary injunctions, start-up generic companies should consider the possible financial burden of countersecurity, and arrange in advance. Fortunately, the specialized IP courts, established in Taiwan and upcoming in China, will enhance court's ability to make a sound and timely judgment of preliminary injunction to avoid unfair abuses of IP rights. Besides, to consider the high invalidation rate of patent litigations and the lack of indirect infringement enforcement implemented in Taiwan and China, branded companies must create their legal localization strategies and strengthen their IP portfolio managements comprehensively to develop or sustain their blooming business in Greater China or in Asia.

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⁶³ See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (demonstrating that 46% of patents litigated to judgment are held invalid; similar invalidity rate was also found in Taiwan’s intellectual property court); see also The American Chamber of Commerce in Taipei, ISSUES-Chinese, <http://www.amcham.com.tw/topics-archive/topics-archive-2012/vol-42-no-07/3625-issues-chinese-449> (last visited Aug. 1, 2014).

⁶⁴ See John R. Allison, Mark A. Lemley, & Joshua Walke, *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 GEORGETOWN L.J. 677, 678 (2011).

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