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The Patent and Non-Patent Incentives for Research and Development of New Uses of Known Pharmaceuticals in Japan

Toshiko Takenaka
University of Washington School of Law

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THE PATENT AND NON-PATENT INCENTIVES FOR RESEARCH AND
DEVELOPMENT ON NEW USES OF KNOWN PHARMACEUTICALS IN
JAPAN

*Toshiko Takenaka**

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ABSTRACT

Japan is one of most innovative drug manufacturer-friendly countries because it revised its patent and drug regulation systems for providing patent and non-patent incentives for new use and treatment R&D based on its pro-patent and pro-medical science policies. This article provides an overview of the pharmaceutical industry and examines patent and non-patent incentives for drug R&D in focusing on incentives for developing new uses of and treatments for known drugs from a comparative law perspective. After discussing the difficulties in establishing infringement and in obtaining injunctions against generic drug manufacturers who infringe new use product patents, the article reviews measure Japanese scholars have proposed to help secure incentives for new use and treatment R&D and proposes an alternative solution.

*Toshiko Takenaka is Washington Research Foundation/W. Hunter Simpson Professor of Technology Law at the University of Washington School of Law. From April 1, 2016, she will be a professor at Keio University Law School through a joint appointment with UW.

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INTRODUCTION

Professor Benjamin Roin¹ argues that the current legal infrastructure in the United States for patent and non-patent incentives is designed to promote new drug development and that, without a mechanism to enforce new use patents, it creates a large gap among the incentives for pharmaceutical innovations. Data protection for a new use of a previously approved drug is limited to three years, which is substantially less than the five years provided for new drugs that contain new chemical entities.² Because of the inherency doctrine, in the United States, pharmaceutical firms can only obtain a method patent for a new use of an existing drug. New use method patents are difficult to enforce because patients directly infringe the patents by taking a known drug for a patented use. Drug manufacturers are only secondarily liable for active inducement. Medical practitioners who might be liable for active inducement are

¹ Professor Benjamin Roin is one of our esteemed panelists in the Future of Innovation in Medicine Symposium. For his argument, Benjamin Roin, Solving the Problem of New Uses, Draft of October 14, 2016 (<https://www.bu.edu/law/files/2016/10/Solving-the-Problem-of-New-Uses-Ben-n.-Roin.pdf>)

² See 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii). See also 21 C.F.R. § 314.108 (2016).

exempted from patent infringement liability under the U.S. Patent Act.³ Moreover, because of active ingredient limitations, U.S. patentees cannot take advantage of patent term extension (P.T.E.) provisions.⁴

Japan provides more incentives for new use Research & Development through both patent and non-patent protection. The Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (L.P.M.D.) provides up to six years of data protection for a new use of a previously approved drug.⁵ The Japanese Patent Law (J.P.L.) allows product patents on new uses to facilitate enforcement against drug manufacturers, patent term extensions on new uses, and dosage regimes for existing drugs. The Japanese government has adopted pro-patent and pro-medical science policies. Despite the exclusive rights afforded new uses of drug products, the government is concerned about insufficient incentives for medical science innovations. This concern results from excluding medical methods from patentability due to a lack of industrial applicability under the JPL even if medical methods are protected indirectly through a patent on a drug product being limited by its use.⁶ The Japanese government organized a committee to examine the impact of the exclusion and innovative measures to secure incentives for new uses and dosage regimens of known drugs.

This article provides an overview of the pharmaceutical industry, in light of the Japanese government's patent and science policy changes. It examines patent and non-patent incentives for drug R&D and focuses on incentives for developing new uses of and treatments for known drugs from a comparative law perspective. Finally, this article discusses the difficulties in establishing infringement and in obtaining injunctions against generic drug

³ 35 U.S.C. § 287(c). *See also* Timothy J. Lithgow, *Patent Infringement Immunity for Medical Practitioners and Related Health Care Entities*, 37 *Jurimetrics* 251 (1997).

⁴ 35 U.S.C. § 156(a)(1).

⁵ *Iryohin, Iryokiki no Hinshitsu, Yukousei oyobi Anzensei no Kakuhonado ni Kan'suru Hōritsu* [The Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices], Law No. 84 of 2013, Art. 14.4 [hereinafter "L.P.M.D."].

⁶ *Tokkyohō* [Patent Act], Law No.121 of 1959, art. 29. For a discussion on the exclusion of medical methods under JPL, *see infra* note 50.

manufacturers who infringe new use product patents. Furthermore, it reviews measures Japanese scholars have proposed to help secure incentives for new use and treatment R&D.

I. THE PHARMACEUTICAL INDUSTRY IN JAPAN

The Japanese pharmaceutical market is the second largest in the world.⁷ However, industry analysts think that the role that Japanese firms play in the global pharmaceutical market is limited, compared with the roles that Japanese firms play in the electronics and automobile industries.⁸ In the 1950s and 1960s, the government capital control policy protected Japanese drug manufacturers from competition from foreign drug manufacturers.⁹ The capital control policy, combined with tariffs and product standards, effectively prevented the entry of foreign firms into the Japanese market. Pharmaceutical products were excluded from patent eligible subject matter until the J.P.L. was revised in 1976.¹⁰ Before the revision, only a method of manufacturing and using a pharmaceutical product was patent eligible. Due to this gap in patent protection, Japanese drug manufacturers could make and sell drugs developed in foreign countries at a relatively low cost.

In the 1970s and 1980s, Japanese drug manufacturers began to invest in new drug R&D as the government began to remove non-tariff barriers via deregulation and open the Japanese market.¹¹ In

⁷ *Assessing the Japanese Generic Pharmaceutical Market*, THOMSON REUTERS (2014),

<http://thomsonreuters.com/content/dam/openweb/documents/pdf/pharma-life-sciences/case-study/newport-case-study-japanese-generics.pdf>.

⁸ In rankings based on sales in 2014, Takeda is ranked 16th globally and the highest among Japanese firms. Waseem Noor, *Pharma Exec's Pharma 50 2014*, PHARMEEXEC (June 9, 2014), <http://www.pharmexec.com/pharm-execs-pharma-50-2014>.

⁹ Shinji Takagi, *Japan's Restrictive System of Trade and Payments: Operation, Effectiveness, and Liberalization, 1950-1964*, (International Monetary Fund, Working Paper No. 97/111, 1997), <http://www.imf.org/external/pubs/ft/wp/wp97111.pdf>.

¹⁰ See Tokkyohotō no Ichibu wo Kaiseisuru Horitsu [Law for Revising Patent Law and Other Acts], Law No. 46 of 1975.

