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The Medicines Patent Pool Plots A Post-Pandemic Future: Interview With Director Charles Gore

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By William Looney

As the global access debate adapts to the stark inequities exposed by the COVID-19 pandemic, the UN-backed Medicines Patent Pool is emerging as a key player on issues ranging from vaccine tech transfer to making more drugs affordable against the spread of non-communicable diseases like cancer to middle- and low-income countries.

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The COVID-19 pandemic has re-energized the debate on global access to essential medicines.

Access to medicines is a big, complex question. For the Medicines Patent Pool, IP is a critical player in access; and negotiating voluntary licensing agreements with drug makers for low- and middle-income countries is its business model. When the MPP was founded in 2010, there was some skepticism about the scope of its ambition. "Every new drug that launches without a license to us at the same time is a missed opportunity to expand patient access to these life-saving innovations," said MPP director Charles Gore, in a recent interview with *In Vivo*.

The group is a way off this goal but Gore remains optimistic because "the dialogue around access and IP is improving." Developed countries continue to rely on IP as a driver of health innovation, he explained, while the record-setting deployment of several highly effective proprietary vaccines has strengthened the pharmaceutical industry's claim to a patent system they contend has made this success possible. At the same time, however, the COVID-19 pandemic has exposed "the massive human failures that arise when new health protections are applied selectively." He noted that the inability so far to limit the spread of infection and defeat the virus globally has made it clear that coordinated joint actions to broaden access

to vaccines and therapeutic drugs must take place – "It's a matter of how, not why."

Q. In Vivo: Can you point to examples of how the global conversation on drug access has changed toward your notion of it being a collective responsibility? Where are the areas of friction that pose a challenge to governments, industry and the international community working together to secure universal access to the technologies necessary to end the pandemic and avoid future threats to public health?

Charles Gore: It's interesting to see the US government position on the WTO TRIPS Agreement waiver on IP rights to address a public health emergency has changed from opposition to support. Waiving patent protection on the new COVID-19 vaccines will probably not make a big difference in eliminating the vaccine shortfall in low- and middle-income countries. Nevertheless, as a political statement the US is recognizing that the world needs to do better on access. All the major players concede the pace of immunizations worldwide is not even close to where it should be. And while the innovation industry and the IP system that underpins it have done a fantastic job in inventing and delivering vaccines with more than 90% efficacy, this great work has been diminished by the fact that millions and millions of the most vulnerable people are going without. From a public relations perspective, the industry's success on the science is clouded by this tragedy of leaving so many people behind while a few rich countries get the bulk of supply.

Stress Points On Access To Meds

We are still seeing substantive disagreement on how best to achieve access. What low- and middle-income countries dislike most about the current situation is the amount of control that big pharma companies insist on in negotiating their access to vaccines. There is a perceived lack of transparency on pricing. Governments believe that pricing information should be shared, and licenses should have the option of being non-exclusive, with provisions reflective of a broader public health orientation. IP holders have licensed their vaccines to other manufacturers, but these deals are not transparent, making it much harder for multilateral players like the WHO to coordinate an equitable, efficient system of access covering all those who need the vaccines. Unfortunately, this is where we are today: while low- and middle-income countries require more than 11 billion doses of vaccine, fewer than 3 billion have been distributed to date.

As the leader of an international public health organization that seeks to balance legitimate commercial interests with public health needs, I have seen that the private sector too often sees medicines access as an afterthought, arising very late, even many years after market authorization is secured. The mindset is to think first about the industrialized country markets that can pay and leave negotiations with everyone else to later.

I do see some shift away from this perspective among a few industry CEOs who have publicly committed to an integrated, global approach to access, from the start. But as yet we haven't seen much evidence of that in practice. Our vision at MPP is to work with companies to ensure no important health technology is launched without an access plan that answers the question, 'How are we going to get this innovation to everyone who can benefit, regardless of geography or income?' That's different than the conventional market model that starts by maximizing revenues and profits in rich countries and, once those financial targets are secured, begins figuring out how to get the product to low- and middle-income countries "at cost."

