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Q&A: Patent expert Karen Sebaski on U.S. IP waiver for COVID-19 vaccines

By Patrick H.J. Hughes

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On May 5, President Joe Biden announced that his administration supports a temporary waiver of intellectual property protection for COVID-19 vaccines. The announcement has evoked varied reactions from other governments, pharmaceutical companies and IP trade groups.

Thomson Reuters interviewed Holwell Shuster & Goldberg LLP counsel Karen Sebaski, a registered patent attorney with experience counseling a broad array of clients, to shed some light on the subject.

Thomson Reuters: What exactly is the U.S. government planning to waive with respect to COVID-19 vaccines?

Karen Sebaski: The Biden administration's announcement relates to a landmark proposal that India and South Africa first submitted to the World Trade Organization last fall to allow member countries to temporarily waive the application of some rules of the agreement on Trade-Related Aspects of Intellectual Property Rights.

In general, TRIPS requires WTO members to provide at least 20 years of patent protection, including for patents directed to life-saving medications; TRIPS also greenlights several tools designed to address public health concerns, including compulsory licensing. India and South Africa's original proposal would suspend global intellectual property protections around products that protect, contain and treat COVID-19 until the pandemic is under control, which would encompass everything from vaccines and therapeutics like remdesivir to reagents and other materials for COVID-19 test kits. However, on its face, the administration's statement is narrower than that original proposal, as U.S. support for a waiver appears to be limited to intellectual property rights for COVID-19 vaccines only.

TR: Is this waiver guaranteed to happen or does the U.S. government still have to overcome some obstacles to further its objective?

KS: Nothing is guaranteed. One reason is that, in order to pass, any intellectual property waiver will require the support of a consensus of the WTO's 164 member countries.

Prior to the administration's announcement, a number of countries, including the U.S. and Canada, had been opposed to the idea of an intellectual property waiver, with some countries requesting evidence that such a waiver actually would accomplish its intended goal of facilitating additional vaccine manufacturing and in fact could swiftly rectify the vaccine and therapeutic shortages that are tearing apart developing countries.

U.S. allies in Europe — Germany, for example — have come out against the administration's provision, citing, for example, long-term concerns that intellectual property waivers will disincentivize pharmaceutical companies from aggressively investing in the necessary research and development to develop future cutting-edge vaccines. Also, as the administration's statement explains, text-based negotiations at the WTO are complex and likely to take time "given the consensus-based nature of the institution."

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TR: Will this waiver bring about vaccine access that is fairer, more affordable or easier than it has been for Americans? How about for those in other countries?

KS: Even if WTO member countries adopt a temporary waiver of intellectual property rights, any such waiver likely will be a small piece of the puzzle to achieving timely, equitable access to COVID-19 vaccines worldwide. One reason is that it is unclear whether a waiver would require companies to share proprietary knowledge and techniques that are essential to their cutting-edge vaccine development — it may simply give other nations breathing room to reverse-engineer the process without fear of litigation.

Indeed, last fall, Moderna pledged not to enforce the patents related to its vaccine during the pandemic, but that has not really changed the production landscape as a practical matter. Likewise, manufacturing the vaccines requires raw materials and manufacturing equipment, which may not be readily available in excess supply. The CEO of Pfizer, for example, explained last week that its vaccine requires 280 materials that Pfizer sources from 19 different countries around the world, and that the biggest

bottleneck to its own manufacturing is "the scarcity of highly specialized raw materials."

Nevertheless, in the U.S. vaccine supplies have exceeded demand in some parts of the country in recent weeks, with research indicating that we may have more than 300 million excess doses by the end of July. Pledges by the U.S. and other high-income nations to donate at least such excess doses of COVID-19 vaccines could be an effective short-term tool to bridge the gap to easier, widespread access worldwide.

TR: How will the waiver affect related drugs and other products?

KS: I think this remains to be seen. For example, the text-based negotiations before the WTO may include whether any temporary waiver of intellectual property rights will be limited to COVID-19 vaccines, as indicated by the Biden administration's statement, or will more broadly include all products that protect, contain and treat COVID-19, as originally proposed to the WTO by India and South Africa.

