

Mr.
General Director of the
National Office of Industrial Property Your Office
City.-

Via: ONAPI General Council

Subject: PFIZER, INC./ Response to the request for a compulsory license under public interest grounds to exploit patent application P2021-0232, entitled "ANTIVIRAL COMPOUNDS CONTAINING NITRILE", deposited at ONAPI by Pfizer, Inc. on November 9, 2021; the compulsory license application was submitted by Luis Gil Abinader, on his own behalf and on behalf of Knowledge Ecology International and James Packard Love, on December 3, 2021.

Dear Mr. Director:

PFIZER, INC., a company organized under the laws of the State of Delaware, United States of America, with address at 235 East 42nd Street, New York, NY, United States of America; who has as constituted lawyers and special proxies the Licdos. María del Pilar Troncoso and Alexander Ríos Hernández, Dominicans, of legal age, married, lawyers of the Courts of the Dominican Republic, bearers of identity and electoral cards Nos. 001-0196765-1 and 001-1678298-8, respectively, domiciled and resident in this city of Santo Domingo de Guzmán, National District, Capital of the Dominican Republic, and with a professional studio open in this same city, located at Gustavo Mejía Ricart Ave., Abraham Lincoln corner, Corporate Building 2010, suite 505, Troncoso Leroux office, Piantini, National District, the latter place where said company makes a formal and express choice of domicile, hereby submit a RESPONSE to the request for a compulsory license for reasons of public interest to exploit the inventions described in patent application P2021-0232.

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I. BACKGROUND

1. On November 9, 2021, PFIZER filed the national phase of the international patent application PCT/IB2021/057281 dated August 6, 2021, marked by ONAPI under No. P2021-0232, entitled "ANTIVIRAL COMPOUNDS THAT CONTAIN NITRILE", hereinafter also referred to simply as the "Patent Application".

2. On December 3, 2021, a compulsory license application was filed with the ONAPI, at the request of LUIS GIL ABINADER, on his own behalf and on behalf of KNOWLEDGE ECOLOGY INTERNATIONAL and JAMES PACKARD LOVE or JAMES LOVE, that the Applicant and his presumed represented, denominate, among other expressions that they use, as "license of government use and an open license of public interest", to exploit the inventions contained in the patent application P2021-0232. Hereinafter, also referred to simply as the "Compulsory License Application."

3. The document that contains the request for the grant of the Compulsory License summarizes the object of the request as follows (number "I. Summary" of said document):

"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."

Under the aforementioned numeral "1. Summary" is added:

"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."

Finally, in that numeral "I. Summary", it states:

"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."

"In November 2021, Pfizer signed a voluntary license with the Medicines Patent Pool (MPP) to facilitate the global production and distribution of PF-07321332. Pfizer's license to the MPP allows for manufacturing anywhere in the world and will create a large supply of the antiviral drug PF-07321332 worldwide, but also has restrictive provisions regarding the sale and use of this drug. The agreement between Pfizer and the MPP authorizes the sale of drugs only in 95

countries, excluding to the Dominican Republic, or in countries where there are no patents granted or patent applications filed.” “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.”

4. Said Request for a Compulsory License was notified to PFIZER INC. on December 14, 2021, by act of bailiff No. 2012, of the ministerial Félix Manuel Medina Ulerio, ordinary bailiff of the First Chamber of the Civil and Commercial Chamber of the Court of First Instance of DN

5. Likewise, through the aforementioned notification, PFIZER, INC. was notified that it has 60 days, in accordance with article 43, numeral 4, of Law No. 20-00 on Industrial Property, to submit their comments and arguments in response to the Compulsory License Request in question. PFIZER, INC., requested an extension of the term, which was granted by ONAPI, having moved the date for submitting the response to March 16 of the year 2022.

6. Therefore, PFIZER. INC., below, submits its arguments in response to the Request for a Compulsory License to exploit the subject matter covered in its patent application P2021-0232

II. ARGUMENTS IN RESPONSE TO THE “APPLICATION FOR A COMPULSORY LICENSE”

II.A. ALLEGED REPRESENTATION

7. ONAPI will notice that in number "2. Applicants" of the Compulsory License Request, it reads: "(...) This request is filed by KNOWLEDGE ECOLOGY INTERNATIONAL (KEI), (...) James Love, director of KEI and Luis Gil Abinader, senior researcher at KEI and citizen of the Dominican Republic residing in the United States (sic)", who, as designated in the brief in question, are collectively called "KEI ". However, in what was notified to PFIZER, INC., there is no support, accreditation and/or accompaniment of any representation document granted in favor of the only individual signatory of the document, that is, Mr. LUIS GIL ABINADER. The foregoing is a flaw that certainly, having processed this request, causes a defect to meet the alleged interests represented by Mr. LUIS GIL ABINADER. Namely, the lack of verification of the qualifications of LUIS GIL ABINADER makes it impossible to accurately determine the applicants and their ability to manage before the ONAPI and, of course, disables the possibility of accessing the final application, since it does not fit in law, as well as, among other technical and economic considerations, the possibility that ONAPI, on the one hand, considers and, on the other hand, grants a compulsory license with respect to a PFIZER, INC., patent application, to alleged parties and of which there is no evidence in the procedure of their ability to request, access and exploit the compulsory license regarding the matters covered in the patent application of PFIZER, INC., already related.

8. Article 39 of Law No. 834 of 1978 provides, under the title “the nullity of acts due to substantive irregularity”, which constitute substantive irregularities that affect the validity of the act:

Lack of capacity to act in justice ;

The lack of power of a party or a person who appears in the process as a representative, either of a moral person, or of a person affected by an inability to exercise;

The lack of capacity or power of a person who ensures the representation of a party in justice.

9. It has been established repeatedly by the Supreme Court of Justice, that the lack of power of a person who ensures the representation of a party in justice, constitutes a substantive irregularity that is sanctioned with the nullity of the action (SCJ. Ira Sala, No. 31, December 11, 2020. BJ 1321); affects the validity of a procedural act and, by way of consequence, of the sentence delivered despite that irregularity (SCJ. Ira. Chamber. No. 46. June 22, 2016. BJ 1267).

10. It is also important to note that, under the terms of article 148, numeral 2, of Law No. 20-00, *“when the applicant or owner of an industrial property right has his domicile or headquarters outside the Dominican Republic, must be represented by a representative domiciled in the country, who will be notified of all resolutions, correspondence, writings and any other documentation that emanates from the National Office of Industrial Property.”* The clear meaning of this legal provision is that if the applicant is domiciled outside the Dominican Republic, then he must be represented by a representative domiciled in the country.

11. In the present case, in addition to the fact that the company KNOWLEDGE ECOLOGY INTERNATIONAL and Mr. JAMES PACKARD LOVE does not have a domicile in the country. Mr. LUIS GIL ABINADER has also stated that his address is *“in the United States, 110 Maryland Avenue NE, Suite 511, Washington, DC 20002,”* however, that he chooses *“to receive any physical correspondence related to this application on the street Desiderio Arias 68, Apartment D-02, VINS A II, Bella Vista, Santo Domingo”*, that is, it is not his real address, since his is in the United States, but a chosen address, but without an accredited representative, as corresponds according to article 148, numeral 2, of Law 20-00 already cited.

