

Richard Gold

Lawyer Richard Gold argues that superfluous patents stifle innovation. Industry should adopt new models, he says, in which knowledge is viewed as a club good.

When Richard Gold's consultancy released a report in September calling for the overhaul of IP laws, it was greeted with skepticism. Industry experts found the study's conclusions exaggerated and its recommendations airy. But Gold, chair of the International Expert Group on Biotechnology, Innovation and Intellectual Property at McGill University, in Montreal, maintains that life sciences IP is misunderstood, mismanaged and change is thus inevitable. He is out to persuade governments, industry, universities and nongovernmental organizations to revamp the way they think about IP.

Gold traces his interest in property rights and the human body to the University of Michigan where he earned his doctorate of law. His curiosity was piqued by the 1990 case of John Moore, who was treated for hairy-cell leukemia at the Medical Center at the University of California at Los Angeles, and whose doctors developed and patented a cell line derived from his spleen cells. Moore sued, but lost his case. Gold wrote his thesis, which was later published as a book, *Body Parts: Property Rights & The Ownership of Human Biological Materials*, to explore the legal and ethical issues raised.

In 2000, Gold became involved with the Canadian Biotechnology Advisory Committee to examine a variety of questions surrounding the patenting of higher life forms. As experts from academia, industry and elsewhere gathered to deliberate the issues, Gold began to question whether sufficient emphasis was placed on the patent system as a whole and its role in innovation. "We were a bunch of people in silos. There was nobody out there with a more global vision on what impact IP was having on the biotech innovation sphere," he says.

The experience led him to join a group of people from a variety of backgrounds—from economists to bioethicists and lawyers—that became The Innovation Partnership's International Expert Group on Biotechnology, Innovation and Intellectual Property.

After seven years of research, the group published their report last September. At the core of their findings was the need for policy makers and business leaders to move into a new era of IP, one where government, academia and industry work together.

Gold points out that innovation was a different animal 30 years ago, when a handful of companies could lay claim to the top R&D rewards. "The easy-to-find drugs have been found. No one has the capacity to do these things by themselves anymore," he says. Now, he says, IP rights have become barriers to innovation, particularly in the health field. He points to the pharmaceutical industry, with its increasingly narrow pipeline and a persistent failure to develop and manufacture drugs for developing countries, and to biotech companies that hoard patents to attract capital, but fail to bring their products to market.

Others find the report's proposals naive and overly academic. "Biotech is expensive and it needs lots of capital investment. You need a means to protect the investment to encourage funding of innovative ideas," says Harriet Strimpel, chief patent counsel at New England Biolabs, in Ipswich, Massachusetts. Biotech, which generally come out of universities and spin-offs, often have a single upstream product and tend to rely on their IP to raise the capital they need to develop the technology. "Patents are symbols that can be used to impress investors," says Gold. "[Biotech] often hold onto [them]

because they see [patents] as the key to everyone's success." But Gold argues that the value is often marginal or unknown.

He doesn't think that IP is inherently bad, but what is needed is "greater knowledge flowing back and forth among the players," he says. To make the transition to the new IP era, the McGill group lays out some recommendations: trust, better communication, new models, new data and metrics. And yet, Gold acknowledges that they offer no prescription for biotech—the model will vary from place to place and on the composition of the partners.

But he does propose some ideas. Biotech firms might participate in precompetitive partnerships with pharma, and governments could facilitate these partnerships by absorbing some of the risk through tax credits or funding priority areas. "The trick is to find a way to compensate a biotech for participating without the normal model, either with no patents or with patents but no licenses," he says. Gold imagines a scenario where the knowledge becomes a club good, that is, a knowledge shared among individuals in a group, who draw up contracts to agree on a fee structure any time the good is used, whether or not something comes of it. Patent pools, such as the Geneva-based drug-purchasing organization UNITAID, set up to address the lack of pediatric and

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fixed-dose anti-retrovirals for developing countries, is a case in point, though more suited at the delivery end of the equation.

Gold's proposal has had a frosty reception from the Biotechnology Industry Organization, the Washington, DC-based umbrella group that represents the biotech sector. "The proposition advanced by the study... has been repeatedly debunked and has no empirical basis in fact," was the response. "A robust system for protecting IP rights is critical to establishing an environment in which biotechnology innovation can flourish."

But Gold does have proponents. Aled Edwards, director and CEO of the international Structural Genomics Consortium and a professor at the University of Toronto, says the report lends legal legitimacy to approaching biotech innovation differently. For drug development, he says, "We need to collaborate with industry because they are the experts. But we have to create knowledge that is free and can facilitate everyone's work," he says. "IP gets in the way of doing that."

From Gold's perspective the change is inevitable. The information technology (IT) industry, which went through this change earlier, is now calling for a narrower scope on patents. "My view is that pharma and biotech will go the way of IT," he says. "It will be an evolution, rather than having a bunch of academics talking to industry and saying this is the way it ought to be."

Hannah Hoag