# A TABLET A DAY: THE EFFECT OF ESCHEWMENT OF COMPULSORY LICENSING IN PHARMACEUTICALS ON THE INDIAN POOR

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## Introduction

Martin Luther King Junior said, *"of all forms of inequality, injustice in health care is the most shocking and inhumane".*

In a move that (if reports are correct) can be reasonably expected to have far reaching implications on social healthcare in India, the Indian government is said to have 'privately reassured' the US- India Business Council that it would no longer make use of compulsory licensing in the pharmaceutical industry.[1] While the Indian government was quick to move into what is ostensibly damage-control mode,[2] even the mere possibility of the truth of such a statement is beyond horrifying.

Through the course of this paper, I shall attempt to analyze the impact of assured non-use of compulsory licensing in the pharmaceutical industry on India's poor. I shall begin with a short history and definition of compulsory licensing in India, and then move onto briefly speculating as to the veracity of the reports of the supposed assurance by the Indian government. Having established a context to this essay, I will then move onto an analysis of the same, taking into account income statistics, medication prices (specifically two medicines: Sorafenib Tosylate and Saxagliptin), and related law on the subject of intellectual property. I will then attempt to draw

[1] PTI, *India 'Privately' Against Patent- Overriding Drug Permits: USIBC*, THE ECONOMIC TIMES (March 8th, 2016), *available at* http://articles.economictimes.indiatimes.com/2016-03-08/news/71309589_1_usibc-compulsory-licensing-commercial-purposes (Last visited on April 4th, 2016).

[2] PTI, *India Has Right to Grant Compulsory Licenses Under WTO: Government*, THE ECONOMIC TIMES (March 22nd, 2016), *available at* http://articles.economictimes.indiatimes.com/2016-03-22/news/71732389_1_compulsory-licences-usibc-wto (Last visited on April 4th 2016).

conclusions from this, and conclude with my recommendations to resolve the conflict between affordable healthcare and the success of the pharmaceutical industry.

Economic analyses have shown that issuing a compulsory license for a medicinal product can cause up to a 97% drop in the sale price of a medication, thus putting it within the hands of millions of more people that otherwise may not have been able to afford it.[3]

*A History of the Compulsory Licensing Regime in India*

Compulsory licensing under the Patent Act of 1970 is defined as *"an exclusive right to sell or distribute … a right under a patent to sell or distribute"*.[4] Put simply, compulsory licensing is when a government "*allows someone else to produce the patented product or process without the consent of the patent owner"*.[5]

The Indian Patents and Design Act, 1911 first introduced the concept of compulsory licensing into the Indian Intellectual Property scenario, by virtue of which any interested person on a number of grounds could submit an application for the grant of compulsory licenses.[6] The issue was subsequently addressed several times, such as in the Tek Chand Committee Report in 1949 (under Dr. Bakshi Tek Chand), which recommended government protection of the "public interest in availability of food and medicines". [7] This report went on to influence the Patent Amendment Act, 1950, *vide* Section 23CC.[8]

Almost a decade after this, in 1959, Justice Rajagopala Ayyangar found that foreigners held almost 80-90% of Indian patents, and around 90% of these patents were not even worked in India.[9] He therefore reached the conclusion that the foreign patent holders were exploiting the Indian system in order to establish a monopoly over the market. This was made evident by the fact that medicines were increasingly moving beyond the financial reach of the general public,

[3] Amit Sengupta, *India Assures the US that it Will Not Issue Compulsory Licenses on Medicines*, THE WIRE (March 12th, 2016), *available at* http://thewire.in/2016/03/12/india-assures-the-us-it-will-not-issue-compulsory-licences-on-medicines-24621/ (Last visited on April 4th, 2016).
[4] Section 24C, Patents Act, 1970.
[5] Information and Media Relations Division of the WTO, *TRIPS and Pharmaceutical Patents: Factsheet*, WORLD TRADE ORGANIZATION (September 2006), *available at* https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm (Last visited on April 4th, 2016).
[6] Section 22, Indian Patents and Design Act, 1911.
[7] Rajeev Dhavan, Lindsay Harris & Gopal Jain, *'Whose Interest? Independent India's Patent Law and Policy'*, JOURNAL OF INDIAN LAW INSTITUTE Vol. 32, 433 (1990).
[8] Section 23CC, Patent Amendment Act, 1950.
[9] R Ayyangar, REPORT ON THE REVISION OF THE PATENT LAW, 60 (1959, New Delhi).

and the drug-price index was shooting up exponentially.[10] The proposals made by Justice Ayyangar in this report formed the basis for the Patents Act, 1970.

