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By electronic submission

Docket ID: PTO-C-2023-0019
Office of Policy and International Affairs
United States Patent and Trademark Office
Department of Commerce
Washington, D.C.

BIOTECHNOLOGY INNOVATION ORGANIZATION

Comments re: WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on text-based negotiations scheduled to begin in 2024 at the World Intellectual Property Organization (WIPO) Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources (GR), Traditional Knowledge (TK), and Folklore (Traditional Cultural Expressions).[1] BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all fifty States.

BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. Most of its members are small and medium sized enterprises (SMEs) that currently do not have products on the market. All of BIO's members, but particularly the SME cohort of members, rely heavily on the strength, scope, and reliable enforcement of their intellectual property (IP) to generate investments needed to develop and commercialize their technologies through collaborations.

The business models for biotechnology-based solutions are built on collaborations among universities, small biotechnology companies, venture capital and larger private company partners. The collaborative agricultural and pharmaceutical biotechnology industries particularly rely heavily on patents and regulatory data protection for legal certainty needed to attract investments. The development of a single biotechnology product in these sectors often takes scientists more than a decade to commercialize, and hundreds of millions (and in the healthcare sector more than a billion) of dollars of capital investment, a significant amount of which comes from private sources.[2]

Biotechnology product development is fraught with high risk – most researched biotech therapies fail to ever reach the marketplace. In addition, while biotech health inventions are entitled to the same patent term as all other inventions − twenty years from the time they are filed – they face the additional hurdle of a rigorous pre-launch regulatory review processes during which they may lose between eight to ten years of the patent life. In agricultural biotechnology, following regulatory approvals in cultivating countries such as the United States, the path to market is also often delayed due to asynchronous approvals in markets that import U.S. grain, such as Europe, Mexico, and China, thus further eroding patent life.

Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe that there will be an attractive return on their investment. Patents and regulatory data protection provide this assurance. According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs reported that potential funders, such as venture capitalists, angel

[1] 88 FR No. 204, October 24, 2023, at 73003.
[2] Private Sector's Critical Role in Biomedical Innovation", Cost & Value of Biopharmaceuticals - https://www.bio.org/toolkit

investors, and commercial banks, indicated patents were an important factor in their investment decisions.[3]

Without strong and predictable patent protection, investors will shy away from investing in biotech innovation, and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society. Strong and predictable IP systems cultivate partnerships around the world, enhance knowledge sharing, support the entrepreneurial journey, and ultimately ensure that innovation is resourced and funded so that technologies with the potential to deliver better care for patients and products for consumers are developed. Legal certainty in the acquisition and enforcement of patents is therefore critical to research and development efforts needed to deliver promising biotechnology solutions to humanity.

Patent Validity Should not be Affected by a New Disclosure Obligation

Member states of the World Intellectual Property Organization (WIPO) will begin in 2024 negotiations at a Diplomatic Conference (Dip Con) for an "international instrument" imposing a new disclosure obligation for patents involving genetic resources (GRs) and associated traditional knowledge (TK).[4] This would be a separate obligation from the existing substantive patent disclosure requirements that valid patents must adequately describe an invention in sufficient detail to enable persons of ordinary skill in the relevant technology to make and use the claimed invention.

The current basis for the IGC negotiations is a 2019 "chair's text"[5]. During a "Special Session" of the relevant WIPO committee, however, member States tabled proposals that would alter the scope and other elements of the instrument. Many of those proposals reflect positions taken by countries over the last 20 years of discussions at the IGC and are reflected in the Federal Register Notice that prompted these comments. While not agreed upon during the "Special Session", the proposals made in 2023 will likely be raised and considered during the Diplomatic Conference.

Proposals for the content of a new mandatory disclosure requirement include: the country of origin of the GRs and associated traditional knowledge (ATK); the source of GRs; chain of custody of the GRs; evidence of compliance with prior informed consent requirements of country or countries of origin.[6] All these terms are subject to varying interpretations that will necessarily increase legal uncertainty in enforceability of implicated patents.

