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A law that cures: The case of secondary patents in India

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Abstract
With India aiming to achieve Universal Health Coverage for its masses and the inception of path-breaking schemes like Ayushman Bharat launched towards this goal, the healthcare scenario in the country is expected to improve. However, there are other areas where the law and policy have contributed towards better access to healthcare. One such contributor is the patent law of India that deserves to be lauded for its role in making important medicines accessible. This paper seeks to deliberate upon the law relating to secondary patents in India and its effective role in mitigation of drug prices.
Research Methodology: This paper analyses the retail drug prices of three best selling drugs in the India in the light of the law and policy practiced in India also drawing a comparison to their respective prices in the USA.

Keywords: patents, drug prices, universal health coverage

Introduction

Patents ensure exclusivity to the owners for a limited time period which in the case of medicines should last as long as the primary patent. The primary patent relates to the API (Active Pharmaceutical Ingredient) [1] of the medicine. Since the presence of an inventive step is *a sine qua non* for any patentable invention [2], the primary patent ensures protection to an inventive claim deserving patentablility. However, patents can be issued on modified compounds, formulations, dosges, particular medical uses, or even for a new method of administering the medicine. These are called secondary patents. Though the Indian law for patents does not lay down an outright denial of secondary patents, it stablishes strict standards for secondary patents thereby filtering out the bad ones.

The period of Patent exclusivity from the patent owner's perspective is the longer the better In order to deal with sharp fall in drug prices at the end of the patent period termed as patent cliff [3], patent owners, who are generally big pharmaceutical companies, take recourse to what is known as "evergreening". The idea is to postpone the exclusivity of a patent by filing secondary patents for derivatives and variants of the API such as a physical variant, a new formulation, dosage regimen or a new method of administering the medicine. By obtaining the secondary patent before expiry of the primary patent the term of exclusivity is stretched beyond the period of twenty years. The process of evergreening, whereby companies extend their patent protection by inventing new follow-on patents that are closely linked but which allow for a longer period of monopoly than would otherwise be permitted, is an important impediment to competition, especially in the pharmaceutical industry [4].

Secondary patents in various countries have led to increased prices of various important drugs by sustaining the exclusive domination of a specific pharmaceutical giant over a particular drug. The price of Humira, a drug popularly prescribed for arthiritis in the US has procured good revenue for the pharmaceutical company, AbbVie Inc. beyond the expiry of its API *adalimumab*. The reason for this is a large number of secondary patents filed by the company AbbVie Inc. The US recognises and supports secondary patents. The price of Humira in the USA is $ 1,300 (Rs.85,000). Likewise the price of a monthly dose of Novartis' Glivec, a crucial medicine for treatment of leukaemia is approximately 1.6 lakh Indian rupees. Spiriva, a medicine for asthma costs Rs. 19,100 for a monthy dose. Comparing these costs with the Indian market we find that the prices of the same drugs are exceptionally low. The price of the Humira drug is Rs. 13,500, the price of Glivec is Rs. 11,100 and the price of Spiriva is Rs.250 respectively.

The above comparative analysis of drug prices in the USA and India in the light of legal framework for patenting in both the countries reveals that the law of Patents in India and the stance of the Indian Patent Office in its policy of striking down flimsy applications for secondary patents has led to the low prices in India whereas a contrary approach in the USA has led to high prices for the same drugs.