12. LUIS GIL ABINADER states that he is a *“senior researcher in KEI and a citizen of the Dominican Republic residing in the United States (sic)”*, however, he has not even mentioned a personal identification document (required by ONAPI for any procedure) that enables or legitimizes him to submit an application for a compulsory license, which casts serious doubt on his suitability, or that of his presumed representatives, to manage and seek to obtain a compulsory license, which in particular requires technical and economic capacity to exploit the patent or, as in this case, the patent application.

13. Since there is nothing in the documents notified to PFIZER, INC, in the case in question that proves the identification and legitimacy of LUIS GIL ABINADER and the presumed represented, the entity KNOWLEDGE ECOLOGY INTERNATIONAL (KEI) and the so-called “JAMES PACKARD LOVE”, it is up to ONAPI to rule on the determination of the exercise of representation of third parties, in accordance with the law and, consequently, regarding such lack of identification and representation, this Compulsory License Request should be rejected.

II. B. OF THE CONFIDENTIALITY CHARACTER OF THE APPLICATION FOR PATENT P2021-0232 AND THE DECEPTION PERPETRATED IN THE PRESENT PROCEDURE.

14. First of all, it is pertinent to highlight that Law No. 20-00 on Industrial Property, in its article 21, numeral 1), establishes the following:

“1) Upon expiration of the 18-month term counted from the filing date of the patent application or, when applicable, from the date of the applicable priority, the application will be open to the public for information purposes. (...) The applicant may require that the publication be made before the expiration of the indicated term.”

15. What has been transcribed above means that during the period of 18 months, from the date of filing with the ONAPI of the patent application, or from the date of the applicable priority, as the case may be, the patent application will be kept confidential to the public.

16. In this case, patent application P2021-0232, National Phase of PCT/IB2021/057281 dated August 6, 2021 (date that corresponds to the filing date in the Dominican Republic), was filed with the ONAPI on November 9, 2021, with priority claim to the applications filed in the United States of America marked with Nos. 63/073,982 of September 3, 2020, 63/143,435 of January 29, 2021, 63/170,158 of April 2, 2021 and 63/194,241 of May 28, 2021. On the other hand, at the date of the application for the compulsory license nor at the date of its notification to PFIZER, INC., the national patent application had not been published by ONAPI. Surprisingly, the publication was made on February 15, 2022, that is, before the 18-month period from the priority date for publication had elapsed and without PFIZER, INC, requesting such publication in advance.

17. In that sense, if we count 18 months from September 3, 2020, which is the filing date of the first applicable priority, we have that the confidentiality period of patent application P2021-0232 was given only until March 3, 2022, that is, 3 months after the date on which ONAPI received the Compulsory License Request and, however, decided to process it.

18. Given the foregoing, it is extremely surprising that despite the provisions of article 21 of Law No. 20-00 on Industrial Property, without justification of cause under the law, the Compulsory License Request was processed, when, in reality, the declaration of inadmissibility prevailed by fact and right, since the status of the patent application P2021-0232 was within its confidentiality period, for which reason, ex officio, by the ONAPI, it should be inadmissible due to confidentiality regarding the same and thereby avoid acting in violation of a public order provision contained in Law 20-00.

19. Indeed, in the event that, in the aforementioned case, ONAPI had its reasons for making an exception to the confidential nature enjoyed by patent application P2021-0232 (the simple fact that a compulsory license request has been made is not sufficient, since there is nothing in Section IV that enables a special regime that lifts the confidentiality of the patent application before the events that this section expressly provides), the ONAPI should have expressed the reasons that, in its opinion and duly supported in Law, they justified upsetting the procedure

established by law for the granting of a patent, otherwise it would be very easy to circumvent it, as has happened with the patent application of PFIZER, INC., which could set an infamous precedent for future patent applications.

11.C. OF THE ARGUMENTS OF THE APPLICANT TO JUSTIFY A COMPULSORY LICENSE AND OF THE ANSWER THAT EVIDES ITS IMPROPERNESS.

11.CI ARGUMENTS OF THE APPLICANT.

20. As indicated in the "Background" section of this response brief, number "1. Summary" of the Compulsory License Request brief reads: "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. (...) an antiviral drug (. . .) as a possible treatment against COVID-19 ... claimed in patent application P2021-0232 (underlining added). In the petition, at the closing of the compulsory license application, the signatory of such application indicates that it requests to ONAPI "Order a public interest license..."

21. The signatory of the application in question adds that it "covers P2021-0232 and any other pending or issued patents that may impose legal barriers to manufacture, import, sell, or export PF-07321332", without specifying any other current or pending patent number and without specifying the "compound" to which it refers. The applicant, based on an imprecise request, intends to transfer to ONAPI the latter to review patent applications or granted patents and determine which, if any, "impose legal barriers" with respect to the aforementioned number PF-07321332 (the applicant fails to identify the product to which it specifically refers) or that it simply makes an "open and extensive" declaration to any patent or patent application that could fall within the criterion expressed by the applicant. This indeterminate request constitutes an irresponsible and arbitrary request, and one that violates the rights that the Constitution and the Laws of the Dominican State provide, since it entails, from the outset, a violation of the right to a contradictory and the right of defense of a holder of an application for a patent of invention or of a granted patent; an "open" declaration is intended without the holders of granted applications or patents being subject to a pre-established procedure in Law 20-00 and practically being affected in their right without having been previously heard and without having previously exercised their due defense, under due process.

22. The applicant presents as arguments that support the Compulsory License Request that concerns us, the following:

- "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 application is initiated by

KNOWLEDGE ECOLOGY INTERNATIONAL (KEI), a nonprofit organization with offices in Washington, DC, and Geneva, Switzerland, focused on access to health technologies;
JAMES LOVE, director of KEI; and
LUIS GIL ABINADER, senior researcher at KEI..."

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

- The applicant adds: “the licenses established 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.”

The petitioner adds the following:

- “COVID-19 is a matter of public interest under article 46 of Law 20-00 ”

- “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.”

- “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.”

- *In cases of public interest, 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.

23. Petition of the applicant for the Compulsory License (paragraph "10. Conclusion", of the application brief):

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. (...)

II.C.ii. REQUIREMENTS TO REQUEST LICENSES OF PUBLIC INTEREST: PRECEDING STATEMENT OF THE EXECUTIVE POWER.

24. International regulations on compulsory licenses of patents or uses not authorized by the holder of a patent, contained in the Paris Convention for the Protection of Industrial Property -Paris Convention- and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) -TRIPS Agreement- of the World Trade Organization -WTO- (supplemented by the Doha Declaration -Declaration on the TRIPs agreement and public health, adopted on November 14, 2001 in the Doha Ministerial Declaration of the WTO-), which apply in the Dominican Republic, clearly establish conditions and requirements that must be fully satisfied so that, in the case at hand, the Dominican State, through ONAPI, can consider a compulsory license application.

