

Raza, Werner G.

Research Report

COVID-19 and the failure of pharmaceutical innovation for the global South: The example of "neglected diseases" and emerging infectious diseases

ÖFSE Briefing Paper, No. 32a

Provided in Cooperation with:

Austrian Foundation for Development Research (ÖFSE), Vienna

Suggested Citation: Raza, Werner G. (2021) : COVID-19 and the failure of pharmaceutical innovation for the global South: The example of "neglected diseases" and emerging infectious diseases, ÖFSE Briefing Paper, No. 32a, Austrian Foundation for Development Research (ÖFSE), Vienna, <https://doi.org/10.60637/2021-bp32e> , <https://www.oefse.at/publikationen/briefing-papers/detail-briefing-paper/publication/show/Publication/covid-19-and-the-failure-of-pharmaceutical-innovation/>

This Version is available at:

<https://hdl.handle.net/10419/232582>

Standard-Nutzungsbedingungen:

Die Dokumente auf EconStor dürfen zu eigenen wissenschaftlichen Zwecken und zum Privatgebrauch gespeichert und kopiert werden.

Sie dürfen die Dokumente nicht für öffentliche oder kommerzielle Zwecke vervielfältigen, öffentlich ausstellen, öffentlich zugänglich machen, vertreiben oder anderweitig nutzen.

Sofern die Verfasser die Dokumente unter Open-Content-Lizenzen (insbesondere CC-Lizenzen) zur Verfügung gestellt haben sollten, gelten abweichend von diesen Nutzungsbedingungen die in der dort genannten Lizenz gewährten Nutzungsrechte.

Terms of use:

Documents in EconStor may be saved and copied for your personal and scholarly purposes.

You are not to copy documents for public or commercial purposes, to exhibit the documents publicly, to make them publicly available on the internet, or to distribute or otherwise use the documents in public.

If the documents have been made available under an Open Content Licence (especially Creative Commons Licences), you may exercise further usage rights as specified in the indicated licence.



32a BRIEFING PAPER

COVID-19 and the failure of pharmaceutical innovation for the Global South: The example of „neglected diseases“ and emerging infectious diseases

Werner Raza

March 2021

OFSE'''

Austrian Foundation
for Development Research

Download: <https://www.oefse.at/fileadmin/content/Downloads/Publikationen/Briefingpaper/BP32en-neglected-diseases.pdf>

IMPRINT

Austrian Foundation for Development Research – ÖFSE
A Austria, 1090 Vienna, Sensengasse 3, **T** +43 1 3174010, **F** -150
E office@oefse.at, **I** www.oefse.at, www.centrum3.at

With funding from



**Austrian
Development
Cooperation**

Contents

Abstract.....	3
1. Intellectual property rights: justifications and areas of tension	4
2. Strengthening international IPR protection through the WTO	4
3. Will stronger IPR protection lead to new and better treatments for diseases?	6
4. Conclusion: The need for a fundamental reform of the pharmaceutical innovation system in the wake of COVID-19.....	12
References.....	15

Index of Figures

Figure 1:	Funding sources for neglected diseases, 2009-2018	9
Figure 2:	R&D funds for ND, by category	10
Figure 3:	R&D expenditures for "emerging infectious diseases", by funding type (2014-2018)	10
Figure 4:	R&D expenditure on emerging infectious diseases, by disease/ R&D area (2014-2018)	11

List of Abbreviations

EU	European Union
IP	Intellectual Property
IPR	Intellectual Property Rights
LDCs	least developed countries
ND	neglected diseases
NIEO	New International Economic Order
OECD	Organisation for Economic Co-operation and Development
PEPs	product development partnerships
R&D	research and development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organization
WHO	World Health Organisation
WTO	World Trade Organisation

Abstract

The debate about the lack of access to COVID-19 vaccines for the countries of the Global South joins a long history of struggle for effective and affordable treatments for those several dozen diseases for which the World Health Organisation (WHO) uses the telling adjective "neglected". Empirical evidence shows that the pharmaceutical innovation system, built over the last thirty years around the global protection of so-called intellectual property rights (IPR), has failed across the board in providing treatments for these diseases. The same applies to the category of new infectious diseases, which also includes coronaviruses. Here, too, there has been little research and development effort, even though the dangers of the diseases they cause had been known for 20 years. The COVID-19 pandemic should therefore be used for a fundamental reform with the aim of aligning pharmaceutical innovation more closely with public health goals. In addition to a stronger financial commitment from the EU, the pharmaceutical industry should also be required to make a greater contribution to the fight against these diseases, for example in the form of a levy to fund research and development (R&D) for "neglected diseases" and new infectious diseases.

Keywords: TRIPS-agreement, COVID-19, neglected diseases, new infectious diseases, patents

1. Intellectual property rights: justifications and areas of tension

Intellectual property (IP), such as patents, copyrights, trademarks, etc., are legally guaranteed exclusive rights of use to intangible goods, such as a technical invention or a work of art. The property rights authorise owners for a certain period of time – in the case of patents usually for 20 years, in the case of artistic works for up to 70 years – to secure the exclusive economic exploitation of the intangible good and thus to exclude others from using it. The granting of this legal privilege or monopoly right is commonly justified in the case of patents as the most important IP right on the grounds that, in view of the public nature of knowledge and the uncertainty of success associated with technical invention processes, the rate of technical progress would otherwise be lower than would be desirable for modern economies. The high profits potentially achievable through intellectual property rights (IPR) thus offer companies an incentive to take risks and develop new technologies and products. In return, society also benefits from these, although it has to accept certain disadvantages for a certain period of time, such as typically high prices and limited availability, as a result of which third parties can also be excluded from using them, for example directly (due to the lack of a licence) or indirectly (due to a lack of purchasing power). IPR protection is therefore always based on a social balancing of interests, where the advantages of greater innovative power must be weighed against the social disadvantages of (temporarily) restricted use (Drahos 2016; Stiglitz 2008).

