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The Attack on Patentable Subject Matter Continues: *Organic Seed v. Monsanto* Pushes Utility to the Limit



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The Public Patent Foundation strikes again! This time, PubPat is representing no less than 59 plaintiffs in a lawsuit filed in the U.S. District Court for the Southern District of New York seeking declaratory judgment that no less than 23 Monsanto patents di-

rected to genetically modified or transgenic seeds and plants are invalid because they are not “useful” within the meaning of 35 U.S.C. § 101. See *Organic Seed Growers and Trade Association v. Monsanto Co.*, No. 11-cv-2163 (S.D.N.Y., complaint filed March 29, 2011) (81 PTCJ 7990, 4/15/11).

No doubt, PubPat is riding high on momentum in the Southern District of New York where it was able to convince Judge Robert W. Sweet that isolated breast cancer genes were not “markedly different” from the chromosomal genes in human cells and therefore were “unpatentable products of nature” under 35 U.S.C. § 101. See *Association of Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09 Civ. 4515, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010) (79 PTCJ 4/2/10); and “The Attack on Patentable Subject Matter: *American Civil Liberties Union v. Myriad Genetics* as a Harbinger of Things to Come.” (80 PTCJ 583, 8/27/10). *Association of Molecular Pathology* is presently on appeal to the U.S. Court of Appeals for the Federal Circuit.

But, success against Monsanto is far from certain as PubPat has a new judge and a new theory to attack Monsanto’s patents. PubPat notes that U.S. Const., Art. I, § 8, cl. 8, promotes the progress of science and *useful* arts, while 35 U.S.C. § 101 states that “[w]hoever invents or discovers any new and *useful* process, machine, manufacture, or composition or matter, or any new and *useful* improvement thereof, may obtain a patent therefore.”

Focusing on the word “useful,” PubPat seeks to convince Judge Naomi Reice Buchwald that Monsanto’s seeds and plants which are genetically modified to resist the effects of the herbicide glyphosphate are not useful because they are “injurious to the well-being, good policy, or sound morals of society” and threaten to “poison people.” For this standard, PubPat reaches

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back no less than 194 years to a Massachusetts jury charge in the patent infringement case of *Lowell v. Lewis*, 15 F. Cas, 1018 (C.C.D. Mass. 1817).

Many cases have addressed utility since *Lowell* including the U.S. Supreme Court case of *Brenner v. Manson*, which is noted in PubPat's complaint. In *Brenner*, the Supreme Court stated that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." *Brenner v. Manson*, 383 U.S. 519, 535 (1966). Such an invention is one where a "specific benefit exists in currently available form." *Id.*

It is unclear whether Buchwald will adopt the language of *Lowell* in deciding whether Monsanto's patents are useful. However, this seems unlikely since *Lowell* was simply a jury charge and Buchwald is not without more recent legal precedent.

Although the jury in *Lowell* found for the accused infringer, the jury charge included instructions on many defenses raised by the defendant and *Lowell* provides no basis to conclude that the jury found in particular that the patent lacked utility. In fact, Justice Story commented to the jury that "the abstract question [of utility] seems hardly of any importance in this cause."

More appropriate to the present case, however, is the notation in *Lowell* that "[a] great number of witnesses were produced on both sides" to support each party's positions. In *Monsanto*, PubPat will no doubt resort to a "battle of the experts," both legal and factual, to establish just how useful an invention needs to be to receive patent protection and whether Monsanto's genetically modified seeds meet that standard.

In the complaint, PubPat argues that the plaintiffs, who are largely certified organic crop producers, will be harmed if their crops become contaminated by transgenic seed through no fault of their own thereby causing them to lose their organic certification. The plaintiffs, PubPat argues, will be forced to accept a lower price for their contaminated crops or have their crops rejected or banned altogether.

PubPat also argues harm in the expensive cost of ensuring that their crops are not contaminated, a cost they believe they would not have to bear but for Monsanto's transgenic seed. PubPat further argues that transgenic crops do not live up to their alleged benefits.

On the issue of health, PubPat argues that expanded use of Monsanto's herbicide resistant seeds will promote the use of the herbicide which PubPat claims is harmful to human health. PubPat raises the issue of "whether transgenic seed itself has an effect on human health" and argues that the threat of infringing Monsanto's patents hamstringing scientists from using the seed to research adverse health effects. PubPat concludes that "since the harm of transgenic seed is known, and the promises of transgenic seed's benefits are false, transgenic seed is not *useful* for society" (emphasis added).

Monsanto will likely counter that genetically modified seed has increased crop production to help feed a

growing United States and world population and is therefore useful to society. Adoption of the technology by farmers will also likely be used as evidence of the usefulness of the transgenic seed.

A simple web search identified a Q&A document on genetically modified foods purported to be authored by the World Health Organization. See <http://www.who.int/foodsafety/publications/biotech/20questions/en/>. The question is asked, "Are GM foods safe?" The answer provided is that "GM foods currently available on the international market have passed risk assessments and are not likely to present risks for human health. In addition, no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved."

The allegations by PubPat and Monsanto's possible counterarguments suggest evidence on both sides and the making of a hotly contested legal and factual issue of whether genetically modified foods are "injurious" and will "poison people." Both sides will be armed with experts to advance their respective positions.

But PubPat may never get to the merits of its utility allegations against Monsanto. Buchwald may be asked to determine whether any or all of the 59 plaintiffs have standing under the Declaratory Judgment Act to sue Monsanto.

In its complaint, PubPat states, "Plaintiffs in this matter represent farmers and seed businesses who do not want to use or sell transgenic seed." PubPat argues that use of transgenic seeds by the plaintiffs is inevitable due to eventual contamination.

So too, it argues, is a lawsuit for patent infringement by Monsanto. It is this alleged threat of infringement as a result of an alleged likely future contamination on which the plaintiffs base declaratory judgment jurisdiction and seek either the invalidity of the patents or judgment that they will not be held liable for patent infringement.

Monsanto may ask Buchwald to decide whether the threat of an infringement suit based on contamination by transgenic seed, that the plaintiffs say is likely, creates a case or controversy under the Declaratory Judgment Act to allow the plaintiffs to sue in federal district court. Under *MedImmune Inc. v. Genentech Inc.*, 549 U.S. 118, 81 USPQ2d 1225 (2007) (73 PTCJ 242, 1/12/07), a case or controversy is determined based on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant" relief.

The issue of standing was raised in *Association of Molecular Pathology* and is being reviewed by the Federal Circuit. Whether the case makes it to the merits or is decided on technical grounds of standing remains to be seen. But *Monsanto's* combination of highly charged allegations of human poisoning with complex genetic engineering technology will provide fascinating reading as the case unfolds before Buchwald.