The following paper was written by members of the public health advocacy group, Universities Allied for Essential Medicines (UAEM). The UAEM movement centres around the belief that universities are well-placed to act as an epicentre for change in the mission to increase access to medicines and other healthcare-related technologies in developing countries. This is for two main reasons: firstly, that many of the most important medicines and medical innovations were developed in university laboratories. Secondly, that universities are social institutions with mission statements that often pledge to promote welfare through knowledge dissemination. UAEM firmly believes that public welfare should not be restricted to high-income countries but should also apply to poor countries.

Introduction

The protection of the Human Right to the benefits of science and its applications necessarily requires the promotion of access to collective knowledge and other public goods. This in turn requires an approach to public goods with a view to making everything that is intrinsically non-rival and non-exclusive available to all, which includes those public goods (such as knowledge derived from research and development) that have been privatised[1]. This has implications for how different stakeholders should be expected to act. States, in constructing legislation and policy, must take into account that the limitations that a privatising knowledge ecosystem places on, for example, access to medicines, undermines long-term participation of their citizenries in economic, social and cultural activities. They must therefore protect the access of their populations to public goods. This model of the state as steward may be examined in relation to the subject matter of this submission, the impact of intellectual property (IP) regimes on the enjoyment of science and culture, as enshrined in article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

In the first section, we examine the incongruity between Intellectual Property Rights (IPR) and Human Rights in terms of their rationale and the impact that increased IPR have had on depriving large populations from access to medicines. In the second section, we examine how states are beholden to international trade agreements which tie them to a maximalist IP regime which limits access to medicines. We also examine how the powerful global trade incentive structure may be adapted to encourage states to defend health primacy over corporate interests. In the third section, we consider how states can support a new paradigm in conducting scientific research and promote universal access to the fruits of scientific research.

Section One: Intellectual Property Rights against Right to the Benefits of Science and its Applications

The starting point for any discussion regarding the interaction between IPR and Article 15 of the ICESCR must be the recognition that Article 15 - inasmuch as it is concerned with the right of everyone to enjoy the benefits of science and its applications - is in conflict with IPR, which legalise individual control scientific of knowledge and criminalise open approaches to science. It must immediately be stated that the name 'Intellectual Property Rights' is a misnomer, because it does not describe a fundamental right in the way that Human Rights do. IPR should not be accorded the status of Human Rights in our discourse, neither should it be conflated with the right to the moral and material interests of authors' work as contained in Article 15c.

Where Human Rights are based on fundamental and inalienable normative content, IP protection was originally formulated to correct market failure arising from the 'free-loader problem', whereby imitators can easily replicate expensively-developed technologies at a fraction of the cost of the original. Its purpose is to offer a financial incentive for research and development (R&D) into the knowledge and technology that drives scientific and societal progress; not to expand or sanctify the scope of private property. WIPO describe patents as a "mechanism which ensures that the knowledge contained in patent applications is accessible to society."[2] With regards to medicines, however, they have failed in this regard, by pricing beyond reach medical technologies critical to the alleviation of the morbidity and mortality of millions. They have furthermore failed as a mechanism to deliver innovations addressing neglected diseases, such as visceral leishmaniasis, Buruli ulcer and Chagas' disease, that affect 1 in 6 people worldwide, predominantly in low- and middle-income countries[3].

Considering this preface, the argument made by supporters of a maximalist IP regime - that IP protection, through incentivising scientific enterprise, increases access to science - must be seen as erroneous and subordinate to Human Rights obligations. The impacts of IP protection extend far beyond access to medicines, including access to the benefits of science in areas spanning from agriculture to information technology. These areas lie beyond the scope of this submission.

