

Improving access to new vaccines: Regulatory, legal and R&D challenges and opportunities

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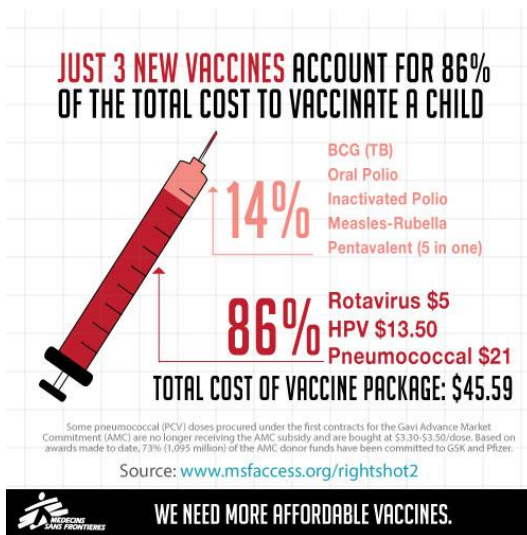
Outline

- MSF's vaccination work & access challenges
- DCVMs as critical market stimulator
- Regulatory opportunities
- Legal challenges and opportunities
 - PCV Case Study
- Research opportunities
- Conclusion



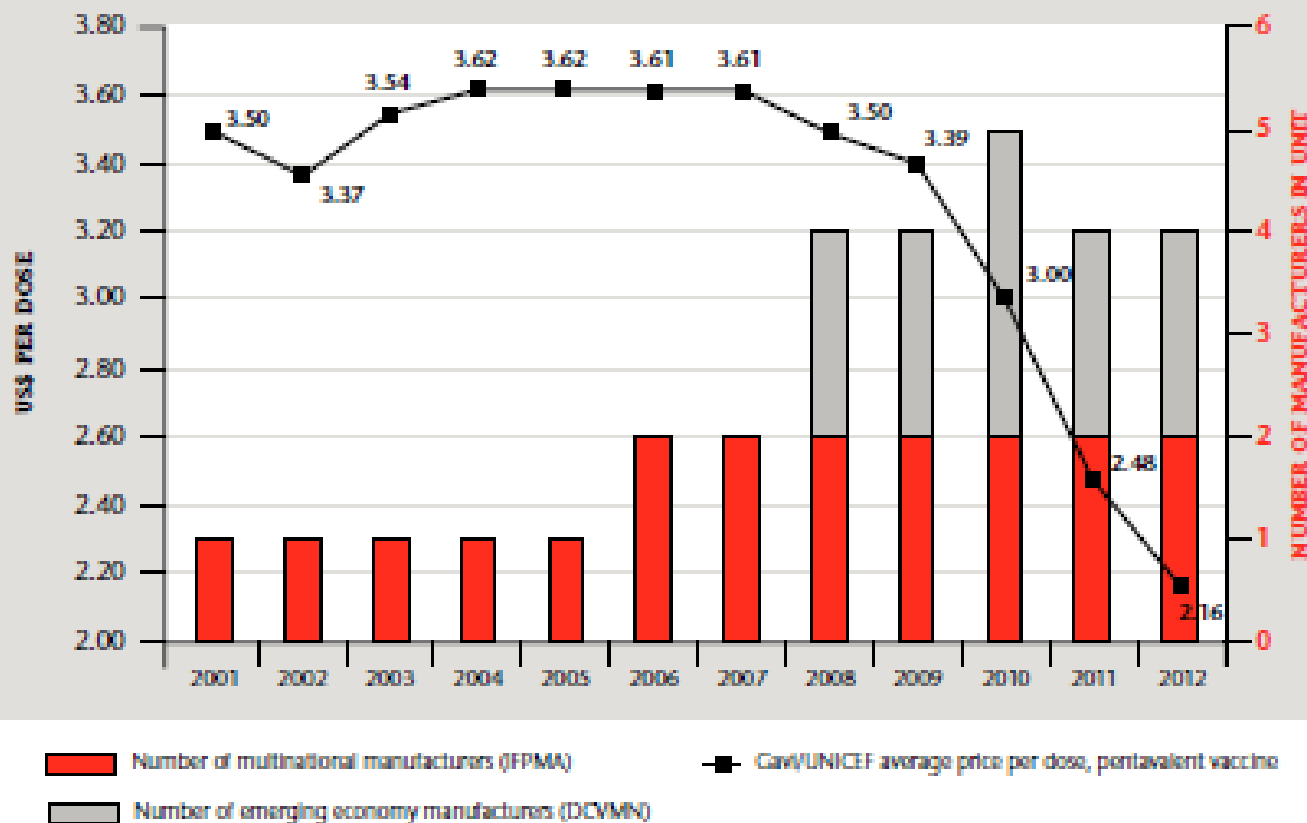
MSF's Vaccination Work & Access Challenges

