



October 29, 2020

Mr. Edward Gresser,
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th St., NW
Washington, DC 20508

Via electronic submission (http://www.regulations.gov)

Re: Comments Regarding Foreign Trade Barriers to U.S. Exports for 2021
Reporting (Docket Number USTR-2020-0034)

Dear Mr. Gresser:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide
comments regarding the National Trade Estimate Report on Foreign Trade Barriers.

IPO is an international trade association representing companies and individuals in all
industries and fields of technology who own, or are interested in, intellectual property
(IP) rights. IPO's membership includes about 175 companies and close to 12,000
individuals who are involved in the association either through their companies or as
inventor, author, law firm, or attorney members. IPO membership spans over 30
countries.

IPO advocates for effective and affordable IP ownership rights and offers a wide array
of services, including supporting member interests relating to legislative and
international issues; analyzing current IP issues; providing information and educational
services; and disseminating information to the public on the importance of IP rights.

IPO's comments below highlight concerns with key issues affecting the effective
protection of intellectual property rights globally, which impact foreign trade.

I. Patent Backlog and Other Administrative Delays

The effective term of a patent begins on the day of grant and, under the Agreement on
Trade-Related Aspects of Intellectual Property Rights (TRIPS), "[t]he term of
protection available shall not end before the expiration of a period of twenty years
counted from the filing date."1 Any examination activity from the filing date that
unreasonably delays the grant date reduces the effective patent term of each patent.
These delays can be the result of patent backlogs that prevent the timely start of
prosecution, piece-meal prosecution that unnecessarily extends the time for completing
prosecution, or other actions that extend the time to grant.

1 Agreement on Trade Related Aspects of Intellectual Property Rights, Article 33.

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Innovators rely upon patent rights to support their research programs. Patents are especially critical for start-up and emerging technology companies. Unreasonable delays and extended uncertainties in the patenting process are major hurdles to these young companies and disincentives for such companies to invest in advanced technology. Thailand and India are countries of particular note for having exceptionally long prosecution times due to a combination of administrative delays arising from a backlog of cases to be examined and inefficient prosecution. Also, while IPO appreciates some of the recent efforts that have implemented by Brazil's National Institute for Industrial Property (INPI) to try to fix the patent backlog, IPO notes that Brazil's lengthy prosecution time still remains an issue for innovators.

IPO advocates for countries to adopt legislative and administrative remedies that restore the term of patents that would otherwise have been diminished due to unreasonable delays in the prosecution of patent applications from filing to grant. IPO also favors adoption of greater prosecution efficiency measures including the use and acceptance of common search results from the IP5 and the Patent Prosecution Highway, which would eliminate repetitious and duplicative search efforts by patent offices and burdensome filing requirements of co-pending applications.

II. Compulsory Licensing

Patents drive and enable the research and development that delivers valuable new innovations to society. However, several countries, such as Argentina, Chile, Colombia, Turkey, and Ukraine, have adopted or considered resolutions, laws, or regulations that promote or provide broad discretion to issue a compulsory license. Compulsory licenses have been issued in previous years in several countries, including India, Indonesia and Malaysia. IPO believes that sharing of IP rights is best accomplished through voluntary, collaborative, and cooperative efforts between all relevant stakeholders, which in turn incentivizes future technological advancements. An active compulsory licensing policy will not be helpful in promoting such partnerships—and it undermines investment in innovative solutions that benefit society. Granting compulsory licenses undercuts the importance of a predictable and reliable patent system.

III. Weak Patent Enforcement

Effective, efficient, and fair means for enforcing patents are foundational principles for a legal system to deliver the intended benefits of patent rights. Patent rights are, upon the sufficient disclosure of inventive discoveries, granted by governments for the exclusive right to practice such discoveries for a limited period of time.

Unreasonable barriers to the legal system, in countries such as China and India, reduce the value of patents by denying access to the means for enforcing these exclusive rights. Examples of such barriers are high evidentiary requirements for initial complaints, such as requiring verified proof of purchase from defendants and detailed allegations showing proof of infringement to which a claimant may not have access. Such high

levels of proof at the beginning of a proceeding can be particularly difficult to acquire for process-related patents. Statutory caps or limited damage awards can reduce the value of pursuing any remedy because the awards may not cover the costs of enforcement, let alone be sufficient to provide any recovery for lost profits, and/or other losses associated with the infringing activity.

Slow resolution of legal disputes reduces the value of patents by eroding the effective term of a patent. Many jurisdictions can take five or more years from complaint to a final decision. Patent holders that are unable to obtain preliminary injunctions can see the final years of their patent term lost due to litigation delays and abuses of process.

Failure to understand technical issues and IP-specific legal concepts reduces the credibility of a court and unfairly diminishes public perception of patents. Patents and their enforcement proceedings require at least a working knowledge and comfort with technical subject matter. Independent and experienced judges allow all parties balanced opportunities to enforce or defend claims of patent infringement.

IPO urges legislative and administrative reforms that allow patent holders improved access to legal systems by adopting reasonable complaint pleading and evidentiary requirements, establishing standards of proof that are aligned with the parties' access to the relevant facts, and appointing experienced and competent judges to adjudicate patent matters. IPO further urges reforms to ensure patent proceedings in Court conclude within an appropriate timeline due to the time sensitivity of these claims and adoption of appropriate legal changes to fully compensate patent holders for their losses in a case of proven infringement.

