

Addressing Patent Barriers to Vaccine Development & Access

Plenary 3: Growing Developing Country Vaccine Manufacture

Global Vaccine and Immunization Research Forum (GVIRF)

20-22nd March 2018, Bangkok

Ms Kate Elder

Vaccines Policy Advisor, MSF Access Campaign



Outline

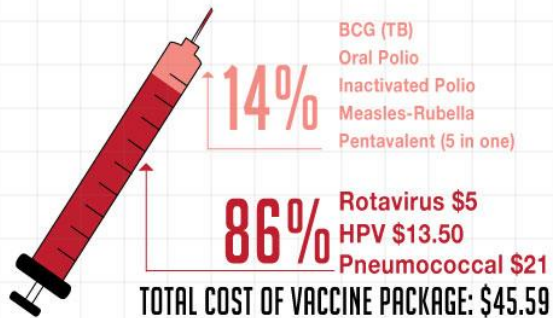
- MSF's vaccination work & access challenges
- Competition & DCVMs as critical market stimulator
- MSF research & findings on role of patents in vaccine development
- Strategies for competitors & broader community to address patent barriers
- Legal challenges / opportunities – PCV13 case study
- Conclusion



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

JUST 3 NEW VACCINES ACCOUNT FOR 86% OF THE TOTAL COST TO VACCINATE A CHILD



Some pneumococcal (PCV) doses procured under the first contracts for the Gavi Advance Market Commitment (AMC) are no longer receiving the AMC subsidy and are bought at \$3.30-\$3.50/dose. Based on awards made to date, 73% (1.095 million) of the AMC donor funds have been committed to GSK and Pfizer.

Source: www.msfacecess.org/rightshot2



WITH MANY VACCINES, YOU HAVE TO MAKE SURE THEY NEITHER OVERHEAT NOR FREEZE.