25. Indeed, the meaning of these conditions and requirements is to avoid arbitrary, unnecessary, and unjustified invocations aimed at limiting or restricting rights that the legislation (both international treaties to which it is a party and local law) recognizes in favor of the holder of an invention patent or an invention patent application. In the Dominican case, article 52 of the Political Constitution establishes: "Right to intellectual property. The exclusive property right of scientific, literary, artistic works, inventions and innovations, denominations, trademarks, distinctive signs and other productions of the human intellect are recognized and protected, for the time, and in the manner and with the limitations established by law. (the underline is added). That is, the Dominican Constituent incorporated within the catalog of economic and social rights, the right to intellectual property, a catalog under which the right to health is also contemplated in the Dominican Constitution. Consequently, the limitation of the right to intellectual property that the constitutional text anticipates, may be limited in accordance with what is established in the law, but it must be fully justified and necessary, and as long as there are no other reasonable ways to achieve the objectives that are invoked for limitation.

26. As indicated by Luis Prieto Sanchis, quoted by Hugo Tortora Aravena, in the *work Limitations on Fundamental Rights*, the expression conditions of limitation of rights implies that the power of limitation is subject to the requirement of justification. Thus, the assumptions or requirements that must be observed by the authorities called by law to impose restrictions on a right, constitute a kind of “limits to the limiting power”, in the understanding that neither the legislator, nor any other person or authority that has the power to restrict rights, can act with absolute freedom, at its discretion, or with absolute powers.

27. PRIOR DECLARATION IMPERATIVE OF “PUBLIC INTEREST, AND IN PARTICULAR, FOR REASONS OF EMERGENCY OR NATIONAL SECURITY” BY THE EXECUTIVE POWER. Limitations or restrictions on fundamental rights can be classified according to different criteria, including whether they are ordinary or extraordinary limitations. The ordinary ones are those that always operate, and that affect the exercise of a right both under conditions of constitutional normality, and under situations of constitutional exception. They represent the general rule and apply at all times. Extraordinary limitations (also called “exceptional”) are those that occur only during circumstances of social or institutional emergency, and that have given rise to the declaration of states of constitutional exception. To this effect, the Constitutions in each State clearly determine the competent authority to declare exceptional states and the guarantees or rights that can be suspended or mandate such development in specific laws. In the case at hand, it is the case that the competent authority in the country has issued a declaration of a state of national emergency or of extreme urgency, or has decreed the invention that is the subject of the patent application or of a patent granted as of “interest public”.

28. As a general rule, the State (in the aforementioned case, including the ONAPI) must comply with the obligations to respect and guarantee the rights recognized both in the Constitution, the laws and in international treaties to which the Dominican Republic is a party. In the case of the so-called compulsory licenses or uses without the authorization of the holder of a patent application or of an invention patent invoked by “public interest, in particular of emergency or national security”, it must previously exist, through the corresponding legal channel, the declaration of what is an emergency or a matter of national security and what is considered to be of public interest; This only happens in situations of extraordinary and very serious crisis, as long as all the requirements established in the Constitution and applicable special laws are strictly fulfilled. Only then, the State has the power to suspend some of its obligations in terms of human rights, rights recognized by the Constitution. This is what is known as “states of exception”. Such exceptional situations must be tools to safeguard the validity of human rights and the rule of law and the measures must be strictly necessary and proportional to the situation. The doctrine and the criteria and judgments issued by international courts in the field of human rights, jealously highlights that the limitations to rights, precisely because of their limiting nature, are subject to restrictive interpretation and to observe the principles of necessity and proportionality. The principle of necessity, in the case of the compulsory license for public interest, emergency or urgency, implies that the measure is justified only when there is no other alternative and, the principle of proportionality implies that the measure is considered and limited to the requirement of the situation and not go beyond what is required to deal with the specific situation, which motivates the state of exception.

29. Due to the application of the Dominican Constitutional context, the so-called logical conditions prevail that must be observed with respect to the limitations to rights recognized by law. These conditions refer to the fact that a limitation or restriction must always be (a) justified and (b) proportional, in view of the “exceptional” nature of a limitation or restriction to rights recognized in the Constitution and the laws. It is required that they be “justified”, because they must have a specific legal cause or reason, clearly demonstrated and understood and that may, consequently, be subject to review. At the same time, it is required that they be “reasonable”, which means that the restrictions or limitations must be “proportional” to the purpose or objective for which they are applied. All this means that restrictions on rights (such as a compulsory license) cannot be invoked or applied in an arbitrary, unjustified, unnecessary, disproportionate or capricious manner.

30. The petitioner incorrectly argues: “COVID-19 is a public interest ground under article 46 of the Law 20-00.” That statement is incorrect because said article 46 clearly indicates that the reasons of “(...) public interest, and in particular for reasons of emergency or national security...” must be so declared by the Executive Power. That is, it is not up to ONAPI to make these declarations, nor to make an assessment of what should be considered as “public interest, and in particular, for reasons of emergency or national security”, but it is up to the competent authority to do so (the Executive Power) and, in that case, to ONAPI to determine, in response to a request for a compulsory license, whether or not a declaration in the sense indicated is valid or not and that such a state of exception is linked to the invention for which the compulsory license is requested; and, if “public interest” is invoked, that there is a specific declaration regarding that invention and the corresponding patent (if granted) or patent application.

31. Notwithstanding the foregoing, the applicant for the compulsory license has failed to meet the criteria determined by law to consider such a request. As explained below, there is not to date, nor was there at the date of filing the application for a compulsory license, in the Dominican Republic, a state of emergency in force (national emergency or national security), or any other form of declaration of “public interest” that enables a request for a compulsory license in the sense of the Request for a Compulsory License that is hereby answered.

32. The ONAPI does not have the power to restrict rights by acting arbitrarily, with absolute freedom or with absolute powers, as wrongly and illegally the applicant for the compulsory license intends to demand it.

33. The applicants have requested a license for government use and an open license of public interest invoking article 46 of Law No. 20-00, to manufacture, import, sell and export PF-07321332, number with which they refer to a antiviral drug as a possible treatment for COVID-19, without identifying its name or designation, and which they refer to as claimed in patent application P2021-0232, in the name of PFIZER, INC., Under said request, the public interest, in particular the reasons of emergency or national security declared by the Executive Power, must be in force and/or verifiable in the national and legal framework of the request, otherwise and as it happens today, the request must be declared null and void, as failing to comply with the provisions in article 46 of Law No. 20-00.

34. By the way, it should be noted that article 46 of Law No. 20-00, regarding the granting of compulsory licenses for reasons of public interest. establishes that:

"For reasons of public interest, and in particular, for reasons of emergency or national security declared by the Executive Power, the National Industrial Property Office, at the request of any interested person or competent authority, or ex officio..."

35. The transcribed article 46, despite starting by establishing "for reasons of public interest" which is an indeterminate notion whose implication is explained in later lines, no less true is that it continues with the phrase "and in particular", which is equivalent to saying -according to the Spanish Royal Academy- "in its own way", "private", "singular", "individual" or "exclusive".

36. The dimension "and in particular -in its own way, exclusive, singular, individual or exclusive-. for reasons of emergency or national security declared by the Executive Power", is extremely important because it establishes the exegesis to which the granting of a license of this type is subject. Namely, the right of exclusivity over an invention, as already indicated before in this writing, is directly protected by the Constitution in its article 52, under the title of Economic and Social Rights, for which it translates into a fundamental right; consequently, although the same Constitution reserves the configuration of said right in the ordinary legislator, it is no less true that, like all fundamental rights, there is a hard or essential nucleus, defined as the minimum content that the legislator must respect of the fundamental right. (Constitutional Court of Colombia, C-756-08).

