

SJ Quinney College of Law, University of Utah

Utah Law Digital Commons

Utah Law Faculty Scholarship

Utah Law Scholarship

4-2020

Research And Repair: Expanding Exceptions To Patent Infringement In Response to a Pandemic

Jorge L. Contreras

Follow this and additional works at: <https://dc.law.utah.edu/scholarship>



Part of the Intellectual Property Law Commons

RESEARCH AND REPAIR: EXPANDING EXCEPTIONS TO PATENT INFRINGEMENT IN RESPONSE TO A PANDEMIC

Jorge L. Contreras¹

Draft 27 Apr. 2020

While public health emergencies such as the recent COVID-19 coronavirus pandemic strain resources, burden the economy and cause significant human suffering, they also provide opportunities to revisit established legal doctrines and consider them in a fresh light. This phenomenon is as true in patent law as it is in many other areas of law.² Commentators have been quick to observe the many intersections between patent law and the coronavirus pandemic, often in connection with longstanding complaints and criticisms of the system.³ This essay does not attempt to address every patent law issue raised by the coronavirus pandemic, of which there are many. Rather, it focuses on two discrete areas of patent law through the lens of the current crisis and considers how we might adjust existing doctrine knowing what we know today.

The doctrinal areas on which this essay focuses are two longstanding but narrow exemptions from patent infringement: one that permits scientific research, and one that permits the owner of a patented device to repair it. Though distinct at first glance, both of these doctrines act to permit activity that would otherwise be considered patent infringement. They are *exceptions* to the exclusivity that the law grants to patent holders – particularly the right to “make” a patented article and, to

¹ Presidential Scholar and Professor of Law, University of Utah S.J. Quinney College of Law, Adjunct Professor, Department of Human Genetics, University of Utah School of Medicine. Several of the concepts in this essay are based on a series of blog posts written by the author for Infojustice.org sponsored by American University Washington College of Law. The author thanks Sean Flynn for the inspiration to undertake this project.

² See, generally, Andrew W. Torrance, *Patents to the Rescue – Disasters and Patent Law*, 1 DEPAUL J. HEALTH L. 309 (2007).

³ See, e.g., Valerie Bauman, *Covid-19 Spotlights Ruling’s Chilling Effect on Diagnostic Tests*, BLOOMBERG LAW NEWS, Mar. 23, 2020 (quoting attorneys blaming the Supreme Court’s decision in *Mayo v. Prometheus*, 566 U.S. 66 (2012), for shortages of reliable coronavirus diagnostic tests in private practice); Editorial, *In the fight against the coronavirus outbreak, life sciences companies need certainty in 101*, IAM BLOG, Mar. 23, 2020, <https://www.iam-media.com/law-policy/they-focus-fighting-the-coronavirus-outbreak-now-more-ever-life-sciences-companies> (“The COVID-19 R&D surge seeking the rapid discovery and commercialisation of diagnostics, therapeutics, vaccines and cures for the present threat will lay the groundwork for a remarkable range of scientific knowledge and potential commercial and clinical applications. The extent to which these promising prospects turn into new products, new businesses and new jobs depends in significant part on restored certainty and breadth of the patentable subject matter”).

a lesser degree, to “use” it, and for this reason they are particularly salient when patents may impact critical lifesaving technologies.

This essay recommends broadening the scope of the research exemption to cover a larger range of research activities conducted prior to the release of a commercial product; and recognizing the right of an owner of a patented product to make, or have made, replacement parts for that product, even if those parts may be covered by the claims of a patent or cross the line of “reconstruction” under current law. The implementation of these adjustments, conceived in light of the current coronavirus pandemic, could facilitate increased research, development and use of patented technologies and better prepare the U.S. to deal with the next great public health crisis.

