

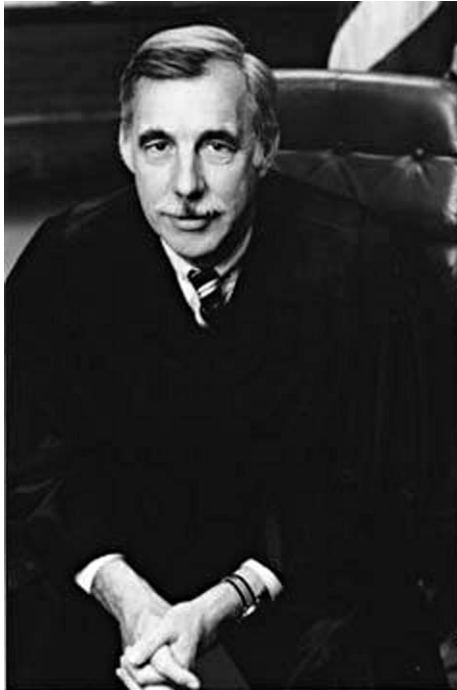
Fed Judge Cancels Human Gene Patents: You Can't Own a 'Product of Nature'

by Marcia Merry Baker

May 5 (EIRNS)—Federal District Judge Robert W. Sweet, on March 29 in New York City, issued a decision invalidating patents on human genes BRCA1 and BRCA2—associated with breast cancer—citing in his written opinion (filed April 2) that, you cannot patent a “product of nature.” This ruling is a welcome salvo against a hallmark practice of globalization over the last 40 years, that of allowing private “ownership” and “intellectual property rights” control over life forms—bacteria, human and animal genes, food seeds and other genetics, and even diseases. Deference to this wrongful policy was forced through, not only in the United States—where it violates the Constitution and tradition—but also internationally, through the enforcement of GATT, the WTO, IMF, World Bank, and the other institutions of globalization.

Be clear on the history: The pile-up of patents on lifeforms, is not the result of modern advances in knowledge and skills in biology, per se—which are valuable, and would be far greater but for the wrongful patenting; it is the result of the attempted control of the means to life by elite financial and political circles, centered in London, who are behind the era of mega-companies, and “free” (imperial) trade.

At present, the Obama Administration is adamant that the patenting of life forms must continue at the service of private financial power centers, especially the food seed control cartel. Private-patenting of lifeforms will not be rolled back, was the decree of a science advisor to the Secretary of State and Agency of Interna-



Federal District Judge Robert W. Sweet's decision, invalidating patents on human genes associated with breast cancer, strikes at a hallmark practice of globalization: that of allowing private “ownership” over life forms.

tional Development, Dr. Nina V. Fedoroff, at the plenary session of the U.S. Department of Agriculture Outlook Forum in February, when questioned by this author. She cited the key free-trade-era changes in U.S. nominal law—the 1970 Plant Variety Protection Act, and a 1980 Supreme Court decision approving patenting of life forms—to justify her declaration.

Now, with Judge Sweet's ruling, and his thorough 152-page decision, this London-subservient viewpoint is called into question, even if implicitly.

The specific patents that were contested in the U.S. District Court, Southern District of New York, were awarded in the 1990s by the U.S. Patent and Trademark Office (USPTO), to the private firm Myriad Genetics Inc., based in Utah, and to its collaborator, the University of Utah Research Foundation. In May 2009, a suit to invalidate the patents was filed

by a host of plaintiffs, including scientific societies (e.g., Association for Molecular Pathology), medical associations (e.g., American College of Medical Genetics), and several private cancer patients, physicians, and other individuals. Their plea to cancel the cited patents, was made in terms of violation of law by the U.S. Patent Office, and also, violation of the U.S. Constitution.

The New York suit thus poses the question at large, of private control over life forms. At present, nearly 20% of the human genome, involving 4,000 genes, is patented, under various legalisms. Because of its BRCA1 and BRCA2 patents, Myriad is the one and

only company in the nation, that tests for the presence of the genes that are associated with the likelihood of breast cancer. The test's cost is \$3,000 and up; most insurance, including Medicare and Medicaid, will not pay for it.

