Association For Molecular Pathology et al v. United States Patent and Trademark Office et al Doc. 224

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY; AMERICAN COLLEGE OF MEDICAL GENETICS; AMERICAN SOCIETY FOR CLINICAL PATHOLOGY; COLLEGE OF AMERICAN PATHOLOGISTS; HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD; WENDY CHUNG, MD, PhD; HARRY OSTRER, MD; DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD; ELLEN MATLOFF, M.S.; ELSA REICH, M.S.; BREAST CANCER ACTION; BOSTON WOMEN'S HEALTH BOOK COLLECTIVE; LISBETH CERIANI; RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE; VICKY THOMASON; KATHLEEN RAKER, Plaintiffs, v. UNITED STATES PATENT AND TRADEMARK OFFICE; MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation, Defendants	Civil Action No. 09-4515 (RWS) **DECLARATION OF JOSEPH E. STIGLITZ, Ph.D.**

1. My name is Joseph E. Stiglitz. I am University Professor at Columbia University and Chair of Columbia University's Committee on Global Thought. I am also founder and co-president of the Initiative for Policy Dialogue at Columbia.

2. In 2001, I was awarded the Nobel Prize in economics for my analysis of markets with asymmetric information. I was also a lead author of the 1995 Report of the Intergovernmental Panel on Climate Change, which shared the 2007 Nobel Peace Prize.

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3. I have been retained by the plaintiffs and their counsel as an expert for this case. I have received no compensation for my services.

4. I received a B.A. from Amherst College and a Ph.D. from the Massachusetts Institute of Technology (MIT) in 1967. I became a full professor at Yale University in 1970, and in 1979 was awarded the John Bates Clark Award, given biennially by the American Economic Association to the economist under 40 who has made the most significant contribution to the field. Prior to coming to Columbia University, I taught at Princeton, Stanford, MIT, and was the Drummond Professor and a fellow of All Souls College, Oxford.

5. From 1993-95, I served on President Clinton's Council of Economic Advisers, and from 1995-97 I served as chairman of the Council. From 1997-2000 I served as Chief Economist and Senior Vice-President of the World Bank. In 2008, I was appointed by French President Nicolas Sarkozy to chair a Commission on the Measurement of Economic Performance and Economic Progress. I was also chair of the Commission of Experts of the President of the UN General Assembly on Reforms of the International Monetary and Financial System.

6. I founded one of the leading economics journals, *The Journal of Economic Perspectives,* and have authored several books, including *Globalization and Its Discontents* (W.W. Norton June 2001), *The Roaring Nineties* (W.W. Norton), *Towards a New Paradigm in Monetary Economics* Cambridge University Press) with Bruce Greenwald, and *Making Globalization Work* (W.W. Norton and Penguin/Allen Lane, September 2006).

7. I helped create a new branch of economics, "The Economics of Information," which explores the consequences of information asymmetries. I have made major contributions to macroeconomics and monetary theory, to development economics and trade theory, to public and corporate finance, to the theories of industrial organization and rural organization, and to the theories of welfare economics and of income and wealth distribution. In the 1980s, I helped revive interest in the economics of R&D. My work has helped explain the circumstances in which markets do not work well, and how selective government intervention can improve their performance.

8. I have written and spoken extensively on the strengths and limits of intellectual property and its role in stimulating innovation. As member and then chairman of the Council of Economic Advisers, and a member of the Cabinet, one of my responsibilities was to provide advice on the impact of alternative intellectual property regimes on growth and innovation in the United States. As Chief Economist of the World Bank, one of my responsibilities was to advise countries around the world about the desirability and impacts of alternative intellectual property regimes. This took on increasing significance as the importance of knowledge for development came to be recognized. I have been a keynote speaker at an international meeting of the World Intellectual Property Organization and have been widely engaged in discussions in the United States and abroad. In these various roles, I have had extensive discussions on intellectual property with relevant American, foreign, and international agencies and organizations responsible for the formation of policies concerned with promoting innovation.