- 2015: MSF delivered ~5.3 Mn doses, >30 countries
- Populations: conflict, natural disasters, no health system
- MSF's main challenges:
 - High prices of the newer vaccines
 - Products ill adapted for the conditions of use (e.g. cold chain)
 - shortages



DCVMs As Critical Market Stimulator

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

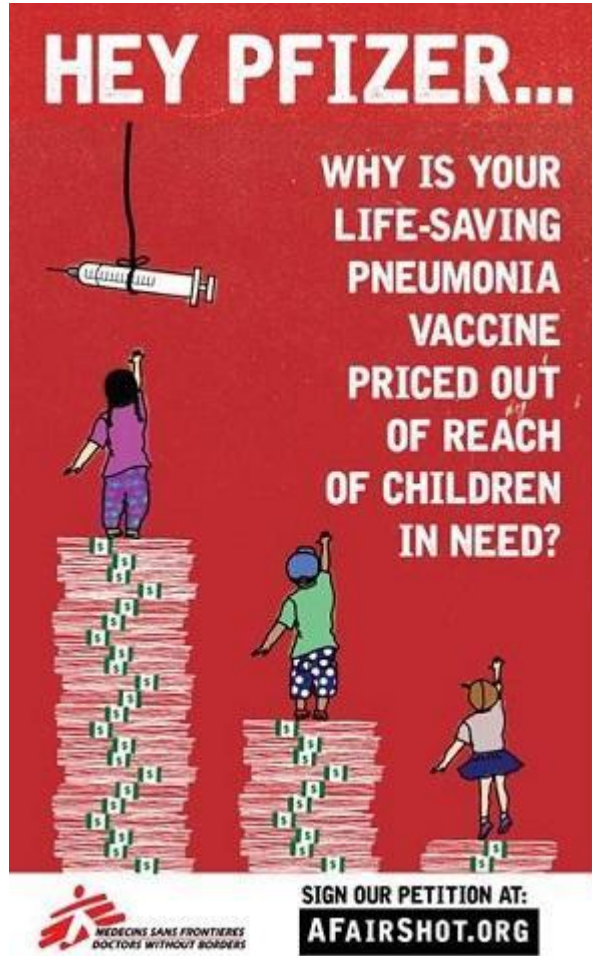


Sources:

UNICEF Supply Division^{21,28}

Source: <https://www.msfaaccess.org/content/report-right-shot-bringing-down-barriers-affordable-and-adapted-vaccines-2nd-ed-2015>