Additionally, early resolution mechanisms that provide for the timely resolution of patent disputes before marketing approval is granted for a generic or biosimilar product is important to the continued investment in research and development that leads to new medicines. The premature launch of a medicine that is later found to infringe a patent may disrupt patient treatment and also may cause commercial damage to the innovative company that is impossible to later repair. IPO welcomes the attempt by China to implement such a mechanism, and hopes that the draft measures being proposed in China will be revised further to provide meaningful protection for innovators' patent rights. Other countries, such as India and Russia, among others, should also seek to implement such a mechanism.

IV. Restrictive Patentability Criteria

To bring new, innovative, and creative products to society, innovators must be able to secure patents on all inventions that are new, involve an inventive step, and are capable of industrial application.² Any policies that impose additional requirements have a very negative impact on innovation. However, national laws or regulations in various countries prohibit patents on certain types of biopharmaceutical inventions or impose additional heightened patentability criteria. Countries that maintain patentability

² *Id.* at Article 27.1.

restrictions include, for example, Argentina, Indonesia, India, the Philippines, and Ukraine.

V. Counterfeiting / Trademarks

Counterfeiting is a global problem that affects more than a brand or brand owner. The sale and manufacture of counterfeit goods harms the public, consumers, patients, hospitals, governments, and more. Counterfeiting has well known links to organized crime, and money laundering, and is a threat to public safety. IPO members have reported counterfeiting issues in countries such as, for example, Canada, China, Russia, Thailand, Turkey, the United Arab Emirates, Vietnam, and the United Kingdom.

It is particularly worthy of note at this time that the COVID-19 pandemic has created an increase in counterfeit personal protective equipment, hand sanitizer and other products in high demand because of the pandemic. The sale of these products, and especially counterfeit respirators and masks, poses a significant health and safety risk which affects consumers in almost every country of the world.

Ecommerce and social media platforms have made it easier for counterfeiters to sell their products. These platforms provide counterfeiters with an opportunity to engage with consumers throughout the world anonymously with very little effort. Many ecommerce and social media platforms allow counterfeit products to be displayed next to authentic products. In many cases, consumers are not even aware they purchased a counterfeit product and only realize this after the product fails. The number of ecommerce platforms increase every year, making it easier for counterfeiters to move from one platform to another to avoid detection. The Covid-19 epidemic has led consumers to increase their purchases through these platforms, exacerbating the already-significant challenges they present.

Many brand owners engage with third party vendors to help enforce their brands on ecommerce and social media platforms. Other brand owners cannot afford to do this and must rely on internal resources and the cooperation of the platforms where they find counterfeit product. Some platforms cooperate well with brand owners, while others are more difficult in this regard. More action is needed by e-commerce platforms to prevent the sale of counterfeit goods on their platforms and provide information on the source of counterfeit goods.

Customs offices throughout the world play a key role in offline enforcement by helping brand owners stop product from entering a country. However, effective border enforcement is not available in many countries, including Brazil, Nigeria, Vietnam, India, Pakistan and Indonesia. The fact some countries do not give their Customs officials the ability to take *ex-officio* action to seize and destroy counterfeit products is a challenge for brand owners. This lack of effective global border enforcement makes it easier for counterfeiters to ship counterfeit products throughout the world and focus their activities on countries with weak border and IP enforcement.

It is difficult for brand owners to coordinate anti-counterfeiting efforts by Customs offices and law enforcement agencies throughout the world. The counterfeiters are

global and therefore there needs to be more international cooperation and collaboration between government agencies and law enforcement agencies. In the U.S., brand owners work closely with the U.S. IPR Center. The creation of similar centers around the world would increase the collaboration and cooperation needed to help brand owners and consumers.

Additional measures are needed, such as: (1) improved police and customs enforcement, (2) processes that facilitate quick identification of counterfeiters and prosecution of counterfeiters; and (3) improved processes by online marketplaces and social media platforms to detect counterfeit products, block or remove those products from their platforms, and prevent relisting of those products. These efforts would need to be global in scope to limit the risk of egregious offenders relocating to countries and marketplaces where the laws against counterfeiting are weak and enforcement of such laws is lax.

VI. Inadequate Protection of Trade Secrets

a. Regulatory Data Protection Failures

Regulatory authorities require as part of marketing authorization submissions the pre-clinical and clinical trial information that demonstrate the safety and efficacy of a medicine before regulatory approval. Regulatory data protection (RDP) provides a minimum level of protection to innovators during which time no unauthorized third party can rely on the data submitted by the innovator for regulatory approval. RDP recognizes the extensive time, effort, and cost of clinical studies required to ensure that drugs developed are safe and effective for patients—and it provides critical incentives to engage in continued research and development of new innovative therapies. Unfortunately, several U.S. trading partners do not provide RDP or have inadequate RDP regimes. Examples include Argentina, Brazil, China, Egypt, India and Turkey.

b. Real World Abuses

Stakeholders continue to be concerned about the possibility in many countries that information may be leaked by a government authority with a remit for regulatory oversight. IPO encourages the implementation by countries of measures to help prevent such disclosures, such as envisioned in Article 1.9 of the Phase One Economic and Trade Agreement between the U.S. and China (whereby China has agreed to provide protection of any “undisclosed information, trade secrets, or confidential business information” provided in the administrative licensing process).

We again thank the USTR for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts in developing the 2020 National Trade Estimate Report on Foreign Trade Barriers.

Sincerely,

A handwritten signature in blue ink, appearing to read "Daniel J. Staudt". The signature is written in a cursive style with a horizontal line crossing through the middle of the name.

Daniel J. Staudt

President