

Pandemic Licensing

The following is an excerpt from Chapter 7 of Fisher & Syed, Rethinking Global Pharmaceutical Policy (forthcoming 2025). As you read these case studies, consider how intellectual property rights might be adjusted or deployed to meet the next pandemic.

The technique of what has come to be known as “voluntary licensing” was developed and refined in three overlapping phases. In the first, it was used to increase the availability of treatments for HIV. In the second, it was used by some of the firms that developed direct-acting antiviral drugs aimed at Hepatitis C. Finally, it was employed to augment the availability in poor countries of therapeutic drugs for COVID-19. The three tales are told below. ...

1. ARVs

Chapter 2 discussed how, beginning in 1987, a series of increasingly effective anti-retroviral drugs (and combinations thereof) designed to mitigate HIV were developed by pharmaceutical firms and approved by regulatory agencies, making it possible for infected persons to survive and to live normal lives. From the beginning of the AIDS pandemic, the large majority of infected persons were located in low-income and lower-middle-income countries, most of them in sub-Saharan Africa. However, the prices at which the ARVs were first introduced (typically between US\$10,000 and US\$15,000 per year for an adult patient) made them unaffordable for patients in those countries or for the countries’ public-health services. As a result, the death rates from AIDS in those countries continued to rise rapidly even after ARVs became available, provoking intensified demands that the companies holding the IP rights to the drugs lower their prices.

A series of events in the 1990s reinforced those demands: Several pharmaceutical firms attempted to prevent South Africa from imposing a compulsory license on their patents, which produced a public-relations backlash;¹ generic drug manufacturers in India (where patents on pharmaceutical products were not available until recently) began producing ARV cocktails and selling them cheaply in other countries;² and the government of Brazil used its bargaining power to extract major price concessions from some of the pharmaceutical firms, which in turn enabled it to curb the HIV pandemic in that country.³

Into this fray entered the fledgling company, Gilead Sciences. Between its founding in 1987 and 2000, Gilead had developed drugs in a wide variety of sectors. After

¹ See William Fisher and Cyrill P. Rigamonti, "The South Africa Aids Controversy: A Case Study in Patent Law and Policy," *Harvard Law School Case Study* (2005), https://ipxcourses.org/GPP/South_Africa_AIDS_Controversy.pdf.

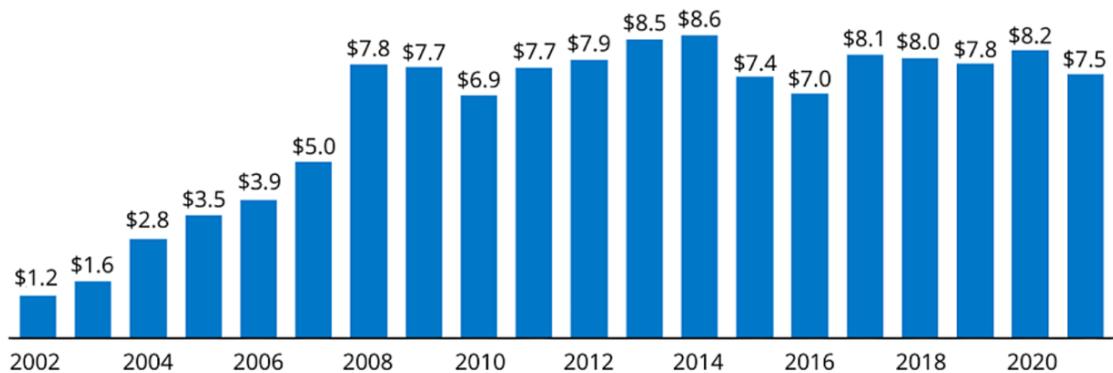
² See AVERT, “Antiretroviral Drug Prices,” <http://www.avert.org/antiretroviral-drug-prices.htm>.

³ See Adele S. Benzaken, Gerson F.M. Pereira, and Lendel Costa, "Antiretroviral Treatment, Government Policy and Economy of Hiv/Aids in Brazil: Is It Time for Hiv Cure in the Country?," *AIDS Research and Therapy* 16, no. 19 (2019).

the turn of the century, it concentrated on antiviral drugs. Tenofovir, Gilead's pioneering HIV treatment, received FDA approval in 2001. Other ARVs soon followed. When the effectiveness of these drugs became apparent, AIDS activists began to demand that Gilead devise a way of making them available in poor countries. The CEO, John C. Martin, instructed Clifford Samuel, the leader of the relevant division in the company, to find a way to do so.

A crucial complement to the company's efforts was the availability of a massive amount of public funding to curb the pandemic. The principal sources of the money were the Global Fund to Fight AIDS, TB, and Malaria (launched in 2002) and the U.S. President's Emergency Program for AIDS Relief (PEPFAR) (launched in 2003). The sums that those programs, in combination, made available are shown in Figure 1, below. These funds not only procured medicines but augmented capacity (infrastructure and medical expertise) in the most affected countries.

Figure 1⁴
**HIV Funding from Donor Governments, 2002-2021,
 In Billions**



Despite the magnitude of these funds, it quickly became apparent that, if Gilead wished to reach the rapidly growing population of infected persons in LMICs, it would have to lower the prices of its products in those countries. Starting in 2003, the company tried to do so by distributing its own branded products in those markets at no-profit prices.⁵ Other companies that had developed ARVs, such as Merck and GlaxoSmithKline, adopted similar “tiered” pricing policies for their branded products at the same time. The results

⁴ Source: KFF and UNAIDS, “Donor Governments Spent US\$7.5 Billion on Efforts to Combat HIV/AIDS Globally in 2021, Largely Flat Amid the COVID-19 Pandemic, KFF-UNAID Report Finds” (July 22, 2022), <https://www.kff.org/global-health-policy/press-release/donor-governments-spent-us7-5-billion-on-efforts-to-combat-hiv-aids-globally-in-2021-largely-flat-amid-the-covid-19-pandemic-kff-unaid-report-finds/>

⁵ More specifically, Gilead selected 11 distributors, which it then authorized to sell its branded ARVs in 130 low-income and emerging economies. Gilead charged the distributors no-profit prices, but allowed them to earn profits of 10 to 15% to cover the costs of registering the products in those countries and cultivating the local medical networks.

were disappointing; too few buyers could afford the branded products manufactured by Gilead – even at no-profit prices. Activists’ criticism of Gilead’s efforts intensified.⁶

In 2006, Gilead shifted to a strategy based upon licensing. This strategy was not altogether novel. A few companies had previously issued so-called “non-assertion” declarations (pledges not to enforce their intellectual property rights in specified jurisdictions) or licenses to generic manufacturers for below-market royalty rates. But these were typically limited in their coverage or “quasi-commercial” in character.⁷ Gilead went further. Under Samuel’s leadership, the company began to issue licenses whose primary objective was maximization of access to its products in poor countries.

It took some time for Gilead to hone this approach. Early versions of the licenses contained some terms that activists regarded as anti-competitive,⁸ and the geographic scope of the policy was initially modest. But the company eventually settled on the following model:

- A limited set of trusted generic manufacturers were authorized to produce tenofovir, all tenofovir combinations, and all future pipeline HIV products and to sell those products in – or export them to – specified countries;
- Low royalties – typically 5% of the licensees’ sales on their finished products;
- Royalties waived on pediatric formulations;
- Broad fields of use (achieved by defining the set of “low-income” countries generously);
- Provisions forbidding diversions of products to other jurisdictions;
- Licensees are free to set their own prices and to sell active pharmaceutical ingredients (APIs) (royalty-free) to each other;
- Technology-transfer obligations – i.e., duties on the part of Gilead to transfer to the licensees the know-how necessary to manufacture the products;
- Quality standards: Licensees agree to seek WHO Prequalification, EMA or Tentative FDA approval;
- Close coordination with LMIC governments and NGOs;⁹
- Implementation of an “awareness and advocacy” campaign in targeted LMICs; and
- Transparency (the terms of all of the licenses were made public).

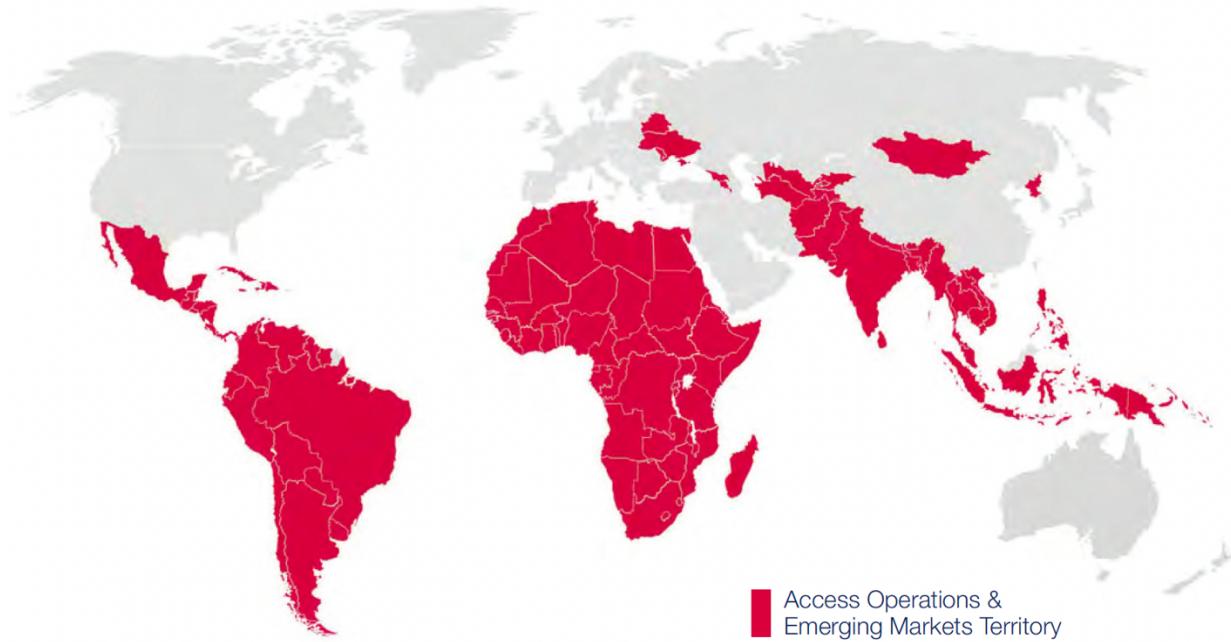
⁶ See, e.g., Nicole Neroulias, "Activists: Deny Patent to Gilead," *East Bay Times*, May 11, 2006 2006.

⁷ See Brook K. Baker, "A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines," *Northeastern University Law Review* 10, no. 2 (2018): 241-42.

