India's First Compulsory License: Its Impact on the Indian Pharmaceutical Market as well as the World Market

Yaeko Mitsumori
Tsukuba University, Tokyo - Japan

Abstract--**India's pharmaceutical industry is the fourth largest in the world, by volume. However, between 1970 and 2005, the country did not have product patent. Without any product patent, the Indian pharmaceutical industry developed at a very rapid pace. However, due to the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), India was required to introduce product patent protection in its patent law. Despite objections to the introduction of product patent, the Indian government revised its patent law in 2005. Specifically, the Patents (Amendment) Act, 2005 includes some sections aimed at supporting a compulsory licensing regime. In 2012, the Indian government issued the country's first compulsory license against a foreign company's patented drug. This article examines the impact of the India's very first compulsory license on both the Indian pharmaceutical market and the world pharmaceutical market. It also analyzes and offers solutions for both developing countries and foreign companies who wish to avoid the compulsory licensing regime.**

I. INTRODUCTION AND OVERVIEW

A. An Introduction

India's pharmaceutical industry is the fourth largest in the world, by volume. However, between 1970 and 2005, the country did not have product patent. Without any product patent, the Indian pharmaceutical industry developed at a very rapid pace. However, due to the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), India was required to introduce product patent protection in its patent law. Despite objections to the introduction of product patent, the Indian government revised its patent law in 2005. Specifically, the Patents (Amendment) Act, 2005 includes some sections aimed at supporting a compulsory licensing regime. In 2012, the Indian government issued the country's first compulsory license against a foreign company's patented drug. This article examines the impact of the India's very first compulsory license on both the Indian pharmaceutical market and the world pharmaceutical market. It also analyzes and offers solutions for both developing countries and foreign companies who wish to avoid the compulsory licensing regime.

B. An Overview of the Indian Pharmaceutical Industry

Due to TRIPS, the Indian pharmaceutical industry was required to change its business model from a conventional generic medicine-only model fully utilizing reverse engineering to a new model. Annual reports of major Indian pharmaceutical companies show that major Indian pharmaceutical companies started expanding their R&D investments in the mid-1990s and launched new drug development.

It is considered that these Indian pharmaceutical companies changed their business models—by launching new drug development—intending to avoid negative impacts from introduction of product patents on their business performances.

C. Background of TRIPS and Product Patent Introduction

India has a long history of patent laws, enacting its first patent law during its colonial days under the U.K. (Great Britain). After India won independence from the U.K. in the 1940s, many foreign pharmaceutical companies entered the Indian market, partly because the Indian pharmaceutical industry in those days was underdeveloped. According to "The Current Status of the Indian Pharmaceutical Industry" compiled by Japan Pharmaceutical Manufacturers Association (JPMA), foreign capital accounted for 68% of the Indian market in those days. [13]

Indira Priyadarshini Gandhi, then the Prime Minister of India, disliked the fact that the Indian pharmaceutical market was largely occupied by foreign capital, and implemented a series of policies intended to kick foreign capital out of the Indian market. One such policy was the Indian Patent Law 1970 (The Patents Act, 1970). The Indian Patent Law 1970, unlike previous regulations, did not have any product patent protection, having only process patent protection for pharmaceutical products.

Foreign companies, which did not like operating in a market without product patent protection, left the Indian market one by one. Eventually, all of foreign capital companies except that of GSK left the Indian market.

Under the Indian Patent Law 1970, which did not offer any product patent protection, pharmaceutical companies in India mimicked brand medicines whose patents were under protection in the other countries and sold those mimicked products not only in India but also in overseas markets, mainly to developing countries. Sales of Indian domestic pharmaceutical companies have expanded.

The 1970 patent law contributed a great deal towards pushing down drug prices in India. Under the Indian Patent Law 1970, many Indian businesses entered the pharmaceutical market, which made drug products highly competitive in terms of price. According to Kubo, today drug prices in India are the lowest in the world. [14] Inexpensive medicines in India won popularity not only in India, but also in foreign markets, and exports of Indian pharmaceutical products have swollen.