Legal foundations for industrial IPR protection were introduced in the wake of the industrial revolution from the late 18th century, especially in the leading industrialised countries. Due to their character as temporary monopoly rights, patent protection remained controversial in the liberal economic discussion of the 19th century for a long time, as it hindered free competition. Prominent examples fuelled this scepticism. After he was granted his first patent in 1769, James Watt spent his energy in the following years not on the further development of steam propulsion, but on preventing his many competitors from doing just that by exploiting his monopoly rights. As the US economists Michele Boldrin and David K. Levine show in their basic work published in 2008, the technical development and broad industrial use of the steam engine, and numerous other technical developments, was thus significantly slowed down (Boldrin/Levine 2008).

Similar corporate practices still employ legions of patent lawyers today with the aim of excluding competitors from using protected technology. The extent to which IPR protection accelerates technological progress or, on the contrary, slows it down, cannot be answered unambiguously in theory, but remains an empirical question. What is clear is that IPR protection rights grant companies monopoly power. The greater the monopoly power, the more likely it is that risk-taking entrepreneurs will become conservative rentiers who are primarily concerned with defending the high incomes associated with their legal privileges. This not only hinders economic competition, but can also be used to exert political influence and thus be converted into political power. It is therefore not surprising that the "pharmaceutical lobby" is considered one of the most influential interest groups in both the USA and the European Union (EU).¹

2. Strengthening international IPR protection through the WTO

Historically, the introduction of (stricter) IPR protection rights has depended on the level of development of the respective national economy (Lerner 2002). The more innovation-driven an economy became, the louder the economic interests in favour of IPR protection became.

¹ For the USA see <https://www.theguardian.com/us-news/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis>; for the EU see <https://corporateeurope.org/en/2020/09/internal-documents-show-pharma-lobby-promoting-commercial-interests-during-corona-pandemic> (12/03/2021)

In turn, countries with catching-up industrialisation strategies had an interest in the unhindered use of technical knowledge. Moderate IPR protection standards or the lack of them in national – and for a long time also in international – law favoured this. The fact that Switzerland, for example, established a national patent law rather late (1888), which, however, completely excluded chemical inventions until the early 20th century, proved to be very advantageous for the development of the chemical and pharmaceutical industry in the country (Chang 2001).

IPR protection norms introduced too quickly in national law therefore enable technologically more advanced foreign producers to have their technologies protected, hindering the catching-up technological development of local industry. This tension forms the basis for the political debate on international IPR protection between industrialised countries and "developing countries" in the 20th century and up to the present.

As long as IPR protection was organised on a purely national basis, it was cumbersome for IPR owners in the industrial pioneer countries to have their technologies protected in other countries. The first successful efforts to create international foundations for the protection of patents and copyrights date back to the 1880s and led to the Paris Convention for the Protection of Industrial Property of 1883 and the Berne Convention for the Protection of Literary and Artistic Works of 1886. These and their successor agreements in the 20th century defined a general framework with minimum standards that contributed to the international enforcement of IPR protection norms, but left the signatory states with certain national policy space for implementation.

Nevertheless, IPR protection remained controversial. In the wake of the great decolonisation movements of the 1960s and 1970s, criticism of it became louder again. The demand of the newly independent states for a New International Economic Order (NIEO) also included demands for a reform of international patent protection. The provisions of the Paris Convention were perceived as too extensive and detrimental to their development efforts. Negotiations on this took place in the early 1980s within the framework of the World Intellectual Property Organization (WIPO), the international organisation that had been founded in 1967 to promote worldwide IPR protection. However, these negotiations failed in 1984 due to the determined resistance of the industrialised countries led by the USA. In addition, the outbreak of the debt crisis in the early 1980s decisively weakened the negotiating position of the Global South (Sell 1998).

Instead of a weakening of IPR protection, the opposite development occurred as a result. The changing international power imbalance, the dissatisfaction of the industrialised countries with the work of WIPO and, last but not least, the growing importance of the world's leading US information and communications, entertainment, pharmaceutical and biotechnology industries led to a regime change in the course of the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT) in the period from 1986 to 1994. International IPR policy became part of trade policy. One of the three pillars of the World Trade Organisation (WTO), established in 1994, was a new agreement to protect so-called trade-related intellectual property rights – the TRIPS Agreement. This agreement defined much more stringent international minimum standards for IPR protection and was also subject to the WTO's much more powerful new sanctions mechanism. It de facto replaced the existing set of international rules on IPR protection administered by WIPO and became the central reference work for the efforts to strengthen international IPR protection that have been intensified until today. Since then, this has mainly taken place within the framework of bilateral trade agreements, through which even more far-reaching IPR protection provisions (TRIPS-plus provisions) are imposed on the basis of the TRIPS Agreement by the leading industrialised nations, such as the USA and EU states. The paradox that far-reaching monopoly rights for companies are being enforced under the title of "trade liberalisation" remained hidden from the general public in the OECD countries for a long time, but not from the countries of the Global South affected by it (Correa 2000).

