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Medical breakthroughs will face 'perfect storm' internationally in 2014

As 2013 draws to a close, medical technology promises encouraging new breakthroughs. Efforts are underway to map the brain, creating potential future treatments for Parkinson's and Alzheimer's diseases.

New vaccines are being created to combat HIV and malaria, while gene therapy continues to provide new treatment options for regenerating bones and combating viral infections.

For the past 10 years, medical research in the area known as "biologics" has mushroomed internationally.

The term "biologics" refers generally to medical products made from a variety of biogenetic materials, such as cells, tissue, blood and other fluids. Unlike traditional "drugs" which are chemically synthesized, "biologics" are created by biological processes.

One of the reasons for the increasing interest in biologics by pharmaceutical companies is the upcoming "patent cliff" for many blockbuster drugs in the next several years. This "patent cliff" is a global phenomenon as the patents for such blockbuster drugs as Lipitor, Plavix and Humira, among others, are due to expire.

This cliff has encouraged pharmaceutical companies to focus increasing attention on biologics as a replacement for such disappearing market advantages. As biologics increase in number and significance in the coming years, they will face a "perfect storm" of shifting rules governing their protection under international patent laws.

The foundation of biologics on biogenetic materials has heightened the international collision between using patent protection to assure the costly investment required to bring new medical treatments to market and applying such protection narrowly to assure that only "inventions" are granted protection.

In the U.S., the Supreme Court in June in *Association For Molecular Pathology v. Myriad Genetics Inc.* held that isolating

the BRCA1 and BRCA2 genes, whose presence is used to test for breast cancer, did not qualify as patentable subject matter under U.S. law. Although the isolated gene might not necessarily occur in nature, the court did not believe that the act of isolation itself was a sufficiently inventive act to alter the fact that a patent would serve only to protect "the genetic information encoded in the BRCA1 and BRCA2 genes."

This decision suggests that early breakthroughs, including mapping activities related to the brain, may not be patentable in the United States.

By contrast, in Australia, in February in *Cancer Voices Australia v. Myriad Genetics Inc.*, the federal court held the isolation of the BRCA gene qualified as patentable subject matter in part as a result of the "immense research and intellectual effort" required to isolate a particular micro-organism.

The court reasoned: "It would lead to very odd results if a person whose skill and effort culminated in the isolation of a micro-organism (a fortiori, an isolated DNA sequence) could not be independently rewarded by the grant of a patent because the isolated micro-organism, no matter how practically useful or economically significant, was held to be inherently non-patentable."

Even when biologics survive inventiveness challenges, because the biogenetic materials from which biologics are created pre-date their creation, there is a strong reluctance in some countries to grant patent protection for new uses of existing medicines. These "new use" patents may include new dosage regimes, new methods for securing efficacy or even new uses for known substances.

Under U.S. law, new uses are subject to patent protection so long as such uses meet remaining patentability requirements. Canada similarly provides that a new use of a "known compound" qualifies as potentially patentable subject matter.

By contrast, in Article 16 of Andean Community Decision 344, new-use patents are expressly

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excluded from patentability. Demonstrating a similar skepticism to new use patents, the Indian Patent Act requires that new uses "result in the enhancement of the known efficacy" of the substance. This "enhancement" obligation requires "therapeutic efficacy."

Perhaps one of the most rapidly changing elements in the upcoming storm relates to the regulatory processes for "generic" marketing approval. The relationship between clinical test data, patent validity and "generic" marketing approval is a complex one in any country.

Under the Trade Related Aspects of Intellectual Property Rights (TRIPS), patent owners are given the right to prohibit others from "making [or] using" patented pharmaceuticals. Internationally, most countries provide an exception to these broad prohibitory use rights to allow third parties to secure marketing approval for generic drugs.

The same use exception applies to patented biologics. The determination of whether a biologic is the medical "equivalent" of another (referred to as a "biosimilar"), however, lacks the clarity of traditional generic drugs.

Patented drugs are historically composed of small molecules whose bio-equivalence with

"generic" versions is readily determined. Most countries grant regulatory "shortcuts" that help generic drugs more quickly reach the market. By contrast, biosimilars often differ in molecular structure and in the method for achieving the desired therapeutic effect from the patented version.

These differences have triggered diverse regulatory processes internationally. Many countries such as the United States, the European Union and Brazil require clinical evidence of both biosimilarity and interchangeability — that the biosimilar product will produce the same clinical result with identical terms of efficacy and safety. Yet the tests for determining such interchangeability, including the use of third party clinical data, remain in flux.

The final element of the approaching perfect storm is the increasing international pressure to permit greater access to patented medicines. This access creates pressures on pricing regimes globally. It raises the undeniable specter of low-priced compulsory licenses. Where such licenses are not imposed, countries are increasingly permitting the importation of gray market drugs to combat pandemic and chronic illnesses.

A proactive response is the best method for dealing with this anticipated storm. The European Medicines Agency, Brazil's Agencia Nacional de Vigilancia Sanitaria and the U.S. Food and Drug Administration have all recently issued position papers or draft regulations governing biosimilars.

Public comments can be made to help shape the regulatory process. Among the most useful sites for monitoring both domestic and international developments in this area generally are the World Health Organization (who.int/biologicals); Genetic Engineering and Biotechnology News (genengnews.com); and the U.S. Food and Drug Administration (fda.gov/drugs).

Whatever the outcome, the oncoming perfect storm promises to alter the landscape for biologics. The shape of that alteration remains an open question.