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Making Covid-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS Flexibilities

By Sudip Chaudhuri

The proposal of Costa Rica to create a voluntary pool mechanism for medical products and technologies for COVID-19 has evoked huge interest and optimism. The World Health Organization (WHO) and Costa Rica have followed it up through a Solidarity Call emphasizing the need for voluntary licensing on non-exclusive basis to the Medicines Patent Pool (MPP). The success of a voluntary pool critically depends on the willingness of the patentees to join the pool. In a public health crisis, boundaries of public policy must not be determined by the patentees. MPP will work much better if the patentees are compelled or induced to join the pool. International cooperation is important in this regard. Highlighting the virtues of voluntary measures and promoting MPP without adequate emphasis on the use of compulsory licensing and other TRIPS flexibilities, actually weakens the MPP. In the light of the experience of MPP, the basic objective of this paper is to analyze to what extent voluntary pool mechanisms can be relied upon to make COVID-19 medical products affordable and accessible. It is important to appreciate the achievements of MPP. But the constraints under which it operates, and its limitations must also be kept in mind.

Supporting generic competition

When new vaccines and other medical products for COVID-19 are developed, it is of critical importance to ensure that these are affordable and accessible to the people of all countries. If the new medical products are patented, then the patentees will have the right to prevent others from entering the market for a prolonged period of time. The resultant monopoly of markets may lead to high prices. Experience shows that the most effective way of ensuring lower prices is generic competition.

Generic competition is possible when patent protection expires, or when patents can be prevented or denied or suspended. The situation arising out of the COVID-19 pandemic is truly extraordinary and it requires an exceptional response to deal with it. One of the proposals is to treat all COVID-19 related medical products and technologies as global public goods with no intellectual property restrictions on their use. In that case anyone, anywhere can manufacture these products. This will lead to a competitive market with more affordable prices. This would be

an ideal policy response to the pandemic. The United Nations (UN) Secretary-General, the inter-governmental organization, South Centre, international civil society organizations (CSOs) such as Médecins Sans Frontières (MSF) and others have supported the proposal.¹ But to implement the idea, countries need to collectively decide to not recognize patents rights in COVID-19 technologies and products or at least to suspend these rights. At the 73rd World Health Assembly (May 2020), while heads of some countries spoke in favor of this, the United States objected to it.²

When product patents are granted, competition is possible when the patentees give voluntary licenses or when generic companies get compulsory licenses.

Costa Rica proposal for a voluntary pooling mechanism

Costa Rica requested WHO on 23 March 2020 to create a voluntary pooling mechanism for “rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic”. The idea is that patented products and other relevant technology for COVID-19 would be placed voluntarily in a pool and be available for licensing in every country to make these affordable and accessible.³ The Costa Rica proposal evoked huge interest and optimism. Within a few days (on 27 March 2020), a number of well-known international CSOs such as Knowledge Ecology International (KEI), Health GAP (Global Access Project) and Oxfam America along with some reputed experts urged WHO and its Member States in an open letter to support the Costa Rica proposal and to act on it.⁴ Some of the experts elaborated on the rationale for voluntary pool and mentioned the “success of the Medicines Patent Pool in expanding affordable access to medicines tackling HIV, TB, and hepatitis C” in support of the proposal.⁵ Unitaid and the Medicines Patent Pool (MPP) announced that they would like to include COVID-19 medical products in its voluntary licensing pool. In a media briefing on COVID-19 in early April 2020, the WHO Director-General responded by welcoming the idea and promising to take the voluntary initiative forward in consultation with Costa Rica. But everyone is not excited about the voluntary nature of the initiative. In another letter on 18 May 2020 to WHO Member States and Unitaid, another group of renowned international CSOs including MSF and the Third World Network expressed doubts about the effectiveness of voluntary mechanisms without binding commitments.⁶ Expressing much less faith on the willingness of the pharmaceutical industry to address public health needs, organizations such as MSF recommended that countries must be encouraged to use all existing policy and legal measures including compulsory licensing and other flexibilities under the TRIPS Agreement.⁷

On 29 May 2020, the WHO DG and the President of Costa Rica announced the launch of the voluntary technology access pool.⁸ They issued a Solidarity Call “to key stakeholders and the global community to voluntarily pool knowledge, intellectual property and data necessary for COVID-19” so that health products are accessible to all. The initiative has also indicated some directions for pooling of resources and equitable global access. Government and other funders of research and development (R&D), for example are urged to “take action to promote innovation, remove barriers, and facilitate open sharing of knowledge, intellectual property and data necessary for COVID-19 detection, prevention, treatment and response, including through national legal and policy measures...”⁹ In this connection it would not have been unusual for WHO to stress the importance of TRIPS flexibilities. This is avoided in the main text (though the Note to the Statement refers to the Doha declaration and the right to use flexibilities under TRIPS). Instead what is specifically mentioned in the text is the need for voluntary licensing on non-exclusive basis to Medicine Patent Pool and/or voluntary non-enforcement of intellectual property rights.

