II-9.4: The US Department of Justice declares itself against the patentability of the human genome.

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MAIN INFORMATION

In an amicus curiae brief of October 29, 2010, in the Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al. case, before the Court of Appeal for the Federal Circuit, the US Department of Justice reversed a longstanding policy by declaring human genes ineligible for patents, because they are part of nature. This new position could have an enormous impact on the medical and biotech industries.

CONTEXT AND SUMMARY

The Department of Justice issued an *amicus curiae* brief on October 29, 2010, in the *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al. case, before the Court of Appeal for the Federal Circuit*, involving two human genes linked with ovarian and breast cancer, BRCA1 and BRCA2. In this brief, it declared itself against the patenting of human genes. It acknowledged that this position is "contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA"[1], however, it remains unsure what the consequences of this position will be.

Genes have been patented in the United States for decades, but the question of their patentability had never been brought before a Court. This governmental statement intervenes in a very particular case. In March 2010, a decision by Judge Sweet of the District Court for the Southern District of New York surprisingly invalidated seven patents related to the genes BRCA1 and BRCA2, whose mutation have been associated with cancer[2], and with the 3.000 USD analysis conducted by Myriad Genetics to see if certain women are genetically predisposed to breast and ovarian cancer. In this case, several medical and cancer associations, amongst which the American Civil Liberties Union and the Public Patent Foundation challenged the awarding of the patents on these genes awarded to Myriad Genetics, a biotech company, and the University of Utah Research Foundation, on the claim that these genes are mainly natural creations, and their patenting stifles research and innovation and limit testing options. The judge

embraced this explanation, stating that genes are important for the information they convey, and as such, genes extracted from the body do not differ from those included in it.

The Patent and Trademark Office (PTO) backed Myriad Genetics in this case, and both appealed Judge Sweet's decision before the Federal Circuit Court, and it is in this particular case that the US Department of Justice wrote this *amicus* brief. Interestingly, even though the brief was written after discussion with the major agencies concerned by this issue, no lawyer from the PTO signed the letter. This agency did not agree with the DoJ's position, and it seems that other agencies, especially the National Institute of Health, have overruled the PTO.

By this change of position, the US Department of Justice endorsed the theory according to which human genes, inside or outside the body, are not patentable because they are products of nature, and not inventions, and thus are part of the common heritage of mankind. The proponents of this thesis mainly underline that allowing human genes to be patented impedes medical progress, for it locks up basic genetic information. On the contrary, the position previously held by the DoJ supported the position of biotechnology firms, which argue that genes isolated from the body are chemically different than those still within, and thus can be patented.

The brief unambiguously stated that the belief that the simple isolation of a chemically unaltered human gene no longer corresponds to the definition of an invention: "The chemical structure of native human genes is a product of nature, and it is no less a product of nature when that structure is 'isolated' from its natural environment than are cotton fibbers that have been separated from cotton seeds or coal that has been extracted from the earth"[3].

However, one should note that this does not concern human manipulation of DNA, such as gene therapies or methods to create genetically modified crops, which constitute the core business occupation for biotechnology industries, and remain patentable.

If this position of the US Department of Justice is a major shift, it should be underlined that the Department did not contest the patentability of manipulated DNA, but solely that of isolated, unmodified human DNA. Indeed, by supporting Judge Sweet's decision, the Government contributes to prohibiting what long has been considered a "lawyer's trick". Indeed, the isolation of a gene in order to patent it is a strategy to circumvent the existing prohibition of directly patenting DNA found within the human body, for this achieves the same purpose without fundamentally altering

the isolated DNA.

This shift of position from the Department of Justice is also an obvious departure from the point of view of the Patent and Trademark Office, and constitutes an important modification of formerly prevailing consensus between the biotech industry and the American Government. The Patent and Trademark Office has issued patents covering about 20% of human genes, amongst which some are associated with Alzheimer's disease, colon cancer, muscular dystrophy, asthma, etc.

Patent lawyers have heavily criticized this decision. Some of them argued that such a decision will undermine American leadership in research and life sciences. Even though it will definitely require some changes in American patent policy, this decision is not yet fully effective, for the Patent and Trademark Office underlined that it will maintain the current status quo while another similar case, also on cancer related genes, is pending resolution. It is still unsure if the new policy will apply only to new patent applications, or if it could be used to revoke existing patents. However, nowadays, fewer and fewer patents on isolated genes are requested by companies, which mostly try to patent manipulated genes, which the US Department of Justice considers to continue patentable.

Furthermore, the argument used by Judge Sweet and backed by the Department of Justice, according to which products isolated from nature cannot be patented, could well be extended to protein-based drugs and antibiotics, whose underlying composants are found in nature. So the practical consequences of the change of philosophy could very well have serious consequences for the organisation of research and biotech industry in the United States, but also could render collaboration and international cooperation on patent issues harder from the American point of view.

