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Pandemics and the Need for U.S. Patent Laws That 'Promote … Progress' and Invention: The Federal Circuit, *En Banc*, Can Fix This

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"Given the expanding uncertainty with the case law on U.S. patents—and whether, for example, they'll protect the subject matter of a million (or even billion) dollar investment—U.S. investment in R&D has dropped. And

perhaps most notably, it has dropped among innovative bio-pharmaceutical companies."

The COVID-19 crisis has once more highlighted the need for incentivizing investment and innovation—and thus, for patent laws that duly "promote" and protect such "progress," precisely as our Founders envisioned. *See* U.S. Const., Art. I., § 8, cl. 8. Indeed, those patent-based incentives over the years have helped produce life-saving medicines, tests, treatments, and cures; once-unimaginable computer technology, robotics, and nanotechnology; LASIK eye-surgery and cochlear implants; personal satellite-based navigation systems; handheld devices seemingly straight out of Star Trek; 3-D printer technology; and much, much more. Nevertheless, a series of judicial rulings over the past 15 years have steadily eroded U.S. patent protections. Consequently, once-innovative companies, including major innovative pharmaceutical companies, have divested in R&D, and investors more generally have diverted funding to non-inventive areas (like entertainment) or to countries (like China) whose patent laws offer protections more favorable than U.S. law. American innovation has fallen accordingly.

The Federal Circuit, specially created to serve as the patent law's good steward, will have sound opportunities to fix this. And to fix it in a way that properly honors and serves the patent laws and Congress's clear purpose. Otherwise, over the last few weeks alone, media accounts have repeatedly reported on the innovative shortcomings evident in the COVID-19 response. These included, for example, a cited need for better diagnostic tests. Just last summer, however, the Federal Circuit undercut incentives to invent in this field when it once again declined *en-banc* review of a ruling that U.S. patent protections do ***not*** extend to medical-diagnostic test kits and methods. *See* *Athena Diagnostics, Inc. v. Mayo Collaborative Servs, LLC*, 927 F.3d 1333 (Fed. Cir. 2019). The Supreme Court recently declined review of this patent-eligibility issue as well, notwithstanding that the full Federal Circuit in *Athena* had issued ***eight*** separate opinions—each of which requested Court intervention. *Id*. Yet, in denying *certiorari*, the Court all

but announced it was turning the patent-law reins back over to the Federal Circuit.

Will the court take them? In addressing that question, we first review the COVID-19 crisis amid the U.S. patent law's current jurisprudence and its negative effects on R&D investment and innovation. In so doing, we show how Congress, to the contrary, designed the Patent Act to promote such investment and innovation, including with respect to its provisions on eligibility and invalidity, *see, e.g.*, 35 U.S.C. §§ 101 & 103. Indeed, Congress later created the Federal Circuit for essentially this same reason, consistent with the Framers' purpose of authorizing patent laws that "liberally encourage[]" innovation. Thereafter, however, we address the Federal Circuit's recent decisions that have further weakened U.S. patent rights—including decisions on the "presumption-of-nexus" in obviousness cases and on indefiniteness. Last, we address the *en-banc* petition pending before the Federal Circuit in *AAM, Inc. v. Neapco Holdings*, expressing hope that the court will grant this petition and use it to properly clarify the court's Section 101 case law. Perhaps now more than ever, the laws addressed to investment and innovation—and to the economic and technological strength they promote—must be properly interpreted.

The Status Quo Must Not Continue

Needless to say, no one involved in U.S. patent law or policy wants the pandemic or its multi-faceted consequences. Nor would a contrary ruling in *Athena, supra,* have meant that an innovator would have had at the ready the desired diagnostic testing for coronavirus. Nor a ready-made or known treatment, cure or vaccine. That said, the famous Burkean wisdom ***of course*** applies here. To paraphrase, "evil" or horrendous things can prevail if good people stand by and do nothing—and allowing bad precedents to go uncorrected has consequences.

Unfortunately, we are seeing those consequences play out with U.S. patent law in real time. For nearly 15 years, the Supreme Court's IP opinions that have had the effect of de-valuing U.S. patent rights, making it increasingly difficult (for

example) for U.S. intellectual-property owners to obtain injunctive relief against those who infringe, trespass on, or otherwise steal their patented ideas and property rights. *See, e.g., eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). (By contrast, the patent laws of China have made such injunctive relief available as a matter of course, with some reporting that prevailing patentees there obtain injunctions for nearly 90% of all requests.) And through the years, whether by Supreme Court precedent or other law-making, it has become increasingly easy to invalidate U.S. patents, *see, e.g., KSR Int'l Co. v. Teleflex, Inc.*, 550 US 398, 415 (2007), and to render the subject matter of a patent ineligible for protection under §101. (We do not tackle here the separate pitfalls created by the 2011 America Invents Act.) This includes ineligibility not just for diagnostic testing, but for software, business methods, and quite possibly ***anything*** else in a patent claim that can be subjectively deemed ***"directed to"*** an "abstract idea, law of nature, or natural phenomena"; and doesn't reflect an "inventive concept," per the Supreme Court's *Mayo-Alice* "framework" for Section101.

