

# Impact Of Compulsory Licensing On Research & Innovation With Reference To Indian Pharma Companies

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## Abstract

The treatment of medicines has a very important role in the policy of every country because of their vital role in the health of citizens. For many years patent protection for pharmaceuticals was not available in many countries, as they were considered too important to be left at the mercy of patent owners. Research and development of new drugs was extremely expensive, thus forcing the policy change to grant pharmaceutical patent protection. Since drugs can be copied relatively easily once invented, patent protection has become increasingly important, especially for the pharmaceutical industry. Consequently, a system has been established that grants an inventor, in exchange for disclosing the invention particulars, a patent right that enables the inventor to exclude others from using it for a limited period. In addition, compulsory licensing was offered as an exceptional policy tool, to ensure that monopolies would not be abused. A compulsory license is a provision under the Indian Patent Act that allows the government to mandate a generic drug maker to produce inexpensive medicine in the public interest even as a patent on the product is valid. The patent system is built on the premise that patents provide an incentive for innovation by offering a limited monopoly to patentees and it will stimulate research in investment. The inverse assumption that removing patent protection will hurt innovation has largely prevented the widespread use of compulsory licensing - the practice of allowing third parties to use patented inventions without patentee permission. The Present study would endeavour to examine the impact of compulsory licensing on research & innovation and suggest some ways to access, availability & affordability of life-saving drugs. Thus, the study could be useful as a reference for pharmaceutical firms and the government of India while deciding the pricing of patented drugs or compulsory licensing. This study would also be useful for countries seeking access to lifesaving medicines and can collaborate in ways that would avoid undermining incentives for innovation and other social costs attributed to compulsory licensing.

**Keywords:** Compulsory Licencing, Patents, Pharmaceutical Companies, Research & Innovation.

## **Introduction**

Several non-profit organizations argue that access to life-saving medication in the developing world is not sufficient. In some cases, such drugs are not accessible at all while in other situations drug prices are not at an affordable level leading many consumers untreated. The World Health Organization (WHO) claims that add-ons by wholesalers, distributors, and retailers plus government taxes and duties result in the unaffordability of the medication in many countries (Cameron et al., 2008). Another explanation for these high prices is the patent award. The patent award gives the producer the sole right to provide the medication. These exclusive rights have the purpose to secure the costs of research and development (R&D) for the inventor and further serve as a dynamic measure, by motivating future inventions. The importance of developing new medication to combat diseases is important, however, problems do arise in the use of patents on medication. One problem is that patents have the function of locking out competition. Through monopoly rights, the patent holder may charge an unaffordable price for consumers in developing countries. According to Subramanian (2004), analytical models predict that introducing patents on medication lead to an increase in price between 25-50 %.

The dynamics of patent protection create a dilemma. On the one hand, it causes a static loss today for consumers through high prices. On the other hand, by securing the inventor his costs of inventing, the world and consumers will have access to medicines in the future that otherwise would not exist. Whether the dynamic gain from intellectual property rights outweighs the consumer loss in the short run is unclear (Goldberg, 2010). The TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement attempts to balance this issue by implementing provisions of intellectual property rights that members of the World Trade Organization (WTO) are obliged to follow.

## **The TRIPS Agreement**

The 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) required all World Trade Organization member countries to provide product patent protection for all products, including pharmaceuticals, within the time specified. Moreover, the United States has used bilateral Free Trade Agreements to promote a “TRIPS-plus” agenda, requiring developing countries to provide patent protection that exceeds the TRIPS minimum standards (Roffe and Spennemann, 2006). Concurrently, an attempt is also being made within the World Intellectual Property Organization (WIPO) to upgrade and harmonize patent standards (Chaudhuri, 2007)). With the introduction of the mailbox facility from 1 January 1995 to receive and hold product patent applications and the re-introduction of full-fledged product patent protection in pharmaceuticals from 1 January 2005 in line with TRIPS, the legal framework is similar to that before 1972.

The establishment of the WTO and the TRIPS Agreement in 1995, ratified by 159 countries in 2018, was an initial marker of today’s globalization and harmonization of international property laws, creating global minimum standards for the creation and protection of intellectual property. These standards would facilitate the transfer of technology and serve to further increase incentives for investing in innovation (WTO, 1995). The TRIPS Agreement describes

the international legal definition of a patent as an exclusive monopoly (use and exploitation) over an invention, whether a product or a process, for a minimum period of 20 years. This makes the patenting of medicines (products) or a method of producing the chemical ingredients for medicines possible today, providing a new area for long-term pharmaceutical companies to explore and grow under this scenario, which was impossible before 1995.

