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# Recent Developments in Patent Rights for Pharmaceuticals in China and India

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# RECENT DEVELOPMENTS IN PATENT RIGHTS FOR PHARMACEUTICALS IN CHINA AND INDIA*

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I. Introduction ..... 303
A. Background on the TRIPS Agreement ..... 304
B. Patent Rights in China Prior to Recent Amendments ..... 305
C. Patent Rights in India Prior to Recent Amendments ..... 306
II. China and India Revise Their Patent Laws to Comply with TRIPS ..... 307
A. The 2000 Amendments to China's Patent Law. 308
B. The 2005 Amendments to India's Patent Law . 309
III. Issues in China ..... 310
A. Challenges Relating to Pharmaceuticals ..... 310
B. Enforcement of Patent Rights in China ..... 312
IV. Issues in India ..... 313
A. "Mailbox" Applications and Compulsory Licensing ..... 313
V. Conclusion ..... 315

## I. INTRODUCTION

The World Trade Organization (the "WTO") seeks to provide intellectual property protection to its Member States through the Trade-Related Aspects of Intellectual Property

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Rights agreement (the "TRIPS agreement" or "TRIPS").[1] The objective of TRIPS is to protect and enforce intellectual property rights, contribute to the promotion of technological innovation and aid in the transfer and dissemination of technology in a manner conducive to social and economic welfare.[2] China and India, two countries with historically less-developed patent protection, recently revised their patent laws to be in compliance with the WTO.[3] TRIPS introduces intellectual property rules into the multilateral trading system for the first time.[4] This article focuses specifically on the newly-amended patent laws in China and India and their effects on pharmaceuticals.

### A. *Background on the TRIPS Agreement*

Effective January 1, 1995, the TRIPS agreement requires its signatories to enact basic patent laws that provide certain minimum patent protection to inventors of the signatory country as well as inventors of all WTO Member States.[5] Member States may implement more extensive protection than is required by TRIPS.[6] TRIPS sets forth the subject matter that is protected, the rights that are conferred, the permissible exceptions to those rights and the minimum duration of the protection.[7] TRIPS states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step

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[1] Marrakesh Agreement Establishing the World Trade Organization Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, *available at* http://www.wto.org/english/docs_e/legal_e/legal_e.htm# TRIPS (last visited Mar. 23, 2006) [hereinafter TRIPS Agreement].

[2] *Id.* The areas of intellectual property covered by TRIPS are copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs (topographies) of integrated circuits; and undisclosed information. *Id.* arts. 9-39.

[3] *See* Patent Law of the People's Republic of China (promulgated by the Standing Comm. of the Ninth Nat'l People's Cong., Aug. 25, 2000, effective July 1, 2001) (P.R.C.), *available at* http://www.sipo.gov.cn/sipo_English/flfg/default.htm (last visited Apr. 28, 2006); The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

[4] *Id.*

[5] *Supra* note 1, arts. 1.1, 1.3, 3.1.

[6] *Id.* art. 1.1.

[7] World Trade Organization, Intellectual Property, Overview: the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Mar. 23, 2006).

and are capable of industrial application."[8] WTO Member States were required to be in compliance with TRIPS by January 1, 2005.[9] For this reason, Member States with basic patent protection that failed to conform with the terms of TRIPS have recently made significant changes to their patent laws in order to be TRIPS compliant.[10] Two such member states include the People's Republic of China ("China") and India.

### B. *Patent Rights in China Prior to Recent Amendments*

Modern patent law in China dates back to 1950 with the issuance of the Provisional Regulations of the Protection of Invention Rights and Patent Rights.[11] These regulations provided patent protection and rewards to inventors, but the ownership of the inventions remained with the State.[12] During the Cultural Revolution from 1966 to 1975, the small rewards granted to inventors were eliminated.[13]

In 1984, China adopted the Patent Law of the People's Republic of China.[14] Article 25 excluded certain classes of items from patent protection: "(1) scientific discoveries; (2) rules and methods for mental activities; (3) methods for the diagnosis or for the treatment of diseases; foods, beverages and flavorings; (5) pharmaceutical products and substances obtained by means

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[8] TRIPS Agreement, *supra* note 1, art. 27.

