CANCER LETTER

Vol. 37 No. 31
Aug. 5, 2011

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Group Chairs Urge NCI To Limit Authority Of Committees That Rule on Trial Funding

By Paul Goldberg

The chairs of clinical trials cooperative groups urged NCI to change the way it reviews and prioritizes clinical trials.

In a "white paper," ten group chairs—those left standing and those whose groups have been reorganized out of existence—asked the institute to limit the authority of steering committees that critics say are causing unnecessary delays in the final stages of protocol review.

The letter from the group chairs is notable, because it focuses on a debate over an obscure but crucially important process that determines which clinical trials get funded by NCI.

NCI operates 11 steering committees, where review is conducted by groups of 20 to 25 people, who typically meet monthly by phone and once or twice a year in person. According to critics, the committees are slow and prone to byzantine exercises of academic politics.

Over the past 15 years, NCI has tried three approaches to protocol review

(Continued to page 2)

Guest Editorial:

Patenting Nature: What Ruling in Myriad Case Means for Biotechnology and DNA Diagnostics

By Robert Cook-Deegan

The author is the director of the Center for Genome Ethics, Law and Policy at the Duke University Institute for Genome Sciences and Policy. He is a visiting researcher at Fondation Brocher of Switzerland.

On July 29, the U.S. Court of Appeals for the Federal Circuit (CAFC) handed down its long-awaited ruling about the patent lawsuit brought against Myriad Genetics and the U.S. Patent and Trademark Office by a group of more than 20 plaintiffs.

The lawsuit has been coordinated and argued by the American Civil Liberties Union and the Public Patent Foundation.

First, some background, then an explanation of what the court ruled—some discussion of why this case matters—and finally a word on possible next steps.

For those in biotechnology and those who eat and live in patent law, Dorothy clicked her heels three times and we're back in Kansas again, where high patent fences protect valuable protein therapeutics, vaccines and other biologics. If you do DNA diagnostics for a living, however, the storm is not over—and you can't be sure whether your house has landed on a good witch or a bad one.

(Continued to page 7)

Implementing this proposal

In summary, we support the creation of the Across Disease/Trials Oversight Panel to assign and prioritize overall scientific objectives for the NCI clinical trials infrastructure. We propose that the current Disease-Specific Steering Committees be renamed the Disease-Specific Study Review Committees, and confine their activities to study review and approval. We also request that the Task Forces of the Steering Committees be eliminated, and replaced by new disease specific committees that are convened by the cooperative groups in collaboration with the NCI. Through this new committee structure, the cooperative groups will work together with the NCI in a more effective environment for collaborative study development, achieving the goals of "information exchange at an early stage of study development" and both cross-disease and within-disease prioritization of studies. With the smaller number of cooperative groups resulting from implementation of the IOM recommendations, this goal is achievable as never before.

Jan Buckner, chair of the Cooperative Group Chairs, chair of North Central Cancer Treatment Group
Heidi Nelson, co-chair, American College of Surgeons Oncology Group
David Ota, co-chair, American College of Surgeons Network
Mitchell Schnall, chair, American College of Radiology Imaging Network
Monica Bertagnolli, chair, Cancer and Leukemia Group B
Peter Adamson, chair, Children's Oncology Group
Robert Comis, chair, Eastern Cooperative Oncology Group
Philip DiSaia, chair, Gynecologic Oncology Group
Norman Wolmark, chair, National Surgical Adjuvant Breast and Bowel Project
Walter Curran, chair, Radiation Therapy Oncology Group
Laurence Baker, chair, Southwest Oncology Group

Guest Editorial:

Myriad Patent Position Weaker Than Before the Case Began

(Continued from page 1)

There may be a bit further to walk on the yellow brick road, with another stop at the CAFC or the U.S. Supreme Court before Dorothy discovers the way home.

After a district court sent you to Oz, three different judges have given you clear directions, but their fingers point in different directions on the crucial question of whether naturally occurring DNA sequences can be patented.