¹¹ Maki Umemura, *Globalisation and Change in the Japanese Pharmaceutical Industry, 1990-2010*, in *COMPARATIVE RESPONSES TO GLOBALIZATION*:

1987, the J.P.L. was revised to introduce a P.T.E. system that recoups the patent term. During this time, innovative drug manufacturers cannot market their patented drugs due to delays in the Ministry of Health, Labor and Welfare (M.H.L.W.)'s drug safety examinations.¹² With the increased investment and additional patent protection, Japanese drug manufacturers began to develop new drugs in the 1990s. The Japanese government adopted a pro-medical science and patent policy, which enhanced this trend.¹³ In 2003, the Basic IP Law was enacted to create the IP Strategy Headquarters in the Cabinet, which began to publish annual strategy programs that charged ministries and agencies, particularly the M.E.T.I. (Ministry of Economy, Trade and Industry) and the J.P.O. (Japan Patent Office), with implementing action plans to enhance patent protection.¹⁴

In 2006, Professor Shinya Yamanaka, an adult stem cell researcher, and his research team successfully generated induced pluripotent stem cells (iPS cells). His research began to attract the attention of the Japanese community, who eagerly awaited news of Professor Yamanaka's Nobel Prize for Physiology or Medicine.¹⁵ In 2008, the IP Headquarters tasked the M.E.T.I. and the J.P.O. to review the J.P.L. in order to enable Japanese life science industries to commercialize Professor Yamanaka's research in regenerative medicine and other types of translational research in medical science.¹⁶

BRITISH AND JAPANESE ENTERPRISE 204 (M. Umemura and R. Fujioka eds., 2012).

¹² For more discussions on the PTE system, *see infra* note 39.

¹³ For a general discussion of the Japanese government's pro-patent policy, *see* Toshiko Takenaka, *Success or Failure? Japan's National Strategy on Intellectual Property and Evolution of Its Impact from the Comparative Law Perspective*, 8 Wash. U. Global Stud. L. Rev. 379 (2009).

¹⁴ Chitekizaisan Kihonhō [Intellectual Property Basic Act], Law No. 122 of 2002.

¹⁵ The Nobel Assembly at Karolinska Institutet, The Nobel Prize in Physiology or Medicine 2012 (Oct. 8, 2012).

¹⁶ *See* Intellectual Property Strategy Headquarters, *Intellectual Property Strategic Program 2008*, INTELLECTUAL PROPERTY STRATEGY HEADQUARTERS (2008), http://www.kantei.go.jp/jp/singi/titeki2/keikaku2008_e.pdf. For the function of Headquarters in IP law and policy making in Japan, *see* Toshiko

Currently, due to its streamlined reimbursement mechanism under the national health insurance system Japan is an attractive market for drug manufacturers. In Japan, after an innovative drug patent expires, the generic drug market share was significantly less than in the U.S. market but has significantly increased with the incentive through reimbursement of the national insurance system.¹⁷ Japanese drug manufacturers are highly ranked by the sales in Japanese market,¹⁸ but a significant portion of Japanese drugs are made and imported from European countries.¹⁹ U.S. also lagged behind on the trade balance because drugs are made in countries where corporate tax is low.²⁰ Furthermore, the global market sales and new drug development of Japanese drug manufacturers exhibit

Takenaka & Ichiro Nakayama, *Will Intellectual Property Policy Save Japan from Recession? Japan's Basic Intellectual Property Law and Its Implementation through the Strategic Program*, 35 IIC 877 (2004) [hereinafter, Takenaka, IP Policy].

- ¹⁷ According to the statistics available from IMS Health, MIDAS, Market Segmentation, the market share of generic drugs in the United States was more than 90% in contrast to less than 40% in Japan in 2010. *Iyakuhin Sangyō Bijon 2013 Shiryō* [Vision of Medical Product Industry: 2013-Materials], MINISTRY OF HEALTH, LABOR & WELFARE (2013) [hereinafter, 2013 Vision Material], http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/iryou/shinkou/dl/vision_2013b.pdf. The share was increased to 56.2 percent as of September 2015. *Kōhatsu Iyakuhin no Shiyō Sokushin nitutite* [Regarding Promotion of Generic Drug Use], MINISTRY OF HEALTH, LABOR & WELFARE (2013), http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/kouha-tu-iyaku/ [hereinafter, Generic Drug Share Promotion].
- ¹⁸ *2013 Iyakuhin Kigyo Uriage Ranking* [2013 Drug Manufacturers' Ranking by the sales], MEDISEARCH (2013), http://www.medisearch.co.jp/doukou_kakukaihatuhi.html
- ¹⁹ *New Vision for the Pharmaceutical Industry-Aiming at the Industry with International Competitive Power taking the Mission of Innovation*, MINISTRY OF HEALTH, LABOR & WELFARE (Aug. 30, 2007) [hereinafter MHWL 2007 New Vision Report], http://www.mhlw.go.jp/bunya/iryou/shinkou/dl/01_0001.pdf.
- ²⁰ *Iyakuhin Sangyō Kyōka Sōgōsen'ryaku Sankō Shiryō* [Strategies for Pharmaceutical Product Industry Promotion, Reference Materials], MINISTRY OF HEALTH, LABOR & WELFARE (Aug. 30, 2007), <http://www.mhlw.go.jp/file/04-Houdouhappyou-10807000-Iseikyoku-Keizaika/0000096429.pdf>.

a significant lag compared to U.S. and European drug manufacturers; only 16 percent of new active ingredients granted market authorization in the Japanese market between 2008 and 2011 were developed by Japanese drug manufacturers.²¹

In 2014, the government promulgated the Law to Promote Healthcare and Medical Strategy to establish the Office of Healthcare and Medical Strategy Promotion in its Cabinet, which should promote R&D in the healthcare and medical industry.²² This new law should overhaul Japan's drug industry and healthcare system through deregulation, and it provides more opportunities for foreign drug manufacturers in the Japanese market by easing regulatory guidelines.²³ Currently, Japan's national strategy focuses on medical science innovations, as well as on promoting health and active aging.²⁴ This strategy benefits innovative drug manufacturers because it provides government funds for R&D in medical science. It also benefits generic drug manufacturers by adopting various measures to promote generic drug penetration through implementing the MHLW's 2013 roadmap,²⁵ wherein the Healthcare Office set a target of cutting five trillion yen from healthcare expenditures by 2025.²⁶

²¹ See 2013 Vision Material, *supra* note 17 at Shiryō 20.

²² Kenkō Iryō Senryaku Suishinhō [Law to Promote Healthcare and Medical Strategy], Law No. 48 of 2014.