37. For its part, the Constitution in its article 74, numeral 2) establishes that "only by law, in the cases permitted by this Constitution, may the exercise of fundamental rights and guarantees be regulated, respecting their essential content and the principle of reasonableness." This constitutional text has been interpreted by the Supreme Court of Justice in the following way: "Fundamental rights have a peripheral that may be affected by the action of the legislature, as would be the case, for example, of closing certain resources for reasons of reasonableness" (SCJ, 1st Chamber, No. 58, May 8, 2013, BJ 1230).

38. For further context, the Constitutional Court established in a judgment of principle (TC-0333-21), the following:

"These limits, which by constitutional mandate can be introduced by the legislator, are subject to a constitutionally admissible justification and they must not be introduced arbitrarily, since each fundamental right has an essential core that cannot be affected by the legislator in any way, since there are minimum parameters that give intrinsic confirmation to the fundamental right and make it recognizable. In other words, the legislator must refrain from exceeding the application of the requirements required to appeal, since, in such a case, this would result in chaos in our positive system of laws. Consequently, in the task of limiting or conditioning the right fundamental to the appeal of judicial decisions, the legislator must respect the criterion that the doctrine recognizes as "the limit of limits" when particular fundamental right in question.

Any limitation that a law makes with respect to a fundamental right must be proportional to the purpose sought, so that the rules that seek to regulate its exercise must be reasonable and allow the right in particular not to lose its hard core and not result in an unrecognizable .

Such restrictions and limitations must meet certain essential requirements, that is, that they be established by law, that they are intended to protect national security, public order, or public rights and freedoms, and that they are consistent with the constitutional principle of reasonableness.

Analyzed within the constitutional exegesis, the power of the legislator to introduce moderations or limits to the exercise of a fundamental right entails a formal aspect: that is, that such regulation emanates from the competent body, in this case, the Legislative Power, and that it adjusts to the formalities and procedures contemplated in the Constitution. On the other hand, it also bears a material aspect: this means that the objectives of the norm to be limited and the means used in said norm are based on rationality and with respect to the irreducible core that identifies each right. (...)

39. In the present case, the essential right or hard nucleus enjoyed by the owner or applicant of a patent, that is, PFIZER, INC, is the exclusivity in the use of the invention, for which it is an obligation of the legislator to establish balanced parameters of exceptions to intellectual property, to avoid, for example, the granting of capricious compulsory licenses. “Since the granting of a compulsory license represents a considerable intrusion on the legal exclusive rights of the patent holder protected by the Constitution, the balance of interests must be subject to the principle of reasonableness (German Federal Court of Justice (BGH), judgment dated December 5, 1995. ref: X ZR 26/92. GRUR 1996. 190 - Polyferon).

40. Along these lines, article 46 of Law No. 20-00, by establishing that “for reasons of public interest, and in particular, for reasons of emergency or national security declared by the Executive Power, the National Office of Industrial Property, at the request of any interested person or competent authority, or ex officio...”, deserves to be interpreted under the premise, and in balance with the fundamental right of an invention, that only the issuance by the ONAPI will be appropriate. of compulsory licenses for reasons of public interest, when there are reasons of emergency -of any kind- or of national security, in any case, previously declared as such by the Executive Power.

41. Indeed, in support of the foregoing, below are norms in the comparative law, where we find the same line of thought:

Decision 486 of the Andean Community, regarding the Common Regime on Industrial Property. Article 65: “*Prior declaration by a member country of the existence of reasons of public interest, emergency, or national security and only while these reasons remain, at any time the patent may be submitted to a compulsory license*”;

Bolivia: Administrative Resolution No. 017/2015 of June 16, 2015. Regulation of Internal Industrial Property Procedure of the National Intellectual Property Service (SENAPI). Article 168: *“To grant a compulsory license for reasons of public interest, emergency or national security, the declaration by the Plurinational State of Bolivia must be accredited”*;

Colombia: Decree No. 1074 of May 26, 2015. of the Ministry of Commerce, Industry and Tourism, which establishes, among other things, the Procedure for the Declaration of Existence of Reasons of Public Interest:

Article 2.2.2.24.3. “Natural or legal persons interested in declaring the existence of reasons of public interest for the purpose of granting a compulsory license on patented products or for the full use of the patented procedure, may request said declaration before the competent correspondent authority (Ministry or Administrative Department in charge of formulating and adopting the policies and projects of the sector they direct)”;

Article 2.2.2.24.5. “The resolution issued by the corresponding Ministry or Administrative Department in which it is declared that there are reasons of public interest that warrant the issuance of a compulsory license must identify the situation that affects the general interest; establish the circumstances that led to the declaration and the reasons why the patent should be licensed; (...)

Ecuador: Organic Code of the Social Economy of Knowledge. Creativity and Innovation, of December 9, 2016, article 314:

“Previous declaration by executive decree or ministerial resolution of the existence of reasons of public interest, emergency or national security and, only while these reasons remain, the State may, at any time and without the need for prior negotiation with the patent holder, provide for the non-commercial public use of a patented invention by a government entity or a contractor, or subject the patent to a compulsory license. The competent national authority in matters of intellectual rights will grant the licenses that are requested, without prejudice to the rights of the patent owner to be remunerated... ”;

Peru Legislative Decree No. 1075 of Iro. February 2009 (modified by Legislative Decree No. 1397 of September 7, 2018), article 40:

“Prior declaration, by supreme decree, of the existence of reasons of public interest, emergency or national security; that is, national emergency and other circumstances of extreme urgency or in cases of non-commercial public use; and only while these reasons remain (...).”

42. In the Dominican Republic, as is known, the procedure outlined by the Constitution and Law no. 21-18 on Regulation of States of Exception, to declare a State of Emergency, consists of the President requesting authorization from the National Congress to declare the country in a State of Emergency and then, once the National Congress communicates the authorization, the President is empowered to declare the country in a State of Emergency. In other words, ONAPI lacks absolute competence, if not by virtue of Law No. 20-00 on Industrial Property, then by virtue of the Constitution itself and Law No. 21-18, to declare that there is a national emergency in order to grant a compulsory license.

43. In this case, the first time that the Executive Branch declared the country in a State of Emergency due to the COVID-19 pandemic, it was through Decree No. 134-2020 dated March 19, 2020, its effects being extended by a multiplicity of decrees until October 11, 2021, the date on which the Executive Branch ordered its official lifting by decree No. 622-2021. **Consequently, on December 3, 2021, at the time of the submission of the Compulsory License Request by the petitioners, in the Dominican Republic there was not, nor is there to date, a State of Emergency declared and in force due to the COVID-19 pandemic. In turn, there has never been a declaration of emergency by the Executive Power in relation to the need for a certain drug to be administered to the population, a *sine qua non* requirement (the declaration of a specific emergency) for the granting of a compulsory license for reasons of public interest.**

44. After the lifting of the State of Emergency, the Ministry of Public Health issued Resolution No. 48 of October 8, 2021, by which it declared the national territory in an epidemic situation. In that resolution, the Ministry of Health declares that "...the inoculation of the population against Covid-19 is indicated by the international authorities and the scientific community as one of the main tools to exercise control over the pandemic, for which reason continuing to encourage people to get vaccinated is of great interest to the Government (...)" and it is stated "that through the National Vaccination Plan it has been possible to inoculate almost 60% of the target population with at least two doses of the Covid-19 vaccine." In response to advances in inoculation and the level of control over the spread of Covid-19, the Ministry, through the aforementioned Regulation, resolved to relax restrictive measures.