Patents can be used for new, useful, and non-obvious inventions. Patents can be granted domestically, regionally, or internationally, depending on the type of innovation and what is deemed most suitable (De Laat, 2005). The price also depends on the type of the invention. The application must meet the requirements indicated in Article 27 of the TRIPS Agreement, mainly the requirements of specification and description, to prevent confusion in patent conflicts and ensure that the knowledge becomes publicly available in the correct manner.

Once a patent is granted, the holder can prevent others from using his/her/its invention, and the patent allows the holder to control the production, distribution, use by others, importation, and, of course, the price of the product (UNDP & Aids Group, 2012). Furthermore, the main justification for granting patents is that they represent an incentive for research and development (R&D). Patents encourage innovation and technological progress (Nicholas, 2013). Thus, given the possibility of gaining millions through the monopoly of medicines, pharmaceutical companies started developing, researching, and spending money on R&D.

WTO's agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was signed and implemented on January 1st, 1995 with the establishment of WTO (Hoekman et al., 2002). The agreement contributes to a worldwide strengthening of the protection of intellectual property by setting down a minimum standard of different related regulations (Ashish & Nigam, 2008). The starting point of the agreement goes back to the eighth round of negotiations in GATT, the Uruguay Round (1986-1994). Before the establishment of WTO in 1995, GATT was the multilateral instrument governing international trade (Ashish & Nigam, 2008). The Uruguay round resulted in the establishment of WTO in 1995. WTO's objective is to implement and monitor a common institutional framework that applies to all its member states. The agreements cover goods, services, and intellectual property, whereas the TRIPS agreement gives provisions for intellectual property rights.

The compulsory license, first established in Article 31 of the TRIPS Agreement is an exception to the rule of monopoly and allows for the government and third parties to produce a patented drug with or without the permission of the patent holder, depending on the regional/domestic laws of each Member State of the WTO. However, the compulsory license made it difficult to grant access to medicines to least-developed countries (LDC) in the exact terms outlined in Article 31; therefore, the TRIPS Agreement was amended in 2001 by the Doha Declaration and in 2005 by the Waiver Mechanism to provide more criteria that would allow LDC to make use of the compulsory licenses and finally obtain medicines. Indeed, the 2001 modification altered the reality of the compulsory license and made it possible for LDC to request and issue compulsory licenses. It began to be a prevalent topic in the commercial world. At first, the compulsory license was used more for HIV medication, but since 2010, it has been possible to

analyze some compulsory licenses for oncology, heart disease, and even anti-inflammatory medicines (Ajzental, 2018).

### **Compulsory Licensing**

Compulsory licensing is “when a government allows someone else to produce the patented product or process without the consent of the patent owner” (WTO, 2006). Compulsory licensing allows a country to either produce or import a copied version of the patented drug (generic drug) without the fear of sanctions being imposed. In return, the patent holder receives adequate remuneration. Since the policy measure was implemented in the TRIPS agreement, many governments have applied it (Beall & Kuhn, 2012). Frequent users are from middle-income countries like Brazil and Thailand. The policy measure may apply to patents in any field but is mostly associated with pharmaceuticals. The goal is to establish a balance between the promotion of access to existing drugs and also promotion of research and development for new drugs (ibid). This flexibility has always existed in the TRIPS agreement, but the Doha declaration in 2001 clarified and enhanced the measure. These clarifications were needed due to some nations being unsure of how to interpret the measures, as well as “how far their right to use the flexibilities would be respected” (WTO, 2006).

Actors in the pharmaceutical industry view compulsory licensing as an intellectual property denial harming their industry and reducing their incentives to do R&D (ChemistryWorld, 2013). Others claim that compulsory licensing could lead to the withdrawal of foreign direct investments (FDI) since the pharmaceutical actor is demotivated to invest and share knowledge with a country issuing compulsory licenses (Bird & Cahoy, 2008). A positive effect in addition to decreased prices for developing countries is that the use of compulsory licensing may bring cumulative innovation (Moser & Voena, 2012). As knowledge is transferred by the use of compulsory licensing, it will create opportunities for innovation.

