No. 12-398

IN THE
Supreme Court of the United States

ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,
Petitioners,
v.
MYRIAD GENETICS, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE PHILADELPHIA INTELLECTUAL PROPERTY LAW ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENT MYRIAD GENETICS, INC.

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Philadelphia Intellectual Property Law Association ("PIPLA") is a voluntary membership, non-profit organization of intellectual property law professionals and law student affiliates living or practicing within the geographical area of the Third Judicial Circuit. Among its purposes, the Association seeks to promote high standards of professional ethics, relationships and competency among its members, to enhance knowledge of intellectual property law and to enhance the development and administration of intellectual property law.[1]

In the record of this case and in much of the public discussion of the case, a great deal of emphasis has been placed on the alleged inhibition of research by the patents at issue. These issues concern PIPLA because they are often fodder for criticism of the patent system. Accordingly, PIPLA submits this brief to explain (i) why these allegations, and the evidence adduced to support those allegations, are misleading and, for the most part, irrelevant, and should therefore be disregarded, and (ii) why these allegations are exacerbated by the current state of case law surrounding the classic judicially created experimental use exception to patent infringement.

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[1] Pursuant to this Court's Rule 37.6, we note that no counsel for any party authored this brief, in whole or in part, nor did anyone other than the Philadelphia Intellectual Property Law Association and its counsel make any contribution, monetary or otherwise, to fund the preparation or submission of this brief. Petitioners have lodged a blanket consent to the filing of amicus briefs and a letter of consent from Respondents to the filing of this brief has been lodged with the Clerk of the Court.

STATEMENT OF THE CASE

The court has directed the parties to address a specific question. Effectively, that question is: assuming other conditions of patentability, such as novelty, non-obviousness, enablement and adequacy of claims, are met, can a human gene, isolated from its native environment, be patented? In this brief, the PIPLA takes no position on this question but urges that certain evidence submitted on behalf of petitioners should be disregarded.

SUMMARY OF ARGUMENT

Petitioners rely heavily on arguments that Myriad's patents inhibit research. Those arguments, and the evidence alleged to support them, prove nothing relevant to the central question to be addressed by the Court. Indeed those arguments and that evidence poison the Petitioners' argument, as well as much of the public discussion of this case. Those arguments and the evidence supporting them should therefore be disregarded.

The central question the Court has asked the parties to address is whether Myriad's patents claim exclusivity to subject matter that is not eligible to be patented because that subject matter is itself a law of nature or a natural substance rather than a practical application of a law of nature or a practical but modified form of a natural substance. In this brief, we take no position on that important question, but we urge the Court not to address it with Petitioner's irrelevant argument and equivocal evidence.

A patentee's right to exclude others from making, using or selling its claimed invention is beyond dispute. So too, is the impropriety of extending that exclusivity to laws of nature and naturally occurring substances. See Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). Patent exclusivity for applications of laws of nature and significantly modified natural substances is proper, however. Id. at 309-10.

This leads to the only question that the parties have been directed to address: Are human genes patentable?

As explicitly stated by Judge Lourie in the decision of the Federal Circuit,

> [This case] is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the patents. The question is also not whether it is desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by patent, i.e., to exclude others from practicing the patented subject matter. It is also not whether the claims at issue are novel or

> nonobvious or too broad. Those questions are not before us.

Assoc. for Molecular Pathology, et al., v. United States Patent and Trademark Office, et al., __ F.3d __ (Fed. Cir. 2012) (slip op. at 37-38). Petitioners' Brief correctly states that

> The Court's seminal Section 101 cases describe three different ways to evaluate patents to determine whether they impermissibly claim natural phenomena: whether the patented composition has markedly different characteristics from any found in nature. [Chakrabarty, 447 U.S. at 309] at 310; whether the patent is based on an inventive concept, Mayo, 132 S. Ct. at 1294; and whether the patent preempts use of the underlying product or law of nature, foreclosing future innovation out of proportion with the patentee's contribution, id. at 1301-03.