Response to the Costa Rica and WHO Call to Action

The Call has been endorsed by 35 other WHO Member States including some developed countries such as Belgium, Norway and the Netherlands. This however does not include developed countries such as the United States, the United Kingdom, France and Germany and developing countries such as China and India. The pharmaceutical giants have opposed the move indicating that they are not willing to sacrifice their intellectual property rights and put their patents in the pool.¹⁰ What they could get in return financially in the form of royalties does not seem to be attractive enough for the patentees to forego the opportunity of making huge profits in markets where patents are granted. The silver lining is that international CSOs such as MSF, KEI and Health GAP have welcomed it. And what is heartening is that their responses suggest that differences among them have narrowed down. Consistent with its earlier stand, MSF has stressed the importance of “effective implementation and enforceable measures to guarantee access to both existing and future COVID-19 technologies for everyone”.¹¹ Health GAP (and also Medicines Law & Policy) admit that voluntary measures alone will not be enough. They want that governments and charities funding R&D to demand that patents and other exclusive rights must be available for open licensing. Medicines Law & Policy goes a step further and indicates the option of compulsory license at national levels.¹² KEI also highlights the crucial role that national governments need to play when voluntary initiatives do not work.¹³

Despite some dissenting voices, there is overwhelming support for the voluntary pool idea. And in particular, there is huge faith on the ability and capability of MPP to deliver. But is the potential of MPP to be effective in the pandemic overestimated? Are the proponents of MPP expecting it to do more than what is possible for it to do?

The Medicines Patent Pool

MPP was set up in 2010 by Unitaid. MPP has been inspired by the virtues of generic competition. A major objective of MPP has been to ensure competition in patented products through voluntary licensing mechanisms and to make products more affordable in low and middle income countries (LMICs). MPP negotiates with patent holders to get voluntary licenses and then enables generic companies to manufacture and sell the patented products on non-exclusive basis on payment of royalties.

A little bit of history is important to understand the potential role that MPP can play in the COVID-19 pandemic.

As in the case of COVID-19 pandemic, there were initially no medicines for the treatment of HIV/AIDS. After effective antiretroviral drugs (ARVs) were developed, the following phases can be distinguished in developing countries. It gives a good idea about the options, the responses, and the outcomes in trying to make essential medicines affordable and accessible in a pandemic.

- 1) **High patented prices:** Exercising their patent rights, the multinational corporations (MNCs) charged exorbitant prices even when people were dying in developing countries unable to afford the cost of more than US\$ 10,000 per person per year for a combination of ARVs.
- 2) **Voluntary price discounts:** The high prices led to an international public outcry. International organizations such as UNAIDS and WHO started dialogues with the

pharmaceutical industry to make the ARVs more affordable. This led to the formation of “Drug Access Initiative” in December 1997 for voluntary price discounts by the pharmaceutical companies. This was followed by the launch of the more elaborate “Accelerating Access Initiative” in May 2000 between five international organizations – WHO, UNAIDS, the World Bank, UNICEF and the UN Population Fund – and the major pharmaceutical companies who held the patents for the ARVs. But with individual countries requiring to negotiate with the patentees and satisfy their conditions, the progress for providing treatment was slow.¹⁴

- 3) **Generic competition from India:** It was after Indian generic companies started supplying the ARVs that prices dropped dramatically. As is well known, with the cost finally reducing to below US\$ 100 and larger international funding, treatment could be scaled up significantly in LMICs. India could manufacture and supply these ARVs because these were not patented in India.
- 4) **Bilateral voluntary licensing:** But with the introduction of the TRIPS Agreement, countries which did not recognize product patent protection, had to do so in all fields including in pharmaceutical products. India re-introduced such protection in 2005. The new patented ARVs could no longer be manufactured by generic companies from India and elsewhere unless they obtained voluntary or compulsory licenses. In the light of apprehensions that the patented products would be high priced and in response to the intense and sustained campaign by the civil society to make the products more affordable by using TRIPS flexibilities including compulsory licensing, the MNCs started entering into voluntary license deals with generic companies. By 2007, pharmaceutical companies like GlaxoSmithKline, Boehringer Ingelheim, Bristol Myers Squibb, Gilead, Merck Sharp & Dohme and Roche issued 32 voluntary licenses to generic companies, all of which except one (for Avian flu) were for ARVs.¹⁵
- 5) **Medicines Patent Pool:** MPP essentially carried forward these voluntary initiatives from 2010 onwards and made voluntary licensing more convenient and effective. Till 2015, MPP focused only on ARVs.