Q. In Vivo: Can you summarize what you think are the most serious flaws in the current pharma approach to global medicines access?

There is a lack of detail in what drug companies commit to in their access programs. Few products are launched with a comprehensive strategy to achieve access worldwide, for all patients who need them. The initiative to do something tangible always seems to come later, and responsibility is devolved not to the commercial side, but to a corporate social responsibility or philanthropic donations program that may carry less clout with top management. And, frankly, industry access programs are of variable quality. This conclusion is underscored by the work of the independent Access to Medicines Foundation and its annual index of access performance among the top 20 big pharma companies. Finally, the geographic reach of these programs is often rather small.

Our MPP model offers a much bigger exposure. To date, we've secured access to life-saving medicines in 148 countries and negotiated more than 100 separate licenses for a wide range of drugs and vaccines, including a majority of the products on the WHO Essential Medicines List. Ten big pharma patent-holding originator companies have signed licenses with MPP along with 23 generic manufacturers located throughout the globe.

Q. In Vivo: Has the MPP done an adequate job reaching out to the innovative industry? Have there been some mixed signals from you along the way?

We have been very persistent about reaching out. On the back of a pledge we secured late last year from our generic manufacturers to increase capacity for COVID-19 immunizations, I wrote to many big pharma CEOs saying we would like start discussions on growing our relationship. I have presented our views on a positive dialogue at numerous high-level fora where industry has a seat at the table. There are ongoing discussions with leaders of the trade group, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and we have solicited many governments' help in getting the industry to talk to us, openly without conditions. Our business development team has talked to the appropriate staff at companies, one-on-one. Finally, we have upgraded our media presence to position MPP as a driver of pragmatic, "win-win" solutions. Personally, I think the problem is rooted in the fact that big pharma is overwhelmed with many conflicting priorities. Drug access in LMICs has dropped off the short list right now. But our door is always open to do something jointly that is productive for patients.

Q. In Vivo: What is your assessment of the contribution of the generics industry to global access?

The generics industry is today much more sophisticated than it was even just a decade ago. Back then, some companies ran two lines of production, one for high income markets and the other for everyone else. There were frequent gaps in regulatory compliance between the two. Today, we find the capabilities of generics producers are greatly improved. The emphasis is on complex biologics, monoclonal antibodies and vaccines. Biosimilars are a lucrative new field with much revenue potential. The competence is there to manufacture all these new products safely, in large quantities, at lower cost, for more countries. The MPP's future also depends on this transition to higher-end products if we are to grow our remit to cover the licensing of biologics for big non-communicable diseases (NCDs) like cancer and diabetes. NCDs will dominate health status and provision in low- and middle-income countries once the pandemic fades, and the speed to market of these new technologies will make a big difference in raising the standard of care, as more people get to experience their long-term therapeutic advantages over older products.

An Early Precedent: Gilead's Hep C Bridge Builder

Q. In Vivo: Can you cite an example of a successful big pharma access program that might serve as a model for others?

I entered the industry more than 20 years ago as an advocate for patients with hepatitis C and B. The arrival of a curative drug for hepatitis C in 2014 developed by Gilead Sciences proved a game-changer after decades where patients had few, if any, options to treat this silent but progressively dangerous condition. Gilead got terrible press because of the high introductory price it set in the US for sofosbuvir (Sovaldi), but they did their homework and actually came to the MPP to discuss the possibility of negotiating a license for this small molecule drug to facilitate entry to lower-income markets abroad. We had to turn down Gilead's offer as at the time our mandate covered only HIV.

However, Gilead ended up using the MPP model in designing its own international access program on hepatitis C. Management took the then unprecedented step of granting licenses for sofosbuvir to 11 generic companies, effectively forcing them to compete against each other, which is exactly what we seek to encourage in

our own licensing deals. In addition, Gilead itself registered sofosbuvir in many of the same low- and middle-income countries, offering its branded drug at a fixed price of $900 or equivalent, which effectively became the ceiling on the local price that generic competitors could charge.

