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EDITORIAL

Intellectual property rights and living organisms

Introduction

One of the most contentious issues accompanying new developments in bioscience, biomedicine and biotechnology has been the debate surrounding the patenting of living things. The debate touches on many of the legal, ethical and social concerns that come bundled with advances in science and technology, and with how these advances are understood, governed and capitalised upon. Indeed, the intellectual property rights (IPR) system has been positioned at the heart of several historical and contemporary controversies to do with how we respond to new developments in science and technology and how we negotiate new ethical, legal, social and/or other boundaries as a result.

What follows will be an attempt to very briefly sketch out some of the principal lines of contention that have characterised the debates around the patenting of life forms. I will look initially at the history of the notion of patentability for living things, then at some of the specific ramifications of the ever-evolving scope and scale of patents on living things focusing on concepts such as the 'patent thicket' and 'patent creep'. Finally, I will look in slightly more detail at a specific controversy in the field, namely that of 'biopiracy'.

Patentability for living organisms

Historically, as the nature of industrial production changed one of the problems that became apparent was that there was a great deal of effort being put into designing new machines, dyes, and other inventions but once these were made and sold, they were relatively easily copied. The idea behind the IPR system was that if inventors knew that they would be somehow rewarded for the amount of time, effort and resources that they put into 'inventing', then they would continue to do so for their (short term) financial benefit, and for the long-term benefit of society.[1] The social benefit would come from the patent process itself, which obliged the inventor to submit a full description of the nature of their invention with the patent.[2] This same logic has been borne out in the patent system's treatment of the biotechnology industry. Indeed, the prevailing logic within the IPR system is that in order for society to reap the benefits that come from the development of new drugs, those making the sizable investment in drug research and development need guarantees that they will be rewarded to an extent that would justify their investment. As the Biotechnology Industry Organization puts it; ''intellectual property protection is the key factor for economic growth and advancement in the biotechnology sector. Patents add value to laboratory discoveries and in doing so provide incentives for private sector investment into biotechnology development''.[3] For their part, the Pharmaceutical Manufacturers of America claim it ''takes 10–15 years and costs $800 million on average to bring

[1] Originally, the patent system was seen to have a primarily social function – the inventor was granted protection to exclude others from making money on their invention for a limited time, after which time the invention, and the knowledge of its use, entered the public domain (c.f. Drahos, P. (1996). *A philosophy of intellectual property*. Sydney, Dartmouth.)

[2] See for example Drahos, P. (1996). *A philosophy of intellectual property*. Sydney, Dartmouth.

[3] Biotechnology Industry Organization (2006). The importance of intellectual property. Online, last accessed Feb 17, 2006 (http://www.bio.org/ip).

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a new medicine to market''.[4] Although these figures have proven controversial,[5] it is clear that the money involved is significant, and that access to drugs, new and old, has a significant impact on the practice of medicine.

As the patent system evolved, the ''product of nature'' doctrine was developed, which suggested that ''while processes derived to extract what is found in nature can be patented, objects discovered there cannot''.[6] This was seen as a means to deter people from simply patenting things they 'discovered' in nature. Some tension in the system emerged, however, when advances in science and technology led to an increase in 'inventions' that directly involved 'products of nature'. As Eisenberg has explained, much of the controversy has come about because the patent system was built for a 'bricks and mortar world' rather than an information economy, which is compounded by the fact that genes can be seen as ''both material molecules and informational systems''.[7] Or, put another way, the patent system might well have been calibrated to deal with a design for Emerson's 'better mousetrap'[8] but not, as it were, with a design for a better mouse.

Currently, the criteria for patentability still vary slightly from country to country, although there are ongoing efforts to harmonise different national patent regimes. For our purposes, however, we can look at what can generally be said to be common criteria of patentability: novelty (that something is new), non-obviousness (that it involves some measure of non-obvious inventive step), and usefulness (that it has some application).[9] It is often people's intuitive reaction that, as they are 'natural', living things simply cannot be 'invented' and thus cannot be patented. There have, however, been several key cases that have called that thinking into question, and have forced a legal, if not always social, reinterpretation of what counts as 'natural' within the IPR system.[10]

Diamond v. Chakrabarty

Although there are other cases that have done a great deal of work to establish the boundaries of patentability for living organisms, very few have been as influential as the now widely known case of *Diamond v. Chakrabarty*.[11] In this case, studied extensively elsewhere,[12] a scientist (Chakrabarty) working for General Electric genetically engineered a strain of bacteria that were able to digest crude oil. Chakrabarty filed a patent on the organism, claiming that by genetically altering the bacteria he had 'invented' something that was not found in nature. The patent was eventually challenged at the U.S. Supreme Court, who ruled that the intent of the patent system was for patentability to include ''*anything under the sun that was made by man*'' and that ''[...] his [Chakrabarty's] discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter [...] [emphasis added]''.[13]

What *Diamond v. Chakrabarty*, and several of the cases that have followed in its wake,[14] have done is to expand notions of what is patentable, as well as expand the practice of describing an invention undertaken to demonstrate that patentability. The limits and scope of patentability are still being negotiated in the courts and by policy makers, but will likely be forever pushed by new developments in technology.

