Introduction[1]

Vaccines are a key component in combating infectious disease and preventing global transmission. Does advancing intellectual property rights impact access to vaccines? In accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights there should be flexibility in order to protect public health, and, in particular, provide access to medicines for all. However patents create a monopoly that raise prices of patented vaccine since they will not experience any true competition. While there exist mechanisms to facilitate access to patented vaccines, including bulk purchasing, compelling and voluntary licensing. Should such means be necessary, or is vaccine research a public domain necessary for public health and equal accessibility that should be protected.

Topic Background[2]

The desperate plight of many of the world's poorest people lacking access to essential medicines and vaccines is absolutely clear. It is self-evident that the high price of a new medicine or vaccine will have a strong impact on its availability in the developing world. In turn, there can be many factors involved in a high end price, of which patent protection might be only one. Nevertheless, given that patents are intended to provide market monopoly rights, they are obviously a prime possible concern.

The recent WHO/UNICEF/World Bank publication, "State of the World's Vaccines and Immunization" addresses the access gap in vaccines. It is indicated that (page 7) "[T]he divide in access to vaccines between wealthy and poorer countries has widened even further over the past two decades, as new life saving vaccines have become available – at prices that most low-income countries could not afford".

The reason for this lack of affordability is said to spring from a number of sources including lack of funds, lack of adequate infrastructure and lack of adequate disease burden surveillance. This latter factor means that, because vaccine production is highly scale sensitive, manufacturers will tend not to devote more capacity to the necessary production than they need at the outset. This will cause difficulty both in the higher price resulting from smaller production runs and the problems of increasing scale at a later date. As far as the setting of the price is concerned, the following is said (page 9):

> "In order to recoup these [vaccine development] costs and make a profit, vaccine manufacturers subsequently set a high price for each new vaccine. Exclusive rights to an

[1] "Immunization, Vaccines, and Biologicals: Research and Development." World Health Organization. http://www.who.int/immunization/research/en/

[2] "Individual Property Rights and Vaccines in Developing Countries." Christopher Garrison. http://www.who.int/intellectualproperty/events/en/Background_paper.pdf

> initial 20-year period following the introduction of the vaccine is protected by patents under the Agreement on Trade Related Aspects of Intellectual Property Rights (also known as the TRIPS Agreement). Patents give the manufacturer exclusive rights to either produce the vaccine themselves or licence production to another manufacturer in return for payment of royalties. Once the patents have expired, other vaccine manufacturers are free to produce the vaccine without payment of royalties. Over time, this leads to competition, which in turn may lead to overcapacity and a willingness to sell at a low profit margin. In the meantime, millions of children's lives are being lost in developing countries, where governments are unable to afford the new vaccines until the price is reduced, 10-20 years later".

Past & Current Background[3]

Much of the access to medicines debate has been about the freedom available to WTO Members to interpret and implement the TRIPS Agreement. On 14th November 2001, all WTO Members agreed the WTO Doha Declaration on TRIPS and Public Health. The Doha Declaration recognises the "gravity of the public health problems afflicting many developing and least developed countries", recognises that "intellectual property protection is important for the development of new medicines" but simultaneously recognizes the "concerns about its effects on prices". The centerpiece of the Doha Declaration (paragraph 4) states that:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Compulsory licensing is one of these flexibilities, as explicitly noted by the Doha Declaration, although an outstanding legal problem with compulsory licensing under the TRIPS Agreement could not be solved in Doha – that of how to enable compulsory licensing (or any other mechanism) that would permit production of pharmaceutical products for export to countries "with insufficient or no manufacturing capacities in the pharmaceutical sector."

It is absolutely clear that there is a significant and unacceptable delay in the introduction of new vaccines to the developing world. It is precisely for this reason that the Global Alliance for Vaccines and Immunization (GAVI) has been set up, not only in terms of long standing problems

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[3] "Individual Property Rights and Vaccines in Developing Countries." Christopher Garrison. http://www.who.int/intellectualproperty/events/en/Background_paper.pdf

such as Hepatitis B and Hib vaccines, but also in terms of the new Accelerated Development and Introduction Plans (ADIPs).