²³ Ames Gross, *Japan's Growth Strategy Promotes Medical and Healthcare Reform*, MEDTECH INTELLIGENCE (Aug. 21, 2014), <http://www.medicaldevicesummit.com/RegulatoryCompliance/Features1/Japans-Growth-Strategy-Promotes-Medical-and-Health-2086.aspx>.

²⁴ *Japan Revitalization Strategy Revised in 2014*, PRIME MINISTER OF JAPAN AND HIS CABINET (June 24, 2014), <http://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/honbunEN.pdf>.

²⁵ *Kōhatsu Iyakuhiin no Saranaru Shiyosokushin notameno R ōdomappu nituite* [Regarding Roadmap for Further Promotion of Generic Drugs], MINISTRY OF HEALTH, LABOR & WELFARE (April 5, 2013), <http://www.mhlw.go.jp/stf/houdou/2r9852000002z7fr.html>.

²⁶ “*Kokumin no Kenkōjūmyō wo Enshinsuru Shakai*” ni Muketa Yobō-Kenkō Kanri ni Kakawaru Torikumino Suishin ni Tusuite [Promotion for Measures of Preventive Medicine and Health Management toward “Society for Japanese Citizens to Prolong Their Active Age”], MINISTRY OF HEALTH, LABOR & WELFARE (Aug. 30, 2013), <http://www.mhlw.go.jp/stf/houdou/0000019326.html>. The government also aims to increase generic drug market share to more than 80% by 2018. See

II. NON-PATENT INCENTIVES

A. *Relationship to Patent Incentives*

Government agencies heavily regulate drug marketing and production. In Japan, the M.H.L.W. and Pharmaceuticals and Medical Device Agency (P.M.D.A.) regulate drug marketing under the P.M.D.²⁷ The level of drug development necessary to file a new drug market authorization involves high risk and intensive investment in R&D; the new drug approval success rate is 0.006 percent, and the average development cost is 50 billion yen.²⁸ Funding for innovative drug manufacturers heavily relies on revenue from marketing exclusivity over a newly approved drug. Both patent and data protection provide marketing exclusivity; these protections prevent generic drug manufacturers from accessing clinical data developed by the innovative drug manufacturers, which is necessary for market approval of generic drugs.

Notably, innovative drug manufacturers cannot likely take advantage of the full patent term because patent applications are filed as soon as the active ingredient's utility is established, and the patent term expires twenty years from the filing date.²⁹ Furthermore, drug manufacturers may require three to ten years to complete clinical trials and develop the data necessary to file a new drug application, which is a substantially longer process than the patent prosecution process at the J.P.O.³⁰ Moreover, the P.M.D.A.

supra note 17, Generic Drug Share Promotion.

²⁷ PMDA was established to conduct scientific reviews of drug and medical devicemarket approvals in 2004 as an independent administrative agency under Dokuritsu Hōjin Iryōhin Iryōkiki Sōgōkikōhō [Independent Administrative Agency Pharmaceuticals and Medical Devices Agency Law] Law No. 192 of 2002).

²⁸ MHRL 2007 New Vision Report, *supra* note 19, at 28.

²⁹ Tokkyohō [Patent Act] Law No.121 of 1959, art. 67.

³⁰ The average period between filing a request for examination and the first office action is less than a year. *Tokkyo Gyōsei Nen'ji Hokokusho 2014* [Patent Administration Annual Report 2014], JAPAN PATENT OFFICE (2014), https://www.jpo.go.jp/shiryō/tōshin/nenji/nenpou2014_xls.htm. A request for examination must be filed within three years from the filing date. *See* Japanese Patent Law Art. 43-3(1).

may require an additional year to review applications.³¹ A P.T.E. system is necessary for innovative drug manufacturers to recoup this pre-approval patent term, during which manufacturers cannot market their patented drugs. Furthermore, because generic drug manufacturers can rely on the expensive clinical data developed by innovative drug manufacturers, which reduces the necessary time and cost for full safety and efficacy studies, they are prevented from using the clinical data for various time periods, depending on the type of drug. As a result, patent protection and data protection are intertwined with the regulatory approval process.

B. The Regulatory Approval Process and Data Protection

In Japan, the regulatory approval process begins by filing a new drug market approval application with the P.M.D.A. The application must include clinical data necessary for the P.M.D.A. to establish the new drug's efficacy and safety. The cost of developing the necessary data is not only expensive, but also involves high risk, because the new drug must be tested on human subjects to establish efficacy/effect and safety. The M.H.L.W. only issues a disposition of market approval when the P.M.D.A. finds that all standards are met.³²

A disposition, a document issued for a market approval, identifies a drug through its active ingredients, efficacy quantities, dosage form, routes of administration, additional details on its manufacturing process, and effective period. When a drug manufacturer intends to sell a product that differs in its details from the previously approved disposition, it must file another application that includes the partial variations from the prior disposition. In short, a drug manufacturer is only authorized to market the drug identified by the dispositions. Thus, a new application is necessary to market a previously approved drug if it is used for a new use or

³¹ See Toshiki Sugita, *Recent Trends and Special Topics in New Drug Review in PMDA*, 2 *Generics and Biosimilars Initiative Journal* 99 (2013).

³² For the new drug application review procedures at the PDMP, see *Pharmaceutical Administration and Regulations in Japan*, JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION (JPMA) (2015) [hereinafter "Pharmaceutical Administration and Regulations in Japan"], <http://www.jpma.or.jp/english/parj/pdf/2015.pdf>.

treatment.

As discussed above, regardless of patent protection, the United States and some other countries, including Japan, provide an additional market exclusivity term by preventing generic drug manufacturers from accessing clinical trial data developed by new drug manufacturers. In Japan, the post marketing surveillance (P.M.S.) period system provides such additional protection. This protection is available not only for a new drug, but also for a new use of a previously approved drug.

To sell generic versions of previously approved drugs, generic drug manufacturers must also file an application with the P.M.D.A. for market approval. A generic drug features the same active ingredients, efficacy/effect, quantities, and dosage as a previously approved drug.³³ Thus, generic drug manufacturers can skip the expensive efficacy and safety clinical trials because they can rely on the data developed by the innovative drug manufacturer for the previous approval. Generic drug manufacturers must only establish stability and bioequivalence between the generic drug and approved drug.³⁴ The period needed to develop such data is two to three years, which is much shorter than is needed for new drug approvals. However, generic drug manufacturers cannot receive market approval until the P.M.S. period ends, even if the P.M.D.A. finds that all the standards are met.³⁵

The P.M.S. was introduced in 1979 and is aimed at ensuring drug efficacy and safety after the drugs are sold.³⁶ Although provision of additional protection to innovative drug manufacturers

³³ Jenerikku Iyaku hin heno Gimon ni Kotaemasu [Answering Questions about Generic Drugs], MINISTRY OF HEALTH, LABOR & WELFARE (July 2012), http://www.mhlw.go.jp/bunya/iryoku/kouhatu-iyaku/dl/02_120713.pdf.