⁸ See *ibid.*, 247-48; Knowledge Ecology International, "Kei Asks Ftc to Investigate Gilead Effort to Control Market for Aids Drugs Ingredients," news release, February 15, 2007, <https://perma.cc/N4Q3-X3SA>.

⁹ Programs implemented by Gilead included studies of disease burden across the various geographies, support for medical education and training, and help to secure diagnostic capabilities.

Figure 2, below, shows the countries covered by this policy in its final form.



In 2010, the emergence of the Medicines Patent Pool (MPP) enabled Gilead to modify and extend this policy. Created by UNITAID, the MPP was intended to be a global “public health organization with a mandate to accelerate access to affordable and quality-assured treatments in developing countries through an innovative voluntary licensing . . . and patent pooling mechanism.”¹⁰ The MPP soon began negotiating licenses with innovators and then issuing sub-licenses to generic licensees, facilitating the entry of pharmaceutical products into countries where innovators lack presence.

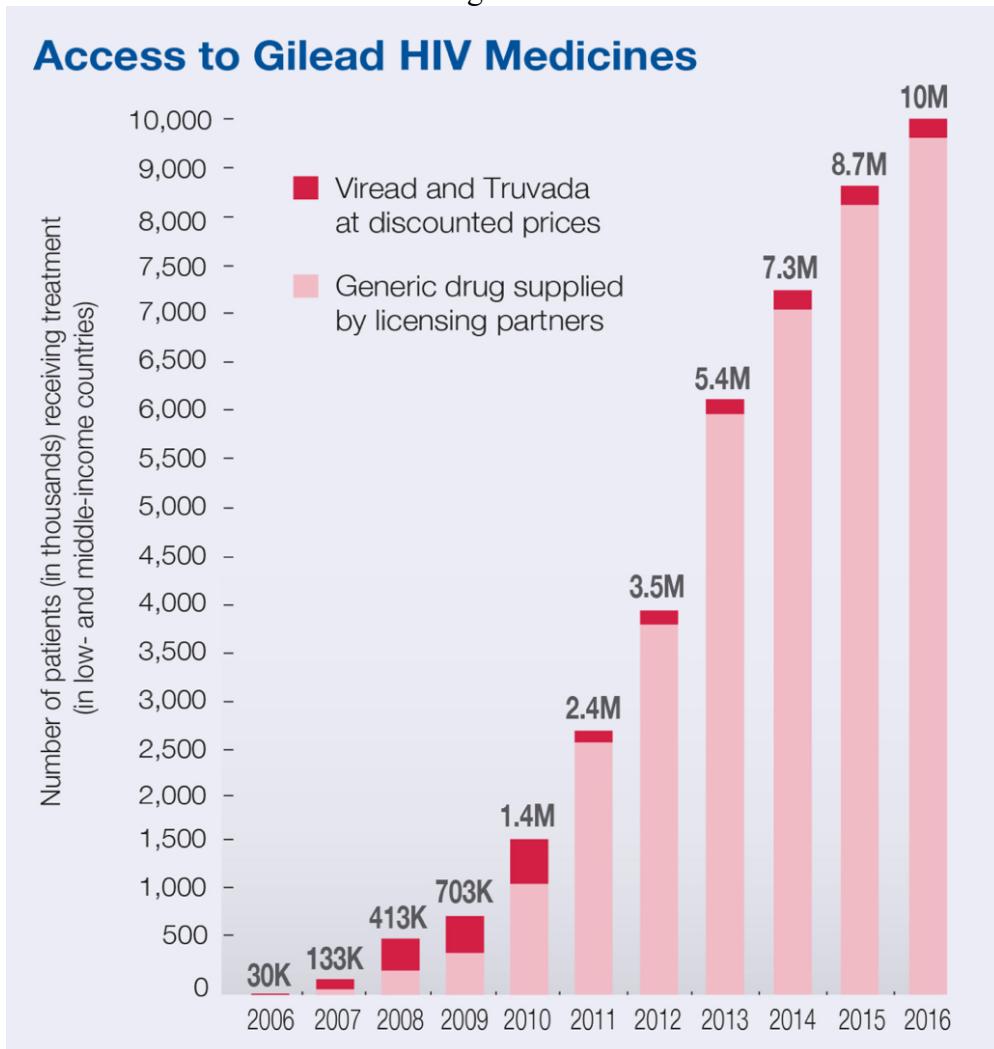
The MPP’s practices also matured gradually. The model upon which it eventually settled included many systems designed to supplement the negotiated licenses. For example, it employs tracking mechanisms to prevent generic versions of the originator’s drugs from being diverted to developed-country markets through an “Alliance Management System” (AMS). AMS supports the sub-licensees in their development and registration activities and monitors them to ensure that they abide by the terms of the head license – i.e., the license that the MPP had negotiated with the originator. In addition, the MPP works with governments and other stakeholders to ensure the licenses result in product access on the ground.¹¹

¹⁰ Medicines Patent Pool, "Report to the Who Expert Committee on the Selection and Use of Essential Medicines," (2019).

¹¹ See William Looney, "The Medicines Patent Pool Plots a Post-Pandemic Future: Interview with Director Charles Gore," *In Vivo*, September 20, 2021; Charles Gore et al., "Negotiating Public-Health Intellectual

Gilead soon took advantage of this combination of services and began issuing licenses through the MPP as well as continuing to negotiate bilateral licenses directly. This composite approach proved highly successful. The prices of Gilead's HIV drugs in LMICs dropped from \$20/month to \$4/month. The number of people treated globally with Gilead's HIV medicines increased from tens of thousands in the mid-2000s to more than 20 million in 2023. As Figure 3 shows, over time a growing percentage of those drugs consisted of generic products produced pursuant to voluntary licenses, rather than Gilead-manufactured branded products.

Figure 3¹²



Property Licensing Agreements to Increase Access to Health Technologies: An Insider's Story," *BMJ global health* 8, no. 9 (2023).

¹²

Source:

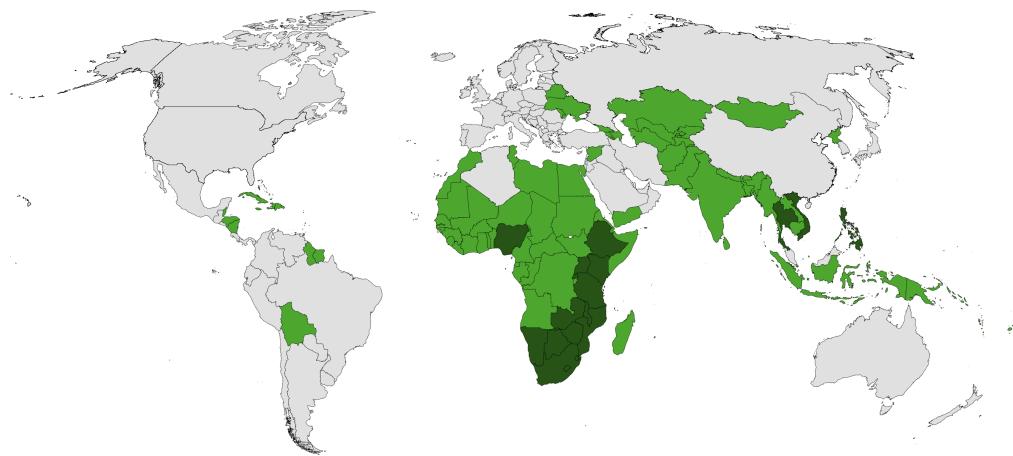
<https://www.gilead.com/-/media/files/pdfs/other/hiv%20access%20backgrounder%20us%20112816.pdf>. See also Gilead Sciences, "Impact Report: Access Operations and Emerging Markets," (2017).

Two factors seem to have been especially important in the success of the voluntary-licensing strategy. First, the generic companies to which the licenses were issued proved capable of manufacturing the ARVs more cheaply than could Gilead. Second, the Global Fund and PEPFAR radically increased procurement of first-line ARVs in the effort to pursue their “90/90/90 Treatment for All” campaign.¹³

Although the adoption of Gilead’s strategy was substantially motivated by altruism, it was – and remains – commercially viable. For example, between 2014 and 2018, Gilead earned, from its “Access and Emerging Markets” program, gross revenues of \$2.2 billion from sales of its branded products and \$29 million in the form of royalties from generic licensees.

The most recent of Gilead’s HIV voluntary licenses pertains to lenacapavir, the injectable drug discussed in Chapter 2 that has proven to be so effective both in treating persons with drug-resistant infections and in preventing infections altogether. Lenacapavir is currently on sale in the United States for \$42,250 per one-year course of treatment. Aware that such a price would make it altogether unaffordable in the regions where HIV is most prevalent, Gilead recently licensed six manufacturers to produce generic versions of lenacapavir and distribute them in a “Territory” that includes 120 countries.¹⁴ Three of the licensees are based in India, one each in Pakistan, Egypt, and the United States. The countries in which distribution of the generics is authorized are shown in the following map.

Figure 4: Countries included in the Voluntary License for Lenacapavir



¹³ See Jacob Levi et al., "Can the Unaids 90-90-90 Target Be Achieved? A Systematic Analysis of National Hiv Treatment Cascades," *BMJ global health* 1, no. 2 (2016).

¹⁴ See Owen Dyer, "Gilead to License Generic Lenacapavir for Hiv Prophylaxis in 120 Lower Income Countries," *BMJ (Online)* 387 (2024); Gilead, "Gilead Signs Royalty-Free Voluntary Licensing Agreements with Six Generic Manufacturers to Increase Access to Lenacapavir for Hiv Prevention in High-Incidence, Resource-Limited Countries," news release, 2024, <https://perma.cc/4U9L-NSAW>. The license itself is available at <https://perma.cc/4FXN-CRFR>.

The lenapacivir license contains a novel provision. Within the overall Territory, it identifies 18 countries (shown in dark green) where HIV prevalence is especially high and resources are especially low. The license then provides that, if any of the licensees is able within three years to obtain marketing approval for its generic products in all 18 countries, Gilead “will consider appointing Licensee as a preferred partner … with respect to any future product formulation of Lenacapavir which Gilead is intending to license.”¹⁵ This promise is vague, but its purpose is clear enough: to encourage the licensees to extend their reach into the most needy countries.

Unfortunately, the set of countries covered by the lenacapaivir license is significantly smaller than the set (shown in Figure 3, above) covered by the HIV licenses issued previously by Gilead. Notably absent are some middle-income countries in Latin America and Eastern Europe where, as Chapter 1 discussed, HIV is now spreading especially fast. Indeed, in some of those countries – Argentina, Brazil, Mexico and Peru – Gilead had conducted clinical trials on lenacapavir and yet has not given their residents the benefit of the new license.¹⁶ These exclusions have exposed the company to sharp criticism. But within the Territory, the license will undoubtedly be highly beneficial.