Pet. Br. at 23-24. The relevance, if any, of the degree to which research or commercial use of the invention is impaired applies only to the third of these three methods of evaluation.

If the isolated BRCA1 and BRCA2 genes in this case are deemed to be not "markedly different" from their native form, that is the end of the inquiry, negating patent eligibility. A similar analysis may be made of the inventive concept inherent in the invention as claimed. If these analyses are not determinative, however, the degree to which research or commercial use of the "invention" forecloses future innovation should not be

determined on the basis of the misleading and inconclusive arguments and evidence offered by Petitioners.

Petitioners broadly assert that research was inhibited by the patents at issue in this case. As discussed in Section I below, it is questionable whether the patents do in fact inhibit research and, in any event, the evidence asserted by Petitioners fails to prove that all research has been inhibited by the patents at issue here. This assertion therefore should be disregarded. Petitioners' arguments apparently are also based on an assumption, shared by certain of the declarants supporting those arguments, that patents can be used properly to preclude others from research to improve on, or to find alternatives to, or simply to evaluate the patented invention. To the contrary, classic patent law includes an experimental use exception that permits such research, as discussed in Section II below.

ARGUMENT

I. PETITIONERS' PREEMPTION ARGUMENTS SHOULD HAVE NO BEARING ON THE QUESTION OF PATENT ELIGIBILITY IN THIS CASE.

Petitioners describe a parade of horrors resulting from Myriad's patents on the isolated BRCA1 and BRCA2 genes. Petitioners, however, make no attempt to distinguish the limited exclusionary rights granted with these patents, properly enforced and interpreted, from an enormously exaggerated view of that exclusionary

right, one that would preempt any and all activity related to the genes, both in and removed from their native environment. Any evidence of these alleged negative consequences is speculative and inconclusive at best, and serves only to cloud the real issue before the Court—whether Myriad's claims to the isolated BRCA1 and BRCA2 genes are, in fact, patent eligible.

As an initial matter, preemption should not be deemed a separate component of the patent eligibility analysis. At most, it is a secondary question that is relevant only if Myriad's isolated BRCA1 and BRCA2 molecules are held to be patent eligible subject matter. *See* Katherine J. Strandburg, Much Ado About Preemption, 50 Hous. L. Rev. 563, 613-614 (2012), available at http://www.houstonlawreview.org/wp-content/uploads/2013/02/7-Strandburg.pdf ("Preemption analysis was not central to any of the Court's determinations of how to apply per se patentable subject matter exclusions, nor, as we have seen, has it been particularly useful as a tool for analyzing potential overbroad downstream impact. Instead, the preemption rubric has served mainly to muddy the water and to distract from more pertinent questions.").

In this case, Petitioners barely address whether the inventors' first recognition of the significance of mutations in the claimed genes and subsequent isolation of those genes to enable the diagnostic tests which followed was in fact an inventive concept worthy of patent eligibility. Instead, Petitioners offer sweeping conclusions regarding the preemptive effect of Myriad's patents on gene research and medicine, such as that the

patents reach "all uses of the two human genes" (Pet. Br. at 42) and "prevent and deter research" (Id. at 43). There is no direct support in the record for these and other of Petitioners' conclusions. Indeed, in many instances Petitioners make no attempt to offer any such support, much less tie the support they do cite to uses other than those which Myriad is entitled to exclude by the specific patent claims at issue.

Here, Petitioner's preemption arguments fall into two basic categories: (A) that the patents give Myriad an unrestricted monopoly on genes and testing procedures, and (B) that the patents generally impede research and innovation. As to the first category, the exclusive rights of patentees are restricted with respect to research on the patented invention. Consistent with this premise, the record gives no indication that Myriad's assertion of its patents represents a departure from long-standing and well-established principles of patent law granting patentees the right to exclude others from commercially exploiting their inventions for a limited period of time. As to the second category, contrary to Petitioners' claims, there is no conclusive evidence that Myriad's patents on the BRCA1 and BRCA2 genes impede or otherwise preempt research and innovation. In fact, the record suggests just the opposite.

