

# **Request for a public interest license to exploit inventions relating to the COVID-19 oral antiviral Paxlovid**

## **Petitioners**

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### **Patent application P2021-0232**

Titled Nitrile-Containing Antiviral Compounds  
Filed 06 August 2021 by Pfizer

## 1. Summary

Knowledge Ecology International (KEI) hereby requests the grant of a government use and an open public interest license under article 46 of Law 20-00 to manufacture, import, sell, and export PF-07321332. Marketed by Pfizer in combination with ritonavir, PF-07321332 is an oral antiviral drug showing promising results as a treatment against COVID-19. PF-07321332 is claimed in P2021-0232, a pending patent application filed by Pfizer in the Dominican Republic on August 6, 2021. The instant request covers P2021-0232 and any other pending or issued patents that may impose legal barriers to manufacture, import, sell, or export PF-07321332.

In November 2021, Pfizer entered into a voluntary license with the Medicines Patent Pool (MPP) to facilitate the global production and distribution of PF-07321332. The Pfizer license to the MPP allows the manufacture anywhere in the world and will create a large supply of generic versions of the PF-07321332 oral antiviral globally, but has more restrictive provisions regarding the sale and use of this drug. The agreement between Pfizer and the MPP authorizes the sale of drugs either in a 95-countries licensed area, which excludes the Dominican Republic, or in countries where there are no granted patents or patent applications pending.

The instant request seeks to enable generic manufacturers, including but not limited to companies that enter into agreements with the MPP, to supply the Dominican market.

## 2. Petitioners

Pursuant to article 46 of the Industrial Property Law 20-00 of the Dominican Republic, “any interested person” can request the grant of a license under public interest grounds. This request is being filed by Knowledge Ecology International (KEI), a non-profit organization with offices in Washington, D.C. and Geneva, Switzerland, focused on access to health technologies; James Love, director of KEI, and Luis Gil Abinader, senior researcher and legal policy analyst at KEI and a citizen of the Dominican Republic residing in the United States (hereinafter jointly referred to as “KEI”). As such, KEI has standing to seek the grant of a license on public interest grounds as provided in article 46 of Law 20-00.

## 3. Paxlovid

Marketed by Pfizer in combination with ritonavir under the brand *Paxlovid*, PF-07321332 is an investigational antiviral designed to be administered orally and prescribed at the first sign of infection or awareness of an exposure to SARS-CoV-2 (the COVID-19 virus). PF-07321332 blocks the activity of the SARS-CoV-2-3CL protease, an enzyme that the coronavirus needs to replicate. A low dose of ritonavir is co-administered to help slow down the metabolism of PF-07321332 and remain active in the body for longer periods of time at higher concentrations.

In July 2021, Pfizer initiated a phase 2/3 study of Paxlovid in non-hospitalized adult patients with COVID-19. Enrolled individuals had a laboratory-confirmed diagnosis of SARS-CoV-2 infection within a five-day period and were required to have at least one characteristic or underlying

medical condition associated with an increased risk of developing severe illness from COVID-19. An interim analysis showed an 89% reduction in risk of COVID-related hospitalization or death compared to placebo in patients treated within three days of symptom onset. On November 16, 2021, Pfizer announced that it had filed for emergency use authorization in the United States,<sup>1</sup> and on November 19, 2021 the European Medicines Agency announced its review.<sup>2</sup>

In the Dominican Republic there are several COVID-19 treatments currently available. The Dominican government acquired a batch of the REGEN-COV antibodies cocktail in September 2021.<sup>3</sup> Tocilizumab<sup>4</sup> and remdesivir<sup>5</sup> have also been used in the country to treat COVID-19. However, REGEN-COV, tocilizumab and remdesivir are injectable treatments that have to be administered in monitored settings such as hospitals. Another disadvantage of these treatments are their cost. According to a press release, the Dominican Republic agreed to pay 85 million pesos, which equals approximately 1.5 million U.S. dollars, to acquire about 825 doses of the REGEN-COV cocktail.<sup>6</sup> This represents around 1,821 U.S. dollars per dose, approximately 87% of the cost recently agreed to by the United States for additional supplies of REGEN-COV.<sup>7</sup> At 1,821 U.S. dollars per dose, wide access to REGEN-COV would impose a significant burden on the public health budget of the Dominican Republic. Moreover, because their manufacture is relatively more difficult, the availability of monoclonal antibodies and other injectable COVID-19 treatments remains limited globally. In fact, at the current infection rate, the 825 doses of REGEN-COV recently acquired by the Dominican Republic will last just a few weeks.

