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WTO Side Event

RESTORING AND ADDING TO THE TRIPS BALANCE

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The Basic Premise of Patent Law

*This Nation's patent laws reflect "a carefully crafted bargain that **encourages both the creation and the public disclosure** of new and useful advances in technology." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). In exchange for disclosing their inventions, inventors are granted the exclusive right to those inventions for limited times. *Ibid.* That exchange—**disclosure in return for a period of exclusivity**—is the "**quid pro quo**" of patent law. *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944).*

TRIPS (MOSTLY) REFLECTS THE PATENT BALANCE

Art. 29.1

*Members shall require that an applicant for a patent shall disclose the invention in a manner **sufficiently clear and complete for the invention to be carried out by a person skilled in the art** and may require the applicant to indicate the **best mode** for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.*

PATENT LAWS/TECHNOLOGY UNDERMINE THAT BALANCE

- **Disclosure requirement applies only at the date of filing**
– making of the claimed invention but **not commercial scale**
- **Elimination of best mode** (otherwise kept a trade secret) disclosure failures **as a basis for invalidation**; also “best mode” is tied to date of filing the application so inadequate
- **No obligation to supplement** disclosure during patent term
- **Most important modern technologies (e.g. biologics) require extensive trade secrets/know-how** to produce
- **No obligation to disclose to public** regulatory information developed to demonstrate safety and effectiveness
- **Effectively undermines Art. 31 compulsory licenses and other TRIPS exclusions or limitations**

RECOMMENDATION 1

- **Adopt a more robust patent disclosure requirement**, including trade secrets needed to commercially practice or to obtain regulatory approval for the invention as commercially supplied
- As part of the new disclosure requirement, **include a duty to update the disclosure** with commercial-scale production information, know-how, and trade secrets

TRIPS *IMPLICITLY* PROHIBITS RETALIATION FOR USING FLEXIBILITIES

- **TRIPS contains carefully balanced provisions**, particularly “exceptions and limitations,” in order to assure its **Article 7 objectives** (“*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology*”) and **Article 8.1 principles** (“*Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement*”)
- Granting permission (“**Members ... may**”) implies the exercise of permissive authorities will not be punished

RETALIATION AGAINST USE OF TRIPS FLEXIBILITIES HAS BECOME ROUTINE

- **Trade sanctions threatened or imposed** for use of authorized Art. 31 patent compulsory licenses on medicines and other public health measures (penalties)
- **Trade negotiations premised upon accepting TRIPS-plus provisions** (denial of benefits of the TRIPS Agreement balance)
- **Other retaliatory measures** (e.g., conditional denial of subsidies and investments)

RECOMMENDATION 2

- Adopt an ***explicit* “peace clause” (non-retaliation provision** for the exercise of legal flexibilities in TRIPS reflecting the intended TRIPS balances) that **expressly prohibits retaliatory penalties and conditional denial** of expected benefits
- Provide for **unilateral, automatic waiver** of TRIPS obligations when such breaches of the peace clause occur, in addition to other TRIPS remedies
- Reinstate non-violation complaints in the WTO to assure that the TRIPS balance is preserved

TRIPS WAS NOT MEANT TO PROHIBIT PUBLIC HEALTH MEASURES

- **Article 8** statement above
- **DOHA Declaration** and subsequent modification of compulsory licensing for exports in **Art. 31bis** to assure that compulsory licenses can be used to **export** needed pharmaceuticals
- **TRIPS flexibilities (e.g., Art. 27.2 “ordre publique”)** to consider public health needs under national laws (e.g., “equitable” consideration of the “public interest” in denying **injunctive relief** in Art. 44 remedies)
- **Inherent national flexibility** to consider public health needs in areas not fully regulated by TRIPS – e.g., public access to regulatory approval data

RECOMMENDATION 3

- Adopt a more **explicit authorization** for national law to **override applicable TRIPS** requirements for **public health purposes**
- E.g., **explicitly authorize denial of injunctive relief for public health** (extending compulsory licensing without the need for pre-grant processes) – see Sarnoff South Centre paper https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3905488
- E.g., **explicitly authorize compulsory licensing of trade secrets** and know-how needed for public health production
- E.g., explicitly authorize **mandatory disclosure of data, trade secrets, and know-how for third-party use** as a condition of regulatory approval

TRIPS DID NOT ADDRESS GENETIC RESOURCES OR AI

- The Convention on Biological Diversity created an **access and benefit sharing regime** for genetic resources, and the World Health Organization has had to address it in pandemic negotiations
- The regime is **premised on sovereign ownership**, and thus does not adequately address global public health needs (nor propriety of ownership when GRs are owned by multiple countries) nor public health obligations to control pathogenic genetic resources
- Even **current efforts** to extend the ABS regime in the WHO **would continue technological colonialism and national self-interest** rather than **promote the global good**
- TRIPS does not **address artificial intelligence**, and its products are generally not patentable under national laws

RECOMMENDATION 4

- Adopt an **explicit ABS TRIPS regime** that recognizes genetic resources as the **common heritage of humanity** and requires **pooling of the benefits for prioritized worldwide distribution on the basis of health and other important public needs**, not on the basis of national origin of GR or technological development
- Adopt a **mandated exclusion** from patent and copyrights **for AI-produced inventions and works**, treating data ingestion as permissible (not prohibited) reproduction, and permitting national law investment protections for databases
- “We must, indeed, **all hang together** or, most assuredly, we shall all hang separately.”
-- Benjamin Franklin

SUMMARY OF RECOMMENDATIONS

1. ADOPT AN EXPANDED AND **CONTINUING DISCLOSURE OBLIGATION** TO ASSURE THE PATENT BALANCE IS ACHIEVED – EXCLUSIVITY IN EXCHANGE FOR PRODUCTION ABILITY
2. ADOPT A **“PEACE CLAUSE”/NON-RETALIATION PROVISION** FOR EXERCISING TRIPS FLEXIBILITIES, WITH AUTOMATIC, MANDATORY SANCTIONS (E.G., WAIVER OF OBLIGATIONS)
3. ADOPT AN **EXPLICIT EXCEPTION** FROM TRIPS PATENT AND TRADE SECRET/DATA PROTECTION RIGHTS FOR REFUSING INJUNCTIONS **FOR PUBLIC HEALTH NEEDS** AND AN **EXPLICIT COMPULSORY LICENSING AUTHORITY FOR TRADE SECRETS**
4. ADOPT AN **ACCESS/BENEFIT SHARING REGIME** BASED ON WORLDWIDE PUBLIC HEALTH NEEDS, NOT ON SOVEREIGN OWNERSHIP AND A **MANDATORY EXCLUSION FOR AI-GENERATED INVENTIONS AND WORKS**
5. **INCREASE GLOBAL COOPERATION AND LIMIT NATIONALISM**