As the analysis of voluntary licenses by Amin¹⁶ suggests, the offer of voluntary licenses by the MNCs reduces the risk of compulsory licenses. In countries such as India where a patent application can be opposed even before it is granted, offering voluntary licenses can also dissuade generic companies from opposing patents. Patentees have no control over terms and conditions of compulsory licenses, and these can be different in different countries. In voluntary licenses, patent holders have bigger opportunity to influence the royalty, geographical areas for sales and other conditions. They can benefit from sales in markets with marketing and distribution challenges while reserving the higher-margin markets for them.¹⁷

MNCs already pursuing voluntary licenses in ARVs were keen to join MPP in their own interests. It is attractive for generic companies and developing country governments too.¹⁸ MPP reduces the transaction costs for both the patentees and the generic companies – they are not required to negotiate on a case by case basis. With the high-level backing that MPP received from international organizations such as WHO and Governments such as the United States and the United Kingdom, joining MPP was considered to be a better option than direct and bilateral voluntary licensing. It enhances their reputation. MPP reduces the risks and uncertainty for the generic companies. They need not wait till the outcome of compulsory license applications or pre-grant opposition to start planning for investments. MPP gives the generic companies access to larger markets than is possible with national compulsory licenses. It is a benefit for

developing country governments also. Compulsory licensing is not easy. Conditions as laid down in the TRIPS Agreement need to be satisfied. It is time consuming. Patentees invariably oppose compulsory licenses and extensive and uncertain litigation follows. It is also subject to political pressure from developed countries. In case of a voluntary license under MPP, the unpleasant and difficult task of imposing a compulsory license for manufacturing or for importing can be avoided by governments. The slow country-by-country and drug-by-drug nature of compulsory licenses was one of the reasons why some activists started favoring MPP.¹⁹

Starting with only ARVs, MPP extended its activity to include hepatitis C and tuberculosis (TB) medicines in 2015. Till date, MPP has in-licensed 13 HIV, three hepatitis C and one TB product from 11 patent holders and out-licensed these to 24 generic manufacturers.²⁰ MPP reported that between 2010 and 2018, ARVs were made available in 136 countries providing treatment to 22 million patient-years through an average price reduction of 73 per cent relative to originator price. The number of people receiving antiretroviral treatment increased from 8 million in 2010 to 21.7 million in 2017.²¹ Surely MPP has contributed to improving access to ARVs. This has been a major achievement. MPP also incentivized the introduction of new paediatric and adult combination formulations.²²

But the functioning of MPP has not been without its criticisms. MPP could not prevail upon the MNCs to agree to grant of voluntary license to all the LMICs. MNCs continued to impose restrictions on the countries eligible for licensing. Many middle-income countries with manufacturing capacities (and also high-income countries) have been excluded from the licenses for HIV and hepatitis C medicines where MPP has been most active.²³ For example, for the ARV, Dolutegravir, upper middle income countries such as Belarus, China, Malaysia and Kazakhstan have been excluded by the patentee, ViiV Healthcare. Among the effective direct action antivirals for hepatitis C, Gilead has bilateral voluntary licenses for sofosbuvir, ledipasvir, velpatasvir and voxilaprevir. MPP has also arranged for voluntary licenses for daclatasvir, glecaprevir/pibrentasvir and Ravidasvir. Territorial restrictions have been imposed not only in Gilead licenses but also in the MPP licenses. For glecaprevir/pibrentasvir, for example, the patentee, AbbVie excluded several high-prevalence countries such as China, India and Brazil from the licenses. MPP had to agree to India being a “manufacturing-only” country.²⁴ In the countries not covered under licensing through MPP, prices remained high and unaffordable, for example US\$ 2190 per person per year for dolutegravir in Belarus.²⁵ So, even in products under MPP, some countries are required to use compulsory licensing or to take other measures to make medicines more affordable. Thus, globally, voluntary licenses under MPP cannot be considered to be a substitute for compulsory licenses.