I. THE RESEARCH EXEMPTION

In the U.S., the so-called “research exemption” to patent infringement (sometimes referred to as the experimental use defense⁴) originated in the venerable 1813 case *Whittmore v. Cutter*,⁵ in which Justice Joseph Story, sitting by designation, wrote that a patent on a machine is not infringed by someone who constructs the machine “merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.” In effect, Justice Story evokes the gentleman tinkerer -- the Enlightenment natural philosopher who, rather than hunting or riding, amuses himself with homemade scientific experiments, and sometimes chances upon an important discovery.⁶

Over the years, the scope of this exemption has waxed and waned, often reaching well beyond the idea of the gentleman tinkerer to encompass most experimental activity conducted by universities and non-profit research institutions.⁷ By the end of the twentieth century, there was a general understanding that most academic research, unless expressly conducted under contract for a commercial entity, would be immunized from patent infringement under the research exemption.

But in 2002, the research exemption in the U.S. experienced a significant contraction. In *Madey v. Duke*,⁸ Duke University continued to use experimental laser equipment developed by Dr. John Madey, a former Duke researcher who held

⁴ Despite its use by both courts and commentators, I avoid the term “experimental use” to avoid confusion with another patent law doctrine, the experimental use exception to the public use bar to patentability under 35 U.S.C. § 102(b).

⁵ 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

⁶ See, e.g., JENNY UGLOW, *THE LUNAR MEN: FIVE FRIENDS WHOSE CURIOSITY CHANGED THE WORLD* (2002) (discussing Matthew Boulton, James Watt, Josiah Wedgwood, Erasmus Darwin and Joseph Priestly).

⁷ See Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA 123 (2007).

⁸ 307 F.3d 1351 (Fed Cir 2002).

EXCEPTIONS TO INFRINGEMENT

patents covering the equipment.⁹ Dr. Madey sued Duke for infringement, but the district court granted summary judgment in favor of Duke. In so doing, it held that Madey failed to raise any genuine issue of material fact that would tend to refute the application of the research exemption to Duke, an institution whose “primary purpose is to teach, research and expand knowledge.”¹⁰ Madey’s burden, in the view of the district court, was to prove that Duke’s use of the patented equipment had “had definite, cognizable, and not insubstantial commercial purposes.”¹¹

The Federal Circuit disagreed. First, it held that the burden of proof in case of the research exemption was not the patent holder’s, but the alleged infringer’s. In order to be excused from infringement under the research exemption, Duke had to show that its activities were conducted “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”¹² Under this standard, most research projects at Duke would not qualify under the research exemption, 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.”¹³ Accordingly, few, if any, research activities conducted at universities today, even if they are not specifically funded by the private sector, would qualify for this exemption from patent infringement.¹⁴ And by extension, it is probably safe to say that virtually no research conducted in the private sector would have the benefit of this exemption.

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),¹⁵ which provides mechanisms for the introduction of generic drug competition once the patents on an FDA-approved drug have expired. In particular, § 271(e)(1) of the Act 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

⁹ The facts of this case are atypical in that Dr. Madey, rather than the university that employed him, owned the patents in question. This situation arose from an arrangement between Dr. Madey and his prior employer, Stanford University. 307 F.3d at 1352.

¹⁰ 266 F. Supp.2d 420, 426 (M.D.N.C.2001).

¹¹ *Id.* at 425.

¹² 307 F.3d at 1362

¹³ *Id.*

¹⁴ One commentator wryly observed that the decision “cabined the (common law) experimental use exemption to activities akin to the Victorian practice of observing with crude microscopes rotifers in a drop of pond water as an after-dinner amusement amongst gentlemen.” Kevin Noonan, *A Glimmer of an Idea on an Experimental Use Exemption*, PATENT DOCS BLOG, Nov. 7, 2018, <https://www.patentdocs.org/2018/11/a-glimmer-of-an-idea-on-an-experimental-use-exemption.html>.

¹⁵ Public Law 98-417, codified at 21 U.S.C. § 301 et seq.