The latter's strong reservations about the implications of the TRIPS Agreement for the fight against widespread epidemic or new diseases such as malaria, tuberculosis and HIV/AIDS led them, in 2001, in the course of the "Doha Declaration", to link their agreement to the start of a new WTO round of negotiations to the adoption of a declaration on TRIPS and public health.² The declaration not only reaffirmed the right of countries to use existing treaty provisions to protect public health, such as the imposition of compulsory licences or the parallel import of medicines, but also extended the transition period for the application of the TRIPS Agreement for "least developed countries" (LDCs) by 10 years. Since countries without (sufficient) own pharmaceutical production capacities – and this is the vast majority of countries in the Global South – do not really benefit from compulsory licences, a separate solution was to be found for them. An amendment to the TRIPS Agreement adopted in 2005 (Article 31bis) allows countries to impose compulsory licences for the purpose of exporting medicines to countries without their own production capacities (Cullet/Yuanquiong 2019). This is part of the so-called "TRIPS flexibilities".

On 2 October 2020, India and South Africa submitted a request for the temporary suspension of certain TRIPS provisions (essentially for patents, trademarks and industrial designs) to combat the Corona pandemic. However, with reference to these "TRIPS flexibilities", several EU states (including Austria), the USA and others rejected the request.³ The use of the "TRIPS flexibilities" has however proved difficult in practice. In view of the time-consuming procedures involved, so far only a few countries have made use of them in the event of a crisis. Last but not least, experience in the context of the fight against HIV/AIDS shows that countries that wanted to introduce compulsory licences were exposed to strong political pressure from the governments of leading industrialised countries and faced threats of legal action.

3. Will stronger IPR protection lead to new and better treatments for diseases?

The pharmaceutical industry is often referred to as a prime example of an economic sector in which the introduction of IPR protection makes sense. After all, pharmaceutical innovation is characterised by high fixed costs and great uncertainty. Private actors will not take on these risks if the prospect of high returns does not beckon. In Austria, too, the pharmaceutical industry never tires of emphasising this.⁴ However, the history of patent protection in the pharmaceutical industry as well as the empirical evidence give few indications of this.

The historical enforcement of patent rights for chemical and pharmaceutical inventions shows strong national differences. In Great Britain, France and the USA, patent protection systems including chemical inventions were already introduced in the second half of the 19th century. In most continental European countries, including Germany and Switzerland, which today are home to leading pharmaceutical companies, patent protection was introduced late and only partially. In Germany, patents were introduced in 1877 for production processes but not for products, and in Switzerland there was no patent protection for the entire 19th century, neither for chemical processes nor substances. Studies in economic history conclude that this situation contributed significantly to the decline of the French chemical industry, which had been leading until the 1860s, and hindered the development of a separate industry in Great Britain and the USA for decades. In parallel, a technologically superior chemical and pharmaceutical industry developed under (more) competitive conditions in Germany and Switzerland, which dominated the international market until World War II (Boldrin/Levine 2013). The two world

² See https://www.who.int/medicines/areas/policy/doha_declaration/en/ (12/03/2021)

³ See <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> (12/03/2021)

⁴ See https://www.ots.at/presseaussendung/OTS_20210217_OTS0129/patentschutz-ist-kein-hindernis-sondern-ein-treiber (12/03/2021)

wars finally reshuffled the cards and favoured the development of technologically strong US and British chemical and pharmaceutical companies.

The post-war period then saw the enforcement of stricter patent protection standards. Not only process patents, but the much more restrictive product patents were gradually introduced in European countries.⁵ This happened in Germany in 1967 and in Switzerland in 1977. In Italy, there had been no patent protection for pharmaceutical inventions at all until the 1970s, which strongly favoured the development of a generic drug industry. Italy only lost its place as the world's fifth largest producer of medicines after patent protection claims by foreign production companies were recognised by the supreme court for the first time in 1978. The expectation that the introduction of IPR standards would increase the innovative strength of the Italian pharmaceutical industry was not fulfilled in any case in the period that followed (Scherer/Weisbrod 1995).

Since the 1980s, Italy's place as an important producer of generic drugs has been taken by a number of emerging countries, above all India, and by a clear margin Brazil and South Africa. By building up an industry without patent protection, through which cheap medicines were produced not only for their own population but for the entire Global South, these countries fulfilled an important social function. It is precisely these countries that were forced by the TRIPS Agreement to introduce comprehensive IPR protection, including product patents, by 2005 at the latest.

Overall, the empirical evidence that increased patent protection leads to more innovation and thus justifies its social costs is surprisingly thin. There is little support in the literature that higher patent protection increases the rate of innovation, neither for the pharmaceutical industries nor for the economy as a whole (Boldrin/Levine 2008). Although the number of patent applications has increased massively in most industrialised countries over the past decades – in the USA, for example, by a factor of four between 1980 and 2010 – this has had no positive effect on either R&D expenditure or overall economic productivity over the same period. Some studies even found a statistically significant negative relationship between patent protection and productivity growth (Baker 2017). As mentioned at the outset, the patent system also led to a sharp increase in transaction costs, especially due to the sharp increase in the number of legal disputes between companies. One study (Bessen et al. 2012) estimates the cost of litigation with so-called patent trolls at USD 29 bn in 2011.⁶ Large companies in particular use legal remedies strategically against competitors, especially also against smaller firms and start-ups. The latter are involved in patent litigation much more often than large firms (Lanjouw/Schankerman 2004). This discourages smaller companies in particular from conducting research in areas where patent density is already comparatively high. Also, so-called *patent thickets* in sectors such as semiconductor production, biotechnology or software development make the R&D processes of competing firms more difficult and expensive, since they first have to acquire licences to use the required technologies (Shapiro 2001). From an economic point of view, these and similar forms of *rent-seeking behaviour* represent costs without social benefits and thus a waste (Stiglitz 2008).