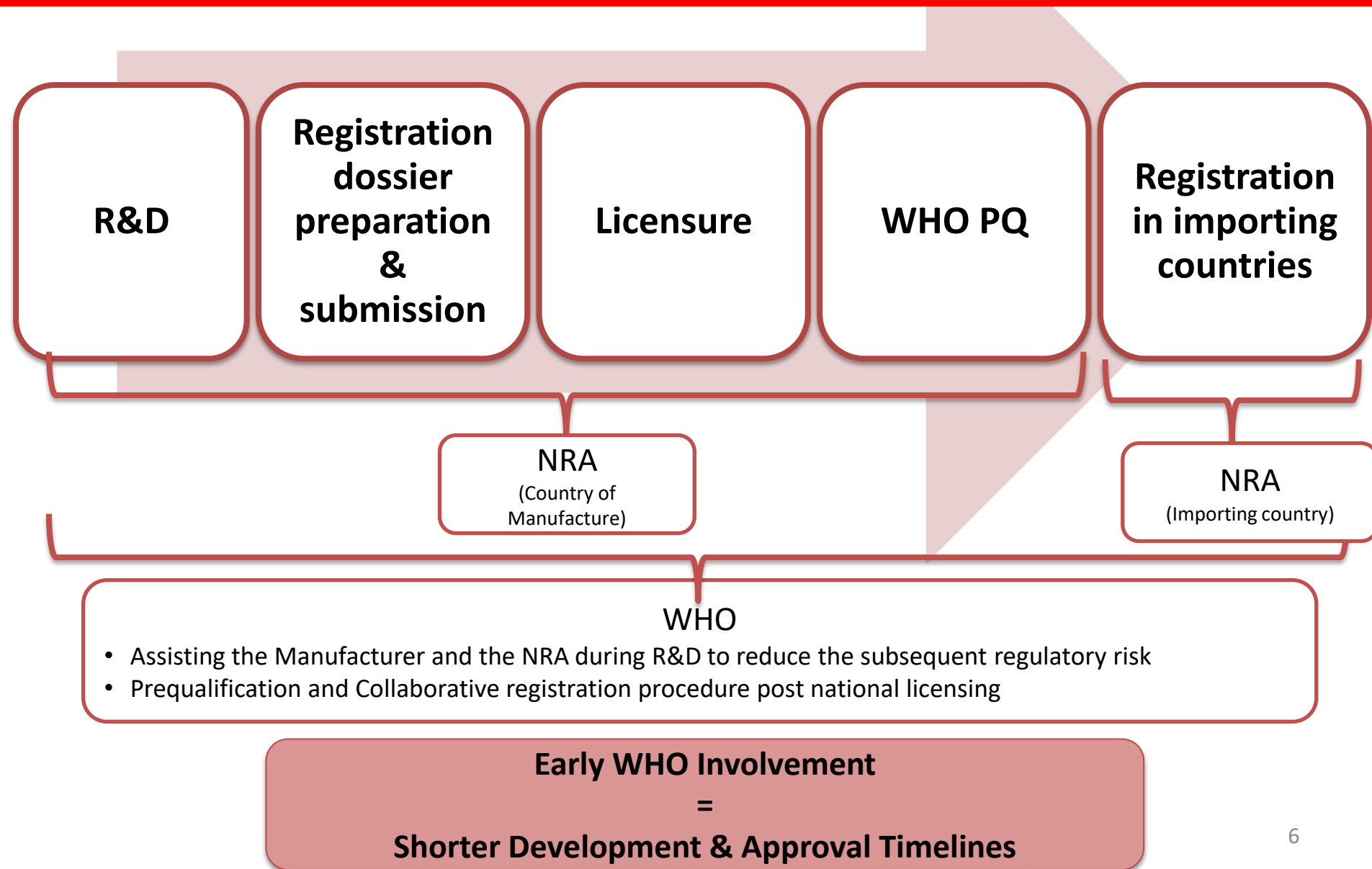
DCVMs: PCV and HPV pipeline



- Several DCVMs have PCVs and HPVs in their pipeline – two vaccines facing particular access challenges



Regulatory acceleration: Licensing & WHO PQ Processes



Opportunity: WHO Prequalification “Partner” Procedures

- **Regulatory task-shifting** through SRA-WHO collaboration
- Leads to WHO PQ based on an SRA assessment

– **EMA Article 58**

- Provide scientific and manufacturing expertise (Companies, WHO, NRAs) from LMICs
- Development and assessment of products for these markets
- So far mainly used by HIC manufacturers (Abbvie, ViiV, Sanofi, GSK)

– **Swissmedic** procedure for scientific advice and Marketing Authorisation for Global Health Products (MAGHP)

- Accessible to representatives of regulatory authorities in resource-constrained countries and the WHO

Opportunity: WHO Collaborative Registration Procedure

- A collaborative procedure between WHO and interested NRAs to **accelerate assessment and registration of WHO prequalified vaccines**
- Manufacturer submits the dossier in CTD or WHO's PSF format to NRA
- WHO gives NRA access to evaluation & inspection reports
- NRA to take a regulatory decision in 90 calendar days