The scheme worked. Using this basic competitive market mechanism, Gilead ensured that prices would adjust to the median that a country could afford, at a point somewhere south of that $900. And by registering the sofosbuvir brand in these countries first, Gilead made it faster and easier for its licensees to get the necessary local regulatory approvals as well. In essence, Gilead's goal here was not to amass profits for itself but to make selling sofosbuvir attractive to generic competitors, at prices low enough to ensure the humanitarian goal of broad access to the drug in neglected lower income markets with a high incidence of hepatitis C. Because Gilead used essentially the same model as MPP, when our mandate expanded to hepatitis C in 2015 and we were able to license Bristol Myers Squibb's drug daclatasvir, generic companies with sub-licenses from both us and Gilead are able to sell the combination of sofosbuvir and daclatasvir at less than $100, for a three-month curative course of treatment.

Q. In Vivo: So how exactly does the MPP work?

We interact with a multiplicity of stakeholders – one of the broadest constituencies in the UN system. WHO is probably the most important of these; Unitaid, the Swiss Agency for Cooperation and Development and, most recently, the government of Japan, are principal funders of the MPP's annual budget of a little more than $8m. Simply put, the MPP works to facilitate the licensing of quality medicines developed in the private sector, in areas where this will have a real impact on global public health. We approach the originators that hold the IP rights to negotiate a license, seeking to convince them that they have both a business interest and a social responsibility in doing so. We talk about them serving a geographic area where the company lacks a presence, or how engaging with us might help achieve a better royalty return than selling only to a tiny, finite pool of elite customers at prices unaffordable to everyone else. We also stress the growing impact of ESG investing and how expanding affordable access to new customers enhances corporate reputation, creates shareholder value and attracts investors.

One of the key reassurances we can give originators wanting to work with us is in allaying concerns about product diversion. We have the tracking mechanisms in place to prevent generic versions of the originator's drugs from ending up being sold in developed country markets. It's part of what we call our Alliance Management system, where we support our generic sub-licensees in their development and registration activities as well as monitor them to ensure they abide by the terms of the license we negotiate with the originator. Of course, we work with governments and other stakeholders to ensure the licenses actually result in access on the ground. All of this is what has made MPP a credible partner.

Using Competition To Make Drugs Affordable, Not Cheap

Q. In Vivo: Can you outline the licensing process with the MPP?

First, we examine the global portfolio of new and existing medicines to identify particular therapies where increased access might make a difference in addressing an unmet need in the core therapeutic areas we focus on. As I mentioned, those core areas are now increasing to major chronic conditions – well beyond our initial focus on HIV.

Next, we approach the originators of those therapies to present our case on unmet need and discuss the terms of a voluntary license. Once we have negotiated and agreed on a license, we initiate a process whereby we solicit interest from generic companies in obtaining a sub-license. The companies undergo a rigorous vetting process and then we choose the candidates that meet our standards for safety, quality and management. We consider how our sub-licensees will contribute to the sustainability of the local market, striking a balance between competition that will keep prices low yet still allows them to earn a fair return on investment. Once we decide on the companies that meet these criteria, we legally contract with them and offer the license.

But our contribution does not end there. Much of the MPP's day to day work is helping the sub-licensees

MEDICINES PATENT POOL

The Medicines Patent Pool (MPP) is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries.

To date, MPP has secured access to medicines in 148 countries and negotiated more than 100 separate licenses for a wide range of drugs and vaccines, including a majority of the products on the WHO Essential Medicines List. Ten big pharma patent-holding originator companies have signed licenses with MPP along with 23 generic manufacturers located throughout the globe.

