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International rules on origin source for biotech patents grow tougher

In "All About Eve," Bette Davis warns guests at a birthday dinner party to "fasten your seat belts, it's going to be a bumpy night."

That advice is also helpful for lawyers seeking to patent their clients' biotechnology-based innovations. This coming September, the World Intellectual Property Organization (WIPO) plans to present a number of changes to the international rules governing disclosure of the genetic origin of biotech inventions.

Particularly, if the adopted changes include rules governing "associated traditional knowledge," the ride for the unprepared may require seat belts, an airbag and, quite possibly, a helmet as well.

Since 1980 when the U.S. Supreme Court recognized the patentability of genetically altered bacteria in *Diamond v. Chakrabarty*, 447 U.S. 303, the biotechnology industry has become a multibillion-dollar enterprise. Biotech innovations lead the field in such diverse areas as medicine, agriculture, food production, biofuels and biodegradable plastics.

Biotech patents have always been controversial because of their foundation in biological processes and organisms. From the recent U.S. Supreme Court decision in *Association For Molecular Pathology v. Myriad Genetics, Inc.*, 2013, rejecting patent protection for the isolation of human DNA to the refusal by the Indian Supreme Court to patent a new salt form for *Imatinib (Novartis AG v. Union of India)*, 2013, medical biotech inventions have faced more exacting scrutiny internationally.

This scrutiny is part of an increasing skepticism towards patentability of biotech innovations generally. In 1999, the U.S. Supreme Court held that a utility patent could be granted for modifications to corn seed that enhanced its yield (*J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 534 US 124). Such modifications fit readily within the scope of generally patentable alterations to naturally occurring phenomenon. Yet utility patents leave no room

for so-called farmer's rights that allow planters to save harvested seeds to plant them for next season's harvest.

This controversy has been reinvigorated with the filing of an opposition in February to the grant of a utility patent by the European Patent Office for insect-resistant peppers (EP 2140, 023). Filed by a broad coalition of farm and breeder organizations from 26 countries in the European Union, the opposition challenges the granting of utility patent protection for plants as a matter of policy.

It further challenges the novelty of the process used to achieve the peppers' insect-resistant nature, claiming that the process was one that was commonly known in the relevant industry.

The latest meeting of the Intergovernmental Committee (IGC) of WIPO in February has added yet another hurdle for biotech inventions to overcome in their quest for patentability. Over the past decade this multi-national group has been working steadily to create an international consensus regarding the protection and use of "traditional knowledge" held by indigenous people.

One particular area of concern has been the protection afforded agricultural, medical and environmental knowledge and practices relating to plants, animals and other elements of the biota. Such knowledge is increasingly sought to fuel the engine of biotech innovation.

There is currently no international obligation to disclose the role of indigenous knowledge in biotech patent applications. As a result, patents have been granted to third parties based on undisclosed traditional knowledge. In a well-known case in the U.S., a patent was granted for the use of turmeric (a plant in the ginger family) to treat wounds. The patent was eventually revoked when it was demonstrated that the use of turmeric for such treatments was a well-established practice in India.

Efforts to impose a disclosure obligation have proven unsuccessful in the past. Time, however,

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may be running out for opposing such an increasingly popular measure. In the recently approved Consolidated Document Relating to Intellectual Property and Genetic Resources, WIPO/GRTKF/IC/26/4 (Consolidated Document), Article 3 requires the disclosure of the source of both genetic resources and the associated traditional knowledge on which patent claims are based. Failure to disclose such associated traditional knowledge can result in a variety of sanctions, including denial of the patent.

Such disclosure could raise new bars to biotech patenting. On the plus side, disclosure would make novelty, non-obvious and enablement determinations easier. It would help ensure that only worthy applications of long-standing practices would be patented. Disclosure would also make it easier for indigenous peoples to secure compensation and other "equitable benefits" for the commercial use of their traditional knowledge, a long-standing goal of the work of the IGC.

On the negative side, however, any such disclosure obligation could raise the costs of biotech innovation. Most significantly, the precise scope of the obligation is unclear. The Consolidated Document defines such "associated traditional knowledge" as "knowledge

which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation, including ... but not limited to know-how, skills, innovations, practices and learning."

This is unfortunately broad language when applied to the highly nuanced world of bioengineering. Moreover, the document's non-exhaustive examples provide little additional clarification about the boundaries and scope of what constitutes disclosable knowledge.

For these reasons, among others, the United States is strongly opposed to any disclosure obligation. In addition, some of the particulars regarding the nature of the disclosure remain open to negotiation, including whether the claims must "involve," "arise from," be "directly based upon" or "utilize" the genetic resource and its associated knowledge. Thus, although the Consolidated Document is already set to be considered by the WIPO General Assemblies in September, there may be some room for alterations.

Irrespective of the final U.S. position, there are steps which biotech innovators should take to prepare for what appears to be the inevitable adoption of an international disclosure obligation.

New protocols for categorizing sources and traditional knowledge usage are a must. Material transfer agreements from indigenous peoples who provide biogenetic materials for research should be secured even if no present research plans exist. Perhaps most importantly, prior informed consent should be obtained for the use of any potentially disclosable traditional knowledge.

WIPO's draft intellectual property guidelines for access to genetic resources and equitable benefit sharing of the benefits arising from their utilization, WIPO/GRTKF/IC/17/INF/12, contain model agreements that may prove particularly helpful. A little pre-planning now can avoid some painful collisions in the future.