But enough about Dorothy.

Myriad Genetics is in a much stronger patent position now than it was last Thursday, but also weaker than before the case began. If this ruling had set expectations in 1998, Myriad would certainly have had patent rights sufficient to ensure a flow of royalties, but quite possibly not strong enough to support the monopoly model of genetic testing that their vigorous patent enforcement led to from 1998 to 2002, resulting in Myriad becoming the only commercial testing service for BRCA mutations in the United States. (Myriad's U.S. business model has not worked in any other jurisdiction in the world, but that is a different story.)

CAFC has sent a mixed message: yes, you can get gene patents, but some of the claims granted are invalid, and some are vulnerable to challenge in subsequent cases.

What will happen now? There is likely to be at least one more level of appeal that could set precedent on whether naturally occurring DNA sequences can be patented—but the real question is how business models will adapt. Only time will tell.

Background

CAFC hears all appeals on patent cases and a few other matters of federal law, and CAFC rulings set nationwide precedents. This is unusual compared to most other areas of law. There is no equivalent authority below the Supreme Court for matters of contract law or tort law, for example. The court can be overruled by the Supreme Court, but otherwise its rulings guide jurisprudence for all patent cases.

Initial appeals are usually conducted by a three-judge panel drawn from the full CAFC (which has a chief judge and 16 circuit judges). In this case, Judges Alan Lourie, Kimberly Moore, and William Bryson

heard the case. Each of them wrote their own analysis—itself an unusual step—and the opinions run up to 105 pages of intricate technical and legal reasoning.

The appeal was from a March 29, 2010 ruling by Judge Robert Sweet in the Manhattan, New York, Federal District Court. Judge Sweet declared invalid 15 claims in 7 patents held by Myriad Genetics. Claims describe the boundaries of the intellectual property in a patent, and notify others what constitutes infringement. Saying claims are invalid is to say they should not have been granted by the patent office.

Judge Sweet's ruling was itself long and complex, running over 150 pages. The longest sections addressed past jurisprudence on patenting "products of nature." His conclusion was that because DNA is an embodiment of information, the standard legal practice of claiming "isolated" DNA did not make DNA patentable subject matter.

He argued that "isolated" DNA is not materially different from the DNA in its natural state. He also invalidated some broad claims on methods of comparing a sample sequence (from a patient or from a tumor) to a reference sequence of BRCA1 or BRCA2 (BRCA1/2) and detecting differences (including, but not restricted to, clinically significant mutations). And he invalidated a final contested claim covering an assay for cancer therapeutics.

His ruling was a surprise to most patent lawyers and those in biotechnology, as it cast doubt on the patentability not only of the diagnostic uses at issue in this case, but any patent on a DNA molecule.

The case attracted 29 amicus curiae briefs, "friend of the court" advisory opinions from outside experts that the court can consider in making its decision. The most significant of those briefs came from the solicitor general, the government's highest official responsible for arguing cases before the Supreme Court.

The solicitor general also made an unprecedented appearance before the CAFC at oral hearings on April 4. The government's formal position was that Judge Sweet was right— that DNA sequences as found in nature should not be patentable—but his ruling was too broad.

Some DNA molecules are clearly man-made and are not found in nature—for example complementary DNA (cDNA) molecules derived from mature messenger RNAs or engineered cloning vectors.

In oral arguments, the solicitor general suggested a gedanken experiment: imagine a "magic microscope" that could distinguish between molecules found inside cells, which would not be patentable, and molecules one would never find in a cell, which would be man-made and patentable.

The U.S. Patent and Trademark Office, although it is also part of the executive branch, did not agree with this position. It has issued many patents on naturally occurring DNA sequences and will continue to do so until and unless a court or Congress tells it otherwise.

What did the Court decide?