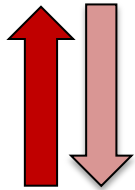
Source:

http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex08.pdf

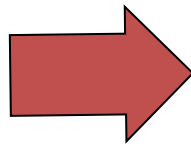
Regulatory Opportunities: Accelerate PCV Market Entry (lessons from MenAfriVac)

Stakeholders' Priorities

Priority: Increased national PCV introduction is a global health priority



Priority: Lowering the budgetary impact of PCV & Supply Security



MSF Access Campaign Proposition

- **The introduction of competition from DCVM** will reduce PCV prices
- **Optimising and Prioritising the Regulatory Process** for PCV licensing and WHO Prequalification will result in an earlier market entry
- **Adequate resources** need to be made available

Legal Challenges: The Role of Patents in PCV & HPV Vaccine Development



A Fair Shot for Vaccine Affordability

Understanding and addressing the effects of patents on access to newer vaccines

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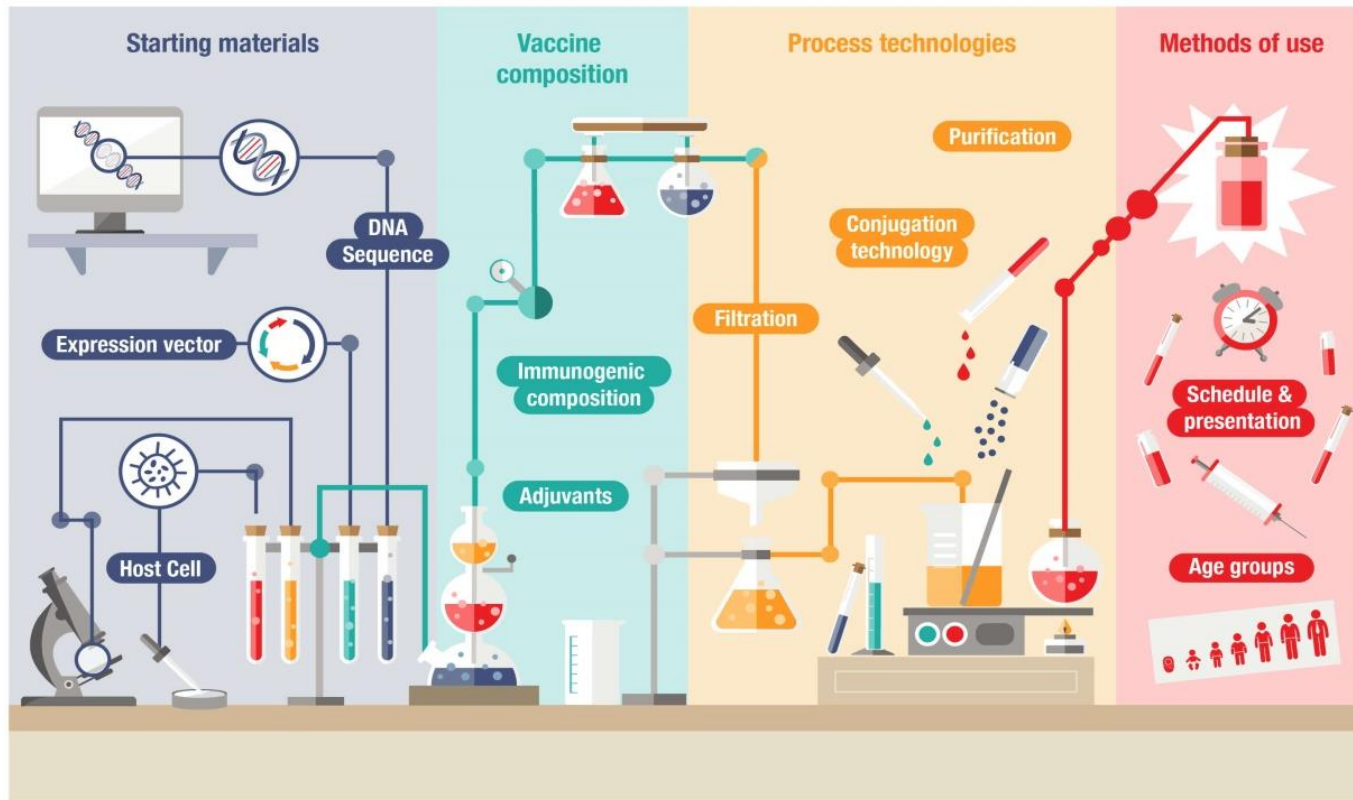
New **MSF report** shows that:

- There are more and more patents taken out during development of newer vaccines
- This can undermine follow-on development and price competition

www.msfaccess.org/vaccine-ip-report

Legal Challenges: Patent Barriers Throughout the Vaccine Development Process

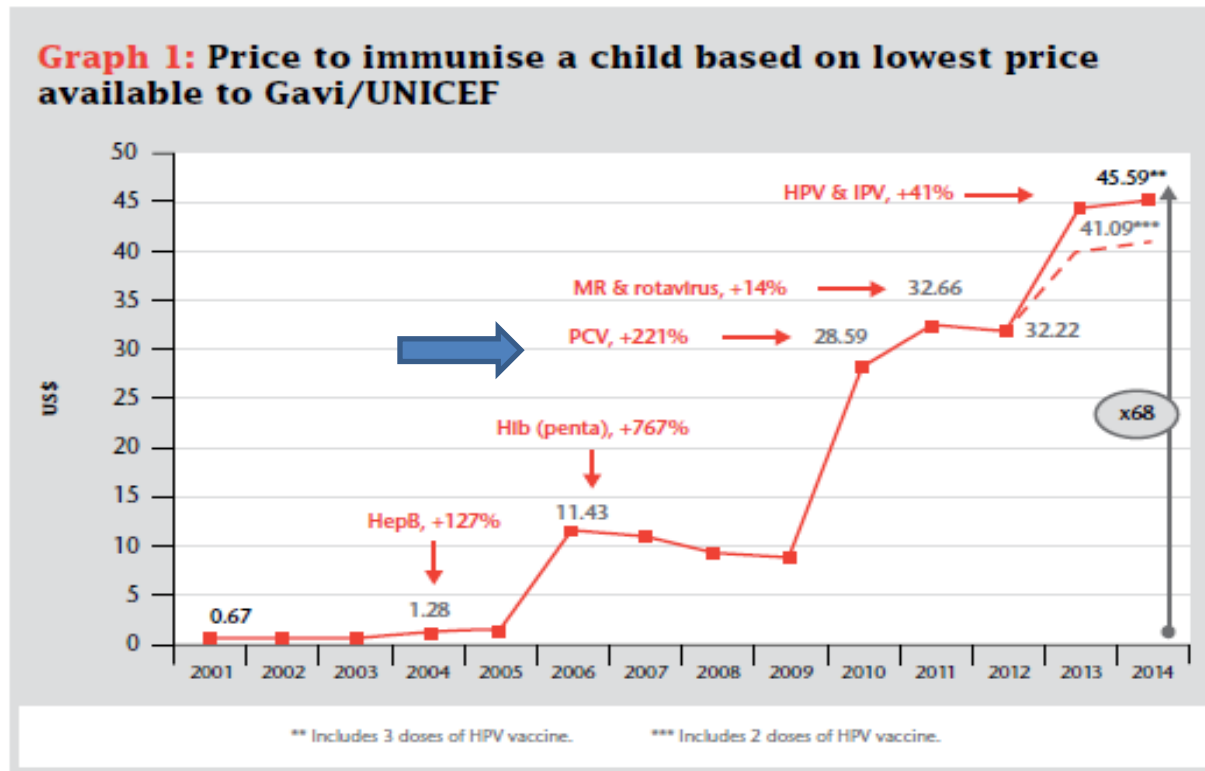
Figure 1:
Examples of Patent Barriers Throughout the Vaccine Development Process and Beyond



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

Case study: Patent barriers to affordable Pneumococcal Conjugate Vaccine (PCV)

- Duopoly market:
Pfizer PCV-13
GSK PCV-10
- PCV among most expensive vaccines
- No competition yet despite promising DCVM pipelines



Sources:

WHO routine Immunisation summary tables,⁹ Gavi,¹⁰ UNICEF Supply Division,¹¹ MSF *The Right Shot* 1st ed.¹²

Pfizer composition patent may block PCV-13 competition, but the patent lacks technical merits and can be challenged.