Gilead has surely not been the only actor in the campaign against AIDS. As indicated above, the success of that campaign has depended heavily on the massive infusion of funds from donor countries. In addition, other pharmaceutical firms have initiated similar access-oriented policies. Some, like Gilead, negotiated licenses directly with generic manufacturers, but a growing percentage have relied instead on the brokerage services of the MPP.¹⁷ Finally, as the patents on the early ARVs expired, some firms have produced and sold generic versions of them without licenses.

The net result has been a remarkable decline in the prices of AIDS drugs in poor countries and an associated expansion of the set of people able to obtain treatment. In 2023, Charles Gore, the director of the MPP, was able to report that:

[T]he price of WHO-recommended daily first-line fixed-dose combination HIV treatment (tenofovir/lamivudine/dolutegravir) is now less than US\$50 per person per year: less than US\$1 per week.¹⁸

2. Hepatitis C

Hepatitis C (HCV) is a viral liver infection typically spread through contact with infected blood, most often as a result of drug use or unsafe sexual practices. A minority of

¹⁵ Section 7.3(a).

¹⁶ See Rick Guasco, "Gilead Licenses Generic Version of Lenacapavir as Prep in 120 Countries Outside the U.S.," *Positively Aware* (2024), <https://perma.cc/EH72-EY99>.

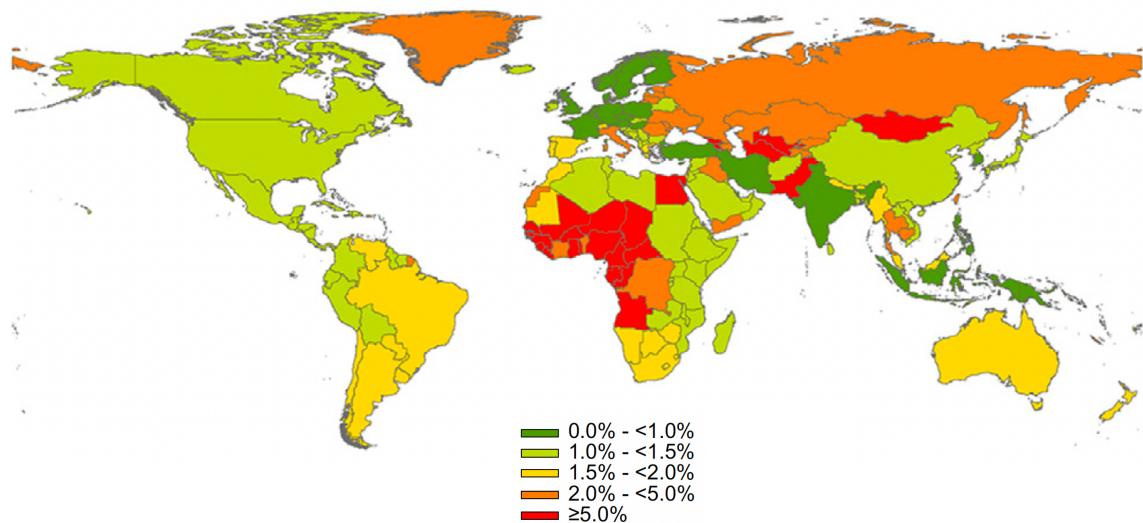
¹⁷ See Gore et al., "Negotiating License Agreements," 1; MPP, "Voluntary Licensing: Right for Health, Smart for Business," (2024); Looney, "Medicines Patent Pool."

¹⁸ Gore et al., "Negotiating License Agreements," 1.

the people who are infected by the virus recover fully without treatment. In the majority of cases, however, the infection becomes chronic. Symptoms typically appear many years after an initial acute phase, after the liver has been damaged. They include fatigue, jaundice, weight loss, and drowsiness. In a subset of those cases, the disease progresses to cirrhosis or liver cancer, which are often fatal.¹⁹

Estimates of the global prevalence rate of HCV vary considerably, because so many infections go undetected. As of 2013 (an important date, for reasons that will soon become clear), approximately 1.6% of the global adult population were infected – in the specific sense that they carried antibodies for the HCV virus. Translated into numbers, that means that roughly 115 million people were infected.²⁰ The distribution among countries is shown below:

Figure 5: HCV Adult Prevalence²¹



Until 2011, the standard treatment for HCV was a combination of pegylated interferon and ribavirin. Those drugs did not attack the virus directly, but rather worked

¹⁹ See WHO, "Hepatitis C," <https://perma.cc/4AQZ-54JP>; "Accelerating Access to Hepatitis C Diagnostics and Treatment: Overcoming Barriers in Low and Middle-Income Countries," (2020).

²⁰ See Erin Gower et al., "Global Epidemiology and Genotype Distribution of the Hepatitis C Virus Infection," *Journal of hepatology* 61, no. 1 (2014). For a substantially higher estimate of the global prevalence rate, see Arnolfo Petruzzello et al., "Global Epidemiology of Hepatitis C Virus Infection: An Update of the Distribution and Circulation of Hepatitis C Virus Genotypes," *World Journal of Gastroenterology* 22, no. 34 (2016). The WHO's estimate of the number of people with chronic infections was also a bit higher than Gower's: between 135 and 150 million. See Mohga Kamal-Yanni, "Hepatitis C Drug Affordability," *The Lancet global health* 3, no. 2 (2015).

²¹ Source: Gower et al., "Global Epidemiology and Genotype Distribution of the Hepatitis C Virus Infection," S52. To estimate the prevalence rates in countries lacking good data, Gower et al. extrapolated from other countries in the region.

by stimulating the body's own immune system.²² This approach had several disadvantages: it was inconvenient (because the interferon had to be administered through weekly injections); it had serious side effects (flu-like symptoms, anemia, neutropenia, rash, and depression); and it was only moderately effective.²³ In 2011, clinical trials of two molecules that, unlike the standard treatment, directly addressed the HCV virus showed considerable promise. However, they too had disadvantages; they had to be taken with interferon and ribavirin; they had significant side effects; and they were only effective against one of the genotypes of the virus.²⁴

2013 witnessed a breakthrough. Once again, the key institutional actor was Gilead. Two years previously, Gilead had purchased (for \$11 billion) from Pharmasset (a small biotech firm) the rights to sofosbuvir, another direct-acting anti-viral ("DAA").²⁵ Clinical trials demonstrated the capacity of sofosbuvir, not just to suppress the disease, but to cure patients altogether in over 90% of the cases. Side effects were minimal, and, because it could be administered orally (once a day), treatment was convenient and inexpensive. In December of 2013, the FDA approved the drug. Gilead began selling it in the United States (under the brand name, Sovaldi) for a startling price -- \$84,000 for a 12-week course of treatment. Shortly thereafter, the EMA approved it, and Gilead began negotiating prices with European governments. Among the outcomes of those negotiations: 50,426 Euros for a course of treatment in Germany, 41,680 Euros in France, and 13,000 Euros in Spain.²⁶

The high prices charged by Gilead in the United States and Europe proved controversial. The company defended them on the ground that, by curing the disease, sofosbuvir enabled recipients not only to avoid years of misery, but also to save the costs of late-stage treatments, such as liver transplants. Not everyone was convinced. In the United States, Congress convened hearings to consider the legitimacy of Gilead's fees.²⁷ In Europe, Gilead's approach was sharply criticized by both governments and activist organizations. In both markets, however, most of the resistance eventually subsided, and Gilead maintained course.

²² See Libin Rong and Alan S. Perelson, "Treatment of Hepatitis C Virus Infection with Interferon and Small Molecule Direct Antivirals: Viral Kinetics and Modeling," *Critical reviews in immunology* 30, no. 2 (2010).

²³ See V. Kasturi Rangam, "Gilead: Hepatitis C Access Strategy (a)," (Harvard Business School Case Study 9-515-025, 2023), 5.

²⁴ The molecules in question were boceprevir (developed by Merck) and telaprevir (developed by Vertex). See *ibid.*, 6. For discussion of their limitations, see Imam Waked, "Case Study of Hepatitis C Virus Control in Egypt: Impact of Access Program," *Antiviral therapy* 27, no. 2 (2022): 2.

²⁵ For the history of Pharmasset – and the role of public funding in supporting the research of its founder, see Hep C Coalition, "Sofosbuvir Turns 5 Years Old: The Vast Majority of People with Chronic Hepatitis C Still Have Not Been Treated," (2018), 7.

²⁶ See MSF, "Not Even Close," (2017): 3; Germán Velásquez, "The Use of Trips Flexibilities for the Access to Hepatitis C Treatment," (South Centre, 2018), 4.

²⁷ See, e.g., Margot Sanger-Katz, "\$1,000 Hepatitis Pill Shows Why Fixing Health Costs Is So Hard," *New York Times*, August 2, 2014 2014.

In the ensuing decade, other similar or complementary HCV drugs became available. Gilead itself developed some of them. For example, a combination of sofosbuvir and ledipasvir proved even better than sofosbuvir alone, so Gilead began selling the combination (under the brand name, Harvoni) – for an even higher price. Bristol Myers Squib (BMS) entered the field with a different compound, daclatasvir (“DCV”), which, when matched with sofosbuvir, also improved its operation.²⁸

Starting in 2013, when the potential benefits of the DAAs became apparent, Gilead and (later) BMS began formulating a strategy that would enable them both to sustain their high prices in their principal markets and to make their products available at lower prices outside of wealthy countries, where the large majority of the people infected with HCV resided. In its mature form, that strategy had two major components, each with several subparts.

The first component was a set of legal shields designed to limit competition and thus to protect the companies’ power to set prices for the pioneering drugs. Three forms of protection were most important. The first was a robust set of patents – product patents on the drugs themselves and supplementary patents on improvements, dosages, etc. Gilead and BMS applied for such patents in most high-income and middle-income countries, and most of those applications were granted. In a few countries, however, they were rejected, on the ground that they failed the novelty or inventive-step requirements.²⁹ Second, relying on the tactic discussed in Chapter 2, the companies either delayed or forewent altogether applying for regulatory approval in many countries. Absent such approval, the drugs of course could not be distributed there.³⁰ Finally, in countries in which the companies did seek and obtain regulatory approval, they relied on data-exclusivity protection to impede the subsequent introduction of generic substitutes, even if patents had not been granted in those jurisdictions.³¹

The second component of the companies’ strategy was a pair of business practices designed to increase the affordability and thus the availability of the drugs in poor countries. The first of those practices was geographic differential pricing – one of the techniques discussed in detail in the previous chapter. In 2013, Gilead announced three “tiers” of prices for Sovaldi – the lowest price offered to the poorest countries (most of them located in subSaharan Africa), a higher price for lower-middle-income countries (including Egypt, which we will discuss shortly), and so forth. The second practice – and

²⁸ See MSF, "Not Even Close," 3.