However, due to TRIPS, India was required to revise its

patent law in order to make it TRIPS-compatible by 2005.[12] The Indian government as a matter of form introduced product patents on Jan. 1, 2005, the deadline set by TRIPS, although there were a number of twists and turns due to objections against the introduction.[12] However the Indian government, which wanted to help the Indian pharmaceutical industry to develop further, inserted Section 3(d) in the Indian Patent Law 2005 [12]

D. Discussions on the Introduction of Product Patents in India

Once TRIPS required all of its member countries, including developing countries, to introduce product patents, numerous concerns were expressed by developing countries as well as organizations that support the third world. The main issues raised by those opponents are as follows:

(1) When product patents are introduced in a developing country, drug prices would go up. As a result, people in these poor countries would lose access to pharmaceutical products (problem of access to drugs).
(2) When product patents are introduced in a developing country, the pharmaceutical industry in the developing country would be destroyed (negative impact on domestic industry).
(3) When product patents are introduced in a developing country, foreign capital companies would enter the developing country, and as a result, the developing country's market would be occupied by foreign capital companies (occupation of the domestic market by foreign companies).

Because India exported numerous pharmaceutical products to developing countries, leveraging its cheap costs and advanced technologies, international NGOs that support developing countries' access to pharmaceutical products raised objections against introduction of product patents in India. [4] Pharmaceutical industry associations, including the Indian Drug Manufacturers' Association (IDMA = an association for small and medium-sized pharmaceutical companies), also raised objections against the introduction of product patents in India.[10]

The main arguments raised by such international NGOs and industry associations are as follows:

With the introduction of product patents in India:

(1) Drug prices in India would increase
(2) Foreign capital would exploit the Indian market
(3) Indian pharmaceutical companies would no longer be able to produce generic medicine, by copying brand medicines under the patent protection, using reverse-engineering technology.
(4) Indian pharmaceutical companies would lose their advantage in the generic market because they would need to wait until the patent protection of brand drugs expire once the product patents system are introduced in India. (Under the Patent Law 1970, Indian domestic pharmaceutical companies were able to produce copy medicines by conducting reverse-engineering without waiting for a patent expiration date.)

As mentioned above, most of the voices predicted that the Indian pharmaceutical industry would decline once product patents were introduced in the market. Based on the concerns expressed by industry associations and NGOs, the Indian government inserted Section 3(d) in the 2005 Indian Patent Law. Section 3(d), which strictly restricts scope of patentability, limits the number of patents granted for foreign pharmaceutical companies' products. [23] The Indian government intended to protect the Indian pharmaceutical market from being exploited by foreign companies.

II. BACKGROUND

A. Position of the Indian Pharmaceutical Industry

According to "OECD Health Policy Studies: Pharmaceutical Pricing Policies in a Global Market," the world pharmaceutical market in 2006 was 608 billion dollars. [20] Among it, the U.S. market accounted for 45.1%. Three major markets (U.S., EU and Japan) collectively accounted for about 80% of the global market, while the Indian market accounted for merely 1%. However, it has been expanding extremely rapidly. Reflecting the low standard of living in India, per capita annual medical consumption in India was merely $5. [21]

B. Current Status of the Indian Pharmaceutical Industry

According to "the Indian Economic Survey 2009-2010," the Indian pharmaceutical market in 2006 was 363.6 billion rupees (8 billion U.S. dollars). [17] Pharmaceutical production in 2005 was 550 billion rupees. Among such results, domestic demand acccounted for 62%, while exports accounted for 38%. Compared to 1990, the production figure had expanded tenfold. Generic medicines occupied the majority of the market. In recent years, the Indian domestic market has been expanding at an annual rate of 9.5% to 10%.