Friday's CAFC ruling brings some clarity to some questions of patent law, with all three judges in agreement. But there is still residual disagreement about whether DNA molecules corresponding to sequences found in nature can be patented or not.The disagreement about DNA as "found in nature" is irrelevant for most biotechnology applications, such as making therapeutic proteins or vaccines, but it is highly relevant for diagnostics.

When using DNA to make a vaccine or therapeutic protein, the DNA is valuable because it is isolated and can be used to make a valuable end-product. When making a diagnosis, however, a test is useful only to the extent it accurately replicates the sequence found in nature.

Judges Sweet and Bryson (CAFC dissent) say "no;" Judges Lourie and Moore say "yes," but for somewhat different reasons. Thus, some kinds of DNA diagnostics are still under a shadow of uncertainty on how courts will interpret "isolated" in the diagnostic context. That could be clarified upon further appeal, or it could remain muddy.

The strength of Myriad's patent protection is less than it was. Myriad certainly has many patent claims remaining, but as noted below, its broadest method claims were deemed invalid, and Judge Bryson flagged problems with broad claims on short DNA fragments.

Myriad certainly has strong rights on the full-length genes (at least on BRCA1; the history of discovering BRCA2 is still subject to dispute). Myriad's claims on specific mutations are largely intact, so anyone detecting one of those mutations and reporting it to a patient in the U.S. would likely need a license. But the scope and strength of patent protection are clearly less than before the case began.

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All three judges agree

All three judges agreed that:

Some kinds of DNA can be patented, such as cDNA molecules that are not found in nature;

Five of the broadest method claims in Myriad's patents are invalid because they claimed any way of comparing sequences to look for differences, a mental act that cannot be patented; and

The claim for an assay on cancer therapeutics is valid because it entailed several "transformative" steps (it is not entirely clear why this claim was in the case at all, and it received very little attention in the briefings or oral arguments).

The patentability of DNA has been the subject of most headlines on the ruling, and indeed this was the foremost worry of most in industry and the patent bar. All three judges were quite clear that cDNA is patentable. cDNA molecules encoding protein therapeutics have been among the most valuable biotechnology inventions, and the subject of at least 11 prior CAFC decisions.

The invalidity of the broadest method claims in these patents is also not a big surprise, and the unanimity of the three judges suggests it may become settled law unless overturned on appeal.

A close reading suggests that the problem is the great breadth of the claims. This problem of claim language would be relatively easy to fix for those seeking patent protection on test methods.

Judge Lourie's majority opinion makes clear that if the claims had included "extracting" the DNA and "sequencing" or "hybridizing" it, rather than just "comparing" sample sequence to BRCA1/2 reference sequences, these claims would have passed muster. Myriad still has hundreds of other claims in its patents.

While a very large number are irrelevant for diagnostics, it only takes one infringed valid claim to win a case.

Patentability of sequences "found in nature"

Most of the prose in all three judges' analysis focuses on the residual disagreement about whether naturally occurring DNA sequences can be patented.

Judges Lourie and Moore agreed that such sequences are patentable, although their reasons are somewhat different.

Judge Bryson dissented, and argued that DNA molecules corresponding to DNA sequences found in nature are not patentable.Judge Lourie argued that even naturally occurring DNA sequences found in chromosomes are different chemicals—different molecules—from the DNA molecules made in the process of diagnostic testing and for other purposes. He focused particularly on the importance of the covalent backbone bonds being broken in "isolated" DNA compared to intact chromosomal DNA containing a gene.

Judge Moore emphasized the functional differences of small DNA molecules. She also put strong emphasis on not disrupting the practices and expectations that have built up in three decades of DNA patenting.

Judges Moore and Lourie argued that any categorical exclusion from patentability, such as DNA molecules, should be for Congress to enact through statute.

They pointed to the bills proposed by Rep. Xavier Becerra (D-Calif.) and former Reps. Lynn Rivers (D-Mich.) and David Weldon (R-Fla.) as evidence that Congress has explicitly decided not to do so (since those bills never even made it to a committee vote).