A. Myriad's Assertion of Its Patents is Consistent With Existing Law.

Petitioners assert that "[b]ecause the patent claims reach all uses of the two human genes, Myriad has the authority to prevent all study of them." Pet. Br. at 42. That assertion is incorrect.

U.S. patent law recognizes experimentation on a patented invention to be excepted from activity that might otherwise be patent infringement. Notwithstanding certain decisions that may be inconsistent with the classic interpretation of that exception (as discussed in Section II below), Myriad cannot preempt all use or study of its inventions. Consistent with the classic experimental use exception recognized under U.S. case law, and as Myriad's President indicates, "[i]t has been, and still is, Myriad's policy and practice to allow scientists to conduct research studies on the BRCA1 and BRCA2 genes freely." JA 332 (Declaration of Gregory C. Critchfield, President of Myriad) ("Critchfield Declaration"); see also JA 623 ("I understand Myriad now asserts that it would never enforce its legal right to sue me for those actions if I were doing them for purely research purposes.").

Despite the experimental use exception and Myriad's stated policy of allowing research on the isolated genes covered by its claims, Petitioners suggest that Myriad's right to exclude has limited the number of other laboratories that provide the same diagnostic services as Myriad. Specifically, Petitioners claim that Myriad uses the challenged claims to prevent clinical testing at any other lab (Pet. Br. at 45), that Myriad prevents other laboratories from providing diagnostic testing at a lower price (Id.), and that Myriad's monopoly on the BRCA genes prevents other laboratories from including these genes when clinically assaying other genes. Id. at 46. To the extent the Court focuses on the issue of preemption, these facts are not relevant to that issue absent objective evidence of the

commercial versus experimental nature of the activity.

Here, in return for disclosing its inventions to the public, Myriad obtained a time-limited right to commercialize those inventions. Thereafter these inventions are donated to the public to freely use. See Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) (noting that a patent represents "a carefully crafted bargain" in which the patentee is granted "an exclusive monopoly for a limited period of time" in exchange for "the public disclosure" of a new invention). This bargain entitles a patentee to assert its patent against commercial exploitation of the invention, as appears to have been the case with respect to Myriad's efforts to curb other diagnostic labs, including some of the Petitioners', from commercially exploiting its patents. These efforts are referred to in at least one of the declarations submitted by Petitioners. JA 341-342; JA 156 ("[W]e were charging patients less than Myriad was charging. If we, or another laboratory, were to begin offering such genetic testing again, I believe that it would be offered at a price significantly lower than Myriad's current pricing for the same or similar testing."). Myriad's efforts to enforce its patents against unauthorized third party commercial use should have no bearing on patent eligibility.

The patent laws were developed to protect this very right of a patentee to exclude others from engaging in this type of commercial activity for a limited time. Accordingly, the negative downstream commercial effects described by Petitioners are not the proper focus of any kind of preemption inquiry since it is an effect that results from almost every patent granted.

Petitioners' preemption arguments are exaggerated in any event. To the extent Petitioners or third parties have refrained from providing BRCA diagnostic testing services, it is unclear whether the services they claim to be foregoing are for profit or are non-commercial in nature, or whether the services they provide would even infringe Myriad's rights. Petitioners do not specify. As for Myriad dictating a "standard" of testing (see Pet. Br. at 46), as at least one other Amicus pointed out, alternate methodologies for sequencing DNA are available, including "revolutionary next-generation technologies capable of determining the sequence of single molecules, without necessitating any isolation of specific DNA sequences." Brief of Amicus Curiae Law Professor Christopher M. Holman in Support of Neither Party at 13-14, Association for Molecular Pathology v. United States Patent & Trademark Office et al., 689 F.3d 1303 (Fed. Cir. 2012) 2012 WL 2884112, at *13-15.