In any case, a significant effect of the tightening of global IPR protection since the 1970s was the concentration process among the large pharmaceutical companies brought about by dozens of mergers and acquisitions. This resulted in the emergence of globally active, listed corporations whose shareholder orientation is primarily geared towards high returns for their shareholders. Indeed, the returns of the pharmaceutical industry in the OECD countries are consistently among the highest of all economic sectors. For example, a recent study shows

⁵ Process patents protect a specific manufacturing process for a chemical agent, leaving it possible for other companies to manufacture the same agent if they find an alternative manufacturing process. Product patents go much further by granting the production and use of a chemical agent exclusively to the patent holder.

⁶ Patent trolls are companies founded solely for the purpose of accumulating patents and enforcing patent rights against third parties, without ever wanting to use the patents for productive purposes as well.

that 35 large pharmaceutical companies generated gross earnings (as measured by EBITDA)⁷ of 29.4 % between 2000 and 2018, around 10 percentage points higher than 357 companies listed in the S&P 500 stock index in various other industries (Ledley et al. 2020). The most important expenditure items for pharmaceutical companies are expenses for advertising and marketing. At around 40 %, these are on average twice as high as those for R&D. The relevant literature has repeatedly criticised the fact that the lion's share of the R&D expenditure, which lies accordingly only at around 20 %, is spent on the development of so-called "me-too" drugs, i.e. only slightly varied drugs based on known active ingredients with no or at best little additional therapeutic value. Studies estimate that only a quarter to a third of the R&D expenditures of pharmaceutical companies go into the development of actually new active ingredients (Angell 2004). Accordingly, the share of novel substances or drugs with high therapeutic value in the total number of regulatory approvals is also low. A study published in the *British Medical Journal* concludes that only about 31 % of the new drugs approved by the competent US and EU authorities in the period from 2007 to 2017 were of high therapeutic value (Hwang et al. 2020). This is similar to what other studies have found for different time periods since the 1980s. Given that total R&D spending by the global pharmaceutical industry increased by around 25 % from 2007 to 2017 (Evaluate Pharma 2017: 19), the stagnation in the approval of novel therapeutically valuable drugs is indicative of an ineffective innovation system.

The bottom line is that there does not seem to be a clear link between increased IPR protection and medical innovation. The majority of private R&D money flows into redundant research with little added health value. Those funds that are actually used for the development of new therapies unsurprisingly focus on diseases that are disproportionately prevalent in countries with higher income levels and for which there is therefore a market with purchasing power. These include diseases such as obesity, hypertension and related cardio-vascular diseases or cancers. Although these diseases have also been on the rise in the Global South for some time, they are not among the dominant diseases, especially in LDCs. The research expenditures for those diseases that occur disproportionately in the countries of the Global South, on the other hand, are almost negligible. No wonder, then, that the term "neglected diseases" (ND) is used for them.⁸

Neglected diseases: little progress despite IPR protection

These "neglected diseases" (ND) have been an unsolved issue of global health policy for decades. In the countries of the Global South, they cause hundreds of thousands of deaths and millions of illnesses every year, often with serious long-term health consequences for those affected. Depending on the definition, NDs comprise several dozen diseases. They sometimes include the so-called "big three" HIV/AIDS, malaria and tuberculosis, but above all the "neglected tropical diseases", including Chagas, dengue fever and leishmaniasis, as well as other poverty-related diseases.⁹

A study published in the renowned journal *The Lancet* shows that medical progress to treat these diseases has been very slow (Pedrique et al. 2013). From 1975 to 1999, only 1.1 % of all globally approbated therapeutic products were approved for the treatments of NDs. In the period from 2000 to 2011, out of 850 new therapeutic products, only 37 (4 %) had indications for ND, of which 25 products had a new indication and 8 were vaccines or biological agents. Only 4 chemical agents were approved for ND (3 for malaria, 1 for diarrhoea), representing 1 % of the 336 approved chemical agents. Of 148,445 clinical trials conducted by the end of 2011, ND accounted for only 2016 (1 %) (ibid).

⁷ EBITDA is a key figure for a company's income from operations before taxes, duties, depreciation and amortisation. The EBITDA rate results in relation to the company turnover.

⁸ See https://rarediseases.info.nih.gov/files/neglected_diseases_faqs.pdf (18/03/2021)

⁹ See https://www.who.int/neglected_diseases/diseases/summary/en/ (12/03/2021)

Since the 2000s, the situation has improved slightly, and especially in the case of the "big three" malaria, HIV/AIDS and tuberculosis, new treatments have been made available to some extent also for the Global South which have significantly reduced the associated burden of disease and especially mortality rates.¹⁰ The fact that relevant parts of the population in industrialised countries also suffered from these diseases favoured drug development in these cases. However, the widespread use of the new HIV/AIDS drugs in the mainly affected countries of sub-Saharan Africa was delayed for decades. More precisely, only after pressure from governments and civil society led pharmaceutical companies to grant significant price reductions for the antiretroviral drugs needed and after the patent-protected technologies were brought into the *Medicines Patent Pool* in 2010.¹¹ This finally made the generic production of these drugs possible.

