Is DNA still patentable?

A recent District Court decision in New York threatens the ability of biotech firms to patent their gene-related inventions

DNA is chemically relatively inert and its primary function is as a carrier of information, although some DNA molecules, such as primers and probes, can be argued to have the ability to bind to complementary sequences as their intended primary function, but that itself is only the inherent result of the sequence information they hold.

Nonetheless, until now, DNA sequences have been treated for patentability purposes as just novel chemical compounds, inventive due to their usefulness for biomedical ends.

Many have argued that DNA sequences corresponding to parts of native sequences, optionally amended to remove introns or to add different terminal sequences, for example to facilitate their transcription, should not be patented as they represent mere discoveries or part of the common human heritage. However, despite such objections, the major patent offices have issued many patents directed to DNA sequences.

The US Patent Office's practice of granting patents for DNA sequences and their use in medical diagnostic methods was recently attacked in a decision by Judge Robert Sweet of the District Court of the Southern District of New York that was handed down on 29 March 2010, AMP v. USPTO, which declared invalid claims to DNA sequences relating to the BRCA1 and BRCA2 cancer-susceptibility genes and their use in diagnostic assays, claims in patents owned by the University of Utah and licensed to Myriad Genetics. While the decision will almost certainly be appealed, if upheld it will have profound and far reaching effects on the ability of biotech companies to patent their inventions, raise capital and sustain their stock prices.

To be patentable in the US, an invention must be new, non-obvious, and useful, and in a famous decision in 1980 (Diamond v. Chakrabarty) the US Supreme Court confirmed that "anything under the sun that is made by man" was potentially patentable subject matter. Judge Sweet however did not rely on lack of novelty, obviousness or lack of utility, but instead argued that the claims failed the statutory subject matter test of Section 101 of the US Patents Act which states that: "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the [further requirements of this law]".

To reach his decision relating to the DNA sequence claims, Judge Sweet relied on US Supreme Court rulings between 1874 and 1948 which held that products of nature, and materials which are not markedly different from products of nature, even if in a purified form that doesn't exist in nature, are not patentable. For Judge Sweet, "isolated DNA" was simply purified DNA and thus an unpatentable "product of nature". Likewise cDNA (i.e. DNA spliced to place the coding sequences (exons) in order and to delete the non-coding sequences or introns) was still a "product of nature" as the omission of the introns did not make the cDNA "markedly different" from the full sequence native DNA since "the particular arrangement of [the] coding sequences is the result of the natural phenomenon of RNA splicing". Even probes and primers, oligonucleotide sequences having the ability to bind to the complementary sequences of native BRCA1/2 DNA, were products of nature as this ability was primarily "a function of the nucleotide sequence identity between native DNA and isolated BRCA1/2 DNA".

By analogy, novel drug substances incorporating a naturally occurring pharmacophore could be seen also to be "products of nature" and thus AMP v. USPTO should be of concern to the pharmaceutical industry in general.

Regarding the diagnostic method claims, Judge Sweet applied the "machine or transformation" test of the 2008 decision of the US Court of Appeals (CAFC) in In re Bilski according to which a process or method is patentable if it is tied to a particular machine or apparatus or "it transforms a particular article into a different state or thing". That test, developed as a response to the explosion in patenting of business methods in the US following the decision of the CAFC in 1998 in State Street Bank v. Signature Financial Group, is considered by many to be an unduly harsh overreaction and is currently on appeal to the Supreme Court, with a decision likely by June 2010. Moreover, Judge Sweet seems to have been pushing Bilski to the limit when he refused to take into account the material transformations necessary in a medical diagnostic test, e.g. in the preparation of the sample, the amplification of DNA, etc on the basis that these were simply part of a data -gathering step. (In Bilski, the CAFC had argued that "adding a data-gathering step to an algorithm is insufficient to convert that algorithm into a patent-eligible process").

To conclude, on appeal we may expect the Court of Appeals not to go quite as far as the District Court has gone, but perhaps claims to DNA sequences in the US will in future have to be narrower than simply to "isolated DNA".

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