TR: Some have called President Biden's announcement a departure from the U.S. government's IP enforcement policies. In what ways is this true?

KS: In many ways, national intellectual property law regimes can have a direct impact on the balance between protecting public health and facilitating innovation and economic growth. Under ordinary circumstances, a successful, strong patent system can incentivize pharmaceutical companies and researchers to invest heavily in research and development to discover and produce life-saving medications. At the same time, however, patent rights afford drug companies a temporary monopoly over development and distribution, which can lead to higher prices and reduced access to life-saving medications, including vaccines, among other roadblocks.

Prior to the administration's statement last week, the U.S. had opposed the idea of a waiver before the WTO. So, in that sense, it is true that President Biden's announcement is a departure from prior policy. More broadly, the U.S. generally has not stepped in during the pandemic to suspend or mandate access to intellectual property. For example, several countries enacted emergency legislation to authorize broader compulsory patent licensing, which is permissible under TRIPS in the case of "national emergencies." Canada, for example, passed the COVID-19 Emergency Response Act, which facilitates compulsory licenses by creating an application procedure whereby, if the Minister of Health believes that there is a public health emergency that is a matter of national concern, i.e., the novel coronavirus, then the Commissioner of Patents may authorize the Canadian government to make, use and sell a patented invention. Also last year, Israel became the first country to put such authority into practice by issuing a compulsory license to permit the country to import a generic version of Kaletra, a combination of two antiviral medications that ordinarily is used to treat HIV, after concerns that the patent holder would not be able to adequately meet Israel's demand for the medication.

The U.S., though, did not follow suit. Rather, a bill introduced last year by Sen. Ben Sasse, R-Neb., that would have suspended the term of eligible patents during the pandemic and, in exchange, extend the term of such patents for an additional 10 years, did not gain traction. Likewise, although the Bayh-Dole Act gives the federal government what are called "march-in rights" if a company patents an invention with federal funding and does not make technology available for production, the government has yet to exercise such authority to license patent use — including during the global pandemic. Rather, here at home, high-profile efforts by IP holders, such as Moderna's prior patent pledge, have been voluntary.

TR: Will other countries follow the U.S. government's example and start waiving IP rights to COVID-19 vaccines or other medical treatments?

KS: It will be interesting to keep an eye on the extent to which other countries follow the example set by the Biden administration. Thus far, the response from other high-income nations has been mixed. In the European Union, for example, although Germany, where Pfizer's partner BioNTech is based, came out against the U.S. statement, other EU leaders, including Spain's prime minister, have signaled support.

Last week, the director of the World Health Organization urged other countries to follow suit. World leaders on both sides of the waiver debate have emphasized the importance of complementary action, including encouraging the U.S. to increase their export of COVID-19 vaccine doses to nonproducing countries and advocating for a scale-up of established production and distribution channels.

TR: What are some of the long-term ramifications from the U.S. government's policy objective?

KS: I have always been a believer in the classic economic theory behind robust intellectual property protection — the idea that a strong system (for example, patent protection) will incentivize private companies to make the necessary, significant investments in research and development and will attract the best and the brightest, resulting in cutting-edge technology that benefits society as a whole and increases public welfare.

At the same time, however, the pandemic has brought into focus that there is a lot of work to do in terms of the equitable distribution of such technology. One recent statistic found that 100 countries had vaccine doses by the end of February, but that 80% were concentrated in just 10 countries. If coupled

with a broader ramp-up of production and export of doses to developing countries, as well as assisting in quality control, I am hopeful that the administration can meet its objective of getting safe and effective vaccines to as many people as possible, while at the same time maintaining the important incentives that have been a cornerstone of groundbreaking innovation in the U.S.

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ABOUT THE AUTHOR

Karen Sebaski is counsel at New York-based litigation boutique **Holwell Shuster & Goldberg LLP**. She has represented clients such as AT&T, Sharp and T-Mobile in patent litigation. She can be reached at ksebaski@hsgllp.com.

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