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BIO is deeply concerned with the Commission's initiative to revise its compulsory licensing (CL) legislation. The proposal of a revised CL regime suggests that the envisioned new framework remedies a dysfunctional system, despite no objective evidence that the existing regime is inadequate. Lacking justification for the introduction of this legislation, the proposal accomplishes nothing else than to breathe oxygen into a global debate which misguidedly characterizes IP rights as a barrier to access rather than as an enabler of innovation.

The decision to prioritize legislation weakening IP rights in this post-pandemic context - and amid an ongoing debate at the WTO on the waiver of IP rights - sends a negative signal to the global community of biotech researchers and investors regarding the attractiveness of the EU for cutting-edge R&D and investment. This proposal runs counter to, and serves as a distraction from, the EU's more ambitious goals to accelerate innovation and promote investment in the life sciences.

Not only is this legislation unnecessary and bad policy, the concept of a Union CL and certain provisions clearly run afoul of TRIPS. For example, the waiver of regulatory data protection proposed in COM(2023)192 violates Art. 39.3, and the provisions on remuneration are inconsistent with Art. 31(h).

CLs are avoidable and, as a matter of last resort, should be made through fair and transparent processes involving all stakeholders. Nevertheless, the proposal establishes no judicial review of any of the key stages of a CL - such as the constitution and role of the Advisory Body, as well as the procedure to determine a CL and levy fines for failure to adhere to the terms of a CL. Compounding this issue, the legislation is vague on key processes and terminology and deviates from international norms by focusing on a CL for products, which may be covered by several patents held by different entities, as opposed to patents. Furthermore, no compensation is provided if a CL has been wrongfully granted, violating the principle of equal enforcement.

Accordingly, an independent judicial review covering all phases of the CL is necessary to ensure rule of law and the right for all parties to be heard - a core tenet of EU law as enshrined in Article 2 of the Treaty of the EU. A CL decision ultimately made with the involvement of impartial courts would enable access to timely judicial review and the right to an effective remedy according to Art. 47(1) EU CFR.

BIO also strongly encourages the Commission to expressly exclude transfer of know-how or trade secrets from the legislation. Art. 13, for example, suggests an obligation to transfer technology to a company benefiting from a CL. The proposal creates a mechanism to levy fines on entities for

failure to comply with the terms of the CL and the imposition of fines if IP rightsholders fail to cooperate in good faith. It is of significant concern for the Commission to support legislation that envisions forced collaboration, subject to monetary fines for lack of cooperation, in a scenario where the EU unilaterally decides that a CL is merited. Furthermore, Art. 14 entitles the Commission to modify or complement with “additional measures” a CL under certain conditions, seeking broad authority to direct the way in which private parties collaborate, which presents concerns around how trade secrets and regulatory data will be protected.

Voluntary collaborations pre- and post-COVID have promoted greater access and eliminated any serious, fact-based policy discussion around the need for compulsory licensing. An entire legislation aiming at facilitating compulsory licensing with the added provisions to levy fines against IP rightsholders for failure to support the success of a CL goes too far and solves no legitimate, objectively demonstrable public health need. Rather, this proposal only upsets the delicate IP ecosystem that enables innovation and promotes economic growth.