April 10, 2020

Members of the Brazil Congress

It is our understanding that some large drug companies have raised objections to a new compulsory licensing authority for Brazil relating to pandemics. I would like to address the several objections reported by Pedro Villardi, coordinator of the Working Group on Intellectual Property, in a message to the listserve, IP-Health.

Below I quote the seven objections listed by Pedro Villardi, followed by my comments.

Arguments against the bill:

1. **This proposal is radical and is it beyond reasonable;**

The compulsory licensing proposal in Brazil is addressing pandemics, which can, and certainly in this case, require exceptional responses. What is beyond reasonable is acting as if nothing extraordinary is taking place, and as if extraordinary measures are not necessary to address a crisis.

2. **It de-incentivizes innovation [claims that each drug requires more than US$1 billion, one out 6k is successful, etc], therefore to protect innovation is key to improve society's good health);**

Research and development (R&D) costs and risks are important for any industry, including drug, vaccine and diagnostic testing industries. That said, it is useful to put some of the reported numbers into perspective. The 'one-out-of-6,000' figure for drugs that fail is more a rhetorical device and is not based upon any real data. Companies can screen thousands of compounds to come up with one that works as a drug or vaccine, but the expensive part is in the human subject clinical testing, and here the risks are better understood and better documented, and there is at least some data on the costs of conducting such trials.

There are a number of published studies on the likelihood of a drug that enters clinical testing being approved by the U.S. Food and Drug Administration (FDA) for marketing. The studies all illustrate the obvious fact that as drugs progress from Phase 1 to Phase 3 testing, the risks are progressively lower. In Joseph DiMasi's often quoted 2016 study, drugs entering Phase 1 testing had an 11.8 percent chance of being approved by the FDA./1/ BIO, the industry trade association, estimated the success rate for non-oncology drugs to be 11.9 percent at Phase 1, in a different 2016 study./2/ By Phase 3, the most expensive phase of testing, risks are lower. For example, in his 2016 paper, DiMasi put the Phase 3 likelihood of approval at 55 percent, for all drugs in his study. In the 2016 BIO study, the likelihood of

success for infectious diseases was 19.1 percent for Phase 1, 27.5 percent for Phase 2, and 64.5 percent for Phase 3.

A 2015 study by Battelle that was published by PhRMA estimated the per patient costs of clinical trials conducted in the United States (which is a high cost area) for several diseases. For infectious diseases, the PhRMA/Battelle study estimated the per patient costs of trials at $15,000, $17,500 and $18,000, for Phase 1, 2 and 3 trials respectively./3/ Various consultants have given lower costs for trials conducted outside the United States./4/

The costs of testing drugs or vaccines for COVID-19 are not yet known, but it is certainly the case that the role of governments and non-profit organizations in funding the research is significant. In the United States, billions of dollars in R&D grants and contracts are being directed at COVID-19 drugs and vaccines, and other governments are also investing heavily.

Chile, Ecuador and Costa Rica have all called upon the WHO R&D Observatory to track R&D spending on COVID-19, including the role of subsidies, and Brazil should join this call for more transparency, so that decisions about pricing and patent rights can be informed by facts, and not self-serving propaganda.

It is true that anything that lowers prices or narrows legal monopolies reduces the incentives for private investments in R&D. This is not, however, an excuse to ignore the importance of making products affordable. In the current pandemic, the global demand for drugs or vaccines that work is large, and the public interest in extensive access is enormous. Universal access is important for patients, but also for the economy.

Governments that want to provide additional incentives for the development of COVID-19 drugs and vaccines do not have to use legal monopolies to do so, Governments can fund innovation inducement prizes/market entry rewards as the incentives, in any amount they want, and still permit competition and low prices for products (See: delinkage.org).

3. **There is already a compulsory license provision in the Brazilian legislation (Articles 68 and 71 of law #9279/96, national emergency, public interest, lack of national exploitation) and therefore there is no need to change the law. Rather, it is a matter of implementing it;**

Anything 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.

Article 68 of the Brazil statute requires a finding by an administrative or judicial body that there has been an abuse of the patent rights. I have been involved in a number of cases involving allegations of anti-competitive conduct, and this can mean time-consuming and complex proceedings. The Brazil statute introduces a number of restrictions that make it even less useful, such as the requirements that only firms with the capacity to exploit the patent can petition for the license, and the limitations on exports, which may unduly limit

economies of scale for domestic manufacturing cases. The requirement that three years be elapsed since the patent was granted can be a problem. Making things worse are the provisions in Article 69 that permit patent holders to challenge, litigate and delay compulsory licenses under this Article.

Article 71 of the Brazil compulsory licensing law allows the patent owner to claim that the licensee fulfils the national need for the invention. Since this can be subject to debate, fact finding and disputes, the patent holder may be able to delay and even block such a license during a pandemic.

4. **There can be no automatic compulsory license, since Brazilian Constitution establishes the adversarial principle. The patent holder has the right to argue and clarify whether the company is able or not to meet the country's demands;**

I am not an expert on constitutional law in Brazil. I do know that automatic compulsory licenses are used in other countries, for specific cases. 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).

As you undoubtedly know, Germany has recently adopted a law for special uses of compulsory licenses relating to the prevention and control of infectious diseases in humans. The new German Act does not require a finding of abuse, and does not allow patent holders to block a compulsory license during a pandemic./5/

India has a mandatory “Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances”, in Article 92A of the India patent act. This involves exports of medicines to countries with “insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems.” The license is mandatory. The Controller General of Patents, Designs and Trademarks, “shall, on receipt of an application in the prescribed manner, grant a compulsory licence” in these cases.

