Bridging Innovations: Technology Transfer for Sustainable Local Production

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Technology Transfer and “Local Production”

- Production of pharmaceutical products (therapeutics, vaccines, diagnostics) and medical devices is technology intensive
- Transfer of technology agreements are a routine feature of the pharma space

  In-licensing from developers, out-licensing to contract manufacturers (CMOs), cross-licensing among holders of complementary technologies
- “Local production” has both geographic and ownership connotations

  In context of improving national and regional public health security both elements important

  Concern that decisions by “remote” owners may not sufficiently take into account domestic effects

  Discussions about “transfer of technology” take on a developmental character

Technology Variables

- Pharmaceutical technology varies by product and process
- Small molecule or biologic; basic component; API/drug substance; formulation; fill and finish/packaging and labeling

  Less and more complex chemical and biological processes
- Substantial portion of global pharmaceutical product production is *not* based on patented innovation

  Commonly used statins, blood pressure regulators, anti-inflammatories, antibiotics, diabetes controls, etc. are generic with published pharmacopeia
- Core issue for local production of generics is whether it can be done cost-competitively (including government incentives)

Technology Transfer Conditions

- Prospective technology transferees require skill sets

  Sufficient familiarity with transferred technology to work out production issues that customarily require on-site adaptation

  Technology transfer licenses – including among sophisticated parties – usually include provision for technical support in implementation
- Some technology transfers require substantial know-how beyond rights to use IP; others do not
- API synthesis often involves complex series of steps; most producers purchase from bulk suppliers that are concentrated in a few countries

Transfer of advanced pharmaceutical technology

- Public health systems worldwide spend most on newer patented drugs
- Cutting edge innovation is expensive (including risk factors)
- The core issue for local production of “new” products is that originator model does not generally encompass licensing of patents (and related know-how) to non-affiliated third-party producers

  Distinguish from controlled supply chain licensing – e.g., contract manufacturers (CMOs)

  Atypical cases: Pfizer in-licenses BioNTech’s mRNA technology for Covid-19 vaccine and pays 50% of net revenues to BioNTech

What are alternatives?

- Develop your own technology

  An attractive idea but unrealistic for low- and middle-income countries where capital more limited and health sector requirements encompass many diseases for which leading edge treatments coming online

- Buy the company? Pfizer-Seagen ($53 billion oncology portfolio acquisition)
- Find patent-avoiding workarounds – Afrigen/Biovac and mRNA Hub; Egypt – HCV treatment (developed alternate production process following patent office rejection of originator sofosbuvir application)
- Access-oriented limited solutions: Originator out-licensing and MPP in-licensing (and sublicensing) of HIV therapies and recent portfolio additions

What are alternatives?

- Using “TRIPS flexibilities”

  Recognized legal mechanisms for overcoming patent barriers that have a role – must be implemented in and through national law

  Have seen limited use – politically controversial

  Lack cooperative elements of technology transfer agreements

- Adapting the “pharma model”

  Finding the right incentives to encourage voluntary licensing to local producers

What are the alternatives?

Pharma business modeling has focused on maintaining tight control over IP, production and distribution

Limited research so far on industry structures that employ local joint venture partners and licensing alternatives

- It is possible that a different model would leave LMIC health systems and local development better off, and pharma "at least not worse off"

- Special purpose "Pharmaceutical Technology Acquisition Funds"

Governments, multilateral institutions, foundations and/or private investors "purchase" new technologies from originators and license to local producers

Space for alternative structures and objectives

WHO Technical Support

- WHO Local Production Unit (LPA) can facilitate training in technology transfer licensing
- The WHO local production unit has developed a strategic assessment tool (SAT), a Biopharmaceutical Training Hub, and model sector development plans
- The Technical Advisory Group on Local Production and Technology Transfer (TAG-LPTT) assists the LPA with review of proposals and projects, and provides recommendations

Thank you!

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