Another major issue is that MPP has not been successful in bringing all the relevant products and firms under voluntary license. MPP has been successful mainly in ARVs for which it was originally set up. In hepatitis C too it has made some good progress. But in tuberculosis, MPP has been able to bring only one product under licensing. Despite appeals from civil society, Johnson & Johnson and Otsuka did not agree to licensing of the costly patented drug-resistant TB medicines bedaquiline and delamanid, respectively.²⁶ In 2018 MPP decided to expand its activities to other life-saving medicines such as cancer and diabetes. No publicly available information is available on the progress made.

This leads us to the structural problem with the voluntary patent pool and the role that MPP can play in the light of the Costa Rica proposal and the Solidarity Call.

The idea for setting up a patent pool for medicines is attributed to James Love who in a conference in 2002 cited the successful example of the US aircraft patent pool of 1917.²⁷ With

different patents held by different companies and with various companies charging very high royalties and threatening to sue others for patent infringements, the development of the military aircraft industry was seriously hampered. The patent pool was created at the initiative of the US Government for cross licensing of patents and reduction in royalty rates. But this was not a voluntary patent pool. The US Government used threats to acquire the patents if the companies did not cooperate.²⁸ If the governments who are funding COVID-19 medical products insist that the pharmaceutical companies should mandatorily place the patents in a pool managed by MPP, then surely it is going to work. But no developed country government (or charitable donors) has yet announced or indicated that R&D funding is or will be conditional.

Patent pools can be effective even without compulsion. Patent pools can be very useful and can be sustained when there is mutual interdependence among the pool members. When there are overlapping patents owned by different companies, placing these in a common pool helps each member. In the absence of a pool, individual licenses will have to be negotiated. But in MPP, the partners, – the MNCs and the generic companies – have different and in fact conflicting interests. MNCs want patents to prevent generic entry and charge higher prices. The generic companies want the entry barriers to be eliminated or reduced to participate in the market. As an editorial in *Nature* said, much of the progress to understand the structure of the coronavirus and to develop a vaccine has been possible because of sharing of knowledge and cooperation in the scientific community. But the same spirit of cooperation in sharing the fruits of this knowledge is not evident.²⁹ This is because the patentees gain by not sharing it. By preventing competition, they can sell at higher prices. Private profit calculations rather than public health considerations influence their decision to share their patents. Depending on the circumstances, they decide whether to join a voluntary pool or not. In the case of ARVs, MNCs decided to join MPP. In fact, they started voluntary licensing even before MPP was set up and their willingness to join the pool was instrumental in starting MPP.³⁰

Similarly, in the case of COVID-19 patented products, if MNCs join MPP without stringent conditions, then it of course can be a step towards a global solution. But if they do not want to join, there is nothing that MPP, the administrator can do. It neither has the power to enforce licensing like the US Government in the case of the aircraft pool mentioned above, nor can it provide any financial incentives – apart from arranging royalties – to induce MNCs to join the pool.

Thus, the success of a voluntary pool critically depends on the willingness of the patentees to join the pool. If the objective is to enhance access without confronting MNCs, then MPP may be an attractive option. But in a public health crisis, why should the boundaries of public policy be determined by MNCs?

In the light of the Costa Rica proposal and the Solidarity Call, the issue is not that MPP cannot or should not play a role. The problem is not with MPP. It has delivered where it could. The problem is to ignore its structural limitations and to expect it to do more than what it was meant to do or can do. When MPP was set up, it was realized that voluntary initiatives may not be adequate. Unitaid, the founder of MPP did not want to sacrifice the use of TRIPS flexibilities. MPP was designed to complement other measures such as compulsory licensing that may be necessary.³¹ It is natural for MPP to offer its services. In fact, if a pool is set up for COVID-19 medicines, MPP will be the best candidate to run it, given its experience. But the board chair and the executive director of MPP went out of the way to propose the voluntary pool as an alternative to government use licensing.³²

MPP should do what it can, but developing countries too must be encouraged to use all the legal and other measures possible. Given the urgency, just experimenting with and relying on MPP may be too costly.

