Comment on "Myriad Genetics: In the eye of the policy storm"

To the Editor:

My deepest congratulations to *Genetics in Medicine* for publishing the recent case studies regarding gene patents. The timing could not have been better, especially in Australia, where the Senate committee investigating the impact of gene patents is due to present its report to Parliament on June 17 (the article by Cook-Deegan et al.[1] on breast and ovarian cancers incorrectly stated that the report was "delayed until at least March 2010"). I have made sure that the Committee has been made aware of this important publication.

That said, I was disappointed by an aspect of the article by Dr. Gold and Ms. Carbone.[1] It was certainly well researched and written, but it contained a most serious error and one that cannot be ignored.

Dr. Gold and Ms. Carbone state as follows:

> "According to the patent laws of these countries [i.e., 'all countries in which disputes over Myriad's genes arose'], human genes purified and isolated or put in a nonnatural state . . . and artificial genes can be patented. . . . Patent law considers an 'invention' to be anything that is in an altered form (from its natural state) because of human intervention. . . . It is for this reason that the District Court decision in Association for Molecular Pathology et al. v United States Patent and Trademark Office et al. will almost certainly be overturned." (p S62)

It is unfortunate that they made this statement, for it is wrong both as a matter of fact and law. I will explain why.

First, neither in the United States nor in Australia is there a patent law that "anything that is an altered form (from its natural state) because of human intervention" is patentable subject matter. This is not a matter of opinion or conjecture. It is the law and it has been the law since the inception of the patent systems of these two countries that patents be granted only for "inventions." And a human gene, even when isolated from its natural environment and even when replicated in an artificial process and one that is identical or substantially identical to how it exists in nature, is not and can never be an "invention." Although it may be the case that the patent offices of both of these countries have been granting patents over such biological materials for more than 30 years, that administrative act does not mean that the patents that they have granted are lawful. The practice of granting gene patents is just that—a practice. It is not the law.

Second, it is by no means certain that the District Court decision will be overturned. Dr. Gold and Ms. Carbone are not soothsayers. They certainly are entitled to their opinion, but to say, as they do, that the decision will be "most certainly overturned" is quite wrong. Unfortunately, they have chosen not to confront the reasoning of Judge Sweet, which, in my opinion, is undeniably correct. What Dr. Gold and Ms. Carbone fail to address is the US Supreme Court's decision in "Diamond v Chakrabarty." That decision, as Judge Sweet points out, did not address the issue that was presented to him in his court. In "Chakrabarty," the invention was a genetically modified bacterium. That is, the genome of the naturally occurring bacterium had been modified by human intervention. And while this resulted in an artificial organism, its artificiality was not why the US Supreme Court held it to be an "invention." The important fact, and what distinguished it from its naturally occurring counterpart, was the way this genetically modified bacterium performed as a result of the genetic modifications. It was able to degrade crude oil. This was not a function that the natural, unmodified, bacterium was able to perform. Nor was this a function that any naturally occurring bacterium could perform. There was, in fact, no naturally occurring precedence for this result. Indeed, its ability to degrade crude oil is precisely the reason for the US Supreme Court holding that this was not "nature's handiwork." It is therefore misleading to state that artificiality alone is the criterion by which "invention" is determined. It most certainly is not. More important is function and performance. In the context of the *BRCA* genes, there has been no modification. The genes are, other than being removed from the human body, identical in every material respect. They contain the same information.

Third, that the practice of granting gene patents has not been the subject of judicial review until now says much about how the patent system has failed to deal with this errant practice. In both countries, once a patent is granted, it remains enforceable until it is revoked by a court. The problem is that patent litigation is extremely expensive. Beyond that obstacle, in the United States, only a person with a sufficient interest in a patent is able to challenge its validity. In fact, Myriad brought a motion to strike out the claim in this case on precisely that ground. Judge Sweet rejected Myriad's argument, but even so, it remains a serious impediment to justice. What this means in a practical sense is that only large and sophisticated organizations, such as biotechnology companies and universities, have the capacity to bring these kinds of legal proceedings. But when these organizations are the very ones that have sought and been granted gene patents, is it any wonder that it has taken 30 years for the issue to be raised in a US court? It has yet to happen in Australia. It is no coincidence that it was the American Civil Liberties Union that facilitated the action brought by the Association for Molecular Pathology and 10 other plaintiffs.

Thank you for the opportunity to clarify these matters.

