European Court Issues Gene Patent Ruling Against Monsanto—A *Myriad* Connection?

by John Conley

In another significant international development, on July 6, the Court of Justice of the European Union (more commonly known by its old name, the European Court of Justice or ECJ) ruled against Monsanto Technology LLC (pdf) in its suit against an Argentine company called Cetera and several other parties.

The Court sat in a 13-member Grand Chamber, which is eurojargon for “really big deal,” and issued a ruling which leaves gene patents essentially intact but warns national courts to construe them carefully. (Travel advisory aside: If you ever have a chance to visit the Court in Luxembourg, do. Its magnificently robed judges sit in medieval splendor in a hideous modern building. Lawyers (usually several per case), robed almost as magnificently, read long and pompous arguments that are translated into many languages. The judges, apparently having already decided the case, ask no questions and seem to pay no attention. The rulings are logically convoluted and delivered in baroque language. Everyone seems immensely pleased with the spectacle.)

**Soybean DNA, Living and Dead.** Monsanto holds a European patent that covers modified soybean DNA sequences that confer herbicide immunity on the plant (so-called “Roundup Ready” soybeans). A “European” patent is in fact a bundle of national patents issued by the European Patent Office (EPO) in Munich. (The EPO was established by a treaty, the *European Patent Convention*, and is not a European Union institution.) The EPO applies a single standard for judging patentability, but enforcement of patents is then delegated to the courts of the individual European countries, and those standards may differ. Monsanto’s European patent is in effect in several countries, including the Netherlands, where Monsanto brought this infringement action.

Cetera tried to take advantage of the fact that Monsanto does not have a patent on the soybean in Argentina. As we noted in an earlier international post, patents have no “extraterritorial” effect—they must be obtained on a country-by-country basis (with some limited opportunities for one-stop shopping, as in the EPO). So it is not illegal to make, use, or sell Roundup Ready soybeans in Argentina. Cetera makes soy meal from Roundup Ready soybeans that are grown in Argentina and exports it to Europe. The soy meal in question was seized by Dutch customs authorities. It contains “dead” versions of the DNA sequence covered by Monsanto’s European patent. Monsanto sued for Cetera for violating a provision of Dutch patent law that forbids importing a patented product—in this case, the DNA sequence—into the Netherlands.

**Conflicting Authority.** Cetera contended that Dutch law was overridden by the EU Biotechnology Directive (the Directive). A directive is a law issued by the EU that all member states must comply with. It doesn’t take effect directly in the individual EU countries, but they must “harmonise” their national laws to make them consistent with the directive. The Biotechnology Directive requires that member states grant patents on “biotechnological inventions” (Article 1), but then provides more specifically in Article 9 that:

> The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material . . . in which the genetic information is contained and performs its function. (emphasis added).

If the protection granted under Dutch patent law exceeds what the Directive allows, then the Dutch law would be invalid. Since this is a question of EU law, the Dutch court hearing the case referred it (along with several other questions) to the ECJ. Even though Monsanto and Cetera settled the case before the ECJ ruled—Monsanto essentially gave up, according to most accounts—the ECJ went ahead and decided the questions put to it.

(Brief jurisprudential recap for those who are scoring along at home: (1) The EPO granted a Dutch patent. (2) Monsanto, the patentee, sought to enforce the Dutch patent in the Netherlands. (3) The Argentine defendant, Cetera, sought an ECJ ruling that the Dutch patent law that Monsanto relied on was invalid because it exceeded what was allowed under the EU Biotechnology Directive. This is a bit like the situation where an American defendant argues that a state law is invalid under the U.S. Constitution—except that the EU doesn’t have a constitution, so don’t carry the analogy too far.)

**The ECJ Decision.** The ECJ decided that the Dutch law does violate Article 9 of the Biotechnology Directive. The reason has to do with verb tenses in the italicized language quoted above. The Court held that genetic material can be protected only when it is performing its function. When, as here, “the genetic information has ceased to perform the function it performed in the initial material”—the living soybean plant—then there can be no patent protection. Because the DNA sequences in the imported soy meal were “dead material” no longer performing their function, they were no longer protectable pursuant to Article 9 of the Directive.

What can we make of this very complex decision on a practical level? A few thoughts:

1) Whatever it means, the decision is the law throughout the 27 member countries of the EU.

2) The ruling does not undercut the patentability of genes in any fundamental way.

3) The ruling does, however, admonish the courts of the EU member countries to pay strict attention to the language of the Biotechnology Directive when enforcing gene patents. We might expect infringement defendants and their lawyers to start scanning the Directive for additional semantic loopholes.

4) On the specific facts of this case, the ECJ held that a gene must be performing its function at the time of the infringing act to be protected.
Here, the infringing act was the importation of the soy meal, by which time the gene was “dead.” But it offered no guidance on what the function of genetic material is. An obvious answer would be “coding for a protein,” but we don’t learn that for sure from the opinion. If that is in fact the right answer, is there a difference between the actual process of making a protein at a given point in time and simply being capable of making a protein? Looked at from a slightly different angle, when does a DNA sequence become “dead” and thus incapable of performing its function?

5) Finally, there may be a subtle but important link between the ECJ’s emphasis on genetic material performing its function and the chemistry versus information argument Judge Sweet presented in his Myriad Genetics opinion earlier this spring. Judge Sweet reasoned that, even though an isolated gene might be chemically distinct from its naturally occurring counterpart, its information-carrying capacity was the same—and that information-carrying function is the whole reason people are interested in genes. As Judge Sweet wrote (pdf):

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).

In a roughly similar way, the ECJ—following the Biotechnology Directive—ignored the fact that “live” and “dead” genes might have the same chemical sequence and focused on the functional (information-delivering?) differences between the two. This logical link between the decisions is attenuated, and neither will bind the Federal Circuit, which will be the next court to tackle the issue of the patentability of genes, but it is a connection that may merit some additional development moving forward.