5. **The law established a 1.5% royalty. Big Pharma claimed TRIPS Article 31 to argue that each license must have a separately negotiated royalty fee.**

I think a 1.5 percent royalty on the price of the generic is unnecessarily low, for a patent that covers the entirety of a drug or vaccine. One has to be mindful of royalty stacking cases, where products have multiple patents.

I would suggest, for a case like the COVID-19 pandemic, that the compulsory license cover all relevant patents on a product, and have an initial royalty of 3 percent for a drug or a vaccine, with the possibility that the royalty be increased to as much as 7 percent or be lowered to less than 3 percent, if either the patent holder or the manufacturer can provide a compelling argument for doing so.

If there are multiple patent holders for a product, the patent holders should have the opportunity to resolve the sharing of royalties by agreement between themselves, or to utilize two other ways to resolving disputes: (1) to enter into arbitration, with the cost of the arbitration paid from from the royalty payments, or (2) to ask the Department of Health to determine the shares of the royalty for each patent holder.

An appeal of the royalty by the patent holder should only be allowed after providing a disclosure of actual R&D costs associated with the specific clinical trials related to the development of the drug or the vaccine, excluding the costs of acquiring rights in patents, materials, knowhow or data.

The compulsory license should address the liability that may arise from applications for patents that have not yet been granted.

6. **Compulsory licensing does not promote quick technology transfer. On the contrary, it tends to increase the risk of poor resource allocation and ineffective use of raw materials.**

Technology transfer is a challenge. In the case of a pandemic like COVID-19, the government can and should mandate deep technology transfer for any effective drug, vaccine or diagnostic test, as well as rights in any test data needed to register products.

7. **If such a legislative proposal is approved, there will be less investments in the country, innovation would be de-incentivized and, therefore, less medicines would be developed, hindering access to medicines.**

To the extent that this argument has currency, it is weak for a pandemic like COVID-19, where governments rather than private companies have generally provided most of the R&D funding. But to elaborate on the point made above in section 2, governments are free to provide all sorts of R&D incentives and subsidies, that are delinked to the prices of products or the grant of a monopoly. There is a public interest in providing incentives and also in expanding access. Enforcing legal monopolies during an international public health emergency is the wrong choice, since it sacrifices affordability, and affordability and expanded access are needed to protect patients and the economy.

We agree with the *Financial Times*, a publication that certainly values innovation and incentives, but which also sees the urgency of providing universal and access to cheap drugs and vaccines for the COVID-19 pandemic as justifying the use of compulsory licenses./6/

> “Diversity of sources of supply, together with stockpiling for emergencies, is the safest policy. Another vital trade policy issue will arise in the near future: the licensing of drugs and vaccines effective against the virus. The world has an overwhelming interest in ensuring these will be universally and cheaply available. Fortunately, trade rules allow compulsory licensing. If necessary, it must be used.”

Additional Comments on Liability Rule Approaches

While the proposed legislation follows the approach of granting a compulsory license, the Congress may want to consider a different mechanism, that of limiting the liability for infringements. This is sometimes referred to as a liability rule. There is a freedom to use a patented invention, conditioned upon payment of a royalty.

The U.S. statute 28 USC § 1498(a) does not actually grant a license to use a patented invention to the government, rather it eliminates the availability of injunctions and limits remedies to the payment of reasonable compensation.

The U.S. Biologics Price Competition and Innovation Act of 2009 is another example. This statute eliminates injunctive relief, and limits remedies for infringement to payment of a reasonable royalty, in cases where a company fails to make constructive and timely disclosures of patent landscapes for biologic drugs.

The advantages of allowing non-voluntary uses through limitations on liabilities are several, but most importantly, none of the WTO restrictions in Article 30, 31 or 31bis are present. The use comes under Article 44.2 of the TRIPS, and this can be far less complex than licenses under Article 31 or 31bis of the TRIPS. A liability rule may also be easier to legislate, requiring only a special rule on remedies for infringement in cases involving pandemics.

Sincerely,

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
http://keionline.org
james.love@keionline.org

FOOTNOTES

/1/ DiMasi, J.A., Grabowski, H.G., Hansen, R.W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. 47:20-33.

/2/ David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay, Clinical Development Success Rates 2006-2015. Biotechnology Innovation Organziation (BIO), Biomedtracker, Amplion.

/3/ Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies. Prepared by Battelle Technology Partnership Practice. Prepared for Pharmaceutical Research and Manufacturers of America (PhRMA). March 2015. Table A-1. Estimated Locally-Based Per Patient Costs by Selected Disease Areas and Phase.

/4/ Any edition of the PAREXEL Biopharmaceutical R&D Statistical Sourcebook.

/5/ Dr. Simon Klopschinski, Update on Patent-Related Measures in Germany in View of Corona Pandemic, Kluwer Patent Blog, April 2, 2020. http://patentblog.kluweriplaw.com/2020/04/02/update-on-patent-related-measures-in-germany-in-view-of-corona-pandemic/

/6/ THE EDITORIAL BOARD: Coronavirus must not destroy an open world economy – The global health emergency makes trade more important, not less, March 27, 2020. The Financial Times. https://www.ft.com/content/4a3bf282-701c-11ea-9bca-bf503995cd6f