²⁹ The status as of 2016 of the patent portfolios on all of the new DAA drugs are described in the following set of reports: WHO, "Patent Situation of Key Products for Treatment of Hepatitis C: Sofosbuvir," (2016); "Patent Situation of Key Products for Treatment of Hepatitis C: Simeprevir," (2016); "Patent Situation of Key Products for Treatment of Hepatitis C: Daclatasvir," (2016); "Patent Situation of Key Products for Treatment of Hepatitis C: Ledipasvir," (2016); "Patent Situation of Key Products for Treatment of Hepatitis C: Paritaprevir/Ombitasvir/Dasabuvir," (2016). All are available through <https://www.who.int/news/item/19-07-2016-who-updates-patent-information-on-treatments-for-hepatitis-c>.

³⁰ See MSF, "Not Even Close," 7.

³¹ See *ibid.*, 5.

the one most relevant to the topic of this chapter – was a system of voluntary licenses closely analogous to the system that Gilead had developed for HIV drugs. In September of 2014, the company granted licenses to seven manufacturers based in India, authorizing them to distribute in 91 countries generic versions of both sofosbuvir and a single-tablet regimen of sofosbuvir combined with ledipasvir.³² The royalty rate of this first wave of licenses was 7%. Gilead pledged to use the proceeds to cover costs associated with regulatory approvals and educational initiatives.³³ The licenses included both technology-transfer provisions (thus accelerating the availability of the generics in the covered territory) and anti-diversion provisions (intended to keep the inexpensive generics confined to that territory). The scope of the license was subsequently expanded to 14 licensees (located in India, Egypt, and Pakistan) and 101 countries, and then to 105 countries.³⁴ When other variants of sofosbuvir came online, Gilead extended the voluntary-licensing plan to cover them. BMS adopted a similar approach, but granted its licenses through the MPP, rather than directly. Abbvie did the same for its (less popular) entry into the field, a combination of glecaprevir and pibrentasvir.³⁵

These two components were intertwined in many ways. For example, a side-effect of the voluntary-licensing system was to reduce the competition that Gilead faced in jurisdictions not covered by the licenses. The reason: one of the terms of the contracts signed by the major Indian generic manufacturers was a pledge not to sell drugs in countries not included in the license. Voluntary licensing also functioned in part as a means of defusing the criticism that the companies received for the prices they charged in markets outside the VL footprint. On one occasion, the VL system also functioned as a safety valve; In response to especially sharp criticism of the prices that it was charging in Belarus, Malaysia, Thailand and Ukraine – and to threats by Malaysia to impose a compulsory license on its patent – Gilead agreed to expand the geographic scope of the voluntary license to reach those countries.³⁶

So how well did this system work? From the companies' standpoint, very well indeed. Estimates of the profits that the companies made from sales of the new HCV drugs

³² See Gilead Sciences, "Chronic Hepatitis C Treatment Expansion," news release, October 20, 2014, 2014, <https://perma.cc/S9V2-DK9>.

³³ See V. Kasturi Rangan, "Gilead: Hepatitis C Access Strategy (B)," in *Harvard Business School Case Study 9-515-044* (2016).

³⁴ See Gilead Sciences, "Chronic Hepatitis C Treatment Expansion," news release, November 17, 2017, 2017, <https://perma.cc/QEL6-NB7M>.

³⁵ See MSF, "Not Even Close," 5; WHO, "Accelerating Access to Hepatitis C Treatment," 28.

³⁶ See Fifa Rahman, "Malaysia Inclusion in Gilead Voluntary Licence – a Product of Compulsory Licence Pressure," *Health Policy Watch* (2017), <https://perma.cc/MGN7-938K>. However, sales to those four countries were accompanied by a royalty rate of 12%, instead of the standard 7%. See Gilead Sciences, "2017 Amended & Restated Voluntary Hcv License Agreement," (2017), <https://www.gilead.com/-/media/files/pdfs/other/form-ar-hcv-license-agmt-gild-11202017.pdf?la=en&hash=EA13A53F28CE66946255B7369B57EEFE>.

vary, but all are high. For example, one reported that, in the first five years following FDA approval of sofosbuvir, Gilead made a profit of \$25 billion from its HCV drugs.³⁷

In one especially important country, the public at large also benefitted enormously. That country was Egypt. The reason for its importance is that, as of 2013, Egypt had by far the highest prevalence of HCV in the world. In the country at large, it was roughly 15%, and in some regions it was as high as 28%.³⁸ 40,000 of the country's residents died from the disease each year.³⁹ The reason for this extraordinary burden is that a 20th-century national vaccination program for schistosomiasis had been conducted poorly; inadequate sterilization of needles had allowed the HCV virus to spread rapidly.⁴⁰

In 2006, the government of Egypt convened a group of experts to study ways of limiting the impact of the HCV outbreak. Relying on the recommendations of that group, the Ministry of Health created a network of centers for treating infected persons with a combination of interferon and ribavirin.⁴¹ As indicated above, that regimen was imperfect. It was especially unsatisfactory in Egypt, because the variant of HCV against which it is least effective is genotype 4, which happened to be the most common in that country.⁴² This approach was also extraordinary expensive, consuming roughly 20% of the Ministry's annual budget.⁴³

In 2013, when Sovaldi's potential power became apparent, the Ministry moved quickly to obtain supplies of the drug. Gilead initially offered it a price of \$15,000 for a 12-week course of treatment. By emphasizing the severity of the epidemic in Egypt, representatives of the Ministry were able to persuade Gilead's executives to offer them instead the lowest-tier price: \$900 for a 12-week supply (approximately 1% of the price in the United States).⁴⁴ To deploy the drugs as quickly as possible, the government waived the requirement for independent clinical trials and approved it for distribution a mere seven months after the FDA had approved it.⁴⁵ Gilead then collaborated with the Ministry on

³⁷ See Coalition, "Sofosbuvir Turns 5." For other estimates, see Velásquez, "Access to Hepatitis C Treatment," 4.

³⁸ See Heba Wanis, "Egypt Will Not Patent New Hepatitis C Drug," (2014), <https://perma.cc/BSK5-NVMN>; Ahmed Hassanin et al., "Egypt's Ambitious Strategy to Eliminate Hepatitis C Virus: A Case Study," *Global health science and practice* 9, no. 1 (2021): 190.

³⁹ See Hazem Abosheisha et al., "The Egyptian Journey from Having the Highest Prevalence of Hepatitis C Virus to Being the First to Achieve "Gold Tier" in Conquering the Disease," *Proceedings - Baylor University Medical Center* 37, no. 5 (2024).

⁴⁰ See Christina Frank et al., "The Role of Parenteral Antischistosomal Therapy in the Spread of Hepatitis C Virus in Egypt," *The Lancet* 355, no. 9207 (2000).

⁴¹ See Waked, "Case Study of Hepatitis C in Egypt."; Hassanin et al., "Egypt's Strategy to Eliminate Hepatitis C," 191.

⁴² See Rong and Perelson, "Treatment of Hepatitis C Virus Infection with Interferon and Small Molecule Direct Antivirals: Viral Kinetics and Modeling."

⁴³ See Rangan, "Gilead: Hepatitis C Access Strategy (B)."

⁴⁴ See Waked, "Case Study of Hepatitis C in Egypt," 2.

⁴⁵ Rangam, "Gilead: Hepatitis C Access Strategy (a)," 11.

many levels – formulating testing and treatment plans, developing an educational program to alert both clinicians and potential patients concerning the new testing and treatment options, and of course delivering growing quantities of drugs.⁴⁶

Soon thereafter, the fruits of the voluntary-licensing programs became apparent. Two Egyptian firms – Magic Pharma and Pharmed Healthcare – relying on licenses from Gilead, began supplying the Ministry with generic versions, and the price of a 12-week course dropped sharply. By 2018, it had declined from \$900 to \$84 for the 12-week course.⁴⁷

Between 2014 and 2020, the Ministry capitalized on the availability of the inexpensive drugs to construct and execute a comprehensive plan to purge the country of HCV. It set up myriad testing facilities, trained thousands of clinicians to do the testing and to administer drugs to persons who tested positive, and advertised the initiative heavily.⁴⁸ Most of the costs of the program were born by the Ministry. (In 2018, the Ministry received a loan of \$530M from the World Bank, which covered a portion of the late stages of the project).⁴⁹ By 2020, the program had tested more than 60 million people and provided treatment to over 4 million.⁵⁰ As a result, the prevalence rate of HCV in the country plummeted: to 4.61% in 2018, 2.39% in 2019; and 0.38% in 2023.⁵¹ In 2023, Dr Tedros Adhanom Ghebreyesus, the Director-General of the World Health Organization, took note of the achievement:

“Egypt’s journey from having one of the world’s highest rates of hepatitis C infection to being on the path to elimination in less than 10 years is nothing short of astounding. “Egypt is an example to the world of what can be achieved with modern tools, and political commitment at the highest level to use those tools to prevent infections and save lives. Egypt’s success must give all of us hope and motivation to eliminate hepatitis C everywhere.”⁵²

⁴⁶ See Rangan, "Gilead: Hepatitis C Access Strategy (B)."

⁴⁷ See Abosheishaa et al., "The Egyptian Journey," 881; Waked, "Case Study of Hepatitis C in Egypt," 2.

⁴⁸ See "Case Study of Hepatitis C in Egypt," 3.

⁴⁹ See World Bank, "Transforming Egypt's Healthcare System Project," (2018).

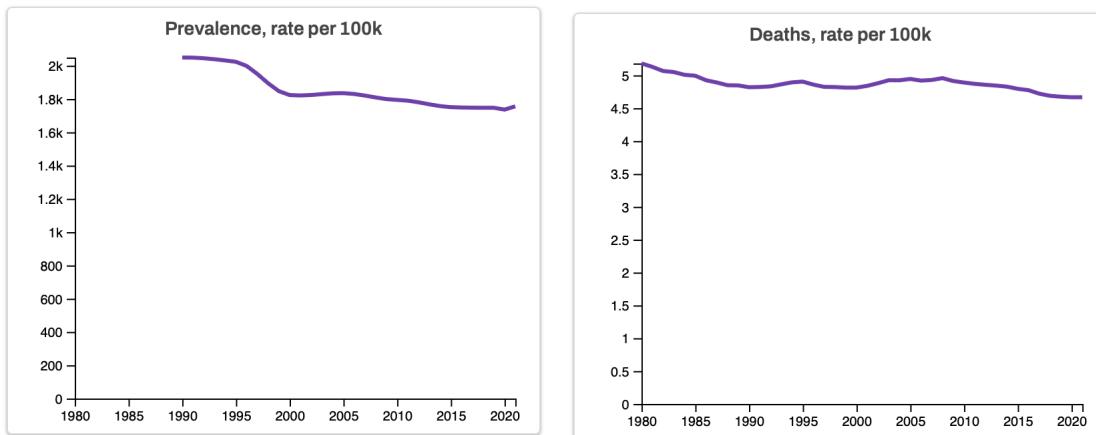
⁵⁰ See World Economic Forum, "The Art and Science of Eliminating Hepatitis: Egypt's Experience," (2022), 5; Hassanin et al., "Egypt's Strategy to Eliminate Hepatitis C," 196.