Patented problems?

Perhaps more so than any other element of the patent system, the patenting of living organisms comes bundled with what many see as significant

[4] Pharmaceutical Manufacturers of America. (2006). Issues: Intellectual property. Online (Online, Accessed Feb 16, 2006. http://www.phrma.org/index.php?option=com_content&task=view&id=123&Itemid=109&cat=Intellectual+Property).

[5] Angell is quite critical of industry claims about the need for rigid intellectual property to encourage innovation as well as the actual costs involved. See for example Angell, M. (2004). The truth about the drug companies: How they deceive us and what to do about it. London: Random House.

[6] Kevles, D. (2002). *A history of patenting life in the United States with comparative attention to Europe and Canada*. European Group on Ethics in Science and new Technologies to the European Commission. Luxembourg: European Commission. p. 2.

[7] Eisenberg, R. (2002). ''How can you patent genes?'' *American Journal of Bioethics* 2(3): 3–11. p. 3.

[8] Ralph Waldo Emerson is reputed to have made the oft quoted (but probably apocryphal) remark ''Build a better mousetrap and the world will beat a path to your door''.

[9] The U.S. and European systems differ slightly on this point, with the U.S. system using the term 'utility' and the European system relying on a concept of 'industrial applicability'.

[10] For an excellent history of IPR in the life sciences see Dutfield, G. (2003). *Intellectual property rights and the life sciences industries: A twentieth century history*. Hampshire, Ashgate.

[11] *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty, Certiorari to the United States Court of Customs and Patent Appeals, 447 US 303, U.S. Supreme Court (1980)*.

[12] For a particularly helpful analysis, see Kevles (op. cit.) and Gold, R. (1996). *Body parts: Property rights and the ownership of human biological materials*. Washington D.C., Georgetown University Press.

[13] ibid.

[14] One example being the oncomouse (aka Harvard Mouse) case as contested in the U.S., in Canada, and in Europe.

ethical implications. As Gold has pointed out,[15] the patent system has undergone a shift, manifested in the *Diamond v. Chakrabarty* decision, whereby it has been determined that the court's role was solely to arbiter on the economic implications of a patent, rather than on its possible ethical implications. If the patent system, particularly where it pertains to living organisms, is interpreted in purely economic terms it leaves open questions as to who is the appropriate authority to arbiter the other questions that arise out of patent decisions (particularly when they traverse such fraught ethical territory as questions about as how 'natural' does something have to be in order for it to be 'too natural' to be invented?).

Along with the pertinent ethical questions, the dramatic expansion of what is patentable stemming from *Diamond v. Chakrabarty* and other cases has facilitated several attempts at developing concepts to characterise the ever-evolving developments at the intersection of IPR and bioscience/biotechnology.

In particular, there have been concerns raised about the effect that patents can have on research in science, technology, medicine and agriculture. One of these concerns involves the 'patent thicket', which is described by Shapiro as an overlapping set of patent rights requiring that ''those seeking to commercialize new technology obtain licenses from multiple patentees''.[16] The problem with a patent thicket, it is surmised, is that the density of patents around a particular area will actually serve to hinder research in that area, for the simple fact that researchers would be worried about the possibility of their research infringing on someone else's patent. Closely related to this is the notion of the 'patent submarine' which describes an instance where, ''drawing on published sources, a company or Public Research Organisation (PRO), such as a university, develops a method for genetic testing or analysis using genetic material and subsequently discovers that such methods infringe a patent''.[17] These two concepts can be seen as quite closely related to the notion of an anti-common that has been put forth by several IPR scholars, where scientific research is actually limited by the increased importance of secrecy bred by the IPR system.[18]

Concerns about biotechnological IPR are not immune from some of the concerns voiced about the expanding scope and scale of IPR in other fields, such as software. For instance, legal scholars such as James Boyle have cautioned that we are entering into what he calls a 'second enclosure movement' where ''things that were formerly thought of as either common property or uncommodifiable are being covered with new, or newly extended, property rights''.[19] This has often been related to what some call an intellectual property 'land grab', or a process of 'patent creep', where the system is forced to expand by ever more ambitious patents being filed.