Compulsory Licenses are provided for between sections 84 and 98 of the Patents Act, 1970. The same has been amended thrice: in 1999,[11] in 2002,[12] and in 2005,[13] in order to comply with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), 1992.[14] The Indian generic medicines industry, now a Rs. 2 lakh crore commercial industry, was a result of the Patents Act of 1970, which denied the significant patent protection encompassed in the British intellectual property jurisprudence, and didn't permit patents on pharmaceutical goods. In providing a contextual history of compulsory licensing in India, it is also material to consider the fact that compulsory licenses have only been exercised once in Indian pharmaceutical history – the landmark case of *Natco Pharma Ltd.* v. *Bayer Corporation.*[15] Since 2005, after the implementation of India's obligations under the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), India currently grants 20-year pharmaceutical patents. The TRIPS Agreement enshrines the right of all WTO member-nations, including India, to issue compulsory licenses for any reason; a right that was again emphaszed in the Doha Declaration on TRIPS and Public Health of 2001, which was signed by all then WTO members.

*Examining the truth behind reports of the Indian Government's 'Verbal Assurance'*

The reports of the alleged assurance issued by the Indian government to the US- India Business Council have stirred up much controversy.[16] Following this, there had been much speculation that the cost of healthcare – especially for life- saving medication – will increase manifold, and that the overall welfare of the population will take a turn for the worse, as life- extending medication will now be out of the reach of the financially unsound. Amidst stark criticism for

[10] M. J. Adelman and S Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, VANDERBILT JOURNAL OF TRANSNATIONAL LAW, Vol. 29, 507 (1996).
[11] The Patents (Amendment) Act 1999.
[12] The Patents (Amendment) Act 2002.
[13] The Patents (Amendment) Act 2005.
[14] Agreement on Trade Related Aspects of Intellectual Property Rights, 1992.
[15] Natco Pharma Ltd. v. Bayer Corporation C. L. A. No. 1 of 2011.
[16] PTI, *Govt Private Assurance on Compulsory Licensing Worring: MSF*, BUSINESS STANDARD (March 15th, 2016), *available at* http://www.business-standard.com/article/pti-stories/govt-private-assurance-on-compulsory-licensing-worrying-msf-116031501038_1.html (Last visited on April 4th, 2016).

seemingly adopting such a policy, the Indian government via the Ministry of Commerce and Industry, released a statement saying:

> *"It is hereby clarified that such reports are factually incorrect. In this regard, it may be noted that India has a well-established TRIPS compliant legislative, administrative and judicial framework to safeguard IPRs … Under the Doha Declaration on the TRIPS Agreement Public Health, each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licenses are granted … even as India is conscious of the need to spur innovation and protect individual rights, it retains the sovereign right to utilise the flexibilities provided in the international IPR regime."*[17]

Naturally, such a diplomatic, matter- of- fact response is to be expected from any entity faced with such scathing criticism. It is further interesting to note that Mr. David Herschmann, the Senior Vice- President of the United States Chamber of Commerce has used the exact same words *("private reassurance…")* in his written submission to the United States Trade Representative:

> *"Industry continues to be concerned by the potential threat of compulsory licensing. While the Government of India of India has privately reassured Industry that it would not use Compulsory Licenses for commercial purposes, a public commitment to forego using compulsory licensing for commercial purposes would enhance legal certainty for innovative industries."*[18]

In my personal opinion, the use of the same *exact* phrase twice at around the same point of time, coupled with the fact that there has not been a single approved compulsory license since Nexavar (the most recent rejection being Lee Pharmaceutical's application for AstraZeneca's drug Saxagliptin)[19] is one that should arouse suspicion in any reasonable person. After all, a mere oral assertion can neither be proven or disproven, and other circumstances must also be taken into account.