Rather than address these points head on, Petitioners gloss over them in favor of blanket assumptions as to the preemptive impact of Myriad's patents on genetic testing. The Court should disregard Petitioners' assumptions regarding preemption in assessing the patentability of Myriad's claims. See Strandburg, 50 Hous. L. Rev. at 568 (Preemption "has been over-emphasized and mischaracterized. Per se exclusions, and their theoretical justifications, deserve more attention.").

B. The Record Does Not Support Petitioners' Claim that Myriad's Patents Impede Research and Innovation.

One of the cornerstones of Petitioners' preemption argument is the idea that the Myriad patents have somehow "prevent[ed] and deter[red] research." Pet. Br. at 43. In support of this proposition, Petitioners cite an example of Myriad asserting its patent rights against a third party who used the claimed invention in the course of paid research. JA 257-58. According to the Critchfield Declaration, however, this third party, an acknowledged competitor of Myriad, was supplying its diagnostic testing services commercially, although in support of undefined research protocols. JA 341-42 (noting that the purpose of Myriad's enforcement efforts was to request third parties to "cease their commercial diagnostic testing"); see also JA 257. There is no indication whether the associated "research protocols" involved research on the relevant genes or related diagnostic or therapeutic methods, much less whether activity in support of that research would have qualified as excepted experimental activity. In any event, such broadly described examples are hardly evidence that Myriad's patents impaired legitimate research.

Petitioners' other evidence on the issue of preemption is similarly equivocal. By way of example, Petitioners cite to a survey finding that some labs "decid[ed] not to develop a new clinical genetic test because of a gene patent or license." Pet. Br. at 43. The fact that a survey respondent elected not to develop a new clinical test because of a gene

patent or license, however, hardly suggests that Myriad's patents actually impaired research and innovation. Indeed, research to develop an improved test may well fit within a properly defined experimental use exception.

If anything, the record shows that with respect to gene patents, firms and research organizations in the United States have developed "'working solutions' which allow them to continue to innovate relatively unimpeded." JA 574-75 (December 23, 2009 Declaration of Joseph Straus, Director Emeritus of the Max-Planck-Institute for Intellectual Property, Competition and Tax Law, Munich) (commenting on a study showing that working solutions included license negotiations where necessary or the avoidance of patent obstacles by working around the claims). Other research shows that academics focusing on biomedical research rarely pay much attention to the others' patents. And for those researchers who have become aware of others' patents, survey evidence indicates that very few, if any, have abandoned or altered their research due to such patents. Id.

Far from having a stifling effect on research, the record shows that gene patents may encourage and foster innovation. According to the Critchfield Declaration, since Myriad's disclosure of the BRCA1 and BRCA2 isolated genes, at least 18,000 researchers have conducted studies on them, and scientists have published over 8,000 reports relating to them. JA 336-37 (noting that "many of these scientists are members of the institutional Plaintiffs in this suit including the Association for Molecular Pathology, American College of Medical Genetics, American Society for Clinical Pathology, and College

of American Pathologists). In addition, there have been over 130 clinical trials commenced on the BRCA1 and BRCA2 genes. Id. Thus, contrary to Petitioners' claims, it is clear that gene patents, such as those at issue here, do not necessarily pose an obstacle to scientific research.

Evidence of Myriad's patents blocking academic research is also lacking. As one of the Petitioners freely admitted, she "sequence[s] human genes, including the BRCA1 and BRCA2 genes for research subjects in [her] research lab" and has been doing so unimpeded. JA 59. This is consistent with Myriad's stated policy of allowing scientists to conduct research studies on the BRCA1 and BRCA2 genes freely.