Patented Food Crop Seeds

In the category of crop genetics, the patents awarded to date—cotton, corn, soybeans, alfalfa, eggplant, sugar beets, and others—are providing vast control over seed-breeding, sales, and research. There are now only a select few mega-players worldwide: Monsanto Co., DuPont/Pioneer Hi-Bred, Dow, Cargill, Syngenta, and Bayer CropScience. The top three—Monsanto, DuPont, and Syngenta—account for half of all sales of propriety (patented) seeds. Monsanto alone accounts for 60% of the corn and soybean seed market in the U.S., through direct sales, and trait-licensing agreements. Monsanto's patented biotech traits are in 90% of U.S. soybeans, and 80% of U.S. corn.

A suit against Monsanto was brought in 2006 by alfalfa seed growers and allies, and won in 2007, at the Federal District level in California. The ruling stayed Monsanto's sales of its brand-name herbicide resistant, bio-engineered (BE) Roundup Ready Alfalfa.

On April 27, a Supreme Court landmark was made, when the Court, for the first time ever, took oral arguments involving the question of a patented BE lifeform, Roundup Ready Alfalfa, occasioned by Monsanto appealing the 2007 judgment staying its sales of the seed. The matter of law is delimited to the issue of the fact that Monsanto started selling its BE alfalfa in 2005, before all required Federal studies were done. However, as one of the principal plaintiffs, Pat Trask, a South Dakota alfalfa seed grower, declared, at a Washington, D.C. briefing after the Supreme Court's April 27 hearing: If we allow this kind of privatized seed control to go on, "then Monsanto, not God, becomes an arbiter of nature."

A judgment is expected on the case (Monsanto v. Geertson Seed Farms, Inc.) by the end of the Supreme Court's term in June. Alfalfa, a high-nutrition fodder, is the fourth-largest crop grown in the United States, by area.



The legal victory, in 2007, in a case brought by California alfalfa seed growers, stayed Monsanto's sales of its Roundup Ready Alfalfa.

Renewed Fightback

The import in both these Federal cases, involving opposition to patent claims to lifeforms, is that there is a renewed fightback underway against the premises and powers that have dominated the last four decades, undermining the sovereign right of governments to see to the betterment of its populations. The court battles occur amidst a mass strike process of opposition to Washington and its connivance with the physical-economic breakdown taking place. The outcome of the process, will not be "decided in the courts" as such, but by the thinking guiding the leaders in the battle, is critical.

To that purpose, Judge Sweet's arguments and clarifications in his 152-page decision, are extremely valuable. Rightly, there has been quick international acclaim, which amounts to recognition of a potential resurgence of the founding principles of the United States, as a republic, not a flunky of London. An April 14 editorial in *The Hindu* of India, titled, "Landmark Judgment," wrote, "What is laudable is Judge Sweet's brilliant assessment of scientific facts to invalidate every claim of the company."

What follows are *EIR*'s summary descriptions of key points in Judge Sweet's written opinion, giving exact text quotations as noted, with page numbers from his decision.

The Case: Plaintiffs, Defendants

The case before the U.S. District Court, Southern District of New York, is that of the *Association for Molecular Pathology et al., Plaintiffs, against the U.S. Patent and Trademark Office et al., Defendants*. The Plaintiffs were represented by attorneys from the American Civil Liberties Union Foundation, and the Public Patent Foundation. A U.S. District Attorney represented the Patent Office (USPTO); and the Jones Day law firm represented the defendants, Myriad Genetics and Directors of the University of Utah Research Foundation.

The plaintiffs asked the court for summary judgment, to declare invalid 15 claims contained in seven patents relating to the human BRCA1 and BRCA2 (Breast Cancer Susceptibility Genes 1 and 2), on three

Its gene patents have given Myriad Genetics Inc. sole ownership of the only U.S. test for the genes associated with breast cancer. The test costs \$3,000 and up; most insurance plans, including Medicare and Medicaid, do not cover it.

grounds, as summarized by Judge Sweet:

“(1) the Patent Act, 35 U.S.C. Section 101 (1952); (2) Article I, Section 8, Clause 8 of the U.S. Constitution, and (3) the First and Fourteenth Amendments of the Constitution, because the patent claims cover products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought” (p. 1, decision).

The Patent Claims Are Invalid

The Defendants presented arguments to justify retaining their patent claims, in which they had been granted two kinds of rights: 1) for the gene itself, and 2) for what they call the “method” of comparing the cancer-associated gene with the non-cancer associated one.