To be sure, this is ***not*** an article focused on Supreme Court Section101 precedent and the harms to innovation that it has wrought, though that has certainly played a major or even primary role in the harm to U.S. innovation. (And indeed, the proper analysis of that Section 101 precedent is a subject that warrants separate, in-depth treatment.) The larger point here is that, given the expanding uncertainty with the case law on U.S. patents—and whether, for example, they'll protect the subject matter of a million- (or even billion-) dollar investment—U.S. investment in R&D has dropped. And perhaps most notably, it has dropped among innovative bio-pharmaceutical companies. *See, e.g., Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, by Christopher M. Holman, 76 Mo. L. Rev. 645, 663-64 (summer 2015) ("In recent years, major innovative pharmaceutical companies have experienced two pronounced and significant trends: a decreasing output of innovative new drugs and cutbacks in research and development (R&D) investment"). And innovation—the lifeblood of the American economy—has dropped with it. *See, e.g.*, *id.* (explaining that the "high level of unpredictability in today's patent law is a significant impediment to the development of new medicines" and cause of the "R&D crisis"); Bloomberg

Innovation Index (2018); *The U.S. Drops out of the Top 10 in Innovation Ranking*, Bloomberg News (Jan. 22, 2018), by Michelle Jamrisko & Wei Lu, available at (visited March 28, 2020).

The U.S. Patent Laws "Liberal[ly]" Promote Investment-and-Innovation—*and* an Active Federal Circuit to Properly Interpret and Apply Those Laws

The Federal Circuit can fix this. And it can do so in a way that serves the text and goals of the Patent Act, and the legislation that created the court itself. Indeed, these sources of law reflect the American Constitution from which they emanate. Our Framers, so cognizant of history and of what had worked and failed in centuries past, were genius enough to repose in Congress the power to create such an innovation-promoting patent system. And for much of our history, that inventive spirit, fostered by our system of robust IP protection and free-market ingenuity, helped make America the most prosperous and powerful nation on earth. *See, e.g.*, Max Roser (2020), "Economic Growth". *Published online at OurWorldInData.org.*

And when we've had dips and confusion in the patent law—when courts across the country were applying different invalidity tests ("flash of genius!"), for example, and undermining patent rights—Congress responded. In 1952, it enacted the Patent Act that we more or less know today. Notable there was Congress's ongoing emphasis that the Act extended eligibility for U.S. patent protection to ***"[a]nything under the sun that is made by man."*** *See, e.g., Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citations omitted) (emphasis added). Congress thus put the law's focus on the provisions that address whether an invention is indeed inventive, i.e., whether it is new, useful, non-obvious, and meets the Act's disclosure and claiming requirements. *See, e.g., id.* As the Supreme Court has explained, the Act's "broad" statutory language adheres to the Founders' vision for "liberal[ly]" encouraging "ingenuity":

The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, 1, 1 Stat. 319. The ***Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement."*** *5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). See Graham v. John Deere Co., 383 U.S. 1, 7 -10 (1966). Subsequent patent statutes in 1836, 1870 and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).*

E.g., id. at 308-09 (holding that a live, human-made micro-organism was eligible for patent protection under §101) (emphases added); *see also* Diamond v. Diehr, 450 U.S. 175, 184-88 (1981) (holding that a multi-step process that used a computer and other "conventional" steps to cure rubber was patent-eligible under §101). For nearly 30 years, these 1980-1981 Supreme Court cases stood as the last word on §101, bridging a period that oversaw so much of the remarkable innovation described above, as well as prolonged U.S. economic growth. And that made sense: The §101 text itself, after all, has remained unchanged.

As to invalidity, Congress adopted the Act's provision on non-obviousness, 35 U.S.C. §103, to ensure that courts did ***not*** require a "flash of genius" moment in order to qualify as inventive or patentable. Rather, the provision made plain that a slow-and-steady analysis leading to the inventive solution could just as well merit patent protection. *See* 35 U.S.C. § 103, 66 Stat. 798 (July 19, 1952) (mandating that "[p]atentability shall not be negated by the manner in which the invention was made"). Even more, Congress created the Federal Circuit, precisely because it wanted a single court to "bring consistency to the patent field" and to "reinvigorate the patent and introduce predictability to the field." *E.g.,* Phillips v. AWH Corp., 415 F.3d 1303, 1330 (Fed. Cir. 2005) (*en banc*) (Mayer, J., dissenting); H.R. Rep. No. 312, 97th Cong., 1st Sess. 20-23 (1981).

Accordingly, the court has both statutory charter and authority to clarify—or to reverse via *en-banc* review—its perceived "anti-patent" rulings of recent years. In that way, an active *en-banc* Federal Circuit would be interpreting and applying the patent laws consistent with their foundation as the "liberally encouraged" driver of investment-and-innovation—the foundation that Congress, the Constitution and the Founders envisioned from the start. *See, e.g.*, *Diamond v. Chakrabarty, supra.* Indeed, that is the main point for having a patent system. *See* U.S. Const., Art. I, §8, cl. 8.