Section Two: TRIPS and Free-Trade Agreements

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) set the international standard for domestic IP legislation when it was adopted by member states in 1994. New bilateral free trade agreements under discussion, including the Trans-Pacific Partnership (TPP) Agreement between the US and eleven other countries*, contain so-called 'TRIPS-Plus' clauses that, if approved, would greatly increase the scope and strength of intellectual property protection[4]. Meanwhile, the capacity of states to overturn policies prescribed by such agreements when population health is under threat would be limited, as private actors would be allowed to sue governments through investor-state dispute settlement bodies when their profits are limited by such actions[4]. Furthermore, the *quid pro quo* nature of international trade means that, even when those flexibilities that do exist within TRIPS are exercised, the political will to exercise them again in future is challenged by a reactionary and combative response by trading partner states, such as the Special 301 mechanism invoked by the US. With the diminution of access to medicines wrought by increased IP protection, the impact of TRIPS and related agreements represents the capture of policy-making capabilities in relation to health by trade interests. The net impact of such agreements is to serve as an incentive to privatise potentially life-saving knowledge and technologies, rather than make it widely available[5], inviting signatories to contravene Article 15 of the ICESCR as well as the fundamental right to health.

* *Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam*

Through FTAs, high income countries have not only been shaping the implementation of the World Trade Organization (WTO) Trade Related Aspects of Intellectual Property (TRIPS) Agreement at the national level, but also at the bilateral and regional level. The US most notably has adopted this method of "forum shifting" on IP protection, thereby increasing the odds of successful negotiation by not expanding its efforts beyond a single international arena[6]. Through this approach, other country governments voluntarily concede to expansion of IP protection in exchange for market access. With each FTA's IP provisions becoming the baseline for the next agreement, the US has been largely successfully in pursuing an ever-stronger IPR agenda for medicines that go beyond TRIPS[7]. The direct relationship between trade agreements, increased IP protection and reduced access to medicines is illustrated in the following case study.

Jordan became the first country to agree to such TRIPS-plus provisions in 2001 in the United States-Jordan Free Trade Agreement (US-Jordan FTA), negotiated shortly after its accession to the WTO. Jordan is a lower middle-income country with an estimated one-third of its population living below the poverty line. Jordan's poor population disproportionately has higher health risks and lower access to health services compared to their wealthier counterparts[8]. Only 60 percent of the population has health insurance leaving the uninsured and low-income populations to pay for health services out-of-pocket at double the price compared to those who are insured.

When negotiations were completed for the US-Jordan FTA in 2001, Jordan agreed to the following TRIPS-plus provisions[8]:

- 3 years of data exclusivity in addition to the already existing 5 years of data exclusivity for new uses of already known chemical entities;
- Compulsory licensing restricted to instances of curbing anti-competitive practice or national emergency;
- Patent extension if there is a delay in the marketing approval process that would reduce the standard patent term;
- Patent linkage

These provisions prevent generic entry of medicines into the market allowing for multinational drug companies to retain a monopoly market. Based on analysis by Oxfam and the Jordan Patent Office of over 100 medicines introduced in the Jordanian market after 2001, it was found that data exclusivity independent of patent protection prevented generic competition. Drugs for non-communicable diseases in particular were significantly more expensive in Jordan compared to Egypt, which did not have TRIPS-Plus rules allowing for generic production of these drugs and marked price reductions. Drug prices increased by 20 percent in Jordan since the FTA was enacted, and the market share of drugs with no generic equivalent increased progressively.

Such tension between IP and access to health is not new or exclusive to the US-Jordan FTA. Indeed, it has been growing over the last two decades, with the surge in international trade of health-related products and the number of bilateral and multilateral FTAs being negotiated[9,10,11, 12].

Changing Incentives

Mechanisms such as investor-state dispute settlement and WTO sanctions are more punitive to states than any formal repercussions that can be made in defence of even the most well-articulated and widely-recognised Human Rights, let alone the historically poorly-understood economic, social and cultural rights such as that under discussion. As such, the sovereignty of governments over almost all policies affecting health is limited by binding trade agreements, diminishing their ability, for example, to uphold 'soft' commitments to health under the auspices of the World Health Organization[13]. We expect this trend to continue.[14] To temper this trend, it has been suggested by the civil society group Knowledge Ecology International that the institutional architecture of the WTO be utilised for the delivery of public goods (including pharmaceutical R&D)[15]. The proposed agreement ('WTO Agreement on the Provision of Public Goods') would be modelled on the WTO General Agreement on Trade in Services, and would allow member states to submit voluntary schedules outlining commitments that they would make to provide public goods. Once submitted, this schedule would be binding, and failure by that state to deliver on the commitments to the provision of public goods outlined in their schedule would render them subject to WTO sanctions. One example would be a commitment to provide annual funding to an R&D fund for prizes and grants to incentivise medical innovation (see the discussion on de-linkage below). This mechanism would provide an economic incentive for states to make public goods available and would modify the incentive structure intrinsic to the global trade regime in such a way as to promote states to uphold the Human Right to the benefits of science and its applications (as well as other rights), just as the current incentive structure invites them to contravene it.