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[17] *Supra* note 2.

[18] 2016 Special 301 Submission, U. S. CHAMBER OF COMMERCE'S GLOBAL INTELLECTUAL PROPERTY CENTER, at p. 96, *available at* http://www.regulations.gov/contentStreamer?documentId=USTR-2015-0022-0026&attachmentNumber=1&disposition=attachment&contentType=pdf (Last visited on April 6th 2016.)

[19] Vikas Dandekar, *India Rejects Compulsory License Application Of Lee Pharma Against Astrazeneca's Saxagliptin*, THE ECONOMIC TIMES (January 21st, 2016), *available at* http://articles.economictimes.indiatimes.com/2016-01-21/news/69960806_1_compulsory-licence-indian-patent-office-antidiabetes (Last visited on April 6th, 2016).

In what can only be seen as further proof of the coming monopoly that could well be enjoyed by large pharmaceutical companies, the share price of such companies rose from a low of approximately $102 per share to a high og $118 per share from the end of February 2016 to the beginning of April 2016.[20]

*Impact of Non-Issue of Compulsory Licenses on India's Poor*

A recent study conducted across patented drugs in India has shown that out of 140 available drugs, only four were being manufactured in India, while the others were being manufactured abroad but sold in India.[21] There is, therefore, a trend of imported drugs gradually becoming a larger and larger part of the Indian market.

| **Molecule** | **Clinical Use** | **MNC** | **Unit Price** | **Treatment frequency** |
|---|---|---|---|---|
| Ixabepilone | Breast Cancer, being investigated for other cancers | BMS | 71175.00 | 1 unit weekly for 4 weeks; cycle may need to be repeated |
| Goserelin | Cancer of Prostate | Astra Zeneca | 28320.00 | Every 12 weeks |
| Zoledronate | To prevent fractures and bone pains in some forms of cancers | Novartis | 19516.00 | Every 3-4 weeks |
| Pegylated Interferon Alpha 2a | Hepatitis C | Roche | 18200.00 | 1 unit every week for 8 weeks |
| Ibandronate | To prevent fractures and bone pains in some forms of cancers | Roche | 13950.00 | Every 4 weeks |

The table above shows the prices of some patent protected medications in India.[22] As is clear from the table, the unit prices (many of which are to be taken multiple times a month) are

[20] Bayer Pharmaceuticals Stock Prices, *available at* http://www.marketwatch.com/investing/stock/bayry.
[21] Sudip Chaudhari, *Intellectual Property Rights and Innovation: MNCs in Pharmaceutical Industry After TRIPS* (Working Paper No. 170, Institute for Studies in Industrial Development, 2014), *available at* http://www.isid.org.in/pdf/WP170.pdf (Last visited on April 6th, 2016).
[22] *Id.*

excessively high. To further put these numbers into perspective, however, a look at some of India's income statistics would be prudent.

The average income per household in India is $1,570 per annum as of 2014.[23] Of this population, around 29.5% is below the national poverty line, which currently stands at Rs. 32 in villages, and Rs. 47 in cities.[24] Considering that India has no healthcare system such as the Afforadable Healthcare Act, 2010, ("*Obamacare*") that prevails in the US and has shown considerable results,[25] and also that the popuation of India (as of the 2011 Census) is 1.21 billion, this means that over 357 million Indians currently live below the poverty line, for whom affording expensive medications is completely out of the question. To make matters even worse, the matter of unaffordable medication does not stop there. Taking into account the fact that in order to be able to afford such a large sum of money on healthcare, an even larger percentage of the population (including people above the poverty line, but below the requisite income level) would be affected by the imposition of a pharmaceutical monopoly in the country.

For the purposes of simplicity in estimation, we may take the example of Nexavar (Sorafenib Tosylate), the aforementioned *life-extending* drug manufactured by Bayer Pharmaceuticals for Rs. 2.8 lakh ($4200) per month, and generically by Natco for Rs. 8,800 per month. In order for a family to be able to afford medication like this for even one patient, they would require a monthly income of well over Rs. 4 lakh per month,[26] which would mean only approximately 1.6 million households would be able to afford the drug without financial assistance from the government. In a country where these 6.4 million (taking 4 people per household on average) forms around 0.528% of the entire population, this is an obviously problematic scenario; one where financial status clearly dictates who gets to live and who does not.