Judge Bryson disagreed with the characterization of "isolated" as a materially relevant difference. He argued that while Utah and Myriad scientists had to work hard to find the BRCA genes and their mutations, "the genetic coding sequence that is the subject of each of the BRCA gene claims remains the same whether the gene is in the body or isolated," and "the discovery of the sequences is an unprotectable fact."

His argument about deference to the patent office was that the office's defense of patentability in the 2001 "utility guidelines" was "perfunctory."

He argued the court should decide patentability just as it did in the Chakrabarty case cited frequently by all parties, in which the Supreme Court gave no deference to the patent office, and did not leave it to Congress to decide if living things could be patented.

Judge Lourie's and Moore's arguments for patentability draw a legal line between DNA molecules in a cell, before isolation, and the DNA made in the process of sequencing (or by inference, hybridization) methods.

There are some flaws in their logic, based on a static view of DNA as solely residing in the form of full-length chromosomes. All three judges talk of "isolating genes" but how this is done is exquisitely dependent on method.

PCR, for example, "isolates" DNA by amplifying only those segments of DNA that have two antiparallel primer sequences and contiguous DNA between them.

Hybridization methods "isolate" DNA by binding to it specifically in a way that can be detected, usually by a fluorescent dye or radioactive adduct linked to a DNA probe.

Judge Lourie puts great stock in the fracturing of covalent bonds in the laboratory methods of "isolation," and claims several times that DNA fragments would not otherwise be found in cells.

Amicus briefs at the next level of appeal may point out that Arthur Kornberg got a Nobel Prize for isolating fragments of DNA from inside cells and showing that DNA replicates by stitching together short stretches of newly synthesized DNA fragments by ligation.

What about the stuff that Rosalind Franklin used to take Photograph 51—which was as isolated as they could possibly make it in 1952 for X-ray crystallography—but was nonetheless presumed to capture DNA in its natural naked essence.

Oops, is that segment patentable? Because it sure used the hand of woman and was useful and novel in undergirding one of the major discoveries of the 20th century.

Or is it not patentable, because its utility was not really commercial, or it was merely purified, or for some other reason? Hard to know. And we never will because no one tried to patent it then or would do so even now, because its considerable utility was to promote understanding, with little thought of commercialization.

This may not make a legal difference, since inside the cell such molecules are not "isolated" in a meaningful sense, but the difficulty in defining "isolated" could raise problems for Lourie's line of reasoning.

His privileging of the covalent bonds in the helical backbone do not seem a promising tack, however. In the list of molecules one would define by covalent bonds, DNA would be near the bottom of the list.

Hydrogen bonds are the main reason Jim Watson called his book *The Double Helix,* and the reason Kornberg's DNA fragments can be ligated in their proper chromosomal position is hydrogen bonding, not covalent bonds.

Indeed the biological function of DNA clearly depends on both kinds of bonds, and a line that separates "natural" chromosomal DNA and "unnatural" and patentable fragments may be harder to draw than Judge Lourie has imagined.

Indeed, it is ironic that the very genes patented here are involved in DNA repair, and would not be needed at all if Judge Lourie's and Moore's fantasies of stable, static chromosomal DNA were the only forms of DNA found naturally in cells.

Judge Moore's point that small DNA fragments have utilities that natural DNA does not reveals a different flaw—all her examples of detectable differences depend on chemical modifications that are clearly man-made: to allow the DNA to be detected (by hybridization or sequencing).

Patent claims could cover those detectable man-made molecules without involving the natural DNA, and the border between patentable and unpatentable DNA would be much easier to patrol.

Myriad and many other patentholders have chosen not to go that route, presumably in order to broaden their scope of exclusivity.

Every general has long known that the longer the fence the harder the defense. Whether stretching for scope was wise or not will now likely depend on how arguments on the meaning of "isolated" play out on further appeal.