INTELLECTUAL PROPERTY: ITS STRENGTHS AND LIMITS

9. Innovation is important; it has transformed the lives of everyone in the world. Intellectual property laws can and should play a role in stimulating innovation. However, the contention that stronger IP rights always boost economic performance is not correct. Poorly designed intellectual property regimes can reduce access to technology and medicine, lead to a less efficient economy, and may even slow the pace of innovation.

10. Intellectual property protection is designed to ensure that inventors, writers, and others who invest their money and time in creative activity receive a return on their investment. Patents give an inventor the exclusive right to market or use his innovation for a limited period of time, currently 20 years.

11. There are two fundamental problems with the IP system. First, it is based on *restricting the use of knowledge*. Knowledge is what economists call a "public good": everybody potentially can benefit from it, and there is no extra cost associated with an additional person gaining those benefits. Restricting knowledge is thus inefficient. Second, the patent system also grants (temporary) *monopoly power*. Monopoly leads not just to inequities but also to major distortions of resource allocations. The monopoly power generates monopoly rents (excess profits).

12. As a society, we tolerate some monopoly power and some restrictions on the use of knowledge in the belief that they might spur innovation. But the social costs of these distortions and inefficiencies can outweigh the benefits. Patents that impede the dissemination and use of knowledge slow follow-on research, innovations based on other innovations, and can slow overall technological progress.

13. Another fundamental problem is that under the patent system the rewards do not correspond to the marginal social returns. The "marginal social return" is having innovation available earlier than it otherwise would have been. In other words, if the invention was to have occurred anyway, then the contribution of the "inventor" is that it occurred earlier than it would have without the incentives offered by the patent system. The patent system does not reward people on the basis of the marginal social return of their contribution. Instead, it gives the individual or corporation that is first the entire value of the innovation, which obviously can well exceed the marginal social contribution. As a result, it introduces a distortion.

14. The inefficiencies of the patent system are especially serious in cases where patents are overly broad or improperly awarded on basic knowledge or ideas or natural laws or phenomena. Patents in these categories privatize what is – and should remain – in the public commons.

15. A well-balanced patent system is one that balances the costs of monopolization and the benefits of innovation, by determining what should not be patentable subject matter, limiting the period of patents, requiring disclosure of the details so that others can build on them, and limiting the ability to use patents for "abusive" monopoly power. When patent systems answer, for instance, the questions in the wrong way of what can be patented and how broad patents should be, competition is reduced and innovation is inhibited.

16. Different intellectual property regimes (patent systems) answer these questions differently. The intellectual property regime which is optimal at one time for one country may not be optimal, or even desirable, for another country at another time.

Intellectual property is a social construct, not a matter of natural law. As such, the provisions of an intellectual property regime have to be examined, and re-examined, in light of changes in the economy and the evolution of society's innovation system. Such an examination requires a balancing out of the benefits, in terms of *possible* impacts in incentivizing innovation, with the costs, including possible adverse effects on innovation (e.g. resulting from reduced access to knowledge, impediments posed by "patent thickets," and the adverse effects on innovation association with reduced competition) and the reduced access to the benefits of innovation. There have been many instances where the intellectual property regime has impeded innovation, or would have done so had the government not intervened (as it did in the case of airplanes) or the Courts had ruled differently (as in the case of the development of the automobile).

17. The balancing is reflected, for instance, in the length of life of the patent—a longer patent life might provide increased incentives but would also increase the adverse effects. There is no reason to believe that 20 years represents the "optimal" life of a patent, and in some cases, e.g. orphan drugs, the lifetime has been extended, because of the belief that there is a need for greater incentives.

18. Similarly, one of the reasons for high standards of "obviousness" and "novelty" is that when the standards are low, the induced innovation is limited, while the costs of reduced access to knowledge are significant.