Compulsory licensing and use of all other TRIPS flexibilities

A voluntary pool is a great idea. But it works when it does not remain merely "voluntary". MPP will work much better if MNCs are compelled or induced to join the pool. MPP as an organization cannot do much in this regard. But developed country governments funding R&D can do so by insisting on the condition that they must share the patents. Developing countries also can put pressure by starting to use compulsory licensing and other TRIPS flexibilities. As mentioned above, the voluntary license initiatives of MNCs culminating in the formation of MPP were in response to the intense international pressure on MNCs to make the patented ARVs more affordable. There was huge support for the use of compulsory licensing and other measures by developing countries. The international civil society played a very positive role in forcing MNCs to act. A similar movement supporting and encouraging the right of the developing countries to use all the TRIPS flexibilities can make MPP more effective. The options which developing countries have – apart from compulsory license – include not granting secondary medical use patents, applying rigorous standards of examination of patent applications and using Article 73(b) of the TRIPS agreement and suspending patent rights for security reasons.³³ Highlighting the virtues of voluntary measures and promoting MPP without adequate emphasis on TRIPS flexibilities, actually weakens MPP.

Compulsory licensing has been one of the most widely used TRIPS flexibilities.³⁴ But this has practically not been used in India which has a large generic sector and is expected to play a major role in manufacturing COVID-19 medical products.³⁵ The Indian generic companies have been more active in voluntary licensing than in compulsory licensing. While the majority of the generic companies with whom MPP struck deals are Indian companies, the latter have applied for only three compulsory licenses in India and have been successful in only one. The reason is not that there are no grounds for the grant of a compulsory license. MNCs have started charging exorbitant prices in India after TRIPS particularly in therapeutic groups such as cancer.³⁶ The reason is that the current compulsory license process in India is excessively legalistic, costly, time consuming and uncertain.³⁷ While MNCs have been keen to sign voluntary license deals with the Indian generic companies, they aggressively fight the grant of a compulsory license. In the case of the only compulsory license granted in India, the patentee aggressively opposed it, first at the Appellate Board then at a High Court and ultimately at the Supreme Court. MNCs have high stakes and have the financial resources to indulge in such legal battles. But for generic companies it is a serious disincentive to pursue compulsory licenses.

If MNCs do not join the voluntary pool for COVID-19 medical products but if procedures are simplified and are supportive of generic companies, then it is unlikely that the latter will not be interested in compulsory licensing. In a product patent regime, if they do not get voluntary license, then a compulsory license is the option for generic companies to enlarge their sphere of operations.

A number of countries including developed ones not part of MPP such as Canada and Germany and developing ones such as Ecuador and Chile have started changing their patent laws, rules and regulations to facilitate grant of compulsory licenses in the pandemic. Similarly, India and other countries including those which may need to import medical products, should start preparations to remove the bottlenecks for an effective compulsory licensing system. Here solidarity and international cooperation is crucial.

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- ⁹ Ibid.
- ¹⁰ Sarah, Newey, “WHO patent pool for potential COVID-19 products is ‘nonsense’, pharma leaders claim”, *The Telegraph*, 29 May 2020. Available from <https://www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/>.
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- ¹² See the “Statement from Health GAP on today’s ‘Solidarity Call to Action’ in support of the WHO COVID-19 Technology Access Pool”, 29 May 2020 (<https://healthgap.org/pressroom/>); “Medicines Law & Policy welcomes WHO’s Solidarity Call to Action to realise equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data”, 29 May 2020. Available from <https://medicineslawandpolicy.org/2020/05/medicines-law-policy-welcomes-whos-solidarity-call-to-action-to-realise-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/>.
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- ²² Brook K Baker, “Access to Medicines Activism” *supra* note 19, pp. 16-17.
- ²³ See, “Médecins Sans Frontières (MSF) Access Campaign position paper, “Mandatory open sharing of technologies for COVID-19 to ensure equitable access for all”, 2020. Available from <https://msfaccess.org>; Baker “Access to Medicines Activism” *supra* note 18, p. 16.
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- ³⁵ Another paper forthcoming as a CDS Commentary paper provides an analysis of the experience of developing countries with compulsory licensing with special reference to India. Available from <http://www.cds.edu/outreach/publications/new-commentary-series/>.
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- ³⁷ If India is a very good example of how to use patent laws before TRIPS to develop the generic industry, India is also an extremely disappointing case of how not to frame compulsory licence laws and rules after TRIPS. Strange as it may appear, the current compulsory licence procedure is inherited from the British Patents Act of 1911 which suppressed the growth of the generic sector. For a brief critique of India’s compulsory licence system, see Sudip Chaudhuri, “Industry Response” in Sudip Chaudhuri, Chan Park and K. M. Gopakumar, *Five Years into the Product Patent Regime: India’s Response*, UNDP, 2010, pp. 29-30. Available from https://www.in.undp.org/content/india/en/home/library/poverty/five_years_into_theproductpatentreimeindiasresponse.html.

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