It bears noting that in one of the first cases involving patentability of genetic organisms, the Court predicted "[t]he grant or denial of patents ... is not likely to put an end to genetic research ...[and that] patentability will not deter the scientific mind from probing into the unknown .... Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all." Chakrabarty, 447 U.S. at 317. The Court's observation in Chakrabarty remains true today.

As a general matter, biotechnology patents have not had a substantial impact upon academic research. In fact, in one study "only about 1% of the random sample of academics reported experiencing a delay or modification in their research due to patents." John P. Walsh, et al., Patents, Material Transfers and Access to Research Inputs in Biomedical Research, Final Report to the National

Academy of Sciences' Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions, 37 (2005), available at www2.druid.dk/conferences/viewpaper.php?id=776&cf=8. In a more recent study, strikingly few documented examples were found in which the fears surrounding gene patents manifested themselves. Christopher M. Holman, The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation, 76 UMKC L. Rev. 295, 299-300 (2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1090562.

Petitioner's evidence concerning research preemption is at best inconclusive. For example, the same report Petitioner cites for the proposition that gene patent law "threatens medical progress" (Pet. Br. at 42) found the following:

> The case studies and literature review support . . . assertions that patents attract investment to fund genetic research. Both the case studies and literature review reveal that when researchers or companies sought private funds to initiate or advance their genetic research, investors were willing to provide funding because of the prospect of patents being granted as a result of the research. For example, according to a policy paper, Eli Lilly agreed to fund Myriad Genetics' ongoing efforts to find genes associated with breast cancer "in return for licensing privileges for diagnostic kits and therapeutic

> products on BRCA1." This agreement was based on the assumption that Myriad would in fact be the first to discover the gene and that the company would then patent the gene. The rights promised to Eli Lilly would then be derived from that patent.

Rep of the Sec'y's Advisory Comm. on Genetics, Health, & Soc'y, HHS, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests 23 ("SACGHS Report") (2010) (footnote omitted), available at http://oba.od.nih.gov/oba/sacghs/reports/sacghs_patents_report_2010.pdf. "In the case of genetic testing companies, the limited period of exclusivity provided by a patent is almost always required to secure sufficient capital needed to establish testing capability on a clinical scale." JA 448.

Petitioners cite the cost of Myriad's BRCA1 and BRCA2 testing as impeding patient access to diagnostic testing. However, patents such as Myriad's appear to have little, if any, monopolistic effect on the price of diagnostic tests. See Robert Cook-Deegan, et al., Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers, 12 Genetics Med. S15, S23-24 (2010), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3047448/.

Regarding Petitioners' assertions of problems associated with "second opinion" molecular genetic testing as a result of Myriad's patents, the Critchfield Declaration suggests the contrary. JA

364-65 (Multiple laboratories provide second opinions regarding BRCA1 and BRCA2 test results). The only conclusive evidence of patient access being limited relates to instances where insurance coverage for a particular test was unavailable. In fact, according to the Critchfield Declaration more than 90% of Myriad's BRCAnalysis® tests ordered by healthcare providers are covered by insurance, and the average reimbursement rate is over 90% of the cost of the test. JA366-67. There are also more than 2,600 insurance payors who reimburse for the BRCAnalysis® test. Id.

The evidence of record falls far short of proving that Myriad's patents inhibit research and innovation. Rather, the record indicates that Myriad has allowed and continues to allow non-commercial research on the BRCA1 and BRCA2 genes freely. Many researchers acknowledge that they have never been contacted by Myriad and that neither the patents at issue in this suit nor Myriad have in any way hampered such research. JA302-04 (December 23, 2009 Declaration of Richard Baer, Ph.D., Professor of Pathology & Cell Biology, Columbia University) (noting that his research involved, inter alia, "plasmids containing BRCA1 cDNA, heterologous cells expressing BRCA1 protein, primers designed to PCR amplify BRCA1 cDNA, and antibodies against BRCA1 protein"); JA 311-14 (December 23, 2009 Declaration of Rong Li, Ph.D, Professor, Department of Molecular Medicine/ Institute of Biotechnology at the University of Texas Health Science Center) (noting same). Ultimately, there is little evidence that any research Petitioners seek to conduct would be prohibited by the patents in suit.