19. There is a broad understanding that in innovative processes, each innovation builds on prior innovation, and that is why there is such concern that the patent system should not reduce follow-on innovations. One of the reasons for strong disclosure requirements is that at least the knowledge that underpins an innovation should

be freely available; the hope is that in doing so, advances in knowledge will be promoted, as inventors trade off the costs of the "loss" of secrecy with the benefits conferred by the patent system. Many scholars have concluded that a system of compulsory licensing (where users of knowledge would pay an appropriately set licensing fee) would be less likely to inhibit follow-on innovations than the current system and at the same time would provide strong incentives for innovation. The U.S. has, so far, not chosen to go that route. This implies that there is a need for even greater care in the determination of what is patentable.

20. The boundaries between what is and is not patentable are, like the other features of the intellectual property regime, an area where judgments have to be made about costs and benefits, and where the boundaries may change with time. The Supreme Court is, for instance, presently reconsidering business process patents – I believe rightly so.

21. In assessing the costs and benefits of issuing patents, it is important to consider broader social costs—access, for instance, to life saving medicines. All governments have recognized this; the US issued a compulsory license for Cipro when confronted with the threat of Anthrax.

22. What is at issue in this case is not a judgment about the patent system as a whole. It is not a judgment about whether the benefits of the patent system exceed the costs. It is not about whether patents can increase incentives, or even, through disclosure, enhance innovation. It is about the desirability of a particular category of patents, those concerning genes. Some countries, including Brazil,[1] committed to a strong intellectual

[1] Lei No. 9.279, de 14 de Maio de 1996, Regula direitos e obrigações relativos à Propiedade Industrial (Brazil), *available at* http://www.wipo.int/clea/en/details.jsp?id=515 (Article X (IX) states that "all or part

property regime, have decided not to allow such patents. Others that allow such patents accompany them with a strong "compulsory license" provision. For example, compulsory licensing is available for researchers in Germany in cases where such licensing is deemed to be in the public interest.[2] In assessing the desirability of this particular category from an economic and social perspective, the issue is not so much whether there are *some* benefits from the issuance of the patent, but whether the benefits exceed the costs.

PATENTS ON HUMAN GENES

23. Genes are the instructions inside each living being that tell it what proteins to produce. Those proteins, in turn, determine growth and affect susceptibility to disease. Knowledge of the genetic code can be of enormous benefit in finding cures and developing vaccines. This was one of the reasons that such importance was placed on decoding the entire genetic structure, which was eventually completed in 2003 by the publicly funded international Human Genome Project (HGP).

24. While the systematic decoding was in progress, there was a race by several private sector firms to patent human genetic sequences. Claims were filed on some 127,000 human genes or partial gene sequences, confronting patent offices around the world with an impossible task and resulting in huge backlogs.

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of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes" are not considered to be inventions).

[2] Patentgesetz [Patent Act], Dec. 16, 1980, last amended by Law of October 25, 1994, § 24 ("(1) If the applicant or patentee refuses to permit the exploitation of the invention by another person offering to pay reasonable compensation and to furnish security therefore, such person shall be given authority to exploit the invention (compulsory license) where permission is in the public interest.") Available at: http://www.wipo.int/clea/en/details.jsp?id=984.

25. Patents on the human genome – including those on BRCA1 and BRCA2 – provide an extreme example of the lack of balance that can occur in our patent system. First, these are patents on *basic scientific knowledge* – the very instructions inside each of our cells that determine what proteins are produced. While all intellectual property rights circumscribe the use of knowledge or information, these patents are on the *information itself* – the isolated human gene sequence, for example. Knowledge is the most important input into knowledge. This is why, to get a patent, you have to disclose enough information that somebody can replicate what is being patented and build upon that knowledge. However, in the case of a genetic sequence, one cannot build upon the knowledge without having "access" to the genetic sequence. But any use of the sequence is barred by the patent. Furthermore, genes and their mutations are *natural phenomena*, not human inventions. The researchers and private companies that applied for these patents did not invent this gene; they only identified what was already there.