Judges Lourie and Moore did not have the same reasons for patentability of naturally occurring DNA sequences, but they did enjoy one joint celebration. Both hurled the solicitor general's magic microscope to the laboratory floor with considerable glee, where it now lies in smithereens. Ouch.

Judge Bryson's argument, however, also has a glaring weakness.

His assertion that there is no material difference between the natural chromosomal DNA and the DNA being sequenced (or hybridized) will confront a strong intuition that Moore and Lourie appear to be struggling to articulate: the only way to detect a DNA fragment or to sequence it is to isolate it in some form first.

Judge Moore points out that cells don't render diagnoses or spit out sequence data. Those useful embodiments of genetic information clearly entail the hand of woman or man. Does that make them patentable? Perhaps we will see, behind the next curtain.

Given that there are weaknesses in the arguments on both sides, it is not surprising that so far the federal judges confronted with DNA patents in a diagnostic context have split 2-2. The tie-breaker will probably now await round three on subsequent appeal.

Very smart and thoughtful people have come up against a hard question. Two judges argue for patentability and a magical word "isolated" that sometimes means isolating a gene's DNA from other DNA, and sometimes means isolating DNA from other

cellular components. Or maybe it means isolating the molecule to measure it.

Using one word, "isolated," makes a DNA molecule "patentable," whereas inside a cell in its "natural" state, it is not.

But is that state Alaska, Hawaii, or somewhere on the mainland? As part of a complete chromosome, it is clear there's agreement it is not patentable. But the distinction between subchromosomal fragments of DNA that are natural and those that are isolated amounts to a tautology: they're isolated if you measure them.

Some in the patent bar contend it's a matter of settled understanding that claims like Myriad's really just pertain to the DNA actually derived from the "gene" in question; but these judges seem sometimes to be using that meaning, but other times not. Judge Sweet called the invocation of "isolated" a "lawyer's trick," and so far the coherent rationale for showing him wrong is a work in progress.

The difference right now seems to be "whatever they did to detect the DNA in a lab as opposed to whatever a cell does with it." And you do the math.

One particularly important claim—number 16 of U.S. Patent 5,747,282—deals with PCR primers, and would be directly relevant to the way Myriad and most laboratories currently do cancer gene testing. That claim, however, was not challenged in this case.

One final aspect of the "composition of matter" claims may prove important, but will require a different case to be litigated.

Judge Bryson took particular pains to suggest that the claims to small DNA fragments, as short as 15 base pairs, would confront serious problems because they "hit" many other genes in the genome, suggesting they would not meet the "novelty" criterion for patenting.

He also noted that Myriad could have been much more specific in describing the molecules they actually identified and characterized, rather than claiming generic very broad categories of DNA molecules that go well beyond what they actually characterized in the patent.

He judges claims five and six invalid because the sweep of the claims includes naturally occurring sequences and not just DNA molecules markedly different from and with uses distinct from naturally occurring sequences. And if Myriad were to lose these claims, his view appears to be it is their own damn fault for overreaching.

His logic also suggests these claims would vulnerable on two other criteria: enablement (whether someone skilled in the art could make and use the invention) and written description (whether it has been described precisely in the patent). These aspects of patentability were never argued in district court, so they cannot be decided on appeal and will not be directly decided in this case. Judge Bryson's comments nonetheless flag the vulnerability of some claims relevant to DNA diagnostics.

These "short sequence" claims matter because they are broad claims that could block full-genome sequence analysis and many methods of genetic testing.

If they are invalid, a careful legal analysis might find more freedom to operate without infringement liability than had been assumed before Myriad's patent claims were challenged, and not just for BRCA1/2, but for a welter of other gene patents with similar patent claim structure.

Such patents are not uncommon, and have been vigorously enforced not only by Myriad, but also by Athena Diagnostics and other firms engaged in genetic testing. While this section of Judge Bryson's ruling is not binding, it does signal that some of the broadest claims that have been enforced against genetic testing laboratories might fall if challenged, or might be narrowed under re-examination in light of the final decision in this case.