Challenging Pfizer PCV13 Composition Patents in Multiple Countries

MSF launches challenge to Pfizer's patent on the pneumonia vaccine in India, to increase access to more affordable versions



Opposition filed by MSF against Pfizer's patent on the pneumonia vaccine at Delhi Patent Office today.

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.

- **European Patent Office:** patent revoked after being challenged
- **India:** pre-grant opposition filed by MSF and local producer; court proceedings continuing
- **South Korea:** patent opposition by local company underway, MSF: amicus brief
- **US:** ongoing patent oppositions by US company

Strategies and Recommendations to Address Patent Barriers and accelerate Access

A role to play for DCVMs and all companies, governments, UN agencies (WIPO, WHO, UNICEF), donors

Apply patentability criteria strictly – only new and inventive; no evergreening

Challenge unmerited patents

More transparency in IP landscape, and in pricing (open databases)

Design around key technologies

Robust access and pricing conditions in licensing and other agreements

Support the use of IP flexibilities, including capacity building and guidance

R&D: MSF's Involvement in Optimising & Adapting (the use of) Existing Products

- Documenting needs and TPPs
- Use of vaccines outside the cold chain and advocacy for CTC relabelling
 - Tetanus Toxoid vaccine in CTC, Chad 2012
 - Cholera vaccine: Out of cold chain & self administration of first dose, Malawi 2016
 - Measles vaccine: Stability testing and modeling 2016/2017
- Interest in new delivery technologies
 - Microarray Patches with Measles vaccine



R&D: MSF's (exceptional) Involvement in Product Development

- **Rotavirus vaccine:**
 - MSF & Epicentre, Serum Institute India, Niger MoH
 - Phase 3 clinical trial of oral bovine rotavirus pentavalent vaccine (BRV-PV) that would be:
 - More thermostable (storage at 25°C)
 - Tailored to epidemiology of least developed countries (viral strains)
 - More affordable
 - <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1609462>



R&D: MSF's (exceptional) Involvement in Product Development

- **Ebola VSV EBOV vaccine:**
 - MSF & Epicentre, WHO, MoH Guinea, NIPH (Norway)

Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial (Ebola Ça Suffit!)



Ana Maria Henao-Restrepo, Anton Camacho, Ira M Longini, Conall H Watson, W John Edmunds, Matthias Egger, Miles W Carroll, Natalie E Dean, Ibrahima Diatta, Moussa Doumbia, Bertrand Drugeuz, Sophie Durauffour, Godwin Enwere, Rebecca Grais, Stephan Gunther, Pierre-Stéphane Gsell, Stefanie Hossmann, Sara Viksmoen Watle, Mandy Kader Kondé, Sakoba Kéïta, Souleymane Kone, Eewa Kuisma, Myron M Levine, Sema Mandal, Thomas Mauget, Gunnstein Norheim, Ximena Riveros, Aboubacar Soumah, Sven Trelle, Andrea S Vicari, John-Arne Røttingen, Marie-Paule Kieny**



Summary

Background rVSV-ZEBOV is a recombinant, replication competent vesicular stomatitis virus-based candidate vaccine *Lancet* 2017; 389: 505–18

Conclusions

- Availability does not necessarily lead to access
- Product profile must be suitable for use in target population
- Price is major barrier
- Competition from DCVMs critical to sustainable and affordable access
- Need to accelerate development and market entry by DCVMs of existing “high-value” vaccines
 - Use Regulatory and legal/IP strategies to overcome barriers
 - Priorities: PCV, HPV, IPV-containing vaccines, multivalent meningococcal conjugate vaccine
- MSF stands ready to support for the benefit of our patients and others without access



Thank you!