³⁴ *Iyaku hintō no Tokkyoken no Sonzokukikan no Enchō Tōroku Seido oyobi Sono Unyō no Arikata* [The Best Practice for Patent Term Extension regarding Drug and other Products], INSTITUTE OF INTELLECTUAL PROPERTY (Feb., 2015) [hereinafter, IIP, Best Practice], http://www.jpo.go.jp/shiryoku/toushin/chousa/pdf/zaisanken/2014_09.pdf.

³⁵ Yukiko Ozaki, *Abstract of Dissertation: Iyaku hin Sangō Shijō niokeru Shijō Dokusenken ni kansuru Kosatsu* [Study of Market Exclusivity in the Drug Product Market], INTERNATIONAL CORPORATE STRATEGY HITOTSUBASHI UNIVERSITY (Mar., 2010) [hereinafter “Study of Market Exclusivity”], http://www.ics.hit-u.ac.jp/jp/phd/article_ozaki.pdf.

³⁶ Pharmaceutical Administration and Regulations in Japan, *supra* note 32, at 73.

was not the original aim, the P.M.S. provisions function in the same manner as data protection under the Hatch-Waxman Act.³⁷ The original P.M.S. period was only two years, but has since been extended, as intellectual property protection has strengthened with adoption of the IP-based national strategy.³⁸ Under the current rules, the P.M.S. period varies depending on the type of approved new drug: (1) four to six years for previously approved drugs with a new use or dosage; (2) six years for new prescription drugs and drugs with new routes of administration; (3) eight years for drugs that include new active ingredients; and (4) ten years for orphan drugs.³⁹ As a result, drug manufacturers who developed a new use for a previously approved drug enjoy revenue from an exclusive market for a maximum of six years from the date of the drug's approval. This period of data protection is independent of patent protection.⁴⁰

In the United States, the Hatch-Waxman Act provides a unique framework that prevents generic drug manufacturers from infringing patents held by innovative drug manufacturers, while encouraging generic drug manufacturers to challenge such patents.⁴¹ Under this framework, filing a U.S. Food and Drug Administration (FDA) marketing application with a certification stating that the unexpired patent is invalid or unenforceable, constitutes patent infringement. The patentee can file a patent infringement suit against the generic drug manufacturer that filed the application.⁴² Generic drug manufacturers receive marketing exclusivity for 180

³⁷ Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417 [hereinafter, "Hatch-Waxman Act"]. For further information on the Hatch-Waxman Act's history and goal, see Margo A. Bagley, *Patent Term Restoration and Non-Patent Exclusivity in the United States* (Aug. 1 2011) (Virginia Public Law and Legal Theory Research Paper No. 2011-25) [hereinafter "Patent Term Restoration"], <http://ssrn.com/abstract=1899533>.

³⁸ Study of Market Exclusivity, *supra* note 35, at 5. For a discussion of IP based national strategies, see *supra* note 16, Takenaka, IP Policy.

³⁹ Pharmaceutical Administration and Regulations in Japan, *supra* note 32, at 82.

⁴⁰ *Drug Re-Examination/Data Exclusivity in Japan and Neighboring Countries, AIPPI Forum & ExCo Workshop*, JPMA (Sept. 6, 2016), https://www.aippi.org/download/helsinki13/presentations/Pres_Pharma_4_Yokumura_300813.pdf.

⁴¹ Patent Term Restoration; *supra* note 37, at 5.

⁴² 21 U.S.C. §§ 355(j)(2)(A)(vii)-(iv).

days if they win the patent litigation.⁴³

Neither the P.M.D. nor the J.P.L. provides such a dispute resolution framework that links patent protection and the regulatory approval process. In practice, under its administrative purview, the P.M.D.A. requires generic drug manufacturers to provide patent information related to the approved drug when they file a market approval petition.⁴⁴ If the P.M.D.A. finds a potential patent dispute, it contacts the patentee/innovative drug manufacturer and requests the patent information. The P.M.D.A. refuses to authorize market approval if the patent is directed to the active ingredient of the generic drug. The P.M.D.A. used to authorize market approval if the patent was not directed to the active ingredient but only to a use of the generic drug. This practice was changed in 2009 when the P.M.D.A. adopted a skinny label practice. Under this practice, if a patent is directed to a use or dosage but not the active ingredient of the generic drug, a disposition is issued for the generic drug, excluding the patented use or dosage.⁴⁵ Thus, generic drug manufacturers are unable to sell drugs indicating the patented use or dosage.

⁴³ See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, *Guidance for Industry 180 Generic Drug Exclusivity under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, FDA (June 1998), <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf>.

⁴⁴ IIP, Best Practice, *supra* note 34, at 33. The administrative guidance, Gyōsei Shidō, is a Japanese government practice under the Administrative Procedure Act of 1993 in which an administrative agency provides to a party guidance, recommendation, advice, and other acts that may be sought to implement the administrative aim.

⁴⁵ Tsutatsu [Notice] No. 065001, MINISTRY OF HEALTH, LABOR & WELFARE (June 5, 2009), https://www.jpo.go.jp/shiryoutoushin/shingikai/pdf/entyou-wg05_shiryou/sankou_2.pdf#search='%E8%96%AC%E9%A3%9F%E5%AF%A9%E6%9F%BB%E7%99%BA%E7%AC%AC0605014%E5%8F%B7. See also, Pharmaceutical Administration and Regulations in Japan, *supra* note 32 at 16. For a discussion of the skinny label practice under U.S. Patent Act, see Herman H. Yue & John D. Garretson, *Skinny Labeling after Hospira v. Burwell: An End-Run Around Pharmaceutical Method of Use*, FOOD AND DRUG LAW INSTITUTE (July/August 2015), http://fdaimports.com/docs/solving_or_compounding_the_problem.pdf.