It would not be surprising to see these sections of Judge Bryson's dissent appear in future cases that push back against enforcement of gene patents for diagnostic use. But some testing laboratory somewhere would need to take a big risk in pushing back.

Standing to sue

Myriad's first argument was that the plaintiffs had no standing to sue.

The three judges agreed that only one plaintiff, Harry Ostrer of New York University, had standing. Myriad had sent him a notification letter in 1998, and when he was precluded from sending samples to the University of Pennsylvania, he reluctantly started sending samples to Myriad for testing.

He made a clear statement that he would immediately offer BRCA testing if the patents were invalidated. The University of Pennsylvania had also gotten not only a notification letter, but also a cease-and-desist letter from Myriad, and indeed was sued by Myriad before agreeing to stop doing BRCA testing for anyone other than University of Pennsylvania patients.

In a passage that must be an embarrassment for

whomever drafted their letters, two potential plaintiffs, Haig Kazazian and Arupa Ganguly, would have had standing to sue, except that their statements of intent hid behind legal weasel words—indicating only that they would consider testing, not affirming they would do so.

They and all other plaintiffs except Ostrer were denied standing. Perhaps someone at UPenn can learn a lesson about bad lawyering, and when preserving your options defeats your purpose.

At the eleventh hour, Myriad challenged Ostrer's standing because of his impending move to Einstein University. On the same date that the ruling was published, the ACLU countered with a letter to the court affirming that Ostrer's job change did not change his intentions or ability to do BRCA testing, and so should not affect standing.

This is a matter that will be raised in the next level of appeals if it still appears relevant.

What a weird case

Most of the legal analysis has been framed as a matter of patent law, and most of the arguments have been crafted to create precedent in patent jurisprudence.

This is not a typical patent case, however. The case has had very little apparent impact on Myriad's business practices. Myriad raised its prices for the BRCAnalysis® test just days after Judge Sweet's ruling in March 2010. That one test generated 88 percent of Myriad's $102 million revenues last quarter, and testing was up 9 percent. Myriad's cash cow has at least postponed its date at the abattoir.

One practical implication of the CAFC ruling may be resumption of patent enforcement against genetic testing laboratories. I have already gotten one email from a laboratory director who states that he has gotten a "barrage" of letters from patentholders in the days after the ruling.

If so, this could invite a flurry of new licensing deals, but it could also induce a push-back from laboratories doing genetic testing who read Judge Bryson's dicta about the vulnerability of the broadest claims.

If the judge is right, then laboratories could prevail in court, invalidate claims blocking diagnostic uses, free up some forms of diagnostic testing, and make enforcement of broad diagnostic claims expensive and difficult.

Sending letters is relatively easy and cheap—prevailing with a vulnerable patent in court is not. Myriad is a case in point.

And it is hard to know if ACLU and PubPat would stand ready to assist laboratories who decide to push back against a new wave of patent enforcement efforts. Both sides are at risk of overplaying their hands. (Again, this is a regular refrain in many patent cases.)

This case was brought for policy purposes. Most of the original plaintiffs were people who would otherwise be Myriad's customers (and some of them still are).

Only a few were potential competitors, and one of those was the only plaintiff that the CAFC left standing with standing.

The purpose of filing the lawsuit was to challenge gene patents. It has succeeded in driving public discussion of the issues well beyond any previous debate, and it has engaged constituencies well beyond industry and the patent bar. That may be this case's most lasting legacy.

A simple "what if" story suggests that the case is not entirely about patenting per se, but as much or more about how exclusive patent rights are used.

Suppose that Mary-Claire King had won the race to find BRCA1. The gene would likely have been patented by the University of California or University of Washington, just as her discovery of a genetic linkage to markers on chromosome 17 was patented and licensed.

