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Dr. Wasif Reza Molla
Assistant Professor, Department of Law, University of Calcutta, West Bengal, India

Correspondence Author:
Dr. Wasif Reza Molla
Assistant Professor, Department of Law, University of Calcutta, West Bengal, India

The human rights to access affordable medicines: A deep dive into compulsory licensing cases for pharmaceutical patents in India

Dr. Wasif Reza Molla

Abstract
We feel elated by the advancement of Human Rights, particularly when we have already entered into the fourth generation of Human Rights. However, it is disheartening to note that the obligations pertaining to the second generation of Human Rights such as accessibility and affordability of healthcare have yet to be fully realized. There could be a lot of reasons for this, but one of the most pertinent is the product patent of pharmaceuticals. It is a fact that pharmaceutical companies go through a rigorous process of research and development for procuring lifesaving drugs and vaccines, as was evident during the COVID-19 pandemic. These medicines with advanced therapeutic value played important role in improving the quality of human life. However, as it is said, there's no rose without a thorn, so the exorbitant price and inaccessibility of these medicines in developing countries have become a global concern. To mitigate this effect of product patents a number of flexibilities have been incorporated into TRIPS, but compulsory licensing is the most effective of them. In light of the catastrophe brought in by the COVID-19 pandemic, it may be justified to argue that the right to health and the quest for living a dignified life should take precedence over the monopoly right that the patent owner acquires for their inventions. Many experts and researchers have also argued that compulsory licensing of patented medicines is one of the effective measures to ensure accessibility of patented medicines. In many cases, developing countries in Asia and Africa like Brazil, Indonesia, Malaysia, Thailand, and Ecuador have issued compulsory licensing to ensure the accessibility of patented medicine. Even though India has extensive compulsory licensing provisions in the Patents Act, 1970, only in one case has a compulsory license in medicine been granted, and all other attempts for compulsory license in medicine has failed miserably. Like many developing countries in India this issue has emerged as a contentious arena for legal conflicts. In this backdrop this article makes a critical analysis of the complexities of compulsory licensing cases for pharmaceutical patents in India. It then goes on to explore the legal provisions as well as the ethical issues that were taken into consideration in dealing with these cases. It examines whether the provisions regarding compulsory licenses under international treaties and the Indian Patent Act are complied with by the Controller of Patents. It will analyse the impact of the Nato Pharma Limited v. Bayer Corporation ruling in India as well as make a comparison with other unsuccessful attempts in India for compulsory licensing of medicine.

Keywords: Compulsory licensing, access to medicine, pharmaceutical patent, TRIPS, flexibilities, Doha declaration

Introduction
Affordability of a standard living is always a challenge for all developing countries in the world, but in recent years, affordable healthcare has attracted considerable global attention particularly in the post-COVID-19 pandemic. The unprecedented disaster caused by the pandemic has unveiled the poor health infrastructure of developing countries. During the pandemic developing countries were trying hard to provide minimal health care to their citizens, where as pharmaceutical companies started counting their chickens. As a result what we experienced is the lack of cheap, fair, safe, on-time, and universal access to medicine and vaccines, which had a direct effect on the right to life and the right to the best possible health care for millions of people. However, despite the fact that we were fortunate enough to produce COVID-19 vaccines in a short span of time, a strange and unwanted circumstance arose because of the unequal distribution of vaccines among different nations. It has been observed that wealthier countries acquire a significant quantity of vaccines in excess of what is required. This attitude made the pandemic even more devastating, particularly for less developed and developing countries and regions.