⁵¹ See Abosheishaa et al., "The Egyptian Journey," 878. One of the physicians involved in the program from the beginning offers the following estimate of its costs and benefits: “Despite the large cost of the treatment program since 2014 and the cost of the screening and treatment program in 2018–2019, the economic return is huge. At a cost of US\$ 350 million for treatment between 2014 and 2018, and US\$ 207 million for the screening and treatment campaign in 2018–2019, the total economic gain in both direct and indirect costs is calculated to be more than US\$ 7 billion between 2020 and 2030, or each US dollar spent in the program will result in an economic gain of more than US\$ 11 over the following 10 years.” Waked, "Case Study of Hepatitis C in Egypt," 5.

⁵² WHO, "Egypt Becomes the First Country to Achieve Who Validation on the Path to Elimination of Hepatitis C," news release, October 9, 2023, 2023, <https://perma.cc/KJZ9-J45S>.

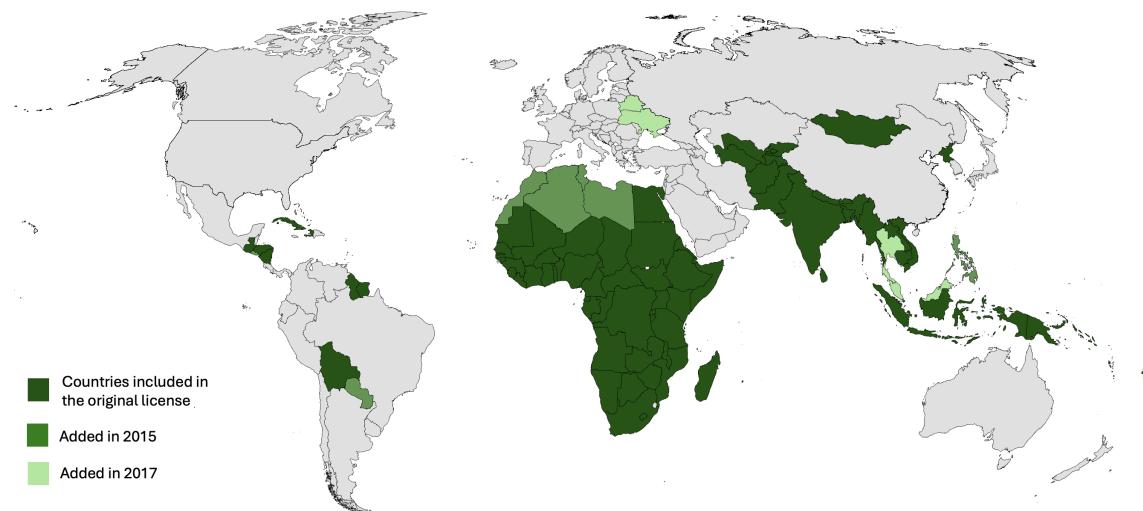
Unfortunately, outside Egypt, far less progress has been made. Globally, the potentially game-changing availability of the DAA drugs starting in 2013 has had only a modest impact on the prevalence of chronic HCV or on the associated death rate. The discouraging numbers are shown below.

Figure 6: Global Prevalence of Chronic HCV and Associated Death Rate⁵³



Several factors seem to underlie this disappointing outcome. The first is the limited scope of Gilead's voluntary-licensing system. Set forth below is a map of the coverage of the license – in other words, the countries in which the 14 licensees are permitted to sell generic versions of the drugs.

Figure 7: Countries included in the Voluntary License for Gilead's HCV Drugs



As one might expect, in most of these countries, generic HCV drugs are now available at modest prices.⁵⁴ The problem is that the majority of the people in the world infected with

⁵³ Source: IMHE, <https://vizhub.healthdata.org/gbd-results/>.

⁵⁴ See, e.g., Isabelle Andrieux-Meyer et al., "Disparity in Market Prices for Hepatitis C Virus Direct-Acting Drugs," *The Lancet global health* 3, no. 11 (2015).

the virus do not reside in these countries and thus do not have access to the inexpensive drugs.

But what about the other part of the firms' access strategy? As indicated above, even before it instituted the voluntary-licensing system for HCV, Gilead adopted a differential-pricing model, under which poorer countries were to be charged less for the branded versions of its drugs than were richer countries – and in each of the press releases since then Gilead has reiterated that commitment. Unfortunately, in practice, Gilead's adherence to the differential-pricing principle has proven to be haphazard at best. A 2020 study by Melissa Barber and colleagues compared the “originator prices” (i.e., the prices the companies charged for the branded versions) of the principal DAAs in the 50 countries where publicly accessible price databases could be found. As one might expect, those prices were much higher than those of the generics – and varied widely across countries.⁵⁵ Much more troubling was their finding that: “Across 50 countries, the pricing of originator DAAs has no apparent correlation to income level. Surprisingly, among high-income countries, pricing of all originator DAAs showed a moderately strong and statistically significant inverse correlation – countries with higher incomes have lower prices.”⁵⁶ The most likely reason for that inverse correlation, the authors suggested, was simply that richer countries had stronger bargaining power.

In sum, in countries outside the footprint of the voluntary license, the high prices of the breakthrough DAAs make a comprehensive program of the sort deployed in Egypt impossible. Neither the public-health systems nor private insurers in those countries can afford to treat all infected people. So instead they typically ration the drugs – making them available only to people whose conditions have deteriorated substantially.⁵⁷ Infected persons can, of course, pay for the drugs out of pocket, but few have the necessary funds.⁵⁸

⁵⁵ See Melissa J. Barber et al., "Price of a Hepatitis C Cure: Cost of Production and Current Prices for Direct-Acting Antivirals in 50 Countries," *Journal of Virus Eradication* 6, no. 3 (2020).: “The median originator price of sofosbuvir was US\$40,502 per 12-week course, ranging from US\$10,730 in Argentina to US\$91,461 in Italy. The median price of daclatasvir across all countries was US\$26,928 per 12-week course, ranging from US\$3144 in Russia to US\$100,415 in Italy. The median originator price of sofosbuvir/ledipasvir was US\$46,812 per 12- week course, ranging from US\$1249 in Morocco to US\$73,771 in Latvia. The median price of sofosbuvir/velpatasvir was US\$ 34,381 per 12-week course, ranging from US\$10,368 in China to US\$92,719 in Italy. The median price of lecaprevir/pibrentasvir was US\$30,710 per 8-week course, ranging from US\$15,628 in Brazil to US\$89,485 in Canada.”

⁵⁶ See *ibid.*, 7. A similar lack of correlation between a country’s wealth and the prices there of the DAAs is evident in the 2015 survey done by Andrieux-Meyer et al., "Disparity in Market Prices for Hepatitis C Virus Direct-Acting Drugs." and in the 2018 survey done by Swathi Iyengar et al., "Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis," *PLOS Medicine* 13, no. 5 (2016).(concluding that "Prices do not increase, and in some cases decrease, with increased standard of living.")

⁵⁷ See Alison D. Marshall et al., "Restrictions for Reimbursement of Interferon-Free Direct-Acting Antiviral Drugs for Hcv Infection in Europe," *THE LANCET GASTROENTEROLOGY AND HEPATOLOGY* 3, no. 2 (2018).

⁵⁸ See, e.g., Iyengar et al., "Prices of New Medicines for Hepatitis C," 12. ("The PPP-adjusted price of a full course of sofosbuvir alone would be equivalent to at least 1 year of the PPP-adjusted average earnings for

Transmissions from infected but relatively asymptomatic persons to naïve persons are thus allowed to continue. Despite these obstacles, in some countries growing percentages of infected people are receiving treatment. But the pace is far slower than in Egypt, in large part because of the costs of the drugs.⁵⁹

In most of the countries inside the voluntary-licensing footprint, generic versions of the DAAs are cheap, just as they are in Egypt. There, the cause of the limited impact of the voluntary-licensing initiative seems to be a lack of foresight and political will. Gilead's representatives attempted to persuade representatives of some of the governments of the wisdom of Egypt's approach, but to no avail. In Pakistan, for instance, their entreaties fell on deaf ears. This lassitude, in turn, can be attributed in part to the absence of an organized and well-funded global eradication initiative comparable the one focused on HIV/AIDS.

The bottom line: despite the existence of a safe, risk-free course of treatment that is inexpensive to manufacture, the number of people suffering from chronic HCV who are cured each year in the world is less than the number of new infections. Roughly 250,000 people continue to die from the disease each year – needlessly.⁶⁰

Three lessons can be derived from this phase of the voluntary-licensing strategy. First, the Egyptian story shows how a VL system can make drugs available at very low prices and in turn facilitate a campaign that eradicates a serious disease. Second, the lack of progress in other countries that lie within the GL footprint makes clear that low drug prices, though necessary for such a campaign, are not sufficient. Third, the high prices charged by Gilead and BMS outside of the VL footprint, seemingly without regard for ability of each country to pay, has enriched both companies, but at the cost of many lives.

individuals in 12 of the 30 countries analysed. In Poland, Slovakia, Portugal, and Turkey, a course of sofosbuvir alone would cost at least 2 years of average annual wages.”)

⁵⁹ See WHO, "Accelerating Access to Hepatitis C Treatment," 7, 12-17; Karin Hepp Schwambach et al., "Cost and Effectiveness of the Treatment of Chronic Hepatitis C in Brazil: Real-World Data," *Value in health regional issues* 23 (2020); Ahmad Shakeri et al., "Spending on Hepatitis C Antivirals in the United States and Canada, 2014 to 2018," *Value in health* 23, no. 9 (2020).

⁶⁰ See WHO, "Hepatitis C". (estimating the number, in ___, at 242,000).

3. COVID

The technologies underlying the mRNA-based vaccines that proved so effective in combatting the COVID pandemic were developed over many years by scientists working in many institutions. Among the streams of research, the following were most important:⁶¹

- mRNA itself was first discovered in 1961. Speculation began soon thereafter concerning its potential for creating vaccines.
- In 1987, Robert Malone, working at the Salk Institute, found a way to induce human cells to translate mRNA and begin producing proteins.
- In 2000, Ingemar Hoerr, working at Tübingen University, was able to induce an immune response in mice by injecting them with mRNA. He later founded CureVac, a private firm focused on commercializing mRNA technology.
- In 2005, Katalin Karikó and Drew Weissman, working at the University of Pennsylvania, discovered that the substitution of pseudouridine for uridine could prevent an injection of synthetic mRNA from triggering an inflammatory immune response.
- In 2014, Pieter Cullis and colleagues, working at the University of British Columbia, developed a system for using lipid nanoparticles (LNPs) to stabilize mRNA, thereby enabling it to be delivered to target cells without degrading. Cullis then helped found two biotech companies in Canada: Arbutus Biopharma Corporation and Acuitas Therapeutics, Inc.