*Medicine Prices vís-a-vís the Right to Health*

Naturally, such numbers begs the question of financial assistance by the Government. However, a quick examination of statistics in this regard also give further cause for worry. Again

[23] *India*, THE WORLD BANK DATA, *available at* http://data.worldbank.org/country/india (Last visited on April 6th, 2014).

[24] Prof. Suresh D. Tendulkar, *Report of the Expert Group on Methodology for Estimation of Poverty*, GOVERNMENT OF INDIA PLANNING COMMISSION (November 2009).

[25] Steve Benen, *Republican Voter Thought He Hated 'Obamacare,' Until He Got Sick*, MSNBC (8th March 2016), *available at* http://www.msnbc.com/rachel-maddow-show/republican-voter-thought-he-hated-obamacare-until-he-got-sick (Last visited on April 6th, 2016).

[26] *Household Consumption of Various Goods and Services in India 2011-2012*, NSS 68TH ROUND, MINISTRY OF STATISTICS AND PROGRAM IMPLEMENTATION (June 2014).

considering a lack of a parallel legislation to the effect of Obamacare in India, the only major step that has been taken by the government thus far has been to launch a relatively small scale Jan Aushadhi Yojana, which was allocated a mere Rs. 6.72 crore in the 2011 budget, and Rs. 4.5 crore in the subsequent one.[27] Up until now, the Indian government had been relying upon the threat of compulsory licenses to incentivize foreign companies into complying with and allowing voluntary licenses to generic companies, because at least in the case of voluntary licensing, the original company could determine the terms of its own contract. However, with compulsory licensing, this no longer remains an option. It is not difficult to see, therefore, how taking away the threat of the stick could stop the horse from working.

In January 2016, the Indian Patent Office refused the grant of a compulsory license to Lee Pharmaceuticals for a compulsory licence against AstraZenca's hyperglycemic (reducing blood sugar) Saxagliptin drug, which costs around $530 per dose at AstraZenca's price. Again, in order for a medicine like this to be within the grasp of the consumer sans government subsidy (a policy that is yet to be implemented), a household income of at least Rs. 2 lakh per month would be required, thus meaning that only about 1% of Indians would be able to afford the same.

All of this presents a sharp contrast to the Right to Health envisioned under Articles 21, 41, and 42 of the Indian Constitution.[28] As the State in a democratic nation, it is an inalienable duty of the State to ensure a respectable and decent standard of living for its citizens. In the past also, the state has striven to meet its burden on various occasions, though I shall not venture to comment on what may or may not have been the intention behind lending such assistance.[29] Past successes notwithstanding, it is still the duty of the state to provide affordable healthcare to *all* citizens, and one cannot shirk this responsibility in favor of anything, let alone something such as pharmaceutical protection.

One especially relevant case that highlights this point is the case of *Mohd. Ahmed (Minor)* v. *Union of India*,[30] where the parents of a child from an underprivileged background were unable

[27] *Jan Aushadhi website*, DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA, *available at* http://janaushadhi.gov.in/finance_and_budget.html (Last visited on April 6th, 2016).

[28] Paramananda Katara v. Union of India 1989 AIR 2039; State of Punjab v. Ram Lubhaya Bagga (1998) 4 SCC 117; Union of India v. Naunihal Singh CIVIL APPEAL NO.319 OF 2001.

[29] PTI, *Baby Damini Brings Great Fortune To Rickshaw Puller Dad*, THE INDIAN EXPRESS (October 25th, 2012), *available at* http://archive.indianexpress.com/news/baby-damini-brings-great-fortune-to-rickshaw-puller-dad/1021905/ (Last visited on April 6th, 2016.)