According to "The Current Status of the Indian Pharmaceutical Industry" compiled by the Japan Pharmaceutical Manufacturers Association (JPMA), the Indian Pharmaceutical Industry has the following features: [13]

- It has expanded rapidly over the past decade. Pharmaceutical production expanded tenfold between 1990 and 2005.
- The Indian pharmaceutical production (in volume) was ranked as number 4; while the Indian pharmaceutical production (in values) was ranked as number 13 in the world.
- The annual development rate was 18%.
- The Indian market is expected to reach 22 billion dollars by 2010.
- Generic pharmaceutical medicines account for 90% of the total Indian market.
- The nation that is the main target of exports is the U.S.

According to "Indian Stock On-line," (a) there are more than 20,000 Indian pharmaceutical companies; (b) the Indian pharmaceutical industry has strong competitive power in the global market; and (c) like the IT industry, the pharmaceutical industry in India has been contributing to a great extent to the economic development of India. [11]

Leading pharmaceutical companies in India include: Dr. Reddy's, Cipla, Lupin, Sun Pharmaceutical, and Wochkardt.

C. Indian Patent Law

India has had a patent protection system since the colonial era. In 1856, India enacted a law that granted exclusive rights to the inventor of a new invention. In 1911, India enacted the Patent and Design Act 1911. Under this act, both product patents and process patents were protected, and the protecting period was at least 16 years.[9]

As mentioned above, India drastically revised its patent law in 1970 and enacted a revised law in 1972 (The Patents Act 1970). [9] Under The Patents Act 1970, product patents for new chemical entities (NCEs) were not protected, but only process patents were protected. In addition, the protection period for process patents was determined to be the shorter of either 5 years from approval or 7 years from patent application. Under the 1970 Patent Law, the Indian pharmaceutical industry has developed extremely rapidly. However, due to enforcement of TRIPS in 1995, India was required to revise its patent system so that it would be TRIPS compatible. TRIPS granted a 5-year grace period for developing countries to revise their patent system and employ TRIPS compatible patents. In addition, TRIPS granted another a 5-year grace period for countries that did not have any product patents in 1995. India was considered to be a developing country and did not have any product patents in 1995. This is why India was granted a total of a ten-year grace period and was required to revise its patent system and introduce product patents by Jan. 1, 2005. The Indian government revised its patent system in three phases.

1st step In 1999, India introduced the Mailbox Application system (the government received applications for product patents and would start examining such applications once the product patent system was introduced in the country in 2005) and the EMR system (the government granted a 5-year exclusivity right to sell and distribute the relevant substances or articles).

2nd step In 2002, India extended the protection period for a process patent to 20 years from original 14 years.

3rd step In 2005, India introduced product patents.

The Indian Patent Law 2005 was believed to be TRIPS-compatible. However, it carries a unique section, Section 3(d), which strictly narrows the scope of patentability. In practice, the Indian Patent Office rejected many patent applications based on Section 3(d). When the Indian Patent Office rejected Gleevec of Novaltis based on Section 3(d), the issue was heavily covered by mass media, not only in India but also throughout the world. [22] In April 1, 2013 Supreme Court of India ruled against Novartis over Section 3(d) .

D. Section 3(d)

Section 3(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 the mere discovery of any new property or new use for a known substance or of the mere new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

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.

Section 3(d) in general admits patentability of NCE. On the other hand, Section 3(d) admits patentability of an already known molecule only when the molecule shows enhancement of efficacy. Section 3(d) does not clearly state what "enhancement of efficacy" means.

Some previous studies studied the roles of the Section 3d of Indian Patent Act on Indian pharmaceutical industry and found Section 3d had a role for lightening negative impact of product patent introduction in 2005 on Indian pharmaceutical industry. [18]

III. COMPULSORY LICENSE

In March 2012, the Indian government issued the country's first compulsory license, which attracted attention on a global scale.

