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 OF MPEG LA, LLC AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae MPEG LA, LLC is a leading packager of patent pools and other one-stop non-exclusive patent licensing solutions offering wide access to important technologies. Its programs include Librassay®, which licenses on a non-exclusive basis nearly 400 patents to isolated human deoxyribonucleic acid (DNA) molecules, biomarkers, diagnostic assays, and other medical technologies. The patents belong to research institution leaders such as Johns Hopkins University, Ludwig Institute for Cancer Research, Memorial Sloan-Kettering Cancer Center, National Institutes of Health (NIH), Partners HealthCare, The Board of Trustees of the Leland Stanford Junior University, The Trustees of the University of Pennsylvania, University of California, San Francisco and the Wisconsin Alumni Research Foundation.

SUMMARY OF ARGUMENT

Contrary to petitioners' absolutist position, Congress did not categorically exclude scientifically isolated DNA molecules from patentable subject matter under 35 U.S.C. § 101. Nor are the competing policy concerns irreconcilable. The life-changing inventions at issue are exactly the kinds of

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[1] The parties' written consents to the filing of this brief are on file with the clerk. No counsel for a party authored this brief in whole or in part, and no person other than MPEG LA paid for or made a monetary contribution toward the preparation and submission of this brief. The views expressed in this brief are MPEG LA's alone. MPEG LA does not speak for participants in its patent licensing programs.

inventions the patent system ought to reward, as respondents' brief explains. But the incentive provided by the patent system to develop biotechnologies need not hinder other important research or uses, as petitioners claim. Real-world experience in other cutting-edge industries has shown that the availability of non-exclusive licenses through patent licensing programs like Librassay strikes an effective balance.

I. Unlike the processes this Court held to be unpatentable in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), this case concerns concrete, and man-made, compositions of matter. The patented strands are different from naturally occurring DNA in important, substantive ways. Those differences are the very reasons why the patented molecules are so beneficial, so inventive, and so costly to develop.

II. Petitioners and others have posited a false dichotomy between providing incentives to innovate through patents, on the one hand, and permitting researchers and health care professionals to make use of others' patented inventions, on the other. MPEG LA solved similar problems during the advent of the digital-video age by assembling and offering a patent pool providing nonexclusive access under a single license to many patents owned by many patent holders. That model—which enabled inventors to recover their investments in patented technologies while also enabling others to use the inventions—has become a template for cutting through so-called patent thickets in many different technological disciplines. As detailed below, that history is already

repeating itself in this context, where Librassay has formed a one-stop, non-exclusive, market-driven license affording convenient access to the kinds of patents at issue here.

Even if market mechanisms did not resolve all of the legitimate policy concerns, Congress or the courts could employ more tailored approaches to balancing patent rights with other interests. The competing policies can be reasonably balanced under the existing patent system—unless petitioners have their way and this Court takes a sledgehammer to the entire enterprise of isolated DNA research and product development.

ARGUMENT

I. SCIENTIFICALLY ISOLATED DNA MOLECULES ARE ELIGIBLE FOR PATENT PROTECTION BECAUSE THEY ARE SUBSTANTIVELY DIFFERENT FROM ANYTHING FOUND IN NATURE

Petitioners argue that patents on isolated human DNA impermissibly claim "abstract ideas." Pet. Br. 17, 26 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)). In contrast to the method at issue in *Mayo*, however, these patents cover specific compositions of matter. *See Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1325 (Fed. Cir. 2012) (Opinion of Lourie, J.). Compositions of matter are concrete. And they are eligible for patent protection so long as they are man-made: While "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter," "a nonnaturally occurring

manufacture or composition of matter"—that is, "a product of human ingenuity having a distinctive name, character and use"—is patentable subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (internal quotation marks and brackets omitted); *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The human DNA found in nature is present in the form of 46 chromosomes, each of which contains a single, large undifferentiated DNA-containing construct. *See Ass'n for Molecular Pathology*, 689 F.3d at 1313. In contrast, isolated strands of specific DNA molecules with specific functions "are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity." *Id.* at 1325.