However, given the scale and severity of these diseases' impact, R&D efforts for the bulk of NDs fall far short of what is needed, with a global total of around USD 4 bn, or around 2 % of total R&D spending in the global pharmaceutical sector (Evaluate Pharma 2019). Given these figures, it is not evident that the global enforcement of stricter IPR protection standards would have led to a significant increase in innovation activity for ND. On the contrary, a look at the R&D funds spent on ND shows that they have hardly increased over the last decade. Moreover, it is predominantly the public sector – and here primarily US funding agencies – that is involved in ND research. The share of industry funding was only 17 % in 2018, while two philanthropic foundations (*Bill and Melinda Gates Foundation*; *Wellcome Trust*) also accounted for around 17 % of the funding (see Figure 1).

Figure 1: Funding sources for neglected diseases, 2009-2018

Funder	US\$ (millions)										2018 % of total
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	
US NIH	1,566	1,498	1,466	1,571	1,372	1,369	1,346	1,438	1,424	1,589	39
Aggregate industry	393	437	412	397	404	486	496	524	576	694	17
Gates Foundation	670	552	549	544	583	556	565	578	550	585	14
EC	123	96	115	99	118	116	141	85	125	134	3.3
UK DFID	78	85	66	40	64	69	55	58	107	121	2.9
Wellcome Trust	60	70	83	129	119	111	87	105	108	120	3.0
USAID	104	105	100	101	87	82	78	81	88	86	2.1
US DOD	113	79	89	87	102	102	77	83	95	77	1.9
Unitaid	-	-	-	0.4	9.0	17	20	49	51	73	1.8
UK DHSC	0.6	0.3							42	64	1.6
Indian ICMR	20	24	24	25	38	35	36	43	66	54	1.3
German BMBF	7.1	9.8	9.0	17	16	18	26	33	46	50	1.2
Subtotal of top 12 [^]	3,226	3,069	3,027	3,109	2,990	3,043	2,995	3,120	3,280	3,647	90
Total R&D funding	3,595	3,416	3,364	3,469	3,348	3,337	3,282	3,437	3,681	4,055	100

[^] Subtotals for 2009-2017 top 12 reflect the top funders for those respective years, not the top 12 for 2018.

– Funding organisation did not participate in the survey for this year. Any contributions listed are based on data reported by funding recipients so may be incomplete.

- No reported funding

Source: G-FINDER Project 2019, Global Funding of Innovation for Neglected Diseases, Policy Cures Research, <https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/07161934/GF-6pSummary2019.pdf>

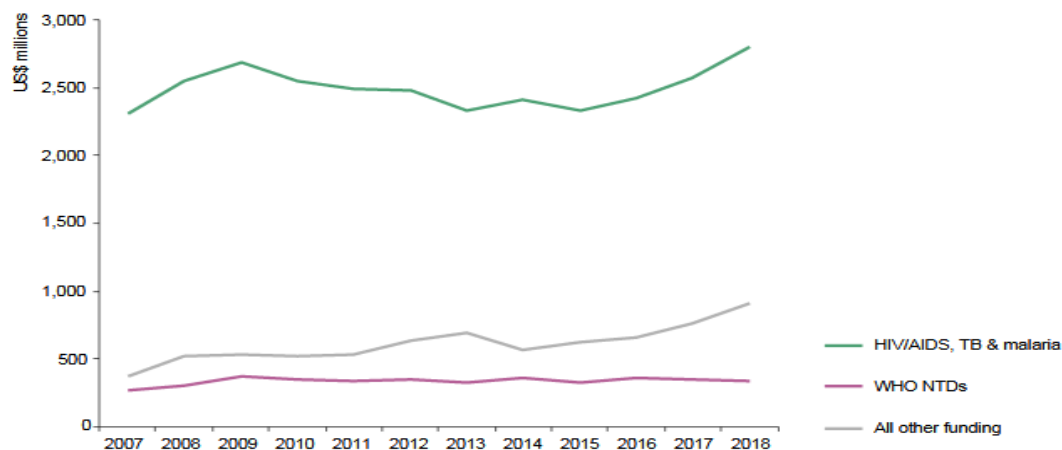
It is also worrying that there has been no increase in research funding for the "neglected tropical diseases". In fact, funding in 2018 was almost 10 % below 2009 levels, and even though pharmaceutical industry R&D spending in this area has increased in recent years, it accounted for only 16 % in 2018 (see Figure 2). Again, the vast majority of funding comes from public –

¹⁰ For statistics see <https://sdg-tracker.org/good-health> (12/03/2021)

¹¹ For more detailed information see <https://medicinespatentpool.org/> (12/03/2021)

and primarily US – institutions. The EU and its member states are not engaged in significant funding.