Indeed, given the plausible role for gene transfer and the possible therapeutic use of the encoded protein that many postulated at the time, it would have been irresponsible not to patent the gene, in case it would require substantial subsequent private investment to translate the discovery into a therapeutic. But there would probably not have been a furor comparable to what arose with the Myriad patents, and almost certainly no suit like that working its way through appeal.

Dr. King would likely have engaged breast cancer advocates in thinking through patenting and licensing. This case is as much or more about business practices as it is about patent law (of course, many patent cases are).

Myriad runs a highly efficient laboratory with excellent turnaround time and clearly written clinical interpretations. It sets a standard for securing third-party payment of an expensive genetic test, reducing the payment burden on those getting tested. It won an intense and difficult race to find the BRCA1 gene, and the BRCA2 race ended in a dead heat.

Myriad should be an ally and hero of the breast cancer movement. But it is not.

Indeed, the organization representing those with

the most to gain from tests to assess inherited cancer risk—and thus logically Myriad's best buddy in the trenches, fighting against cancer—is Facing Our Risk of Cancer Empowered (FORCE), which supported the plaintiffs (although it was not a plaintiff itself).

Exactly how and why Myriad alienated its natural allies may eventually make this a teaching case for business schools. This patent lawsuit is another chapter in that story.

Next steps

Both sides in this case have something to appeal, and one or both sides may well do so. Myriad could appeal the invalidation of its method claims; ACLU and PubPat seem likely to appeal in hopes that Judge Bryson's dissent might become the majority opinion of the CAFC or the Supreme Court.

Either side can petition the entire CAFC to hear the case "en banc." The case could also go to the Supreme Court. Either the entire CAFC, the Supreme Court, or both could decide to hear the case.

The next steps are at the discretion of the courts (this first level of appeal was not discretionary). The immense amount of public attention, the entry of the solicitor general into the case, the number of amicus briefs, the presence of a very long district court opinion, and three CAFC judges' arguments that show sharp disagreement about the patentability of naturally occurring DNA sequences, all suggest that Friday's ruling may not be the last court decision in this case.

In a final irony, the judicial process is in a race with patent expiration.

The lawsuit was filed in May 2009, and decided in district court in March 2010. This first CAFC decision was handed down in late July 2011.

The next appeal, if granted, would likely be decided in 2012, and if there is a subsequent appeal to the Supreme Court, a final court decision could be handed down just a year or two before the broadest and most important BRCA patents begin to expire in 2014 and 2015.

[For those interested in background documents and other details about this case, or finding a link to a parallel case that will go to trial later this year in Australia, see http://www.genome.duke.edu/centers/gelp/Myriad/index.php]

Funding Opportunity:

DoD Offering $150 Million For Breast Cancer Research

THE DEPARTMENT OF DEFENSE Breast Cancer Research Program is providing $150 million to support "innovative, high-impact" breast cancer research through a series of grants and awards.

The Clinical Translational Research Award provides maximum finding of $12 million for direct costs. Investigators must be at or above the level of assistant professor and preliminary data is required.

The award supports research with a potential for direct clinical benefits and significant improvements in current breast cancer prevention or therapy. Phase I of the award will enable completion of preclinical translational studies and possible FDA approvals. Phase II will begin and carry out the clinical trial.

The Impact Award offers $2 million in funding for direct costs. This award supports unique research projects that focus on scientific and clinical breast cancer issues, with an aim to revolutionizing patient care and therapy. Applications that focus on less explored or poorly understood areas are strongly encouraged.

Pre-proposals for either award are due before Sept. 20. Full application submission is by invitation only.

Application instructions are available for download from www.grants.gov.

A listing of all US Army Medical Research and Materiel Command funding opportunities can be obtained on the Grants.gov website by searching for CFDA Number 12.420.

The pre-application must be submitted through the Office of Congressionally Directed Medical Research Programs eReceipt website (http://cdmrp.org).