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## “CONTEMPORARY ISSUES: THE IMPOSITION OF PRICE CAPS ON PHARMACEUTICAL DRUGS IN INDIA”

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### **Abstract**

This paper explores the key issues in intellectual property which is being an ongoing debate around the world. It recognizes and questions intellectual property law's fundamental justifications, intangible assumptions and important practices through the lens of different modes of genetic, cultural and scientific production that oppose the legal regime.

Intellectual property will moreover be understood to encompass not only intellectual property law, but also copyrighted, patented, trade marketed practices and strategies that concern knowledge. Knowledge can be gain by readings drawn from the multi-disciplinary scholarship on intellectual properties, including anthropology, history, science studies, economics and social theory, etc. It aims to provide with a rock-hard understanding of legal internal ways of idea and arguing about intellectual property, as well as an introduction to wider theoretical resources which will inspire a differentiated and crucial assessment of intellectual property law's effects and limitations.

### **Introduction**

The dominion of intellectual property (IP) rights has been in survival and been a driving force for innovation and revolution for spans and can be dated back to at least 500 BC and ensuring innovators can monopolize and reap benefits out of their innovations.<sup>1</sup> Being so, the 1<sup>st</sup> international convention (known as the 'Paris Convention') was enforced much later in the year 1883, founding a union for the protection of 'industrial property'. Since then, we have seen

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<sup>1</sup> Jeff Williams, *The Evolution of Intellectual Property*, Law Office of Jeff Williams PLLC; link: <https://txpatentattorney.com/blog/the-history-of-intellectual-property>(published on November 11, 2015)

instant growth in the field of IP rights. It is true that from the time of entrepreneurs are incorporating companies, innovators are inventing technology or artists are creating their works of art and/or literature, the domain of IP will only progress further.

Although the evolution of international IP regime has been rapid and the laws have become a lot more complicated than they initially were, it appears that we have only scratched the surface of the extent and reach of IP rights. It cannot be stressed enough that IP rights are crucial to every company, creator and inventor since it ensures that their rights and interests are protected and gives them the right to claim relief against any violation.

Insofar as the Indian IP regime is concerned, we have seen a gradual but crucial development in our laws which has now motivated not only foreign corporations to seek IP protection in India but has also supported start-ups in seeking protection of their IP to the extent that these enterprises have the liberty to seek the protection of their IP at significantly reduced fees (barring copyright and geographical indications). The Indian Intellectual Property Office (IPO) has also taken measures to promote e-filing by reducing costs associated therewith and improving its e-filing system/mechanism. However, the issues arise when start-ups and small enterprises seek to register their IP and are unaware of these common, but cost-effective mechanisms in place.

Besides, our intellectual property policies (especially patent policies) have been a subject matter of criticism for a long time at a global stage due to the government's intervention in the enforcement of patent rights. One of the primary concerns for foreign corporations and organizations have been related to working of patented inventions in India and the issue of compulsory licensing.

**Few queries included in Intellectual regime:**

1. Do patents drive human beings into 'object'?
2. Whether nature can be patentable?
3. Who generates knowledge? Who can retain the access to knowledge?
4. Patents on pharmaceuticals in developing countries – is it justiciable?
5. Mentioning or translating in literature or art – whether it is amount to copying? Is not a creative work?

6. What is the significance of free software?
7. Is plagiarism amounts to theft?

### **Lack of Awareness of Intellectual Property Rights**

Launched by the Government of India in 2014, the ‘Make in India’ project has motivated entrepreneurs to establish their business with the help of government funding and foreign direct investments (FDI) of up to 100%.<sup>2</sup> This step has led to a boost in people exploiting their entrepreneurial skills to establish a successful business (in most cases). Although the Make in India project also focuses on the importance of IP rights by attempting to educate the entrepreneurial minds of the importance and benefits of their IP, it appears that small businesses are yet to benefit from the IP aspect of the project. These businesses/start-ups do not realize the importance of their IP and tend to often misuse violate another’s. This leads to the institution of a lawsuit seeking infringement (or passing off) against such businesses by big corporations and since defending such Suits is an expensive and time-consuming process, it becomes an uphill task for the entrepreneurs to defend the Suits and run their business effectively. Entrepreneurs are often misinformed and miseducated of the basics of IP by professionals who do not have an expertise in the area of IP law, which leads them to believe that their acts of adopting an identical or deceptively similar trademark would go unnoticed or would not constitute infringement or passing off. Due to their lack of knowledge in the domain of IP and lack of proper guidance by professionals, these entrepreneurs tend to believe that: –

