KEI Response to Questions from USTR on Special 301, USTR-2020-0041-0001
March 5, 2021

Q1. Are there any national policies that foreign countries have adopted in response to the COVID-19 pandemic that you recommend that we highlight in the 2021 Special 301 Report and why? How would those examples fit with the purpose of the Special 301 review?

The Special 301 review is presently a forum for rights holders, particularly drug companies and publishers, to complain about the lack of enforcement of intellectual property rights. It's not really designed to have a discussion of what intellectual property policies and practices should be. That said, KEI will share some examples of national government responses to the COVID-19 pandemic, including some that have been helpful in terms of protecting the public from a virus that is deadly, and having an enormous negative impact on the economy, household incomes, education opportunities and even mental health.

1. Germany - Prevention and Control of Infectious Diseases in Humans Act

In March of 2020, the German enhanced the power of the Federal Ministry of Health (Bundesgesundheitsministerium - BMG) in the event that the Bundestag (German Federal Legislature) declared a national epidemic. The 'Epidemic Protection Act' provides for a number of amendments in the name of protecting the population in the event of an epidemic situation of national importance. One such amendment is to the Act on the Prevention and Control of Infectious Diseases in Humans (Infektionsschutzgesetz – IfSG), which authorises the Ministry of Health to issue an authorisation for compulsory license upon the declaration of a national epidemic by the Bundestag. Under § 5 of the IfSG, the Federal Ministry of Health can take measures to ensure the supply of pharmaceutical products, medical devices, laboratory diagnostics, and PPE, amongst other products. In the amended IfSG, § 5 (2) No. 5, it allows the limitation of patent rights under § 13 (1) of the German Patent Act (Patentgesetz) by government or third parties to ensure the supply of the aforementioned products in the "interest of public welfare of in the interest of the security of the Federal Republic of Germany". Unfortunately, the effective period for the broadened powers of the Ministry of Health is limited and will expire on April 1, 2021.
Links

- https://www.loc.gov/law/foreign-news/article/germany-amendments-to-infectious-diseases-protection-act-enter-into-force/
- https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents
- https://www.oppenhoff.eu/en/news-detail/bundestag-adopts-amendments-to-the-german-act-on-the-prevention-and-control-of-infec-tious-diseases

2. Canada - Bill C-13, the 'COVID-19 Emergency Response Act'

In March 2020, Bill C-13 titled 'COVID-19 Emergency Response Act' received royal assent. Amongst other amendments, Bill C-13 amended the Canada Patent Act, adding a provision on the use of patented inventions by the government. It authorizes the Government of Canada, on application of the Minister of Health, to construct, use and sell a patented invention to the extent necessary to respond to a public health emergency (section 19.4(1)). There is no requirement under section 19.4 to seek the patentee's consent, and third parties may use the patented inventions.

> 19.4 (1) The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.

While Canadian legislators responded rapidly to the COVID-19 pandemic, section 19.4 was restricted with the inclusion of section 19.4(9) which states that the Commissioner may not make an authorization under section 19.4(1) after September 30, 2020.

Links

- https://laws-lois.justice.gc.ca/eng/AnnualStatutes/2020_5/

3. The Canadian Access to Medicines Regime (CAMR)

The Canadian Access to Medicines Regime (CAMR) is the implementation of the WTO's waiver to allow generic versions of patented pharmaceutical products to be exported to lower-income countries. For an application for authorisation to export to a WTO member, the CAMR required that a manufacturer apply to the Commissioner for authorisation. However, while the informational requirements for the application seem manageable, the process is rife with unanswered questions and dead ends. For example, on the CAMR contact website, they provide two phone numbers. The first number, for the Director of the Patent Policy Directorate of Industry Canada, is invalid. When calling the second provided number, for the Bureau of Policy, Science and International Programs, there was no response. Additionally, the only way to get the compulsory license authorization in Canada is to fill out the necessary forms. However, these forms are not readily available. Applicants are directed to call the Canadian Patent Office in order to get access to the required forms. Yet, the only contact numbers provided are general phone numbers for the CIPO, there is no specific compulsory license contact, enquiry form or webpage. This renders the applications process, while seemingly straightforward, a convoluted and difficult task. KEI is aware of one Canadian company seeking a license from Johnson and Johnson to manufacture the Ad26.COV2.S vaccine, both to supply the Canadian market and to export to developing countries under 31bis of the TRIPS Agreement. This effort will be a test of the actual intentions of the Canadian government to scale production of vaccines and to permit exports of vaccines or drugs under a compulsory license to developing countries to address unmet needs.

