13 September 2024

UN "Pact for the Future" intellectual property actions need revision to ensure innovation and access to health products for all

At the United Nations in New York, a group of countries is drawing up the "Pact for the Future" to be adopted at the Summit of the Future, which will be held on 22-23 September this year in NY. The purpose of the Summit and the Pact are to reaffirm the UN Charter, to reinvigorate multilateralism, to boost implementation of existing commitments, to agree on solutions to new challenges and to restore trust.

The latest draft of the Pact contains sixty actions in the areas of sustainable development and financing for development; international peace and security; science, technology and innovation and digital cooperation; youth and future generations; and transforming global governance.

On science, the Pact quite rightly notes that "Innovations and scientific breakthrough that can make our planet more sustainable and our countries more prosperous and resilient should be affordable and accessible to all." But one of the action points could throw a wrench in the works of this noble goal.

Somewhere in the middle of the list of actions is an action point on intellectual property (IP), which reads: "Uphold intellectual property rights to support developing countries achieve sustainable development". The document goes on to explain that:

We recognize the importance of intellectual property rights to progress on science, technology and innovation. We decide to:

> *(a) Protect and enforce intellectual property rights to promote technological innovation, build trust and contribute to the transfer and dissemination of technology on mutually agreed terms.*
>
> *(b) Uphold the agreements enshrined in relevant international legal obligations related to trade and intellectual property rights, including the right of Member States to use the flexibilities contained therein, to facilitate access for developing countries to scientific and technological innovations.*

This is followed by Action 33: *We will ensure that science, technology and innovation contribute to the full enjoyment of human rights by all.*

The paper does not recognise the tension between Action 32 and 33 or the decades-long debates at various multilateral institutions, including the the UN, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO), about the shortcomings of the IP system, particularly in achieving the human right to health. Securing access to medicines in the face of strong IP protection has been a huge challenge for low and middle-income countries as are the shortcomings of pharmaceutical innovations to meet the health needs of less affluent populations. Shortcomings in health innovations include a) the lack of research and development (R&D) to deliver critical innovations, in particular for neglected populations, and b) ensuring access to existing health innovations.

These shortcomings have been well-documented in the last two decades. The high-profile 10/90 report on health research published in 2002 by the Forum for Health Research documented the lack of R&D for neglected diseases. 10/90 refers to the finding that less than 10% of worldwide resources devoted to health research were put towards health in developing countries, where over 90% of all preventable deaths worldwide occurred.

In the years after, a number of not-for-profit product development initiatives were established. For example, in 2003, Médecins sans Frontières (MSF, known also as Doctors without Borders) and other organisations and governments established the Drugs for Neglected Diseases Initiative (DNDI). The Global Antibiotic Research and Development Partnership (GARDP) and the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) have been created to fill the gap of antibiotic drug development. IP-reliant companies have abandoned R&D of new antibiotics because of limited profitability prospects. After all, new antibiotics need to be used sparingly to avoid the rapid development of resistance and cannot be aggressively marketed. Antimicrobial resistance is a threat to the entire planet; IP protection has no effect on the ability to create the innovations necessary to address this threat.

Not-for-profit R&D initiatives have delivered several important products, but securing funding for their work is still a challenge.

In 2006, the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) called attention to the need for changes in the way health R&D is prioritised and financed. Its report lists 60 recommendations to increase access and move towards a more health needs-driven innovation system. Following the CIPIH report, the WHO formulated a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which was adopted by the World Health Assembly in 2008 and is still operational today. The Strategy includes actions towards broadening health innovation incentives beyond IP monopolies, such as patent pools, prize funds and

delinkage models. Some of those are now being implemented for antibiotic drug development. The strategy also includes the proposal to "encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical treaty'.