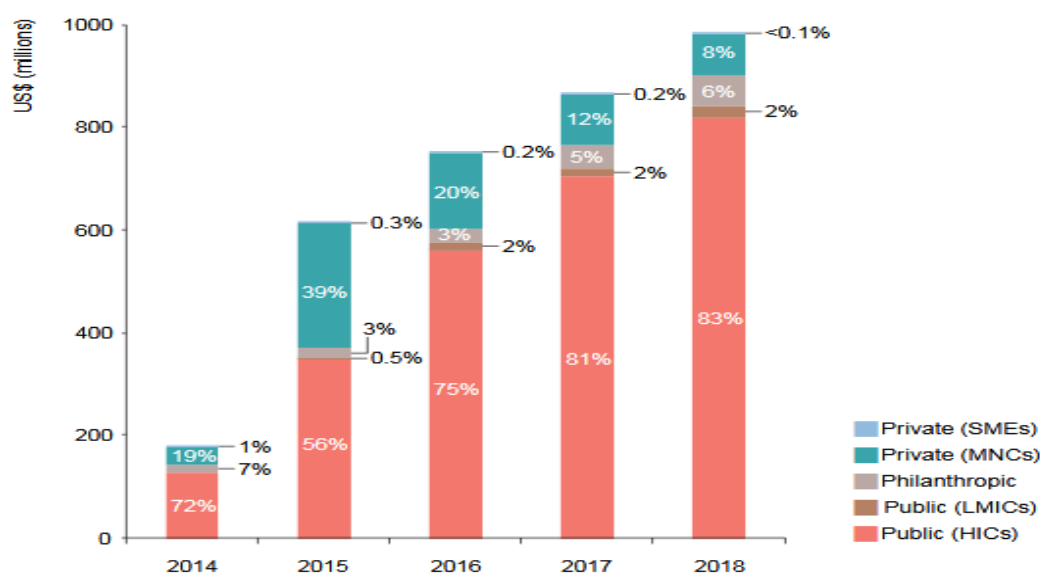
Figure 2: R&D funds for ND, by category



Source: G-FINDER Project 2019, Global Funding of Innovation for Neglected Diseases, Policy Cures Research, <https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/07161934/GF-6pSummary2019.pdf>

The picture is similar for the category of "emerging infectious diseases". These include new infectious diseases caused by viral pathogens such as Ebola, Zika, Lassa fever, but also those caused by coronaviruses such as MERS and SARS. Although R&D spending has increased significantly since 2015, it remains modest, totalling around USD 1 billion (2018). Once again, the bulk of the money (85 %) comes from public funds. The pharmaceutical industry's commitment shows a strong downward trend over this period, and in 2018 amounted to only 8 % of total spending. Philanthropic institutions, such as the *Bill and Melinda Gates Foundation* in particular, accounted for around 6 % of expenditure (see Figure 3).

Figure 3: R&D expenditures for "emerging infectious diseases", by funding type (2014-2018)



Source: G-FINDER Project 2020, Landscape of emerging infectious disease research and development: preventing the next pandemic, Policy Cures Research, https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/10/30095357/EID_Report.pdf

In the wake of the 2014 Ebola outbreak in West Africa and the 2015 Zika epidemic in Latin America, there was a sharp increase in R&D spending on these two diseases. Spending on these accounted for around 40 % of the money spent between 2014 and 2018. Although the first SARS outbreaks occurred as soon as the early 2000s and were followed by outbreaks of new virus strains later (e.g. MERS from 2012), and even though there was no effective therapy available, research on coronaviruses was neglected. The small amount of money spent on this amounted to a share of only 4.6 % of R&D expenditures for "emerging infectious diseases" (see Figure 4). And once again, these expenditures came from the public purse, with no significant research effort on the part of the pharmaceutical companies – a serious omission, as we now know.

To sum up, research spending on diseases that affect large populations in the Global South, and for which there is a clear public health need, is low overall and largely funded by public institutions and by foundations. Improvements in this area that have taken place in the last two decades are primarily due to publicly or philanthropically funded R&D. In the absence of purchasing power in the countries of the Global South, both on the part of the population and on the part of most governments, the R&D commitment of the private pharmaceutical industry to these diseases is extremely limited. The global enforcement of strict IPR protection standards including in the countries of the Global South since 1995 has not been able to fundamentally change this.

Figure 4: R&D expenditure on emerging infectious diseases, by disease/R&D area (2014-2018)

Disease or R&D area	US\$ (millions)					Cumulative total 2018 % of total	
	2014	2015	2016	2017	2018		
Ebola & Marburg [^]	178	595	470	343	362	1948	41
Zika		6.1	170	243	202	621	23
Lassa fever		9.6	32	34	45	121	5.1
Coronaviruses (MERS & SARS)			25	44	41	110	4.6
COHF & RVF		2.0	9.7	18	19	49	2.1
Nipah & other henipaviruses			14	13	11	37	1.3
Core funding of a multi-disease R&D organisation			11	13	34	58	3.9
Disease X & Other R&D			14	73	171	259	19
Other R&D			0.5	20	78	99	8.9
Multi-disease vector control products				26	36	62	4.1
Platform technologies			4.7	15	39	59	4.4
Fundamental research			6.3	8.7	16	31	1.8
Broad-spectrum antivirals			2.6	2.9	2.0	7.4	0.2
Total EID R&D funding*	178	612	745	781	886	3203	100

Category not included in G-FINDER

[^] Ebola was the only disease included in the 2014 survey. Value for Ebola in 2014 may include combined filoviral R&D.

* Due to significant changes in the survey scope, totals for 2014 and 2015 cannot be directly compared to totals in later years, or to each other.

