

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANAFYLLOS TAFAS,
Plaintiff,
v.
JON W. DUDAS, et al.
Defendants.
Civil Action No. 1:07cv846 (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM
CORPORATION, et al.,
Plaintiffs,
v.
JON W. DUDAS, in his official capacity as,
Under-Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office,
et al.,
Defendants.
Civil Action No. 1:07cv1008 (JCC/TRJ)

BRIEF FOR AMICUS CURIAE HUMAN GENOME SCIENCES, INC. IN SUPPORT OF
THE "GSK" PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Human Genome Sciences, Inc. ("HGS") respectfully submits this amicus curiae brief in
support of the anticipated motion of Plaintiffs ("GSK") for Summary Judgment. As discussed
below, HGS fully supports GSK's arguments seeking to prevent the implementation of new rules
governing the filing and examination of patent applications proposed by the U.S. Patent and
Trademark Office ("the USPTO"). See 72 Fed. Reg. 46716 ("the New Rules"). Like GSK, these

wide-ranging rules have a significant adverse impact on HGS including, in particular, its ability to obtain patent protection for its work on life-saving medicines.

I. Background

HGS is a biopharmaceutical company dedicated to the discovery, development, manufacture and marketing of innovative drug products for patients with unmet medical needs. HGS is based in Rockville, Maryland and currently has about 880 employees.

HGS primarily focuses on protein and antibody drugs with a clinical development pipeline that includes drugs to treat hepatitis C, lupus, cancer, rheumatoid arthritis and HIV/AIDS. HGS' two lead products – LymphoStat-B for lupus and Albuferon for hepatitis C – are currently undergoing Phase III clinical trials on hundreds of human patients. Furthermore, in an arrangement with the U.S. Government, HGS is conducting laboratory and clinical testing on ABthrax for the treatment of anthrax disease necessary to obtain approval from the U.S. Food and Drug Administration (“FDA”) as well as supporting the use of ABthrax in the event of an emergency prior to FDA approval. Other HGS compounds in clinical development include TRAIL receptor antibodies for the treatment of hematopoietic and solid malignancies, and an antibody to the CCR5 receptor for the treatment of HIV/AIDS.

HGS relies heavily on patents for the protection of its gene-based biopharmaceutical inventions. Patents are one of the foundations to supporting the continued investment by HGS in the development of new pharmaceutical products to meet society's unmet medical needs. At present, over 550 U.S. patents have been issued to HGS since its founding in 1992. Currently, HGS has over 200 U.S. patent applications pending at the USPTO.

II. The Retroactive Application of the New Rules to All Pending Applications Will Significantly Harm HGS

Across all industries in the United States, there has been a significant increase in the growth of innovation. *See* 2007-2012 Strategic Plan, United States Patent and Trademark Office, at 10 (available at <http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf>).

This growth is evidenced by the growth of the Gross Domestic Product, Research and Development expenditures, and productivity in the United States over the past several years that have outpaced other industrialized economies in the world. *Id.*

Not surprisingly, the number of patent application filings over the past several years has increased. *See* Federal Trade Commission Report, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (October 2003), Chapter 5 at 4 (available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>). The Director of the USPTO, Jon W. Dudas, emphasized the role of the USPTO in this era of exploding growth: “American ingenuity continues to fund our economy. USPTO is honored to help our inventors and innovators.” 2007-2012 Strategic Plan, cover page.

HGS is one such innovator. Patents play a critical role in the development of new medicines by HGS. Nevertheless, contrary to the Director Dudas’ assertion about the role of the USPTO, the New Rules only serve to hurt HGS and other drug discovery companies as well as all other companies and individual inventors that have a pending patent application.

As explained by GSK, the New Rules are especially egregious in view of their retroactive impact on pending patent application families that include at least two continuing applications

and at least one Request for Continued Examination (“RCE”) application.¹ The limitations on the number of continuing applications and RCEs set forth in 37 C.F.R. § 1.78(d) and 37 C.F.R. § 1.114(f) apply to applications filed prior to November 1, 2007. *See* 72 Fed. Reg. at 46716; *see also* Questions and Answers, Claims and Continuations Final Rule, at 49-50 (Oct. 22, 2007) (available at <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrfaq.pdf>).