4. Israel compulsory license on lopinavir 200mg/ritonavir 50mg (Kaletra) patents

On Wednesday, March 18, 2020 (22nd of Adar, 5780), Israel's Minister of Health, MP Rabbi Yaacov Litzman, issued a Permit to the State to Exploit an Invention Pursuant to Chapter Six, Article Three of the Patents Law 5727-1967 for the importation of Kaletra (lopinavir 200mg/ritonavir 50mg) for the sole purpose of medicinal treatment of covid-19 patients. Knowledge Ecology International (KEI) has obtained the original Permit (published in Hebrew). Ariel Katz, Associate Professor at the Faculty of Law, University of Toronto, provided an unofficial translation of Israel's Permit authorizing the importation of Kaletra for the sole purpose of treating patients with covid-19. This authorization is the first time Israel invoked Section 104 and Section 105 of the Israeli Patents Law, 1967 for public non-commercial use.

At the time of the issuance of this Permit, the Health Ministry endeavored to obtain Kaletra directly from Abbvie and its authorized importer but was notified by Abbvie and its authorized importer that they would not be able to supply the requested quantities of Kaletra in the requested time frame. Israel determined that the exigent circumstances of the covid-19 pandemic dictated the need to invoke Section 104 and Section 105 of the Israeli Patents Law, 1967 for public non-commercial use.

The Permit is narrowly drafted to authorize K.S. Kim International Ltd. (the importer) the right to import lopinavir 200mg/ritonavir 50mg) from Hetero (based in India). The unofficial English translation of the Permit states:

> In accordance with the power vested in me under Cabinet Decision #4888 from March 13, 2020 pursuant to Section 112 of the Patents Law 5727-1967 (hereinafter –the Law), I hereby grant permission,in accordance with Sections 104 and 105 of the Law,to the Emergency Department at the Ministry of Health and to K.S. Kim International Ltd. to exploit the invention protected in patents numbers 173939, 207260, 185390 by way of importation of the lopinavir 200mg/ritonavir 50mg medication manufactured by Hetero, for the sole purpose of medicinal treatment of Corona patients (Novel Coronavirus 2019, pursuant to a Notice of a Dangerous Infectious Disease, under the Public Health Ordinance, 1940, dated 27.1.20). The permission to exploit is necessary in the interest of the maintenance of essential supplies and services.

5. Ch*ile - Resolution No. 896*

On March 17th 2020, the Chilean parliament passed Recolution No. 896 in light of the global COVID-19 pandemic, highlighting the public health emergency and its possible devastating consequences.[1] The resolution states that the availability of medicines, supplies and state-of-the-art equipment may be restricted due to legal monopolies resulting from patent rights or other forms of industrial property, thus limiting the possibility of production and import of products. Law No. 19.030 on Industrial Property (*de Propiedad Industrial)* establishes the

[1] https://www.camara.cl/verDoc.aspx?prmId=3885&prmDestinoId=3&prmTipo=RESOLUCIONENVIO

possibility of compulsory licenses on patents for reasons of public health declared by the competent authority (article 51 No. 2). Thus, with Resolution No. 896, the COVID-19 pandemic constitutes a sufficient justification for the granting of a compulsory license. Thereby facilitating access to vaccines, drugs, diagnostics, devices, supplies and other technologies for the prevention, detection, diagnosis and treatment of people infected with COVID-19 in Chile.