45. Finally, through an address on February 16, 2022, the executive branch ordered the elimination of all the restrictions imposed due to COVID-19, which was followed by the Ministry of Public Health, through a publication in the press dated February 17, 2022, making the caveat that the "president has not decreed an end to the pandemic, he has only wanted to flexibilize the measures" but reiterated "that the vaccination program will remain the same and that for this they have nine million vaccines (today 10 million in inventory), two million tests and the medicines necessary to serve the entire population."

46. It is worth mentioning some considerations issued at the international level on what can be considered "of public interest" and its application in the context of Article 46 of Law 20-00. Namely, the "Public Interest" is an indeterminate legal concept, and it is applicable to it "...the theory of the indeterminate concept and its function in the legal system clearly establishes that it is not about giving rise to arbitrariness or justifying abusive situations, since contrary to what one might think, it serves to delimit the administrative discretion that it supports, and allows control of its exercise (...)."

Court of Justice of the Andean Community, process 144-IP-2019 of March 16, 2021: "3.5...reasons of public interest may be...the need for the population to have access to certain products (such as medicines, food), (...) if it is a health emergency caused by a pandemic, the authority has to prove the existence of the pandemic and the harmful effects on the population, the characteristics of the disease, the percentage of the population that is affected -or may be

affected-, the possibility that the disease be treated satisfactorily with other available drugs, etc. Simultaneously, it must be proven that the purpose pursued could not be viable if compulsory licenses were not adopted.”;

Court German Federal Justice, judgment of December 5, 1995, ref.: X ZR 26/92, GRUR 1996, 190 - Polyferon: “A compulsory license cannot be granted on a pharmaceutical product, if the public interest can be satisfied with other more or less equivalent alternative products”.

47. In the Compulsory License Request, the petitioners subjectively motivate the alleged “public interest” for the following assumptions:

a. PFIZER, INC. signed a voluntary license with the Medicines Patent Pool, to facilitate the production and distribution of PF-07321332 in 95 countries, but did not include the Dominican Republic;

b. Based on a study by PFIZER, INC, itself, without anything further, the applicants argue that the drug claimed in patent application P2021-0232 reduces the risk of hospitalization or death related to COVID-19 by 89%;

c. According to the applicants themselves, there are already several treatments in the country, but they are injectable and, therefore, must be administered in controlled environments, such as hospitals;

d. According to the applicants themselves, these other treatments are very expensive, but the PFIZER, INC. drug is emerging as a candidate that is easier to manufacture, easier to administer, and, therefore, less expensive;

e. Finally, they acknowledge that the Executive Branch is already in talks with PFIZER, INC., to acquire several batches of the drug.

48. As can be seen, the applicants (i) do not present the decision of the Executive Branch that has declared the need for the drug claimed in patent application P2021-0232 to be of “public interest”; and (ii) are in no way conclusive about the reasons that make patent application P2021-0232 of public interest, or of necessary exploitation that requires a compulsory license, as we can see below:

a. The voluntary license granted by PFIZER, INC, regarding the drug claimed in patent application P2021-0232, cannot be the reason for public interest.

b. The applicants have not deposited a single proof that justifies that the drug claimed in patent application P2021-0232, is the treatment of excellence for COVID-19, or that without it it would be almost unfeasible to combat it in the Dominican Republic; to be precise, the applicants do not even affirm in their application the suitability of the product or confirm the strategy of its suitability for treatment, but only expose characteristics subject to verification with respect to it,

as can be seen when they state: “all of these factors make Paloxid a good candidate for a possible test-and-treat strategy, if its safety is confirmed.”

c. Alleging that the other existing treatments are expensive, without providing data or elaborating what leads to that qualification or demonstrating the impossibility of the State acquiring them for that reason, is not a basis to order a compulsory license with respect to another treatment.

49. In the case of the Dominican Republic, as elaborated below, access to medicines to confront the COVID-19 pandemic has been satisfactory, the State has implemented and adopted timely and adequate measures to serve the population. For its part, PFIZER. INC., through its corresponding entities, has maintained a constant and fluid collaboration with the Dominican Government to support public health objectives in response to the Covid-19 pandemic. The Compulsory License Request, as demonstrated in this brief, is unfounded, does not comply with legal requirements, is unnecessary, and is capricious.

11.C.iii. LACK OF LEGITIMACY TO APPEAL COMPETENCES OF THE DOMINICAN STATE AND LACK OF SUITABILITY AND COMPETENCE OF THE EXPENSIVE DRUGS PROGRAM TO EXPLOIT, VIA A COMPULSORY LICENSE, THE "PATENT REQUEST"

50. LACK OF LEGITIMACY TO APPEAL COMPETENCIES OF THE DOMINICAN STATE: THE PETITIONERS DO NOT HAVE THE AUTHORITY OR POWER TO REQUEST A COMPULSORY LICENSE ON BEHALF OF, IN FAVOR OF, OR AT THE CHARGE OF THE DOMINICAN STATE. In line with what has already been argued regarding the alleged representation and powers of LUIS GIL ABINADER, in particular and in alleged representation of KNOWLEDGE ECOLOGY INTERNATIONAL and JAMES PACKARD LOVE, it is also relevant to highlight the lack of legitimacy of these to promote a license in favor of an administrative dependency of the Executive Body of the Dominican State; LUIS GIL ABINADER and his alleged representatives are prevented from requesting a compulsory license charged to the “Expensive Drugs Program” of the Dominican Republic, as they do in the brief they presented to ONAPI.

51. In the first place, in our law the following maxim prevails: "no one can litigate by proxy", which means, applied to the species, that no one can be an intermediary person to act in justice because the conditions of quality and interest are personal and that reality makes each act necessarily indicate at the request of who is done, in other words, the interested party or in favor of whom the action is sought, must appear in the brief; (SCJ. 3ra. Sala. No. 67, December 20, 2019, BJ 1309).

52. Second, specifically when state representation is linked, is Law No. 1486 of March 28, 1938 on Representation of the State in Legal Acts, in its article 2, which establishes that “to represent the State or to in any way act for him or at his expense in legal acts, when it does not appear in the law, it must be in writing signed or authentically granted by the person who confers it, without which it will be presumed, until proven otherwise, as non-existent.” In plain words, this text establishes that the representation of the State falls, first, on the official to whom the Constitution or the law attributes representation, and when this attribution does not exist, the

power of representation of the State or in any other way to act by the State or at its expense, the authorization must be in writing, this being the only legal means of adjudication. Therefore, it is not possible for the petitioners, without having the due representation granted in accordance with the law, to abrogate state jurisdiction and manage a compulsory license that they intend to be granted to an administrative agency of the State for it to dispose of. The presentation of the State cannot be usurped, as in practice LUIS GIL ABINADER and his alleged representatives intend.