Petitioners contend that "adding the word 'isolated'" to the patent claims is merely "clever draftsmanship," because "[i]solated DNA does not have markedly different characteristics from any found in nature." Pet. Br. 27. While "isolated" is a word, it is one that conveys an important, substantive difference. Resp. Br. 51–53. Even without wading deeply into the science, there are at least three clear indications that the differences between the claimed molecules and naturally occurring DNA are substantively important.

First, far from being immaterial, the differences are the very reasons why the isolated molecules are useful in scientific, medical, and research applications. The isolated molecules are used "to 'probe' for target DNA in a patient sample or to 'prime' the production of copies of the target DNA in

the laboratory." Resp. Br. 7. These functions are possible only because of the way the lab-created, isolated molecules react with naturally occurring DNA. *Id.* at 7–8. Only by providing an isolated, exogenously manufactured, and specific DNA molecule can a specific target DNA sequence embedded in the entire human genome be identified. *Id. at* 8 & n.3.

Second, the claimed compositions are the "product of human ingenuity." *Chakrabarty*, 447 U.S. at 309–10. Successfully isolating DNA molecules involves difficult scientific judgments about "how to define the beginning and end of the[] genes" and how to separate those genes from larger DNA molecules—judgments that are nothing if not "inventive." Resp. Br. 6–7.

Third, while not dispositive in itself, the enormous cost required to isolate and develop the claimed molecules is telling. *See, e.g.*, *id.* at 5. If the claimed molecules were not materially different from naturally occurring DNA molecules, they would not be so difficult or costly to come by.

II. THE MARKET IS SOLVING ANY PURPORTED POLICY PROBLEMS

Petitioners posit a false dichotomy between providing an incentive for innovation and allowing the public to use the resulting inventions in further scientific and medical research and product innovation. As MPEG LA's own experience shows, the availability of patent pool and other one-stop non-exclusive licenses can resolve that concern. The whole point of the patent system is to *balance* these

interests across a wide spectrum of fields of human endeavor. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). Petitioners would annihilate that balance in one of the areas where it is needed most.

A. Respondents' Inventions Are Among Those Most Deserving Of Patent Protection

The reasons for providing patent protection are at their zenith here. Successfully isolated DNA molecules provide enormous benefits for society, leading to new cures for diseases, new diagnostic technologies that enable health care providers to detect and treat illnesses, and new tools that enable researchers to discover therapies and diagnostics for the future. Insulin, human growth hormone, and erythropoietin are just three of the many recombinantly produced human protein therapies made using isolated DNA molecules. *See* Courtney J. Miller, *Patent Law and Human Genomics*, 26 Cap. U. L. Rev. 893, 900 (1997). Petitioners themselves recognize the benefits of isolated DNA molecules, as their own policy arguments depend on them. *See* Pet. Br. 41–42.

But without some means for those who develop isolated DNA molecules to recoup their substantial investments, these important inventions may never come to be. Under our Constitution and Patent Act, the patent system provides that means, and "motivate[s] invention," by granting exclusive rights for a limited time. *Pfaff*, 525 U.S. at 63. As Abraham Lincoln explained, patents add "the fuel of interest to the fire of genius, in the discovery and production of new and useful things." Abraham

Lincoln, Second Lecture on Discoveries and Inventions (Feb. 11, 1859), *in* 3 THE COLLECTED WORKS OF ABRAHAM LINCOLN 356, 363 (Roy P. Basler, ed., 1953). That incentive is especially important in contexts like this, where the costs and investment risks required to develop breakthrough inventions that advance the health sciences and grow the American economy are enormous.

Moreover, denial of patent protection could be counter-productive even from the limited standpoint of promoting public access to others' existing inventions. It could force inventors to keep their discoveries confidential, in hopes of relying on trade secret protections. That would undermine the patent system's fundamental objective of encouraging "public disclosure of new and useful advances in technology." *Pfaff*, 525 U.S. at 63. It also would provide an insufficient incentive for invention, because "trade secret law provides far weaker protection in many respects than the patent law." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 155 (1989) (brackets and internal quotation marks omitted).