[9] The timeframe in which least-developed countries must be in compliance with TRIPS was extended from January 1, 2006 to January 1, 2016. *See* Commission on Intellectual Property Task Force on TRIPS, Dept. of Policy and Business Practices, *Initial Views on the Post-Doha Agenda of the Council for TRIPS*, (June 24, 2002) at 2 http://www.wto.org/english/forums_e/ngo_e/icc_trips_e.doc; Nathan Stacy, *The Efficacy and Fairness of Current Sanctions in Effecting Stronger Patent Rights in Developing Countries*, 12 TULSA J. COMP. & INT'L. L. 263, 279-80 (2004).

[10] On November 14, 2001, the WTO adopted the Declaration on the TRIPS Agreement and Public Health in an effort to ensure that WTO Member States implement and interpret the TRIPS Agreement in a way that does not prevent Members from taking measures to protect public health. Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited May 10, 2006).

[11] The Embassy of the United States, IPR Toolkit, http://beijing.usembassy-china.org.cn/iprpatent.html (last visited Dec. 30, 2005).

[12] *Id.*

[13] *Id.*

[14] Patent Law of the People's Republic of China (promulgated by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, effective Apr. 1, 1984) (P.R.C.), *reprinted in* ROBERT H. HU, RESEARCH GUIDE TO CHINESE PATENT LAW AND PRACTICE, at app. 5 (2002).

of a chemical process; (6) animal and plant varieties; [and] (7) substances obtained by means of nuclear transformation."[15]

After threat of sanction by the United States Trade Representative, the United States and China signed a Memorandum of Understanding on the Protection of Intellectual Property, whereby China agreed to revamp its intellectual property protection.[16] The amendments, put into effect in 1992, omitted the exclusion from patent protection of pharmaceutical products, substances obtained by means of a chemical process, and food, beverages and flavorings, thereby expanding the scope of protection.[17] In addition, the amended laws increased the patent term for inventions from fifteen to twenty years from the date of filing an application.[18] In an effort to conform to the relevant provisions of TRIPS, China amended its patent law in 2000, effective July 2001.[19]

### C. *Patent Rights in India Prior to Recent Amendments*

India's patent law dates back to 1856 with the enactment of Act VI of 1856 on Protection of Inventions, which is based on the British Patent Law of 1852.[20] Patents were called "exclusive privileges," and were granted fourteen year terms.[21] In 1959, the Act was expanded to include protection for designs.[22]

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[15] *Id.* art. 25; Stacy, *supra* note 9, at 300-01.

[16] Memorandum of Understanding Between the Government of the People's Republic of China and the Government of the United States of America on the Protection of Intellectual Property, 1992 *reprinted in* ROBERT H. HU, RESEARCH GUIDE TO CHINESE PATENT LAW AND PRACTICE, at app. 6 (2002); Andrew Evans, Note, *Taming the Counterfeit Dragon: The WTO, TRIPS and Chinese Amendments to Intellectual Property Laws*, 31 GA. J. INT'L & COMP L. 587, 597 (2003).

[17] Patent Law (promulgated by the Standing Comm. of the Seventh Nat'l People's Cong., Sept. 4, 1992, effective Dec. 21, 1993) (P.R.C.), *reprinted in* ROBERT H. HU, RESEARCH GUIDE TO CHINESE PATENT LAW AND PRACTICE, at app. 3 (2002).

[18] *Id.* art. 45. For utility models, patent term was extended from five to ten years. *Compare* Patent Law, art. 45 (1984) (P.R.C.), *with* Patent Law, art. 45 (1992) (P.R.C.).

[19] Patent Law (2000) (P.R.C.)

[20] History of Indian Patent System, http://www.patentoffice.nic.in/ipr/patent/history.htm (last visited Mar. 23, 2006); Patent Office, India, Manual of Patent Practice and Procedure 1, 7 (2005), *available at* http://www.patentoffice.nic.in/ipr/patent/manual-2052005.pdf.

[21] Patent Office, India, Manual of Patent Practice and Procedure 1, 7 (2005), http://www.patentoffice.nic.in/ipr/patent/manual-2052005.pdf.