For many, the ethical situation with patents on life forms gets even more fraught and complex when the consideration of the patentability of living organisms expands to include material of human origin. For example, a recent article in *Science*, picked up on by many prominent newspapers, claims that nearly 20% of human genes are explicitly claimed as intellectual property in the U.S.[20] The debate about IPR on human material has had several flashpoints, such as the substantial controversy surrounding the sequencing of the human genome in the latter part of the 90s. This very public controversy pitted a public consortium versus a private company in a race to sequence the human genome, and perhaps more importantly, in a race to determine whether this data would be made freely accessible to the public, or whether it would be held in a database available only to subscribers.[21]

More recently, there have been activists/scientists who have sought to press the boundaries of what is patentable. In an attempt to demonstrate some of the shortfalls of the patent system when it comes to patents on human beings, one scientist is attempting to patent human animal hybrids, which he calls 'chimeras'.[22] Ostensibly the purpose of his patent application is to draw attention to the expanding notions of what is patentable, and to the ways in which new biotechnological developments,

[15] op. cit.

[16] Shapiro, C. (2001). Navigating the patent thicket: Cross licences, patent pools, and standard setting. *Innovation Policy and the Economy*. A. Jaffe, J. Lerner and S. Stern, MIT Press. p. 1.

[17] Oldham, P. (2004). *Global status and trends in intellectual property claims: Genomics, proteomics and biotechnology*. CESAGEN United Kingdom, p. 37.

[18] Heller, M. and R. Eisenberg (1998). ''Can patents deter innovation? The anticommons in biomedical research.'' *Science Magazine* 280: 698–701.

[19] Boyle, J. (2003). ''The second enclosure movement and the construction of the public domain.'' *Law and Contemporary Problems* 66: 33–74, p. 37.

[20] Jensen, K. and F. Murray (2005). ''Intellectual property landscape of the human genome.'' *Science* 310 (14 October 2005): 239–240.

[21] For a discussion of this controversy, see Roberts, L. (2001). ''Controversial from the start.'' *Science* 291(5507): 1182–1188.

[22] Slater, D. (2002). ''Humouse tm.: Can you patent a monster?'' *Legal Affairs* (November/December 2002).

combined with the expanding purvey of IPR, can serve to challenge ethical, legal and social understandings of what should or should not be patentable.[23]

Biopiracy

Along with the aforementioned concerns about the haziness of the current landscape to do with patents involving living things come concerns about how the rules of IPR will be played out internationally, especially in the developing world. This becomes especially pertinent when combined with certain international agreements, particularly the World Trade Organization's (WTO) Trade Related Intellectual Property Measures Agreement (TRIPs) which mandates that all countries that are part of the WTO implement a minimum standard of intellectual property rights.

One of the other particularly contentious areas of IPR for living things is an alleged process called 'biopiracy'. The allegation of 'biopiracy' is generally designed to characterize a situation where a patent is taken out in the developed world on a genetic resource (or the knowledge of that resource's use) that has its origins in the developing world.[24] As it pertains to medicine, the allegation of 'biopiracy' has been most famously made on patents that involve the medical uses of plants, especially where these uses were known before, for instance to do with the wound-healing properties of turmeric.[25] Allegations of 'biopiracy' have also been made in situations where patents have emerged on materials derived from the collection of human samples from populations in the developing world. In general, allegations of 'biopiracy' are made where these patents are present, and where there has been a perceived inadequate or incomplete attempt to share the benefits (economic or otherwise) accruing from the patent, although instances of 'biopiracy' cannot often be dealt with simply in economic terms.[26] Along with seeking to problematize how the 'benefits' of genetic resources are generated and shared via IPR, allegations of 'biopiracy' can be seen as attempting to make interventions in the patent system in order to clarify what should and should not be patentable.

Conclusions

The patent system is an organic one, and has been forced to grow and change in response to developments in science and technology. As has been pointed to in this brief outline, the relationship between the patent system and living organisms is not as straightforward as might be assumed.

Through new developments in science and technology as well as with the corresponding IPR challenges, definitions of patentability have now been stretched to encompass living organisms, in previously unforeseen interpretations of various IPR concepts. Issues such as biopiracy, patent creep and the persistence of patent thickets, however, point to legitimate concerns as to the impact that the expanded scope and scale of IPR will have on innovation as well as our understanding of ethical practice in medicine and beyond.

It seems clear that the patent system plays an integral one in the world of innovation and research. However, the philosophical and ontological questions raised by its expansion are fundamental ones: What counts as living in the IPR system? What counts as human? What does this mean for society? What social effects will the IPR system have as the patent system expands in its conceptual as well as its territorial scope?

While obviously these are not easily answered, the question that remains has to do, in a more tangible sense, with how we will balance the competing perspectives on invention, nature, humanity, and IPR as we deal with new developments in medicine, science, and technology.

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[23] op. cit.

[24] This becomes more relevant when it is considered that a vast majority of the world's biodiversity-derived 'genetic resources' are located in developing countries.

[25] Shiva, V. (1998). ''The turmeric patent is just the first step in stopping biopiracy'', Third World Network, online, last accessed November 2005.

[26] Many claims of 'biopiracy' are also intimately bound up with contestations about what prevails as a system of property, what it means to 'own' knowledge (if such a thing is even possible), and other concerns which fundamentally transcend mere economic redistribution.