World Health Organization

Understanding patents and other intellectual property relevant to local production

Training workshop: Key enabling factors for successful local production & supply of quality-assured medical products

Local Production & Assistance Unit (LPA)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)
World Health Organization
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Trends in Local Production of Medicines and Related Technology Transfer

China policies to promote local production of pharmaceutical products and protect public health

Indian policies to promote local production of pharmaceutical products and protect public health

Studies on Local Production Prepared for WHO

- Enabling factors complex
- Technology a necessary element
- Intellectual property (IP) is the vessel holding technology
- IP can both facilitate and limit local production opportunity

Patent Fundamentals

- Patents are granted by national authorities (the patent office) to inventors of new and innovative technologies
- Technically patents are rights to exclude others from making, using selling or importing*products, or using processes
- Patents have a limited term, typically 20 to 25 years from the filing date, at the end of which the technology enters the public domain
- Patents on many pharmaceutical and other health technology products have expired, *allowing production of generic (or off-patent) products*

*Subject to rule on exhaustion of rights

The Patent Landscape

- Understanding the patent landscape for a product is an essential pre-condition to local production
- Patent applications and patents do not typically refer to a known drug, but rather to chemical compounds and biologic information (e.g. DNA sequences)
- This is a complex matter, though in recent years several institutions and groups have made such landscapes publicly available, including WHO and WIPO
- Some drug regulatory authorities maintain registers (e.g., the US FDA Orange Book) that associate patents with drugs

Options for Local Producer

- If a drug proposed for a local production is covered by a patent(s) there are various options
- Negotiating a licensing agreement with the patent owner
  - Whether feasible depends on various considerations, including potential value of local market to patent owner
  - Licensing agreements subject to a range of potential conditions
    - Geographical limitations common
- Production outsourcing and joint ventures more common than independent third-party licensing
  - Presents advantage of deeper technology transfer, but may limit local control

Options for Local Producer

- For certain important drugs, including to treat HIV, malaria, tuberculosis and hepatitis C, low-cost licenses available from Medicines Patent Pool. Licenses are limited in territorial scope, and local producer must have capacity for strict regulatory compliance
- Though not common, some companies have announced non-enforcement of patent policies, either globally (e.g., Moderna regarding COVID-19 vaccine during pandemic, willingness to license post-pandemic), or with country income level parameters (GSK for LDCs, voluntary licensing program for non-G20 LMICs)

WTO Flexibilities

- For LDCs, governments may elect to waive enforcement of patent protection until 2033 pursuant to WTO rules
  - Bangladesh has taken advantage of this flexibility
- All governments may issue compulsory (including government use) patent licenses, subject to compliance with WTO rules
- Virtually all national Patent Acts prescribe rules for issuance of compulsory licenses
- WTO rules operate at the international level – rules between Member states – whereas companies are governed by local law
  - For companies wanting to take advantage of WTO flexibilities, encourage governments to implement and provide options

Trade Secrets and other Technical Information

- Local production of health products requires (substantially) more than access to patents
- Typical commercial license in pharma sector includes data regarding production processes, testing protocols, assays, materials (including chemicals and sources of supply), equipment, computer software, packaging
- Access to data necessary or useful in seeking approval from national drug regulatory authority
- Much of this information may be held by originator as “trade secret”, i.e., commercially valuable information that holder has taken reasonable steps to protect

Regulatory Exclusivity

- Independent of patent status, originator may hold exclusive position on national market based on rights secured by virtue of registration
  - Minimum terms of market exclusivity a common requirement of trade and investment agreements (TIAs)
  - Based in WTO rule (Article 39.3 of TRIPS Agreement), but more restrictive than required
  - For LDCs WTO rule subject to waiver just as patents, but TIAs may not be subject to waiver
- Patents and regulatory approval may be linked by rules flowing from TIAs
  - Patent owner may be given right to block marketing approval based on patent

Biologics

- From patent perspective biologics generally subject to same rules as small molecule chemicals, including coverage of process technologies
  - Specific types of biologic information (e.g., DNA sequences) may be subject to “as found in nature” limitations
- Biologic market exclusivity rules may differ significantly from small molecule chemical rules, potentially inhibiting (or allowing) introduction of biosimilars
- Article 39.3 of TRIPS Agreement limited to “new chemical entities”, so biological materials and information not expressly covered, but TIAs may extend reach and confer extended term of protection – an evolving area
- Production process technologies and access to samples may be important to local production, and trade secret protection may be relevant to both

Summation

- For local production, patents may be either enabling (e.g., through licensing) or disabling (e.g., through blocking by patent owner)
- Many products no longer covered by patent protection and may be produced as generics
- LDCs benefit from wide exemption under WTO rules (for patents and regulatory exclusivity), but national rules govern
- MPP and other voluntary licensing (or non-enforcement) programs
- Compulsory and government use licensing typically part of national law
- Transfers of other important technical information may be covered by license, including trade secret data
- Attention must be paid to regulatory market exclusivity

Thank you

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