- Adopting an identical mark (intentionally) in a different class does not constitute infringement or passing off;
- Adopting a similar mark in the same (or allied and cognate) class does not constitute infringement or passing off;
- Even if the competing marks are identical or deceptively similar, filing a trademark application with a user claim would give them a defensible stand against the true proprietor’s claim.

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<sup>2</sup> *Foreign Direct Investment*, published by Make in India; link: <http://www.makeinindia.com/policy/foreign-direct-investment>.

Needless to say, these are some of the common misconceptions which lead to a claim of infringement or passing off being raised by true proprietors of the marks. Also, the possibility of the Court of law imposing damages and/or costs on a defendant cannot be ruled out either. In such a scenario, due to the limited funding of these start-ups, they are often forced to reconsider their entire business strategy in-line with the pending lawsuit. This can, however, be avoided if the entrepreneurs are either well-educated in the field of IP law or take necessary steps to ensure that they receive proper guidance regarding risks involved in registration and use of their mark, from a professional with expertise in the field of IP laws. Instances of start-ups adopting a similar or identical mark of a big corporation/start-up are quite common nowadays with some of the known cases being instituted by 'Bookmyshow' against 'Bookmyoffer', 'Shaadi.com' seeking relief against use of 'Secondshaadi.com', 'Naukri.com' suing 'naukrie.com', etc.<sup>3</sup>

In instances involving the pharmaceutical industry, the issue becomes far severe since adopting a similar or identical mark can result not only in infringement of IP but can only be extremely harmful to the patients/consumers. Unlike any other consumable item, patients/consumers are at much greater risk if they consume wrong medication and such instances where corporations adopt a similar or identical mark for its pharmaceutical drug, the consequence can be fatal to the extent that it may even lead to death. In one such famous instance in India where the Defendant was a repeated/hardened infringer, the High Court of Bombay while imposing exemplary costs of INR 1.5 crores stated "Drugs are not sweets. Pharmaceutical companies which provide medicines for the health of the consumers have a special duty of care towards them. These companies have a greater responsibility towards the general public. However, nowadays, the corporate and financial goals of such companies cloud the decision of its executives whose decisions are incentivized by profits, more often than not, at the cost of public health. This case is a perfect example of just that".

Another issue these entrepreneurs/start-ups tend to face in the realm of IP law is vis-a-vis use of copyrighted material without knowledge/intention to infringe upon someone else's IP rights. For instance, when start-ups launch their online portals, they tend to use images/GIFs or music for their videos which are copyrighted and use thereof without permission is illegal. On account of

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<sup>3</sup> *Top 17 Startup Legal Disputes*, published by Wazzeer; link: <https://wazzeer.com/blog/top-17-startup-legal-disputes> (published on May 02, 2017).

lack of knowledge of IP laws and consequences of such misuse, they often violate rights residing in the copyrighted work and are then subject to either a legal notice from the owner/proprietor of the copyrighted material or a lawsuit before the Court of law.

The United States of America's (USA) Chamber of Global Innovation Policy Center (GIPC) which promotes innovation and creativity through intellectual property standards, in its 2019 list of countries performing in the field of IP law, places India at a substantially low rank of 40 out of 53<sup>4</sup> which indicates that USA considers India as a major threat when it comes to development and investment the field of IP rights in India (especially in the field of patents). Additionally, India also lacks in the number of patent applications filed before the Indian Patent Office, averaging at around 9,500 filings per year, compared to 2,69,000 filings in the USA.<sup>5</sup> One of the primary reason behind this difference might have something to do with India's lack of support towards the encouragement of IP protection, especially for start-ups.