III. PATENT INCENTIVES

A. Patentability of New Uses for Known Products

Under the J.P.L., a known product may meet the novelty and inventive step requirements if: (1) the product features an inherent function or property and (2) is limited to a use based on the function or property, so long as the inherent use is unknown and unpredictable to one skilled in the art of the invention, at the time the patent application is filed.⁴⁶ The J.P.O. applies a special rule to products in unpredictable arts, such as chemical compounds, to determine novelty and inventive step. Even if the J.P.O. examiners find that a product described in a claim under examination is expressly or implicitly disclosed in a reference, the unpredictable art special rule prevents the examiners from citing the reference, unless the reference meets the enablement requirement for the disclosed subject matter.⁴⁷ Courts require the J.P.O. applying a high enablement standard for citing a reference in unpredictable arts. A reference must include sufficient information, such that one skilled in the art of the invention will “readily” understand how to make and use the disclosed subject matter in light of the technical common knowledge at the time of patent application.⁴⁸ Therefore, a claim directed to a product in the unpredictable arts meets the novelty requirement, even if detailed structures of the product are disclosed in a reference, so long as no use or manufacturing process for the product is known to one skilled in the art at the time the patent application is filed.⁴⁹ Examiners can cite such reference in combination with another reference for failing to meet the inventive step to show that a use or manufacturing process for the product is

⁴⁶ Tokkyohō [Patent Act] Law No.121 of 1959, art. 29(1)-(2).

⁴⁷ *Tokkyo Jitsuyo Shin'an Shin'sa Kijun* [Exam Guidelines for Patent and Utility Model in Japan], JAPAN PATENT OFFICE (Sept. 2015) (*see* Part III, Chapter 2, 3.1.1(1)b) [hereinafter JPO Examination Guidelines], https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm. *See also Shimako Kato, Kagakubun'ya niokeru Shinposei no Kangaekata* [Examination of Inventive Step on Inventions in the Chemical Field], JAPAN PATENT ATTORNEYS ASSOCIATION (2008) (*see* 61 *Patento* (No. 10) 86).

⁴⁸ Tokyo Kotō Saibansho [Tokyo High Court] October 16, 1986, Sho 59 (Gyoke) no. 303.

⁴⁹ JPO Examination Guidelines, *supra* note 47, at Part III, 3.1.1.(1)b

obvious to one skilled in the art of the invention.

This special rule is particularly relevant in determining the novelty and inventive step for patent protection of medicinal inventions because materials such as chemical compounds in medicinal inventions are in the unpredictable art. The rule applies to claims directed to a new medical use of a known chemical compound based on discovering a property of the compound. The J.P.O. established an examination practice to deny patentability to method claims directed to use of a drug product for medical treatment, based on a lack of industrial applicability.⁵⁰ Instead, such use is patentable as a product used for treatment because a product patent can be enforced against drug manufacturers.⁵¹ The J.P.O. has published special guidelines on medical inventions. The introduction to the J.P.O.'s Medicinal Invention Guidelines defines 'material' as a "a component used as an active ingredient, including a compound, a cell, a tissue and a chemical substance (or a group of chemical substances) whose chemical structure is not specified, such as an extract from a natural product, and a combination thereof [hereunder, an 'active ingredient component']."⁵² Under the Medicinal Invention Guidelines, J.P.O. examiners cannot cite a reference to reject a claim directed to an active ingredient component limited by a particular use, unless the reference includes sufficient information that one skilled in the art could understand not only the particular use for the component, but also a process for making the component.⁵³ An examiner can only cite a reference that fails to disclose the particular use limited to the active ingredient

⁵⁰ Tokyo Koto Saibansho [Tokyo High Ct.] April 11, 2002, Hei 12 (gyo ke) 65. Hanrei Jihō No. 1828, 88. For a general discussion on patentability of medical method under the JPL, see Yusuke Sato, *Patent Protection of Medical Methods—Focusing on Ethical Issues—From Current Situation and Problems on Intellectual Property Law, Annual of Industrial Property Law, June 2007*, 20 Pac. Rim. L. & Pol'y J. 125, 129 (Jiameng Kathy Liu trans., 2011).

⁵¹ Shoichi Okumura, JAPAN PATENT ATTORNEYS ASSOCIATION, BIO-SCIENCE COMMITTEE TŌSHINSHO (Feb. 10, 2012) (see page 8) [Hereinafter, "Okumura Bio-Science Committee"], <http://jpaa.or.jp/seisaku/pdf/F1-11.pdf>.

⁵² *Tokkyo Jitsuyoushinhan Handobukku* [Examination Handbook for Patent Utility Model], Japan Patent Office (Annex B, Chapter 3), https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/7_3.pdf

⁵³ *Id.* at 2.2.2 (2).

component for an inventive step-based claim rejection. However, examiners must cite another reference to show that the particular use of a claimed product is predictable or obvious to one skilled in the art.

The J.P.O.'s special unpredictable art rule significantly differs from the inherency doctrine under U.S. case law. Under the inherency doctrine, U.S.P.T.O. examiners can cite a reference disclosing a product to reject a claim directed to a product in the unpredictable art for a novelty (anticipation) rejection, even if the reference does not disclose a property or function as long as the property and function are necessarily present in the disclosed.⁵⁴ The J.P.O.'s inherency doctrine also significantly differs from the U.S. inherency doctrine because the U.S. doctrine does not require that a reference disclose sufficient information for one skilled in the art to recognize the presence of a natural result, as long as the reference meets the enablement requirement for the process.⁵⁵ Discovery of a new use or purpose for a product cannot prevent an anticipation rejection, as long as the product is structurally identical to an old product, and, thus, applicants cannot rely on an inherent claim feature to distinguish a product in the prior art at the U.S.P.T.O.⁵⁶ This case law eliminates patents for known products, whether or not an application discloses a new and nonobvious use, based on discovery of an inherent function and property. As a result, only a method patent is available for a new use of a known product as long as the use is new and nonobvious.

⁵⁴ For a general discussion on the inherency doctrine, *see, i.e.*, Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 Hous L. Rev. 1101 (2008); Dan L. Burk & Mark A. Lemley, *Inherency*, 47 Wm. & Mary L. Rev. 371 (2005); Bradford J. Duft & Eric P. Mirabel, *Principles of Inherency*, 77 J. Pat. & Trademark Off. Soc'y 539 (1995). For a general discussion of the product of nature doctrine, *see* John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 J. Pat. & Trademark Off. Soc'y 301 (2003).

⁵⁵ *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).

⁵⁶ *Ansonia Brass & Copper Co. v. Electrical Supply Co.*, 144 U.S. 11 (1892).