### **Grounds for compulsory licenses**

The TRIPS Agreement is characterized by some ambiguities, notably the lack of specification or limitation of the grounds for granting licenses. While the agreement mentioned that some of the possible grounds for granting compulsory licenses include circumstances of national emergency, noncommercial use by the public, anticompetitive use, or patent blocking (Ristanic, 2016), nevertheless, it leaves the states to determine what is an appropriate ground for it (Ho, 2011). This perspective has also been declared by paragraph 5(b) of the Doha Declaration, which states that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”.

As noted earlier, depending on the circumstances, compulsory licenses may be granted to satisfy the interests of citizens, such as in a national emergency, blocking patents for subsequent dependent inventions, or anti-competitive methods, however, the use of compulsory licenses has been recently extended to other interest of the citizens, such as the larger access to patented drugs by the reduction in the price. Given the freedom provided to states in this regard, this expansion may appear to comply with TRIPS, but it certainly undermines the original advantage of compulsory licensing under TRIPS.

## **Compulsory Licensing in India**

This section briefly presents the current specifications of compulsory license in the Indian Patents Act 1970, which were presented by the Patents (Amendment) Act of 2002, further slight changes by the Patents (Amendment) Act of 2005, and was written as per the TRIPS compliance. India's long-time reluctance to enable the patent of pharmaceutical drugs resulted in the implementation of a lenient regime for compulsory licensing.

The Indian patents act, of 1970 incorporates compulsory licensing in sections 84 to 94 and rules 96 to 102. The controller needs to be convinced that a prima facie case has been made out of the application which has been filed by the applicant seeking a CL for the proposed patent. Under Section 84 of India's existing patent law, any concerned party may apply for a compulsory license three years after the grant of a patent based on the following reasons: if the necessities of the people have not been fulfilled as per the requirements, if there is no availability of the patented drug at an affordable price or if the patented invention is not worked in India. In addition to several grounds that are expressly mentioned in the TRIPS Agreement, the Indian Patents Act, relying on the given freedom in that regard, has thus introduced two new grounds, namely, "the reasonable requirements of the public" and "a reasonably affordable price" (Ristanic, 2016).

Furthermore, as can be seen, even though TRIPS has been silent on the issue of the timing (excluding the non-working ground as per the Paris Convention, which requires a gap of three years after the patent issuance), India decided to differentiate between various types of compulsory licensing, adopting the three years only in respect of those three specific grounds.

The possibility that practically any person interested can make an application for a compulsory license is yet another peculiarity of the Indian patent law, which places an additional burden on patent owners. In addition to this, under Section 146 of the Patents Act 1970, patentees and licensees in India must submit to the Controller information about the extent the patented invention has been commercially worked in India (Form 27). Under the law, the Controller may then decide to publish that information. Indeed, in 2012 the Indian Patent Office, for the first time, published the Form 27s submitted by patent holders. Hence, potential compulsory license seekers in India may also benefit from the statutory requirement of periodical reporting of working of patents, which contains "a significant amount of competitive information" (Phillips, 2013).

When evaluating an application for the grant of compulsory license, the Controller would consider the nature of the invention; the time which has passed after the sealing patent; the procedures already adopted by a patentee for full use of the invention; and check the ability of the applicant to benefit the public from the invention; the capacity of the applicant to accept the risk involved with finance and the invention; and whether the applicant has attempted to obtain a voluntary license on prescribed terms and conditions, but has not succeeded within a reasonable time (normally no more than six months) as the Controller may deem fit (The Patents Act 1970, India).

The Patents Act has also attempted to explain the scope of the ground “reasonable requirements of the public”. It has first noted that this requirement would cover situations of the patent holder’s refusal to grant a license on reasonable terms, to such an extent that it causes prejudice to an existing business or the development of new business or commercial activities in general. Furthermore, it would cover various situations of issuing licenses under unreasonable terms or situations when the patentee simply fails to take steps to meet the demand of the patented product adequately. Lastly, the Act has clarified that domestic production under any circumstances should not be hindered by importation (The Patents Act 1970, India).

The Patents Act has finally provided that the Controller of Patents, when considering applications, has to observe, in particular, the two main objectives of compulsory licenses, namely, that patented inventions are to be worked on a business scale in the territory of India without delay and upto the reasonably practicable extent, on condition that the benefits of patent holders are not unethically withdrawn (The Patents Act 1970, India).

### **Special provisions for the grant of Compulsory Licensing**

Section 92 of the Indian patent act, refers to special provisions for compulsory license upon notification by the central government. The three clauses considered for the same are:

1. When a circumstance of national emergency arises.
2. When in a state of extreme urgency.
3. When there is a case of public non-commercial use.

