Intellectual Property Rights & Vaccines in Developing Countries

by

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Developing Country Vaccine Manufacturers Network
DCVMN

- an overview

- Formed in November 2000.
- 7 members steering committee.
- Full members are developing countries vaccine manufacturers (public and private) that are WHO pre-qualified for sale by UN agencies, or that have taken demonstrable steps towards doing so, located in countries with fully functional NRAs - **Quality is key.**
- Vaccinology institutions (WHO, IVI, RIVM/NVI) are resources for technical support.
| 1)     | Bharat Biotech          | 11)    | Kangtai                  |
| 2)     | Biological E            | 12)    | Lanzhou Institute        |
| 3)     | Bio Farma               | 13)    | Panacea                  |
| 4)     | Bio Manguinhos/Fiocruz  | 14)    | Razi Institute           |
| 5)     | Birmex                  | 15)    | Serum Institute of India |
| 6)     | Butantan                | 16)    | Shantha Biotech          |
| 7)     | Chengdu Institute of Biological Products | 17)    | VACSERA                  |
| 8)     | CIGB                    | 18)    | Cheil Jedang             |
| 9)     | Finlay Institute        | 19)    | LG Lifesciences          |
| 10)    | Institut Pasteur        |

**RESOURSE INSTITUTES**

- IVI.
- RIVM / NVI.
DCVMN Goals

1. To provide quality vaccines at affordable prices to the developing world.

2. To obtain recognition that developing country vaccine producers have an essential role in assuring availability of vaccines to immunize every child.
DCVMN Objectives

• To provide a repository of information, such as an inventory of current and potential production capacities and facilitate information exchange amongst members.

• Facilitating training on vaccinology and technology transfer.

• To provide independent laboratory support for members projects and harmonize regulatory requirements.
Pre-qualified vaccines currently available from DCVMN

- Made available through UNICEF and WHO and have private export markets.
- Most are expanding capacity and adding new technologies including DTwP based combination vaccines and Hib.
- Have R&D efforts toward Rotavirus, Pneumococcus, Menigococal and other vaccine needs.
<table>
<thead>
<tr>
<th></th>
<th>Mfg with Pre-Qualified vaccines</th>
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<tbody>
<tr>
<td>1</td>
<td>BioFarma, Indonesia</td>
</tr>
<tr>
<td>2</td>
<td>BioManguinhos, Brazil</td>
</tr>
<tr>
<td>3</td>
<td>CGEB, Cuba</td>
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<tr>
<td>4</td>
<td>LuckyGoldstar, Korea</td>
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<td>5</td>
<td>Cheil Jedang, Korea</td>
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<td>6</td>
<td>Green Cross Vaccine, Korea</td>
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<td>7</td>
<td>Institute Pasteur Dakar</td>
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<td>8</td>
<td>LG Sciences, Korea</td>
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<td>9</td>
<td>NCIPD, Intervax, Bulgaria</td>
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<tr>
<td>10</td>
<td>Panacea Biotech, India</td>
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<td>11</td>
<td>Serum Institute of India</td>
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<td>12</td>
<td>Shanta Biotech, India</td>
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UN agency Vaccines demand

Number of Products Requested, UNICEF and PAHO

- PAHO: 1979 baseline and vaccines added
  - BCG
  - Measles
  - Polio
  - DTP
  - DT (Pediatric)
- UNICEF: 1986 baseline and vaccines added
  - BCG
  - TT
  - DT
  - DTP
  - Measles
  - OPV
  - Yellow Fever
  - Men A

Source: UNICEF and PAHO
### Distribution by Source of Vaccines Purchased Through UNICEF Tenders

<table>
<thead>
<tr>
<th>Source of Vaccines</th>
<th>Number of Prequalified Vaccine Manufacturers*</th>
<th>UNICEF Supply specific to Global Fund purchase (HepB, Hib, DTwP- HepB, penta, YF)</th>
<th>UNICEF Supply for basic EPI vaccines excluding OPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industrialized Country Vaccine Manufacturers</td>
<td>9</td>
<td>73%</td>
<td>36%</td>
</tr>
<tr>
<td>Developing Country Vaccine Manufacturers</td>
<td>12</td>
<td>27%</td>
<td>64%</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

* *Note: not all prequalified vaccine manufacturers submit bids to UNICEF's tenders.*
DCVMN, WTO TRIPS & IPR ISSUES
“On 12th April 1955, Dr. Jonas Salk announced that his team had developed an effective and safe vaccine for Polio. That evening Edward R. Murrow interviewed Salk and Inquired “‘Who owns the patent on this vaccine?”

_He responded, “Well, the people, I would say, There is no patent : could you patent the Sun?”_
Why IP is Important?