A. WHAT is a compulsory license?

The WTO defines compulsory licensing as follows:

> "Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement." [26]

Article 31 of TRIPS contains the conditions that govern the use of compulsory licensing by WTO member countries. The main thrust of these conditions is as follows:

(1) the entity (company or government) applying for a compulsory license should have been unable to obtain a voluntary license from the right holder on reasonable commercial terms;
(2) if a compulsory license is issued, adequate remuneration must be paid to the patent-holder, and
(3) a compulsory license must be granted mainly to supply the domestic market. [2]

According to the Indian Patent Office（IPO）, provisions for granting a compulsory license exist in the patent laws of developed countries, such as Canada, France, the United Kingdom, the United States, and Australia, as well as various developing countries, such as Zimbabwe, Ghana, Brazil, Ecuador, Malaysia, Thailand, and India. Additionally, compulsory licenses have been issued by both developed and developing countries, even very recently. [3]

B. Compulsory licensing in Indian Patent Law

India's Patents (Amendment) Act, 2005, contains provisions for compulsory licensing from Section 84 to Section 103.(6) A compulsory license can be issued under Section 84 or Section 92 of the legislation. According to Section 84, a compulsory license can be issued in India if the patented drug is unavailable, unaffordable, or not in sufficient supply in the local market. Section 92 contains provisions that apply when a compulsory license is issued on notification by the central government. [7]

C. India's first compulsory license

In March 2012, the Indian government issued India's first compulsory license to Natco Pharma Limited for Sorafenib (Bayer's brand name: Nexavar), a drug designed to treat kidney and liver cancer. The controller of the IPO, Mr. P.H. Kurian examined the case by considering the following three issues:

(1) the reasonable requirements of the public, with respect to the patented invention, have not been satisfied;
(2) the patented invention is not available to the public at a reasonably affordable price, and
(3) the patented invention is not worked in the territory of India.

With regard to these questions, Mr. Kurian concluded that:

(1) "Section 84 (7) (a) (i) was invoked beyond doubt. Accordingly, reasonable requirement of the public with respect to the patented invention have not been satisfied.";
(2) since Sorafenib was selling at Rs. 2,800,000 per month, "…the patented invention Sorafenib was not available to the public at a reasonably affordably price", and
(3) since Bayer was importing Sorafenib into India but not manufacturing it in India, "…mere importation can not amount to working of a patent invention and said this case is attracted to the case (3) -- patented invention is not worked in India."

This India's very first compulsory license won much attention not only in India but also in the world.
Since product patent was introduced in India in 2005, almost all of the leading pharmaceutical companies entered the Indian market and applied for patent in India. However, the compulsory license issued in March 2012 by the IPO was a discouraging incident for foreign companies in India.

D. Three additional candidates

According to The Indian Express, a daily newspaper published in India, the Indian government has been considering issuing compulsory licenses for three more medicines. [7] The three medicines under consideration are Trastuzumab (Roche), Ixabepilone (Bristol-Myers Squibb), and Dasatinib (Bristol-Myers Squibb). Compiling information from news articles, the Health Ministry of India in January 2013recommended that the Department of Industrial Policy & Promotion (DIPP) issue compulsory licenses for these three medicines—Trastuzumab, Ixabepilone, and Dasatinib. Subsequently, in July 2013, the DIPP decided not to issue a compulsory license for Transtuzumab because the patent had expired. In September 2013, an expert panel recommended that the DIPP issue a compulsory license for Dasatinib. [19]

In a separate development, BDR Pharma, a generic pharmaceutical company in India, submitted an application for a compulsory license for Dasatinib (BMB). As of April 2014, the application is still under consideration. [8]

IV. IMPACT ON THE INDIAN MARKET

Compulsory licensing is a fairly new development in India. Thus, it might be too early to consider the impact of the compulsory licensing regime on the Indian pharmaceutical industry. However, in the wake of India's very first compulsory license grant and a series of reports on the potential for three more compulsory licenses being issued, many people now believe that other compulsory license applications might be submitted, making compulsory licensing a potentially significant issue for India in the future. For instance, Mr. Ashwani Balayan, a partner at ALG India Law Offices in New Delhi, told the World Intellectual Property Review that applying for and the issuance of compulsory licenses is a trend and one that is likely to increase. In particular, he believes that anti-diabetes and hepatitis drugs will be considered next. [19]