Source: G-FINDER Project 2020, Landscape of emerging infectious disease research and development: preventing the next pandemic, Policy Cures Research, https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/10/30095357/EID_Report.pdf

4. Conclusion: The need for a fundamental reform of the pharmaceutical innovation system in the wake of COVID-19

As this brief historical outline has shown, IPR policy always involves a trade-off between the social benefits of IPR protection norms and the associated costs to society. While the social benefit should primarily consist of reliable and affordable supply of medicines and high medical innovation, the costs are associated with restrictions in the availability of medicines due to high prices or limited access to new technical knowledge for research, for other companies and thus also for society. For the pharmaceutical innovation model established over the last 30 years, this trade-off looks unfavourable. Although R&D expenditure has been increasing overall, most of the money has been and is being spent on incremental innovation with little additional therapeutic value. Only just under one-third goes into risky and cost-intensive, but from a health policy perspective valuable research into new therapeutic treatments. On top of that R&D funds are almost exclusively used for work on diseases that occur in countries with high purchasing power. Research on the “neglected diseases” that are so important for the Global South is passed on to the public sector and to foundations.

This raises the question of whether the adoption of far-reaching IPR protection standards by the countries of the Global South in the wake of the implementation of the WTO TRIPS Agreement has been worthwhile. With regard to the supply situation for the “neglected diseases”, which especially in LDCs are the most significant and widespread diseases, as well as for the new infectious diseases, the answer is negative. This assessment is also confirmed by the situation regarding access to COVID-19 vaccines for the countries of the Global South. Here, too, they have to take a back seat. However, the COVID-19 pandemic also teaches that if political pressure is great enough and public funding forthcoming, the pharmaceutical industry can quickly and successfully develop treatments for New Infectious Diseases. The pharmaceutical industry's neglect of ND and new infectious diseases is therefore not a question of ability, but of will.

The current crisis situation should therefore be used to reform global IPR protection with the aim of aligning pharmaceutical innovation more closely with public health objectives. In the academic debate, a whole range of alternatives to the current IPR protection model have been presented, based primarily on the *delinkage* of R&D expenditure from the sales volume of a pharmaceutical treatment. Essentially, the following four general approaches can be distinguished (cf. Stiglitz/Jayadev 2010; Baker 2017: 103ff.):

- (i) Premium model: Here, premiums are offered within the framework of a competition for the development of effective therapies for certain diseases. The participating company with the treatment with the highest therapeutic value is awarded the prize. The treatments and related technologies developed are then available to the public or other companies free of charge and can be produced on a competitive basis.
- (ii) Value-based pricing: Public purchasers assess the therapeutic benefits of pharmaceutical treatments and, on this basis, set the price they are willing to pay for a drug. The higher the therapeutic benefit, the higher the price paid. This at least limits the monopoly power of pharmaceutical companies, even though IPR protection rights continue to exist in principle.
- (iii) Public funding of clinical research: The particularly expensive clinical research will not be funded by the big pharmaceutical companies, as is currently the case, but by the public purse. All research results must be published. The typical conflicts of interest (such as collusion between pharmaceutical companies and general practitioners) in the current system can thus be avoided. The public sector can also steer research towards treatments with high therapeutic value and thus prevent the existing bias towards “me-

too" drugs. The resulting treatments are subject to no or limited IPR and can thus be brought to market at lower prices. The resulting costs to the public purse are raised, for example, through a tax on sales turnover.

- (iv) Public funding of research on defined diseases: The public sector concludes research contracts with private pharmaceutical companies within the framework of public tenders and assumes the company's R&D costs for a certain period of time (up to a ceiling). All data, research results and technologies are to be published and made available to others free of charge. R&D carried out by third parties based on this, which leads to patents, would also have to be made publicly available. The existing IPR protection system would remain in place, but would only apply to privately funded R&D or products based on it.

The academic critique and the alternative policy proposals based on it, together with the heated discussions in the early 2000s about supplying the Global South with the antiretroviral drugs needed to fight the HIV/AIDS epidemic, led to the establishment of a number of so-called product development partnerships (PEPs). These are special alliances of different actors (public institutions, foundations, companies, research institutions, NGOs, etc.) for the development of treatments for ND.¹² Here, R&D expenditures are primarily funded through public grants and money from foundations, but PEPs are independent organisations. PEPs typically operate on the basis of an "open innovation approach". The R&D results are either (i) made publicly available on a free-of-charge basis, or (ii) are available to participating partners and third parties under variable conditions. The latter model follows a so-called *commons* approach, which is interesting from three points of view. Firstly, the granting of IP protection and thus usage rights is based on graduated criteria. Access to the DNDi knowledge pool, for example, is based on the waiver of patenting of technologies or products derived from it. Secondly, all research cooperations follow the goal of using the knowledge and treatments gained for the purpose of broad and affordable access, especially for vulnerable groups. Thirdly, the pool of knowledge built up this way is seen as a common resource for global health research and policy. However, despite certain successes, PEPs have so far not been able to address the great need for R&D for ND (Abecassis et al. 2019). The main reason for this is insufficient funding. As shown above, the main funding contributions for R&D on ND and the New Infectious Diseases come from public institutions in the developed world (mainly the US) and foundations, most notably by the Bill and Melinda Gates Foundation. The contribution of private pharmaceutical companies remains extremely modest, despite the enforcement of strong IPR protection also in the Global South over the last 20 years.