In the event of an outbreak of an epidemic or health crisis, such as AIDS/HIV, the government must take immediate action to acquire, distribute and store the necessary drugs. Negotiations must be conducted with the branded drug producers to allow the generic manufacturers to produce the drugs for non-commercial use. In such circumstances, the central government must act to meet the immediate needs of the nation. Similarly, Section 92-A (CL) of the Indian Patents Act, 1970 grants permission to export patented pharmaceutical products in exceptional cases where a country has limited or no manufacturing capacity for a pharmaceutical product to meet the needs of its public. Upon notification by the country, the required pharmaceutical product can be imported from India under the authority of the controller (Soujanya, 2017).

### **Advantages of Compulsory Licensing**

Compulsory licensing (CL) serves as a mechanism to regulate drug prices in developing or underdeveloped countries, where affordability issues among the population are particularly critical. In such cases, CL serves as a safeguard, as the patentee may not be working on the invention to its full potential, thus preventing the invention from being available to the population. CL ensures that contingency funds are adequately managed by the countries, thus ensuring that the population is adequately supplied. CL has been instrumental in the development of generic drugs, and has provided a platform for nations to support one another in times of need (Soujanya (2017).

### **Problems with Compulsory Licensing**

1. Normally when a nation issues CL, it reflects on its ease to accommodate foreign investors and leads to a notion that the nation is non-patent friendly.
2. The above point may have a cumulative effect on investment opportunities.
3. Normally the countries issuing CL are believed to be weak in their IP regime as they frame their laws favoring themselves.
4. Discouragement of research and development has been a long-standing argument against CL as research needs investment opportunities.
5. Patentee whose product has been issued CL is dissatisfied when it comes to royalties as they can never be compared to the expenditure of the invention, development of the invention, obtaining a patent, and its maintenance.
6. CL transfers the lead from the branded manufacturer to the generic manufacturer thus leading to price wars amongst the generic manufacturers.

### **The Impact of Compulsory Licensing on Innovation**

Developing a new drug is a time-consuming, costly, and high-risk process (Mullin, 2014), making patent incentives even more important (Chien, 2003). A patent system offers pharmaceutical companies as patentees an exclusive right to produce, sell, and use their inventions, allowing them to recoup their R&D costs and invest in improving their existing and developing new products. This is the underlying principle upon which the patent system is developed (Chien, 2003). The widespread use of compulsory licensing has been suggested to negatively impact the patent system's ability to encourage innovation.

Pharmaceutical companies generally lose significant revenues due to compulsory licenses, reducing their funds for reinvestment in research and development as a result. Moreover, research-based drug companies are exposed to the risk of governmental arbitrariness when it comes to issuing licensing agreements. As a consequence, companies may choose to redirect or lay aside their R&D investments, or even choose to trade secrets over patent protection. (Chien, 2003).

However, there is disagreement over whether compulsory licensing negatively impacts R&D and innovation in general. Even when it comes to empirical evidence, there are various interpretations. For instance, Pires de Carvalho pointed out that Canada's regular practice of giving compulsory licenses resulted in the closure of several research-based pharmaceutical enterprises and the emergence of the generics industry. (Bonadio, 2012). The Eastman Commission noted in its report on the same case that Canada's extensive compulsory license regime contributed to the growth of its generic industry. However, it did not find any substantial impact on innovation in Canada. (Chien, 2003).

Numerous studies reveal that compulsory licensing does not always lead to a decrease in innovation. (Chien, 2003). However, these surveys have a limitation in that they primarily focus on the compulsory licenses awarded in developed nations to discuss antitrust violations. (Ho, 2011). The potential impact of compulsory licenses issued for public health reasons in

developing countries on future pharmaceutical innovation is yet to be identified. Serious research in this area is warranted, especially as developing countries have a vested interest in building autonomous innovative pharmaceutical industries that can meet local consumer demand. (Bonadio, 2012).

In the existing literature, there are at least two elements of compulsory licensing and innovation that have been identified so far. These factors include the predictability of the licensing and the significance of the market impacted by the license. The study found that “unpredictable licenses typically do not pose a significant risk to pharmaceutical innovation,” and concluded that “the element of surprise”, combined with the unpredictability of ‘sporadic licenses’ that cover only existing inventions, often prevent companies from changing course of action in advance of the license. (Chien, 2003).