EXCEPTIONS TO INFRINGEMENT

which regulates the manufacture, use, or sale of drugs or veterinary biological products.¹⁶

This provision creates a safe harbor for research and experimentation with drugs (including medical devices) 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*,¹⁷ 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.”¹⁸

What does this mean for coronavirus and other urgent biomedical 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. Second, to the extent that FDA approval is *not* required for the manufacture or sale of certain technologies (e.g., approved drugs and devices that have already received FDA approval,¹⁹ laboratory-developed diagnostic tests,²⁰ mobile software apps,²¹ etc.), this may be an opportunity for the courts, and the Federal Circuit in particular, to re-think the narrow formulation of the research exemption as currently stated in *Madey v. Duke* along the lines of the Supreme Court's more expansive interpretation of § 271(e)(1).²² That is, research activities should be immunized from patent infringement to the extent that they do not involve the manufacture of products for commercial sale or their use in a commercial setting. Pure research, even if conducted with a commercial goal in mind, should qualify under the research exemption.²³

¹⁶ 35 U.S.C. § 271(e)(1).

¹⁷ *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

¹⁸ *Id.* at x. 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).

¹⁹ U.S. Food & Drug Admin., Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency - Guidance for Industry and Food and Drug Administration Staff (Mar. 2020).

²⁰ See Jonathan R Genzen, *Regulation of Laboratory-Developed Tests: A Clinical Laboratory Perspective*, 152 AM. J. CLINICAL PATHOLOGY 122 (2019).

²¹ U.S. Food & Drug Admin., Policy for Device Software Functions and Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff (Sept. 2019).

²² Another route to expansion of the research exemption might be statutory. See Noonan, *supra* note 14 (proposing an amendment to the Bayh-Dole Act to permit academic researchers to experiment with patented inventions made using federal funding).

²³ One ancillary result of expanding the research exemption in this manner could be the reduction of so-called reach-through royalties imposed by the holders of patents covering research tools. That is, if researchers are not required to enter into patent license agreements in order to practice certain research techniques (e.g., PCR, CRISPR, etc.), then the holders of patents on those

II. RIGHT TO REPAIR

In March, 2020, two engineers in Brescia, Italy used a desktop 3D printer to fabricate replacement valves for more than 100 ventilator machines being used to treat coronavirus patients at a local hospital.²⁴ There is some debate about what happened next, but early news reports indicated that a parts manufacturer threatened to sue the engineers for infringing patents on the replacement valve.²⁵ While the existence of the threat and the patents themselves remains murky, the incident sparked a flurry of legal commentary regarding the risk that volunteers fabricating parts for lifesaving devices, and the hospitals that use them, could be liable for patent infringement.²⁶

Under U.S. law, the owner of a patented device has the right to repair that device so as to preserve its useful life.²⁷ The recognition of this ‘right to repair’ can be traced to the 1850 Supreme Court decision in *Wilson v. Simpson*,²⁸ in which the Court “distinguished the right of a purchaser of a patented planing machine to replace the machine's cutting-knives when they became dull or broken, from the patentee's sole right to make or renew the entire machine.”²⁹ The right to repair concept has been recognized in numerous recent cases, including some relating to medical devices.³⁰

techniques will lack a contractual vehicle with which to impose royalties on revenue generated by downstream users of discoveries made using such research tools. *See, generally*, Alfred C. Server, Nader Mousavi & Jane M. Love, *Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools*, 1 *Hastings Sci. & Tech. L.J.* 21 (2009).

²⁴ Cristian Fracassi & Alessandro Romaioli, *We Made Copies of Ventilator Parts to Help Hospitals Fight Coronavirus*, N.Y. TIMES, Mar. 22, 2020.