Several of the institutions in which these lines of research were conducted sought and obtained patents on their innovations.

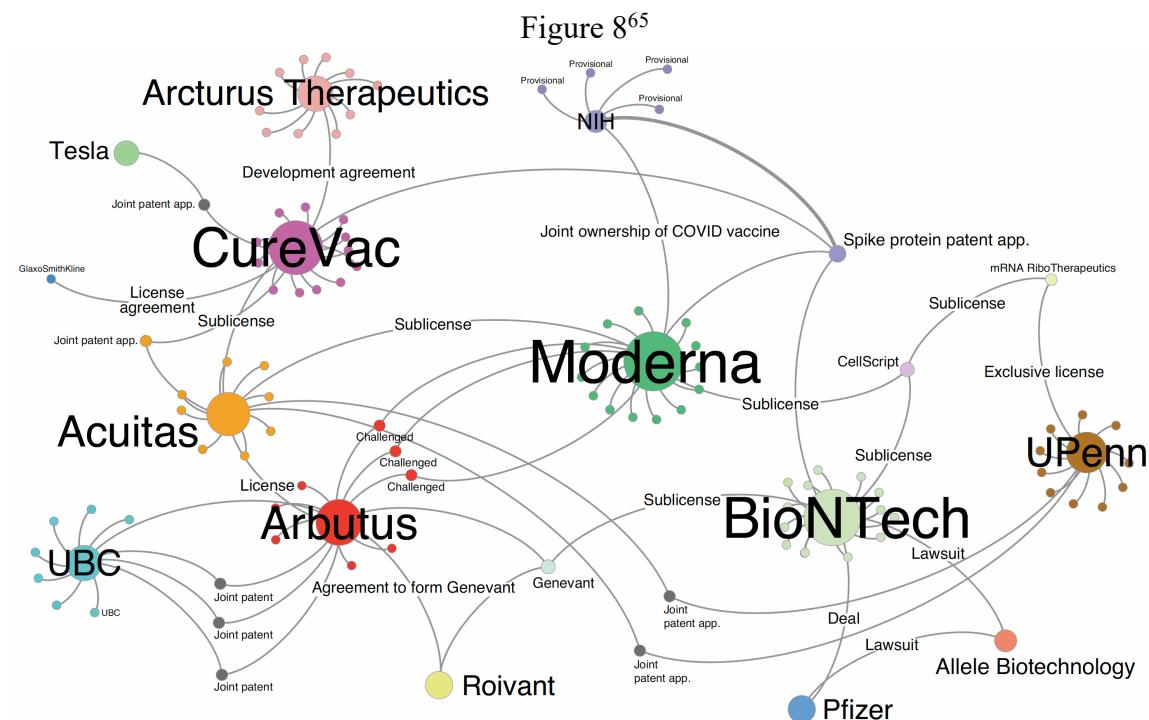
Well before the COVID threat appeared, researchers at a few private firms – most notably, Moderna (based in Cambridge, Massachusetts), BioNTech (based in Mainz, Germany), and CureVac (based in Tübingen, Germany) – relying on these discoveries, began to develop vaccines aimed at various diseases. To do so, they typically obtained (either directly or through intermediaries) licenses to the patents obtained by their predecessors. As the firms refined the technologies, they sought patents of their own on their incremental innovations. By the end of the century, several of these non-COVID vaccine candidates were in early-stage clinical trials.⁶²

⁶¹ The following chronology has been derived from: Robert Burrows and Ellen Lambrix, "Mrna Vaccines: A Growing and Complex Ip Landscape," *Vaccine Insights* 1, no. 4 (2022); Mario Gaviria and Burcu Kilic, "A Network Analysis of Covid-19 Mrna Vaccine Patents," *Nature biotechnology* 39, no. 5 (2021); Ulrich Storz, "The Covid-19 Vaccine Patent Race," *ibid.*40, no. 7 (2022).

⁶² See Dan Shores, Dylan Haversack, and Andrew J. Storaska, "The Mrna Ip and Competitive Landscape through One Year of the Covid-19 Pandemic — Part I," *IP Watch* (2021), <https://ipwatchdog.com/2021/04/11/mrna-ip-competitive-landscape-one-year-covid-19-pandemic-part-ii/>; "The Mrna Ip and Competitive Landscape through One Year of the Covid-19 Pandemic — Part II," *IP Watch* (2021), <https://ipwatchdog.com/2021/04/21/mrna-ip-competitive-landscape-translate-bioarcturus-etherna-startups-lnp-technology-part-ii/>; "The Mrna Ip and Competitive Landscape

The emergence of the COVID virus prompted researchers at the three firms (as well as the National Institutes of Health) to accelerate their work, seeking to apply mRNA-based technology to develop vaccines to meet the new threat.⁶³ Almost immediately after the work began, all three firms sought patents on the potential fruits of their projects. Most of those initial applications were weak and are unlikely ultimately to pass muster. But as their work proceeded, the firms were able to obtain extensive portfolios of more durable patents. Some asserted rights to the APIs; others claimed supporting technologies, such as methods of use, optimal dosages, delivery systems, and manufacturing processes.⁶⁴

The net result, by 2021, was an extraordinarily complex pattern of interlocking rights, well represented by the following diagram developed by Mario Gaviria and Burcu Kilic.



through One Year of the Covid-19 Pandemic — Part III," *IP Watch* (2021), <https://ipwatchdog.com/2021/04/30/mrna-patent-competitive-landscape-pioneers-litigation-outlook-big-pharmas-next-moves-part-iii/id=132936/>; Burrows and Lambrix, "Mrna Vaccines."

⁶³ See Kizzmekia S. Corbett et al., "Sars-Cov-2 Mrna Vaccine Design Enabled by Prototype Pathogen Preparedness," *Nature (London)* 586, no. 7830 (2020); Storz, "The Covid-19 Vaccine Patent Race."

⁶⁴ See Shores, Haversack, and Storaska, "The Mrna Ip Landscape, Part 3"; Storz, "The Covid-19 Vaccine Patent Race."

⁶⁵ Source: Gaviria and Kilic, "A Network Analysis of Vaccine Patents." The authors' explanation of the diagram: "Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology." For a similar but less detailed diagram, see Shores, Haversack, and Storaska, "The Mrna Ip Landscape, Part 3". Figure 8.

Soon, tensions among these various players gave rise to opposition proceedings and infringement suits – both in the United States and in Europe. In some of these disputes, the defendants were accused of relying on patented technologies without permission; in others, the validity of the defendants’ patents was challenged, either on the ground that they did not accurately identify all of the inventors of the technology in question or that they failed the novelty or inventive-step requirement. Many of those lawsuits are still ongoing, but they are unlikely to thin significantly the thicket of exclusive rights.⁶⁶

The fights were counterbalanced, in part, by a growing set of collaboration agreements – the most important of which was a collaboration between BioNTech and Pfizer, which ultimately gave rise to the most commercially successful of the vaccines.⁶⁷

Patents were not the only shields deployed by the firms. At least as important were trade secrets. The mRNA vaccines are substantially more complicated and difficult to produce than the HCV antivirals, discussed in the preceding section. Some of the supporting technologies, such as the LNP delivery systems, are also complex. To protect their competitive positions, the firms refused to reveal crucial details concerning this know-how.⁶⁸ Without access to it, other firms would have had great difficulty attempting to replicate the leaders’ products.

Additional protections were provided by data-exclusivity rules, supply limitations, and the costs of securing regulatory approvals. In an interview, Stéphane Bancel, the CEO of Moderna, explained how these layers of protection interlocked:

Drugmakers interested in manufacturing a similar mRNA vaccine would need to conduct the clinical trials, apply for authorization and then scale the manufacturing, which could take upward of 12 to 18 months, Bancel said. “This is a new technology,” Bancel told analysts regarding mRNA. “You cannot go hire people who know how to make mRNA. Those people don’t exist.”⁶⁹

⁶⁶ For surveys of these suits, see Burrows and Lambrix, "Mrna Vaccines," 196-97; Storz, "The Covid-19 Vaccine Patent Race."; Gaviria and Kilic, "A Network Analysis of Vaccine Patents."; Shores, Haversack, and Storaska, "The Mrna Ip Landscape, Part 3".

⁶⁷ "Collaboration Agreement between Pfizer, Inc. And Biontech Se," (2020); Shores, Haversack, and Storaska, "The Mrna Ip Landscape, Part 3". For evidence of the commercial success of the BioNTech/Pfizer vaccine, see Global Commission for Post-Pandemic Policy, "Covid-19 Vaccine Production, to January 31st 2022," (2022).

⁶⁸ See Shores, Haversack, and Storaska, "The Mrna Ip Landscape, Part 3". (describing how Moderna improved upon the LNP delivery system it had licensed from Arbutus – and then refused to reveal the details concerning its new “proprietary” system).

⁶⁹ Noah Higgins-Dunn, "Moderna Ceo Says He's Not Losing Any Sleep over Biden's Support for Covid-19 Vaccine Waiver," *Fierce Pharma* (2021), <https://www.fiercepharma.com/pharma/moderna-ceo-says-he-s-not-losing-any-sleep-over-biden-s-endorsement-for-covid-19-ip-waiver>.

The net result is that, even in the many countries in which the firms had not obtained (or even sought) patents, they were unlikely to face competition.

In the end, two of the three mRNA vaccines proved both safe and remarkably effective. The BioNTech/Pfizer product received an emergency use authorization by the FDA on December 11, 2020; the Moderna product did so a week later. Approvals by the EMA followed shortly thereafter. Distribution of both products in developed countries began immediately. (Clinical trials of the CureVac product were less successful, and it was never launched.)

Meanwhile, other companies had been using more traditional technologies to develop COVID vaccines. Johnson & Johnson's product received an EUA a few months after the mRNA entrants. Unfortunately, concerns about possible adverse side effects prompted the FDA and CDC to "pause" their endorsements of it. Those concerns were soon addressed and the pause ended,⁷⁰ but the J&J product never recovered commercially. By contrast, several other traditional vaccines stood the test of time. Among them were those by Sinovac and Sinopharm (distributed primarily in China), Gamaleya Research Institute (distributed primarily in Russia), Bharat Biotech and the Indian Council of Medical Research (distributed primarily in India), and, last but not least, AstraZeneca and Oxford University (distributed throughout the world).⁷¹ None of these traditional vaccines, however, matched the mRNA vaccines in demonstrated effectiveness.