Myriad Genetics in its appeal of Judge Sweet's decision, stated that the plaintiffs had no right to sue, for Myriad did not accuse them of infringement. These arguments were already rejected by Judge Sweet. However, the Court of Appeal for the Federal Circuit could accept such an argument if it wants to avoid making a statement on this matter, and delivering an important precedent which would potentially force the industry to reorganise itself.

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[1] Brief for the United States as *amicus curiae* in support of neither party, n° 2010-1406, p.18, accessible on *patentdocs.typepad.com/files/ipo-**amicus**-**brief**.pdf*

[2] See « Judge invalidates human gene patent », New York Times, March 29th, 2010

[3] Brief for the United States as *amicus curiae* in support of neither party, n° 2010-1406, p.11

BRIEF COMMENTARY

This decision proves the difficulty of regulating biotechnological issues, when they meet with ethical issues, for this is an area on which consensus has not yet been reached. Indeed, the patentability of isolated human genes is ambiguous: awarding patent protection is a regulatory incentive, for it rewards investments in fundamental research and the development of technological products for genetic therapies, by creating an temporary monopolistic situation for the inventor (in this case, biotech firms). However, the opponents of such a system argue that patent protection excludes other researchers and thus restricts competition and impedes the discovery of new therapies, thereby slowing medical and scientific progress.

By endorsing the argument of the non-patentability of Nature, the Department of Justice seeks to create other incentives by promoting competition between laboratories to eventually create more genetic therapies, and break down the barriers thrown up by patents on isolated genes. This occurs at a point in time where several laboratories claim that, without such patents, they could offer multiple genetic tests which could help individuals, or even entire genome sequencing, helping them knowing their genetic predispositions to certain diseases and, if necessary, do their own genetic testing. The concern for the increase in supply of therapy to the market, and the corresponding decrease in their price, is legitimate, especially in the U.S.A. where consumers are very price-sensitive, since they either pay costly private insurance to cover such costs, or decide whether or not to pay for treatment themselves.

In the lack of unanimous scientific and political consensus on what exactly is natural, thus not patentable, and what is not because of human transformation, it is a judge who finally decided to move the limit of what is morally accepted or not in a society, fully embracing the power he has in the pronouncement of what is legally acceptable. By doing so, Judge Sweet has forced the actors of the sector to renew their positions, which the Department of Justice did. How the Court of Appeal for the Federal Circuit will rule remains unsure, however, the administrative repositioning it created will have important organisational effects.

Furthermore, the law's apprehending of concepts such as the human body and Nature is difficult. Here, the judge decided to protect the accessibility of human genes, in order to protect innovation by putting them into the non-patentable concept of Nature, a conceptual black box that allows human genes to be considered biological common goods. Indeed, the law is traditionally distant from the body, which it does not take into account as such, but rather, simply identifies subjects of law, be they natural or legal persons. The development of biotechnologies results in a dislocation between the formerly indivisible human body, the simple physical support of the subject of law. Therefore, when the law attributes property rights to human intervention in human biology, including body parts, this leads to a theoretical dilemma on what is a human invention or not, and on what in the body is or is not removable to be modified, and marketed.

During the 18th century, science was considered as the observation of the world, and was therefore knowledge accessible to everyone. The resulting knowledge, because of its essential accessibility, could not be patentable. What the patent protected was the technological object, or process, resulting from the knowledge acquired.

This ontic distinction between science and knowledge can no longer apply to our current reality. Indeed, even the discovery of new knowledge can no longer be made through a careful observation of the world, but must result from technical—and therefore patentable—knowledge, made possible only by very expensive investments. The resulting knowledge, such as isolated human DNA, can become patentable and the classical distinction between science and knowledge obsolete, for mere careful observation of the world is no longer sufficient to acquire the knowledge. Title 35 of the United States Code, under which patent law is defined, relies on this modern approach.

Therefore, once the original distinction is void, the need for Political intervention is a requisite to state – and express social ties – on the matter, ruling that products of the human body are not patentable because of their origin. However, one cannot state that they come from Nature, such as coal extracted from the earth, or fibres extracted from cottonseeds, since they are the result of costly investments and technical knowledge. Therefore, it is difficult to argue that human DNA isolated from the body is not patentable because it is part of Nature, since the distinction between Nature and human creation no longer stands.

All the more, the concept of Nature is ambivalent: it appears to be a convenient black box, a conceptual shelter for products, which should, for political and moral reasons, be considered accessible to all, however, it contributes to the externalization of an object, such as isolated human DNA, in the indefinable concept of Nature. Because of the lack of temporal and geographical consensus around what is Nature, and what is part of it, an argument such as the one defended by the Department of Justice does only provide a fragile and revocable consensus. Nature tends therein to be considered as a large extension of the notion of public common goods, a concept morally stronger but conceptually weaker.