²⁵ Jay Peters, *Volunteers produce 3D-printed valves for life-saving coronavirus treatments*, VERGE (Mar 17, 2020, updated Mar., 18 2020), <https://www.theverge.com/2020/3/17/21184308/coronavirus-italy-medical-3d-print-valves-treatments> (one person involved recounted, “Let’s say the risk to be sued exists since they bypassed a patent.”)

²⁶ *See* Lucas Osborn, *3D Printing, Patent Infringement, and the Coronavirus*, PATENTLY-O BLOG, Mar. 19, 2020, <https://patentlyo.com/patent/2020/03/printing-infringement-coronavirus.html>. There are numerous other issues arising from unauthorized attempts to repair medical equipment, including ventilators. These include tight manufacturer controls on copyrighted service manuals and locked control software. *See* Jason Koebler, *Hospitals Need to Repair Ventilators. Manufacturers Are Making That Impossible*. Vice.com, Mar. 18, 2020, https://www.vice.com/en_us/article/wxekgx/hospitals-need-to-repair-ventilators-manufacturers-are-making-that-impossible. These issues are beyond the scope of this article.

²⁷ *See* *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094, 1102 (Fed. Cir. 2001).

²⁸ 50 U.S. (9 How.) 109 (1850).

²⁹ *Id.* at 123.

³⁰ *See, e.g.*, *Kendall Co. v. Progressive Med. Tech., Inc.*, 85 F.3d 1570 (Fed. Cir. 1996) (permitting replacement of pressure sleeve in a patented medical device as “repair”).

However, the right to repair does not permit the owner of a patented device to ‘reconstruct’ that device in whole or in substantial part.³¹ Reconstruction, as opposed to mere repair, represents a “second creation of the patented entity” and thus infringes the exclusive right of the patent holder to “make” the device.³² In distinguishing between permitted repair and prohibited reconstruction, courts must consider and weigh “the remaining useful capacity of the article, and the nature and role of the replaced parts in achieving that useful capacity.”³³ Thus, if the owner of a patented device creates new patented parts to extend the life of the device beyond its anticipated lifespan, this would likely constitute impermissible reconstruction, whereas if the owner simply fixes a defect in an existing part, or replaces it with an unpatented part, during the normal lifetime of the device, this would likely constitute permissible repair.

What, then, about 3D printed replacement valves for ventilator devices? 3D printing technology gives consumers an inexpensive way to fabricate replacement parts for complex mechanical devices that were previously available only from specialized manufacturers.³⁴ Should it matter that a particular ventilator is past the end of its normal product lifespan, or that the design of the valve in question is covered by the claims of a patent? The implications of 3D printing technology on the patent law right of repair have been recognized in the literature for some time.³⁵ Yet these discussions have been largely hypothetical. With the emergence of coronavirus and the sudden surge in global demand for ventilators and other medical equipment, the doctrine is likely to receive renewed attention. This is particularly the case if replacement parts made using 3D printing technology are themselves covered by patent claims (as may have been the case with the Italian ventilator parts discussed above).

In an effort to reduce household waste, in 2019 the European Union adopted “right to repair” regulations for a number of appliances including televisions, washing machines, dishwashers and refrigerators.³⁶ The regulations require that

³¹ See *Sandvik Aktiebolag v. E.J. Co.*, 121 F.3d 669 (Fed. Cir. 1997) (making a new drill bit to replace a patented bit that could no longer be sharpened and reused constituted an infringing reconstruction of the patented article); *Lummus Indus., Inc. v. D.M. E. Corp.*, 862 F.2d 267 (Fed. Cir. 1988) (finding that fabrication of new cutter wheels that formed a material part of the patented invention was reconstruction).

³² *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961).

³³ *Jazz Photo*, 264 F.3d at 1106.

³⁴ News reports claim that the ventilator valves fabricated in Italy for a cost of about 1 Euro each were previously sold by the manufacturer for 10,000 Euro each. Peters, *supra* note 25.