Running parallel to the race to develop vaccines was a similar race to find therapeutic drugs that, when given to people who have contracted the virus, could mitigate symptoms and reduce the risk of death. Some of the therapeutics consisted of applications or adaptations of existing treatments for other diseases; others were new. They varied widely in effectiveness. For a while, it appeared that remdesivir, developed previously by Gilead as a remedy for Ebola, would be also effective against COVID, but its benefits proved modest. The drugs that eventually proved most efficacious were three antivirals (Paxlovid, developed by Pfizer; Lagevrio, by Merck; and Xocova, by Shionogi) and four monoclonal antibodies (Bebtelovimab and Bamlanivimab, developed by Lilly; Xevudy, by GSK and Vir; and REGEN-COV, by Regeneron and Roche).⁷²

The developers of the therapeutics used a similar set of shields to augment their ability to control prices. Like the creators of the vaccines, they sought and obtained patents, both on the APIs and on supporting technologies, in many jurisdictions. The result was a

⁷⁰ See "FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review," April 23, 2021, <https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough>.

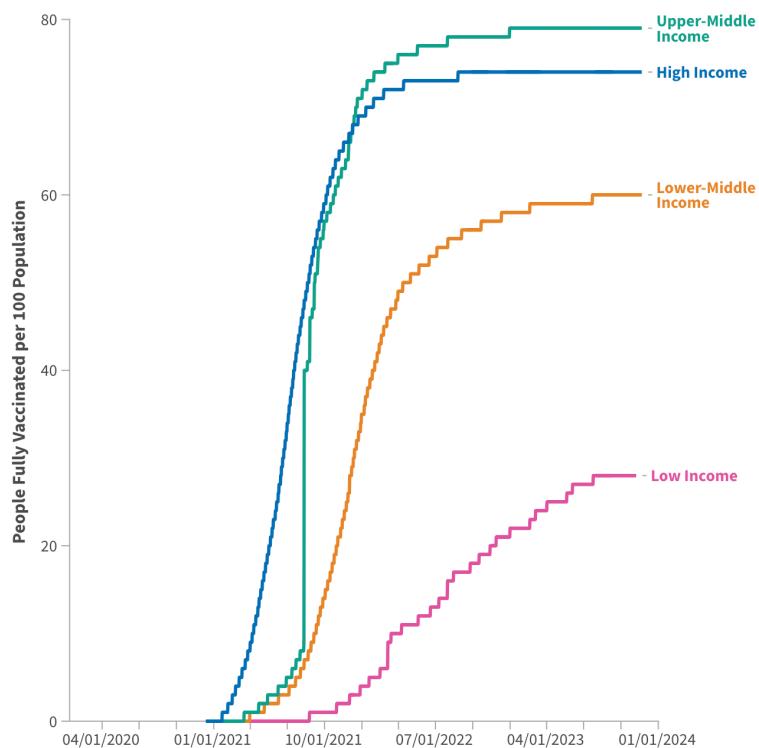
⁷¹ For data concerning the total production of these vaccines (as of January 2022), see Policy, "Covid-19 Vaccine Production."

⁷² See US International Trade Commission, "Covid-19 Diagnostics and Therapeutics: Supply, Demand, and Trips Agreement Flexibilities," (2023), 107, 12.; FDA, "Coronavirus (COVID-19) Drugs," <https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs> (last visited January 13, 2025).

formidable hedge of exclusive rights analogous to the hedge that shielded the vaccines.⁷³ In addition, limits on access to proprietary know-how provided powerful protection against competitors. This was especially true with respect to the monoclonal antibodies, which are far more difficult to reverse engineer than the small-molecule antivirals.⁷⁴ As was the case with vaccines, the firms that developed the therapeutics sometimes contested each other's rights – and sometimes instead collaborated.⁷⁵

As Chapter 2 explained, both the vaccines and the therapies were initially distributed primarily in developed countries. The delay in their availability in poor countries is shown below.

Figure 9: Vaccination Rates by Income Group⁷⁶



As these gaps became increasingly glaring, criticism of the firms intensified. Public-health advocates sought ways to provoke, help, or compel them to make their products available more widely.⁷⁷ Among their initiatives was the COVID-19 Technology

⁷³ See Mengru Lyu et al., "The Global Patent Landscape of Mrna for Diagnosis and Therapy," *Nature biotechnology* 41, no. 9 (2023); Commission, "Covid-19 Diagnostics and Therapeutics," 71-72.

⁷⁴ See "Covid-19 Diagnostics and Therapeutics," 74.

⁷⁵ See *ibid.*, 178-82.

⁷⁶ Source: UNDP, "Global Dashboard for Vaccine Equity," (2024).

⁷⁷ See, e.g., "Who's Tedros Says Covid-19 Vaccine Inequity Creates 'Two-Track Pandemic,'" *Reuters* (2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/whos-tedros-says-covid-19-vaccine-inequity-creates-two-track-pandemic-2021-06-07/>; J. Peter Figueroa et al., "Urgent Needs of Low-Income

Access Pool (C-TAP), created in May of 2020 by the World Health Organization in collaboration with the government of Costa Rica. The Pool is similar to the MPP in that it solicits contributions (in the form of nonexclusive voluntary licenses) of intellectual property and know-how – and then issues sub-licenses to other companies and institutions. Its primary difference from the MPP pertains to the scope of the licenses; all are global in their coverage. C-TAP enjoyed considerable support. 44 other countries quickly endorsed it, and its partners include the UNDP, Unitaid, the UN Technology Bank, and the MPP.⁷⁸

For the most part, the firms were unresponsive to the pleas of the public-health advocates. This was especially true of the companies that had developed the mRNA vaccines. To be sure, in response to criticism, Moderna pledged not to “enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.”⁷⁹ However, as the comment by Mr. Bancel quoted above makes clear, this was a hollow promise. In the absence of technology transfer and regulatory support, no other company would have been able to make and distribute a replica of the Moderna vaccine within a reasonable period of time.⁸⁰

The best indicator of the posture of the firms was their response to the formation of C-TAP. During its first three years, only two organizations (the Spanish National Research Council and the U.S. National Institutes of Health) issued licenses through the C-TAP,⁸¹ and only one company (Biotech Africa) obtained a sublicense (specifically, on a COVID

and Middle-Income Countries for Covid-19 Vaccines and Therapeutics," *The Lancet (British edition)* 397, no. 10274 (2021); Carlos Correa, "Expanding the Production of Covid-19 Vaccines to Reach Developing Countries: Lift the Barriers to Fight the Pandemic in the Global South," (South Centre, 2021); Peter Loftus, "Pfizer, Moderna and J&J Face Shareholder Pressure to Broaden Covid-19 Vaccine Access," *Wall Street Journal*, March 22, 2022 2022; Siva Thambisetty et al., "Addressing Vaccine Inequity during the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond," *Cambridge law journal* 81, no. 2 (2022); Editorial Board, "The World Needs Many More Coronavirus Vaccines," *New York Times*, April 24, 2021.

⁷⁸ See <https://www.who.int/initiatives/covid-19-technology-access-pool>.

⁷⁹ Moderna, "Statement by Moderna on Intellectual Property Matters during the Covid-19 Pandemic," news release, October 8, 2020, 2020, <https://perma.cc/R9VB-2ULH>.

⁸⁰ In 2021, Martin Friede, the leader of the vaccine research initiative at the World Health Organization, estimated that, in the absence of technology transfer from Moderna, it would take Afrigen, a sophisticated biotech firm, “from three or four years” to replicate the Moderna vaccine. See Nurith Aizenman, “Moderna Won’t Share Its Vaccine Recipe. Who Has Hired an African Startup to Crack It,” *National Public Radio* (2021), <https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun>. That prediction proved remarkably accurate.

⁸¹ The license by the former is available at <https://www.who.int/initiatives/covid-19-technology-access-pool/csic-license>. The license by the latter is available at <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses>. The NIH’s own summary of their contributions is available at <https://www.techtransfer.nih.gov/policy/ctap>. The resistance by all other potential licensors is described in Ed Silverman, “Pharma leaders shoot down WHO voluntary pool for patent rights on Covid-19 products,” STAT, May 28, 2020, <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>.

diagnostic test).⁸² Not until August of 2023 (when the pandemic was effectively finished) was a vaccine candidate licensed through the system.⁸³

The center ring for the prolonged struggle between the companies and the public-health advocates was a multi-year effort to secure from the World Trade Organization a “waiver” of the provisions of the TRIPS Agreement that curtailed countries’ ability to overcome the companies’ shields. That effort was initiated by the governments of India and South Africa. In October of 2020, they requested “a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19.” They asked that the waiver remain in place “until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”⁸⁴ After seven months of fraught negotiations, both public and private, the United States announced (to the surprise of most observers) that it could support some kind of waiver “for COVID vaccines.”⁸⁵ India and South Africa, now with the support of many other developing countries, then proposed a waiver only slightly narrower than their original version. Unlike the statement by the U.S., the revised proposal encompassed, not just vaccines, but all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.”⁸⁶ Soon thereafter, the European Union, apparently unmoved by the temperate stance taken by the U.S., offered an extremely narrow accommodation of the request by the developing countries. The EU proposal merely acknowledged that the COVID pandemic constitutes a “circumstance of extreme urgency” within the meaning of Articles 31 and 31bis and loosened slightly the requirements with which countries must abide when issuing compulsory licenses applicable to patents on vaccines and medicines aimed at COVID.⁸⁷

After yet another year of negotiations, the Ministerial Conference of the WTO finally announced a clarification of the TRIPS Agreement nearly as circumscribed as the

⁸² See https://cdn.who.int/media/docs/default-source/medicines/c-tap/sublicence-agreement-mpp-biotech-africa.pdf?sfvrsn=59cc142e_1 ; “New C-TAP agreement aims to improve global access to COVID-19 testing technologies,” June 16, 2022, <https://www.who.int/news-room/16-06-2022-new-agreement-under-c-tap-aims-to-improve-global-access-to-covid-19-testing-technologies>

⁸³ See WHO, “Who Initiative Signs New Licensing Agreements on Covid-19 Technologies,” news release, August 29, 2023, 2023, <https://perma.cc/3477-5SQF>; Priya Venkatesan, “New Licences for the Covid-19 Technology Access Pool,” *The Lancet. Microbe* 4, no. 12 (2023).

⁸⁴ World Trade Organization, “Communication from India and South Africa: Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19,” (2020).

⁸⁵ United States Trade Representative, “Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver,” news release, May 5, 2021, 2021, <https://perma.cc/JN53-Y5UW>.

⁸⁶ World Trade Organization, “Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the Ldc Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe: Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19,” (2021).

