No. 12-398

IN THE
# Supreme Court of the United States

THE 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 INHOUSE PATENT COUNSEL, LLC AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

ROCHELLE K. SEIDE, PH.D., J.D.
*Counsel of Record*
RKS CONSULTING
21299 Harrow Court
Boca Raton, FL 33433
(954) 295-3512
rseide21729@gmail.com

*Of Counsel:*

MICHELE M. WALES, PH.D., J.D.
INHOUSE PATENT COUNSEL, LLC
11816 Centurion Way
Potomac, MD 20854

MARK J. HYMAN

March 14, 2013

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

## TABLE OF CONTENTS

**Page(s)**

## TABLE OF AUTHORITIES

**Page(s)**

**Other Authorities**

## INTEREST OF AMICUS CURIAE

InHouse Patent Counsel LLC ("IHPC") submits this brief in support of Respondents in an effort to provide the Court with perspective from the genomics industry on the importance of gene-based patents to biotechnology companies and the patients they serve, particularly with regard to the example of Human Genome Sciences, Inc. ("HGS") of Rockville, Maryland, a company that was a leader in the discovery of human genes.[1]

From its founding in 1992 until its acquisition in 2012, HGS was a biopharmaceutical company dedicated to the discovery, development, manufacture and marketing of innovative drug products for patients with unmet medical needs. HGS researchers explored the human genome to identify and isolate novel DNA and protein targets to develop useful treatments for human disease. Like many start-up biotechnology companies, much of the funding that made HGS' research and development

---

[1] Pursuant to this Court's Rule 37.6, Amicus affirms that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or persons other than amicus and its counsel made such a monetary contribution. Petitioners' consent to the filing of all amicus briefs is on file with the Clerk's office. Respondents' consent to the filing of this brief was obtained from respondents' counsel on March 13, 2013 by e-mail correspondence, a copy of which accompanies this brief.

possible was obtained on the basis that patents would protect its human gene-based discoveries. Those investments led to important new therapies for patients, such as Benlysta®, the first new drug approved for the treatment of lupus in more than 50 years. Without the protections offered by gene patents, the life-changing products developed by HGS would not currently exist, and it is likely that many fewer such products will be developed by others in the future.

As leaders and in-house counsel for HGS since the mid-1990s, we helped HGS develop its gene-based patent portfolio, which at one time included applications directed to more than 10,000 human genes and resulted in nearly 700 issued U.S. patents. HGS' patent portfolio was recognized in 2010 as one of the industry's top three portfolios in the Patent Board's Biotechnology Patent Scorecard. HGS understood the strength of its portfolio, and HGS' goal was always to utilize that strength to bring new and better medicines based on human genes, proteins and antibodies to patients while balancing its interests with those of the broader scientific community. HGS' portfolio enabled HGS and its partners to bring two important drugs to the market, thus providing doctors with important new treatment options for both lupus and anthrax infection. Another drug is awaiting regulatory approval and a fourth is near the end of lengthy clinical trials.

HGS was acquired in August 2012 by GlaxoSmithKline ("GSK") for $3.6 billion dollars. We are no longer affiliated with HGS (or GSK), and HGS no longer exists as an independent company. But all

that HGS achieved would not have been possible had it not been able to patent its human gene discoveries.

## SUMMARY OF ARGUMENT

The present appeal relates to the patent-eligibility of DNA, particularly isolated human DNA. While the parties and other amici have focused on the legal analysis of the question presented to the Court, less attention has been paid to the practical experience of companies other than Myriad with gene patents. For this reason, we write to offer the Court additional perspective on both the importance of gene patents to biotechnology companies and the positive impact that companies holding such patents can have on further scientific research using human genes.

Failing to uphold the many issued U.S. patents directed to isolated human genes would have a dramatic negative effect on the biotechnology industry and its ability to fund the discovery and development of new treatments for serious unmet medical needs. Such patents were integral to HGS' foundation and success in developing new drugs, such as Benlysta®, the first new treatment for the autoimmune disease lupus in more than fifty years. Over its twenty-year history, HGS obtained hundreds of U.S. patents covering genes, proteins, antibodies and related proprietary technologies. Those patents enabled HGS to generate funding and form strategic partnerships, without which the development of Benlysta could not have occurred.