### **Raising Awareness on Intellectual Property Laws for Entrepreneurs**

With almost 50% of litigations within the domain of IP pertaining to trademark infringement and passing off,<sup>6</sup> entrepreneurs and small businesses must take the following necessary steps to ensure that their rights and interests in their business are protected: –

- Entrepreneurs/Business owners must entrust lawyers/law firms specializing in the field of IP rights to advise and prosecute their trademark applications;
- Understand or attempt to understand each and every step involved in prosecuting and registering a trademark application and participate in discussions leading to every step taken in the prosecution of their IP; and,
- Approach IP lawyers/law firms to get a gist of importance of IP protection along-with freedom to use a mark either before registering it or using the said mark for goods in classes not forming part of the trademark registration.

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<sup>4</sup> *GIPC IP Index 2020*, published by Global Innovation Policy Center; link: <https://www.theglobalipcenter.com/ipindex2020-details/?country=in>.

<sup>5</sup> Darrell M. West, *India-U.S. relations: Intellectual property rights*, Brookings India; link: <https://www.brookings.edu/opinions/india-u-s-relations-intellectual-property-rights> (published on June 04, 2016).

<sup>6</sup> Thehasin Nazia & Rajarshi Choudhuri, *The Problem of IPR Infringement in India's Burgeoning Startup Ecosystem*, IPWatchdog; link: <https://www.ipwatchdog.com/2019/11/16/problem-ipr-infringement-indias-burgeoning-startup-ecosystem/id=116019> (published on November 16, 2019).

It is also the duty of IP lawyers/law firms to promote IP protection for entrepreneurs and small businesses by organizing interactive sessions with new and/or domestic clients and providing competitive charges for prosecuting and enforcing IP rights of these entrepreneurs and businesses.

Statistics reflect that majority of IP infringement cases in India involve a small enterprise being unaware of the basics of IP rights and therefore, using an IP that is either deceptively similar or virtually identical to a registered and/or well-known IP.<sup>7</sup> Often businesses expanding their presence in the online portal (either through their website or a social media page) use copyrighted material without realizing that their use of the same would tantamount infringement. Raising awareness of the importance of IP and consequences of infringement (and passing off) would ensure that start-ups avoid misusing an IP belonging to someone else.

### **The imposition of Price Caps on pharmaceutical drugs in India and its work-around**

One of the primary reasons why the USA considers India's IP regime a major threat has something to do with India's patent laws, especially vis-à-vis the pharmaceutical industry. Albeit the US Trade Representative (USTR) last year stated that the USA is attempting to restrict patentability for new pharmaceutical drugs which are "essentially mere discoveries of a new form of a known substance which does not result in enhancement of the known efficacy of that substance ..... machine or apparatus" (which is identical to Section 3(d) of the Indian Patents Act, 1970),<sup>8</sup> it still considers India as a threat to its IP regime, especially due of India's patent laws.

To better understand the problems faced in the Indian pharmaceutical industry, it would be prudent to point out that unlike developed nations, the Indian government (through its Patents Act and policies) keeps strict control over the drug pricing with an intention to make healthcare (specifically medication) accessible amongst all States and income groups. This can especially

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<sup>7</sup> Press Trust of India, *Absence of legal awareness root cause of rights' deprivation*, Business Standard, Nagpur; link: <https://www.business-standard.com/article/pti-stories/absence-of-legal-awareness-root-cause-of-rights-deprivation-119081800664-1.html> (published on August 18, 2019).