To ameliorate this problem, the "instrument" should explicitly establish that the new disclosure requirement is a correctable formality not a substantive patentability requirement on the merits of

[3] Graham, Stuart J. H. and Sichelman, Ted M., Why Do Start-Ups Patent? (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008. Available at SSRN: http://ssrn.com/abstract=1121224. See also, Pugatch, "Building the Bioeconomy, Sixth Edition, 2019, at 14; available at: https://www.pugatch-consilium.com/reports/BIO%202019%20report_final.pdf.
[4] WIPO General Assembly July 2022 Decision to initiate Diplomatic Conference, available at: https://www.wipo.int/export/sites/www/about-wipo/en/assemblies/docs/brochure_a63_list_decisions.pdf; Pages 7-9.
[5] Chairs Text accessible at: https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_ss_ge_23/wipo_grtkf_ic_ss_ge_23_2.pdf.
[6] See, 88 FR No. 204, October 24, 2023, at 73005.

the claimed invention.[7] Shortfalls in complying with the new disclosure obligation should not impact in any way the validity or enforceability of patents.

In addition, we strongly oppose any attempt to link non-compliance with disclosure obligations as a basis for potential issuance of a compulsory license.

Legal Uncertainty from Ambiguous Content Obligations and Digital Sequence Information

Uncertainty caused by the phrases proposed as the disclosure content identified above can be illustrated with the term "source". There is no agreed definition of the concept of "source."[8] The simplest, most literal definition would be the vendor or individual from whom the resources were directly accessed. Many proponents of the disclosure requirement, however, would also include the country providing the resources (perhaps indirectly through a third party), countries of origin,[9] or even "traditional" countries of origin, i.e., those countries where the resources historically are found and where the resources have some cultural or other ties to that country. In addition, many inventions may involve many different resources that can come from different "sources". Tracing the relevant "sources" would be difficult, and at times impossible, to accomplish. Also, if a resource is a commodity made freely available, it may be difficult or impossible to know the required "source," assuming disclosure is required in those instances. Making failure to comply a ground to reject/revoke a patent adds a wholly disproportionate sanction to a the inherently uncertain requirement.

Proponents of a new disclosure obligation in patent applications allege that these requirements are needed to ensure benefit sharing or to eliminate "bio-piracy" and "unjust enrichment" of owners of patents on inventions arising from illegitimately obtain resources. There is little, if any, tangible evidence to support these arguments. Moreover, "disclosure of source" or country of origin requirement, or the other suggested disclosure content are backward-looking requirements imposed well after the "access" to GRs and associated TK takes place. There can be significant uncertainties in "tracing" resources because many patent applications are filed years after initial sourcing.

In addition, lack of clarity around how access and use of Digital Sequence Information (DSI) is to be treated within the text creates great uncertainty and exposure to biotech firms. Most biotech firms do not engage in *in-situ* bioprospecting. Rather, BIO members largely rely on DSI in the development of innovative biotech products. DSI is reviewed and studied, often without knowledge or ability to obtain knowledge of the geographic or origin of the sequence

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[7] This outcome may be required by the TRIPS Agreement which requires that "patents shall be available for any inventions, . . . in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." TRIPS Article 27, Paragraph 1.

[8] *See, e.g.*, Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and Tanzania, *Doha Work Programme – The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, IP/C/W/474 (July 5, 2006). The proposal would require applicants to disclose "the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin." It is not clear which of these concepts would be the "source." *See also* Switzerland, *Further Observations by Switzerland on Its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, IP/C/W/433 (Nov. 25, 2004). It is noted that the "concept of source" is broad and may include "primary" and "secondary" sources that a patent applicant may be required to disclose.

[9] CBD Article 2 defines "country of origin of genetic resources" as "the country which possesses those genetic resources in *in-situ* conditions.

information and then these sequences are studied and often altered to drive R&D efforts. In some instances, chimeric sequences – sequences that are combined from multiple sources and that may be entirely novel and not found in nature – may have beneficial characteristics for R&D and product development purposes. Our companies leverage hundreds and thousands of sequences to drive research efforts making compliance with a potential patent disclosure obligation entirely impossible.

