The death of gene patents: or merely a hiccup?

On 29 March 2010, Judge Robert Sweet of the US District Court, Southern District New York, handed down a decision which, if upheld on the appeal there will almost certainly be, will significantly impact the ability of biotechnology and medical diagnostics firms to patent their inventions, to raise capital, and to maintain their share prices.

The decision, AMP v. USPTO, relates to patents concerning the cancer genes BRCA1 and BRCA2 and to diagnostic tests for susceptibility to BRCA1/BRCA2-related cancers, e.g. breast, ovarian and prostate cancers, that are licensed to Myriad Genetics by the University of Utah, tests for which Myriad Genetics charge in the region of $3000. The decision arises from a request by the Association for Molecular Pathology (AMP) and others, including physicians and patients, for the District Court to revoke patent claims relating to DNA sequences related to BRCA1 and BRCA2 and to diagnostic tests utilising such sequences.

Inventions, to be patentable, must be new, non-obvious, and useful - however, the basis for Judge Sweet's decision in relation to the DNA sequences and the diagnostic methods is instead to be found in the statutory subject matter test of Section 101 of the US Patents Act. This Section 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 therefore, subject to the [further requirements of this law]". On the face of it therefore, as long as the subject matter claimed, i.e. the DNA sequences and the diagnostic methods, are new, useful and inventive, it would seem that they must also be patentable.

For the DNA sequences, Judge Sweet's decision is based on the reasoning that these, being sequences occurring in nature, are products of nature and as such are unpatentable. For the diagnostic methods, his decision relies on a recent decision by the US Court of Appeal for the Federal Circuit (CAFC), In re Bilski, which itself is currently under appeal to the US Supreme Court. Since the core of the argument is completely different for the two, I will discuss the DNA sequence claims first before turning to the diagnostic methods.

One 30-year old US Supreme Court decision made it clear that "[t]he laws of nature, physical phenomena, and abstract ideas [are] ... not patentable" and that the relevant distinction is "between products of nature ... and human-made inventions" (Diamond v. Chakrabarty, 1980). The Court of Appeals (CCPA), in a case dating from 1931 (In re Marden, 1931), had rejected claims to uranium as being "a product of nature", but Judge Sweet relied more heavily on a 1931 case from the Supreme Court which rejected claims to borax-treated fruit which acknowledged that the product as claimed was not to be found in nature but held that the product did not become an article of manufacture unless it "possesses a new or distinctive form, quality or property" compared with the naturally occurring product (American Fruit Growers v. Brogdex, 1931). Likewise, in a 1948 case, the Supreme Court had found of a microorganism cocktail that its "qualities are the work of nature ... [and] are of course not patentable" (Funk Bros Seed Co v. Kalo Inoculant, 1948). Further early cases had made it clear that purifying or separating a natural product did not render that product patentable (e.g. refined cellulose, considered by the Supreme Court in 1874 in The American Wood-Paper Co v. The Fibre Disintegrating Co).
On this basis, Judge Sweet found that "isolated DNA", not being markedly different from native DNA, was unpaitentable "[i]n the light of DNA's unique qualities as a physical embodiment of information" as being an unpaitentable product of nature. More particularly the absence of the chromosomal proteins asssociated with DNA in its natural state merely constituted a difference in purity that was insufficient to establish patentability. This finding was extended to short sequences of DNA which might be found within the larger sequences of the BRCA1/BRCA2 genes in native DNA. Moreover, even for claims directed to cDNA (i.e. DNA sequences omitting the introns found in native DNA), 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".

While Myriad had argued that isolated DNA (and primers/probes based on it) could be used for purposes for which native DNA could not be used, e.g. in diagnostic tests, due to its ability to target and interact with other DNA, Judge Sweet found this ability to be primarily "a function of the nucleotide sequence identity between native DNA and isolated BRCA1/2 DNA".

Thus we are left with a judgement rejecting claims to novel forms of DNA on the basis that the functionality of the novel forms derives only from the identical inherent functionality of the corresponding sequences of native DNA, making the novel forms not "markedly different" to the natural form and so unpaitentable as a product of nature. This decision should be of concern to the pharmaceutical industry in relation to novel drugs incorporating a naturally occurring pharmacophore.

It is possible, but not probable, that an equivalent result for DNA claims could have been reached in Europe under the European Patent Convention (EPC) on the basis that the claimed DNA represented "a presentation of information", unpaitentable under Article 52(1) (d) EPC.

Regarding the diagnostic method claims, Judge Sweet applied the "machine or transformation" test of the 2008 decision of the Court of Appeals (CAFC) in In re Bilski - 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". Judge Sweet however was pushing the analogy with 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". In any event, Bilski is under appeal to the Supreme Court and a decision as to whether the "machine or transformation" test is too severe is currently awaited.

On appeal we can expect some retreat from the position adopted by the District Court, but it seems not improbable that in future it will be necessary in the US to claim DNA more narrowly than simply as "isolated DNA". This will contrast with the position in Europe where Rule 27(a) EPC confirms that "[b]iotechnological inventions shall ... be patentable if they concern ... biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature".

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