6. **Russian Federation compulsory license on remdesivir**

December 15, 2020, the amendments to the Russian Civil Code expanding the list of grounds for granting compulsory licences were approved by the Russian State Duma. On January 11, 2021, a compulsory license on Gilead's patents on remdesivir was granted. (This was the first use of Article 1360 of the Civil Code of the Russian Federation, but not the first compulsory license on a drug or vaccine in Russia). The following is a google translation of the order.

https://translate.google.com/translate?sl=ru&tl=en&u=http://www.garant.ru/products/ipo/prime/doc/400069350/

> Order of the Government of the Russian Federation of December 31, 2020 N 3718-r On the permission of Pharmasintez JSC to use inventions protected by Eurasian patents N EA025252, EA025311 and EA029712, owned by GAILID SAYENSIZ, INC. (US), Eurasian patents N EA020659 and EA032239, owned by JILID SAYENS, INC. (US), as well as the Eurasian patent No. EA028742, owned by JILID PHARMASSET, LLC (US), for 1 year without the consent of the patent holders in order to provide the population of the Russian Federation with drugs with the international non-proprietary name "Remdesivir"
>
> January 11, 2021
> In accordance with Article 1360 of the Civil Code of the Russian Federation, in the interests of security:
>
> 1. To authorize Pharmasintez Joint Stock Company to use inventions protected by Eurasian patents N EA025252, EA025311 and EA029712, owned by GAILID SANCIES, INC. (US), Eurasian patents N EA020659 and EA032239, owned by JILID SAYENS, INC. (US), as well as Eurasian patent No. EA028742, owned by JILID PHARMASSET, LLS (US) (hereinafter - the patent holders), for 1 year without the consent of the patent holders in order to provide the population of the Russian Federation with drugs with the international non-proprietary name "Remdesivir".
>
> 2. The Ministry of Health of Russia, no later than 30 days from the date of the first sale of the drug with the international non-proprietary name "Remdesivir" in the territory of the Russian Federation, notify the patent holders of the use of the inventions specified in paragraph 1 of this order.

3. The Ministry of Industry and Trade of Russia shall, within 3 months, submit to the Government of the Russian Federation information on the payment by Pharmasintez Joint Stock Company of commensurate compensation to the patent holders.

4. The Ministry of Economic Development of Russia shall notify the Council on Trade Aspects of Intellectual Property Rights of this order.

Chairman of the Government of the Russian Federation M. Mishustin

Pharmasyntez's generic of remdesivir has the trade name Remdeform. The price of Remdeform is capped at 7,400 rubles per vial (excluding VAT), about USD$100. The U.S. price is $520 per vial.

Vikram Punia was quoted in Meduza stating: "I don't know how important the lives of Russian citizens are to Gilead Sciences, but they are important to us. We want us to also have the opportunity to receive effective treatment and a chance for a full recovery."

Additional Links

- http://patentblog.kluweriplaw.com/2021/03/04/russia-first-public-security-compulsory-license/
- https://www.reuters.com/article/health-coronavirus-russia-remdesivir/russian-firm-seeks-to-produce-covid-19-drug-without-patent-vedomosti-reports-idUSL8N2HO0XS
- https://www.thepharmaletter.com/article/russia-s-pharmsynthez-seeks-compulsory-license-to-produce-generic-remdesivir
- https://www.petosevic.com/resources/news/2021/01/4419
- https://meduza.io/en/feature/2021/01/13/uncertain-benefits

7. Hungary: Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation Within Hungary

The Hungarian Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation Within Hungary entered into force on May 17, 2020. The decree was temporary, designed to cease to have effect upon the termination of the "State of Danger." The Act is described on a WIPO webpage as follows:

https://www.wipo.int/news/en/wipolex/2020/article_0009.html

The Government Decree provides, inter alia, the following elements:

(i) enabling the Hungarian Intellectual Property Office (hereinafter "HIPO") to issue nonexclusive public health compulsory licenses ("license") in order to satisfy domestic needs related to the health crisis situation;