[22] *Id.* "'Design' means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two di-

Although India had patent laws before the 1900s, formal patent protection was introduced with the enactment of the Patent Act of 1911.[23]

During the middle of the twentieth century, the Indian government appointed two committees—the first in 1949 and the second in 1957—to review India's patent law and suggest potential modifications to the law.[24] The 1957 committee's recommendations inspired a Patent Bill that was passed by India's Parliament and effective as the Patents Act, 1970.[25] The 1970 Patent Act provided protection for processes, but did not provide protection for compositions of matter.[26] The term of patent protection for process patents was seven years from the filing date of a patent application.[27] India revised the 1970 Act in 1999, 2002 and 2005.[28]

## II. China and India Revise Their Patent Laws to Comply with TRIPS

There are three basic requirements for patentability under the current patent laws of China and India. First, the invention must be new or novel.[29] Second, the invention must be inventive.[30] Specifically, China's patent law requires "inventiveness" meaning "as compared with the technology existing before the date of filing of the patent application, the invention has prominent substantive features and represents a notable progress."[31] India's patent law requires an "inventive step," which is defined

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mensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye. . . ." *See* The Designs Act, 2000, No. 16, art. 2(d), Acts of Parliament, 2000 (India), *available at* http://www.patentoffice.nic.in/ipr/design/design_act.PDF. A utility patent protects the way an invention is used or works.

[23] Rajkumar Dubey, *Making it TRIPS Way - India's New Patent Regime,* Mondaq Bus. Briefing, July 18, 2005, *available at* 2005 WLNR 11268677 (Westlaw).

[24] *See* Manual of Patent Practice and Procedure, *supra* note 20, at 7.

[25] The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India).

[26] *Id.* § 5.

[27] *Id.* § 53(1).

[28] *See generally,* http://www.patentoffice.nic.in/ipr/patent/patents.htm.

[29] *See* Patent Law, art. 22 (2000) (P.R.C.); The Patents (Amendment) Act, § 2(l), 2005 (India).

[30] *Id.*

[31] Patent Law, art. 22 (2000) (P.R.C.).

as "a feature of an invention that involves technical advance as compared to existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."[32] Lastly, the invention must have a utility. China's patent law requires "practical applicability," namely, that the invention "can be made or used and can produce effective results."[33] In India, the patent law requires the "industrial application" of an invention, meaning that the invention is capable of being made or used in industry.[34] These basic requirements for patentability are just one element of the modern patent laws of China and India. Substantive revisions, discussed below, were made to the patent laws of China and India as part of the requirements for membership in the WTO.

### A. *The 2000 Amendments to China's Patent Law*

China amended its patent law in 2000 in a further effort to comply with TRIPS and obtain membership into the WTO.[35] Some key amendments include changes to the law concerning the burden of proof in the infringement of process patents and compulsory licensing.[36] The burden of proof with regard to actions for the infringement of process patents is now shifted to the alleged infringer.[37] This places the onus on the alleged infringer, who presumably is in possession of the relevant facts regarding potential infringement or lack thereof.[38]

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[32] The Patents (Amendment) Act, § 2(ja), 2005 (India). For comparative purposes, U.S. patent law requires "non-obviousness": the invention must not have been obvious to one with ordinary skill in the art to which the subject matter of the invention pertains at the time of the invention and in light of the teachings of the prior art. 35 U.S.C. § 103(a).

[33] Patent Law, art. 22 (2000) (P.R.C.).

[34] The Patents (Amendment) Act, § 3, 2002 (India). In the United States, the invention must have "utility": it must be useful or perform some function of positive benefit to society. 35 U.S.C. § 101.

[35] On December 11, 2001, China became a member of the WTO. *See China's WTO Achievements Recognized*, CHINA DAILY, Dec. 15 2005.

[36] A compulsory license is an exception to the exclusive rights granted to patent owners to prevent third parties not having the patent owner's consent from making, using, offering for sale, selling, or importing a patented product or product obtained by a patented process. It allows the Member State to license a patented product without the authorization of the rights holder. Requirements for compulsory license vary among Member States. TRIPS Agreement, *supra* note 1, art. 34.

[37] Patent Law, art. 57 (2000) (P.R.C.).

[38] TRIPS Agreement, *supra* note 1, art. 34; Patent Law, art. 57 (2000) (P.R.C.).