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REFERENCE

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Response to Dr. Palombi

To the Editor:

We are pleased that Dr. Palombi appreciated our case study, *Myriad Genetics: In the eye of the policy storm*.[1] However, his letter does confuse and conflate two separate types of opinion: (1) opinions on the desirability of gene patents; and (2) legal opinions on whether isolated genes and cDNA are patentable subject matter in the United States.

As for the first point, in 1996 one of us wrote extensively on the issue of patenting human genes, arguing that, for social and economic policy reasons, it would be better not to grant such patents.[2]

Many commentators came to similar conclusions. Many others disagreed. The opinions expressed drew on a combination of economic, social, scientific, and religious arguments to argue for or against such patents. These policy opinions influenced some legislative bodies around the world to pass legislation that either specifically prohibited the patenting of human genes (for example, in Mexico) or specifically acknowledged such patenting (for example, by Member States of the European Union). Government-sponsored commissions also discussed the wisdom or unwisdom of patenting human genes, such as the Secretary's Advisory Committee on Genetics, Health, and Society.

The discussion of human gene patenting in the passage that Dr. Palombi highlights was not of this type. Instead, it provided a legal judgment of the current status of United States law on the patent-eligibility of isolated DNA and cDNA claims. Unlike an opinion on policy, which, while often informed, can easily be disputed on many levels, a legal judgment draws on the nature of legal argumentation, building on agreed principles motivating law in general and, in this case, patent law in particular. These principles are, in the United States system, enunciated by the courts. The most important courts on matters of patent law are the United States Court of Appeals for the Federal Circuit and the Supreme Court of the United States. The Federal Circuit has exclusive jurisdiction over all appeals on patent law in the country and is largely composed of experts in the field. Although the Supreme Court sets out the principles motivating patent law, the Federal Circuit implements those principles.

Elsewhere, we have discussed the application of patent law to human genes.[3] Here, we summarize the reasons why isolated human genes are "almost certainly" a patentable subject matter in the United States.

First, ever since *Diamond* v. *Chakrabarty*,[4] the United States is acknowledged to have the broadest patent law in terms of what kind of inventions can be patented. Second, over the past 30 years, the Federal Circuit has ruled numerous times on the validity of gene patents, including isolated DNA and cDNA patents. Much recent jurisprudence of that court and of other district courts was not discussed in the District Court decision in Association of Molecular Pathologists et al. v. USPTO et al.[5] (There have been at least 31 law suits involving gene patents between 1987 and 2008; see Ref. 6) Third, US patent law has long recognized patents over "isolated and purified chemical products that exist in nature only in an impure state, when human intervention has made them available in a new form that meets human purposes."[7] As Professor Eisenberg notes, this is exactly what the courts found with respect to isolated vitamin B12.[8] Fourth, in those countries that determined, for policy reasons, not to permit patents over DNA, the legislatures passed laws to explicitly say so. For example, the Industrial Property Law of Mexico, in Article 16, states that "Inventions that are new, the result of an inventive step and susceptible of industrial application within the meaning of this Law shall be patentable, with the exception of . . . biological and genetic material as found in nature." Although Mexican or other foreign law has no bearing on the interpretation of US patent law, it illustrates a global consensus among law makers and experts that, absent a specific exclusion, naturally occurring genes are eligible to be patented. Fifth, the distinction often made when discussing policy between the information and physical nature of human genes does not translate well to patent law. This is because patents are not granted over the information or physical nature of genes separately, but together. The same patent that is directed to the use of a gene for a genetic test also applies to the use of the same gene in a therapeutic context. If patent law were to create a rule that one cannot patent the "informational" nature of genes, patent agents would simply arrive at the same result by claiming the use of genes in drug discovery. On the other hand, the distinction is useful in the policy realm because it may help develop legislative exceptions such as those proposed by the Secretary's Advisory Committee on Genetics, Health, and Society.

Although this is not an exhaustive justification of the statement that the decision on gene patents by the District Court for the Southern District of New York "will almost certainly be overturned," it provides strong reasons for believing so. The fact that no previous case has specifically addressed the issue of whether isolated DNA or cDNA is patent eligible is probably due to the strength of these arguments. Further, our opinion on the patentability of isolated DNA is supported by the vast majority of experts in United States patent law (for example, see Ref. 9), raising its confidence level to that expressed in the case study.

In the case study, we expressed no opinion on the District Court's holding that the type of diagnostic testing method set out in Myriad's patent claims were not eligible to be patented. This is because the law on this point is currently in flux, as observers await the decision of the Supreme Court in *In re Bilski*. Building on the Federal Circuit's decision in that case, the District Court raises a plausible argument that these method patents are not eligible for patent protection in the United States, even if new, nonobvious, and useful.

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