Possible Solutions

Why does it matter?[4]

Not only is there a disparity in the access to vaccines that we must breach but this access posses a public health threat. Delegates agreed to strengthen immunization to achieve the goals of the Global Vaccine Action Plan (GVAP). In 2012, the Health Assembly endorsed GVAP, a commitment to ensure that no one misses out on vital immunization by 2020. However, progress towards the targets laid out in that plan is off track. Halfway through the decade covered by the plan, more than 19 million children were still missing out on basic immunizations.

Today's resolution urges Member States to strengthen the governance and leadership of national immunization programmes. It also calls on them to improve monitoring and surveillance systems to ensure that up-to-date data guides policy and programmatic decisions to optimize performance and impact. It calls on countries to expand immunization services beyond infancy; mobilize domestic financing, and strengthen international cooperation to achieve GVAP goals. It requests the WHO Secretariat to continue supporting countries to achieve regional and global vaccination goals. It recommends scaling up advocacy efforts to improve understanding of the value of vaccines and of the urgent need to meet the GVAP goals. The Secretariat will report back in 2020 and 2022 on achievements against the 2020 goals and targets.

Immunization averts an estimated 2 to 3 million deaths every year from diphtheria, tetanus, pertussis (whooping cough), and measles. An additional 1.5 million deaths could be avoided if global vaccination coverage were improved.

Collaboration[5]

Revitalizing home-based records to improve immunization coverage Deepika Attygalle and Andreas Hasman, UNICEF Regional Office for South Asia; Marta Gacic-Dobo, World Health Organization; Anna Rapp and Bhupendra Tripathi, Bill and Melinda Gates Foundation The vaccination card, also known as the home-based vaccination record (HBR) can play an important role in documenting immunization services, providing information to caregivers and creating demand for vaccines. HBRs have been associated with improved health seeking behavior and service utilization, and timely and full immunization of children. But utilization of HBRs remains low in many countries. To address this lost opportunity, in March 2016 UNICEF Regional Office for South Asia and Bill and Melinda Gates Foundation organized a four-day workshop in Sri Lanka on HBR revitalization. The event brought together national and state

[4] "Seventieth World Health Assembly update, 29 May 2017." World Health Organization. http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refuguees/en/

[5] "Intellectual Property and Health in Developing Countries."Jean Tirole. https://pdfs.semanticscholar.org/cfd3/f48234ef43ed0eb8239bde71827648405848.pdf

officials, development partners, data experts and design professionals. Participating countries included Afghanistan, India, Nepal, Pakistan, and Sri Lanka. Countries in South Asia have very different experiences of using HBRs, from immunization-only cards to broader child health and nutrition booklets. In Sri Lanka, the HBR has for a long time been a key tool in communication between caregivers and the health system and card retention is high. Other countries are only just coming to realize the full potential of the cards. The aim of the workshop was to optimize the quality, availability, and use of HBRs through collaborative south-south exchange. In an innovative approach, practitioners and experts seized the opportunity to share best practices between countries and learn from each other. Advice from experienced designers enabled powerful visions and targeted approaches to the development of HBRs. During the four-day workshop, participants worked in country and cross-country teams to discuss challenges and gaps associated with the use of the records. Participants learned from each other, uncovered opportunities to improve HBRs for demand generation and service delivery, and built innovative prototypes. They also agreed plans of action and concrete next steps. Although several platforms for electronic recording are under development, the HBR remains an important document and a largely untapped resource for improved immunization coverage. Countries and partners will continue the work to promote innovation and best practice in this area.

Future Research

Guiding Questions:

- Where do you stand on the argument?
    - Is vaccine access an issue for your country? OR Is your country hoping to expand intellectual poverty rights so as to benefit your country?
- If access is an issue what are the main contributing factors? Strict regulation, geographic isolation, limited materials, etc.?
- If you country has intellectual rights on certain vaccines or medical research how do you justify keeping this information private?
- For both perspectives what are the pros and cost of having universal access to vaccine research?

Research Resources

- Look at bibliography

Questions to Consider

- How can we disrupt the monopolies that limit the access of vaccines of developing countries?
- Would limiting intellectual property rights create more universal access?
- What is the importance of universal access to medical research especially when it comes to preventing the spread of disease?

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