On the other hand, a general order to license future inventions could make such an impact. Let’s look at the Bayer vs. Natco license in this context. Bayer v. Natco was a case in which the patentee was faced with the unanticipated consequences of a compulsory license of an existing drug. It was widely believed that the first license issued by India would be the first of many to come, but to date, it has remained the sole compulsory license issued. However, the wide interpretation of national and TRIPs provisions on compulsory licensing by the Indian Patent Office leaves no doubt that many patent holders can find themselves in a position similar to Bayer.

Another factor to consider is the market significance that is relevant to the patent owner as a potential inventor. For example, compulsory licensing in significant markets should have a significant effect on innovation. Another correlated issue is the disease type and its related drug. There are two categories of diseases and drugs developed to treat them. In the first category, some diseases are common to both developed countries and developing countries and medicines proved to be useful to both groups. Examples include Diabetes, Heart disease, Various forms of cancer, and AIDS. In the second category, some diseases are specific to developing countries for example, Malaria, Tuberculosis, HIV strains found in certain African countries.

Concerning the first group, it has been argued that compulsory licenses for drug patents issued in developing countries, which are primarily aimed at developed country markets, have little effect on overall research and development (R&D). Thus, as long as the patentee’s exclusive right is maintained in rich markets, where the patentee can recoup its costs, there would not be a negative impact on innovation in general (Ho, 2011). However, the fact that most rich markets do not enforce compulsory licenses does not guarantee that the interests of drug companies in rich markets are protected. The main concern is the practice of parallel imports, which is, of course, perfectly legal under the TRIPs Agreement. Many rich countries do apply the principle of “national exhaustion” (or, within the EU, regional exhaustion) or have laws banning parallel imports (Chien, 2003). Nevertheless, there are still insufficient safeguards that ‘global drugs’ produced under compulsory licenses in developing countries may not reach rich markets through parallel imports and thus reduce the profits of the drug companies (Ho, 2011)



While it is true that primary rich markets may be able to protect innovation by licensing drugs that are suitable for both developed and developing countries, this would not be the case if imposed licenses were to cover medicines being developed specifically for the treatment of diseases associated with developing countries. Since, in this case, the developing market would become the primary market, the loss of patent exclusivity will almost certainly eliminate the incentive to innovate. This could also lead companies to avoid these markets (Chien, 2003).

One of the best examples of the lack of appropriate medicines due to the lack of incentive to produce them is tropical, neglected, and poverty-related diseases. Because the value of relevant markets is very low, there has been almost no research and development (R&D) of drugs for these diseases by research-driven companies. If by chance such research and development occurs, the negative impact of compulsory licenses on this area must be prevented.

In the Bayer v Natco case, Nexavar was included in the first category of drugs applicable equally to both developed and developing markets. Consequently, it can be argued that Bayer was able to recover its R&D expenditure in primary markets. Nevertheless, even supposing that Nexavar is perfectly suited to the requirements of the Indian market and that no further investigation is required (although Bayer asserted the contrary), it can still be argued that the compulsory license at issue reduces the incentive to invest in local R&D. Given the current situation of the Indian pharmaceutical industry, there are still numerous reasons for companies to resort to the much more cost-effective copying of drugs. The compulsory license case in question does not suggest otherwise (Ristanic; 2016).

A recent study by Ajzentel (2018) demonstrated and concluded that innovation has not been affected by the existence of the compulsory license, the legal framework created by TRIPS Agreements, and subsequent treaties mentioned in section three. The companies continued to expend on R&D to create new medicines to sell to Western countries that would indeed spend their money on the medicines, instead of lowering the prices to maintain the monopoly. Therefore, innovation and R&D have not changed over the last 15 years.

## **Conclusion**

Innovation plays a critical role in the survival of patents. Stimulating innovation and promoting research and development is essential for the development of individuals, nations, and the global economy. With this growth and development comes a multitude of difficulties, particularly in terms of R&D and pricing of inventions. Compulsory licenses may appear to jeopardize exclusive ownership, but they serve as a barrier against monopolistic rights. It is important to note that while compulsory licenses may appear to impede growth and development, they should not be seen as a hindrance to it (Soujanya, 2017).