(ii) the subject of a license can be (a) a medicinal product or active substance subject to a patent or a Supplementary Protection Certificate (SPC), or medical device or investigational medicinal product subject to a patent (referred jointly as "healthcare product"); or (b) a procedure, equipment or device necessary for manufacturing a healthcare product;

(iii) the public health compulsory license holder ("licensor") cannot issue a sub-license;

(iv) the period of the license is defined by the HIPO based on the information of the National Institute of Pharmacy and Nutrition (OGYÉI), with regard to the needs for management of the health emergency, but in any event not extended beyond March 31, 2021;

(v) the patent holder is entitled to "appropriate" remuneration for the license, which is determined by the HIPO;

(vi) healthcare products produced on the basis of a license shall be distinguished from products produced by the patent holder by a unique marking, with the packaging and related documents clearly indicating that such product was produced on the basis of a license; and

(vii) decisions granting licenses shall be entered into the HIPO's patent/SPC registers and published in the Official Journal of the HIPO.

Additional Links

- Hungary's Richter has manufactured Remdesivir for 3,000 COVID-19 patients, Reuters. October 7, 2020. https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter-idUSKBN26S283
- WTO TRIPS Council (October 2020): Hungary answers queries posed by South Africa regarding Hungarian compulsory licensing provisions, https://www.keionline.org/34268
- https://www.lexology.com/library/detail.aspx?g=bb6ad4c1-3dab-40ae-ae8d-35d2954f9a6c
- https://bakerxchange.com/rv/ff0063ef62da666383aeb623364ebc8010bb7a79/p=4182777

8. Costa Rica asked WHO to create a global program to “pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.”

A March 23, 2020 letter from Costa Rica, signed by Carlos Alarado Quesada, the President, and Dr. Daniel Salas Peraza, the Minister of Health, to Dr. Tedros Adhanom Ghebreyesus, called for a global program to “pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.” Costa Rica proposed the pool “should include existing and future rights in patented inventions and designs, as well as rights in regulatory test data, know- how, cell lines, copyrights and blueprints for manufacturing

diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country."

The WHO announced it would set up a COVID Technology Access Pool, (C-TAP), but the proposal has been plagued with a slow implementation and a lack of focus. Some have blamed the lack of progress on non-transparent pressures from Bill Gates, a major WHO donor, and a handful of countries seeking to protect domestic pharma industries. Gates and some WHO member states want to avoid measures that would weaken proprietary control over COVID patents or manufacturing know-how,

9. Nationalism

Since the beginning of the pandemic, there has been a wave of actions by governments to secure inputs and final goods used to prevent or treat COVID 19. Much of this has been non-transparent, treated like a national security issue, although some contracts with drug or vaccine manufactures have been made partially public, with redactions.

Some European Commission contracts are restrictive as regards where vaccines can be used. For example, an EC advanced purchase agreement contract with Curevac states, on page 14, the following: "The participating Member States shall take the appropriate measures to ensure that the Products supplied to them pursuant to this APA will not be (i) re-sold or (ii) exported, distributed or donated for free to another country outside the EU and EEA and Switzerland, including for donation via NGOs or the World Health Organization, without prior consent of the contractor."

The European Union HERA Incubator announcement on February 17, 2021 included a "dedicated licensing mechanism to facilitate technology transfer," and earlier the "Temporary framework for the assessment of anti-competitive practices in the cooperation put in place between companies to react to emergency situations arising from the current COVID-19 pandemic." The EU licenses will involve non-disclosure agreements as regards manufacturing know-how, and is designed to put European access first.

The EU HERA proposals are motivated in part by the USA initiatives which include a combination of export controls and contractual agreements that favor or mandate production in the United States or imports to the United States. Standard government use and march-in provisions in some US research and development contracts have been modified under exceptions allowed for "Other Transaction Authority" to refer exclusively to consumption in the United States. (See: https://www.keionline.org/covid-contracts). For example, a Janssen (Johnson & Johnson) contract with HHS/ASPR/BARDA limits its march-in rights as follows:

> "to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States."

