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New US Policy on Exercise of March-In Rights to Curb High Drug Prices: Lessons for the Global South

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In response to soaring prescription drug costs, the United States government recently announced 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. This article explores the implications of the US policy shift on global pharmaceutical pricing and access, particularly for developing countries. Drawing parallels between the US approach and flexibilities under intellectual property laws such as compulsory licensing and government use authorizations that are allowed under the WTO TRIPS Agreement, the article suggests that similar strategies could be employed by developing nations to address public health needs and economic considerations.

En réponse à la flambée des coûts des médicaments sur ordonnance, le gouvernement des États-Unis a récemment annoncé des propositions de modification de l'exercice des droits de marche dans le cadre de la loi Bayh-Dole, permettant aux agences fédérales de concéder des licences sur des inventions financées par le contribuable à d'autres parties sur la base de facteurs tels que l'accessibilité et le caractère abordable. Cet article explore les implications du changement de politique des États-Unis sur la tarification des produits pharmaceutiques et l'accès à ces produits, en particulier pour les pays en développement. En établissant des parallèles entre l'approche américaine et les flexibilités prévues par les lois sur la propriété intellectuelle, telles que les licences obligatoires et les autorisations d'utilisation par le gouvernement permises par l'accord ADPIC de l'OMC, l'article suggère que des stratégies similaires pourraient être mises en œuvre par les pays en développement pour répondre aux besoins en matière de santé publique et aux considérations économiques.

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En respuesta al aumento exorbitante de los costos de los medicamentos recetados, el gobierno de Estados Unidos anunció recientemente una serie de cambios propuestos en el ejercicio de los derechos de intervención bajo la Ley Bayh-Dole, que permite a los organismos federales otorgar licencias de invenciones financiadas por los contribuyentes a otras partes, teniendo en cuenta factores como la accesibilidad y la asequibilidad. Este artículo explora las implicaciones del cambio de política de Estados Unidos en la fijación de precios y el acceso a los productos farmacéuticos a nivel mundial, en particular para los países en desarrollo. Estableciendo paralelismos entre el enfoque estadounidense y las flexibilidades de las leyes de propiedad intelectual, como las licencias obligatorias y las autorizaciones de uso gubernamental permitidas en el Acuerdo sobre los ADPIC de la OMC, el artículo sugiere que los países en desarrollo podrían emplear estrategias similares para abordar las necesidades de salud pública y las consideraciones económicas.

On 7 December 2023 the government of the United States (US) announced a number of measures to support lowering prescription drug costs in the US. A statement released by the White House in this regard said, "The Biden-Harris Administration believes taxpayer-funded drugs and other taxpayer-funded inventions should be available and affordable to the public. When an invention is made using taxpayer funds, under certain circumstances march-in authority under the Bayh-Dole Act enables the federal government to license the invention to another party."[1] Accordingly, the US Department of Commerce and the Department of Human and Health Services released "a proposed framework for agencies on the exercise of march-in rights that specifies for the first time that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public."[2]

The *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (hereinafter "Draft Framework") - which was placed for public consultation by the National Institute of Standards and Technology (NIST)[3] - reviews the factors that an agency may consider when deciding whether to exercise march-in rights to ensure that its application will both fulfill the purpose of such rights and uphold the policy and objectives of the Bayh-Dole Act. NIST and the Interagency Working Group for Bayh-Dole (IAWGBD) will make use of the comments received through this public consultation in developing a final framework document that may be used by an agency when making a march-in decision. Comments were due by 6 February 2024.

The Bayh-Dole Act of 1980 seeks to enable the use of the patent system to promote the utilization of inventions that arise from federally supported research and development and ensure that inventions by non-profit organizations and small businesses are utilized to foster open competition and entrepreneurship.[4] It allows individuals and

[1] The White House, "Fact Sheet: Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition", 7 December 2023. Available from https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/.

[2] Ibid.

[3] "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights", *Federal Register: The Daily Journal of the United States Government*, 12 August 2023. Available from https://www.federalregister.gov/public-inspection/2023-26930/draft-interagency-guidance-framework-for-considering-the-exercise-of-march-in-rights.

[4] See Council on Government Relations, "The Bayh-Dole Act: A Guide to the Law and Implementing Regulations", 2021. Available from https://www.cogr.edu/bayh-dole-act-guide-law-and-implementing-regulations-october-2021-update.

entities, collectively referred to as "contractors", to retain the title to inventions derived from federally funded research and development and lays down specific rights and obligations of the contractors, as well as rights retained by the federal government. One of the rights of the federal government is the funding agency's right to require the contractor, an assignee, or exclusive licensee of an invention that comes under the scope of the Bayh-Dole Act to grant a license to such invention on reasonable terms to a responsible applicant. If the contractor refuses to grant a license to an applicant the federal agency may elect to grant a license to the applicant. The grant of such license, which is similar to a compulsory license on a patent, is referred to as the exercise of "march-in" rights under the Bayh-Dole Act. March-in rights can only be exercised if the federal agency determines that action is necessary to address one of four statutory circumstances:

- to ensure effective steps are taken to achieve practical application of the subject invention;
- to alleviate health or safety needs that are not reasonably satisfied by the contractor, assignee, or their licensees;
- to meet requirements for public use specified by any federal regulations; or
- to address requirements under the Bayh-Dole Act that a subject invention be manufactured substantially in the US.