B. MPEG LA's Experience Shows that Non-Exclusive Licensing Solutions Are Capable of Addressing Petitioners' Policy Concerns

Patent pool and other one-stop non-exclusive licensing solutions can address the policy concerns raised by petitioners. In the 1990s, for example, as video technology was transitioning to digital media, product and content developers faced a problem. Technology in the form of the MPEG-2 video-

compression standard was available to bring high-resolution digital video into consumer products, but hundreds of patents owned by many patent holders threatened its implementation.

Following a review by the U.S. Department of Justice, MPEG LA offered the first modern patent pool providing nonexclusive access under a single license to many patents owned by many patent holders. DOJ explained that the MPEG-2 pool was "likely to provide significant cost savings to [l]icensors and licensees alike, substantially reducing the time and expense that would otherwise be required to disseminate the rights to each MPEG-2 Essential Patent to each would-be licensee." Letter from Joel I. Klein, Asst. Att'y Gen., Dep't of Justice, to Garrard R. Beeney, Sullivan & Cromwell LLP (June 26, 1997), *available at* http://www.usdoj.gov /atr/public/busreview/215742.htm.

By making MPEG-2 video widely available, the patent pool enabled an explosion of innovative new products for delivering digital video to consumers, including televisions, DVD and Blu-ray Disc players, personal computers, video discs, digital cable boxes, satellite TV receivers, cameras, and game devices. The vast majority of these products are licensed by nearly 2,000 companies through MPEG LA's patent pool.

MPEG LA's model has become the pro-competitive template for many different technologies. Today, MPEG LA operates licensing programs consisting of some 8,000 patents in 74 countries featuring more than 160 patent holders and some 5,500 licensees.

Just as the MPEG-2 platform ushered in a new era for digital video, the Human Genome Project enabled a new era of genetic diagnostics and personalized medicine. And today's genetic researchers and product developers face some of the same patent-related problems that the 1990s' digital-video developers faced: the need to obtain access to essential patent rights while also respecting the need to compensate inventors for their significant investments and contributions. To address these problems, MPEG LA launched Librassay in September 2012. *See* Librassay Press Release, September 27, 2012, *available at* https://www.librassay.com/Media.aspx; News Flash, *Gene Patent Pool Set to Launch*, 155 Am. J. Med. Genetics x (2011), *available at* http://onlinelibrary.wiley.com/doi/10.1002/ajmg.a.34380/pdf; Lawrence A. Horn, *The MPEG LA Licensing Model: What Problem Does It Solve in Biopharma and Genetics?*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS 33–41 (G. Van Overwalle, ed., 2009); Lawrence A. Horn, *Alternative Approaches to IP Management: One-stop Technology Platform Licensing*, 9 J. Comm. Biotech. 119 (2003).

Librassay balances the interests of all concerned by making patent rights for genetic diagnostics and research tools available to anyone who wishes them on reasonable, affordable, and non-discriminatory non-exclusive licensing terms. By joining Librassay, patent holders grant MPEG LA the right to sublicense. The patents are made searchable using key words and placed into general categories for online browsing, free of charge. *See* http://www.librassay.com. Sublicensees sign a

standard agreement providing a royalty-free license for basic research and education-related uses, and a royalty-bearing license for commercial products and tests. MPEG LA collects the royalties and distributes them to patent holders according to set formulas, while retaining a portion of the royalties as an administrative fee.

Presently, the facility contains nearly 400 patents including claims to isolated DNA molecules and other biomarkers. The patents come from research institution leaders such as Johns Hopkins University, Ludwig Institute for Cancer Research, Memorial Sloan-Kettering Cancer Center, NIH, Partners HealthCare, The Board of Trustees of the Leland Stanford Junior University, The Trustees of the University of Pennsylvania, University of California, San Francisco and the Wisconsin Alumni Research Foundation.

