INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed

www.ijlra.com

ISSN: 2582-6433

DISCLAIMER

ISSN: 2582-6433

EDITORIALTEAM

EDITORS

Dr. Samrat Datta

Dr. Samrat Datta Seedling School of Law and Governance, Jaipur National University, Jaipur.Dr. Samrat Datta is currently associated with Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Datta has completed his graduation i.e., B.A.LL.B. from Law College Dehradun, Hemvati Nandan Bahuguna Garhwal University, Srinagar, Uttarakhand. He is an alumnus of KIIT University, Bhubaneswar where he pursued his post-graduation (LL.M.) in Criminal Law and subsequently completed his Ph.D. in Police Law and Information Technology from the Pacific Academy of Higher Education and Research University, Udaipur in 2020. His area of interest and research is Criminal and Police Law. Dr. Datta has a teaching experience of 7 years in various law schools across North India and has held administrative positions like Academic Coordinator, Centre Superintendent for Examinations, Deputy Controller of Examinations, Member of the Proctorial Board

Dr. Namita Jain

Head & Associate Professor

School of Law, JECRC University, Jaipur Ph.D. (Commercial Law) LL.M., UGC -NET Post Graduation Diploma in Taxation law and Practice, Bachelor of Commerce.

Teaching Experience: 12 years, AWARDS AND RECOGNITION of Dr. Namita Jain are - ICF Global Excellence Award 2020 in the category of educationalist by I Can Foundation, India.India Women Empowerment Award in the category of "Emerging Excellence in Academics by Prime Time &Utkrisht Bharat Foundation, New Delhi.(2020). Conferred in FL Book of Top 21 Record Holders in the category of education by Fashion Lifestyle Magazine, New Delhi. (2020).Certificate of Appreciation for organizing and managing the Professional Development Training Program on IPR in Collaboration with Trade Innovations Services, Jaipur on March 14th, 2019

ISSN: 2582-6433

Mrs.S.Kalpana

Assistant professor of Law

Mrs.S.Kalpana, presently Assistant professor of Law, VelTech Rangarajan Dr.Sagunthala R & D Institute of Science and Technology, Avadi.Formerly Assistant professor of Law,Vels University in the year 2019 to 2020, Worked as Guest Faculty, Chennai Dr.Ambedkar Law College, Pudupakkam. Published one book. Published 8Articles in various reputed Law Journals. Conducted 1Moot court competition and participated in nearly 80 National and International seminars and webinars conducted on various subjects of Law. Did ML in Criminal Law and Criminal Justice Administration.10 paper presentations in various National and International seminars. Attended more than 10 FDP programs. Ph.D. in Law pursuing.

Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship.He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi.Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi.He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ISSN: 2582-6433

ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN

2582-6433 is an Online Journal is Monthly, Peer Review, Academic Journal, Published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essay in the field of Law & Multidisciplinary issue. Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS ISSN 2582-6433 welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

ISSN: 2582-6433

TRIPS FLEXIBILITIES AND INDIA: IS INDIA USING COMPULSORY LICENSING ENOUGH?

AUTHORED BY- DIKSHA SHARMA

Introduction-

India's generic market was valued at USD 24.19 billion in 2024 and is expected to reach USD 35.62 billion by 2030[1]. India's generic drugs market is primarily driven by factors such as cost-effectiveness, increasing demand for affordable healthcare solutions, and a robust pharmaceutical manufacturing base.[2].

However, the situations were not always the same; India faced a major challenge when it joined the World Trade Organization in 1995, which required India to adhere to the framework of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement.[3].

Before entering into compliance with the TRIPS agreement, back in the 1970s, India had amended its patent laws in an impactful way. Instead of giving patents on the final product (i.e., the medicine itself), it gave a patent on the process to make the product. This move paved the way for the Indian generic industry to grow rapidly.

However, after adopting the TRIPS agreement, India was required to grant patents only on the actual medicine and not just the process, which raised concerns because stronger patent protection could make access to drugs more difficult and expensive.[4].