The shortages of essential medicines during the COVID-19 pandemic in various nations resurfaced the debate on universal access to medicines and patent rights. It is need of the hour to find a balance between patent rights and public health. Governments around the world are exploring various mechanisms to strike this balance. One of such mechanism is compulsory licensing, which allows generic versions of patented drugs to be produced at lower costs. In the past many developing countries of Asia and Africa like Brazil, Indonesia, Malaysia, Thailand, and Ecuador had utilised this legal mechanism and had found it very useful for making patent medicines affordable and accessible. Despite having comprehensive compulsory licensing provisions under the Patents Act of 1970, it remained in dormant state as no application was filed in India for compulsory licence of pharmaceutical patent till 2011. For the first time a successful attempt was made by Natco Pharma Ltd for compulsory licensing of Bayer's anti-cancer drug, Nexavar. Because of this case, there was a sky-high anticipation that India would become more lenient in years to come in granting compulsory licences for medicine. However the expectation did not meet the reality and the dismal situation of compulsory licences remained with only two applications were made for compulsory licences of medicine under section 84 of Patent Act till date. After the Nacto case, the first application was filed by BDR Pharma, an Indian drug manufacturer, for the production of the cancer drug Dastanib, a patented medicine of Bristol-Myers Squibb. The application was initially rejected by the controller on technical grounds. The second attempt was made by Lee Pharma Ltd. for compulsory licence of a diabetes medicine, Saxagliptin which was again rejected for lack of evidence of non-availability, non-affordability and non-working of the patented drug in India. Thereafter during Covid-19period [1] it was reported in some news portal that Bajaj Healthcare Limited (BHL) has applied for compulsory licence of Baricitinib, for treatment of Covid-19. The status of this case is unavailable till date. During the devastating second wave of the pandemic, the time seemed ripe for a grant of compulsory licence with both the Supreme Court [2] as well as the Delhi High Court [3] advised the central government to consider the options available under the Patents Act, 1970. In spite of this, the government had shown reluctance in going ahead with a compulsory licence for Covid drugs like Remdesivir and Tocilizumab. In its affidavit to the Apex court, it argued for collaborations through negotiations and voluntary licenses.

Human Rights to access affordable medicines

The right to access affordable medicines is closely linked to the broader concept of the right to health, which is recognized as a fundamental human right. Access to affordable medicines is crucial for the realization of the right to health because it plays a vital role in preventing, treating, and managing health conditions. The high cost of medicines can be a significant barrier to accessing healthcare, particularly for vulnerable and marginalized populations.

The right to health is enshrined in various international human rights instruments, including the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). Several international human rights documents address the right to access affordable medicines as an integral part of the right to health.

1. **Universal Declaration of Human Rights (UDHR) (1948):** Article 25(1) of the UDHR recognizes the right to a standard of living adequate for health and well-being, including medical care. Access to affordable medicines is implied in the broader right to health.
2. **International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966):** Article 12(1) of the ICESCR recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. States parties are required to take steps to prevent, treat, and control epidemic diseases, which involves ensuring access to essential medicines.
3. **Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) (1979):** The CEDAW recognizes women's right to health, and access to affordable medicines is a critical component of ensuring women's health, including reproductive health.
4. **Convention on the Rights of the Child (CRC) (1989):** The CRC, in Article 24, emphasizes the right of the child to the highest attainable standard of health. This includes measures to combat disease and malnutrition, which involves ensuring access to affordable medicines for children.
5. **International Covenant on Civil and Political Rights (ICCPR) (1966):** Though the ICCPR focuses more on civil and political rights, the right to health indirectly plays a role in access to affordable medicines, particularly in relation to non-discrimination and equal protection under the law.
6. **The UN Political Declaration on HIV/AIDS (2011):** This document reaffirms the commitment to providing universal access to HIV prevention, treatment, care, and support, including access to affordable antiretroviral drugs.
7. **UN High-Level Panel Report on Access to Medicines (2016):** While not a binding document, this report provides recommendations on how to promote innovation and access to medicines in the context of international human rights.

There several other international agreements that address the right to access affordable medicines as an integral part of the right to health. This document aims to promote innovation and improve access to medicines, particularly in developing countries. It encourages research and development of new medicines, as well as the transfer of technology to improve local production capacities.

World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS agreement outlines the minimum standards for intellectual property protection, including patents on medicines. It provides flexibility for countries to take measures to protect public health and promote access to medicines.