Furthermore, the amendments add more stringent conditions for issuing compulsory licenses.[39] Under the amended law, a party must first request authorization from the inventor to exploit the patent.[40] If such request is denied, the requesting party may apply for the grant of a compulsory license from the Patent Administration Department Under the State Council.[41] The scope and duration of the exploitation must be specified and the patentee may request the Patent Administration Department Under the State Council terminate the compulsory license "if and when the circumstances which lead to such compulsory license cease to exist and are unlikely to recur."[42]

### B. *The 2005 Amendments to India's Patent Law*

The 2005 revisions to India's patent law expand patent protection to food, drugs and medicines.[43] Until the 2005 amendments, India's patent law did not provide protection for pharmaceuticals.[44] As a result, the generic pharmaceutical industry flourished in India. The amendment expanding patent protection to pharmaceuticals is the most significant change in India's modern patent law and will certainly have great impact on India's position and role in the global pharmaceutical market.

The amendments also provide for compulsory licensing for the manufacture and export of pharmaceutical products to any country having insufficient or no manufacturing capacity of its own to address public health problems.[45] Before granting a compulsory license, the government considers whether the ap-

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[39] Patent Law, arts. 48-55 (2000) (P.R.C.).

[40] Patent Law, art. 48 (2000) (P.R.C.). Under the 1984 patent laws, compulsory licensing was available upon request to the Patent Office, if the patentee failed, without any justified reason, to make or use the process or product in China after three years from the grant of patent right. *Id.* arts. 51-52.

[41] Patent Law, art. 48 (2000) (P.R.C.); Louis Sorell, *A Comparative Analysis of Selected Aspects of Patent Law in China and the United States*, 11 PAC. RIM. L. & POL'Y J. 319, 336 (2002).

[42] Patent Law, art. 52 (2000) (P.R.C.); *see also* Yahong Li, *The Wolf Has Come: Are China's Intellectual Property Industries Prepared for the WTO?* 20 UCLA PAC. BASIN L.J. 77, 86 (2002).

[43] The Patents (Amendment) Act, § 5, Acts of Parliament, 2005 (India).

[44] *Compare* The Patents Act, § 5(1), 1970 (India), *with* The Patents (Amendment) Act, § 5, 2005 (India) (omitting § 5.

[45] The Patents (Amendment) Act, § 92A(1), 2005 (India).

plicant has made efforts to obtain a license from the patent holder for a "reasonable period," defined as a period of six months.[46] Once this six-month period expires, if the patent holder refuses to grant a license, the applicant may approach the government for grant of a compulsory license without the patent holder's consent.[47] The compulsory license must be granted by the country to which the request is made, or such country must have previously allowed importation of the patented pharmaceutical from India.[48] Notably, these provisions encourage domestic production and bolster generic pharmaceutical manufacturers.[49]

## III. Issues in China

### A. *Challenges Relating to Pharmaceuticals*

Historically, copying in China was viewed favorably and encouraged as a means of disseminating information to all people.[50] Imitating and copying were seen as forms of flattery.[51] With respect to pharmaceuticals, Chinese patent law before the 1992 amendments did not provide patent protection for compositions of matter.[52] Therefore, while the process of making a compound was patentable, it was not considered infringement to make the compound using an unpatented process since the underlying composition was not protected subject matter.[53] The 1992 amendments afforded patent protection to pharmaceuticals.[54] Even with the added protection for pharmaceuticals, however, the production, manufacture and sale of counterfeit

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[46] The Patents (Amendment) Act, § 84(iv), 2005 (India).

[47] *Id.*

[48] The Patents (Amendment) Act, § 92A(1), 2005 (India).

[49] Rochelle Chodock, *TRIPS: Transformation of the Indian Patent System and Its Effect on the Indian Pharmaceutical Sector*, 2 No. 2 ABA SciTech L. 4 (2005).

[50] Evans, *supra* note 16, at 588-89.

[51] Yahong Li, *The Wolf Has Come: Are China's Intellectual Property Industries Prepared for the WTO?*, 20 U.C.L.A. Pacific Basin L. J. 77, 93 (2002).

[52] *Compare* Patent Law, art. 25 (1984) (P.R.C.), *with* Patent Law, art. 25 (1992) (P.R.C.). Article 25 of the 1984 patent law prohibited the granting of patents directed to pharmaceutical products. However, this prohibition was removed in the amended 1992 patent law.

[53] Patent Law, art. 25 (1984) (P.R.C.).