TABLE 4. MAJOR EVENTS REGARDING COMPULSORY LICENSING

Jan. 2013	Health Ministry recommended DIPP issue CL against Trastuzumab, Ixabepilone and Dasatinib
May. 2013	patent for Trastuzumab becamse invalid
Jul. 2013	DIPP dropped its recommendation to Trastuzumab
Sept. 2013	DIPP's expert panel accepted Health Ministry recommendion for Dasatinib; but not for Ixabepilone

The Japan Pharmaceutical Manufacturers Association (JPMA) in July 2013 released a comment on compulsory licensing in India, which stated:

> "Compulsory license may solve drug access problems of the poor in India in a short-term; however in a long term, compulsory license may discourage investment into pharmaceutical market in India and eventually may deteriorate Indian people's access to medicine." [6]

Conversely, on March 12, 2012 Doctors Without Borders/Médecins Sans Frontières (MSF) issued a press release in which the international NGO stated:

> "This decision marks a precedent that offers hope: it shows that new drugs under patent can also be produced by generic makers at a fraction of the price, while royalties are paid to the patent holder. This compensates patent holders while at the same time ensuring that competition can bring down prices." [5]

Bayer was disappointed by the issuance of the compulsory licence issued to Natco for Sorafenib. In an interview with the World Intellectual Proper Review, Jörg Thomaier, Chief IP counsel at Bayer, stated:

> "Increased reliance on compulsory licensing by some countries undermines the incentives for innovation. India is a case in point. Its policies do not, in fact, provide its poor population better access to medication. For the majority of Indians, even essential, off-patent medicines remain unaffordable. The economic reality of India means that even after the issuance of the compulsory licence for Nexavar, the number of patients who take the drug has increased only marginally." [24]

After the Supreme Court ruled against Novartis over Section 3(d) on April 1, 2013, Ranjit Shahani, managing director of Novartis India Ltd, told Bloomberg:

> "We (Novartis) will continue to build our business in India, but we will certainly be cautious in investments in R&D and innovation in India. Until the climate for intellectual property and the ecosystem is fully in place, I don't think any investment in R&D will take place here (India)." [1]

V. IMPACT ON THE WORLD MARKET

In 2012, the Indian government issued the first compulsory license in favor of Natco. As mentioned above, according to the IPO, provisions for granting a compulsory license exists in the Patent Laws of various countries, including both developed countries as well as developing countries, and compulsory licenses have been issued by developed countries as well as developing countries recently. [3] However, India's very first compulsory license won much attention, locally and globally. It is relevant if the current Indian pharmaceutical industry is considered: (a) the Indian pharmaceutical industry is the fourth largest (in volume) and thirteenth largest (in value) in the world, (b) the Indian pharmaceutical industry expanded at a rapid pace, (c)the Indian pharmaceutical industry has been exporting large volumes to both regulated markets as well as to the third world, and (d) since India introduced product patent in 2005, almost all global pharmaceutical companies have returned to India.

As noted above, after the Supreme Court determined the Glevec case, Novartis said it would cease making investments in the Indian market and cease R&D activities in India. As of 2014, Novartis is the only foreign pharmaceutical company that has openly declared that it will decrease its engagement with India. However, all foreign pharmaceutical companies are carefully watching the developments in India. They may follow Novartis. If that occurs, the Indian market may be isolated, just like it occurred under the 1970 Patent Law. Consequently, the Indian people may eventually lose access to new medicines.

VI. FUTURE DIRECTION

There are gaps between global pharmaceutical companies and Indian stake holders (the Indian government, the Indian pharmaceutical industry, and the general public). While all agree that innovation is important and should be promoted, the large pharmaceutical companies argue that in order to support innovation, they have to pour significant resources into R&D and thus the outcome (for instances, IP) should be legally protected. Otherwise, they cannot develop new medicine and cannot provide much-needed medicine to their customers. On the other hand, the Indian government, the Indian pharmaceutical industry, and the general public contend that access to medicine is the most important issue. These stakeholders claim that access to much cheaper medicines is needed. Intellectual property protections are not important to them. Rather, intellectual property laws are an obstacle for them because those laws cause medicine prices to increase, thus making medicine unaffordable for the general public.

