WORKING PAPER

COPY OR COMPETE?

How India's patent law harms its own drug industry's ability to innovate

Summary

India's patent law may be putting India at a competitive disadvantage. The data presented in this research note shows it is preventing Indian generic pharmaceutical companies (several of whom are beginning to innovate) from developing new formulations, compositions, and combinations of existing medicines, which they instead undertake and commercialise abroad.

This analysis shows about one-third of the United States patents of a selection of major Indian generic pharmaceutical companies claim subject matter that appears to be unpatentable in India under Section 3(d). Our survey suggests that they usually do not attempt to patent the same subject matter in India.

Introduction

Countries that develop successful innovative industries have patent laws that enable innovators to build on existing inventions. That is particularly true for pharmaceutical innovation. For example, new formulations of existing medicines may be more stable for storage or may be absorbed or tolerated better by specific patient populations. Combination drugs, in which two already known drugs are combined, provide significant therapeutic benefits to patients.[1] These products have been widely adopted for diseases such as diabetes and cardiovascular disease, providing significant advantages over monotherapies, and resulting in improved patient compliance.[2] Similarly, perfecting the production of a biologic may require significant R&D itself, and innovation that improves that process may make the drug more reliably available or cheaper to produce. Notably, the investments required to take these improved inventions through clinical trials to commercialisation would not be possible in the absence of patent protection.[3]

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While improvements to existing pharmaceutical inventions are patentable in the vast majority of jurisdictions, including the United States and the European Union, that is not the case in India. Under section 3(d) of the Indian Patent Act, for a pharmaceutical invention related to a known substance to be eligible for a patent, it must demonstrate heightened therapeutic efficacy, a requirement that is inconsistent with India's international obligations. This heightened requirement for patentability specifically precludes many categories of invention that allow follow-on innovation, including "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances."[4]

Meanwhile, India's generic pharmaceutical industry finds itself at a crossroads. On the one hand, it faces growing competitive pressures from China, which is now taking market share from India in the volume generics market which it dominates.[5] At the same time, China is working to harness pharmaceutical innovation, undertaking significant pro-innovation reforms to its intellectual property and regulatory frameworks.[6]

Against this backdrop, India's generic pharmaceutical industry will need to find new ways to generate revenue if it is to remain a meaningful contributor to domestic economic development. This would include an increase in R&D to improve existing treatments and drug delivery systems, which represent a viable entry into de novo drug development for generic companies transitioning their innovative capacities from simple reverse engineering of existing medicines into more value-added innovation. The question is whether India's intellectual property framework is hindering these ambitions.

This paper attempts to shed light on how Indian generic pharmaceutical companies are responding to the reduced scope of patentability for pharmaceutical inventions provided by the Indian intellectual property framework. Specifically, it examines if Indian companies are seeking patent protection in the United States, the world's largest market, for inventions that would be unpatentable in India. If they are doing so, it suggests that India's intellectual property framework is hindering their ability to innovate at home. This has implications for India's wider competitiveness.

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Objectives

This paper examines what proportion of U.S. patents of Indian pharmaceutical companies claim subject matter that is apparently unpatentable in India under Section 3(d) of the Patents (Amendment) Act of 2005.[7] While the types of subject matter listed in Section 3(d) (salts, esters, ethers, polymorphs, etc.) are theoretically patentable in India if they "differ significantly in properties with regard to efficacy," the leading case of Novartis AG versus Union of India suggests that this standard may be virtually impossible to reach.[8]

Although Indian companies cannot patent subject matter listed in Section 3(d) in India, they can patent the same types of pharmaceutical inventions in the U.S. and other countries. We looked at U.S. patents that issued since January 1, 2000, of the top five (by sales volume) Indian pharmaceutical companies, Dr. Reddy's Laboratories, Cipla, Lupin Limited, Sun Pharmaceutical Industries Limited, and Glenmark Pharmaceuticals. This paper also examines whether these companies try to patent the same inventions in India.

Methods

Referencing the USPTO online Patent Full-Text and Image Database (PatFT),[9] this paper reviews U.S. patents granted to the selected Indian companies since January 1, 2000. For each of these patents, the claims were reviewed to determine those patents claiming subject matter that appears to be unpatentable in India under Section 3(d).