Sanctions of patent invalidity or unenforceability would undermine reliability of the patent system for investors and inventors. It would also undermine the often-cited goal of ensuring benefit sharing. If a patent is revoked or rendered unenforceable, competitors with no connection to "holders" or "providers" of the resources at issue could freely practice and profit from use of the invention without obligation to the "holder" or "provider" of the GR or ATK. An explicit provision in the text ensuring that countries could not invalidate patents or render them unenforceable for shortfalls in compliance with the new disclosure obligation would avoid the undesirable results of legal uncertainty and elimination of a potential source of benefit sharing.

Legal Uncertainty Concerning When an Obligation Arises

Additional uncertainty is created by ambiguity in the definition for an appropriate "trigger" for when a disclosure obligation would arise. Current proposals refer to situations when the invention "concerns," "is derived from," "is developed with," "is directly based on," the relevant genetic resources.[10] All of these terms are subject to widely varying interpretation and would leave patents at risk. It is not clear how to sufficiently define such a relationship that would trigger the requirement but would also give certainty to applicants.

There is also a problem of multiple "sources" for many inventions – i.e., identical biological resources may be sourced from several sources requiring a specific "regime" to determine the appropriate "source" to disclose. In addition, many countries may "claim" to be the rightful source of a particular genetic resource, even if the source is directly and legitimately obtained through a vendor or individual in a third country. Even where the patent applicant is aware of this claim, it makes the appropriate country to disclose unclear. Here again the negative consequences of legal uncertainty can be diminished with an explicit clause in the agreement ensuring that non-compliance will not result in invalidation of patent rights.

The legal uncertainties could lead to significant litigation globally, and in the U.S., on validity of patents for failure to meet a disclosure requirement without any benefit to preserving patent quality and underlying patent validity concepts such as novelty, non-obviousness, enablement, and written description. The litigation challenges would be difficult to manage for biotech firms of all sizes, but would have a disproportionate impact on small- and medium-sized biotech firms, which account for the majority of the innovative biotech pipeline. The costs and risks associated with seeking patents globally will increase dramatically, raising the costs and risks of an already inherently risky and cost-intensive research sector.

[10] 88 FR No. 204, October 24, 2023, at 73005.

BIO is also very concerned about the extent to which signatory states will have broad discretion to determine consequences for potential breach of disclosure requirements. Legal uncertainty will be exacerbated by diverging national patent disclosure obligation standards.

Conclusion

A new disclosure obligation on GRs and associated TK is not warranted and do not result in any demonstrable benefits, rather, these obligations would create significant legal uncertainty, raise the costs of biotech research, and have the potential to undermine U.S. competitiveness and leadership in the life sciences. The proposed attributes of a new disclosure requirement will create undesirable legal uncertainty. There is no evidence that this disclosure requirement would lead to fulfillment of stated objectives and we therefore strongly object to this new requirement. If a new disclosure requirement were to result from the diplomatic conference, it should be clear that non-compliance should not result in invalidation of otherwise lawfully granted patent rights.

Furthermore, as a non-signatory to the Convention on Biological Diversity (CBD), proposed patent disclosure requirements could inadvertently place CBD- type Access and Benefit Sharing (ABS) Obligations on the U.S., a non-signatory to the CBD. In addition, the patent disclosure requirement effectively amounts to a backwards looking "track and trace" mechanism for ABS purposes. With ongoing discussions at the CBD on possible financing mechanisms for ABS that may not require a "track and trace" system, we question this false and manufactured sense of urgency of determining a patent disclosure requirement at this WIPO Diplomatic Conference - an issue loaded with legal and practical uncertainties, which, as aforementioned, has been debated for over twenty years. BIO, therefore, also strongly encourages the USPTO to question the urgency of this debate given ongoing CBD discussions and the long list of technical and legal uncertainties with the proposed patent disclosure requirement.