[30] Mohd. Ahmed v. Union of India W.P. (C) 7279/2013.

to bear his treatment expenses. In an inspirational judgment directing the State to fund the child's treatment, Justice Manmohan said:

> *"To conclude, today, on account of lack of Government planning, there is 'pricing out' of orphan drugs ... therapy is so expensive that there is a breach of constitutional obligation of the Government to provide medical aid on fair, reasonable, equitable and affordable basis. By their inaction, the Central and the State Governments have violated Articles 14 and 21 of the Constitution ... Just because someone is poor, the State cannot allow him to die. In fact, Government is bound to ensure that poor and vulnerable sections of society have access to treatment ... After all, health is not a luxury and should not be the sole possession of a privileged few. Although obligations under Article 21 are generally understood to be progressively realizable depending on maximum available resources, yet certain obligations are considered core and non-derogable irrespective of resource constraints. Providing access to essential medicines at affordable prices is one such core obligation."*[31]

## Conclusion

Before we jump to one conclusion or another, we must first realize that the problem we are faced with currently is not merely due to overpopulation or underproduction; improper allocation of resources is another major problem: as long as we as a nation have almost Rs. 1000 crore to spend on a bullet train, or Rs. 6000 crore on government publicity,[32] we also have money to spend on subsidizing essential medications. That being said, it cannot be denied that the government has the dual burden of striking a balance in the dichotomous relationship between establishing a liberal Intellectual Property regime, as well as protecting commercial interests. And this is not an easy balance to strike: leaning too much to the consumer welfare side by promoting compulsory licensing would lead to the inevitable disincentivization of research, development, and production by the pharmaceutical companies that are currently responsible for our pharmacological and pharmaceutical advancements, and leaning to the other would lead to a direct toll on social welfare.

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[31] *Id.* at ¶ 84.

[32] Rakesh Dubbudu, *The Central Government Spent More Than 6000 Crore On Publicity In The Last 11 Years*, FACTLY (July 11th, 2015), *available at* https://factly.in/the-central-government-spent-more-than-6000-crore-on-publicity-in-the-last-11-years/ (Last visited on April 6th, 2016).

Apart from this obvious dilemma, supporters of the abolishment of compulsory licensing point to the argument that compulsory licensing has only been used once in its century-long history for pharmaceutical products ergo, must not be a significant contributor to the current scenario of medicine pricing. However, I believe that compulsory licensing is to be used like a whip – used to ensure remedy, but only when absolutely needed, if other methods fail. Therefore, I argue that the theory that compulsory licensing – by virtue of its non-use – cannot be said to be ineffective.

Through the course of this essay, I have painted a rather grim picture of the future of the Indian healthcare scenario in the near future if the government eschews compulsory licensing. However, a matter of small solace may be that it is entirely possible that the alleged assurance by the government was in fact what it was claimed to be – a false report. Additionally, even if true, the impact of what is in essence a non-binding, unenforceable, oral statement from one party to another upon something as major as the health of the population cannot possibly be enough to allow Big Pharma to lean back and call their accountants.

As a citizen of India, I have faith in the government, and its ability to look after the welfare of its citizens. My faith notwithstanding, however, the economic and welfare effects of a pharmaceutical monopoly are too much to risk. Therefore, I would like to present my own suggestions to resolve the welfare- commercial interest dichotomy we are currently faced with. *Firstly*, considering how attempts to regulate prices by engaging in discussion with pharmaceutical companies have previously failed,[33] and how the actual use of compulsory licensing is not (in my opinion) the correct way forward, I believe that having a comprehensive healthcare bill, not dissimilar to the Affordable Healthcare Act ("*Obamacare"*) of the USA would be a prudent first step in ensuring affordability of healthcare. *Secondly*, I believe that additional incentives (such as tax rebates or concessions) should be provided to pharmaceutical companies that choose to voluntarily license their products to generic companies for sale at lower rates. *Thirdly*, I realize that this issue is too complex to be legislated upon without due deliberation, which is why I would recommend the formation of a panel to review the situation in extensive detail. This panel would ideally consist of an economist, pharmaceutical representative, doctor, lawyer, and a government representative, to enable a holistic review of all aspects surrounding this issue.

[33] REPORT OF THE COMMITTEE ON PRICE NEGOTIATION FOR PATENTED DRUGS, *available at* https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2012/August/India%20Patent%20Drug%20Pricing%20Report.pdf (Last visited on April 6th, 2016).

I believe that compulsory licensing is a whip. And the function of a whip is to make the horse move, not to draw its blood.