The draft Pact for the Future text also ignores these developments. It further fails to recognise the significant role of public financing of innovations. Take, for example, the COVID-19 vaccines, which were developed at record speed because governments derisked the R&D efforts to develop vaccines and therapeutics with over $90billion from the public budget leading to the rapid roll out of vaccinations but initially only in wealthy nations. Not only were the vaccines withheld from LMICs also the technology and knowledge necessary to locally or regionally produce most COVID-19 vaccines were never shared. The WHO COVID-19 Technology Access Pool never held any vaccine related technologies. Bilateral technology and know-how transfer to developing country manufacturers only occurred for the Oxford University/AstraZeneca vaccine. The mRNA vaccine manufacturers promised to establish manufacturing capacity in Africa but Moderna has abandoned those plans. BioNTech is moving ahead with establishing its manufacturing plant in Rwanda with a $145 million grant from the Coalition for Epidemic Preparedness Innovations (CEPI). (In 2022 Pfizer/BioNTech generated $100 billion in Covid-19 vaccine sales.) In response to the lack of sharing of mRNA technologies, WHO, the Medicines Patent Pool and others established the mRNA vaccine technology transfer hub in South Africa which is developing its own mRNA technology with the aim to transfer it to other countries.

Since the adoption of the WTO's Agreement on Trade-related Aspects of Intellectual Property (TRIPS) in 1994, high levels of IP protection have become available worldwide. The promised trade-off from the TRIPS Agreement was that the higher levels of IP protection would lead to technology transfers from high-income to lower-income countries and that the benefits of this technology transfer, creating research and industrial activities in lower-income countries, would outweigh the cost of expanded levels of IP protection. However, the promise of increased R&D activity to meet the unmet health needs of poor people has not been fulfilled. Neither has the promise of increased technology transfer.

The failure to transfer vaccine know-how and technologies during the COVID-19 pandemic continues to be a flashpoint in the ongoing negotiations for a Pandemic Agreement currently taking place at the World Health Organization. Low- and middle-income countries are seeking firmer commitments to sharing of technologies and know-how needed to produce products needed to respond to a pandemic.

One can go back further in time: the HIV pandemic could not have been addressed without the development of antiretroviral medicines (ARVs). The first HIV medicines were primarily developed by the US National Institutes of Health (NIH) with government financing. Yes, IP and the market monopolies encouraged pharmaceutical companies to put the ARVs on the market, but the companies initially only focussed on lucrative markets where they could maximise profits. In early 2000, ARVs were not available in the developing world where over 30 million of the people with HIV lived. It was not until IP barriers were cleared away that low-priced generic HIV medicines became available. This did not happen overnight, and political action was demanded at all levels, including at the UN and the WTO, which in 2001 adopted the Doha Declaration on TRIPS and Public Health which recognised the concerns about the effects of IP protection on prices of health products.

Unfortunately, the struggle for access to ARVs continues. The company Gilead, once at the forefront of licensing to the Medicines Patent Pool (MPP), today refuses to share its IP of the long-acting HIV medicine lenacapavir. The product has shown to be 100% effective in preventing HIV infections. Each year, 1.3 million new HIV infections occur. According to UNAIDS, recent studies demonstrate that lenacapavir has the potential to end HIV. But ending HIV is not in sight with the current price tag of $42,250 per person per year and without MPP licences to enable generic production of which the estimated price is $42.50 per person per year.

In 2015, the then United Nations Secretary-General Ban Ki-moon established the High-Level Panel on Innovation and Access to Health Technologies to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies. The Panel published its report in 2016. The drafters of the Pact would benefit from the many recommendations the Panel makes, particularly the recommendation that public financing for research should require that the research results be shared and that IP be licensed, including through patent pools, to promote technology transfer and enable broad access to innovations.

The draft Pact for the Future's actions on IP seem to be based on obsolete insights on the role of IP and ignores the abundance of evidence of the limitations of the IP system as the main driver of innovation and the challenges of monopoly pricing of health products, in particular in LMICs. A Pact for the Future that is relevant for the future should contain forward-looking and bold actions for innovation in health and embrace a wider range of incentives for health innovations beyond IP that assure access to those innovations for all in need.