Intellectual Property and Technology Transfer for the Local Production of Health Products

WHO Local Production and Assistance Unit and the WHO Regional Office for the Western Pacific

Holistic Training Workshop on Key Enablers for Sustainable Local Production of Health Products in Western Pacific Region, Kuala Lumpur, Malaysia, November 19-21, 2024

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Technology a Key Component

- Technology is a key component of medicines production
  - It is part of a larger framework needed to build up a national or regional pharmaceutical sector
- Other essential components involve infrastructure (energy, water supply, transport), sustainable financing, addressable product market, adequate regulatory framework and human resource capacity
- This presentation to focus specifically on intellectual property and technology transfer, recognizing this is a "necessary but incomplete" part of a local production initiative

Medicines Technology Varies Widely

- The technology needed to manufacture medicines varies widely depending upon the type of product and whether it is a newer or older product
- Broad categories
  - Small molecule chemical or biological
  - Originator/protected or generic
  - Therapeutic, vaccine or diagnostic
- Technologies differ along value chains: API, formulation, packaging and labelling; biologic entity, formulation, fill and finish

Patent Licensing

- Newer products (in whichever category) are typically protected by "patents" and regulatory market exclusivity
- Licensing agreements for newer products typically cover patents to enable the technology recipient to produce and distribute without infringing exclusive rights of patent owner
- Newer products are often covered by more than one patent, and originator companies avoid identifying the full range of patents covering specific products
- Decision by third party to produce without a license requires assessment of patent landscape and undertaking "freedom to operate" analysis

Know-How Licensing

- Manufacture of medicines is a complex undertaking that requires substantially more knowledge and skill than provided by access to patent documents
- A typical medicines-related manufacturing license includes a range of "know-how" transfer that may encompass "trade secrets" as a form of IP, and other information that might otherwise be available in the public domain but challenging to assemble
- Non-patented know-how may involve production processes, component materials and potential suppliers, methods and materials used in testing and analysis at various stages of production, information regarding manufacturing-related computer software
- Licenses may also include hands-on training of manufacturing team

The Regulatory Dossier

- Commercialization of medicines requires approval by national or regional drug regulatory authority (DRA)
- Establishing scientific basis for initial approval, which typically includes clinical and manufacturing information, is expensive and time-consuming
    - Regulatory approval data for NCEs is considered a form of intellectual property under the WTO TRIPS Agreement – a complex subject
- Local producer "in-licensing" rights to produce and distribute benefits substantially from access to licensor's regulatory dossier and at least "right of reliance" to avoid duplication of efforts needed to establish scientific basis for approval
- Regulatory dossiers are often updated, and continuing flow of information should be included

Other Forms of IP and Confidentiality

- Commercialization (public or private) of medicines may also be affected by other forms of IP that should be included in a license, such as copyright on materials that may be included in packaging and information, trademarks that may (or may not) be used in association with commercialization, and in some cases design rights
- Confidentiality: IP licensing agreements often impose requirements on each party to maintain information exchanged between the parties confidential, except as may be necessary to comply with government regulation. Public interest groups object to the scope of some of these confidentiality restrictions, including with respect to pricing and distribution

Generic Medicines

- The term "generic" is customarily used to refer to a medicine that is no longer protected by patent or regulatory market exclusivity, and so may be produced by a party other than the originator without risk of infringing exclusive rights – “biosimilar” for a generic biological
- Generic producers do not require "in-licensing" of patents, but may enter into licensing agreements covering know-how which still may be closely held (e.g., production process, testing and analysis)
- The technical capacity of generic producers ranges across a spectrum, and less well-resourced generic producers may benefit substantially from information and training from producers with established capacities

Important Terms and Conditions

- Are the licensee's rights exclusive or non-exclusive, and with what (if any) territorial or other market restrictions (e.g., public or private)
- Level of stage and/or royalty obligations
- Who owns rights to improvements, and with what obligations for cross-licensing (e.g., grant back)
    - If licensor secures additional patents or otherwise improves the product technology, are rights to these patents or other technology automatically provided to the licensee
- Which party is responsible for securing regulatory approvals
- Compliance with good manufacturing practices and other quality control
- Does licensor retain any control over licensee pricing determinations
- Duration (term) of license and related obligations

Many Other Customary Terms and Conditions

- Allocation of tax liabilities
- Currency conversion
- Warranty of rights to technology and noninfringement of third-party rights
- Obligations of the parties with respect to adverse effects/injuries
- Indemnification obligations
- Rights of inspection/audit
- Governing law and dispute settlement
- Obligations on termination

The License Setting

- IP licensing is often part of a larger commercial relationship
- Direct investment, joint venture, product development, contract manufacturing, distribution, etc.
- Technology licensing as part of a larger agreement may include financing components, assignment of management responsibilities, progress reporting and benchmark requirements, shared distribution rights

Access

- Determining whether a particular IP licensing arrangement for local production will expand access to medicines, including on a more equitable basis, depends on specific circumstances – one solution does not fit all
- Local manufacturers must be financially viable to be sustainable
- Local producers face competition from foreign suppliers as well as from other local producers
- A mix of supportive government policies and local producer initiative is needed

Local Production and COVID-19

- The COVID-19 pandemic gave rise to great interest in local production, particularly of vaccines, as a means to promote more equitable access
- Establishing vaccine production capacity with new technologies such as mRNA takes time. New technologies such as lipid nanoparticle (LNP) encapsulation entail trade secret processes and are challenging to implement. Whatever role IP “as such” may have played during the pandemic, more comprehensive technology transfer solutions than avoiding infringement are needed

Thank you

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