It is important to be mindful of the use of compulsory licensing, as it is an exception and flexibility of the patent's general rule. This provision falls in the middle; it does not grant full patent protection, nor does it deny it entirely. It has a direct impact on innovation funding, and its unfettered application may lead global pharmaceutical companies to be reluctant to introduce new medicinal products in other nations. Companies are therefore required to set the price of their patented drugs in accordance with the prevailing economic circumstances of the

country in which they wish to safeguard their drugs from compulsory licensing. In recent years, compulsory licensing has emerged as a viable option for economically disadvantaged patients in developing nations. India necessitates compulsory licensing due to the economic situation of the majority of its population. However, the challenge lies in the fact that it must comply with international standards for patent protection, while also safeguarding public health (Shukla, 2019).

Although patent encourages monopoly and overpricing, it is a necessary evil because without patent protection firms have no incentive to develop new products. Thus, patent protection is necessary to ensure innovation; the patent is therefore an imperfect but effective instrument to promote the development of new products. The effectiveness of pharmaceutical patent protection can be attributed to the fact that it is only effective in highly developed countries where citizens possess the financial resources to purchase costly patented pharmaceutical products. It is not effective in developing and least developed countries due to a variety of reasons, the most significant being the availability of drugs at affordable prices. (Abbas, 2013).

As a result, compulsory licensing is yet another impediment to innovation. It is also a violation of the patent proprietor's rights. However, in certain circumstances, this violation may be necessary to prevent the abuse of monopoly power and to safeguard the fundamental right to health. Compulsory licensing is one of the most comprehensively debated concepts at the international level (Abbas, 2013).

Representatives of developing countries and non-governmental organizations express concern that stringent patent laws will inhibit access to essential drugs (Rozek, 2000). On the contrary, some argue that not protecting IPRs will inhibit access to health care because the monopoly provided to pharmaceutical companies through patent protection enables them to recover costs of research and development and to finance further research and development projects (Matthews, 2010). Not protecting IPRs adversely affects access to essential medicines because of the reluctance of pharmaceutical firms to introduce products in countries lacking patent protection (Rozek, 2000). To sum up, a compulsory license falls mid-way; neither full patent protection is granted, nor is it denied altogether.

On April 1, 2016, the National Human Right Commission (NHRC) requested the Indian Government to provide information regarding claims that the Government of India had privately assured the United States that India would take a strict stance on compulsory licensing of patented drugs (Agarwal & Agarwal, 2016). However, In a press release in March of that year, the Ministry of Commerce & Industry refuted these claims. (PIB, 2016). In the wake of Nexavar, India has seen an increase in the number of compulsory license applications filed, prompting one to question whether India has played to the gallery when it comes to the US. However, in the absence of any order that reflects the Indian Patent Authority's ideology in regard to the granting (or rejection) of compulsory license applications. Therefore, it is premature to assume that such an agreement has been reached between the United States and India (Agarwal & Agarwal, 2016).

Sixty organizations have submitted a letter to the Prime Minister, requesting immediate availability of bedaquilines and delaminids for drug-resistant tuberculosis (DRTB) patients in

India. Additionally, doctors in Karnataka had sent a letter to the Government of India regarding the same issue. A compulsory license must be established for the use of bedaquilins and delamanids in India, as there are an estimated 1.3 lakh DRTB patients in the country. Bedaquilines and Delamind may provide hope in this regard. Furthermore, bedaquilines for adults and delaminides for children were added to the World Health Organization's Essential Medicine List in 2015 and 2017 respectively (Bhuyan, 2018).

India is home to a robust generic pharmaceutical sector, which is capable of producing more cost-effective versions of existing medications. However, this is not likely to be possible for the foreseeable future, as the patents of these drugs are held by two Japanese companies, Janssen and Otuka. As a result, patient groups from across the globe have been appealing to the Indian government to take action and utilize the available legal provisions (e.g. compulsory licensing) to stimulate competition and reduce prices (Bhuyan, 2018).

In line with our analysis, Ajzental (2018) has also concluded that innovation has not been affected by the existence of the compulsory license, the legal framework created by TRIPS Agreements, and subsequent treaties mentioned in section three. The companies continued to expend on R&D to create new medicines to sell to Western countries that would indeed spend their money on the medicines, instead of lowering the prices to maintain the monopoly. Therefore, innovation and R&D have not changed over the last 15 years. Hence, based on the above analysis we can conclude there is no relationship between compulsory licensing and research and innovation. However, there would be a positive impact of compulsory licensing on the pricing of medicines in India, and would be beneficial for the availability of affordable medicines for the society in India.

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