⁸⁷ “Communication from the European Union to the Council for Trips: Draft General Council Declaration on the Trips Agreement and Public Health in the Circumstances of a Pandemic,” (2021).

one advocated by the EU. It was limited to vaccines, applied only “to the extent necessary to address the COVID-19 pandemic,” was available only to self-declared “developing countries,” and, rather than “waiving” the limits imposed by TRIPS upon countries’ authority to issue compulsory licenses, loosened only modestly the procedural and substantive requirements with which they had to abide.⁸⁸

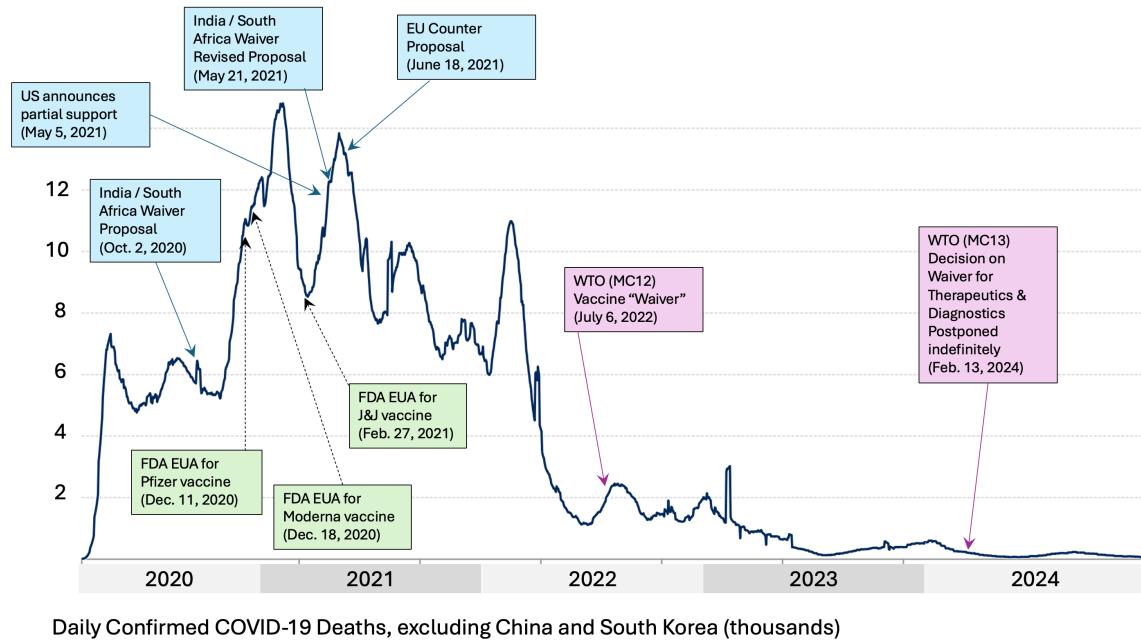
The 2022 Decision left open the question of whether the partial suspension of TRIPS would be “extended” from vaccines to COVID therapeutics and diagnostics. After 20 months of additional discussions and negotiations (in which one of the authors played a minor role) and the publication of a comprehensive report by the US Trade Commission, the WTO Ministerial Conference decided not to resolve the issue – in effect postponing an answer to the question forever.⁸⁹

For three independent reasons, neither of decisions by the WTO Ministerial Conference had any material direct effect on the availability of COVID vaccines or therapeutics. First, as we have seen, only the first of the two rulings modified in any way the constraints imposed by TRIPS – and its ambit was narrow. Second, even generous waivers of the TRIPS constraints would have weakened only one of the shields the firms used to suppress competition – namely, their patent portfolios. All of the other shields would have remained intact. Third, as the timeline set forth below shows, by the time the WTO issued its rulings, the pandemic had largely subsided.

⁸⁸ "Ministerial Decision on the Trips Agreement," (Ministerial Conference, Twelfth Session, 2022).

⁸⁹ For some of the contributions to the prolonged debate over what came to be known, inaccurately as the “waiver extension,” see American Federation of Teachers et al., "Please Extend the Wto Trips Decision to Treatments and Tests and Support Countries Using Wto Flexibilities to Access Covid-19-Related Medical Technologies," (2022); European Federation of Pharmaceutical Industries and Associations, "A Fact-Based Analysis of the Trips Waiver Extension," (2022); World Trade Organization, "Council for Trips Paragraph 8 of the Ministerial Decision on the Trips Agreement: Informal Thematic Session for External Stakeholder Input, Report by the Chair," (2024). The decision itself is available at "Paragraph 8 of the Ministerial Decision on the Trips Agreement Adopted on 17 June 2022: Report to the General Council," (2024).

Figure 10: The COVID Waiver Debate Juxtaposed to Global Deaths⁹⁰



This is not to say, however, that the controversy over the “COVID waiver” was entirely a sideshow. By helping to sustain public awareness of the plight of developing countries, the debate added significantly to the pressure on the firms to find some alternative way of reducing global inequity in access to their products.

The principal response of the developers of the vaccines was to enter into contracts with a few companies located in low-income or middle-income countries to manufacture branded versions of their products. For example, in July of 2021, Pfizer and BioNTech contracted with Biovac, a South African biopharmaceutical company, to produce the Pfizer vaccine in its Cape Town facility. The deal contemplated that “manufacturing of finished doses will commence in 2022. At full operational capacity, the annual production will exceed 100 million finished doses annually. All doses will exclusively be distributed within the 55 member states that make up the African Union.”⁹¹ AstraZeneca entered into similar

⁹⁰ The reason for the exclusion of China and South Korea from the representation of global deaths is not that those countries are unimportant, but rather that the long delays between deaths in those countries and the time at which those deaths were reported produces a distorted picture of the progress of the pandemic.

⁹¹ Pfizer, “Pfizer and Biontech Announce Collaboration with Biovac to Manufacture and Distribute Covid-19 Vaccine Doses within Africa,” news release, July 21, 2021, 2021, <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac>. The tone of the press release made clear the extent to which the deal was provoked by criticism of the company in the previous year: “From day one, our goal has been to provide fair and equitable access of the Pfizer-BioNTech COVID-19 Vaccine to everyone, everywhere,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. “Our latest collaboration with Biovac is a shining example of the tireless work being done, in this instance to benefit Africa. We will continue to explore and pursue opportunities to bring new partners into our supply chain network, including in Latin America, to further accelerate access of COVID-19 vaccines.”

contracts with Serum Institute in India and Fiocruz in Brazil.⁹² These were not voluntary licenses in the special sense in which that term is now conventionally used. Rather, they were traditional manufacturing contracts for the production and distribution of branded versions of the vaccines at issue. The output of products through these channels was substantial, but did not begin to reach most poor countries until roughly a year and a half after the vaccines were being widely distributed in rich countries.

The developers of the therapeutics, by contrast, began to employ voluntary licenses of the sort that had been developed and refined in the context of HIV and HCV. The principal terms of the most important licenses they granted are set forth (in chronological order) in the following table.⁹³

Figure 11: Voluntary Licenses for COVID Therapeutics

Licensor	Drug	Date	Mode	Countries	Licensees
Gilead	remdesivir	May 2020	bilateral	127	9
Merck	molnupiravir	April 2021	bilateral	106	8
Lilly	baricitinib	May 2021	bilateral	?	8
Merck	Molnupiravir (Lagevrio)	October 2021	MPP	106	27
Pfizer	Nirmatrelvir + ritonavir (Paxlovid)	November 2021	MPP	95	38
Shionogi	Ensitrelvir (Xocova)	October 2022	MPP	117	7

In most respects, these licenses mirrored the voluntary licenses pertaining to HIV and HCV. Each authorized the licensees to produce and to distribute, within the specified countries, generic versions of the licensor's products. The licensees were free to set the prices for their products. Typically, the licensor promised to assist the licensees in various ways – most importantly by disclosing proprietary know-how to facilitate manufacturing, but also by providing various forms of assistance in obtaining regulatory approval. Most provided that royalties would be waived altogether during the pandemic and would remain modest thereafter – typically 5% of sales.

⁹² See Thambisetty et al., "Addressing Vaccine Inequity during the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond." The Fiocruz contract is available at Fiocruz, "Technological Order Agreement Entered into by Fundacao Oswaldo Cruz — Fiocruz, Instituto De Tecnologia Em Imunobiologicos — Bio-Manguinhos and Astrazeneca Uk, Ltd.," (2020).

⁹³ The information contained in this table has been assembled from MPP, "Accelerating Access through Community Partnership: Annual Report 2023," (2024); Commission, "Covid-19 Diagnostics and Therapeutics."; Chenglin Liu, "Beyond Compulsory Licensing: Pfizer Shares Its Covid-19 Medicines with the Patent Pool," *Legislation and Public Policy* 25 (2021); Morgan Pincombe and Javier Guzman, "Lessons from Expanding Access to Covid-19 Treatments in Lmics through Voluntary Licensing," (Center for Global Development, 2022).

On paper, these licenses were and are impressive. Unfortunately, in practice their contribution to the mitigation of the pandemic was modest. One of the factors that limited their impact was their modest geographic scope. The broadest in coverage was the Gilead license for remdesivir, but unfortunately that drug proved less effective than the other therapeutics. The licenses to the other drugs on the list typically excluded large upper-middle-income countries that the firms regarded as significant potential sources of revenue. Among the countries left out of all of the licenses (other than Gilead's) are Mexico, Brazil, Chile, Argentina, Turkey, and China.

Even more important than this geographic limitation was the constraint imposed by the timing of the licenses. By the time they were issued, the pandemic was already starting to fade. Most of the licensees, recognizing that building their manufacturing capacity and securing regulatory approvals for their products would take many months, never even started those processes.⁹⁴ For example, as of the end of 2023, only 7 of the 27 sublicenses issued by the MPP for molnupiravir were "active," and most of the licensees were still awaiting regulatory approval. Similarly, only 12 of the MPP sublicenses for nirmatrelvir/ritonavir were "active," and only 4 of those licensees had received WHO prequalification approval.⁹⁵

The licenses surely did some good. The MPP reports that, by the end of 2023, 606,000 courses of molnupiravir had been supplied in India and Guatemala, and 76,000 courses of nirmatrelvir/ritonavir had been supplied in 13 low-income and lower-middle-income countries.⁹⁶ But by that time, there had been roughly 750 million confirmed COVID cases in the world. The number of therapeutic treatments enabled by the MPP voluntary licenses represents 0.09% of that total. In sum, for the most part, the fruits of the voluntary licenses for COVID therapeutics must be considered too little, too late.

⁹⁴ See Commission, "Covid-19 Diagnostics and Therapeutics," 191.

⁹⁵ See MPP, "Annual Report 2023," 51.

⁹⁶ See *ibid.*

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