In determining whether these statutory criteria are met, the Draft Framework provides some key questions that the federal agency making such determination may consider. These include whether the price at which the product is currently offered is reasonable and whether only a narrow set of customers may access a product due to its high price; whether an initial price or any price increase appears to be extreme, unjustified, or exploitative of a health situation. In addition to price, federal agencies can also exercise march-in rights when a product is not developed or licensed due to the lack of diligence by the contractor. In determining health and safety needs, the Draft Framework also directs agencies to identify the scope and duration of the health or safety issues and assess whether march-in rights can timely address these issues, how the product can address the health or safety need, whether alternative products can be used to address these needs instead, and also whether greater quantity of a specific product is needed to address the identified health and safety need. The Draft Framework also directs federal agencies to consider how the exercise of march-in rights would impact the addressing of the statutory criterion by considering whether the license will be sufficient to enable manufacturing of the product, or whether the product relies on numerous patented inventions, etc.

The approach of the US government in providing policy guidance to federal agencies to exercise march-in rights under the statutory criterion in the Bayh-Dole Act bears important lessons for developing countries on how administrative policy guidelines can be used to enable government authorities to exercise the grant of authorizations such as a compulsory license or government use for noncommercial purposes (government use) over patented products. Such authorizations are part of the flexibilities available under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). Ironically, although the US has claimed (notably in a World Trade Organization case brought against

Brazil)[5] that the TRIPS Agreement does not allow compulsory licenses to remedy the lack of local production, one of the grounds to use march-in rights under the Bayh-Dole Act is that the contractor has failed to 'substantially' manufacture the invention in the US.[6]

A compulsory license is an authorization granted by a government allowing third parties to produce a patented product or to utilize a patented process without the consent of the patent holder, and which use will not amount to an infringement of the patent. The grant of a compulsory license constitutes a proactive governmental intervention when market forces result in a disequilibrium between the objectives of rewarding innovation and ensuring social and economic welfare. 'Government use' authorization is a grant by the government, to itself, other entities or contractees acting on behalf of the government to make use of a patented product or process without the consent of the patent holder.

Compulsory licenses and government use authorizations are legal instruments widely recognized in the laws of both developed and developing countries, that can be used to address a variety of situations, such as insufficient supply or excessive prices of products, national emergencies, etc.[7] Over the past decade, many developing countries have granted compulsory licenses in the area of pharmaceuticals.[8] Compulsory licenses can therefore be legitimately used to implement public policies aiming at ensuring the production or procurement of medicines and other health technologies in situations of global health crises such as the COVID-19 pandemic. While the Bayh Dole Act only applies to products that are subject inventions that have been developed with public funding received from federal agencies,[9] similar approaches to guide the application of compulsory licensing and government use authorization under patent law could also be pursued by developing countries.

Drug pricing is one of the major areas of focus in the Draft Framework. It particularly emphasizes that prices can be a relevant consideration for the exercise of march-in rights. Similarly, in invoking the grounds for a compulsory license or government use authorization, developing countries could also weigh in price considerations, particularly for medical products.

The approach of the US government towards enabling federal agencies to make use of march-in rights for ensuring that inventions are affordably accessible to the public should also be seen alongside proposals by the European Commission to implement a new European Union wide regime for compulsory licensing to remove hurdles to compulsory licensing in the region.

[5] See World Trade Organization, Brazil – Measures Affecting Patent Protection, DS-199. Available from https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm#:~:text=Complaint%20by%20the%20United%20States.&text=More%20specifically%2C%20the%20US%20noted,in%20the%20territory%20of%20Brazil.

[6] 35 U.S.C. §203 – 204.

[7] See Carlos M. Correa, "Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries", South Centre Working Paper No. 5, October 1999. Available from https://www.southcentre.int/sc-working-paper-trade-related-agenda-development-and-equity/.

[8] See Carlos M. Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, Research Paper, No. 41 (Geneva, South Centre, 2011), pp.17-19. Available from https://www.southcentre.int/wp-content/uploads/2013/05/RP41_Pharmaceutical-Innovation_EN.pdf.

[9] Knowledge Ecology International, "Several march-in and royalty free rights cases, under the Bayh-Dole Act". Available from https://www.keionline.org/cl/march-in-royalty-free.

This demonstrates that even developed countries regard compulsory licensing as a legitimate and relevant tool for enabling access to patented inventions and are adopting policies to advance the same.

Developing countries should also review their legal frameworks to facilitate issuance of compulsory licenses and government use authorizations. Guidelines should be adopted that enable relevant agencies of the government to grant compulsory license or government use authorizations to address public policy objectives. In this context, the Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents published by the South Centre is a useful reference material for developing countries.

The South Centre provides capacity building to policymakers, patent examiners and the judiciary to promote the alignment of policies on intellectual property with health and other development goals (please go to https://ipaccessmeds.southcentre.int/).

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