- The high investment means increase in price in market to recoup the investment and show a net profit.
- Control of the market through IP ownership means to help investor obtain return on their investment for proprietary products.
- No company would invest the funds required to bring New vaccine to the market, if another qualified company would launch the same products in market at lower price as they have not spent money for the development of the same.
WTO TRIPS Agreement
- an overview

- WTO rules prohibit manufacture of generic copies of patented drugs:
  - From 1995 for developed countries,
  - From 2005 for developing countries
  - From 2016 for under developed countries.

- Developing countries should be allowed to import generics if they have no manufacturing capability.

- To give them same bargaining power as those who can issue compulsory license.

- Can prohibit resale in developed countries to preserve research incentives.
AIDS, Anthrax and Patents

- Brazil threatened to issue compulsory license in negotiations with Merck (US) and Roche (Swiss).
- US filed WTO complaint against Brazil (withdrawn).
- US and Canada used similar strategy with Bayer (German) during Anthrax scare.
- US/Canada actions against Bayer weakened their negotiating position at Doha.
- Brazil, India and 38 African countries joined together to fight US, Canada and Switzerland position at Doha, resulting in Doha Declaration on TRIPS.
Developing countries have been reluctant to employ the safeguards, largely because the U.S. government has long history of working with the pharmaceutical industries to fight initiatives by countries like South Africa, Thailand, and Brazil to prioritize low cost generic versions of AIDS drugs and other medicines.
To Break the dead lock: EU has launched an initiative by suggesting multi-laterally a list of diseases that have the most damaging impact on developing countries, which includes:

*HIV/AIDS*, malaria, tuberculosis, Yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertusis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, hemorrhagic, fevers and arboviruses
An Important TRIPS safeguard is compulsory licensing, whereby a government can license the production of medicine to a third party (for e.g. a generic drug manufacturer) without the consent of the patent holder. Compulsory licensing breaks up a patent monopoly and pieces fall as a result. “parallel importing” another safeguard, describes countries procuring a patented medicines from a third party other than the patent holder.
Doha Declaration

- break dead lock

- Members have right to grant compulsory licenses and determine grounds for granting

- “Public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency…”
Japan in its comments, reportedly insisted that the Doha declaration about pharmaceutical products and did not cover vaccines and these should not be included.

The EC however agreed that “Vaccine” were very much covered by term ‘pharmaceutical product’. Sri Lanka argued strongly that vaccines were not part of the pharmaceutical sector, to which the declaration applied.

India argued that everyone understood ‘pharmaceutical sector’ to include vaccines but since Japan was taking such position that it was not the decision to be adopted would have an ‘explicit understanding that vaccines are included.'
Besides the known issues- another real concern and not understood by us i.e. DCVMN (Developing Countries Vaccines Manufacturers Network) are the unknown, which will hit us after 2005 for e.g. we are aware of a patent, which is launched for use of AlPO$_4$ in manufacturing of combination vaccines.

To us the adjuvant, which is used for several decades can’t be patented. Similarly we also know that cross flow filtration for concentration has been patented for manufacturing of Hib Vaccine and therefore we don’t know till we face 2005 what are the different things that are going to affect us.
IPR is complicated and difficult to deal with for many developing world vaccine producers. Manufactures have identified specific general assistance from which all could benefit including:

- Development of template document for IPR agreements for use by developing and middle income country vaccine manufacturers;
- Access to unbiased legal review;
- Assistance in the writing of patent applications; and
- Training on how to better detect and understand infringements.
DCVMN - IPR

- Identify and secure the services of a team of highly-qualified intellectual property specialists and/or an institution that has this expertise in house.

- Sponsor and arrange a meeting for all manufacturers to better understand the affect WTO 2005 will have on vaccine manufacturing and supply for use in developing countries. Include all perspectives (multinationals to domestic producers) to facilitate meaningful discussion. The meeting should include representatives from WTO, IPR legal advisers, manufactures and ministers of government.
Goals of the meeting should be to:

- Begin with an explanation of the agreement and its affect in vaccine manufacturing.

- The possible affects from 2005 on joint ventures, formulating and filling and bulk purchasing agreements amongst manufacturers.

- Provide separate break out opportunity for discussion in small group and large group forum. Those manufacturers on the edge of contributing to global supply will benefit as they are now making supply decisions beyond 2005.

- Address specific concerns regarding patents for adjuvants, particularly GSK’s regarding Aluminum phosphate.
We expect WHO and other UN agencies to take a lead and come out with a white paper explaining in details as most of our member don’t really understand current situation on IPR and guide us to how vaccine industries in DCVMN will sustain and continue its contribution in saving millions of life by making the vaccines available at an affordable price to the poor people of developing countries.
All vaccines have deep roots in history

All vaccines, either involve Live/killed bacteria or live attenuated viruses. It may also involve a production of antigen by genetic manipulation, but basically the vaccines are derived from naturally existing information. Therefore, *should not be allowed* to have product patents. *Process of making* the same can be IP protected.

**It looks to be the best solution for vaccines for all but still with an IP protection for innovation.**
As health professionals and an international community...
we have a lot left to do...
all of us, together