In turn, referencing Innography's PatentScout database, it is possible to examine whether those companies were trying to patent the same subject matter in India. The majority of those U.S. patents claimed benefit of a patent application in India. The status of the applications in India was verified using the Indian Patent Advanced Search System available from the Office of the Controller General of Patents, Designs and Trademarks of India.[10]

Analysis

A. U.S. Patents of Subject Matter That Is Not Patentable in India

The five major Indian pharmaceutical companies together were granted 412 patents in the U.S. since January 1, 2000. Of these, almost a third appear to be for inventions that would be subject to the heightened patentability requirement imposed by Section 3(d) of India's Patents Act. The results are shown in the following table:

Company	Total US patents issued since 2000	No. of patents subject to Section 3(d)	Percentage of US patents subject to Section 3(d)
Dr Reddy's Laboratories	103	40	39%
Lupin	99	33	34%
Cipla	98	25	26%
Sun Pharmaceutical	48	28	58%
Glenmark	64	7	11%
Total	**412**	**133**	**32%**

Thus, 32% of the U.S. patents of these Indian pharmaceutical companies claim subject matter that we believe they could not patent in India due to Section 3(d).

B. Patent Activity in India

In order to determine the impact of Indian patent law on the patenting activity of Indian companies, the next step was to examine whether these companies tried to patent the same Section 3(d) subject matter in India. Although most of their patents begin with priority to an Indian patent application, the top-five Indian companies have not patented and generally do not try to patent Section 3(d) subject matter in India. However, because many of the relevant Indian priority applications have not yet been exam-

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ined in India, and in some cases have not even been published, the intent of the Indian companies regarding those applications is not known.

Although the majority of their U.S. patents claim benefit to Indian priority applications, there are 27 U.S. patents with no corresponding Indian application. Those applications entered the U.S. directly from a Patent Cooperation Treaty application or in some instances from a U.S. provisional or British application. Since there never was a corresponding Indian patent application, there clearly was no attempt to patent the same subject matter in India. There are also 29 Indian patent applications for which priority was claimed in the U.S., but since have been abandoned or withdrawn.

It is not yet possible, however, to determine the disposition of the remaining Indian applications that provided priority for the U.S. patents. There is no record of any activity regarding those applications, and quite a few have not yet been published. In a few applications there has been some activity, such as a First Examination Report or a first Office Action, but with no response yet from the applicant so we do not yet know what the companies will do. For these unexamined applications there are several possibilities. They could eventually be abandoned or withdrawn. Or the applicants could instead pursue claims that do not fall within Section 3(d), such as methods of making. For example, two issued patents claim methods of making polymorphs, but not the polymorphs themselves.[11] Thus, although we cannot prove that the Indian companies will never try to patent subject matter that appears to fall within the Section 3(d) categories, there is no evidence of such patenting activity.

Conclusion

India's heightened criteria for the patentability of pharmaceutical inventions, as codified in Section 3(d) of its Patent Act, is a significant barrier to pharmaceutical innovation and commercialisation in India. As discussed in this paper, Indian generic pharmaceutical companies have a strong appetite for investing in innovation, yet their patenting behaviour shows them unwilling or unable to undertake it in India.

The fact that Indian pharmaceutical companies file patents on improvements to existing medicines in the United States but are unable to in India is a loss to the country as a whole as it seeks to strengthen its competitive position. It is also a loss to Indian patients, who will not benefit from innovations that could make existing treatments more efficacious and easier to store or deliver.

Endnotes

1. **Philip Stevens and Jack Ellis,** "The power of combination drugs" Geneva Network, 2017, available at https://bit.ly/2DRmQ8r
2. **Christopher M. Holman, Timo Minssen, and Eric M. Solovy.** "Patentability Standards for Follow-On Pharmaceutical Innovation", Biotechnology Law Report, June 2018, http://doi.org/10.1089/blr.2018.29073.cmh
3. **Christopher M. Holman,** In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination, 50 Indiana Law Review 759 (2017)
4. **The Patents Act, 1970, Section 3(d),** available at http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps3.html
5. **Global Times, October 7th 2018,** "Chinese pharma firms enter golden era, set to surpass Indian counterparts", available at http://www.globaltimes.cn/content/1110240.shtml
6. **Sharon Thiruchelvam,** "How China became a leader in intellectual property", Raconteur, April 20th 2018, available at https://www.raconteur.net/risk-management/how-china-became-leader-intellectual-property
7. "[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."
8. **See W.J. Bennett,** Indian Pharmaceutical Patent Law and the Effects of Novartis AG v. Union of India, Washington University Global Studies Law Review, 13: 535-57 (2014) at 545-56.
9. Available at http://patft.uspto.gov/netahtml/PTO/search-bool.html
10. http://ipindiaservices.gov.in/PatentSearch/PatentSearch/ViewDocuments.
11. **Indian patent 255388**, corresponding to U.S. patent 8,349,863, claims only a process of making a polymorph. Indian patent 233701, corresponding to U.S. patent 8,377,950, similarly claims only a process of making a crystalline form.