53. Finally, thirdly, Law No. 20 00, in its article 46, letters a) and b), clearly provides that the ONAPI will grant a compulsory license for reasons of public interest at the request of a competent authority, or of any interested person, or even ex officio, depending on the circumstances of the case, to be exploited by one or more state entities or by one or more individuals, respectively, ultimately by whoever requests it; that is, there is no possibility of requesting a compulsory license in favor of another who is not involved in the request; in accordance with what was mentioned above, the interest is personal, therefore it is not possible to act through an intermediary, much less charged to the State.

54. LACK OF SUITABILITY OF THE EXPENSIVE DRUGS PROGRAM, DIVISION OF THE MINISTRY OF PUBLIC HEALTH, AS A BENEFICIARY OF A COMPULSORY LICENSE FOR THE MANUFACTURE OF MEDICATION. As is public knowledge, it is stated that the Expensive Drugs Program was conceived through resolution No. 00003 of March 5, 2015 of the Ministry of Public Health, which in one of its Considerations establishes: “That the high costs of medications for catastrophic illnesses, promoted the implementation of a program aimed at supplying these medications, free of charge...” Said program was first called “Protected Program,” but being structurally inorganic, it was renamed “Expensive Drugs and Medical Aid Program”, having its structure with a director, a technical coordinator, a Qualification Unit, a Monitoring Unit and a Multidisciplinary Evaluation Committee. The role of the aforementioned program is to subsidize the acquisition of medicines in favor of consumers, for the treatment of qualified illnesses of high financial impact to the citizen, not so that “manufacturer designates”, or what amounts to the same, to grant licenses or sub-licenses to individuals or legal entities for the exploitation of patents.

55. For what has been verified, the aforementioned program, in the case of a division of the Ministry of Public Health, is only authorized for public tenders in accordance with Law No. 340-06 on Purchases and Contracting of goods, Services, Works and Concessions, a procedure in which bidders participate and it chooses the offer that is most adjusted to the budget, or it can acquire them through international cooperation organizations, etc., and then supplies the medicines purchased to the citizen, even though its function and legal powers do not contemplate the legal possibility of exploiting inventions for the effect of compulsory licenses, much less granting exploitation licenses (or sub-licenses), especially since the only one with competence to grant compulsory licenses is the ONAPI and said function cannot be delegated, whether it is a compulsory license in favor of one or more more persons of public or private law, or to declare a patent or patent application open to the grant of compulsory licenses.

11.C.iv. OF THE AMBIGUITY AND INACCURACY ABOUT WHICH COMPULSORY LICENSE IS REQUESTED FROM ONAPI.

56. ONAPI will notice that there is no clarity regarding the request of the applicants, who based their request for a compulsory license on article 46, letters a) and b), of Law No. 20-00. In this regard and in its relevant parts of the request, they state that “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.”

57. On the other hand, the applicants then indicate: “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.”

58. Finally, in their conclusions, the applicants specifically request:

1. That a public interest license be ordered to exploit the inventions described in patent application P2021-0232; and
2. That the Expensive Drugs Programs be authorized to designate manufacturers so that they can exploit the inventions described in patent application P2021-232.

59. In addition to the arguments already stated about the lack of the condition of a declaration of a state of exception, the impossibility of accessing what was requested will have already been noted, since the claim of the applicants is unintelligible due to the lack of consistency in their writing, foundation and arguments. The confusion and incomprehensibility of the request clearly exposes ONAPI to the possibility of incurring in the violation of the principle of correspondence, consistency and the principle of legality, therefore, incurring in a legal transgression to the detriment of legal certainty and, in this particular case, of PFIZER INC. Namely, article 46 of Law No. 20-00, it has only two (02) types of compulsory licenses for reasons of public interest; we cite:

“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; or

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.”

60. As verified in the entire transcript of article 46, ONAPI for reasons of public interest declared in advance by the Executive Branch and at the request of a competent authority or other interested person, or ex officio, depending on the circumstances of the case:

a. May order a compulsory license on an invention patent or a patent application, in favor of one or more persons of public or private law:

OR (note the disjunctive wording)

b. That an invention patent or a patent application be open to the granting of compulsory licenses in favor of anyone who requests it and demonstrates the capacity to exploit it.

61. However, in this case, the applicants do not request the compulsory license for themselves, but under the Expensive Drugs Program, so that, in turn, it is this who designates anyone who shows interest in exploiting the patent application P2021-0232, that is, it is a kind of hybrid that does not fit into the legal regulations, since:

- On the one hand, the granting of a compulsory license is requested specifically in favor of the Expensive Drugs Program (granting of a compulsory license under the terms of letter A)

And,

After said division of the Ministry of Public Health is the one that makes the respective designations (declaration of the Patent Application open to the granting of compulsory licenses, under the terms of letter B).

62. It is not possible, it is not legally feasible, that for particular convenience: established rules for the origin of compulsory licenses or the established procedure for granting them to be upset, in particular, when it is requested that a program “be enabled to grant compulsory licenses”, being ONAPI the only entity with competence to do so.

11.Cv LACK OF EVIDENCE OF THE APPLICANTS' CAPACITY TO EXPLOIT THE "PATENT APPLICATION".

63. Throughout their application brief, the applicants have omitted, perhaps due to their inconsistency in having applied for the license charged to the “Expensive Drug Program”, the legal requirement established by the regulations to demonstrate the technical and economic capacity to exploit the patent or the patent application, which is mandatory for ONAPI, whose reference in the case in question has not been met, since nothing can attest to the capabilities of the applicant LUIS GIL ABJNADER and the alleged represented, the entity KNOWLEDGE ECOLOGY INTERNATIONAL (KEI) and JAMES PACKARD LOVE. In the case of the “Expensive Drugs Program”, this has already been demonstrated in the previous paragraphs, that said state program does not exist to grant licenses for the exploitation of medicines, since its role does not coincide with the matter of the request for compulsory licenses, in addition, without forgetting that the Compulsory licenses are granted to whoever requests them, and it is not possible to request a compulsory license in favor of another who is not involved in the request (the interest is personal). Since the petitioners do not provide this legal requirement, having not evidenced in any way any ability to exploit the invention for which they seek a compulsory license, it must be stated that neither ONAPI nor any other authority can qualify it as suitable for these purposes.

11.D. LICENSE WITH THE MEDICAL PATENT POOL ENTITY (MPP) AND ACCESS TO VACCINES TO COVID-19 AND OTHER MEDICINES TO ATTEND PUBLIC HEALTH OBJECTIVES REGARDING COVID-19 IN THE DOMINICAN REPUBLIC.

64. On November 16, 2021, PFIZER INC announced that it had signed a license agreement with the MPP for a candidate product for COVID-19 oral antiviral treatment; the goal of that license is to expand access to treatment in low- and middle-income countries. This agreement is based on PFIZER INC's comprehensive strategy to work towards equitable access to COVID-19 vaccines and treatments for all people, particularly those living in the poorest parts of the world.

65. PFIZER INC. is committed to working to achieve equitable access to treatment with the compound covered by the Dominican patent application P2021-0232 (compound internally referred to as PF-07321332) in combination with ritonavir for all people, with the aim of offering safe and effective antiviral therapies as soon as possible and at an affordable price.

66. The so-called Medicines Patent Pool (MPP) established in 2010 by UNITAID develops programs for access to medicines in low- and middle-income countries (LMIC) through voluntary licensing with patent holders. In 2021, the MPP expanded its scope of management for medicines (vaccines and other medicines) related to treatments for COVID-19.