Current Partnerships With Innovators

Hep C

AbbVie
glecaprevir/
pibrentasvir

BMS
daclastavir

Pharco Corporation
ravidasvir

Tuberculosis

Johns Hopkins University
sutezolid

HIV

AbbVie
lopinavir
ritonavir
(adults)
lopinavir
ritonavir
(paediatrics)

Boehringer Ingelheim
nevirapine
(non-assert)

BMS
atazanavir

Gilead
bictegravir
cobicistat
elvitegravir
emtricitabine
tenofovir
alafenamide
tenofivir
disoproxil

Janssen
darunavir
(paediatric)
(non-assert)

MSD
raltegravir
(paediatric)

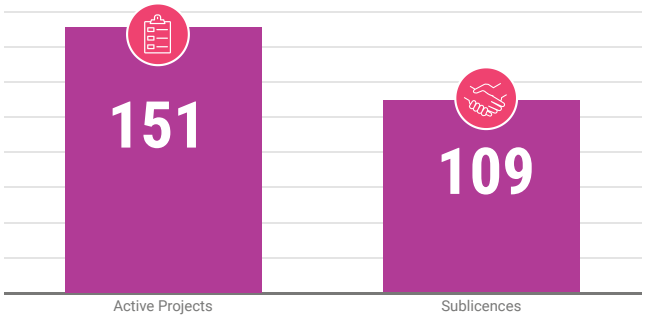
NIH
darunavir
related

Roche
valganciclovir
(pricing
agreement)

University Of Liverpool
solid drug nano
particles
technology

ViiV Healthcare
abacavir
(paediatrics)
dolutegravir
(paediatrics)
dolutegravir
(adults)

Current Portfolio Figures



COVID-19 Pledges

March 2020, MPP temporarily expands its mandate to include any health technology that could contribute to the global response to COVID-19.

May 2020, WHO calls MPP to join the C-TAP (COVID-19 Technology Access Pool) initiative, a global collaboration to accelerate development, production and equitable access to COVID-19 tests, treatments and vaccines.

May 2021, MPP expands its mandate into the licensing of technology with an initial focus on COVID-19 vaccines and pandemic preparedness.

MPP launches VaxPaL, its new patents database devoted to COVID-19 vaccines.

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Pharma Intelligence: In Vivo, Design Lucie Ellis

with their late-stage development, registration and manufacturing requirements. And we provide them with market information, including data like where each licensee ranks on plans for filing with a Stringent Regulatory Authority, such as the US FDA or WHO or an in-country registration, although of course doing that anonymously. Or we can disclose that none of the other licensees are registering in a particular country market – a market that might present an interesting competitive opportunity for them. A key tool we rely on is our *MedsPaL* data base on IP status of patented essential medicines in low- and middle-income countries, which is now being supplemented by *VaxPaL*, for IP on vaccines, an area where we expect to do more in the future – particularly as pressure builds for more local production of vaccines to address the substantial inequities in access revealed by the pandemic.

Three Steps To 'Yes'

Q. In Vivo: Based on this, MPP does not present as a typical UN procurement agency. You seem to believe in competition and the market as the best way to deliver on your access objectives.

Right. We don't do procurement. We are highly entrepreneurial, not a policy body; most of our time is spent trying to strike a balance between three diverging requirements. The first is finding that sweet spot amidst the commercial interests of the originator companies. Second, is building a sustainable transaction model to attract the generic companies to come to the table. Third, is the need to position all this in the broader context of public health – expanding access to neglected patients.

What this means is every single one of our licenses is a compromise. IP holders in industry want to retain exclusivity in certain markets they see as a commercial opportunity; generic firms want the biggest market they can get. Civil society and low- and middle-income governments want the cheapest generic drugs, period.

In fact, the biggest criticism lodged at the MPP is that we usually have so few voluntary licenses that include the higher range of the middle-income spectrum. Is it right that an upper middle-income country should pay the same for an MPP-licensed drug as the lowest of the low-income countries? We think not. Countries with higher incomes should be contributing to innovation by paying more for their medicines. What the MPP seeks is to make sure drugs are available at affordable prices in the locations where they are sold. Our mantra *is affordable* drugs, not *cheap* drugs. There is a difference between the two.