<sup>8</sup> Kristina M. L. Acri née Lybecker, *India's Patent Law is No Model for the United States: Say No to No Combination Drug Patents Act*, IP Watch Dog; link: <https://www.ipwatchdog.com/2019/06/26/indias-patent-law-no-model-united-states/id-110727> (published on June 26, 2019).

be observed in pharmaceutical drugs for cancer and diabetes medication. The Government of India has imposed strict price restrictions for its pharmaceutical drugs, thereby diluting IP rights and causing a severe impact on IP valuation of those pharmaceutical drugs.<sup>9</sup> Although the impact might seem insignificant to consumers since they benefit from these price reductions, making cancer medicines 90% cheaper due to price control would not make IP holders happy or promote invention. Simply put, once the government slashes prices of pharmaceutical drugs intending to make them easily accessible to the majority of patients, it severely impacts the profit margin of the pharmaceutical industries, forcing them to invest more into the industry of generic drug manufacturers because of a bigger profit margin and lesser costs, rather than invest into inventing new drugs, which might although tackle a currently incurable disease (or a curable disease more effectively), but would at the same time, lead the corporation into losses. These price cuts would also force the pharmaceutical corporations to compromise on the quality of drugs which might, in a longer run, have a severe impact on healthcare.

At the same time, a concerned person always reserves their right under Section 84(1) of the Indian Patents Act, 1970 to request for issuance of a compulsory license (after the expiry of three years from the date of grant of the patent) against the said pharmaceutical drug in case it does not comply with the guidelines issued under Section 83 of the afore-mentioned Act like in the case of *Bayer Corporation v. Union of India*.<sup>10</sup> In essence, the Indian government must invest more in its healthcare sector policies to reduce out-of-pocket expenses incurred by patients/consumers and reduce the price caps by a significant amount to promote innovation in the field of patent laws, especially in the pharmaceutical sector.

### Conclusion

India's investment in its healthcare sector has been a major concern since the Indian States ideally spend as low as 1.3% of their gross domestic product (GDP) on healthcare which results in a substantial increase in out-of-pocket expenses and placement of poor healthcare

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<sup>9</sup> Amir Ullah Khan, *India's drug price fix is hurting healthcare*, Live Mint; link: <https://www.livemint.com/politics/policy/india-s-drug-price-fix-is-hurting-healthcare-11572334594083.html> (published on October 29, 2019).

<sup>10</sup> Special Leave to Appeal (C) No(S). 30145 of 2014.

mechanisms<sup>11</sup>. India's heavy reliance on generic drugs supporting the lesser privileged consumers has been expressed as a concern by the USTR<sup>12</sup> and global pharmaceutical giants to the extent that investors and pharmaceutical corporations have restricted their investment into the Indian pharmaceutical industry since their price margin would result in government either forcing price caps on the drugs or implement compulsory licensing for the expensive and life-saving drugs. As stated above, this approach of placing price caps towards the Indian and global (vis-à-vis their sale of drugs in India) pharmaceutical industry has a major impact on India's patent laws since it affects innovation, and since innovation is an essential part of the invention in the healthcare sector, pharmaceutical industries tend to focus more on generic drug production, profit from out-of-pocket expenses of consumers/patients, hospitalization costs, etc. The imposition of price caps has shown to have no significant improvement in accessibility of pharmaceutical drugs.

Although the imposition of price caps is necessary for a developing nation, the same should be practiced to a limited extent. For instance, instead of capping the price of a pharmaceutical drug and dropping its price by 90%, the price caps should be dependent on the situation and need for the drug. For instance, cancer and diabetes medication are in high requirements in India<sup>13</sup> (and other nations) and therefore, the government can impose price caps and reduce the cost of the drugs by 50%. Insofar as other (less crucial/critical) pharmaceutical drugs are concerned, the government can either refrain from price caps or impose a price cap of a maximum of 20%. This would not only promote investment in innovating patented drugs but would also increase FDI in the Indian pharmaceutical sector, thereby permitting Indian pharmaceutical corporations to invent new and possibly better pharmaceutical drugs.

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<sup>11</sup> Ibid.

<sup>12</sup> E Kumar Sharma, *Hard bargaining ahead*, Business Today; link: <https://www.businesstoday.in/magazine/focus/us-to-pressure-india-change-intellectual-property-ipr-regime/story/214440.html> (published on February 01, 2015).

<sup>13</sup> *Key diabetes, anti-cancer drugs among 92 in price-ceiling list*, published by ET Bureau, The Economic Times; link: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/key-diabetes-anti-cancer-drugs-among-92-in-price-ceiling-list/articleshow/65433283.cms?from=mdr> (published on August 17, 2018).