Mr. Rodrigo Maia  
PRESIDENT OF THE HOUSE OF REPRESENTATIVES  
Brazil

SUBJECT: Law bill #1462/2020 that accelerates compulsory licenses during COVID-19 pandemic

Your Excellency Rodrigo Maia,

We are lawyers, academics and other experts working in fields including intellectual property, trade and health, writing to support Brazil’s initiative regarding the issuing of compulsory licenses. We would like to stress the importance to enact a law that accelerates compulsory licenses for patented technologies combat COVID-19, with immediate effects during this and any other declared health emergencies in the future either by Brazilian authorities or by the World Health Organization (WHO). This law bill surely will promote public interests in assuring access to additional sources of supply and more affordable health products.

Brazil’s law bill #1462/2020 proposes the temporary licensing of patents on any and all health technologies that can be used against the Covid-19 pandemic, and is awaiting designation for vote in the Chamber of Deputies' plenary. This bill follows the action of countries such as Germany, Canada, Israel, Chile, Ecuador and Colombia that have taken legislative measures to favor speedy access to technologies useful to contain the pandemic.

The law bill #1462/2020 also prepares Brazil for possible future pandemics by defining that the legal provision of the Compulsory License (CL) comes into effect from the moment there is a public health emergency declaration by the responsible Brazilian authorities or, at the international level, the WHO. The measure, which already has the support of the National Health Council, aims to remove any existing monopoly on medical devices, personal protective equipment (PPE), medicines for treatment and prevention, vaccines, diagnostic kits, reagents, among other health products that may tackle Covid-19.

A wide base of producers, both domestic and international, is essential for Brazil to overcome scarcity and exclusion from access to essential health technologies. Preventing monopolies is a strategic and important measure, which is fundamental to ease the pressure over overworked health systems. Compulsory licenses, which are immediate and mandatory, are lawful under international law, so long as they provide for adequate compensation to patent holders.

Article 31 of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property (WTO’s TRIPS), as further clarified by the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), permits all WTO members, including Brazil, to issue compulsory licenses at any time on grounds of their choosing. Similarly, Brazil has freedom to determine which matters are emergencies or matters of extreme urgency, a category that certainly applies to the COVID-19 pandemic. The only compensation due to patent-holders in instances of compulsory licensing is “adequate remuneration”, a reasonable royalty, which governments may determine at their discretion.

The Doha Declaration explicitly recognizes the impact of intellectual property on medicine prices and states that countries patent obligations under WTO rules “should be interpreted and implemented in a
manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”

Issuing a compulsory license does not expropriate the property rights of the patent holder. Rather, the right of a government to purchase a patented invention from other sources is embedded and lies in the grant of a patent itself. Furthermore, a compulsory license does not prevent the patent holder from selling its product. In fact, it allows the government to purchase a given technology from any available supplier, including the licensed patent owner.

This legislative proposal entirely consistent with the terms of international trade agreements Brazil has signed, expressly the public health safeguards. Besides, any change that makes the compulsory licensing procedures faster, simpler and less uncertain regarding the outcome will be more useful in a pandemic like COVID-19, where it is important to act quickly and decisively.

Concerns have been raised by representatives of pharmaceutical industry to certain aspects of this proposed legislation. We consider those objections to be without merit.

1) The first objection is that “the proposal is radical and without merit.” As stated above, compulsory licenses are completely lawful under international law and have been recognized as such as far back as the Paris Convention for the Protection of Intellectual Property (1883). The majority of countries, including high-income countries have compulsory and government use license procedures, which have been used extensively in response to the AIDS pandemic and other diseases. Furthermore, given the urgency posed by pandemics, the proposal to create a more rapid path to issue compulsory licenses must be welcomed.

2) The second objection is that the Bill “disincentivizes” innovation. Of course, innovation is important and must be paid for. But it does not have to be paid for with monopolies and extortionate prices on new medical technologies. Much of the research on COVID-19 is currently being subsidized by governments and charities, both with respect to basic research and clinical trials designed to investigate the safety and efficacy of investigational medicines, vaccines, and devices. Under the bill, innovators will receive royalty payments and they will also have ample opportunity to earn back their investments in high volume sales worldwide.

3) The third objection is that there are already compulsory licensing provisions in Brazilian law, suggesting that these measures are equal to the task. Brazil does have certain compulsory license provisions, but they have several shortfalls in terms of meeting Brazil’s emergency needs. For example, current Brazilian law under Article 71 of the Patents Act requires proof that the right holder is unable to supply Brazil’s needs. This provision is ill-designed to deal with situations where price alone can be a deterrent to access. A second provision, Article 68 requires proof of abuse of a patent, a condition that requires complexities of proof and process ill-suited to an emergency and which fails to respond to the need for urgent access to multiple sources of supply. Therefore, the proposed bill can adapt Brazilian legislation to this unprecedented health crisis, in line with the recommendation made at the highest level of the United Nations calling for "quick" compulsory license legislations.

4) The fourth objection is that there can be no “mandatory” compulsory licenses. This is incorrect as a matter of logic and precedent. First, the licenses will be granted on a category of products, those related to COVID-19 or other declared health emergencies. Thus, it is a categorical based standard not dissimilar to any recognized standards such as inadequate supply, unreasonable prices, refusal to
license or the like. Second, there is precedent globally and in academic literature for mandatory and/or presumptive compulsory licenses. For example, in the United States, the federal government has the automatic right to use any patented invention, without a requirement for a finding of abuse, under 28 USC § 1498(a).

5) The fifth objection is that the law sets a 1.5% royalty, which according to the critics must be individually negotiated. To the contrary, under historical precedent, many countries have adopted royalty guidelines or royalty rates, and Brazil is free to do so as well.

6) The sixth objection is that compulsory licenses do not encourage technology transfer. Of course, that is not true when the technology can easily be reverse-engineered. However, it is true that the legislation would be even stronger if it allowed access to manufacturing know-how, software, industrial blueprints and specifications, and other intellectual property and data rights. Nonetheless, the bill does allow licensees access to basic patent rights, which commonly are the most important barrier to generic production.

7) The seventh objection is that the legislation adversely impact investment in Brazil. This is not reasonable given Germany and Canada have already strengthened domestic legislation to allow compulsory licenses to address the COVID-19 pandemic and the United States has the easiest to use government use license mechanism in the world 28 USC sec. 1498. Moreover, multiple economic studies have challenged industry’s claims that direct foreign investment, including in the pharmaceutical sector, is tied to the level of intellectual property protections in a country or whether a country has compulsory licensing legislation.

Passing the bill promotes the principles of innovation for all, access for all, solidarity and global cooperation and good governance and transparency.

We hope this letter will support Brazil's efforts to combat Covid-19 and put to rest any concerns regarding the international legitimacy of compulsory licensing. Compulsory licensing is a key tool for protecting public health and ensuring access to medicines and health services for all.

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