26. The marginal social benefits of patenting genes clearly do not measure up to the profound costs. Since the publicly financed HGP has succeeded in decoding the entire human genome, there was really little value added by a race to decode a part of or even the whole genome. And the lock on knowledge resulting from the granting of these patents has served to impede follow-on research. In the case of Myriad Genetics' patents on BRCA1 and BRCA2, the value of Myriad's efforts was minimal: the knowledge of the precise sequence of the BRCA1 and BRCA2 genes was produced at best a little sooner than if not at the same time as it might have been otherwise. But the costs to society have been enormous. The high price that Myriad charges for its test (more than $3,000 for full sequencing) means that many women who could otherwise have been

tested, discovered that they were at risk, and taken appropriate remediation might die instead. In addition, the patents have interfered with the ability of other labs to offer diagnostic testing and have discouraged the search for better screening tests.

27. Myriad and advocates of sustaining the BRCA patents claim that the high profitability of each test provides Myriad with an incentive to ensure that more people are tested and to ensure that such testing is covered by insurance. The flaws in this reasoning should be obvious. To be sure, a monopolist has a greater incentive to market and advertise his product, because of the large margin between price and marginal cost; yet the overwhelming consensus within the economics profession is that, nonetheless, the social cost of monopoly is great. Higher prices resulting from monopoly power inevitably lead to lower utilization, especially on the part of those without full insurance. Currently, some 50 million residents in the United States do not have health insurance, and not all of those with health insurance – including some of the plaintiffs in this case – have full coverage for the costs of testing.[3] Given the high price of the tests, most of these will not be tested, and many of these may, as a result, not take appropriate actions which would have prevented their premature death.

28. The argument that because of its monopoly profits, Myriad has a greater incentive to promote testing is especially not persuasive, given the widespread awareness of breast cancer and the active role of the public and NGOs in promoting this awareness. Myriad's experts do not provide evidence that the extent of testing is greater in the United States, where the patent has been honored, than, say, in Ontario, Canada, where it has not been honored.

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[3] Complaint in *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, ¶ 93.

29. The argument that Myriad has succeeded in getting some insurance companies and third party payers to pick up the tab does not obviate the economic and social costs. Costs borne by the insurance company are shifted to the buyers of insurance; the higher costs lead to more uninsured. A considerable portion of the costs are shifted to taxpayers. The higher health care costs mean that access to other services are curtailed. Budget stringency overall inevitably will mean that government research budgets will be cut, impeding the flow of basic research on which so much depends.

30. That there are high economic and social costs simply cannot be denied. The only question (from an economic perspective) is whether the benefits of the extension of patent protection in this area is worth the cost. The alleged benefit is increased innovation. In fact, this is one of the areas in which innovation may be impeded.

PATENT PROTECTION ON GENES IS NOT NECESSARY TO STIMULATE BIOMEDICAL RESEARCH BUT INSTEAD MAY HINDER FOLLOW-ON INNOVATION

31. Proponents of excessively strong IP rights argue that without IP protection there will be no research at all. This is clearly wrong: countries without IP rights – Switzerland had none until 1907, the Netherlands until 1912 – were highly innovative. IP is part – but only part – of a country's "innovation system."

32. Traditionally, IP has played little role in promoting basic science. Major breakthroughs – including understanding the genetic structure of life – have bubbled out of research universities and government-funded research laboratories. Traditionally, academia has believed in "open architecture," meaning that the knowledge that research

produces should be made public to encourage innovation. The great scientists are driven by an inner quest to understand the nature of the universe; the extrinsic reward that matters most to them is the recognition of their peers.

33. One of the reasons that basic research is advanced most by *not* resorting to intellectual property protection is that, while doing so would have questionable benefits, the costs are apparent. Universities thrive on a free flow of information, with each researcher quickly building on the work of others, typically even before it is published. If every time a researcher had an idea, he ran down to the patent office, he would spend more time there – or with his lawyers – than in his lab.

34. Many of the most important ideas of basic science and mathematics – mathematical theorems, for instance – cannot be patented, and rightly so: the cost in terms of discouraging follow-on innovation would be enormous, and the benefit would be small.

