Pigs Fly: Federal Court Invalidates Myriad's Patent Claims

by John Conley and Dan Vorhaus

Late on the afternoon of Monday, March 29, 2010, Judge Robert W. Sweet of the United States District Court for the Southern District of New York issued a jaw-dropping summary judgment ruling (pdf) in *Association for Molecular Pathology v. USPTO* that invalidates certain of Myriad Genetics' patents related to the BRCA 1 and 2 breast and ovarian cancer susceptibility genes. In a post written immediately after the release of the opinion, Dan gave a thorough summary of the ruling. Our objective here is to offer a bit more depth on what the ruling means—and what it doesn't mean. On the one hand, Judge Sweet's order is radical and astonishing in its sweep. On the other, it will be some time before we have any idea what impact it will ultimately have.

We should first disclose that one of us (John) has a dog in this fight, albeit a small one. In 2003, (along with biologist and patent lawyer Roberte Makowski), John published an article in the *Journal of the Patent and Trademark Office Society* entitled Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (pdf). In that article, Roberte and John laid out an argument for challenging Myriad-style patents on "isolated" genes as claiming products that are only trivially different from the naturally-occurring versions. Judge Sweet cited this article and, in several parts of his opinion, followed the roadmap it created. So, if you oppose the Myriad patents, you're welcome; if you like them, we're sorry.

What Summary Judgment Means. As Dan noted, and John first wrote last fall, it is rare for plaintiffs to win on summary judgment. For either side to receive summary judgment, it must show that there are no disputed issues of fact that require a trial to resolve, and that, on the undisputed facts, the law mandates judgment in its favor. This standard is especially hard for a plaintiff to meet, since it bears the burden of proof at trial. At the summary judgment stage, a defendant can usually create an issue of fact and thereby avoid summary judgment just by saying "they have the burden of proof at trial, and a jury might not believe them." Although this is an unusual case in that the basic facts—most notably Myriad's patent claims and the fundamental biology and genetics that makes possible those claims—really are not in dispute, a summary judgment ruling for the plaintiffs nonetheless sends a clear message about how strong this particular judge thought their case was—and how weak he thought Myriad's was.

The Road to Invalidation. The court broke Myriad's patent claims into two major groups: (i) those claiming isolated DNA sequences and (ii) those claiming methods for comparing or analyzing gene sequences to identify the presence of mutations corresponding to a predisposition to breast or ovarian cancer (p. 2). Both sets of patents were rejected under Section 101 of the Patent Act, which enumerates the permissible categories of patentable subject matter: processes, machines, manufactures, and compositions of matter. As the judge noted, a long history of cases forbids claims on laws of nature, abstract ideas, and natural phenomena, which include products of nature.

Isolated DNA Sequences. The claims to DNA sequences in isolation were held to be insufficiently distinct from naturally occurring genes in the body—the product of nature version. This conclusion embodied several critical steps. First, the court emphasized that whether a patent applicant claims patentable subject matter is a free-standing inquiry, separate from the determination of whether the invention also satisfies the standards of novelty, utility, and non-obviousness. In other words (and contrary to arguments often made by patent lawyers), you cannot prove that something is a patent-eligible, human-made invention—and not a product of nature—by showing how new and useful it is. It either is patentable subject matter or it isn't.

Having established this principle, the court went to assess just how different an "isolated" gene would have to be to avoid characterization as a product of nature. Myriad defined "isolated" in its patents as "substantially separated from other cellular components which naturally accompany a native human sequence [such as] human genome sequences and proteins" (p. 92). Myriad relied heavily on some cases going back to the early twentieth century—especially one involving purified adrenaline—to argue that this was enough of a difference.

The judge disagreed, strongly. He went back even further, to nineteenth-century cases involving line fibers and wood pulp, as well as later cases involving such things as pure tungsten, and concluded that "purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess 'markedly different characteristics' in order to satisfy the requirements" (p. 121).

Not Markedly Different. Myriad's isolated genes failed this test. In his search for "markedly different characteristics," Judge Sweet focused—and this is the most radical part of the opinion—on the critical functional property of a gene, whether in the body or in isolation: its ability to carry the information sufficient and necessary to code for a protein.

DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an 'isolated' form alters neither this fundamental quality as it exists in the body nor the information it encodes (pp. 3-4).

And again:

In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.' This conclusion is driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form. The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature. (p. 125).

Why is this so radical? Since the inception of gene patenting a generation ago, patent lawyers have taken the position that genes are just chemicals. Their information-carrying function is irrelevant to their patentability, the lawyers say. Because genes are chemically different in

isolation, at least in a literal sense, they can't be considered products of nature. The USPTO and the courts, including the Federal Circuit (the patent court of appeals), have uniformly acquiesced. Now a federal court has said that, no, genes aren't just chemicals—precisely because they carry information. Genetic exceptionalism has become a principle of law, at least in Judge Sweet's court.

Next Go the Process Claims. Myriad's process claims got even less respect. In just a few pages, out of 156 in total, the court concluded that they all failed the Federal Circuit's "machine or transformation" test for method claims. (This test comes from the recent *Bilski* case. Although the Supreme Court will soon issue its own opinion in *Bilski*, the machine or transformation test is the law unless and until the Supremes order otherwise.) Judge Sweet found that none of the methods were tied to any particular machine, nor did they bring about a tangible transformation of anything. Rather, "because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter" (p. 4).