There are huge gaps between developed countries and developing countries regarding intellectual property protection. There is no easy solution. Kensuke Kubo of The Institute of Developing Economies (IDE) argued that foreign companies might be able to avoid the compulsory license regime by concluding licensing agreements with Indian pharmaceutical companies. [15] Mitsuo Fujii, the Director of the Intellectual Property section of the JPMA, contends that in order to fulfill dual requirements—meeting demands from the poor people while manufacturing a large quantity of products in India—foreign companies should sell directly to the rich Indian people, while letting Indian companies manufacture generic version for the poor people. [6]

According to JETRO, foreign pharmaceutical companies and Indian pharmaceutical companies have been negotiating over licensing of some patented drugs in India. For instance, Pfizer and Natco are in negotiations over Sutent (generic

name: Sunitinib malate), and Selzantry (generic name: Maraviroc). Similarly, MSD and Cipla are negotiating over Isentress (generic name: Raltegravir. [16] If these negotiations go smoothly, and these companies are able to conclude a license agreement, generic companies may be able to manufacture these patented drugs, on the basis of agreed conditions. In this way, all sides might avoid litigation and the compulsory licensing regime.

VII. IMPLICATIONS FOR JAPAN

Almost all of the large Japanese pharmaceutical companies entered the Indian market after product patent law was introduced in India in 2005. However, the Supreme Court decision in April 2013 against Novartis and India's first compulsory license issued in favor of Natco against Bayer, impacted Japanese pharmaceutical companies greatly. Some Japanese companies have made significant commitments in the Indian market—Daiichi-Sankyo purchased Ranbaxy in 2008, and Eisai constructed a factory in Visakhapatnam in 2009. These firms may stay in India even though Indian intellectual property laws are not favorable to them. At the same time, however, other Japanese pharmaceutical companies may consider reducing their engagement in business in India.

VIII. CONCLUSION

Pursuant to requirements contained in TRIPS, India in 2005 revised its Patent Act 1970 and introduced product patent laws. The revised patent law (The Patents (Amendment) Act, 2005) is supposed to be a TRIPS compatible law. However, the Patents (Amendment) Act, 2005 has a unique article, called Section 3(d). Due to Section 3(d) many patent applications have been rejected by the IPO. After product patent law was introduced, almost all of the global pharmaceutical companies re-entered the Indian market. However due to the situation, the Indian market was considered, by foreign companies, a difficult market in which to obtain and enforce patent protection.

In 2012, India issued its first compulsory license for Natco against Bayer. Some other countries have issued compulsory licenses in the past. However, this compulsory license won much attention because: (1) India is the fourth largest (by volume), thirteenth largest (in value) pharmaceutical market; (2) its pharmaceutical market has grown at a rapid pace, and (3) India has been exporting many pharmaceutical products to both regulated markets, as well as the third world. After 2005, almost all of the global pharmaceutical companies have re-entered the Indian market. Some observers believe that India might issue more compulsory licenses in the future. At the moment, foreign pharmaceutical companies are carefully watching the developments in India.

IX. LIMITATIONS

India's very first compulsory license was issued in March 2012. According to news reports, the Indian government is considering issuing more compulsory licenses. Compulsory licensing is quite a new issue for India. It may take more time to analyze the development of the compulsory licensing regime and its impact on the Indian pharmaceutical industry.

ACKNOWLEDGEMENTS

This study was funded by a research grant provided by the Japan Society for the Promotion of Science's Grants-in-Aid (Kakenhi) program.