67. As indicated above, the MPP uses specific criteria to determine the countries to which it targets the object of its management, which include, in particular, low-income and middle-income countries; in the case of the license entered into with PFIZER for a product related to the treatment of covid-19, the parties defined a geographical list, describing the following: “The Territory of the proposed Agreement consists of 95 countries.” The list includes

all low-income countries, lower-middle-income countries, upper-middle-income countries in sub-Saharan Africa, and upper-middle-income countries that have graduated to such status in the last five years. The classification of low and middle income countries is configured according to the available information organized and projected by the World Bank; This institution classifies the world's economies into four income groups: low-, lower-middle, upper-middle, and high-income countries. These categories are updated every year, and are based on gross national income (GNI) per capita calculated in United States dollars (USD). In this case, it is appropriate to point out that the Dominican Republic, due to its GNI, has been classified since 2008 as a country with upper middle income. As indicated earlier in this paragraph, countries whose indicators classify them as upper-middle income, for more than 5 years prior to the execution of the agreement, are not covered in the Territory. The Dominican Republic has a higher economic profile than the countries covered by the Agreement and this is not an arbitrary exclusion.

68. Notwithstanding the foregoing, PFIZER INC has been and is at the disposal of the Government of the Dominican Republic to meet the interests of the State in terms of supplying medicines related to Covid-19. PFIZER INC and the Dominican Government are currently negotiating access to the drug whose active ingredient is covered in the patent application filed with ONAPI.

69. The relationship of PFIZER INC., by itself or through related entities, with the government of the Dominican Republic has been fluid, transparent and agile with respect to the common objectives of caring for the health of people on the occasion of the Covid-19 pandemic. Both parties have been totally open to effective and timely cooperation; Negotiation processes have been carried out in a fluid and concatenated manner with the competent authorities in order to supply the vaccines developed by the company. Currently, the Dominican Republic has its supply assured for the year 2022.

70. During the last quarter of 2020, PFIZER INC and the Government of the Dominican Republic reached an agreement to supply vaccines (Pfizer-Biontech) during the first quarter of 2021 (known and approved by the Senate of the Republic through Decree 9-21 of January 29, 2021). In this regard, the Vice President of the Dominican Republic, Raquel Pena, stated that this event constitutes "an approach to the goal of guaranteeing that the Dominican people have safe access to the vaccine, as President Abinader promised in his speech of taking possession".

71. The efforts between the Dominican Government and PFIZER INC, aimed at guaranteeing access to vaccines developed by the company for Covid-19 materialized in the guarantee of supply and consequent attention to the Dominican population, in addition to other vaccines already available in the country. The agreement with PFIZER was qualified by health system specialists as positive. Qualifiers such as "crucial", "excellent", "timely" and "positive" were expressed by the Dominican Medical Association (CMD), the National Union of Nursing Workers (Sinatrae) and the Vice Ministry of Collective Health in relation to the signing of the agreement made between the Dominican Government and the pharmaceutical company.

72. PFIZER INC. maintains its commitment to continue working with the Government of the Dominican Republic. The experience developed in negotiating the supply of vaccines has shown

that through open, concrete and objective communication, it is possible to align efforts to serve the main objective of serving the Dominican population and its health needs. As stated by Mr. Bradley Silcox, General Manager of PFIZER for Central America and the Caribbean, the PFIZER team *“is deeply honored to work with the government of the Dominican Republic and to direct our scientific and productive resources towards our common goal; provide the citizens of the Dominican Republic with a vaccine against COVID-19, as soon as possible.”*

73. Regarding the compound of interest cited for the Compulsory License in the aforementioned case, ONAPI should note that the reality is that PFIZER INC has never denied or excluded the access of said medicine to the country, including, it is relevant to share that the government of the Dominican Republic, since before the request for the Compulsory License was raised, had already established contact with PFIZER INC. as a main interested party of the countries of the region for the acquisition of this medicine and high-level meetings have been held in order to specify the terms and conditions of the case. In fact, the Dominican Republic is one of the first countries in Latin America that anticipated interest in the drug and could ensure its supply.

ILE. DATA ON THE EVOLUTION OF COVID-19 IN THE DOMINICAN REPUBLIC AND VACCINE SUPPLY.

74. After the lifting of the State of Emergency in the Dominican Republic, the Ministry of Public Health issued resolution No. 48, dated October 8, 2021. In that resolution, the Ministry of Health states *“... That through the National Vaccination Plan, almost 60% of the target population has been inoculated in the national territory with at least two doses of the vaccine against Covid-19.”* According to data published by John Hopkins University, which developed a system for monitoring and presenting data on the impact of the Covid-19 pandemic in terms of infections and deaths, in the Dominican Republic, about 20% of the population had received a 3rd booster dose. The Government data correspond to data from approximately 4 months ago, which makes it reasonable to presume that both the percentage of vaccination of two doses and that of the third have increased. It is desirable to achieve higher levels of vaccination and it is evidenced by publicly available information that the Government of the Dominican Republic has continued to develop direct and effective efforts to guarantee an adequate supply of vaccines and continue with its vaccination management. The Dominican State rightly invests in preventing the spread of the Covid-19 virus and mitigating the effects that the virus develops by infecting a person. Information communicated by the Ministry of Public Health (or officials of said Ministry) regarding the supply of vaccines has been known in the media. On February 17, 2022, it was published that the country has 9 million vaccines, two million tests and the necessary medicines to serve the population. Through the publication of data, statistics and reports, it follows that the Dominican Government has implemented timely measures to have the supply of medicines to address the health problem that Covid-19 represents in the country and in the world, and that to date, the country is not in crisis, nor limitations to continue serving the population, in particular, and very importantly, in the area of preventive health, through vaccination. Consequently, it has issued statements informing about the capacities: On February 2, 2022, it was published that the Health authorities reported that for the third consecutive week the positive cases of COVID-19 continue to decrease, placing the Dominican Republic among the countries

that register a significant reduction in the number of infections and in data on positivity (<https://msp.gob.do/web/?p=14590>). The COVID-19 monitoring dashboard, published daily by the Government of the Dominican Republic, reports encouraging data regarding the level of infections and active cases in the country. The Dominican Republic is not in crisis, nor is there any data published by the State that suggests that there is a risk of a crisis due to Covid-19, and that is positive news for the country. The President of the Republic, Mr. Luis Abinader, recently stated that the Government "... will maintain and will continue to voluntarily invite the population to be vaccinated to complete the vaccination program and continue to guarantee full access to the vaccine for all and in any circumstance. (...) The country can also be sure that, unlike in the past, our health system today is prepared to deal with any eventuality". He emphasized that as a country "We were at the forefront, we are committed to contracting the greatest variety of vaccines, we applied novel treatments and we were among the first in the world to propose a third dose..."

75. The government of the Dominican Republic, through the Essential Medicines Program and Logistics Support Center (Promese/Cal), reported that it has been in permanent coordination with the Ministry of Public Health and the National Health Service (SNS), in order to meet the demand for antigen tests, PCR and medicines required to treat patients affected by COVID-19 and the new omicron variant. In this sense, the inventories of medicines and medical supplies continue to be strengthened so that any increase in hospital tasks by the National Health Service can be faced.

