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India stance against "TRIPS-plus" provisions

1-Trade-Related Aspects of Intellectual Property Rights (TRIPs). When countries sign TRIPs agreements, they commit to modifying their Patent Act, Copyright Act, Trade Mark Act, and other relevant laws to align with TRIPs provisions. In India, significant amendments were made to the 1970 Patent Act in 2005 and the Copyright Act in 2010 to accommodate TRIPs requirements.

TRIPs agreements play a crucial role in shaping intellectual property rights globally, ensuring fair protection for innovator companies while also allowing for the flourishing of generic drug industries. India's stance reflects its commitment to balancing these interests and fostering economic ties through trade agreements.

TRIPs provisions extend beyond the WTO's obligations, and they impact various aspects of intellectual property rights across nations.

2-India's firm stand against "TRIPS-plus" provisons.

India has consistently safeguarded the interests of its domestic generic drug industry in Free Trade Agreements (FTAs).

Notably, India rejected the European Free Trade Association (EFTA) bloc's demand for the inclusion of a 'data exclusivity' provision in proposed trade agreement. This decision ensures that India remains supportive of its generic drug industry and does not compromise its interests.

In addition, FTAs proposals from developed countries include TRIPS plus provisions on Data Exclusivity, Patent Term Extensions, Evergreening of Patents, Broader Patentability Criteria, and Patent Linkage. India has taken a firm stance against such provisions. Here is India's position on these.

I. Data Exclusivity: Data exclusivity involves granting the originator company exclusive rights over the clinical trial data submitted for regulatory approval of a new product.

Following data exclusivity would require Indian generic companies to conduct their own clinical trials in India even if the drug is already approved elsewhere. This would mean delay and higher costs in introducing generics.

Article 39.3 of TRIPs requires nations to protect undisclosed test data submitted for new chemical entities (NCEs) against "unfair commercial use." However, it doesn't mandate data exclusivity. The interpretation of "unfair commercial use" is contested. Many see it as protecting confidentiality but not granting exclusive marketing rights.

India doesn't explicitly grant data exclusivity. Instead, it relies on Section 3(d) of the Patents Act which protects undisclosed information submitted for regulatory approval. This provision doesn't grant a period of monopoly and allows regulators to use data for public health purposes.

India argues its approach safeguards public health access to affordable medicines, aligns with TRIPS' flexibility, and encourages domestic innovation.

The Indian approach allows quicker entry of generic medicines, promoting affordability and access. It also discourages "evergreening" practices where minor changes extend patent protection.

Data exclusivity would inflate medicine prices, hurt affordability.

II. Patent Term Extensions: India challenges the notion of automatic extensions for delays in regulatory approval, advocating for a case-by-case evaluation to prevent the unfair prolongation of monopolies.

III. Evergreening of Patents: India scrutinizes patent applications rigorously to avoid "evergreening," where minor modifications to existing patents extend monopolies, a practice not explicitly addressed by TRIPS but requiring new inventions for patentability.

IV. Broader Patentability Criteria: India's patentability criteria are stricter than the TRIPS minimum standards, excluding non-

patentable subjects such as mere discoveries, traditional knowledge, and incremental innovations.

V. Patent Linkage: India opposes patent linkage, which connects marketing approval to patent status, arguing that it hampers generic competition and restricts access to essential medicines.

Overall, India's stance focuses on: India's approach underscores a commitment to balancing innovation with public health needs, adopting a flexible interpretation of TRIPS to align with its developmental goals, and preventing the establishment of unfair monopolies, especially in the pharmaceutical sector. This stance reflects a broader effort to protect traditional knowledge and ensure the availability of affordable medicines, addressing significant global challenges in healthcare and intellectual property rights.

2-Advantages of India’s approach

1. By opposing data exclusivity and patent linkage, India ensures that generic drug manufacturers can access the market sooner, significantly reducing the cost of life-saving medicines.

2. India's stance allows for greater flexibility in addressing public health emergencies. By not granting automatic patent term extensions and scrutinizing evergreening practices, India can prevent monopolies that delay the entry of affordable generics, ensuring that public health takes precedence over intellectual property rights.

3. Encouraging the production of generic drugs not only makes healthcare more affordable but also stimulates the local pharmaceutical industry.

4. India's stricter patentability criteria protect traditional knowledge and practices from being patented by corporations, thereby preserving the country's rich cultural heritage and biodiversity. This protection ensures that communities retain control over their traditional resources and knowledge.

5. India's resistance to TRIPS-plus provisions positions it as a leader among developing countries in advocating for more equitable global IPR regulations.

6. By setting high standards for patentability and opposing evergreening, India encourages genuine innovation. This approach ensures that patents are awarded for truly groundbreaking inventions, promoting a healthy competitive environment that drives scientific advancement.

3-The potential losses if India accepts TRIPS-plus provisions

The potential losses associated with each provision:

1-Data Exclusivity:

Increased drug prices: Data exclusivity grants pharmaceutical companies exclusive rights to their clinical trial data for a set period, delaying generic versions and potentially keeping prices high.

Reduced access to essential medicines: Higher prices could limit access to essential medicines for low-income populations in India and other developing countries.

Disincentivization for domestic research and development: Reliance on imported drugs could stifle local research efforts and reduce India's self-sufficiency in medicines.

2-Patent Term Extensions:

Similar concerns as data exclusivity: Longer patent terms can lead to higher prices and reduced access to essential medicines.

Anti-competitive practices: Extensions could reward pharmaceutical companies for minor innovations, hindering competition and innovation in the long run.

3-Evergreening of Patents:

Maintaining monopolies: This practice involves making minor modifications to existing drugs to extend patent protection, delaying generic competition and keeping prices high.

Reduced access to affordable treatments: Similar concerns as with the above provisions regarding reduced access to essential medicines.

4-Broader Patentability Criteria:

Hinderance to generic competition: Expanding the scope of patentable inventions could make it harder for generic manufacturers to develop and produce affordable versions of drugs.

Reduced access to innovation: Broader criteria could stifle access to essential research findings and knowledge needed for generic development.

5-Patent Linkage:

Delaying market entry of generics: This provision ties marketing approval of generic drugs to the patent status of the originator drug, potentially delaying access to generics.

Increased litigation and costs: Pharmaceutical companies could use patent linkage to file lawsuits against generic manufacturers, driving up legal costs and delaying generic availability.