Model Deal For The Future

Q. In Vivo: Is there any recent MPP licensing agreement you can cite as being a precedent in terms of innovating to increase access to high quality medicines?

Late last year we secured what I think is a novel, highly promising voluntary license agreement with ViiV Healthcare, a joint venture between GlaxoSmithKline plc, Pfizer Inc., and Shionogi Ltd., specializing in HIV therapies. It's a breakthrough because the deal on their drug, dolutegravir (*DTG*), covers access in four upper middle-income countries. We were able to provide ViiV with a significant royalty stream that reconciled its commercial interest in these markets with a broad patient access model – specifically, one that enabled the countries to switch from an older pill regimen to the generic version of the latest WHO recommended first-line DTG-based regimens for HIV treatment. I call it a win-win: we were able to recognize the commercial value of the innovation to the originator with a strong royalty structure; negotiate a price point that was commercially interesting to the generic business; while giving access to an improved, high-quality treatment at an affordable cost, in line with what the four governments could pay.

This agreement is especially important to us as it is precisely the approach we may need to deploy in the future, in line with our new priority on access for low- and middle-income countries to quality drugs in the NCD space. I'd go so far as to say MPP's future depends on more of this type of arrangement.

Q. In Vivo: The MPP has in its charter a commitment to ethical business behavior by its contracted sub-licensees. Have you had to enforce this commitment against any breach?

We've had a few cases where generic producers were a bit slow in fulfilling their obligations, but no situation where we've been forced to take action. That is due to the close relationships we have with both the licensors and the licensees. As I have noted, all our interactions start with the premise that a deal must work for everyone – it's the centerpiece of the MPP business model. To keep everything in line, we are expanding our Alliance Management team, including at our branch office in India, where many of our generic companies are based. We run regular quarterly meetings with each generic company in addition to the day-to-day support we give them to ensure smooth administration of the licenses on the ground. We know that commitment is valued; many of our generic partners say they prefer to have a license from us rather than having one directly from the originator company. Our Alliance Management initiative has been so well received that some originator companies have turned to us to help them with some of their own bilateral agreements.

A Bigger Mandate: Biologics, Cancer And Other NCDs

Q. In Vivo: The MPP has been in a growth phase of late. What are your current priorities as executive director?

Our mandate is significantly expanded. From the sole priority on HIV at the beginning to our first expansion into TB and hepatitis C, we then moved in 2018 to include all of the products on the WHO Essential Medicines List. This signaled our entry to the vast landscape of non-communicable diseases (NCDs), which also incentivizes us to begin looking at licensing opportunities much earlier in the development phase of medicines than we had done previously. Finally, in the midst of the pandemic last year we were asked by the UN and WHO to pursue the global availability of COVID-19 health technologies. What that has done in turn is put MPP in the center of another set of multilateral discussions on technology transfer that promotes equity in global access to vaccines.

Although the pandemic has complicated our mandate to tackle NCDs, one of my priorities is to understand how to partner with the companies, foundations and advocacy groups active in fighting the big NCDs like cancer, diabetes and heart disease. Partnering was easier around our original remit on HIV due to the direct involvement of major procurement entities like the Global Fund and PEPFAR in fighting the disease.

We don't have those existing infrastructure links ready to employ for cancer or diabetes. It requires an entirely new effort addressing the fact that in low- and middle-income countries delivery capabilities for NCD products are weak; some countries don't have the trained staff, logistics networks or the academic and medical institutions conducting research. Medical education is an important element in building access in the NCD space but not traditionally something that generic manufacturers cover, so we are working with existing initiatives like Project Echo, a global telehealth model for rural care based in the US state of New Mexico.

Separately, we are initiating conversations with many of these organizations – starting with the WHO's NCD department, as well as the Union for International Cancer Control, the World Heart Federation and the International Diabetes Federation – signaling our interest in a more holistic approach to the access proposition. It's been noted that some big patient organizations are now becoming directly involved in drug development, which is why they represent an important constituency for us going forward.