B. Patent Term Extension

Under the J.P.L., owners of new use patents can request a patent term extension to recoup the patent protection period lost while waiting for market approval.⁵⁷ The objective of Japan's patent term extension (P.T.E.) system is set forth under the J.P.L. as follows:

Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Laws that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition are necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding five years.⁵⁸

To request an extension, innovative drug manufacturers must file a P.T.E. application and may receive a patent rights extension that does not exceed five years if the application does not fall into one of grounds for rejecting a request for patent term extension.⁵⁹ One of such grounds is "where the disposition designated by Cabinet Order is deemed unnecessary for working of the patented invention which is under the examination for P.T.E."⁶⁰ The J.P.L.'s P.T.E. provision did not clarify the definition for "working" the patented invention in connection with the "disposition". However, the scope of the drug is limited by the claims, which differs from market approval of a drug, which is limited by the disposition description.

The "unnecessary disposition" ground for rejection led to considerable uncertainty in the scope of the market approval disposition for P.T.E.s. The J.P.O. has a long-established examination practice of granting patent extensions for new uses of

⁵⁷ Tokkyohō [Patent Act] Law No.121 of 1959, Art. 67 (2) [hereinafter JPL].

⁵⁸ JPL, Art. 67(2).

⁵⁹ JPL, Art. 67(2), 67-2.

⁶⁰ JPL, Art. 67-2(1)(i).

known drug patents. However, it interpreted the grounds for rejection in a manner that that denies P.T.E. applications for patents directed to a new dosage and administration of a known drug for a known use. Innovative drug manufacturers have challenged the J.P.O.'s interpretation. In *Genentech v. the JPO*, the Intellectual Property High Court of Japan (IP High Court) sided with the patentee and struck down the J.P.O.'s interpretation by reversing the J.P.O.'s rejection of Genentech's P.T.E. application.⁶¹ Instead, the IP High Court adopted an interpretation that entitles drug manufacturers to a patent term extension—even if the ingredients, use, and efficacy/effect are identical—as long as the quantity and dosage differ. This interpretation was upheld by the Supreme Court of Japan.⁶²

As a result, patent owners are given P.T.E. incentives with an opportunity to recoup the portion of the patent term sacrificed for market approval due to changes in the ingredients, use, efficacy/effect, quantity and dosage from the previous approval. However, the scope of exclusivity for an extended patent may be narrower than the scope defined by the claim. In dicta, the IP High Court stated in *Genentech* that a patent extension directed to an active ingredient can exclude a drug product defined by not only (1) the ingredients, use, and efficacy/effect included in the claim, but also (2) quantity and dosage not included in the claim, but only described in a subsequent disposition.⁶³ The IP High Court also stated that the extended patent may exclude equivalents of the drug product defined by these elements in the claim and subsequent disposition.⁶⁴ This dictum led to considerable uncertainty in the exclusive scope of patent extensions.⁶⁵

⁶¹ *Chiteki Zaisan Kōtō Saibansho* [Intellectual Prop. High Ct.] May 30, 2014, Hei 25 (gyo ke) no. 10195, Hanrei Jiho No. 2232, 3, http://www.ip.courts.go.jp/eng/hanrei/g_panel/index.html [Hereunder “IP High Court Genentech decision].

⁶² Saikō Saibansho [Sup. Ct.] Nov. 17, 2015, Hei 26 (gyō hi) no. 356, 69 Saiko saibansho Minji Hanreishu [Minshu] 1912, Hanrei Jiho No. 2309, 127.

⁶³ *Supra* note 61, IP High Court Genentech decision.

⁶⁴ *Id.*

⁶⁵ *Tokkyosken Sonzoku Kikan Enchō ni kansuru Chizai Daigougi Hanketsu nituite* [Regarding the IP High Court's Grand Bench Decision on Patent Term Extension], JAPAN GENERIC DRUG MANUFACTURERS ASSOCIATION (May 29, 2015), <http://www.jga.gr.jp/wp->

This IP High Court interpretation of P.T.E. eligibility in *Genentech* based on a subsequent market approval differs markedly from the patent extension system in the United States.⁶⁶ The U.S. Patent Act⁶⁷ includes active ingredient limitations that prevent innovative drug manufacturers from obtaining P.T.E.s on new technologies associated with pre-approved drugs that include the same active ingredients.⁶⁸ When approval is granted to a combined drug product, the product must include at least one ingredient that was not previously approved for a P.T.E. grant.⁶⁹ The scope of patent extensions for active ingredient claims is broader than a Japanese patent extension; it not only includes the product specified in the market approval, but also products with the same active ingredients, and any salts or esters of the ingredients.⁷⁰

The IP High Court's eligibility interpretation is more consistent with the European Union's patent extension system, which relies on a Supplemental Protection Certificate (S.P.C.) under the EU S.P.C. Regulations.⁷¹ Similar to the J.P.L., the EU S.P.C. Regulations may grant multiple S.P.C.s for drug products with the same active ingredients. The EU S.P.C. Regulations prevent drug manufacturers

content/uploads/2015/05/efe7b8ac2da1edf77e9ca08f23f2a6d3.pdf. The IP High Court's grand bench tried to clarify the scope in *Debiopharm Int'l v. Touwa Yakuhin, Chiteki Zaisan Kōtō Saibansho* [Intellectual Prop. High Ct.] Jan. 20, 2017, Heisei 28 (ne) no. 10046. The grand bench held that the extended patent can exclude products which are substantially the same as the drug products defined by the claim and subsequent deposition.

⁶⁶ 35 U.S.C. § 156.

⁶⁷ Title 35 U.S.C.

⁶⁸ 35 U.S.C. § 156(a)(1).

⁶⁹ *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, U.S. FOOD AND DRUG ADMINISTRATION (Apr. 22, 2015), www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069959.htm.

⁷⁰ *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004).

⁷¹ Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, 1992 O.J. (L 182) 2; Regulation (EC) No. 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products, 1996 O.J. (L 198) 8 [hereinafter SPC Regulations]. For a comparative study on patent term extension systems, see IIP, Best Practice, *supra* note 34, at 91.

from obtaining S.P.C.s on drug products if (1) the authorization granted to a drug product is not the first authorization⁷² or (2) an S.P.C. has already been granted to the drug product.⁷³ However, the Court of Justice for the European Union (C.J.E.U.) has interpreted the conditions to not preclude an S.P.C. grant for a new use of a drug product, even if the drug product includes the same active ingredient previously authorized for another use.⁷⁴ Although the C.J.E.U. suggests that an S.P.C. may not be available if the patent under examination based on a subsequent market approval includes a prior patent for which an SPC was granted based on a prior market approval; a prior market approval does not completely prevent innovative drug manufacturers from obtaining another S.P.C. on the same drug, regardless of the identity of the active ingredient.⁷⁵

Although the C.J.E.U.'s eligibility interpretation differs from the United States' approach, the S.P.C. scope is similar to the United States' approach. An S.P.C. enjoys the same scope of exclusivity as the scope of the original patent.⁷⁶ If a patent that has been granted an S.P.C. is directed to a product, the scope includes any drug product with the same active ingredient, regardless of additional active ingredients or uses of the product.⁷⁷ The scope of S.P.C. exclusivity not only includes the active ingredient described in the authorization, but also its derivatives, such as salts and esters, that fall within the scope of the patent that was granted the S.P.C.⁷⁸ This scope is broader than the extended patent scope under the J.P.L. because the extended patent scope only includes the drug product described in a subsequent disposition. However, the IP High Court has suggested that the scope may include equivalents of such approved drug products.