The COVID-19 pandemic once again underlines the existing global imbalance. IPR protection standards should therefore be recognised again for what they are: Privileges granted by society for which the holders have to provide something in return. This social obligation can be fulfilled in different ways. In the current situation, the following three measures in particular would make sense from a health policy perspective:

- (i) Conditions attached to the granting of IPR protection rights to companies for research on "neglected diseases";
- (ii) Obligations to license technologies relevant to the fight against "neglected diseases" or new infectious diseases, e.g. by contributing corresponding protected technologies to public patent pools such as the COVID-19 Technology Access Pool (C-TAP), the Medicines Patent Pool, amongst others;

¹² Well-known examples are: International Aids Vaccine Initiative (IAVI), Medicines for Malaria Venture (MMV), Foundation for Innovative Diagnostics (FIND), Global Alliance for Tuberculosis Drug Development (TB Alliance). The second generation of PEPs includes, above all, the Drugs for Neglected Diseases Initiative (DNDi) (Abecassis et al. 2019).

- (iii) A levy on pharmaceutical companies based on sales of patented medicines, the proceeds of which benefit international initiatives for research into ND (such as DNDi) and/or are channelled into an international fund administered by, for example, the WHO, to finance projects to develop treatments for ND.

In view of the pharmaceutical industry's high profits and its glaring failure to innovate, especially in the case of ND and new infectious diseases, implementing these measures would at least be a first step towards a pharmaceutical innovation system that really takes health seriously as a global public good in the sense of Goal 3 of the UN Sustainable Development Goals (SDG 3). The COVID-19 pandemic should be taken as an opportunity to tackle such a reform of the pharmaceutical innovation system.

References

- Abecassis, Philippe/Alesandrini, Jean-François/Coriat, Benjamin/Coutinet, Nathalie/Leyronas, Stéphanie (2019): DNDi, a Distinctive Illustration of Commons in the Area of Public Health. Research Paper #2019-93AFD – Agence Française de Développement.
- Angell, Marcia (2004): Excess in the pharmaceutical industry. In: CMAJ : Canadian Medical Association Journal, 171(12), 1451-1453. <https://doi.org/10.1503/cmaj.1041594>
- Baker, Dean (2017): Rigged: how globalization and the rules of the modern economy were structured to make the rich richer. Center for Economic and Policy Research. Washington, D.C.
- Bessen, James E./Ford, Jennifer Laurissa/Meurer, Michael J. (2012): The Private and Social Costs of Patent Trolls (SSRN Scholarly Paper Nr. ID 1982139). Rochester, NY: Social Science Research Network.
- Boldrin, Michele/Levine, David K. (2013): The Case Against Patents. In: Journal of Economic Perspectives, 27(1), 3-22. <https://doi.org/10.1257/jep.27.1.3>
- Boldrin, Michele/Levine, David K. (2008): Against intellectual monopoly. New York.
- Chang, Ha-Joon (2001): Intellectual Property Rights and Economic Development: Historical lessons and emerging issues. In: Journal of Human Development, 2(2), 287-309. <https://doi.org/10.1080/14649880120067293>
- Correa, Carlos María (2000): Intellectual property rights, the WTO, and developing countries: the TRIPS agreement and policy options. London; New York; Penang (Malaysia). Third World Network.
- Cullet, Philippe/Yuanquiong, Hu (2019): Medical Patents and the Right to Health – From Monopoly Control to Open Access Innovation and Provision of Medicines. In: German Yearbook of International Law 2018. Berlin, 153-182.
- Drahos, Peter (2016): A philosophy of intellectual property, Dartmouth.
- Evaluate Pharma (2019): World Preview 2019, Outlook to 2024
- Evaluate Pharma (2017): World Preview 2017, Outlook to 2022
- Hwang, Thomas J./Ross, Joseph S./Vokinger, Kerstin N./Kesselheim, Aaron S. (2020): Association between FDA and EMA expedited approval programs and therapeutic value of new medicines: retrospective cohort study. In: BMJ, 371, m3434. <https://doi.org/10.1136/bmj.m3434>
- Lanjouw, Jean O./Schankerman, Mark (2004): Protecting Intellectual Property Rights: Are Small Firms Handicapped? In: The Journal of Law and Economics, 47(1), 45-74. <https://doi.org/10.1086/380476>
- Ledley, Fred D./McCoy, Sarah Shonka/Vaughan, Gregory/Cleary, Ekaterina Galkina (2020): Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies. In: JAMA, 323(9), 834-843. <https://doi.org/10.1001/jama.2020.0442>
- Lerner, Josh (2002): 150 Years of Patent Protection. In: American Economic Review, 92(2), 221-225. <https://doi.org/10.1257/000282802320189294>
- Pedrique, Belen/Strub-Wourgaft, Nathalie/Some, Claudette/Olliaro, Piero/Trouiller, Patrice/Ford, Nathan/Pécoul, Bernard/Bradol, Jean-Hervé (2013): The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment. In: The Lancet Global Health, 1(6), e371–e379. [https://doi.org/10.1016/S2214-109X\(13\)70078-0](https://doi.org/10.1016/S2214-109X(13)70078-0)

Scherer, Frederik M./Weisbrod, S. (1995): Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy. In: *International Review of Industrial Property and Copyright Law*, 6, 1009-1024.

Sell, Susan K. (1998): *Power and ideas: North-South politics of intellectual property and anti-trust*. SUNY series in global politics. Albany.

Shapiro, Carl (2001): Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting. In: *SSRN Electronic Journal*. <https://doi.org/10.2139/ssrn.273550>

Stiglitz, Joseph E. (2008): Economic Foundations of Intellectual Property Rights. In: *DUKE LAW JOURNAL*, 57, 32.

Stiglitz, Joseph E./Jayadev, Arjun (2010): Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals. In: *Journal of Generic Medicines*, 7(3), 217-226. <https://doi.org/10.1057/jgm.2010.21>