[54] Patent Law, art. 25 (1992) (P.R.C.).

pharmaceuticals remains a significant issues facing pharmaceutical companies.[55]

Counterfeit pharmaceuticals deprive brand-name drug manufacturers of sales and revenue and may potentially harm consumers.[56] Due to their low cost, counterfeit pharmaceuticals are attractive to consumers. Lost revenue deprives companies of resources to invest in pharmaceutical development, innovation and research activities.[57] Products with sub-quality active ingredients, no active ingredients or harmful inactive ingredients emerge in the marketplace along side brand name products, indistinguishable in all other respects.[58]

Pharmaceutical companies are taking action to combat counterfeiters.[59] Companies have developed sophisticated packaging, logos and structures for their drug products.[60] Strategies include holographic labels on packaging, unusually-shaped products that are difficult to reproduce and labeling the inside of glass vials.[61] In the future, more advanced methods of deterring counterfeiters are expected.[62] The goal is to make patented products difficult to copy, and if copied, easily recognizable as fakes to both companies and consumers.[63]

China is taking positive steps toward strengthening protection of intellectual property and patent rights.[64] Not only has China amended its patent laws to be TRIPS compliant, it has established a court dedicated to the resolution of patent disputes.[65] Founded in October 1996, the No. 3 Civil Division han-

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[55] Merri C. Moken, *Fake Pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices*, 29 AM. J.L. & MED. 525, 525 (2003).

[56] *Id.* at 531-32.

[57] *Id.* at 532-33.

[58] *Id.* at 527.

[59] *Id.* at 535.

[60] *Id.*

[61] *Id.*

[62] Moken, *supra* note 55, at 536.

[63] *Id.*

[64] Chris Buckley, *On Piracy, an Advocate for China's Progress,* INT'L HERALD TRIB., Oct. 4, 2005, *available at* http://www.chinaiprlaw.com/english/forum76.htm.

[65] Intellectual Property Courts in China, Judicial Protection of IPR in China: The organization, functions and powers of the People's Courts, *available at* http://www.chinaiprlaw.com/english/courts/court1.htm (last visited Mar. 30, 2006).

dles intellectual property rights cases.[66] This Intellectual Property division hears approximately 100-200 intellectual property right cases per year.[67]

B. *Enforcement of Patent Rights in China*

There are three routes of enforcement of patent rights of China: administrative, judicial and criminal.[68] The law allows for negotiation and settlement of patent disputes.[69] If settlement between the parties fails, an aggrieved patentee may institute legal proceedings in the People's Court or the party may request the Patent Affairs Administration to assist in settling the matter via an administrative route.[70] Under the administrative route, damages include confiscation of the illegal income of the infringer, a fine of no more than three times the illegal income and/or a discretionary fine where there is no illegal income.[71]

A party may also pursue the judicial route. A cardinal principle of China's judicial system is independent judicial power in accordance with the law. There is no court precedent and no case law system.[72] Moreover, judges are authorized to cite to laws and regulations but are prohibited from citing to facts.[73] Therefore, similar facts may result in different judgments by different courts.[74] There is a risk that this may lead to inconsistent application of the law and unpredictability.

In the event the infringement constitutes a crime, the patent holder may seek criminal prosecution under the Criminal

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[66] *See* Judicial Protection of IPR in China: Enforcement of Intellectual Property Law in Post-WTO China, http://www.chinaiprlaw.com/english/forum/forum40.htm (last visited Mar. 31, 2006). The No. 3 Civil Division was formerly called the Intellectual Property Division. *Id.*

[67] *See* Judicial Protection of IPR in China: Enforcement of Intellectual Property Law in Post-WTO China, http://www.chinaiprlaw.com/english/forum/forum69.htm (last visited May 12, 2006).

[68] Patent Law, arts. 57-58 (2000) (P.R.C.).

[69] *Id.* art. 57.

[70] *Id.* The Patent Affairs Administration has concurrent jurisdiction with the People's Court over patent infringement actions. *Id.* art. 3.

[71] *Id.* art. 58.

[72] Sorell, *supra* note 41, at 330-31.

[73] *Id.* at 331.