Judge Sweet also added that, even if the claims were construed in such a way that they constituted "physical transformations associated with isolating and sequencing DNA, they would still fail the 'machine or transformation' test under §101 for subject matter patentability." (p. 147).

Taking it to the Next Level. Where do we go from here? Myriad will surely appeal to the Federal Circuit (it has a right to that appeal), a process that could take a year or more. It is possible that the District Court's judgment invalidating the Myriad patents will be stayed, or suspended, during that appeal. Judge Sweet's order will not affect any patents not directly involved in the case, nor be binding on any other court, and it is highly unlikely that the USPTO will change its gene patent examination standards just because of this decision.

Then it will be up to the Federal Circuit. Our initial guess is that the court will end up affirming Judge Sweet on some or all of the process claims, but will cut way back on his broad attack on gene patents. But that decision is way down the road and, of course, will be informed by what the Supreme Court decides to do with *Bilski*. Even farther down the road is an appeal from the Federal Circuit to the Supreme Court, where all bets would be off.

To summarize, as breathtaking as this opinion may be, its legal effect is currently very limited. Another federal district judge would be free reach exactly the opposite conclusion tomorrow (if another comparable case were pending, which it isn't). Things won't get serious (legally) until the Federal Circuit rules, since its opinion will bind all federal courts except the Supreme Court.

Practical Implications. With the decision only hours old, the headlines are already starting to roll in. "The End of Gene Patenting?" "Judge Rejects Patents on Genes." "Judge Nullifies Gene Patents." While it is clear that this decision is headline news, it is equally important not to overstate either its legal significance or its likely practical effect. The limited legal reach of the opinion—unless and until it is upheld by a higher court—has been discussed above. Less certain is its practical effect, including how businesses, clinicians and patients may change their behavior in response to the ruling.

As a recent report on gene patents (pdf) from the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) emphasized, the existing gene patent landscape has created considerable uncertainty as to how and by whom many genetic and other diagnostic tests may be performed. That uncertainty prompted SACGHS to recommend a pair of exemptions from patent infringement liability: one for genetic testing for "patient care purposes" and another for the "use of patent-protected genes in the pursuit of research."

It would, of course, be incredibly risky to rely on the SACGHS recommendations—which are only recommendations, and not binding law—to justify otherwise infringing activities for, as we wrote last month, there is a very long road from advisory committee recommendation to Congressional legislation. Similarly, it would be mistake to view a District Court decision as paving the way to ignore all of Myriad's BRCA patents, let alone providing the ability to disregard gene patents more broadly. This opinion may stick, but it is at least as likely that it won't.

Of course, just because something would be risky, legally speaking, does mean that it won't happen. It's within the realm of possibility that commercial or even non-commercial (e.g., academic or research) laboratories could take Judge Sweet's opinion as an invitation to challenge Myriad's monopoly of BRCA1/2 testing head on. (Isaac Ro and Jeff Ares, of equity research firm Leerink Swann, however, think that a commercial challenge would be unlikely to succeed (pdf) given the combined strength of Myriad's current commercial position and its remaining, unchallenged BRCA patent portfolio.) Risky or not, there is a possibility that Judge Sweet's opinion will prove in time to have let the gene patent horse out of the barn in a way that cannot easily be undone, even by a subsequent reversal at a higher court. For the moment, however, we do not foresee this decision producing any radical changes in commercial, clinical or other activity surrounding Myriad's BRCA patents, or gene patents more broadly.

In the broader policy debate surrounding gene and biotechnology patents, however, this decision is the latest, unmistakable shot across the bow of gene patent holders, particularly those such as Myriad Genetics that have developed businesses around patent-protected genetic tests supported by exclusive rights in underlying gene patents. As we wrote last summer, and as the SACGHS report pointed out in detail, there is a coming crisis at the intersection of multiplex genetic testing and whole-genome sequencing and biotechnology patents, particularly gene patents. This decision is sure to intensify the public policy discussion surrounding the appropriateness of gene patents, and ratchet up the media and public attention paid to the issue.

But to what practical effect? It seems unlikely that this decision, at least for the moment, will make Congress any more likely to take up the Supreme Court's longstanding invitation—recently reiterated by SACGHS—to sort out the whole biotech patent area. In fact, it might make legislators even more reluctant to act, on the (erroneous) assumption that the courts have everything under control. Biotechnology businesses and investors are similarly unlikely to use this decision as the basis for significant departures from their current approaches with respect to gene patents.

What everybody will undoubtedly be doing is waiting and watching, closely, to see what comes next. The patentability of genes—as well as the broader issues of biotechnology commerce and access to and development of genetic tests that today's opinion touches upon—is an issue that has long demanded a clearer resolution. To that chorus of voices we can now add Judge Sweet in the Southern District of New York. This

is an important step—but only a step—along the road to resolving that issue. Next stop, in all likelihood: the Supreme Court's decision in *Bilski*.