⁷² SPC Regulations Art. 3(c).

⁷³ SPC Regulations Art. 3(d).

⁷⁴ *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*, Case C-130/11 (Euro. Ct. of Justice Jul. 19, 2012).

⁷⁵ Edward Oates, *Neurim judgment of European Court of Justice liberalises SPC system*, AIPPI E-NEWS (Sept. 2012), https://www.aippi.org/enews/2012/edition26/Edward_Oates.html.

⁷⁶ SPC Regulations, Art. 5.

⁷⁷ *Novartis AG v Actavis UK Ltd*, Case C-442/11 (Euro. Ct. of Justice Feb. 9, 2012).

⁷⁸ *Farmitalia Carlo Erba Srl.*, Case C-392/97 (Euro. Ct. of Justice Sept. 16, 1999).

C. New Use Patent Infringement Remedies

Despite the patent-friendly view of the P.T.E. system, new use patents are difficult to enforce, even if a patent issues on a drug product instead of a method under the J.P.L. Strong public policy for keeping post-patent expiration products in the public domain prevents courts from granting an injunction against such products. Under the J.P.L., a product patent can exclude others from making, using, assigning, exporting, importing, and offering to assign the product.⁷⁹ An exception applies to product patents, the scope of which is limited by a new use. This is because the new use distinguishes the prior art product, which is structurally identical to the claimed product. To maintain the prior art product in the public domain, the creation, assignment, exportation, and importation of the product should be free from patent protection, so long as the product use is not the patented use.⁸⁰ In other words, a patentee must establish that the product made or sold by an alleged infringer will be used for the patented use.

Due to the burden necessary to establish use, a new use drug product patent functions more like a method patent, which excludes acts of using a method of treatment.⁸¹ Under current case law which is supported by the majority of legal commentators, a patentee can meet the burden when it shows that the product is sold with a description, which indicates that the product is used for the patented

⁷⁹ See JPL Art. 2(3)I; Art. 68. Scholars view the nature of new use drug product inventions as method inventions. See Hiroshi Yoshida, *Yōtohatsumei ni kan'suru Tokkyoken no Sashitome Seikyū no Arikata – “Mono”ni Chakumoshikushita Handan kara “Mono”ni Chakumokushita Handane* [Appropriate Injunction for Patent Infringement of New Use Invention: From the Focus on “Product” to the Focus on “Person”], 16 Chiteki Zaisan Seisaku Kenkyu 167, 173 (2007), http://lex.juris.hokudai.ac.jp/coe/pressinfo/journal/vol_16/16_5.pdf [hereinafter, “Yoshida, Appropriate Injunction”].

⁸⁰ Shimako Kato, *Yōto Hatsumei oyobi Yōto Genteiwo Fukumu Hatsumeino Kenrikōshi nikan'suru Ichikōsatsu* [A Study of Enforcement of Patents on Use Inventions and Inventions Limited by Use], in CHITEKI ZAISHONONO ATARASHII NAGARE [New Trends in Intellectual Property] 189 (2010) [hereinafter “Kato, A Study of New Use Patent Enforcement”].

⁸¹ Tokkyohō [Patent Act] Law no.121 of 1959, art. 2(3)ii, art. 68.

use.⁸² This description is included in a package insert attached to the drugs or containers, as required under the P.M.D.. The package insert must include dosage, administration, and other necessary precautions and information necessary to the use and handling of the drugs.⁸³ The P.M.D.A. skinny label practice requires that the insert be clear with respect to the exclusion of patented use or dosage. However, prior to the adoption of this skinny label practice, when the insert expressly or implicitly indicated a patented use or dosage, the drug product infringed a new use patent. In the Ketotifen Fumarate case, which was decided before the P.M.D.A. adopted its skinny label practice, the Tokyo District Court found that the patentee met the burden for showing that the drug will be used for the patented use, even if the package insert did not expressly indicate the patented use.⁸⁴ The court held that the patented use, the prevention of allergic asthma, was implicitly indicated in the package insert when the document included descriptions indicating that (1) the drug is for treating bronchial asthma and (2) the drug is not administered for trachea expansion during an asthma attack, but is regularly administered daily.⁸⁵

When a patented use is not included in a package insert, courts may find an infringing use based on the totality of circumstances surrounding the creation and sale of the drug product at issue.

In the Ketotifen Fumarate case, the Tokyo District Court emphasized that infringement must be determined based on whether an accused product falls within the patent scope by considering the asserted claim, and the written description and drawings in light of the general knowledge of one skilled in the art. Thus, although the defendant secured market approval on the patented use under the P.M.D., this fact did not necessarily lead to the conclusion that the product was used for the patented use.⁸⁶

In the Cilostazol case, the IP High Court found that a drug was

⁸² Kato, A Study of New Use Patent Enforcement, *supra* note 80, at 192.

Japanese scholars use “label theory” to find limit infringement of new use patents to the circumstances where a package insert indicates a patented use.

⁸³ See L.P.M.D. Art. 52-1. See *supra* note 5.

⁸⁴ Tokyo Chihō Saibansho [Tokyo Dist. Ct.] Oct. 23, 1992, Hei 2 (wa) 12094. 24 Chiteki zaisanken kankei minji, gyōsei saiban reishū. [Chiteki Saishū] 805, Hanrei Jiho No. 1469, 139.

⁸⁵ *Id.*

⁸⁶ *Id.*

used for a patented use, even though the scope of the defendant's market approval did not include the patented use, because the defendant emphasized that the patented use encourages doctors to participate in clinical trials.⁸⁷ Thus, it is likely that Japanese courts are willing to find infringement under some circumstances to support a drug being used for a patented use, even if a patented use is clearly excluded from the disposition and a package insert clearly excludes the patented use under the post-2009 skinny label practice.