As a practical matter, without gene patents, innovative biotechnology companies like HGS would be crippled in their efforts to raise the money needed to develop new life-saving and life-enhancing therapies. Past experience has shown that calling the patentability of such inventions into question has a

strong negative influence on the investment community and can erase billions of dollars of market capitalization.

Moreover, HGS' practical experience interacting with academia over its twenty-year history demonstrates that even companies with an extensive portfolio of gene patents can encourage, rather than chill, further scientific research. Such gene patents are due to expire in the near term in any event, which calls into question the need for rebalancing the patent system to address the specter of a negative effect on scientific research that will soon be moot.

## ARGUMENT

### I. FAILURE TO UPHOLD HUMAN GENE PATENTS WILL NEGATIVELY IMPACT THE BIOTECHNOLOGY INDUSTRY

#### A. HGS Needed Gene Patents to Generate the Funding Necessary to Support Research and Development of New Therapies

Biotechnology companies generally start as small companies that garner initial funding through patenting basic research. For example, a company might patent the isolated DNA encoding a novel and useful protein that it has identified. Such fundamental patent claims can be used by the start-up as a basis for attracting funding that will enable research into strategies to impact the target of

interest—for example, to bind the target or cause increased or decreased production of the target—in order to develop a useful therapeutic. Without the foundational DNA patents to encourage this funding, the later development would not occur. These types of start-up companies will be severely disadvantaged in their funding efforts if isolated genes were found to be excluded from patent-eligibility.

HGS is a case in point. By patenting gene-based inventions, HGS was able to attract funding from the investment community, which HGS used to develop novel therapeutic agents to address unmet medical needs and advance scientific research. Indeed, patent protection for genetic sequences was a central pillar in HGS' business model.

HGS was founded in July 1992 with initial investment from HealthCare Investment Corporation, the largest health care venture capital fund in the world. Concurrent with its founding, HGS gave a $70 million grant to The Institute for Genomic Research ("TIGR"), a non-profit organization engaged in "the elucidation of gene structure and function as a basic research tool in order to develop new methods of diagnosing and treating genetic disease." (See, *Human Genome Sciences Formed to Develop New Therapeutics From Basic Research on the Human Genome and Makes a $70 Million Grant to the Institute of Genomic Research*, PRNewswire, (July 7, 1992), http://www.thefreelibrary.com/HUMAN+GENOME+SCIENCES+FORMED+TO+DEVELOP+NEW+THERAPEUTICS+FROM+BASIC...-a012304664.) The purpose of this grant was to fund TIGR's basic research and gene sequencing efforts in exchange for

the ability for HGS to obtain intellectual property rights for TIGR's gene-based discoveries, thus facilitating their commercialization.

HGS also quickly developed its own world-class scientific infrastructure and expertise to sequence and research the human genome. On the basis of its basic research into gene structure and function, and the expected promise of the resulting patents on gene-based inventions, HGS signed a $125 million collaboration agreement with SmithKline Beecham Corp. ("SmithKline") in May 1993. (See, *Glaxo Looks for Gene-Research Payoff on Other Drugs,* MarketWatch, (March 11, 2011, 11:38 AM), http://www.marketwatch.com/story/glaxo-expects-more-products-from-gene-research-2011-03-10.) Through this agreement, HGS granted SmithKline the right to develop and market certain health care products based on human genes discovered by HGS. This investment (one of the largest in the industry at the time and with no then-existing products being transferred), and the research that it spurred, would very likely not have occurred without the existence of gene patents. Armed with its initial collaborations and the prospect of patent protection for its gene-based inventions, HGS was able to raise $31 million in its initial public offering of December 1993 and more than $2 billion over the subsequent twenty years to fund its research and development efforts.