Librassay will thereby speed the development and commercialization of new diagnostic tests and products. By aggregating complementary patents under one roof, Librassay also allows licensees to license multiple patent rights from many different patent holders at an "anti-stacking" royalty rate, which is the same for all licensees and is likely lower than a licensee could negotiate on its own in a series of bilateral negotiations. At the same time it offers patent owners the opportunity for wider adoption of their technologies, reasonable compensation for their research investments and the incentive to invest more. This aggregation also provides value to patent holders with patents whose value can be realized

principally in conjunction with other pieces of a larger diagnostic puzzle.

If MPEG LA's experience with consumer-electronics pools is any indication, outlying patent holders will join as Librassay becomes the established way of doing business.[2] More and more patent holders in the diagnostics field understand that nonexclusive licensing is viable. For example, NIH recommends that, "[w]henever possible, non-exclusive licensing should be pursued as a best practice." Nat'l Institutes of Health, *Best Practices for the Licensing of Genomic Inventions: Final Notice*, 70 Fed. Reg. 18413, 18415 (Apr. 11, 2005); *see also, e.g.*, Org. for Econ. Dev. and Co-operation, *Guidelines for the Licensing of Genetic Inventions* § 5.3 (2006) ("License agreements relating to foundational genetic inventions should generally be non-exclusive to encourage broad access for researchers and patients and broad use of the genetic invention."), *available at* http://www.oecd.org/sti/biotech/36198812.pdf.

"Before making any changes that could serve to undermine the time-tested structure for stimulating investment in innovation, market-driven approaches including patent pools or patent clearinghouses and/or incentives to stimulate non-exclusive licensing . . . should continue to be explored . . . ." Frances Toneguzzo, *Editoral: Impact of Gene Patents on the Development of Molecular Diagnostics*, 5 Expert Opinion on Med. Diagnostics 273, 275 (2011).

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[2] MPEG LA's MPEG-2 patent pool started with eight patent holders and 100 patents and grew to include 27 patent holders with more than 1,000 patents worldwide.

Especially considering that the marketplace is already moving toward this solution, removing all patent incentives for these important inventions would be a wholly disproportionate and unbalanced response.

C. Other Finely Tuned Solutions Are Available To Address Any Remaining Issues

Of course, no patent holder is required to include its patent in a facility like Librassay. And in some instances, an exclusive license may be necessary to recoup particularly high development costs. *See* 70 Fed. Reg. at 18415. In any case the market should be given every opportunity to work within the existing system. Even if non-exclusive license pools do not always provide a solution, they greatly ameliorate the concerns raised by petitioners. And other, less drastic remedies can solve any remaining problems.

If market mechanisms do not develop adequately, Congress could consider enacting a finely tuned legislative package to balance appropriately the various interests at stake, as it has before. *See* Gregory P. Lekovic, *Genetic Diagnosis and Intellectual Property Rights: A Proposal to Amend "The Physician Immunity Statute"*, 4 Yale J. Health Pol'y L. & Ethics 275, 278 (2004); *see also, e.g.*, 35 U.S.C. § 287(c) (providing that "medical practitioner[s]" and "related health care entit[ies]" are generally immune from awards of damages, injunctive relief, and attorneys' fees for claims arising out of surgical procedures); 35 U.S.C. § 271(e) (immunizing a limited category of medical research

related to Food and Drug Administration regulatory processes from infringement liability).

If problems persisted, courts might consider exercising their "equitable discretion . . . consistent with traditional principles of equity." *eBay v. MercExchange LLC*, 547 U.S. 388, 394 (2006). For example, a court might, in an appropriate case, consider both the conduct of the patent holder and the public's need for access to a particular technology in determining whether to grant an injunction against infringement. Equity allows courts to proceed on "a case-by-case basis . . . with awareness of the fact that specific circumstances, often hard to predict in advance, could warrant special treatment in an appropriate case." *Holland v. Florida*, 130 S. Ct. 2549, 2563 (2010) (internal quotation marks omitted).

Allowing the market to work, supplemented if necessary by tailored legislative or judicial action, remains the correct approach. Throwing the baby out with the bathwater is not.

CONCLUSION

The Court should hold that isolated human DNA molecules are patent-eligible subject matter.

Respectfully submitted,

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