REFERENCES

[1] Bloomberg news: "Novartis Cancer-Drug Patent Denied by India Supreme Court" April 1. 2013. http://www.bloomberg.com/news/2013-04-01/novartis-cancer-drug-patent-denied-by-india-supreme-court.html

[2] Bond E., "Compulsory licensing, price controls, and access to patented foreign products", Vanderbilt University working paper April 2012 P.3 http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf

[3] Compulsory License Application No. 1 of 2011 by IPO P3. http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf

[4] Doctors Without Borders/Médecins Sans Frontières website: http://www.msforum.org/pressroom/pr.shtml

[5] Doctors Without Medicine press release: "Access to Medicines: India Offers First Compulsory License," March 12, 2012. http://www.doctorswithoutborders.org/press/release.cfm?id=5816&cat=press-release)

[6] Fujii M., "Compulsory License in India," JPMA News Letter No. 150 (2012/07) P.8. http://www.jpma-newsletter.net/PDF/2012_150_04.pdf

[7] IIPTA website: "Compulsory License for three more drugs" http://www.iipta.com/ipr/blog/compulsory-license-three-more-drugs-1216

[8] Imaura H. "BDR applied for compulsory license," JETRO report, March 20, 2013. JETRO website: https://www.jetro.go.jp/world/asia/in/ip/pdf/news_20130320.pdf

[9] Indian Patent Office (2010) "History of Indian Patent System" http://ipindia.nic.in/ipr/patent/patents.htm

[10] Indian Drug Manufacturers' Association (IDMA) website: http://www.idma-assn.org/about-idma.html

[11] "Indian Stock On-line," (2010) http://indokeizai.com/industry/medicine.html

[12] Iwata, Keiji (2008) "Impact of Revision of Indian Patent Law," Patent, Vol. 61. No. 2. pp.42-28

[13] Japan Pharmaceutical Manufacturers Association (JPMA) "The Current Status of the Indian Pharmaceutical Industry" (2009) No.400.

[14] Kubo, Kensuke (2007) "Japanese Generic Pharmaceutical Market & Indian & Chinese Pharmaceutical Institutes," Asian Economic Research Institute P.34.

[15] Kubo K., "Observation on Compulsory License in India" , July 2012 P.9 http://www.ide.go.jp/Japanese/Publish/Download/Overseas_report/pdf/1207_kubo.pdf

[16] Kubo K., "Indian Policy Changes after Revision of the Patent Law," June 2011. http://www.ide.go.jp/Japanese/Publish/Download/Overseas_report/pdf/1106_kubo.pdf

[17] Ministry of Finance, Govt of India (2010) "Economic Survey 2009-2010." http://indiabudget.nic.in/es2009-10/esmain.htm

[18] Mitsumori Y.,"Study on the roles of the Section 3d of Indian Patent Act for lightening negative impact of product patent introduction in 2005 on Indian pharmaceutical industry" Japan MOT Association 2010-7 pp.50-57, (Published in Dec. 2010)
[19] Newspaper articles: Live Mint Sept. 11, 2013; JETRO report Sept. 13, 2013, IP Watchdog Aug. 21, 2013, Times of India July 23, 2013 & Sept. 12, 2013
[20] OECD (2009) "OECD Health Policy Studies: Pharmaceutical Pricing Policies in a Global Market," pp.1-234.
[21] Sawhney, A.（2007）"Globalization of Indian Pharmaceutical Industry" CPhI Japan 2007 Big Sight, Tokyo, April 18, 2007.
[22] Yamana, Mika （2007） "Indian Pharmaceutical Industry and Patent Laws," Patent Studies, No.44. 2007/9. pp.37-47.
[23] Yamane, Hiroko （2008） "Globalization of Intellectual Properties" Iwanami Shoten Publishers P358, P353, P355, P362.
[24] World Intellectual Proper Review report: "A giant's perspective: interview with Bayer Group", World Intellectual Proper Review, Nov. 1, 2013. http://www.worldipreview.com/article/a-giant-s-perspective-interview-with-bayer-group
[25] World Intellectual Property Review report: "India Recommends Compulsory license for anti-cancer drug" the World Intellectual Property Review Sept. 13, 2013 http://www.worldipreview.com/news/india-recommends-compulsory-licence-for-anti-cancer-drug
[26] WTO website: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)