Doha Declaration on the TRIPS Agreement and Public Health (2001)

Adopted at the WTO Ministerial Conference in Doha, this declaration clarified that the TRIPS Agreement should be interpreted and implemented in a manner supportive of

public health. It affirmed the right of countries to take measures to protect public health and ensure access to medicines for all.

United Nations Sustainable Development Goals (SDGs) [4]

Goal 3 of the SDGs focuses on ensuring healthy lives and promoting well-being for all. Target 3.8 specifically addresses access to essential medicines and vaccines for all.

United Nations Political Declaration on Universal Health Coverage (2019)

This declaration emphasizes the importance of ensuring that all people have access to quality health services, including essential medicines, without facing financial hardship.

World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (2008)

UNITAID Statute (2006)

UNITAID is an international organization that works to increase access to treatment for HIV/AIDS, malaria, and tuberculosis. Its statute focuses on innovative financing mechanisms to address market failures in the development and distribution of medicines.

These documents collectively contribute to the international framework for promoting access to affordable medicines, addressing issues related to intellectual property, public health, and the broader goal of ensuring universal access to essential healthcare.

A Turning Point in Indian Patent Law: Nato Pharma Limited v. Bayer Corporation [5]

Bayer Corporation is a pharmaceutical giant famous for developing many lifesaving medicines. In the 1990s, the company developed a liver and kidney cancer drug called 'Sorafenib' (Carboxy Substituted Diphenyl Ureas) [6]. The company introduced the medicine in India after getting a patent number of 215758 and government approval to import it under the brand name “Nexavar” in 2008. In 2010, Hyderabad-based generic pharmacy company Natco Pharma Ltd. tried to obtain a voluntary license to produce Nexavar from the patentee [7]. However after failing to obtain a voluntary license Nacto applied for a compulsory license on 29.07.2011. It is important to mention here that Section 84 of the Patents Act of 1970 has been used for the first time by any generic company to obtain a compulsory licence in India. Natco argued that the medicine was hardly accessible and affordable to the Indian population, in addition, the patentee did not produce the medicine in India. As of the time of application, the patentee was charging roughly Rs.2,80,428/- for one month of therapy, but Nacto offered to sell the medicine for Rs.8800/-. The application for a compulsory licence was filed three years after the patent was granted. Upon considering all facts the controller held that a prima facie case under Section 87(1) of the Act has indeed been constituted, and directed Nacto to serve a copy of the application on the Patentee, and the application was published in the official journal on the 12th of August, 2011. In the meantime, things get complicated when in 2010, Cipla, an Indian pharmaceutical firm, began offering a generic version of Sorafenib at a substantially cheaper price than Bayer. A month's supply of the Cipla medication cost around $600 at the time. Bayer sued Cipla for patent infringement. However, after exhausting all the processes of law to prevent the grant of compulsory licence Bayer failed and history under the patent regime in India was created on March 9, 2012, when the Controller granted licence to Nacto with some terms and conditions but most importantly the royalty rate was fixed at 6 percent of Natco's net sales. Being utterly disappointed with the controller`s decision Bayer took the issue to the IP Appellate Board. Instead of interfering with the decision of the controller the Board's March 2013 ruling just modified the earlier decision. Bayer's lone success was an increase in the royalty fee from 6% to 7%. The Appellate Board's decision did not conclude the legal dispute. Bayer, dissatisfied with the Board's decision, took it to the High Court. Sadly for Bayer, the High Court ruled in July 2014 [8] that the Controller's and Board's decision on compulsory licences were valid. Undaunted, Bayer appealed the ruling to the Supreme Court. It was the last nail in the coffin when the Supreme Court refused Bayer's request for Special Leave to appeal against the compulsory licence in a two-sentence judgment dated December 12, 2014 [9].