35. The sequencing of genes and the uncovering of disease-gene correlations are basic scientific research. Gene sequences are basic scientific knowledge. They are products of nature, not of invention. Genetic sequences are also laws of nature in that they dictate instructions for the building of proteins. As such, not only are patents on genes and gene-disease correlations unnecessary for stimulating research in genetics, but they also impede the dissemination of information, slowing further research and technological advancement.

36. Unlike in the area of drug development, expensive clinical trials are not necessary before a gene sequence can be used in the development of a molecular diagnostic test. Thus, patent protection is not necessary for ensuring that genetic tests

come to market. Instead, gene patents prevent others from developing and offering additional, alternative, and perhaps cheaper tests for individual or combinations of genes that have been patented.

37. The adverse impacts on innovation of the failure to grant this and other patents for genes is particularly questionable for two reasons. The first is that, by the mid-eighties, it was clear that it was simply a matter of time before the human genome would be decoded. The basic methodological research had already been done. Governments around the world had already committed the resources for the decoding. This is one of those instances where there was little benefit to the "patent race." Net, there was a social cost: while the discovery occurred a little earlier, the cost of lack of access discussed in the paragraphs above and the impediment to follow on research (discussed in ¶ 19) almost surely outweigh these slight benefits. Scarce research talent was diverted from areas where the social returns would have been far higher.

38. The Myriad and similar patents and the discovery that they entailed thus did not contribute to the store of knowledge, but they impeded innovation in several ways. I have discussed two of these: the reduction of public funds available for research and the diversion of scarce talent in the socially unproductive race to be first. But more significant perhaps is the impediment to follow-up research, which might, for instance, result in a lower cost or a more accurate test. This is especially so given the presence in this market of universities and government agencies interested in detection of the risk of breast cancer, and willing to provide the benefits of the knowledge that they produce at the marginal cost of testing. Impediments to research hold even for basic research. An empirical analysis performed by Murray and Huang (2005) showed that patents on genes

resulted in a 5%-17% decline in public knowledge generation (as measured by the annual rate of forward citations) as compared with genes that were simply published and not patented. This study additionally showed that the negative impact of a gene patent grant on follow-on publications was worse when the patent assignee was from the private sector, when the patent was especially broad in scope, and when the gene was closely linked to human disease.[4]

39. More generally, while the enclosure of the knowledge commons resulting from patents has adverse effects in limiting usage, it has also had perhaps more serious negative impacts on discouraging further innovation by insisting on expensive licenses or not allowing any usage of the scientific information at all. Williams (2009)[5] compares the subsequent scientific research and product development outcomes on genes sequenced by the private firm Celera and the public Human Genome Project. Her analysis suggests that Celera's intellectual property which enclosed knowledge led to a 30 percent reduction in subsequent scientific and product development outcomes.

40. Advocates of the Myriad and similar patents wish to shift the discussion from whether the patent system encourages or discourages innovation. That is not the issue. The issue is whether the particular category of patents under discussion does so, and does so to a sufficient extent to justify the large social costs of the restrictions on the use of knowledge and the extension of monopoly power. It is clear that the framers of the Constitution could not have had in mind the patenting of genes when they gave the

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[4] Kenneth G. Huang and Fiona E. Murray, "Does patent strategy shape the long-run supply of public knowledge? Evidence from human genetics," (September 1, 2008). *Academy of Management Journal*, Forthcoming. Available at SSRN: http://ssrn.com/abstract=1249522

Heidi Williams, Intellectual Property Rights and Innovation: Evidence from the Human Genome, unpublished, Dec. 30, 2009, available at: http://www.people.fas.harvard.edu/~hlwill/papers/Williams_jmp.pdf

Federal government the right to grant patents. So too, most of the Court decisions that have helped shape America's intellectual property regime could not have taken into account the fast evolution of America's complex innovation system. One of the factors that this Court will need to assess are the marginal social costs and benefits of the extension of patent coverage to genes, and the terms and conditions under which such coverage is extended. In my judgment, the overwhelming evidence is that the Myriad patents have brought few benefits, but significant social costs.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and belief.

Joseph E. Stiglitz, Ph.D

Executed on ~~November —, 2009~~ January 19, 2010