³⁵ See, e.g., Kelsey B. Wilbanks, *The Challenges Of 3D Printing to the Repair-Reconstruction Doctrine In Patent Law*, 20 GEO. MASON L. REV. 1147 (2013), Tesh W. Dagne & Gosia Piasecka, *The Right to Repair Doctrine and the Use of 3D Printing Technology in Canadian Patent Law*, 14 CANADIAN J. L. & TECH. (2016), Marc D Mimler, *3D printing and patent law – a UK perspective: apt and ready?* in 3D PRINTING AND BEYOND - INTELLECTUAL PROPERTY AND REGULATION, at Ch. 5 (Dinusha Mendis, Mark A. Lemley & Matthew Rimmer, Eds., 2019).

³⁶ Eur. Comm’n, Regulation laying down ecodesign requirements 1 October 2019, https://ec.europa.eu/energy/topics/energy-efficiency/energy-label-and-ecodesign/regulation-laying-down-ecodesign-requirements-1-october-2019_en?redir=1.

EXCEPTIONS TO INFRINGEMENT

manufacturers make spare parts for these appliances available for installation by independent service providers for at least ten years following the date of purchase. The EU has recently considered expanding this regulation to smartphones and other electronic equipment.³⁷ Similar legislation has recently been proposed in the U.S. state of Maryland.³⁸ But like the EU rules, these do not address the patent law issues arising from the fabrication of new parts by 3D printing or otherwise.

Two Canadian authors, anticipating some of these issues, have argued for an expansion of the repair right under Canadian patent law (which is similar in this respect to U.S. law), proposing that

a consumer should be granted an all-encompassing legal right to repair and modify patent-protected items given three conditions: (1) the consumer legally purchased the original good; (2) the consumer uses the repaired or modified item for private purposes; and (3) the consumer gains no financial benefit from posting the repair or modification online for others.³⁹

This proposal is sweeping in scope, permitting all consumers to repair and modify patented articles for their personal use, no matter how extensive those repairs or modifications might be.⁴⁰

Whatever the merits of this proposal, addressing the issues raised by coronavirus need not go so far. Thus, an alternative, more modest, proposal might be to expand the patent law right to repair to permit the fabrication of replacement parts for patented articles to address pressing public health needs. Consideration of public health needs in fashioning an exemption from patent infringement resonates with the “public interest” factor that is considered by courts when deciding whether to issue a permanent injunction against a patent infringer.⁴¹ The expansion of the repair right proposed in this article would stop short of eliminating a patent holder’s ability to enforce its rights against all consumers, but would at least permit the owners and users of patented equipment (including hospitals, suppliers, first

³⁷ See Roger Harrabin, *EU brings in 'right to repair' rules for appliances*, BBC News, Oct. 1, 2019, <https://www.bbc.com/news/business-49884827>.

³⁸ Matthew Gault, *Maryland Suddenly Looks Like it Might Break John Deere's Repair Monopoly*, Vice.com, Mar. 12, 2020, https://www.vice.com/en_us/article/k7ekzw/maryland-suddenly-looks-like-it-might-break-john-deeres-repair-monopoly.

³⁹ Dagne & Piasecka, *supra* note 35, at 264.

⁴⁰ Expanding the scope of patent repair rights for consumer users of patented articles has been raised beyond the context of 3D printing in broader discussions of user innovation. *See, e.g.*, Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 UC IRVINE L. REV. 265, 284-85 (2011).

⁴¹ *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (establishing four-factor test for issuance of injunctions in patent infringement cases, including one factor addressing the public interest).

EXCEPTIONS TO INFRINGEMENT

responders, relief organizations and volunteers) to eliminate this threat during the coronavirus crisis.

CONCLUSION

The two exceptions to patent infringement discussed in this essay – the research exemption and the right to repair – are each implicated in the coronavirus pandemic. Expanding these time-worn doctrines to address the urgent needs of the healthcare and biomedical sectors today could contribute to ending the current crisis and preparing for the next such crisis to emerge.