Impact analysis of the Nato Pharma Limited v. Bayer Corporation ruling in India

If we compare what was thought to happen after the Nacto ruling and what actually happened we can understand the actual impact of the case in India. It was expected that being influenced by this licence local companies and government will start applying for more compulsory licenses but the fact is that even after 10 years of this licence few applications were made but no Compulsory licence has been granted till date. The long time it took to settle this case is evident from the fact that Natco approached Bayer to seek a voluntary licence case on 6th December 2010 and Supreme Court rejected Bayer's petition for special leave to appeal on 12th December 2014. This case proves again the reality of the unnecessary intricacy of Indian patent law. Natco shows how a patent holder may use every legal loophole to oppose an award. The Indian compulsory licensing system is too legalistic and allows patentees to purchase time via litigation. Thus some amendment was expected but no such amendment to the Patents Act has been made till date. In regard to FDI in the Pharmaceutical sector it was thought that the compulsory licence to Nacto will have an adverse impact on FDI but as per data available it shows that pharmaceutical remains one of the top ten attractive sectors for foreign investment in India, FDI inflows in Pharmaceutical sector, which includes both pharmaceuticals and medical devices reach Rs.5846 core as on 2021 [10]. The most important issue, in this case, was the price of medicine at the time of application, Bayer was charging roughly Rs.2,80,428/- for one month of therapy of 'Sorafenib', but Nacto offered to sell the medicine for Rs.8800/-.Thus what was expected regarding the price of medicine seems to happen. As expected by civil society Nacto decision came upon the multinational pharma companies as a perfect storm. They irrationally question the decision on the ground of inconsistency with TRIPS. Though is fully aware of the fact that Doha Declaration has declared that the member states have complete right to adopt policies that suits them best to safeguard public health. Thus India acted within its sovereign authority so there is no issue of violation of any international treaty or agreement [11]. Many industrialised nations, particularly the US, have condemned the decision.

As a result, India was put on the Priority Watch List in 2015, 2016 and 2017 [12] because the US suspected India of using compulsory licensing in other areas.

BDR Pharmaceuticals International Pvt Ltd v. Bristol Myers Squibb Company [13]

Bristol-Myers Squibb is a worldwide pharmaceutical firm with its headquarters in New York City, United States. On November 16, 2006, the patent was awarded for Dasatinib [14] to the firm. Thus the company is the patent holder for Dasatinib which is a medicine that is used to treat patients with chronic myeloid leukaemia. It is manufactured and distributed by the patentee under the trade name Sprycel. The medication has been designated as an orphan drug in the United States, Europe, and Switzerland. On March 4, 2013, BDR Pharmaceuticals International Pvt Ltd, a pharmaceutical company located in Mumbai, applied for a compulsory licence of Dasatinib under Section 84 of the Patents Act, 1970. In its application BDR specifically, asserted that Dasatinib is an appropriate chemotherapeutic option for the treatment of chronic myeloid leukaemia and that it should be used when a patient is resistant or develops resistance to the drug Imatinib. The improved tolerance and efficacy of the drug, according to BDR, make it an attractive treatment option. BDR Pharmaceutical further said that the price of each pill supplied by the patentee is INR 2761/-, which equates to INR 1, 65,680/- for 60 tablets per month per patient and about INR 19, 88,160/- for a total of 60 tablets per patient per year. According to the BDR submission, the drug will be made available to the general public at a proposed price of Rs. 135/- per tablet, which works out to Rs. 8100/- per month for the treatment of Chronic Myeloid Leukemia patients, and in addition, a certain percentage of patients suffering from Chronic Myeloid Leukemia will be offered the drug-free of cost, as determined by a cancer specialist. Despite the fact that BDR contacted BMS in February 2012 to obtain a voluntary licence but after a month had passed, in March 2012, the patentee responded to this request by raising a number of questions, for example, BMS inquired as to how BDR could ensure a steady supply of the medication to the market. Apart from that, BMS inquired about the applicant's litigation history as well as any other variables that may harm BMS's market position [15]. The patent holder was also worried about the compliance with local requirements, the quality of the product, and the effectiveness of the quality assurance system, among other things. BDR took this reply as the rejection of its request for a voluntary licence. The important issue, in this case, was whether the applicant has made a proper effort to obtain a voluntary licence from the patentee. In this regard the claim of the applicant that the reply to the letter by the patentee with some inquiry should be treated as a rejection of its effort to obtain a voluntary licence. The controller however did not buy the argument and held that the failure to respond by the applicant to letter dated February 2nd, 2012, is not justifiable even if the strategy of the patentee is considered as delaying tactics. The controller noted that the applicant should have the idea that a compulsory licence can be considered after exploiting all other processes thus it should be treated as a last resort. Thus the controller questioned the bonafide intention of the applicant in obtaining a voluntary licence and held that the applicant could have obtained a licence from the patentee if the applicant had attempted to do so. According to the controller, the applicant has not followed and complied with the process of law and failed to justify any ground for an order of compulsory licence under the Act. Thus the application was rejected more on the technical ground than on merit.

