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Patents and Coronavirus – The Research Exemption in the U.S.

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The recent COVID-19 coronavirus pandemic has raised numerous legal issues around the world. In this series of posts, Professor Jorge Contreras of the University of Utah (Salt Lake City, USA) discusses some of the patent and other intellectual property law implications arising from coronavirus and efforts to contain, diagnose and cure it.

As of March 20, 2020, one industry source catalogs no fewer than fifty different vaccines, diagnostics and treatments that are being developed and tested for the COVID-19 coronavirus around the world. Many of these technologies were originally targeted at other diseases including malaria, rheumatoid arthritis, hepatitis C, influenza, Marburg virus, Ebola, Middle East Respiratory Syndrome (MERS), severe acute respiratory syndrome (SARS), and human immunodeficiency virus (HIV). As a result, there is already a large body of scientific literature addressing many of the underlying compounds, and many are covered by existing patents and patent applications (collectively "patents"). One recent study by the American Chemical Society identified over 2,000 patents relating to SARS and MERS treatments alone. These patents are held by a range of companies and institutions across North America, Asia and Europe. In addition to these, a large number of patents cover the manufacture, operation and components of devices and equipment that are used to treat the symptoms of coronavirus, and to monitor and prevent its spread, including respirators, ventilators, diagnostic kits, facial masks, software, mobile apps, and the like.

Given the existing patent holdings in this field, it is worth asking what effect these patents, and new ones that are doubtless being filed week by week, may have on the latest research relating to coronavirus vaccines, diagnostics and treatments. In the U.S., the so-called "research exemption" to patent infringement (sometimes referred to as the experimental use defense) originated in the venerable 1813 case *Whittmore v. Cutter*, in which Justice Story wrote that a patent on a machine could not be infringed by a person who constructed the machine "merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." Over the years, the scope of this exemption has waxed and waned (see Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA 123 (2007)). Today, the research

exemption in the U.S. is largely defined by the Federal Circuit's 2004 decision in *Madey v. Duke*, which limits its protection to activities conducted "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Notably, the court in *Madey* held that most research projects at universities like Duke do not qualify as non-commercial, as they "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects[,] increase the status of the institution and lure lucrative research grants, students and faculty." Accordingly, few, if any, research activities conducted at universities or companies today would likely qualify for this exemption from patent infringement.

A second U.S. research exemption, however, arises under the 1984 Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch–Waxman Act), which provides mechanisms for the introduction of generic drug competition once the patents on an FDA-approved drug have expired. In particular, 35 U.S.C. § 271(e)(1) provides that:

"It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

This provision creates a narrow safe harbor for research and experimentation with drugs (including medical devices) that are conducted in anticipation of an application for FDA approval. The provision was created in order to allow generic drug manufacturers to begin testing their products during the last years of a drug patent's life without infringing that patent, but it has been expanded through judicial interpretation to encompass a wide variety of drug-related R&D activity. Thus, in *Merck v. Integra* (2005), the Supreme Court indicated that, in addition to clinical trials, pre-clinical testing of drug candidates – even candidates that are eventually rejected — may be protected under the § 271(e)(1) safe harbor. Justice Scalia, writing for the Court, explained that the statute gives "wide berth for the use of patented drugs in activities related to the federal regulatory process." (For a good discussion, see Alicia A. Russo & Jason Johnson, Research Use Exemptions to Patent Infringement for Drug Discovery and Development in the United States, 2015 Cold Spring Harbor Perspectives in Med. 5:a020933 (2015)).

What does this all mean for coronavirus research in the U.S.? First, the Hatch-Waxman safe harbor under § 271(e)(1) could protect a significant swath of R&D relating to diagnostics, vaccines and therapeutics, so long as the resulting information might eventually be submitted to the FDA for approval. Second, to the extent that FDA approval is not required for the manufacture or sale of certain technologies (e.g., modifications to approved ventilator devices, laboratory-developed diagnostic tests, software apps, etc.), this may be an opportunity for the courts, and the Federal Circuit in particular, to re-think the narrow definition of the general research exemption along the lines of the Supreme Court's more expansive interpretation of § 271(e)(1).

Of course, the research exemption and § 271(e)(1) safe harbor relate only to *research*, and not to the commercial manufacture, sale or importation of coronavirus-related technologies. Manufacturers will also need to contend with patents in order to bring their products to the public. This, however, is a separate topic that will be addressed in a later post.

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