10. Global Public Goods

KEI is among those supporting a global public goods approach, as regards manufacturing know-how and rights in inventions and data. Products are going to be in short supply for some time, and unequal access (as measured by timing of access) is inevitable, no matter what policy makers do. When money and power is unequal, there will also be unfairness. But while products are rival in consumption, the knowledge of how to manufacture a drug or vaccine could be shared openly and globally without depriving anyone of a product. The more widely shared the manufacturing knowledge, the faster will be vaccinations, and additional competition will lower prices. With the virus mutating, the speed at which vaccines are available is important.

The past emphasis on privatizing manufacturing know-how, even when research and development has been funded by government grants and research contracts, runs counter to the public goods approach. But governments can use a variety of measures, including coercion and incentives and subsidies, to move manufacturing know-how into the public domain. Government buyouts of proprietary manufacturing know-how are one policy option that is always on the table.

11. WTO role

On March, 1, 2021, KEI wrote to Dr. Ngozi Okonjo-Iweala, the new Director-General of the World Trade Organization (WTO) regarding the WTO's COVID-19 response. KEI called on the WTO to do the following:

- Support Members opting in under the TRIPS Agreement Article 31bis;
- Provide model patent law exceptions to address pandemics or other emergencies;
- Establish modalities to facilitate the sharing of manufacturing know-how in a pandemic; and
- Establish modalities to consider the notion of a WTO agreement on the supply of public goods.

The last recommendation was as follows:

> **WTO Agreement on the Supply of Public Goods.** Establish modalities to consider the notion of a WTO agreement on the supply of public goods. As you rightly noted in your inaugural press conference on February 15, 2021, the pandemic is part of the problem of the global commons. The WTO has been asked to consider a new agreement, based in some ways on the GATS, to create voluntary offers of binding commitments to supply public goods. The COVID-19 crisis would have benefited if such an agreement had been in place.

Links

- **The Use and Abuse of the Phrase "Global Public Good",** https://www.globalpolicyjournal.com/blog/28/09/2020/use-and-abuse-phrase-global-public-good

Q**2. According to your submission, Special 301 submissions are primarily from right holders and their representatives. Which types of organizations or individuals would you suggest should also submit comments that did not submit comments this year, and how would you recommend encouraging their involvement?**

If there was an explicit request for comments on the fundamental policy objectives, not just a list of bad actors, this would be a useful conversation.

At present, a key issue is the sequence. The public needs an opportunity to respond to the right holders' initial filings. Right holders would first make requests for sanctions, and then the public should have a formal ability to push back. In this year's approach, there is no public hearing, and we are supposed to respond only to questions put to us.

3. In KEI's view, are there foreign countries that lack adequate and effective protection and enforcement of intellectual property rights? What foreign countries should USTR identify in the 2020 Special 301 Report?

Since 179 countries are members of the Berne Convention (1886) and 109 are already members of the WIPO Copyright treaty (1996), there are few countries that do not offer adequate and effective protection of works and the rights of their authors. These 2 treaties are supposed to provide creators such as authors, musicians, poets, painters etc. with the means to control how their works are used, by whom, and on what terms. The copyright norms are set. Countries are still pressured into high levels of enforcement often costly if not socially harmful policies.

However, there are areas where we see a lack of protection:

1. Some countries that do not provide adequate and effective protection of legitimate geographical indications (GIs).
2. Some countries that do not provide artists with resale rights for physical works of art.
3. Many countries fail to protect performers from unfair contracts.
4. Some academic or scientific journals do not allow authors to retain copyrights in works, even when authors are not remunerated.
5. There is a lack of adequate metadata on streamed music, making it more difficult for creative communities to get the attribution and/or remuneration that they deserve, and depriving listeners with information they value.

6. Countries could find ways to provide for the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications, without creating new lawyers of exclusive rights.
7. Inadequate exceptions to copyright or related rights in national laws for archiving works leads to losses of culture and history.
8. Some countries permit broadcasters to obtain a layer of related rights on works created by third parties, even when the actual creative parties are not remunerated and even when works are intended to be placed in the public domain.