Comparison of Natco and Bristol-Myers case

Natco case was the first instance of compulsory licence of medicine in India in which Natco has been granted a compulsory licence to manufacture and distribute an anticancer medicine for which Bayer has a patent. However, in the second case a compulsory licence application submitted by BDR Pharmaceuticals was denied. A comparative analysis of two cases will help us to understand the circumstances that resulted in the award of a compulsory licence to Natco while denying a compulsory licence to BDR pharmaceuticals. It is important to note that in both cases, the requirements of Section 84 (1) of the Indian Patent Act, i.e. the conditions for awarding a compulsory licence, were met. Both the drugs Nexavar and Sprycel were priced extraordinarily high while the Bayer anticancer medicine has a monthly cost of INR 2,80,000 the anticancer medicine from Bristol-Myers Squibb is priced at INR 1,65,680 per month for 60 tablets. Both the medicines were imported and not manufactured in India. They didn't meet the public requirement. In regard to the request for a voluntary license both the cases have a different approach. A request for a voluntary licence from Bayer had been conveyed by Natco in an effort to secure the licence. Natco's proposal for a voluntary licence had been turned down by the German pharmaceutical company. Another interpretation is that Natco undertook considerable attempts to secure the licence from the patentee, and so, the prima facia case has been established according to Sec. 84(6). (iv). However, before filing for a compulsory licence, BDR had sought a voluntary licence from BMS for Dasatinib on 02.02.2012. In a letter dated March 13th, 2012, BMS (the patentee) expressed a number of concerns. BDR interpreted BMS's response as a denial of their proposal for a voluntary licence. In fact, it failed to undertake any negotiation talks with the patentee within the prescribed time of 6 months. For reasons best known to the applicant, it filed a compulsory licensing application on March 4th, 2013, nearly one year after the patent holder's response. It is a statutory rule that the applicant must make reasonable attempts to get a voluntary licence from the patentee in order to be eligible for a patent. It is one of the factors taken into consideration while evaluating the application for a compulsory licence. It shall be noted that efforts made by the applicant to seek a voluntary license from the patentee are a mandatory requirement. It is one of the grounds for consideration of the application filed for a compulsory licence. Thus is a justified ground for the Controller to reject an application for a compulsory licence, if the above-mentioned requirement is not complied with by the applicant for a compulsory licence. Thus, as a result, the Compulsory licence was rejected to BDR on the technical issue, not really on merit. One may wonder why BDR did not take another shot at triggering this license.

Lee Pharma Ltd v. Astrazeneca AB [16]

On April 30, 2007, Bristol Myers Squibb Company (BMS) was awarded a patent for Saxagliptin, an active component for the treatment of Type-II diabetes, under Patent Number