Section Three: Responsible Science

In the current knowledge ecosystem, access to the benefits of science and its applications is decided by a process of systematic financial discrimination. A citizen may gain access not because they are a human being, and have a right to access knowledge, but because they are fortunate enough to exist within the boundaries set by those that, through IP protection, control our collective understanding of the universe and, moreover, our ability to use it.

Inasmuch as IP protection in the field of pharmaceuticals is failing to deliver sufficient advances in medical technology and to distribute existing technologies, it needs reforming. With regards to the question of the access gap maintained by IP maximalism, we call for states to make full use of the flexibilities enshrined in the Doha Declaration in order to protect the public health of their populations. It could reasonably follow that a trigger mechanism be developed, such that the use of compulsory licences or parallel import by governments become mandatory should their failure to invoke them perpetuate reduced access to medicines - a breach of the Human Right to the benefits of science and its applications. We also support the suggestion by Boldrin and Levine that the scope of patent protection should be reduced as much as possible without causing a reduction in the rate of innovation[16].

However, these solutions remain mere compromises as long as they rely on alterations to an innovation regime dependent on the incentive of intellectual property. We should be looking to intervene upstream of patent challenges.

Governments, in honouring their duty to uphold the Human Right to the benefits of science and its applications, must support (and even lead) the implementation of an alternative innovation system established on the principle of de-linkage of market price from R&D costs, in line with the recommendations of the CEWG of the WHO[17]. This would involve establishing a series of grants and prizes, to respectively 'push' and 'pull' research efforts. Each stage would be conducted in an open source manner (for example, through contributions of relevant intellectual property to a patent pool), allowing potentially more rapid and more innovative developments to take place. The fruits of such efforts, having been produced with public funds, would be licensed openly for generic manufacture, allowing market forces to reduce prices to a much more affordable level than allowed by patent monopolies. An example of such an incentive structure has been outlined by Médecins Sans Frontières in their '3P Project' for anti-tubercular research and development.[18] Similarly, the adoption of open licensing policies by universities has been the outcome sustained campaigning efforts by UAEM. We argue that all research facilitated by public funds and institutions should be licensed in a manner consistent with our WHO-approved Global Access Licensing Framework. In essence, this requires medical technologies developed by universities to be openly licensed to generic manufacturers in a manner that promotes maximum access, preventing the loss of public knowledge to the private monopoly sphere. In this way, universities may fulfil their mission of advancing human understanding and welfare. In relinquishing their intellectual property to private sector monopolists, they actively contradict this aim.

RECOMMENDATIONS

1. **Be vigilant against arguments conflating intellectual property rights with economic, social and cultural rights such as 'rights to protection of the author'.**
2. **Invoke Human Rights law and discourse to support intellectual property challenges, including use of TRIPS flexibilities.**
3. **Support the development of new mechanisms to incentivise governments to protect health as a public good, including the proposed 'Agreement on the Provisions of Public Goods' at the WTO.**
4. **Strongly and publicly oppose those trade agreements which strengthen intellectual property protection and undermine international agreements such as the Doha Declaration on TRIPS flexibilities that aim to protect public health at the expense of access to medicines.**
5. **We call on every member to state to support, financially or otherwise, or participate in a de-linkage R&D project. Furthermore, we ask that knowledge generated through public funding should never be appropriated under IP protections, and instead should be openly-licensed in a manner consistent with the Global Access Licensing Framework.**

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