II. MUCH OF THE RESEARCH ACTIVITY ALLEGEDLY CURTAILED IN DEFERENCE TO THE MYRIAD PATENTS CAN BE TRACED TO A MISGUIDED VIEW OF U.S. PATENT LAW.

Scientists generally, and particularly those involved in this case along with Myriad and its inventors, are constrained by questionable case law regarding what may be referred to as the experimental use exception to patent infringement. Research possibly leading to improvements on, or alternatives to, a patented invention, should be exempt from claims of patent infringement under classic U.S. patent law, just as certain uses of copyrighted material is exempt from infringement as "fair use," and for the same reason. 17 U.S.C. § 107 (1992). *See* Campbell v. Acuff-Rose Music, 510 U.S. 569, 575 (1994) ("From the infancy of copyright protection, some opportunity for fair use of copyrighted materials has been thought necessary to fulfill copyright's very purpose '[t]o promote the Progress of Science and useful Arts'"). Indeed, patent law recognizes an exemption for experimentation on an invention. Unfortunately, the current state of the case law may lead to a different conclusion with respect to experimentation not limited to philosophical purposes only.

To the extent any patent evaluation, or search for alternatives or improvements, may have been inhibited in connection with the patents in suit here, that is an unfortunate consequence of the uncertainty in the law, for which Myriad should not be held accountable.

As discussed more fully below, the exception for experimental use of an invention dates back in U.S. case law nearly two hundred years. But when the U.S. common law of patents was codified in 1952, no provision was included that recognized this exemption. Subsequent case law recognized the exemption but progressively interpreted it more narrowly. Calls for Congressional or judicial correction of this narrow interpretation have gone unheeded.

The experimental use exception originated in 1813 with an opinion by Supreme Court Justice Joseph Story. Applying the common law of patents to render a decision in favor of an accused infringer, Justice Story stated that they provided no remedy where the alleged infringement was "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). Justice Story elaborated on that position shortly afterward, claiming that a finding of infringement required "an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery." Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391). Taken together, those statements crafted a relatively broad infringement defense that covered the use of a patented invention provided the use did not usurp the benefits afforded to the inventor by the patent system.

As originally set forth by Justice Story in Whittemore, the defense included two distinct activities. First, it covered "philosophical experiments," by which Justice Story presumably

referred to acts of scientific inquiry. But it also covered actions taken "for the purpose of ascertaining the sufficiency of the machine to produce its described effects." The distinction is critical. While the former protects general acts of research for philosophical purposes only, the latter explicitly protects the actual use of an invention when such activity would otherwise fall squarely within the scope of infringement, provided the use is to verify the ability of the claimed invention to function as claimed. Thus properly excepted experimental uses were not limited to uses for philosophical inquiry only.

The purpose of that broad experimental use exception fit comfortably within the framework of the country's nascent patent laws by promoting further innovation. By 1890, it was well-settled that the exception provided a safe harbor for certain alleged acts of infringement. Yale University Professor William C. Robinson, in his seminal treatise, The Law of Patents for Useful Inventions, emphasized that:

> The interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these

> emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one.

W. Robinson, The Law of Patents for Useful Inventions, § 898 (1890). Robinson went on to qualify this generalization, however:

> [W]here [an alleged infringement] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.

Id. This qualification may have engendered the emphasis on the commerciality of uses not encompassed by the exception, as the exception was interpreted in the second half of the twentieth century.