The work of HGS inured to the benefit of the scientific community and the public at large. Since its founding, HGS worked to develop therapies stemming from its genetic discoveries. This effort employed hundreds of scientists and technicians and resulted in, inter alia, the discovery of the B-

lymphocyte stimulator protein, or BLyS, in 1996. The BLyS protein is believed to contribute to the production of "autoantibodies"—antibodies that attack and destroy the body's own healthy tissues—in lupus, a disease that afflicts 1.5 million Americans and millions more worldwide, as well as certain other autoimmune diseases. HGS applied for and obtained U.S. patents on the BLyS protein, the DNA encoding that protein, and other related compositions and methods.

HGS' patent portfolio was instrumental in attracting the investment money required to take its BLyS gene discoveries from the laboratory and bring them to market to benefit patients. The discovery of BLyS led to the development of Benlysta, a human monoclonal antibody that binds to and inhibits the biological activity of BLyS, thus decreasing the production of autoantibodies. Benlysta was the first specific treatment for lupus to be successfully developed in over fifty years. (See, *FDA Approves Benlysta to Treat Lupus, First New Lupus Drug Approved in 56 Years,* U.S. Food and Drug Administration, (March 9, 2011), http://www.fda.gov/newsevents/newsroom/pressAnnouncements/ucm246489.htm.) Reaching this point took an enormous financial investment. Benlysta had to undergo lengthy and rigorous clinical testing, culminating in two double-blind, placebo-controlled, multi-center Phase 3 trials. (See, *Id.)* Each of the two studies included nearly 900 patients at scores of clinical sites in multiple countries, with the first study lasting 52 weeks and the second lasting 76 weeks.

In March 2011, the FDA approved Benlysta for the treatment of lupus, the most significant advance in the treatment of lupus in more than half a century. (See, *Id.)* But it is very unlikely that Benlysta would have been developed without gene-based patents.

### B. The Investment Community is Heavily Influenced by the Ability of the Biotechnology Industry to Secure Patent Protection

HGS learned through hard experience that the ability to obtain patents on human genes correlates closely with its investors' confidence. On February 11, 1994, the National Institutes of Health ("NIH") announced that it would not appeal the USPTO's rejection of NIH patent applications to uncharacterized gene fragment sequences. The response by HGS investors was swift and damaging: HGS' stock fell by 14.4% on the day of announcement and then an additional 7.7% the following day. (See, Bloomberg Business News, *Human Genome Stock Continues to Slide*, Baltimore Sun, (Feb 15, 1994), *available at* http://articles.baltimoresun.com/1994-02-15/business/1994046174_1_human-genome-sciences-gene-fragments-patent).

Similarly, HGS' stock tumbled by approximately 20% in March 2000, when comments by President Bill Clinton and United Kingdom Prime Minister Tony Blair suggested to the investment community that gene patents should be restricted. Nor was HGS alone; the biotechnology industry as a whole lost roughly $50 billion in market

capitalization as a result of these comments. (See, Alex Berenson and Nicholas Wade, *THE MARKETS: STOCKS AND BONDS; A Call for Sharing of Research Causes Gene Stocks to Plunge*, N.Y. Times, Mar. 15, 2000.) HGS' stock price, like the rest of the biotechnology sector, rebounded when the comments were better explained.

Quite simply, patents provide an incentive for investment. Without DNA patents, neither the diagnostic tests developed by Myriad nor the lupus treatment developed by HGS might ever have come to fruition. As HGS' experience with Benlysta demonstrates, successful drug development can take more than 10 years and require more than $1.0 billion in investment. (See, Jon Entine, *FDA Balances Costs, Patient Safety in the Biologics and Personalized Medicine Revolution*, Forbes, (July 23, 2012, 12:05 AM), http://www.forbes.com/sites/jonentine/2012/07/23/fda-balances-costs-patient-safety-in-the-biologics-and-personalized-medicine-revolution-will-it-get-it-right-or-damage-the-miracle-industry/) Appellants complain about the cost of Myriad's screening tests, but absent its patents, Myriad might never have had the funding or incentives to develop the tests. Without DNA patents, the incredible advances in testing and therapeutics that have occurred in the last three decades — advances that have, unfortunately, been taken for granted because of they have become so common — would likely not have occurred, or would have occurred much more slowly.