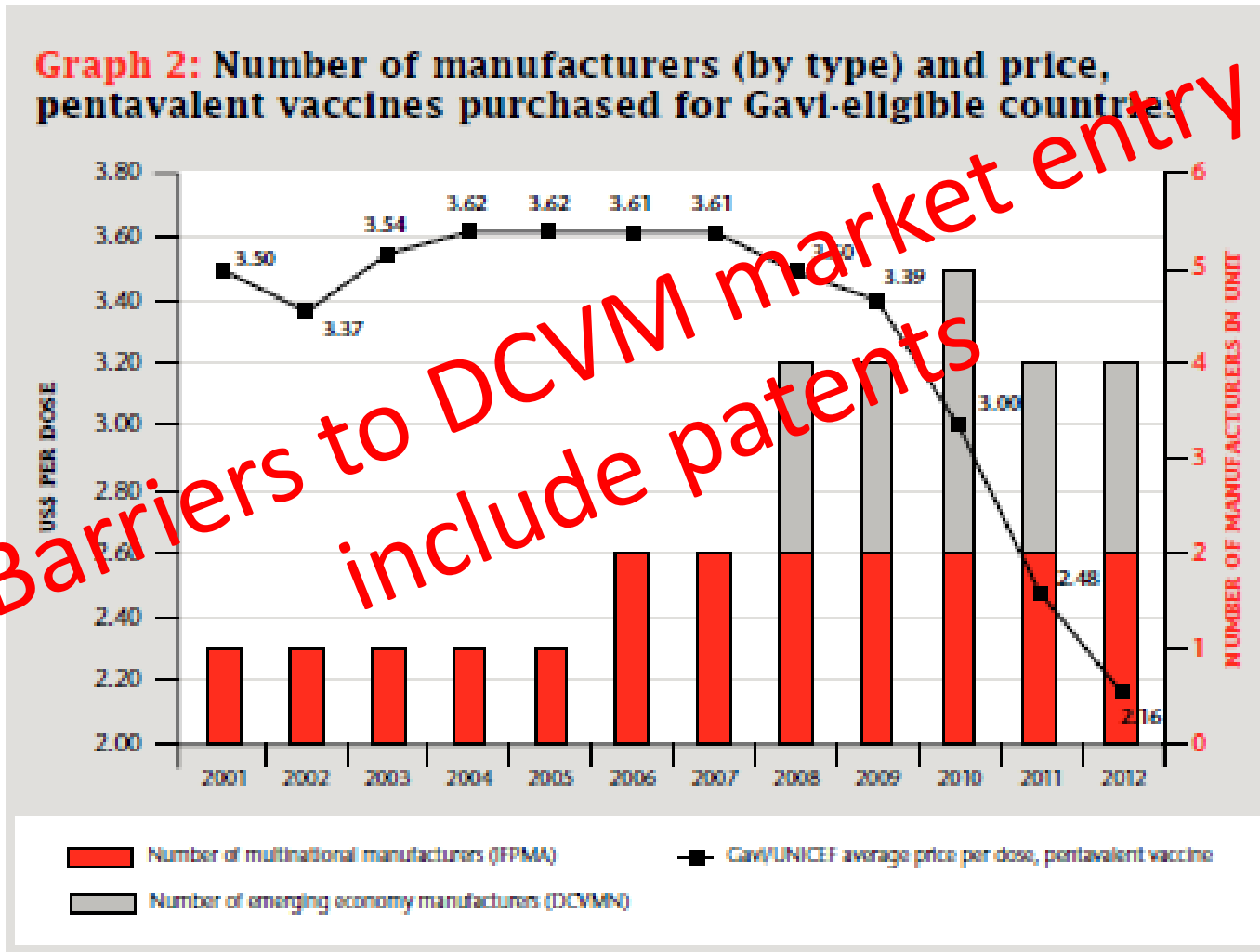
NOT TOO HOT

NOT TOO COLD

BOTH CAN LEAD TO VACCINES NEEDING TO BE DISCARDED.

WE NEED VACCINES THAT ARE EASIER TO USE TO REACH KIDS IN REMOTE PLACES

Competition as a critical market stimulator



Sources:
UNICEF Supply Division^{21,22}

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

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

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

September 2017

MSF Access Campaign
Médecine Sans Frontières
Rue de Lausanne 78
CP 118-DH-1211 Genève 21
Switzerland

T + 41 (0) 22 849 84 06
F + 41 (0) 22 849 84 04
E access@msf.org | www.msfaccess.org
T twitter.com/MSF_access
F facebook.com/MSFaccess