HGS has over 200 applications currently pending at the USPTO. Many of these application families will be adversely affected by the New Rules just as with GSK’s patent family. *See* Mem. In Support of Plaintiffs’ Mot. for a Temporary Restraining Order and Preliminary Injunction, at 5-7; Declaration of Sherry M. Knowles in Support of Plaintiffs’ Mot. for a Temporary Restraining Order and Preliminary Injunction, at ¶¶ 23-39. These adverse effects would certainly arise if the New Rules are permitted to be implemented and can be directly attributed to HGS’ previous reliance on the current rules for prosecuting patents to biotechnological inventions, which have been in place for over twenty years.

HGS is a small biopharmaceutical company that has yet to introduce any product to market. Consequently, costs have been and continue to be a dominant concern for all aspects of HGS business planning, including the protection of its intellectual property. With costs in mind and in reliance on the present patent rules, HGS implemented a strategy for consolidating its applications to best protect its intellectual property rights. By retroactively changing its rules, the USPTO has undermined HGS’ patent strategy, which may lead to the loss of patent rights to which HGS is currently entitled and consequential effects on its pipeline. As a result of these

¹ HGS fully supports GSK’s arguments in support of its motion for a temporary restraining order and preliminary injunction including, for example, the likelihood of success on the merits that the USPTO exceeded its authority in promulgating the New Rules. For purposes of this *amicus* brief, HGS focuses on the significant harm it will suffer as a result of the retroactive application of the New Rules.

new rules, HGS may, in certain circumstances, be unable to protect rights to inventions that it had planned to commercially develop, removing potential incentives it would have to further this development, thus depriving the public of new life-saving medicines as envisioned by HGS and its investors and collaborators.

As an example, in one particular HGS application, the specification discloses hundreds of species. While claims to a genus have been pursued in this family (which includes at least two continuing applications and one RCE), only a few species have been claimed to date, and HGS fully intended to pursue additional species in other continuing patent applications in accordance with the current USPTO rules. Indeed, HGS filed the original application in this family and prosecuted the original application and related applications in this family in reliance on the current USPTO rules. Since the USPTO Examiner has never raised a formal restriction requirement during prosecution of this patent family, HGS may be precluded from filing further continuing applications to obtain claims to other species described in the original application as it and its investors and collaborators had originally envisioned and counted on.² In the absence of the contemplated further continuing applications, the vast majority of the species invented by HGS will not be protected by patents. While this result is quite detrimental to HGS and its investors and collaborators, this result – most importantly – removes any incentive for *anyone* to spend the considerable time and money (typically estimated at between \$800 million and \$1 billion) to determine the efficacy of the species invented by HGS in clinical trials as a necessary precursor to obtaining FDA approval to provide the public with these species.

² Although the “one more” exception to 37 C.F.R. § 1.78(d)(1) would apply in theory to this application, only one species would likely be examined in the “one more” application. Moreover, the USPTO already has indicated through its instructional materials concerning the New Rules that a petition under 37 C.F.R. § 1.78(d)(1)(vi) necessary to permit the filing of an additional continuing application (required where two continuing applications have already been filed) would not be granted in this type of situation.

In sum, HGS cannot now seek protection for the full scope of the inventions disclosed in its original application. The New Rules have eliminated HGS' ability to pursue protection for the full scope of the inventions described in the original application in the family. The retroactive impact of the New Rules on this HGS patent family is significant.

III. Conclusion

Pursuant to the authority provided by the United States Constitution "to promote the Progress of Science" (U.S. Const. Art. I, Sec. 8, cl. 8), Congress has enacted the Patent Laws (35 U.S.C. § 100 *et seq.*) that allow inventors to obtain patents for their discoveries. The USPTO's New Rules significantly undermine the ability of inventors to protect the fruits of their labor. In particular, HGS as well as other individuals and companies engaged in the discovery of new life-saving medicines will no longer be able to pursue patent protection to the full extent permitted by the Patent Laws.

Society as a whole will suffer from the reduced incentive to conduct research and development necessary to bring innovative drugs to market that serve unmet medical needs. Incentives for innovation must not be diminished to meet some illusory efficiency objectives. Accordingly, Plaintiffs' motion to prevent implementation of the USPTO's New Rules should be granted.

Dated: This 19th day of December, 2007.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

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