If authorized or approved, Paxlovid will have several advantages in comparison with other COVID-19 treatments. As an oral treatment, Paxlovid can be administered easily and outside of a hospital setting. PF-07321332 is easier to manufacture than monoclonal antibodies and

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<sup>1</sup> "Pfizer seeks emergency use Authorization for Novel COVID-19 oral antiviral candidate." Pfizer, November 16, 2021. Available here:

<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-seeks-emergency-use-authorization-novel-covid-19>

<sup>2</sup> "EMA starts review of Paxlovid for treating patients with COVID-19." November 19, 2021. Available here: <https://www.ema.europa.eu/en/news/ema-starts-review-paxlovid-treating-patients-covid-19>

<sup>3</sup> "RD introduce medicamento REGEN COV para tratamiento de COVID-19, es el primer país de AL que cuenta con este fármaco." Ministerio de Salud Pública de la República Dominicana. September 29, 2021. Available here: <https://www.msp.gob.do/web/?p=13436>

<sup>4</sup> "Avanzan trabajos para instalación farmacia del Programa de Medicamentos Alto Costo en Azua." Ministerio de Salud Pública de la República Dominicana. July 12, 2021. Available here: <https://www.msp.gob.do/web/?p=12073>

<sup>5</sup> "MSP oficializa uso de medicamento REMDESIVIR 100 Mg, para tratamiento de COVID-19." Ministerio de Salud Pública de la República Dominicana. November 2, 2021. Available here: <https://www.msp.gob.do/web/?p=9058>

<sup>6</sup> "MSP y SNS resaltan efectividad del medicamento Regen-Cov que ya ha sido aplicado en 65 pacientes." Ministerio de Salud Pública de la República Dominicana. October 14, 2021. Available here: <https://www.msp.gob.do/web/?p=13645>

<sup>7</sup> Regeneron announces new U.S. government agreement to purchase additional doses of REGEN-COV (casirivimab and imdevimab) antibody cocktail. Regeneron. September 14, 2021. Available here: <https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-new-us-government-agreement-purchase>

several companies have already expressed interest in producing this drug.<sup>8</sup> If those manufacturers enter the market, the global supply of Paxlovid could eventually be large. All of these factors make Paxlovid a good candidate for a potential test and treat strategy, if its safety is confirmed.

Several governments around the world have already entered into procurement agreements or are in ongoing negotiations to acquire Paxlovid. On October 20, 2021, the United Kingdom announced the acquisition of 250,000 courses of Paxlovid for an undisclosed amount of money.<sup>9</sup> On November 18, 2021, the United States announced the acquisition of 10 million courses of Paxlovid for 5.29 billion dollars.<sup>10</sup> Israel also entered into a procurement agreement with Pfizer.<sup>11</sup> Pfizer is reportedly in talks with several other countries, including the Dominican Republic.<sup>12</sup>

#### **4. Pfizer license to the MPP**

Although some governments are procuring Paxlovid directly from Pfizer, the company is also authorizing the commercialization of safe generic versions in many countries. On November 16, 2021, Pfizer and the MPP announced a voluntary license to facilitate the global manufacture and distribution of Paxlovid.<sup>13</sup> Pfizer licensed their patent applications and know-how to the MPP, which can now grant sublicenses to qualified generic manufacturers. Under the terms of that agreement, Paxlovid can be manufactured anywhere in the world and generic sublicensees will be exempted from paying royalties while COVID-19 remains classified as a public health emergency by the World Health Organization (WHO). As several generic producers have already expressed their interest in partnering with the MPP, their voluntary license agreement with Pfizer will help facilitate the global manufacture and distribution of Paxlovid.