Another priority – linked to NCDs – is making certain we can adapt to the new world of advanced biologics drugs, which will drive the innovative agenda on health care for the remainder of the decade. Our MPP model must incorporate a more sophisticated approach to tech transfer; henceforth, more of this will need to be done ourselves or with partners because the originator companies may not be able to devote the human resources necessary to familiarize a generic sub-licensee with a complex biologic. One objective we are exploring is to establish an in-house MPP panel of experts to provide such guidance and support.

Overall, the NCD agenda is critical for us, but it's going to take time to see results. I am hopeful for something tangible in terms of a first NCD license by the end of the

Thoughts From Philippe Douste-Blazy

Co-Founder, Medicines Patent Pool, Former UN Undersecretary-General And Former French Minister of Foreign Affairs

A decade ago, the MPP was a new and untested concept. We have now proved its effectiveness. With the participation of both the originator and generic sides of the business, 18 billion doses of medicines for HIV and other infectious diseases have been accessed by patients in 148 countries. The MPP has given lower-income populations the same quality treatments previously reserved only for the richest, with prices that are competitively differentiated and therefore adapted to the solvency of each market.

Now is the time to extend this model to major non-communicable diseases like cancer. Ultimately, we should take what we have done for medicines to address other global challenges like climate change, water and scalable electricity. But the inequities revealed by the COVID-19 vaccines shows we still have many battles to fight to make health care a human right for all...

year – and my goal is to increase that to three by 2023. A challenge is that in the NCD space, industry access responsibilities in emerging markets often rests with the CSR department rather than the commercial business. And it is incumbent on us to educate the business first on the details of how we can expand an originators market reach through sub-licensing.

With specific reference to COVID, our expertise in licensing has been sought by the international community to consider how our model might work to expand access to antiviral drugs and therapeutics in low- and middle-income countries. Right now, MPP is discussing one such license with Merck (MSD) for its antiviral drug, *molnupiravir*, originally developed for influenza but now being tested for use among patients with COVID-19. Phase three results aren't due until October, but we want to be ready to secure commitments on access as quickly as an eventual Emergency Use Authorization allows.

Leading The Way On Tech Transfer, Post-Covid

The pandemic is also giving the MPP more prominence as a key player in discussions now taking place on how to boost regional/local production of vaccines to fight future public health emergencies. The lack of vaccine supplies in areas hard-hit by COVID-19 – especially the African continent – has put tech transfers that encourage local manufacture at the top of the UN agenda this year. We are contributing our expertise and experience in voluntary patent licensing and tech transfer for the first WHO-sponsored mRNA vaccine manufacturing hub now being set up in South Africa.

Q. In Vivo: Is there anything you see as a missed opportunity in the ongoing efforts of the international community to increase equitable access to life-saving drugs?

We must not let the inequities surfaced during the course of this pandemic be a missed opportunity. There is now a clear rationale to increase the pace in awarding voluntary, non-exclusive licenses for the patented NCD products on the WHO Essential Medicines List. This has not happened to date, so I see this as a missed opportunity – one that I am confident can be rectified over the next few years.

There is a real opportunity now for the major drug regulatory bodies to make permanent the faster vaccine and drug approvals we saw during the first round of the pandemic. We could use more standardization of approvals across countries. We must avoid situations where we negotiate a license, see the generic developed and then wait years for the local market authorization that gives people in need access to it. Unfortunately, in our business the whole process is only as fast as the slowest element in it. That's a big missed opportunity if we don't adapt ourselves to the urgency.

Partnering has always been a challenge, but the good news it has become a reflex action through the course of the pandemic. The best evidence of that is the decision of 18 of MPP's generic partners last November to sign an open pledge to work with us in increasing capacity and access to hundreds of millions of doses of COVID-19 treatments immediately as they become available over the next year. Likewise, I believe big pharma and its trade associations understand they must do more on access – and the best proof of that is many more of them are now coming to the table to work with us. When you put all this together, the zeitgeist is in our favor.

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