In 1935, a district court citing Robinson applied the exception in favor of a university that was using patented machine parts, finding that the parts were used only in laboratory experiments. *See* Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 703, 713 (D. Colo. 1935). The exception, however, did not cover similar parts sold commercially. Id. at 713. Another court found that the exception protected research and testing on a product performed before the defendant put the product into commercial production. *See* Akro Agate Co. v. Master Marble Co., 18 F. Supp. 305, 333 (N.D. W. Va. 1937). Yet another held that an accused device did not infringe because

the defendant did not manufacture it for sale. See Dugan v. Lear Avia, 55 F. Supp. 223, 229 (S.D.N.Y. 1944).

Initially, the Court of Claims, predecessor to the Federal Circuit, continued to focus on the experimental nature of the alleged use and twice applied the exception to find non-infringement. In 1958, it held that the government's use of a patented heat-resistant alloy was not an infringement when it was used only for testing. See Chesterfield v. United States, 159 F. Supp. 371, 376 (Ct. Cl. 1958). Then, in 1975, it held that exception covered NASA's use of a patented glove during a training experiment. See Finney v. United States, 188 U.S.P.Q. 33, 35 (Ct. Cl. Trial Div. 1975). Soon afterward, however, the analyses of the Court of Claims, and then the Federal Circuit, shifted.

Just one year after its decision in Finney, the Court of Claims began to narrow the exception. In Pitcairn v. United States, the court ruled that the federal government's use of patented helicopter rotors for "tests, demonstrations, and experiments" of its helicopters did not fall within the scope of the exception because those uses were "in keeping with the legitimate business of the using agency." Pitcairn v. United States, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976). Thus, instead of analyzing the commercial aspect of the claimed experimental use, the court applied a narrower "legitimate business" test that disregarded whether the use in fact deprived the patentee of any benefit to which it was entitled.

The Federal Circuit used that new analysis in 1984, when it was asked to extend the classic experimental use exception to the activity of a generic drug manufacturer's activity to prepare to

make and sell a patented drug following expiration of a patent covering the drug. Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), cert. denied, 469 U.S. 856 (1984). In refusing to do so, the court relied on the defendant's intent to profit from their activity in the future as sufficient commercial activity to remove that activity from the ambit of the experimental use exception Id. at 863. [2]

The Federal Circuit subsequently narrowed the judicially-created experimental use exception even further when asked to extend it to any research by a public research institution. Madey v. Duke Univ., 307 F.3d 1351, 1361-62 (Fed. Cir. 2002). According to the court, Duke University's status as a non-profit institution did not protect its use of a patented laser for experimental research purposes because research was the university's business. Id. at 1362. Although Duke University did not contend that its research was on the patented laser, its effort to extend the experimental use exemption to cover use of the laser in other research led the court to narrow the exception in a manner that would seem to disentitle any experimental use of an invention that had any commercial implication whatsoever, irrespective of even the use originally included by Justice Story in the original statement of the experimental use exemption. As set forth in Madey:

> Our precedent clearly does not immunize use that is in any way

[2] Congress responded to the Federal Circuit's Roche Products v. Bolar decision with an amendment of the Hatch-Waxman Act, legislatively exempting such activity as it related to FDA regulatory approval. Drug Price Competition and Patent Term Restoration Act, PL 98-417, 98 Stat 1585 (1984); Patent Act, 35 USC §271(1) (1984) (discussed infra).

> commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.
>
> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

Id.

That narrow application of the judicially-created experimental use exception is cast in sharp relief when compared to the broad interpretation of the legislatively-created safe harbor provision of the Hatch-Waxman Act by both the Supreme Court, Merck KGaA v. Integra LifeSciences, Ltd., 545 U.S. 193 (2005) and the Federal Circuit, Integra LifeSciences Ltd. v. Merck KGaA, 331 F.3d 860 (2003) (on remand, 496 F.3d 1334 (2007)) and Momenta Pharmaceuticals v. Amphastar Pharmaceuticals, 686 F.3d 1348 (Fed. Cir. 2012).

