NON-VOLUNTARY PATENT LICENSING IN INTERNATIONAL LAW

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WORKSHOP ON THE HISTORY, EXPERIENCES, AND PROSPECTS OF COMPULSORY LICENSING OF MEDICAL PATENTS IN THE UNITED STATES

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FROM VIENNA TO PARIS TO THE HAGUE

- Proposals for licensing without consent of patent owner debated in earliest meetings convened to consider international rules in Vienna in 1873
  - “The most notable decision of the conference was paragraph (f) of this resolution which recommended compulsory licensing of patents ‘in cases in which the public interest should require it.’” (E. Penrose, 1951)
  - Paris Convention for the Protection of Industrial Property of 1883 did not contain express rules when initially adopted – non-voluntary licensing rules added mainly by Hague Conference in 1925
  - Article 5A introduced broad authority to address abuse and to cancel for non-working

TOWARD LAKE GENEVA

- 1986 GATT Uruguay Round negotiations added substantive patent rules
  - Moved center of gravity from WIPO to new WTO
- WTO TRIPS Agreement included Article 31 on non-voluntary patent licensing ("Other Use Without Authorization of the Right Holder”)
  - Covers both government use and private third party licenses
  - Lays out substantive and procedural licensing parameters

THE 2001 DOHA AGREEMENT ON INTERPRETATION AND THE 2005 AMENDMENT

- Following Pharma confrontation with South Africa, WTO Members (including the US) in 2001 confirm rights under TRIPS, including para. 5(b): “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”
  - Follows HHS Secretary Thompson's threat to issue non-voluntary license for Bayer's Cipro in wake of Anthrax mailings
- Further negotiations amend TRIPS to add non-voluntary licensing predominately for export
  - US opts-out as importing country - inexplicably relinquishes right to address public health emergency in US

BASIC ARTICLE 31 RULES

- Licenses considered on individual merits, but governments may define criteria (e.g., essential medicine or formulary)
- Prior negotiation for license on reasonable terms and conditions within reasonable time – can set time limits
- Prior negotiation waived for public non-commercial use, emergency and extreme urgency
  - No search or prior notice required to accommodate 28 USC §1498 – US automatic government use license
  - Article 44.2 of TRIPS similarly accommodates US law regarding remedies – no injunction need be available

ARTICLE 31 CONTINUED

- Adequate remuneration in circumstances of case
- Non-exclusive
- Termination when conditions no longer present
- Review of grant and remuneration by independent authority available
- Conditions on remuneration and export relaxed for antitrust remedies
- Means to overcome blocking patents

NON-VOLUNTARY LICENSING PROVISIONS IN PATENT LAW THE GLOBAL NORM

- Included in technical advice of WIPO, World Bank, WTO, WHO, UNCTAD, etc.
- The United States an outlier in lacking express provision in Patent Act (though see 28 USC §1498, Bayh-Dole "march-in", etc.)
- Available as judicial equitable remedy (see, e.g., in antitrust, United States v. General Electric Co., 82 F. Supp. 753 (D.N.J. 1949), 115 F. Supp. 835 (D.N.J. 1953))
- US bilateral and regional trade agreements do not preclude – typically acknowledge Doha rights
- Other speakers addressing the political economy of situation