Addressing Patent Barriers to Vaccine Development & Access

Plenary 3: Growing Developing Country Vaccine Manufacture

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Outline

• MSF’s vaccination work & access challenges
• Competition & DCVMs as critical market stimulator
• MSF research & findings on role of patents in vaccine development
• Strategies for competitors & broader community to address patent barriers
• Legal challenges / opportunities – PCV13 case study
• Conclusion
MSF’s vaccination work & access challenges

- 2016: MSF delivered ~6.57 mil doses, >30 countries
- Populations: conflict, natural disasters, no health system
- MSF’s main challenges:
  - High prices of newer vaccines
  - Products ill adapted for the conditions of use
  - Shortages or manufacturer refusal to sell
Competition as a critical market stimulator

Graph 2: Number of manufacturers (by type) and price, pentavalent vaccines purchased for Gavi-eligible countries.

Barriers to DCVM market entry include patents.

MSF research project: what role do patents play in vaccine development (PCV & HPV)?

Methods:
• Literature & patent reviews
• Interviews w/ 15 manufacturers & 5 gov/inter-gov/non-profit organizations in Brazil, China, India, US

Limitations:
• Restricted to patents
• Patents held by IFPMA companies
• Not a comprehensive patent landscape
• Only covered PCV & HPV vaccines
September 2017 MSF report shows that:

- There are more and more patents taken out during development of newer vaccines
- Patent applications use overly general language to maximize scope
- This can undermine follow-on development and competition
Patent barriers throughout the vaccine development process

- Many potential unmerited patents (lack of inventive step)
- No transparency
- Little legal and public health experience to overcome patent barriers
Strategies for competitors to address patent barriers

• **Prerequisite:** comprehensive patent landscape, FTO report (& country-by-country analysis)

• Licensing-in necessary technology
  – Costs; geographic restrictions; other restrictions; obligations (ex. ‘grant back’ obligations)

• Designing around necessary technology
  – Sometimes impossible; requires highly skilled technical team; time- & resource-consuming

• Challenging patents (eg formal patent oppositions, less formal submissions, other admin or legal procedures)
  – Risky; costly; lengthy & time-consuming
Strategies and recommendations for the collective community to address patent barriers

- More transparency in IP landscape (open databases)
- Improve national / international laws & policies
- Apply patentability criteria strictly – only new and inventive; no evergreening
- Robust access conditions in licensing and other agreements
- Challenge unmerited patents
- Support the use of IP flexibilities, including capacity building and guidance

A role for all companies, governments, UN agencies (WIPO, WHO, UNICEF), donors
Case study: patent barriers to affordable Pneumococcal Conjugate Vaccine (PCV)

- Duopoly market: Pfizer PCV13 & GSK PCV10
- PCV among most expensive vaccines resulting in major access barriers
- No competition yet despite promising pipelines

Pfizer composition patent may block PCV-13 competition, but patent lacks technical merits and can be challenged
Challenging Pfizer’s PCV13 composition patent in multiple countries

- **European Patent Office**: patent revoked after being challenged; Pfizer appealing
- **US**: ongoing post-grant review and inter-partes review to challenge its validity
- **India**: pre-grant opposition filed by MSF and local producer; patent granted (Aug 2017) & court proceedings continue
- **South Korea**: pre-grant, post-grant to challenge validity; now at SKr Supreme Court; MSF submitted amicus brief in support of opposition

**New Delhi/ New York, March 11, 2016** – Médecins Sans Frontières/Doctors Without Borders (MSF) has filed a “patent opposition” in India to prevent US pharmaceutical company Pfizer from getting a patent on the pneumococcal conjugate vaccine (PCV13), so more affordable versions can become available to developing countries and humanitarian organisations. This is the first time a vaccine (biosimilar) patent has been challenged in India by a medical organisation, with the goal of millions more children being protected against deadly pneumonia.
Conclusions

- Competition critical to sustainable and affordable vaccine access – DCVMs essential to competition
- General lack of consideration / documentation of patent barriers in R&D and resulting competition
- More feedback needed from manufacturers
- Patents increasingly an issue for development of newer vaccines
- Governments should set strict standards of patentability
- Unmerited patents should be challenged
- MSF will continue vaccine IP work for the benefit of our patients and others without access

Feedback on the report welcome
Thank you!