## II. HGS' PORTFOLIO ENCOURAGED, RATHER THAN DISCOURAGED, SCIENTIFIC RESEARCH

Like other biotechnology companies, HGS employed people who loved science. World-class scientists were found at all levels of the company from the lab bench to the boardroom, and excellence in science was a basic tenet of the company from the very beginning.

HGS fulfilled its commitment to science and scientific collaboration in the ensuing years. Academic scientists approached HGS throughout its twenty-year history for access to its extensive collection of human genes and gene products. In keeping with that commitment, HGS (like many other biotechnology companies) entered into hundreds of material transfer agreements and provided universities with research reagents that enabled and supported academic research around the world. These substantial contributions were acknowledged in numerous scientific journal publications reporting the scientists' subsequent work.

Moreover, at no point in HGS' history did it ever enforce its patents against academic researchers. As evidenced by its contributions of materials, HGS wanted to encourage further research on human genes so that new medical treatments could be discovered and developed to address unmet medical needs and ease patients' suffering. In addition, the cost of litigation would have far outweighed any potential recovery in damages that might be obtained from patent litigation against academic researchers.

We believe that this philosophy was (and continues to be) shared by many other genomics companies. Indeed, the dearth of patent litigation brought by genomics companies against academic researchers and institutions over two decades is telling.

Evidence of academic researchers' ability to study HGS' patented inventions can also be seen by examining academic research surrounding one of HGS' most important discoveries, the BLyS protein that led to the development of Benlysta, HGS' lupus treatment. Although HGS held numerous patents directed to BLyS, more than one thousand scientific papers have been published regarding the structure, activity and biology of the BLyS protein, most by third parties. Clearly, HGS' patents did not exert a significant chilling effect on academia.

Similarly, HGS did not pursue litigation against research tool companies, gene chip companies or diagnostic tool companies even though they were potentially making profits based on its patented inventions. Again, the cost of such litigation would have far outweighed the limited amount of damages that could have been obtained. Moreover, these companies were often enabling academic scientists to further research HGS' patented genes, research which indirectly benefited HGS as noted above. And again, we are unaware of evidence that other genomics companies were behaving differently.

These actions show that collaboration between industry and academia can go hand-in-hand with the availability of patents on human genes, and that gene patents advance research and discovery. If isolated genes are held to be excluded from patent-eligibility, however, biotechnology companies such as

HGS would be forced to reevaluate their relationships with academia and non-profit research institutes and in many cases may be tempted to rely on trade secret law to protect the value of their discoveries. The negative consequences of such actions on open sharing of scientific discoveries in the biotechnology field are clear.

## III. THE MONOPOLY ON HUMAN GENE PATENTS IS NEARING EXPIRATION.

The Human Genome Project published multiple versions of the human genome in 2000-2003. With a twenty-year patent term, the majority of the human gene patents that were on file just prior to that publication will expire within the next 7-10 years. In fact, many of the human gene patents that were filed in the early to mid-1990's have already expired or abandoned.

Currently, it takes about ten years from discovery to bring a new biological therapy to market. Thus, if a company does not start clinical trials in the very near future, it is likely that any human gene patent now in force will expire *before* the company has progressed through clinical trials, obtained FDA approval and could potentially enter the marketplace.

We urge the Court to consider whether it is necessary to make dramatic and sweeping changes in rights that have existed for over 30 years to "solve" a problem that is close to being a non-issue due to the patent system's limit in granting monopolies.

## CONCLUSION

The judgment of the Federal Circuit should be affirmed.

Respectfully submitted,

ROCHELLE K. SEIDE, PH.D., J.D.
*Counsel of Record*
RKS CONSULTING
21299 Harrow Court
Boca Raton, FL 33433
(954) 295-3512
rseide21729@gmail.com

*Of Counsel:*

MICHELE M. WALES, PH.D., J.D.
INHOUSE PATENT COUNSEL, LLC
11816 Centurion Way
Potomac, MD 20854

MARK J. HYMAN

March 14, 2013