[74] *Id.*

Law of the People's Republic of China.[75] Criminal punishment for counterfeiting is minimal: imprisonment of not more than three years, and/or a fine.[76]

## IV. Issues in India

### A. *"Mailbox" Applications and Compulsory Licensing*

When India acceded to the WTO in January 1995, it agreed to bring its patent laws into compliance with TRIPS within ten years from the day it was accepted into the WTO.[77] At that time, India's patent law did not protect compositions of matter. Knowing that by 2005 the necessary legal framework would exist under which composition of matter applications could be examined, India established a patent office "mailbox" into which patent applications for products were deposited.[78] The patent office held the applications for examination until after revised patent laws were promulgated.[79] Now that the laws have been enacted, the applications are being removed from the mailbox and reviewed in the order in which they were deposited.[80] The patent term for mailbox patents will be calculated from the date of deposit.[81]

The delay between the deposit of an application in the patent office mailbox and the issuance of the patent has consequences on the ability of the patent owner to institute infringement actions.[82] A patentee cannot institute a patent infringement action against an entity or company that has been

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[75] Criminal Law (promulgated by the Standing Comm. of the Fifth Nat'l People's Cong., July 1, 1979, revised Mar. 14, 1997), art. 216 (P.R.C.), *available at* http://www.cecc.gov/pages/newLaws/criminalLawENG.php.; Interpretation by the Supreme People's Court and the Supreme People's Procuratorate on Several Issues of Concrete Application of Laws in Handling Criminal Cases of Infringing Intellectual Property (promulgated by the 13th Sess. of the Jud. Comm. of the Supreme People's Ct., Nov. 2, 2004, and the 28th Sess. of the Tenth Procuratorial Comm. of the Supreme People's Procuratorate, Nov. 11, 2004, effective Dec. 22, 2004), art. 10, *available at* http://www.chinaiprlaw.com/english/laws/laws20.htm(P.R.C.).

[76] Criminal Law, art. 216 (1979) (P.R.C.).

[77] *See* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health,* 99 Am. J. Int'l. L. 317, 320 (2005).

[78] *Id.* at 321.

[79] *Id.*

[80] *Id.* at 320 n.24.

[81] *Id.* at 321.

[82] *See* Chodock, supra note 49, at 5.

producing and manufacturing a patented product before 2005 and who continues to manufacture the product on the date of the patent grant.[83] Typically, the infringer is a generic drug manufacturer that manufactured the now-patented product while the patent application for the product sat in the mailbox.[84] This provision is essentially a compulsory license to the manufacturer. The only remedy available to the patent holder is a reasonable royalty.[85]

The 2005 Amendments to the Patent Laws and a Shift Toward Innovation and Outsourcing

Currently, more than twenty percent of the world's generic pharmaceuticals are produced in India.[86] With the recent changes to India's patent laws, the historically generic pharmaceutical companies will likely shift their focus toward innovation. As there is a shift toward innovation, research and development outsourcing will become an important issue.[87] Manufacturing costs are estimated to be fifty percent below manufacturing costs in Europe and the United States.[88]Moreover, India has the largest number of U.S. FDA-approved plants outside the United States and Indian manufacturers are now required to be compliant with Good Manufacturing Practices.[89] In contrast to its historic position, India's current patent system supports innovation and the protection of patent rights while simultaneously protecting the dominant generic market.

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[83] *Id.*

[84] *Id.*

[85] The Patents (Amendment) Act, § 11A, Acts of Parliament, 2005 (India); Manisha Singh, *India's Patent Law — is it TRIPS Compliant?,* MANAGING INTELLECTUAL PROPERTY, July 1, 2005, at 67; Elizabeth Engdahl, *India Alters Patent Views: The New Law Looks More Innovation Friendly and Mostly TRIPS-Compliant*, LEGAL TIMES 56, July 11, 2005, at 56, 58.

[86] *India Set For Solid Growth in Pharmaceutical Industry, Says New PwC Report*, PHARMA MARKETLETTER, Aug. 1, 2005, *available at* 2005 WLNR 12162024 (Westlaw).

[87] Eric Bellman, *India Senses Patent Appeal; Local Companies Envision Benefits in Stronger Protection*, WALL ST. J. (Eastern Ed.), Apr. 11, 2005.

[88] *See* Chodock, *supra* note 49, at 4.

[89] Eric Ladley, *Patent Reform Has Global Effect*, MED AD NEWS, May 1, 2005, *available at* 2005 WLNR 8860450 (Westlaw).

## V. Conclusion

China and India are actively globalizing their patent systems through compliance with the international standards of TRIPS. However, with China's relatively short patent law history and fractured judicial system, the risk of counterfeiting and the difficulty with patent enforcement remain decisive factors in companies' considerations as to whether to make and sell patented pharmaceuticals in China. In India, it remains to be seen how the newly-created patent protection for pharmaceuticals will be enforced in a country that until now has thrived on the generic pharmaceutical industry.