Understanding TRIPS Flexibilities

Since it raised concerns that a stronger patent policy would make the medicine expensive and harder to access, India altered its patent law again in 2005. These amendments fulfilled the framework set by TRIPS, but at the same time, some special features were included.

TRIPS Flexibilities -

[1] https://www.techsciresearch.com/report/india-generic-drugs-market/10642.html
[2] https://www.researchandmarkets.com/report/india-generics-market
[3] https://commerce.uct.ac.za/school-public-governance/articles/2021-11-06-making-trips-agreement-work-effectively
[4] https://journals.law.harvard.edu/ilj/wp-content/uploads/sites/84/561Liu.pdf

ISSN: 2582-6433

TRIPS flexibilities are negotiated provisions that allow countries to protect their public health interests and maintain access to medicines for the public at an affordable cost.

TRIPS sets some non-negotiable rules, such as

a) Member countries must grant a patent in all areas of technology, including medicines.
b) These patents must last at least 20 years.

Thus, after becoming a member country in TRIPS, India could no longer deny product patents. However, TRIPS exhibited some flexible provisions in its framework, which allowed member countries to adapt their Intellectual Property laws to suit their own public policy needs, such as national development and easy access to affordable medicines, while still blending in with the TRIPS framework.

Examples of TRIPS flexibility include:

- Compulsory Licensing (Article 31 of the TRIPS Agreement) –
  Compulsory licensing is a legal mechanism under the TRIPS agreement that allows the government to authorize the use of a patented invention without the consent of the original patent holder, subject to certain conditions.
- Parallel Importation (Article 6 of the TRIPS Agreement) [5]
  Parallel importation refers to the import of genuine, non-counterfeit products from one country to another without the permission of the intellectual property owner. These products are typically first sold in one country by or with the consent of the IP owner, and then imported into another country where the IP owner may sell the same product at a higher price or under different conditions.
- Transitional period for developing and underdeveloped countries (Article 66 of the TRIPS agreement)
  The TRIPS agreement was a culmination of various member countries, i.e., developed, developing, and underdeveloped. The developed countries mainly pushed the rules set by TRIPS as they wanted to protect their inventions; hence TRIPS agreement provided a transitional period to developing and underdeveloped countries to adjust to the regulations of the same.

[5] https://en.wikipedia.org/wiki/Parallel_import

ISSN: 2582-6433

Compulsory licensing

A compulsory license means the government issues the license or the right to make or sell the patented product to someone other than the original patent holder. This authorization is given to the third party by the government without the consent of the owner, although a compulsory license can only be issued when certain conditions are fulfilled.

TRIPS and Compulsory licensing-

TRIPS permits compulsory licensing only when the conditions below are met.

- Compulsory licenses should be evaluated on a case-by-case basis, with each application judged on its merits.[6]
- Before applying for a compulsory license, the applicant must attempt to obtain it from the original owner in a reasonable manner; however, this requirement can be waived in case of a national emergency or extreme urgency.[7]
- The license's scope and duration should be limited to its purpose.
- The patent owner must be paid reasonable remuneration.

Role of the Doha Declaration –

Many member countries were concerned that the TRIPS agreement's provisions regarding compulsory licensing were too strict and ambiguous. Subsequently, in 2001, the WTO introduced the Doha Declaration on the TRIPS agreement, which clarified that

- Public Health is a valid reason to grant a compulsory license.
- The main focus should be protecting the public health interest and making the medicine accessible to the public at an affordable price, rather than protecting the interest of big pharmaceutical companies.

India's 2005 amendments –

In light of the Doha Declaration, India introduced clear rules in patent law in 2005.