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<sup>8</sup> Viswanath Pilla & Teena Thacker, Local firms gear up to seek licence for Pfizer's Covid drug. The Economic Times of India. November 18, 2021. Available here: <http://www.ecoti.in/oSHFjZ>

<sup>9</sup> Alistair Smout, Britain secures COVID-19 antivirals from Merck and Pfizer. Reuters. October 20, 2021. Available here:

<https://www.reuters.com/world/uk/britain-secures-covid-19-antivirals-merck-pfizer-2021-10-20/>

<sup>10</sup> "Biden Administration Secures 10 Million Courses of Pfizer's COVID-19 Oral Antiviral Medicine as Additional Tool to Reduce Hospitalizations and Save Lives." HHS. November 18, 2021. Available here: <https://www.hhs.gov/about/news/2021/11/18/biden-administration-secures-10-million-courses-pfizers-covid-19-oral-antiviral-medicine-as-additional-tool-reduce-hospitalizations-save-lives.html>

<sup>11</sup> Pfizer's Covid pill to arrive in Israel after FDA approval. i24NEWS. November 14, 2021. Available here: <https://www.i24news.tv/en/news/coronavirus/1636868164-pfizer-s-covid-pill-to-arrive-in-israel-after-fda-approval>

<sup>12</sup> Luis Silva. Gobierno busca comprar píldora que reduce los efectos del covid-19. El Caribe. November 17, 2021. Available here:

<https://www.elcaribe.com.do/destacado/gobierno-busca-comprar-pildora-que-reduce-los-efectos-del-covid-19/>

<sup>13</sup> "Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries." MPP. November 16, 2021. Available here: <https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries>

The Pfizer agreement with the MPP limits the territory where Paxlovid can be commercialized to 95 listed countries. Currently, the Dominican Republic is not among those 95 countries.

The Pfizer agreement with the MPP provides a path to selling Paxlovid outside of the 95-country territory. In particular, Section 2.4 of the Pfizer agreement with the MPP, reproduced below, acknowledges that sublicensed generic manufacturers are allowed to commercialize Paxlovid outside of the territory in countries that issue a non-voluntary license.

Section 2.4 of the Pfizer licensing agreement with the MPP for Paxlovid

No Waiver. For the avoidance of doubt, nothing in this Agreement or the Sublicenses shall be construed to prevent Sublicensees from engaging in activities inside or outside the Territory where such activities would not (a) infringe the Patents and/or any other intellectual property rights of Pfizer; (b) use or misappropriate Licensed Know-How; and/or (c) use or require the use of any of Pfizer's Confidential Information. Pfizer expressly reserves all its rights under the Patents, except as expressly set forth in this Agreement and Sublicenses, and under any additional patents and/or patent applications Controlled (either as of the Effective Date or at any time during the term of this Agreement) by Pfizer or its Affiliates. For the avoidance of doubt, it shall not be deemed a breach by a Sublicensee to supply Compound, Product or Licensed Product outside the Territory into a country where the Government of such country has, to the extent permitted by Applicable Law, granted or required to be granted to Sublicensee a compulsory license under the Patents relating to such Compound, Product or Licensed Product allowing for the importation of such Compound, Product or Licensed Product into such country, provided that (a) such Sublicensee's supply of Compound, Product or Licensed Product into such country is solely within the scope and geographic range of such compulsory license and only for the duration that such compulsory license is in effect and (b) such Sublicensee does not use or misappropriate Licensed Know-How and/or misappropriate, use or require the use of any of Pfizer's Confidential Information. Pfizer does not waive any applicable statutory and/or regulatory exclusivities owned or controlled by Pfizer, except as expressly set forth herein. Nothing in this Agreement or any Sublicense shall provide a right to Vend, donate, distribute, offer for sale or otherwise sell the Compound, Product or Licensed Product outside the Territory for further offer for sale, sale, donation or distribution of the Compound, Product or Licensed Product outside or for use outside the Territory.

Stated otherwise, the Dominican Republic can still benefit from the large supply that will be created by the Pfizer agreement with the MPP. To import from MPP sublicensed manufacturers, the Dominican Republic can issue non-voluntary licenses including under public interest grounds pursuant to articles 46 and 47 of the industrial property Law 20-00.

## 5. Legal grounds

This request is based on Articles 46, sections a) and b), and 47 of the Industrial Property Law 20-00. Articles 46 and 47 of Law 20-00 authorize the grant of public interest licenses to allow the exploitation of inventions affected by patents or pending applications.

Public interest licenses "*shall*" be granted by the National Industrial Property Office (ONAPI) at the request of any interested person or authority, according to article 46 of the Law 20-00.