76. The information that the Dominican Government has publicly provided allows us to reasonably presume that there are no shortages of pharmaceutical products to continue providing adequate attention to the Covid-19 pandemic and that the Dominican health system is not facing a crisis in the future. treatment and care of the pandemic. The effort in preventive health is important, to mitigate the risks of a greater effect resulting from infections.

III. OTHER REQUIREMENTS OF THE PETITIONERS, ACCESSORIES TO THE "APPLICATION FOR A COMPULSORY LICENSE"

77. Given that this Application for a Compulsory License is inadmissible, unfounded and lacking any legal basis, it makes it unnecessary to consider other secondary requests that result from the main request, and therefore we will not address or reply to them.

IV. CONCLUSIONS

78. The request for a compulsory license that concerns us is irrelevant for the following reasons, in summary:

a. Mr. LUIS GIL ABINADER: (i) has not shown that he has the authority or power to represent KNOWLEDGE ECOLOGY INTERNATIONAL and JAMES PACKARD LOVE; (ii) residing in the United States of America, has not appointed a representative domiciled in the country, as required by article 148, numeral 2, of Law No. 20-00, for those domiciled outside the country;

b. ONAPI should never have processed it, since the patent application whose compulsory license is being pursued, marked under No. P2021-0232, was in the confidential stage at the time the compulsory license application was filed; the confidentiality stage expired on March 3, 2022, while the compulsory license application was filed on December 3, 2021;

c. The compulsory license to exploit patent application P2021-0232 has been requested for reasons of public interest, however, there is currently no State of Emergency previously decreed by the Executive Power and, consequently, much less a public interest, to issue a compulsory license; Furthermore, the Executive Power ordered the elimination of all the sanitary measures imposed due to COVID-19;

d. It is important to note that:

d.i) The granting of a voluntary license by PFIZER, INC, regarding the drug claimed in the patent application P2021-0232, cannot be the reason for public interest;

d.ii) The applicants themselves acknowledge that the Executive Branch is in talks with PFIZER, INC., to acquire several batches of the drug;

d.iii) According to the applicants themselves, there are several treatments available in the country to treat COVID-19;

d.iv) The high cost of other existing treatments for COVID-19 is not a reason to order a compulsory license for another treatment;

d.v) The aforementioned drug does not replace vaccines, a resource that continues to be the main tool and priority of the Dominican State to combat COVID-19, and which, in the words of the Ministry of Public Health itself, has sufficient quantity to attend to the entire population;

c. Applicants request a compulsory license not for themselves but for the Expensive Drugs Program. First, the ONAPI is prevented from granting a compulsory license that is not in favor of the applicant himself, that is, according to our current legal system, it is not possible to request a compulsory license in favor of or at the expense of another who is not part of the request. Second, the Expensive Drugs Program exists to subsidize the acquisition of medications in favor of consumers, for the treatment of qualified illnesses with a high financial impact on the citizen, not so that it “designates manufacturers”, or what is the same, to grant licenses for the exploitation of patents; in fact, the only one with competence to grant compulsory licenses is the ONAPI, whether it is a compulsory license in favor of one or more persons of public or private law, or to declare a patent or patent application open to the granting of compulsory licenses, and said function cannot be delegated for particular conveniences;

F. Finally, the impossibility of the ONAPI to grant compulsory licenses that are not in favor of the applicant himself, goes hand in hand with the condition that all applicants for a compulsory license must justify their ability to exploit the patent, which in no way has happened in the species.

V. REQUEST

For all of the foregoing and for all those reasons that this honorable General Management may wish to supply, the company PFIZER, INC., through its constituted attorneys, wishes to conclude as follows:

FIRST: Declare the nullity of the application for a compulsory license to exploit patent application P2021-0232, entitled "ANTIVIRAL COMPOUNDS CONTAINING NITRILE":

A) In relation to the petitioners KNOWLEDGE ECOLOGY INTERNATIONAL and JAMES PACKARD LOVE, due to lack of power of attorney of Mr. LUIS GIL ABINADER to represent them.

B) In relation to Mr. LUIS GIL ABINADER, due to the lack of appointment of a representative with domicile in the country, in clear violation of article 148, number 2, of Law 20-00, for those who have domicile outside of, as is the case of Mr. LUIS GIL ABINADER, who resides in the United States.

SECOND: Subsidiarily, and only in the hypothetical and unlikely event that the previous nullity exceptions are dismissed, that the application for a compulsory license to exploit patent application P2021-0232, entitled "ANTIVIRAL COMPOUNDS CONTAINING NITRILE" for the following reasons:

A) Mainly:

For lack of purpose, since it was requested for reasons of public interest, under the terms of article 46 of Law No. 20-00 on Industrial Property (modified by Law No. 424-06), however, there is no state of exception, be it a state of emergency or national security, decreed by the Executive Branch, which declares the need for the drug claimed in the patent application P2021-0232 and, even more so, on February 16, 2022, the Executive Power ordered the elimination of all the sanitary measures imposed due to COVID-19, so there is no place to weigh a compulsory license for reasons of public interest.

B) Subsidiarily and only in the hypothetical and unlikely event that the above reason is dismissed:

A compulsory license has been requested, not in favor of the applicants themselves, but charged to the Expensive Drugs Program, so that this, in turn, is the one who grants the compulsory licenses to anyone interested in exploiting the invention claimed in patent application P2021-0232. However:

1. The role of the Expensive Drugs Program is to subsidize the acquisition of medicines in favor of consumers, for the treatment of illnesses classified as having a high financial impact on the citizen, not to grant operating licenses for patents; and

2. The only one with competence to grant compulsory licenses is the ONAPI;

3. Therefore, it is impossible and therefore unacceptable to request a compulsory license in favor of the Expensive Drugs Program, either to exploit the invention claimed in patent application P2021-0232, or to delegate said division of the Ministry of Public Health has the power to grant compulsory licenses or sublicenses.

THIRD: In a more subsidiary way and only in the hypothetical and improbable case that the previous means of non-admission are dismissed, that this honorable Directorate General please reject, AS TO THE SUBSTANCE, this application for a compulsory license, for the following reasons:

1. Absence of public interest. In addition to the fact that there is no State of Emergency:

a. The voluntary license granted by PFIZER, INC., regarding the drug claimed in the patent application P2021-0232, cannot be the reason for public interest;

b. The applicants themselves acknowledge that the Executive Branch is in talks with PFIZER, INC., to acquire several batches of the drug;

c. The applicants have not deposited a single piece of evidence that justifies said drug as the treatment of excellence for COVID-19, or that without it it would be almost unfeasible to combat it;

d. According to the applicants themselves, there are several treatments in the country;

e. The high cost of the other existing treatments could not be a reason to order a compulsory license with respect to another treatment;

f. The aforementioned drug does not replace vaccines, a resource that continues to be the main tool and priority of the Dominican State to combat COVID-19, and which, in the words of the Ministry of Public Health itself, has sufficient quantity to attend to the entire population.

2. Finally, the applicants have in no way demonstrated their ability to exploit patent application P2021-0232, a sine qua non condition for granting a compulsory license.

In Santo Domingo, National District, Dominican Republic, on the sixteenth (16th) day of March of the year two thousand twenty-two (2022).

Maria del Pilar Troncoso
Alexander Rios Hernandez

