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.

Luigi Palombi, LLB, BEc, PhD

Centre for the Governance of Knowledge and Development
The Regulatory Institutions Network
College of Asia and the Pacific
The Australian National University
Australian Capital Territory, Australia

Disclosure: The author declares no conflict of interest.

REFERENCE

1. Cook-Deegan R, DeRienzo C, Carbone J, Chandrasekharan S, Heaney C, Conover C. Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: comparing breast and ovarian cancers with colon cancers. *Genet Med* 2010;12:S15-S38.

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