## Article 46 of the Dominican Industrial Property Law 20-00

Article 46.- Public interest licenses. For reasons of public interest, and in particular for reasons of emergency or national security declared by the Executive Power, the General Agency for Industrial Property, at the request of any interested person or competent authority, or on its own initiative, shall at any time order the following: a) that an invention which is the object of a patent or patent application being processed be exploited by a government agency or by one or more public or private persons designated for the purpose. b) that an invention that is the object of a patent or of a patent application being processed be open for the granting of licenses in the public interest, in which case the General Agency for Industrial Property shall grant a license for exploitation to any person who applies for it and has the ability to carry out such exploitation in this country.

Unofficial translation: <https://wipolex.wipo.int/en/legislation/details/1190>

As indicated above, the licenses authorized in article 46 of Law 20-00: a) can be granted under public interest grounds; b) cover issued patents and pending applications; c) can enable the exploitation by or on behalf of a government agency, but also can be open to any person who can exploit the inventions; d) can be ordered at any time, without the need for prior negotiation; and e) are mandatory after a request from a government agency or any other person. Next, this request will address each one of the characteristics set forth by article 46.

### *a) COVID-19 is a public interest ground under article 46 of the Law 20-00*

Access to COVID-19 antivirals in the Dominican Republic is a matter of public interest concern. COVID-19 remains an international public health emergency, declared by the WHO on February 12, 2020. Since the beginning of the pandemic, COVID-19 has claimed over 4,200 lives in the Dominican Republic. COVID-19 has also brought economic and social crises in the country, in part due to the public health measures that were necessary to protect Dominicans against the virus. Coupled with vaccines, wide access to affordable and effective oral antiviral drugs may be a turning point in the pandemic. Oral antiviral drugs could be widely deployed alongside vaccines to implement a test and treat strategy, significantly reducing the impact of COVID-19. Since most mutations occur in the spike, oral antiviral drugs that block enzymes might still be effective against new variants like Omicron. This possible effectiveness against new COVID-19 variants further illustrates the urgency in accessing oral antivirals to protect the public interest.

Paxlovid is the leading COVID-19 oral antiviral candidate in development. Molnupiravir, an oral COVID-19 antiviral being developed by Merck and Ridgeback, initially showed promising results in an interim analysis. However, the final analysis indicates that molnupiravir only reduced the

risk of hospitalization and death among high-risk patients by 30%.<sup>14</sup> Moreover, molnupiravir has also raised safety concerns among experts, which is why, pending future information regarding the safety and efficacy of molnupiravir, this request has focused on PF-07321332.

*b) Paxlovid is subject to a pending patent application in the Dominican Republic*

Public interest licenses can be granted over issued patents and pending applications, pursuant to article 46 of Law 20-00. According to the Pfizer voluntary license agreement with the MPP, PF-07321332 is affected in the Dominican Republic by a pending patent application number P2021-0232, filed on 6 August 2021 and titled *Nitrile-Containing Antiviral Compounds*.

*c) Several prospective manufacturers could uptake a public interest license*

Article 46 of Law 20-00 authorizes the exploitation of an invention a) by or on behalf of the government and b) by any party that applies for an open license. Under article 46 section a), ONAPI can order that an invention subject to a patent or pending application be exploited by a government agency or a person designated for that purpose. A license granted under section a) would allow designated manufacturers to import and distribute PF-07321332 on behalf of a governmental agency. KEI requests that ONAPI authorize the Expensive Drugs Program to exploit the inventions described in P2021-0232 and any other patent or pending application relating to PF-07321332. In that case, the Expensive Drugs Program will be able to designate anyone to manufacture, import and distribute PF-07321332 on their behalf to be exploited by the public sector. Such designation would be compatible with the Pfizer license to the MPP.

Pursuant to article 46 section b), ONAPI can also order that a license granted under public interest grounds remain open to anyone that applies for it and has the ability to exploit the inventions in the Dominican Republic. In contrast with government use licenses, section b) allows use by anyone. Several manufacturers have already expressed interest in entering into sublicenses with the MPP to distribute PF-07321332, which indicate that there will be several suppliers of this drug. In addition to the government use license explained in the paragraph above, KEI requests that ONAPI grant an open license under section b) of article 46 of Law 20-00 to allow any prospective manufacturers of PF-07321332, including eventual MPP sublicensees, to declare their interest in distributing the antiviral in the Dominican Republic. Such a license would also be compatible with the agreement between Pfizer and the MPP.