The Federal Circuit's *En-Banc* Denials Continue to Diminish U.S. Patents and Inventiveness

Nevertheless, as the current COVID-19 crisis has continued, so too have the court's *en-banc* denials on decisions that have once more weakened U.S. patent rights and innovation. That is, by ***not*** revising overreach in panel rulings, these *en-banc* decisions have put the capstone on a weakened U.S. patent law and system.

For example, as to obviousness and the often-critical "objective" evidence supporting a patent's validity, the Federal Circuit has long required a nexus between the patent's claim and the evidence pertaining (for example) to the patented product's commercial success. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd*., 851 F.2d 1387, 1392 (Fed. Cir. 1988). But the case law also recognized a "presumption-of-nexus," depending on (1) the patentee's showing that its patent claim's features were present in the commercial product; and (2) whether the accused infringer could rebut this *prima facie* presumption by showing that something other than the claimed invention—such as additional, unclaimed features or marketing—accounted for the product's success. *E.g., id*. at 393-94. Further, and for at least 30-plus years, this patentee evidence for the presumption could alone suffice. That is, the patentee ***could*** still obtain this nexus-presumption even if (for example) the claimed product had "additional, unclaimed features." *E.g.*, *PPC Broadband, Inc. v. Corning Optical Comm'ns RF, LLC*, 815 F.3d 734, 747 (Fed. Cir. 2016) (reversing finding that the nexus-presumption

was inapplicable; "[b]ecause the evidence shows that the SignalTight connectors are 'the invention … claimed in the patent,' ***we presume that any commercial success of these products is due to the patented invention. This is true even when the product has additional, unclaimed features."***) (citation omitted) (emphasis added); *Ecolochem, Inc. v. S. Cal. Edison Co*., 227 F.3d 1361, 1378 (Fed. Cir. 2000) (applying nexus-presumption even though commercial product had additional, unclaimed mobility feature); *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (presumption applicable even when product has additional, unclaimed features).

But that has now changed. In *Fox Factory, Inc. v. SRAM*, *LLC*, a Federal Circuit panel substantially tightened the requirements for obtaining this presumption, holding for the first time that the claim and its commercial product must indeed prove "essentially" identical, ***with no additional unclaimed features*** between them. *See* 944 F.3d 1366, 1374 (Fed. Cir. Dec. 18, 2019) (admittedly establishing this "unclaimed features" requirement for the first time and thereafter assessing whether the additional, unclaimed feature was "significant"). Judge Michel filed an amicus brief supporting *en-banc* review. Nonetheless, despite decades of precedent to the contrary, *see, e.g.*, *PPC Broadband; Ecolochem; J.T. Eaton, supra,* the Federal Circuit declined the *en banc* request. Likewise, it has allowed other recent panel decisions to stand when those decisions have also made it easier to invalidate U.S. patents. In *HZNP Finance Ltd. v. Actavis Labs, Inc.*, for example, the court again declined *en-banc* review for a decision that held certain composition claims indefinite, even when those claims used the well-established transitional phrase "comprising essentially of …." –F.3d–, Nos. 2017-2149, 2017-2152, 2017-2202 (Fed. Cir. Feb. 25, 2020). Notably, four judges there voted for *en-banc* review, joining Judge Lourie's dissenting (and well-reasoned) opinion.

A Time for Action—*En Banc* Action

Will this jurisprudence of shrinking U.S. patent rights end? One hopes as much, especially given concerns with encouraging innovation, maintaining competitiveness, and timely inventing the technology, vaccines, cures or

treatments so vitally needed now, whether for pandemics or in any field of human endeavor "under the sun."

And there is reason for hope. Pending before the court is an *en-banc* petition in *AAM, Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. Oct. 3, 2019), the panel decision for which extended §101 ineligibility to subject matter that seems entirely concrete and physical—namely, to an industrial process for making certain physical auto-parts ("drive shafts"). *Id*. The case has drawn substantial interest and prompted several *amici* filings (including Judge Michel's) that have also supported *en-banc* review. And with good reason: The panel's *AAM* decision, after all, would subject seemingly ***any*** technology to a §101-ineligibility attack, and would thereby expand the reach of an ***ineligibility*** test based on a provision that Congress cited as a basis for ***promoting*** inventiveness—indeed, as expanding U.S. patent protection to "anything under the sun that is made by man."

AAM v. Neapco thus presents the *en-banc* Federal Circuit with the opportunity to properly fix, clarify or cabin its erroneous §101 rulings. We surely will face crises like COVID-19 again, to say nothing of the ongoing challenges with American competitiveness in the world marketplace and the growth of the U.S. economy and employment—all matters of grave importance. The question is whether the Federal Circuit will now cure its rulings that have hobbled U.S. innovation and once again "promote … progress" and invention.