SOUTHVIEWS NO. 272

WWW.SOUTHCENTRE.INT
@SOUTH_CENTRE

8 August 2024

Lessons for the Global South from U.S. Legislation on Patent Thickets

By Nirmalya Syam

The US Senate's passage of the Affordable Prescription for Patients Act (S-150) targets patent thickets, strategic barriers used by pharmaceutical companies to delay the entry of biosimilar drugs and maintain high prices. This US legislative act offers valuable lessons for the Global South, where similar reforms can strengthen patent review processes, encourage competition, and utilize TRIPS flexibilities to improve access to affordable medicines, fostering a more equitable healthcare system.

L'adoption par le Sénat américain de la loi sur les prescriptions abordables pour les patients (S-150) vise les brevets chevauchants qui couvrent le même produit, barrières stratégiques utilisées par les sociétés pharmaceutiques pour retarder l'entrée de médicaments biosimilaires et maintenir des prix élevés. Cet acte législatif américain fournit des leçons précieuses pour les pays du Sud, où des réformes similaires peuvent renforcer les processus d'examen des brevets, encourager la concurrence et utiliser les flexibilités des ADPIC pour améliorer l'accès à des médicaments abordables, favorisant ainsi un système de santé plus équitable.

La aprobación por el Senado de EE.UU. de la Ley de Prescripción Asequible para los Pacientes (S-150) se centra en la maraña de patentes, barreras estratégicas utilizadas por las empresas farmacéuticas para retrasar la entrada de medicamentos biosimilares y mantener precios elevados. Este acto legislativo estadounidense ofrece valiosas lecciones para el Sur Global, donde reformas similares pueden reforzar los procesos de revisión de patentes, fomentar la competencia y utilizar las flexibilidades del ADPIC para mejorar el acceso a medicamentos asequibles, fomentando un sistema sanitario más equitativo.

SOUTH CENTRE

In a significant legislative move, the United States of America (U.S.) Senate recently unanimously passed a bill known as the Affordable Prescription for Patients Act (S-150),[1] aimed at curbing patent thickets by pharmaceutical companies, which are strategic barriers created to extend the exclusivity period of their drugs and delay the entry of generics. The bill will now be considered by the House of Representatives in order to be passed as law with Presidential assent. This new legislation is among a host of other measures that have been adopted or are being considered in the U.S. to deal with soaring costs of prescription drugs, such as proposed changes to the exercise of march-in rights under the Bayh-Dole Act, allowing federal agencies to license taxpayer-funded inventions to other parties based on factors such as accessibility and affordability.[2] These developments hold valuable lessons for countries in the Global South, where access to affordable medicines remains a critical issue and patent thickets and evergreening by pharmaceutical companies are a common and extended practice.

Understanding Patent Thickets

Patent thickets involve the filing of numerous patents around a single drug, making it difficult for generic manufacturers to enter the market even after the original patent expires. This practice not only hampers competition but also keeps drug prices high, limiting access for populations in both developed and developing countries.

The U.S. Legislative Response

S-150 approved by the Senate seeks to limit the number of patents drugmakers can assert in litigation on individual biological products. This would allow for earlier entry of biosimilar drugs into the market, potentially lowering their prices and increasing accessibility.

The law also addresses several key issues in the pharmaceutical industry to enhance competition and reduce monopolistic practices:

Prohibition of Product Hopping: The law bans drug manufacturers from engaging in product hopping, a tactic where manufacturers switch patients to a new version of a drug with extended patent protection when the original patent is about to expire. The Federal Trade Commission (FTC) is authorized to enforce this prohibition.

Definition and Presumption of Product Hopping: Product hopping is defined as introducing a follow-on product, which is a modified version of the original drug, with a similar or identical indication, especially after the original drug's patent expiry. The law presumes product hopping has occurred if, after the Food and Drug Administration (FDA) receives an application for a generic or biosimilar version, the original manufacturer withdraws the original drug and promotes the follow-on product.

Drug manufacturers can challenge this presumption by proving that their actions were not intended to stifle competition.

Limits on Patent Litigation for Biological Products: The law restricts the number of patents a reference biological product manufacturer can assert in patent infringement lawsuits against biosimilar manufacturers. Specifically, it limits patents filed more than four years after the reference product received market approval, provided the biosimilar manufacturer follows an abbreviated pathway for FDA approval.

Implications for the Global South

For countries in the Global South, the U.S. approach offers a blueprint for legislative reforms. Here are key takeaways:

[1] S. 150 — 118th Congress: Affordable Prescriptions for Patients Act of 2023. Available from https://www.govtrack.us/congress/bills/118/s150 (accessed 17 July 2024).
[2] See N. Syam, "New US Policy on Exercise of March-In Rights to Curb High Drug Prices: Lessons for the Global South", SouthViews No. 258, 11 March 2024. Available from https://www.southcentre.int/wp-content/uploads/2024/03/SV258_240311.pdf.

1. Strengthening Patent Review Processes: Implementing rigorous criteria for the examination of secondary patent applications can prevent the proliferation of patent thickets.[3] This would involve improving the capacity of patent offices to scrutinize patent applications more effectively.

2. Encouraging Generic Competition: Policies that support the production and distribution of generic and biosimilar drugs can make essential medicines more affordable. This includes creating a regulatory environment that facilitates the quick approval and market entry of generics and biosimilar drugs.

3. Adopting TRIPS Flexibilities: The World Trade Organization's Agreement on Trade Related Aspects of intellectual Property Rights (TRIPS Agreement) allows for flexibilities which can be used to ensure that patents do not impede the attainment of public health objectives.[4] Countries in the Global South can utilize these provisions to improve access to medicines.

4. Collaborative Approaches: Regional cooperation among countries in the Global South can lead to joint strategies against patent thickets.

Conclusion

The recent U.S. Senate bill against patent thickets represents a crucial step toward a more competitive drug pricing and enhanced accessibility of biological medicines which account for a growing part of new drugs and the pharmaceutical market and are generally very high priced. Countries in the Global South can draw valuable lessons from this initiative to implement their own reforms covering all pharmaceuticals (including those produced by chemical synthesis and biologicals), fostering a more equitable healthcare system that prioritizes public health over monopolistic practices.

Author: Nirmalya Syam is Senior Programme Officer of the Health, Intellectual Property and Biodiversity Programme (HIPB) of the South Centre.

[3] See C.M., Correa, *Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain*, Research Paper, No. 52 (Geneva, South Centre, 2014). Available from https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf.

[4] See C.M. Correa, *Interpreting the Flexibilities Under the TRIPS Agreement*, Research Paper, No.132 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/06/RP-132.pdf.

For more information, please contact Anna Bernardo of the South Centre:
Email abernardo@southcentre.int, or telephone +41 22 791 8050.

Front cover photo credit: Anna Shvets from Pexels