*d) Public interest licenses under article 46 are exempt from prior negotiation*

Law 20-00 authorizes the grant of non-voluntary licenses under several different grounds. In some cases, the law requires a prior negotiation before the license request. In the case of public interest grounds, however, a license can be requested and ordered at any time. Article 43 section 2) of the Law 20-00 further clarifies that the need for prior negotiation is exempted in

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<sup>14</sup> Rebecca Robbins. Merck says its antiviral pill is less effective than initially reported. New York Times. November 26, 2021. Available here: <https://www.nytimes.com/2021/11/26/science/merck-molnupiravir-antiviral-covid-pill.html>

cases of national emergency and government use licenses. For reasons explained before, COVID-19 is a public health emergency that falls under the exemption for prior negotiation in article 43 section 2). That exemption also applies to government use licenses exploited by generic manufacturers on behalf of the Dominican Republic. As such, the instant request is timely and complies with the requirements set forth in article 43, 46, and 47 of the Law 20-00.

*e) Following a request under public interest grounds, ONAPI is required to grant the license*

Article 46 of Law 20-00 states that ONAPI “*shall*” grant a public interest license following a request from any interested party. The term “*shall*” indicates that ONAPI lacks discretion to decide whether to grant or reject the request for a license under public interest grounds. As long as the petitioner establishes that the public interest ground has been met, ONAPI is required to grant the license. If the rights holder opposes, the only role that ONAPI can play is to mediate or set a reasonable remuneration. Since access to oral antivirals to fight against COVID-19 is clearly a public interest ground, ONAPI is required to grant the requested public interest license.

## **6. Additional legal grounds**

KEI reserves the right to amend the instant request to add additional facts and legal grounds for a license. In particular, as information about the price offered by Pfizer to the Dominican Republic per each course of Paxlovid becomes available, we reserve the right to request a compulsory license for anti-competitive grounds under article 42 of Law 20-00.

## **7. Data used the register products**

Without prejudice to the request for a public interest license to the patents and pending applications, KEI requests a waiver of the requirements set forth in article 181, paragraph 1, of the industrial property Law 20-00 concerning the information and protection of data for marketing authorization. This provision currently states:

"Article 181. – Information and protection of data for marketing authorization.

1) Where a competent national authority requires or permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed information concerning the safety or efficacy of said product, the competent national authority shall not permit third persons, without the consent of the person that provided the information, to market a product on the basis of: (1) the information, or; (2) the approval granted to the person that submitted the information for a period of five years for pharmaceutical products and 10 years for agricultural chemical products from the date of approval in the Dominican Republic.

KEI notes that on August 5, 2004, the United States, the Dominican Republic and five other countries signed a side letter titled “Understand Regarding Certain Public Health Measures.” This understanding, which refers to the DR-CAFTA trade agreement, states:



The obligations of Chapter Fifteen do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.<sup>15</sup>

## 8. Terms of the license

KEI proposes that the public interest license include payments to Pfizer equal to 10 percent of the sales price of the generic product, and require companies to disclose the prices charged and the quantities of drugs sold, consistent with the World Health Organization resolution on transparency WHA78.2.<sup>16</sup>

## 9. Option to withdraw this request

KEI will withdraw the instant request if Pfizer agrees to add the Dominican Republic to the list of countries in the *territory* as set forth in Exhibit C of their license agreement with the MPP.

## 10. Remedies

Considering the facts and legal provisions cited above, KEI request the following:

1. Order a public interest license under article 46 of Law 20-00 to exploit the inventions described in the application P2021-0232, filed by Pfizer on 06 August 2021, and any other patent or application that may affect the manufacture, import, sell, or export of PF-07321332.
2. Authorize the Expensive Drugs Program to designate manufacturers that can exploit the inventions described in patent application P2021-0232, on their behalf for the public sector.
3. Notify Pfizer of this request for a license, and the proposed terms.
4. Schedule a hearing to mediate the terms of the license, if necessary.



Luis Gil Abinader

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<sup>15</sup> Understanding regarding certain public health measures, signed between the Dominican Republic, the United States, Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua on August 5, 2004. Available here:

[https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset\\_upload\\_file697\\_3975.pdf](https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file697_3975.pdf)

<sup>16</sup> WHA72.8. Mejora de la transparencia de los mercados de medicamentos, vacunas y otros productos sanitarios. [https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R8-sp.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-sp.pdf)