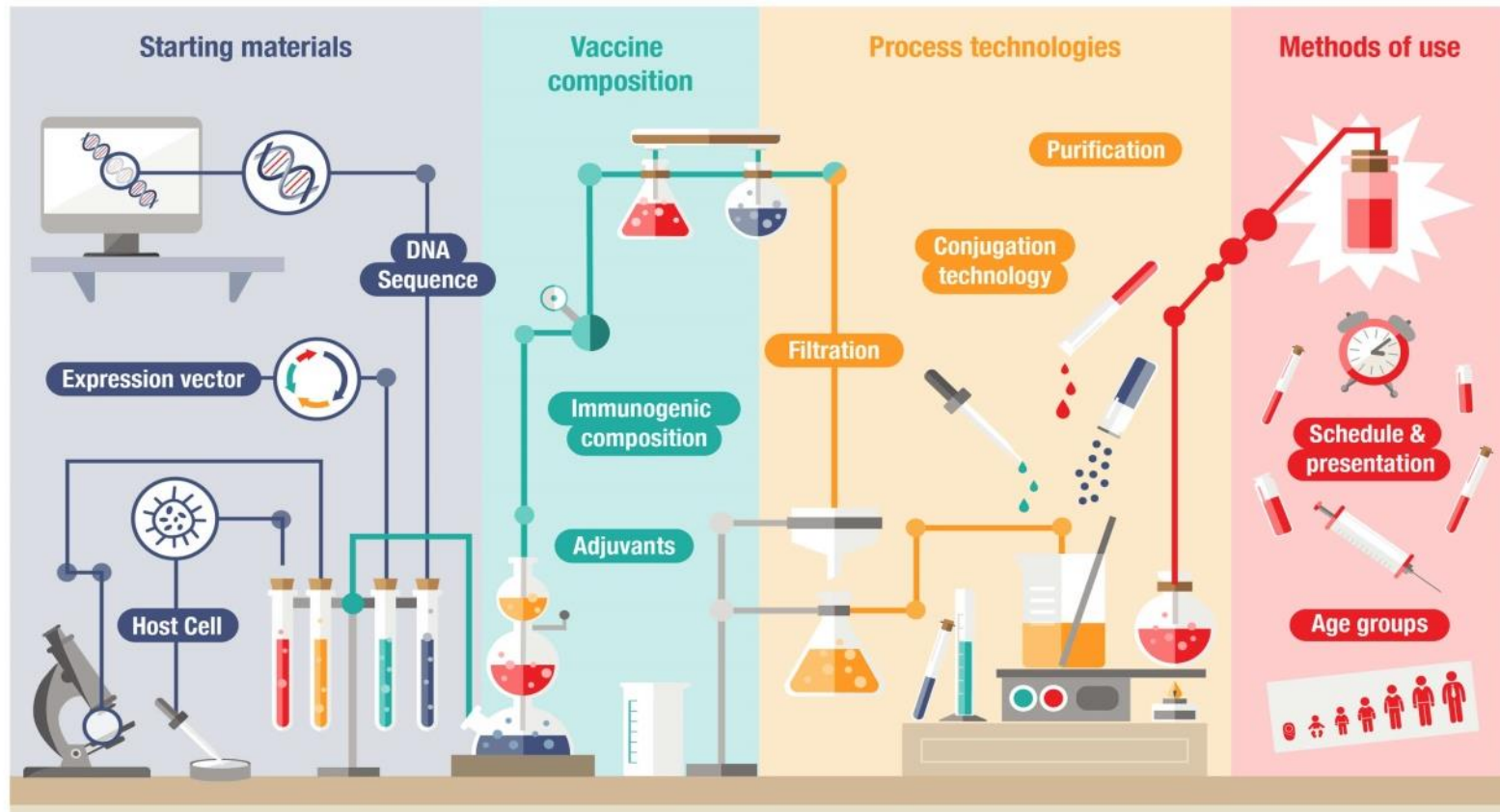


September 2017 **MSF report** shows that:

- 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

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

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

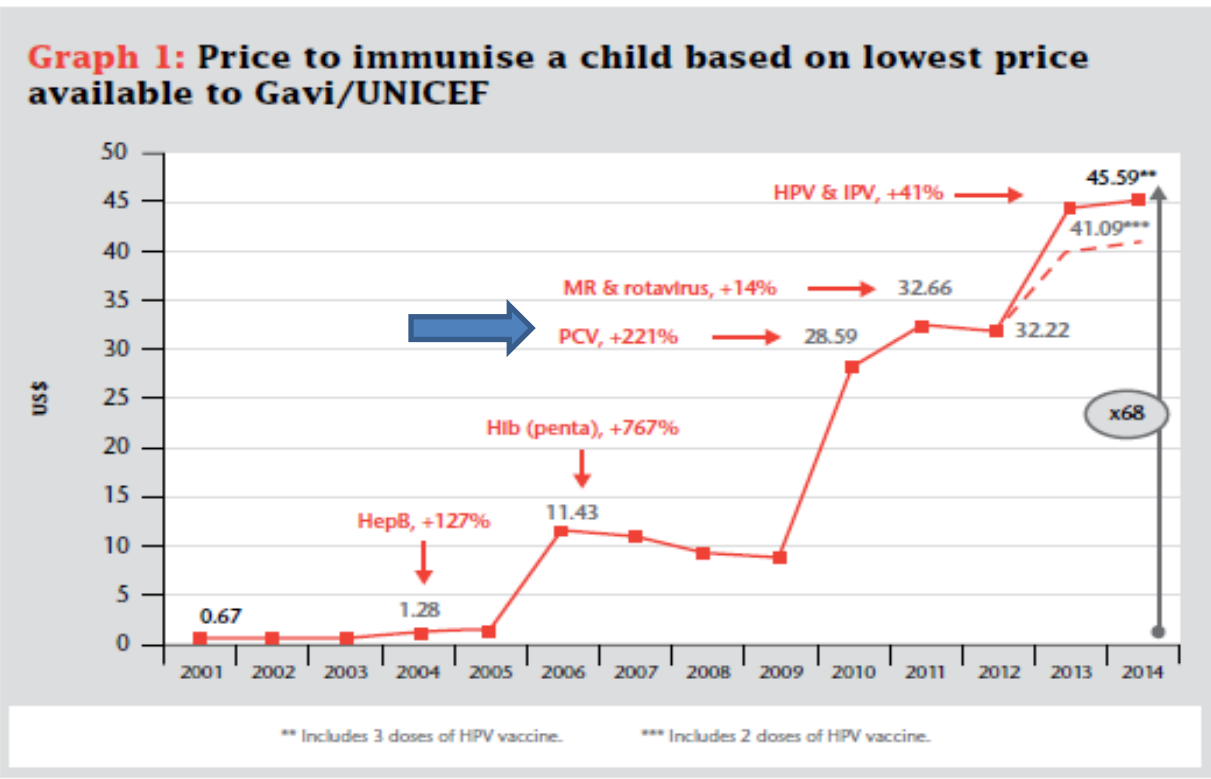
**Challenge
unmerited patents**

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



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 patent lacks technical merits and can be challenged

Challenging Pfizer's PCV13 composition patent in multiple countries

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

**INTELLECTUAL
PROPERTY INDIA**
PATENTS / DESIGNS / TRADE MARKS
GEOGRAPHICAL INDICATIONS



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; 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

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!