Section 84 of the Patents Act 1970 allowed any person to apply for a compulsory license after three years from the date a patent if granted; moreover, the license was only granted on the fulfillment of the following conditions -

[6] https://www.ifpma.org/wp-content/uploads/2023/01/i2023_4.-Compulsory-Licensing-Procedural-Requirements-under-the-TRIPS-Agreement.pdf

[7] https://www.ifpma.org/wp-content/uploads/2023/01/i2023_4.-Compulsory-Licensing-Procedural-Requirements-under-the-TRIPS-Agreement.pdf

ISSN: 2582-6433

- The reasonable requirements of the public concerning the medicine are not satisfied.
- The patented invention is not available to the public at an affordable price [8]
- The patented invention is not being made or sold in the territory of India.[9]

Thus, if a patented invention is too hard to obtain, too costly, or not being sold in India at all, the government can step in and grant a compulsory license to a third party.

By incorporating provisions like section 84, India made complete use of the flexibilities provided by the TRIPS by embedding its sanctioned rules in its provisions.

Bayer Corporation vs Natco Pharma – India's first compulsory license

In the case of Bayer vs. Natco, the Indian Patent Office issued India's first-ever compulsory license, which paved the way for the application of TRIPS flexibility in India. Natco Pharma was permitted to manufacture and sell a generic version of Bayer's patented cancer drug, i.e., Nexavar.[10]

Natco's compulsory license application was under the provisions of Section 84 of the Indian Patent Act, 1970[11]:

(1) The public's reasonable needs were unmet,

(2) The invention wasn't affordably available

(3) The invention wasn't "worked' in India.

Bayer's Nexavar was priced at around ₹280,000/month, making it inaccessible to most Indian patients.

Hence, the abovementioned case is commonly regarded as a landmark example for using compulsory licensing, as this approach aligns with the flexibilities allowed under the TRIPS Agreement and is supported by the Doha Declaration on TRIPS and Public Health.[12]

Is India using the Compulsory License enough for the benefit of the Public?

As evidenced in the Bayer vs Natco case, on the application of compulsory licensing, the price of a life-saving drug dropped by 90%.

Despite the potential use of the compulsory license, its use remains rare. India has granted very few compulsory licenses since the legal framework was established.

Why are compulsory licenses not used enough?

[8] https://ipindia.gov.in/writereaddata/portal/ev/sections/ps84.html
[9] https://ipindia.gov.in/writereaddata/portal/ev/sections/ps84.html
[10] https://indiankanoon.org/doc/130225488/
[11] https://ipindia.gov.in/writereaddata/portal/ev/sections/ps84.html
[12] https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

ISSN: 2582-6433

1) Complex application procedure- The system of obtaining a compulsory license is too lengthy since it involves a case-by-case process with non-negotiable requirements.
2) Judicial Delay- Compulsory licences are often challenged in courts by the patent holder, triggering a prolonged process and delayed access to medicine for the general public.
3) Foreign Diplomatic Pressure- A strong pressure is exerted by foreign countries and multinational pharmaceutical companies on India to restrict the use of compulsory licensing.
4) Lack of political will – There is often a lack of anticipatory governance to invoke the action on compulsory licensing, even when the public health is at stake.

Conclusion: India's Imperative in Global Health Justice

India's pivotal role in shaping the Doha Declaration and its rise as a global pharmaceutical powerhouse reflects its strategic use of patent law and TRIPS flexibilities.

Although its capability to produce low-cost generics has saved numerous lives but the true strength of India's legal framework lies in how consistently and ethically it exercises the rights it has secured.

The global health industry looks up to India for not only affordable medicines but also for the leadership in defending the legal and ethical foundation of public health.

Path Forward-

To drive the global health justice forward, India must-

1) Exercising the TRIPS Flexibilities – Increasing the usage of the compulsory license and other flexibilities provided under the TRIPS, but not just during emergencies, as a standard approach to deal with public health.
2) Champion public health in law and policy- Defend and enhance the legal provisions that prioritize health over commercial interests.
3) Set global precedents- By invoking and defending its rights, India can set an example for other Countries, strengthening the united power of the nations.
4) Balance Innovation with access- Continue to promote pharmaceutical innovations, but never at the cost of fair access to essential medications.

Thus, India holds both legal tools and moral responsibility to lead the world in equitable healthcare. If it fails to act strongly on compulsory licensing, it risks surrendering public health to private monopolies. Rights unused are rights denied.