Judge Sweet decided against the validity of both of their types of claims. Regarding the first category, he said that, the human genetic material in question is a product of nature, not patentable:

“While many inventive steps may be necessary to allow scientists to extract and read a gene sequence, it is undisputed that the ordering of the nucleotides is determined by nature” (p. 31, decision).

Secondly, he judged that the process of making comparisons is an intellectual act, not a patentable “method.”

Sweet based his decision in both categories of patents, on how the defendants’ claims violate the relevant

Patent Law 35 U.S.C. Section 101,¹ giving copious citations of Federal Court rulings and clarifications from the past.

For example, he cited several decisions from the 1920s and ’30s, especially involving the condition and use of uranium, vanadium, and other elements:

“*Gen. Elec. Co. v. De Forest Radio Co.*, 28 F. 2d 641 (3d Circ. 1928), noting that ‘a patent cannot be awarded for a discovery or for a product of nature, or for a chemical element’” (p. 99, decision).

Among Sweet’s citations from the more recent period:

“The exclusion of products of nature as patentable subject matter under Section 101 also reflects the Supreme Court’s recognition that ‘phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.’ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).’ Thus, as Justice Breyer has observed, ‘the reason for this exclusion is that sometimes *too much* patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection.’ *Lab. Corp. of Am. Holdings v. Metabolute Labs., Inc.* 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting) (quoting U.S. Const., Art. I, Section 8, cl. 8.) (emphasis in original).

“For these reasons, ‘manifestations of laws of nature [are] free to all men and reserved exclusively to none.’ *Funk Bros. Seed Co. v. Kalo Inoculant Col.* 333 U.S. 127, 130 (1948).”

However, Sweet, in his decision, specifically excluded taking up the Constitutional questions raised by the Plaintiffs, saying that it serves the nation best when judges refrain from interpreting the Constitution when

1. The text of the United States Code, Section 101 of Title 35 states: “Whoever 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 conditions and requirements of this title.”



USDA/Lynn Betts

In strictly legal terms, Sweet's decision leaves to future determination, the question of rolling back the patent eligibility for "man-made" lifeforms, including crop seeds. Shown: a soybean farm in central Iowa.

there is no need to. He determined that the scope of Patent Act, 35 U.S.C. Section 101, was sufficient to make a judgment on the patent-eligibility of the human genes and the methods contested in the case before him.

[In strictly legal terms, Sweet's decision now leaves to future determination, the question of rolling back the patent eligibility for "man-made" lifeforms, namely crop seeds, not naturally occurring].

The Nature of the Case

Sweet described the nature of the cancer gene case, and his task, in the opening section of his decision:

"As discussed *infra* in greater detail, the challenged patent claims are directed to (1) isolated DNA containing all of portions of the BRCA1 and BRCA2 gene sequence and (2) methods for 'comparing' or 'analyzing' BRCA1 and BRCA2 gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer. Plaintiffs' challenge to the validity of these claims, and the arguments presented by the parties and amici, have presented a unique and challenging question:

"Are isolated human genes and the comparison of their sequences patentable?

"Two complicated areas of science and law are involved: molecular biology and patent law. The task is to

seek the governing principles in each and to determine the essential elements of the claimed biological compositions and processes and their relationship to the laws of nature. The resolution of the issues presented to this Court deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health."

A 'Lawyer's Trick'!

"The claims-in-suit directed to 'isolated DNA' containing human BRCA1/2 gene sequences reflect the USPTO's practice of granting patents on DNA sequences so long as those sequences are claimed in the form of 'isolated DNA.' This practice is premised on the view that DNA should be treated no differently from any other

chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. Many, however, including scientists in the fields of molecular biology and genomics, have considered this practice a 'lawyer's trick' that circumvents the prohibitions on the direct patenting of the DNA in our bodies, but which, in practice, reaches the same result. The resolution of these motions is based upon long recognized principles of molecular biology and genetics: 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 of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. Section 101.

"The facts relating to molecular biology are fundamental to the patents at issue and to the conclusions reached. Consequently, in the findings which follow, the discussion of molecular biology precedes the facts concerning the development, application, and description of the patents...."