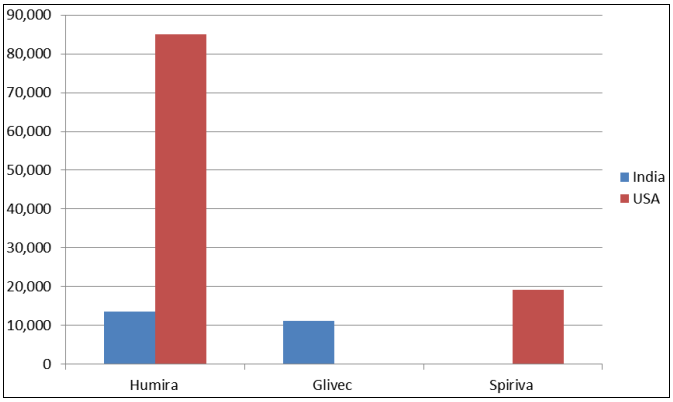

Fig 1

The Indian patent law and the remarkable amendment of 2005

The law in India lays down stringent provisions for patentablility. As per section 2 (1) (ja) of the Patents Act, provides that the product in question must feature a technical advance over what came before that's not obvious to a skilled person.As pharmaceutical companies often fail to satisfy these conditions, trivial claims face dismissal. Further under section 3(d) when a medicine is a variant of a known substance an improvement in its therapeutic value must be established. Patents for new uses and new properties of known substances are also barered under thisn particular section. This unique feature of India's Patent law filters out bad patents. Section 3(e)futher tightens the noose around unworthy claimants by laying down that patents for combinations of known substanes are allowed only if there is synergistic effect. Secction 3(i) ensures that no exclusivity can be claimed over methods of treatment. A combined effect of these provisions in combination with the strict approach of the Indian Patents Office has culminated in weeding out bad patents and resultant low drug prices especially blockbuster [5] medicine prices.

The role played by IPO

The Indian Patents Office has ruthlessly quashed applications for trivial patents. A recent study has shown that in the last decade the IPO has made more than 1,700 rejections for pharmaceutical companies. This report identifies the 1723 pharmaceutical patent applications that were rejected by the Indian Patent Office (IPO) between January 2009 and January 2017 [6]. Despite the pressure exerted by these giants, the IPO has been guided by a strict policy of discouraging bad patents. The ability to question an application at the IPO itself eradicates expensive and time-consuming litigation which is more convenient from the perspective of practicability.

Table 1: Grounds of Rejection (under different sections) [7]

Sections of the Act	2 (1) (j)	2 (1) (ja)	10	8	16	59	77	3
No.of Applications	945	466	386	186	118	75	4	1113

The judicial view

In the landmark case of Novartis Ag v. U.O.I [8] the Supreme Court has also favoured the approach of the IPO. The question before the court was whether the appellant was entitled to get the patent for the beta crystalline form of a chemical compound called Imatinib Mesylate which is a therapeutic drug for chronic myeloid leukemia and certain kinds of tumours and is marketed under the names "Glivec" or "Gleevec". There was a challenge to the constitutionality of 3(d) which both the Madras High Court as well as the Supreme Court in appeal upheld.

The Fallout

It has been seen that the combined effect of the policy and law in India regarding patents has resulted in low prices of drugs especially drugs which are crucial for treating deadly diseases like cancer, AIDS, asthma and cardiovascular diseases in comparison to developed countries like the USA.

A room for disagreement

It has been argued that strict rigours of patenting procedure for secondary claims could lead to a lag in research development in India as pharmaceutical companies would flock to countries like the US with more flexible environment for business. The more recent experience of Japan, Korea, and even more recently China, also provides strong evidence against the view that stringent IPRs are necessary for the inflow of foreign investment, domestic technological development and the transfer of technology [9]. However, the social implications of any deviation from the prevalent policy may have adverse implications.There is a need to balance the need for innovative research and investment incentives with the uncompromisable social implications especially in so far as universal health coverage is concerned

References

1. The Active Pharmaceutical Ingredient (API) is the part of any drug that produces its effects.
2. Intellectual Property Law P. Narayanan Easterm Law House Private Ltd, 2017, p43.
3. A patent cliff is when a firm's revenues could "fall off a cliff" when one or more established products go off-patent, since these products can be replicated and sold at much cheaper prices by competitors.
4. Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century. Dean Baker, Arjun Jayadev and Joseph Stiglitz, 2017 p27.
5. A blockbuster drug is an extremely popular drug that generates annual sales of at least $1 billion for the company that sells it
6. Rejected in India: What the Indian Patent Office Got Right On Pharmaceuticals Patent Applications, 2009-2016-2017, p6.
7. 7Ibid 7
8. Novartis Ag v. Union of India, 2013, 6 SCC 1.
9. Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century. Dean Baker, Arjun Jayadev and Joseph Stiglitz, 2017, p30.