Patent Laws And Regulations In The Indian Pharma Industry
written by King Stubb & Kasiva | April 15, 2024

Introduction

A revolutionary movement is quietly taking shape in a society where the pursuit of innovation frequently comes into conflict with the requirement of ensuring access to essential medicines.[1] This society is currently experiencing a significant amount of tension. The conviction that healthcare should never be a luxury and that drugs that can save lives should be available to every individual, regardless of their financial standing, is the driving force behind this movement. They believe that medical care should be accessible to all people. A number of recent events, the most notable of which is the adoption of the Draft Patents (Amendment) Rules, 2023, point to the fact that the landscape of affordable healthcare will undergo a significant transformation in the years to come.

Taking a stand against evergreening

Evergreening, which is the process of making only minor adjustments in order to extend a pharmaceutical company's monopoly over a medication that has the potential to save lives, has been a source of concern in the healthcare industry for a very long time. Evergreening is a term that was coined by the pharmaceutical industry. A significant amount of action has been taken by India, which is well-known for its resilience and commitment to public health, in order to combat this practice.

Under the circumstances of the case Novartis v. Union of India and Others, which was heard by the Supreme Court of India in 2013, the court issued a decision that was revolutionary.[2] One decision that stands out as a landmark decision is this one. The decision to reject a secondary patent for Novartis' Glivec, which is an essential therapy for leukemia, was upheld by the Supreme Court of India. The idea of evergreening was completely debunked

by this decision, which also highlighted the importance of having medications that are easily accessible and have the potential to save lives. The Indian government has further reaffirmed its dedication to providing affordable medical care by granting a mandatory license for the cancer medication Nexavar, which is manufactured by Bayer. With this license, generic manufacturers are able to produce the patented drug at significantly reduced prices, which is a significant step toward achieving the goal of providing affordable healthcare.

In the process of negotiating trade-related intellectual property rights and the pharmaceutical monopoly, India played a pioneering role.

India's efforts to challenge evergreening are in accordance with the standards that are outlined in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement that was established by the World Trade Organization (WTO).[3] These standards guide India's efforts to challenge evergreening. Despite the fact that the Trade Related Intellectual Property Rights (TRIPS) were conceived with the intention of fostering innovation and safeguarding intellectual property, the impact that it had on the accessibility of medicines varied from country to country.

By denying secondary patents in landmark cases, India has demonstrated that it is committed to ensuring that people have access to medications that have the potential to save their lives. This is evident from the fact that India has rejected secondary patents. India brought attention to the fact that the value of life is not dependent on the business objectives of pharmaceutical companies by boldly confronting the established quo. This was accomplished by India.

Striking a Balance Between Innovation and Access Problems in the Pharmaceutical Industry Monopoly in the Pharmaceutical Industry

It is difficult to provide affordable medical education and treatment due to the fact that the pharmaceutical industry is dependent on blockbuster pharmaceuticals, which generate a significant amount of revenue. Evergreening is a strategy that pharmaceutical companies frequently employ in order to extend their monopolies when the expiration date of a significant number of patents is drawing near. When it comes to the issue of pharmaceuticals that are used to fulfil essential public health requirements, the utilization of obligatory licenses in India provides a crucial instrument for resolving the problem of excessively priced pharmaceuticals.

The modifications that have been made to research and development, as well as India's role in promoting innovation for public health

When it comes to the pharmaceutical industry, research and development (R&D) is an endeavor that is both expensive and risky. It is frequently driven by the reliability of the market in regions such as the European Union, the United States of America, and Japan. India's one-of-a-kind patent regulations discourage evergreening methods used by pharmaceutical companies. These regulations place an emphasis on significant therapeutic improvement as a prerequisite for clearance, which is a requirement for evergreening. It is clear that India is dedicated to enhancing public health and lowering the cost of medications that can save lives, as evidenced by the approach that the country takes.

The Draft Patents (Amendment) Rules

Despite the fact that it is commendable that India has been making efforts to broaden access to medications that are priced within reasonable ranges, there

are a few concerns regarding the Draft Patents (Amendment) Rules, 2023.[4] These planned modifications have been met with criticism because they have the potential to restrict access to medicines that are affordable and to hinder the process of compulsory licencing. Despite the fact that these modifications are intended to speed up processes and improve efficiency, they have been met with criticism.

However, in order for India to continue its journey towards patent independence and affordable healthcare, it is necessary for the country to negotiate the challenges that are associated with intellectual property rights and patents. A concerted effort on the part of governments, pharmaceutical corporations, and groups representing civil society is required in order to ensure that a balance is achieved between innovation and access. To bring about the realization of the ideal of medications that are available to everyone and of the highest quality, there must be communication, innovation, and a reimagined ecology between the pharmaceutical industry and those who hold patents.[5]

Conclusion

It is India's participation in the fight against pharmaceutical monopolies and the promotion of access to essential medications that has been a significant factor in the formation of the landscape of healthcare all over the world. On the other hand, as the pharmaceutical sector continues to develop, India must continue to be diligent in maintaining international standards and ensuring that everyone continues to have access to relatively inexpensive medical care. It is possible for India to pave the way for a future in healthcare that is more equitable and sustainable if it gives priority to public health while also encouraging innovation.

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[1] https://www.oecd.org/education/ceri/GEIS2016-Background-document.pdf

[2] https://academic.oup.com/book/25618/chapter/192990772

[3] https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[4] https://ipindia.gov.in/newsdetail.htm?916

[5] https://www.niti.gov.in/sites/default/files/2023-07/TCRM-Matrix-Framework-FAD3.pdf

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