Even with a finding of infringement, courts may be willing to grant an injunction against drug sales, but are reluctant to grant an injunction against manufacturing if a product has both infringing and non-infringing uses. In the Ketotifen Fumarate case, the Tokyo District Court granted an injunction against the defendant to stop the sale of the drug product, despite its non-infringing use for treating bronchial asthma.⁸⁸ The prosecution record supported the notion that the original claims included the non-infringing use, but were limited through an amendment, which indicated that only the allergic asthma prevention use was covered to overcome prior art.⁸⁹ The court explained that the broad scope of the injunction was necessary because it was impossible to distinguish infringing and non-infringing uses of the drug product. However, the court did not grant an injunction against the party making the Ketotifen Fumarate compound because the compound alone has non-infringing uses before it is processed as a drug product. Patent law scholars criticized the broad scope of the injunction granted by the Tokyo District Court.⁹⁰

⁸⁷ Chiteki Zaisan Koto Saibansho [Intellectual Prop. High Ct.] Nov. 21, 2006, Hei 17 (ne) 10125. This is not a patent infringement case but an employee invention compensation case in which an employee sued his employer for a reasonable compensation. Whether the employer worked a new use patent invented by the employee was an issue in calculating reasonable compensation for the employee because the JPL provides for mandatory compensation to work an invention when the right of the invention is transferred from an inventor to his employer. JPL Art. 35.

⁸⁸ Tokyo Chihō Saibansho [Tokyo Dist. Ct.] Oct. 23, 1992, Hei 2 (wa) 12094. 24 Chiteki zaisanken kankei minji, gyōsei saiban reishū. [Chiteki Saishū] 805, Hanrei Jiho No. 1469, 139.

⁸⁹ *Id.*

⁹⁰ Patent scholars criticize this broad injunction scope. *E.g.*, Mimura Ryoichi, *Tokkyohan'I no Kaishaku to Keizaikatsudou no Jiyū* [Construction of Patent Claim and Freedom of Commercial Activities], Bessatsu NBL No. 120, 217

Although using a drug product for a patented use constitutes infringement, such use is exempted from infringement liability when a patient takes the drug product for the patented use. This is because the J.P.L. requires that a patented product is used for business purposes to find infringement liability, which, then excludes private uses.⁹¹ Courts do not typically find that doctors and pharmacists are secondarily liable through the indirect infringement theory because courts emphasize that strong policy favors maintaining freedom in medical practice to provide patients with the best treatments.⁹² In all aspects of their medical practice, doctors should be exempted from patent infringement liability, regardless of a patent. Pharmacists should also be protected from liability as long as their activities constitute preparing a drug in accordance with a prescription prepared by a medical doctor.⁹³

Further, suing generic drug manufacturers for indirect infringement is difficult because the J.P.L. does not afford an infringement claim for acts equivalent to active inducement under the U.S. Patent Act.⁹⁴ When an accused product has a non-infringing use, patentees must establish the following: (1) the product is used for the patented product use; (2) the product is indispensable for solving the problem of the patented method; (3) the defendant knew of the asserted patent; and (4) the defendant knew that the product would be used to infringe the patent.⁹⁵ Courts are divided as to the interpretation of the indispensable requirement; certain courts require novelty to consider the product indispensable.⁹⁶ This view precludes indirect infringement liability for a new use product patent because the drug product is a known product, and thus, does not meet the indispensable requirement. Other courts do not require novelty and find a product indispensable if the product is necessary to solve a technical problem of the

(2007).

⁹¹ JPL Art. 68. *See* Toshiko Takenaka et al., Patent Enforcement in the US, Germany and Japan 265 (2015).

⁹² Tokyo Koto Saibansho [Tokyo High Ct.] April 11, 2002, Hei 12 (gyo ke) 65, Hanrei Jiho No. 1828, 99.

⁹³ JPL Art. 69(3).

⁹⁴ 35 U.S.C. § 271(b).

⁹⁵ JPL Art. 101 iv.

⁹⁶ *E.g.*, Tokyo Chihō Saibansho [Tokyo Dist. Ct.] April 23, 2004, Hei 14 (wa) 6035 Hanrei Jihō No. 1982, 89.

invention.⁹⁷ Even with this perspective, establishing that a product is indispensable remains difficult because the product may not solve the technical problem independent of its use, which was illustrated in case on a new treatment delivery.⁹⁸

Generally, establishing infringement of a new use product patent and obtaining an injunction against making, assigning, importing, and exporting infringing products remains difficult. Thus, securing incentives for market exclusivity through data protection remains important. The current maximum six-year P.M.S. period for previously approved drugs with a new use or dosage is essential for securing such incentives for new use R&D. Under the P.M.D.A. practice, generic drug manufactures cannot receive market approval for a patented use until the patent expires. Because the patented use is excluded from market approval, the burden should be shifted to generic drug manufacturers to show that the description in the package insert clearly excludes the patented use to avoid an injunction against drug products. The Tokyo District Court's approach in the Ketotifen Fumarate case suggests this burden shift, based on the notion that distinguishing infringing and non-infringing uses is impossible.

Innovative drug manufactures can argue that patent incentives for new use and treatment R&D are insufficient because of the difficulties in obtaining injunctions. Certain Japanese scholars propose that a right to compensation should be established for medical treatment inventions and that a right to injunctive relief should be eliminated.⁹⁹ This proposal might be difficult to implement due to the difficulties in compensation calculation and the high cost to administer compensation. Instead, an injunction should be granted to prevent the production and sale of unpatented drug products if: (1) a description clearly avoids a patented use or (2) the totality of circumstances indicates that drugs are made solely for a patented use, despite a description in the package insert.

⁹⁷ *E.g.*, *Chiteki Zaisan Kōtō Saibansho* [Intellectual Prop. High Ct.], September 30, 2005, Hei 17 (ne) 10040, Hanrei Jihō No. 1904, 47.

⁹⁸ Kato, *A Study of New Use Patent Enforcement*, *supra* note 80, at 199. -

⁹⁹ Yoshida, *Appropriate Injunction*, *supra* note 79, at 231.

CONCLUSION

Japan is one of most innovative drug manufacturer-friendly countries because it revised its patent and drug regulation systems for providing patent and non-patent incentives for new use and treatment R&D based on its pro-patent and pro-medical science policies. Fundamental patent policies for maintaining unpatented products in the public domain and securing doctors' freedom of medical practice to provide the best medical treatments limit the remedies available for infringement of new use product patents. To enhance dispute resolution between innovative and generic drug manufacturers without involving patients, doctors, and medical practitioners, Japanese courts should use their discretion to flexibly define the scope of an injunction. Such scope should reflect to a fine balance on competing interests between securing incentives for new use and treatment R&D and allowing freedom for generic drugs to enter in the market.