Relative to the judicially-created experimental use exception, the Integra LifeSciences case is notable for the fact that patentee/plaintiff did not even appeal the district court finding that certain experimental activity of the accused infringer (clearly a for-profit entity) was protected by the judicially-created experimental use exception. In writing for the Court, Justice Scalia noted this without comment. 545 U.S. at 197, n.3.

While the majority of the Federal Circuit panel in that court's first decision in Integra LifeSciences favored a more narrow reading of the Hatch-Waxman legislative exemption, Judge Pauline Newman registered a strong dissent, urging application of the judicially-created experimental use exception even to activity that the district court had found to be an infringement. In that dissent, Judge Newman articulated both the history of, and the policy justification for, the judicially-created experimental use exception. 331 F.3d 860, 866 (Fed. Cir. 2003).

In her sharply-worded dissent, Judge Newman accused the majority of eliminating the judicially-

created experimental use exception altogether, contrary to established precedent and policy. Id. at 875. The consequence of the majority's opinion, according to Judge Newman, would be to place all information disclosed through the patent system "on ice," allowing a patentee to "bar not only patent-protected competition, but all research that might lead to competition, as well as barring improvement or challenge or avoidance of patented technology," thereby halting the advance of technology. Id. As for the case itself, Judge Newman indicated the activities in question constituted research into patented science and technology, which she deemed to be protected by the experimental use exception. Id. at 878.

More recently, Judge Newman, writing for a panel majority in which Judge S. Jay Plager concurred, again noted that broadened view of the experimental use exception. See In re Rosuvastatin Calcium Patent Litigation, __ F.3d __, 2012 WL 6217356, at *12 (Fed. Cir. December 14, 2012) ("[P]atenting does not deprive the public of the right to experiment with and improve upon the patented subject matter.")

The need for clarification of the law regarding the experimental use exception has been recognized by others. After an historic study of the U.S. patent system, a National Academies Report identified several "performance criteria [of the system] that are widely thought to be important if not necessary conditions for innovation," one of which specifically targeted the problem identified in the Madey decision.

> In light of the Federal Circuit's 2002 ruling that even non-commercial scientific research conducted in a university enjoys no protection from patent infringement liability [implicitly referring to Madey] and in view of the degree to which the academic research community especially has proceeded with their work in the belief that such an exception existed, there should be limited protection for some research uses of patent inventions.

Executive Summary: A Patent System For the 21st Century, page 7.[3]

Other academic studies have reached similar conclusions: "[O]ver time, the focus of the inquiry shifted from whether the alleged infringing use was for profit or financial gain to whether it furthered one's legitimate business interests (regardless of profit)." Elizabeth A. Rowe, The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?, 57 Hastings L.J. 921, 926 (2006), available at http://scholarship.law.ufl.edu/facultypub/91. See also Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017, 1086 (1989) ("[A]s the line between basic and applied research becomes blurred in certain fields, patent protection increasingly threatens to encroach on the domain of research

[3] Report of the Committee on Intellectual Property Rights in the Knowledge-Based Economy, Board on Science, Technology, and Economic Policy and Global Affairs Division of the National Research Council of the National Academies, available at http://www.nap.edu/openbook.php?isbn=0309089107.

science, making it necessary to work out an accommodation between the two perspectives. A carefully formulated experimental use exemption from patent infringement liability is an important first step in that direction.").

The uncertain status of the judicially-created experimental use exception and the acknowledged need to revisit (or legislatively redefine) the extent of that exception is harmful to innovation because it provides cover for the efforts of those seeking to discredit the patent system generally, and the Myriad patents specifically.

CONCLUSION

For the foregoing reasons, Amicus Philadelphia Intellectual Property Law Association urges the Court, in reaching its decision on the patent eligibility of the patents at issue here, to disregard, as irrelevant and inconclusive, all arguments (and supporting evidence) that the patents at issue have inhibited or will inhibit. research.

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