206543. The patent is titled "A Cyclopropyl-Fused Pyrrolidine-Based Compound." AstraZeneca, a British-Swedish multinational pharmaceutical and biotechnology corporation with its headquarters at the Cambridge Biomedical Campus in Cambridge, acquired ownership rights in Indian Patent No. 206543 from (BMS) by the execution of an assignment deed. Saxagliptin was first introduced to the market under the brand name "Onglyza". In May 2014, Lee Pharma Ltd, a Hyderabad-based pharmaceutical firm, sought Astra Pharmaceuticals for a voluntary licence of Patent No. 206543. After a month, the patent holder responded, requesting further information from the applicant. This response, which was delivered through email, did not, however, reach the applicant. Astra responded to Lee Pharma`s reminder of October 2014 on November 7, 2014, by asking for the applicant's production and marketing data, R&D expenditures, and other pertinent information. Although Lee Pharma responded once again on November 22, 2014, the company got negligible cooperation from Astra. Lee Pharma made the last request on March 2, 2015, and AstraZeneca remained deafeningly quiet. Thereafter Lee Pharma filed the compulsory licence application under Section 84 on June 29, 2015. However, even though the Controller was satisfied that the applicant had attempted in a reasonable manner to obtain the voluntary licence, the application was denied because the applicant failed to provide sufficient justification for its request on any of the three grounds specified in Section 84 of Patent Act 1970.

Lessons from rejected compulsory licensing cases in India: As per the scheme of the Patents Act, it is the applicant's responsibility to prove that the grounds for filing a compulsory licence application have been met, in both instances of BDR Pharmaceuticals v. Bristol-Myers Squibb (hereinafter, BDR case) and Lee Pharma *v.* Astrazeneca AB (hereinafter, Lee Pharma case), where even a prima facie case could not be made out by the applicants. The decisions in these two cases were a huge setback to the hope that there would be more applications for the compulsory licence after the Nacto case. As expected, BDR and Lee Pharma decided not to appeal the Controller's rulings, blaming the lack of goodwill of the policymakers to utilise compulsory licence. Both companies applied for a compulsory licence to produce cheap copies of medicines manufactured by big global drug makers. However, the two Indian generics drug makers now claim that their efforts have been impeded because of the proactive policy taken to safeguard intellectual property, which they claim is getting in the way of the pledge to offer affordable pharmaceuticals for the poor and working class. However, activists and watchdogs expressed concern about what seemed to be a change in policy orientation from the previous case of Bayer, where Compulsory licence was allowed and now the government seems hesitant to provide licences and would only do so in limited circumstances. They claimed that other firms who were considering applying for licences will not proceed after these cases. Though India's Controller General of Patents and Trademarks, part of the commerce ministry, did not respond to any such concerns.

Conclusion

The key conclusions that may be drawn from this discussion are First, the efficacy of any provision of law can be understood when it will be applied in a case the same happened when the compulsory licensing provision under Indian Patent Act was applied in Nacto case. There are a number of drawbacks to the system that was identified when India gave Natco a compulsory licence. Since the award of a compulsory licence, Bayer has left no stone unturned to topple or mitigate the effects of that licence. This case proves again the reality of the unnecessary intricacy of Indian patent law. When compared to Bayer's tenacity to avoid compulsory licensing the rest of the applicants for compulsory licences like BDR, Lee Pharma gave up after losing at the Controller stage and decided not to appeal the Controller's rulings. There is a possibility that their lack of resources might be a factor in their discontinuity. Though the provision of compulsory licensing goes back in India a long way and based on recommendations of all committees on patent reforms Indian law-makers seemed to have developed a very sophisticated and broad compulsory licensing system that could protect the public interest and not just the monopoly interest. But on critically analysing the legal provision, it may be ascertained that provisions of the compulsory licence are more decorative than practical as if to appease developed nations and just to meet the terms of the TRIPS agreement. It is evident from the rejection of two compulsory licence applications that the Controller of Patents has taken a hard stance on the establishment of a prima facie case and admission of evidence in satisfying the grounds of patent proceedings. The most crucial is the grounds of affordability and availability where the applicant must demonstrate the actual number of patients with the help of some authentic report from the government but the fact is data may not be available to the government in regard to all categories of diseases. The rejection of all post-Natco compulsory licence petitions by the Controller of Patents shows that India has not implemented flexible patent protection.

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