

Patenting pieces of people

Something very strange is going on in Canada. While patent offices in the United States and Europe have been granting patents on all things genetically modified—whether microbe or mammal, human or nonhuman-derived material—Canada has decided to call everything to a halt. At the end of 2002, the Supreme Court of Canada took the unprecedented step of ruling that the country's Patent Act must be amended before Canadian courts can continue to consider biotechnology patent applications on higher forms of life (*Nat. Biotechnol.* 21, 9, 2003).

The stakes are high. According to industry association BIOTECCanada, around 400 Canadian companies generated US\$3 billion of business in 2002, making the sector the second largest in the world after the United States. If the Canadian parliament disqualifies certain areas of biotechnology research from patent protection, multinational companies could flee and commercialization of Canadian research could be stymied—99% of companies rely on patents (rather than products) as their sole source of value. No patents equates to no funding equates to no companies. Intellectual property drives research. As BIOTECCanada's president puts it: "The decision stops our pursuit of knowledge and innovation dead in [its] tracks. It is a great loss to Canada at both the social and economic level."

The critter that precipitated this crisis is none other than the Harvard Oncomouse, a transgenic mouse line carrying a human *v-Ha-ras* oncogene fused to a mouse zeta-globin promoter. The Oncomouse has been courting controversy ever since Phil Leder, Timothy Stewart, and Harvard University were first granted patents by the US Patent and Trademark Office (US PTO) in 1988 and the European Patent Office (EPO) in 1992. Since then, oppositions to the European Oncomouse patent have been filed by numerous individuals, animal-rights groups, church organizations, the campaign against "patents on life," and various factions of the German Green party. The patent remains valid.

Controversy over patenting living creatures is nothing new. The issue first reared its head in 1972 when Ananda Chakrabarty applied for a US patent on a bacterium engineered to break down petroleum in oil spills. At the time, the US PTO denied the application, but the decision was later overturned in a federal court appeal, which in turn was appealed by the patent office in March 1980. In the subsequent ruling, the justices held that Congress intended "anything under the sun that is made by man" to be patentable, including living bacteria. A 1987 case known as *Ex parte Allen* extended the principle to nonhuman multicellular organisms. Following issuance of the Oncomouse patent in 1988, the floodgates opened and all manner of transgenic fauna (rats, rabbits, fish, sheep, pigs, and cows to name a few) have now been patented.

In contrast to the US PTO's 'open door' approach to patenting animals (and the movement of the EPO in the same direction), the Canadian Intellectual Property Office has remained reluctant to grant patents on transgenics. Initially rejecting the Oncomouse patent in

1985, it stated it had no authority to grant ownership rights over a species of mammal. A Canadian federal court upheld this decision in 1998, but two years later, the appellate court overturned the ruling and Harvard got its patent. Now, in the latest twist of the mouse's tale, the Supreme Court of Canada has upheld an appeal by the Canadian Intellectual Property Office, ruling that the Oncomouse does not constitute a "composition of matter" and therefore does not qualify as an invention worthy of a patent. The court went on to state that higher life forms could only be patented "under the clear and unequivocal direction of the Canadian parliament."

At present, human beings are unique in being the only living creatures that remain off limits to patents. No country's patent system has yet found a way of extricating itself from the philosophical and political morass associated with patent applications that encroach on definitions of humanness. In 1998, US PTO's former commissioner Bruce Lehman refused a patent application for human and animal chimeras filed by biotechnology provocateurs Jeremy Rifkin and Stuart Newman. As the basis for rejection, Lehman invoked a *moral* utility doctrine set by an obscure federal court decision in 1817. Essentially, he argued "there will be no patents on monsters."

But moral standards are clearly an unsatisfactory benchmark for establishing patentability: morality (like obscenity) is one of those things that arbiters (more specifically, patent examiners) are likely to have a hard time defining. Clearly, better definitions are needed. One potential criterion, for example, could be to reject patent applications on any product that requires the use or inclusion of human embryos over 14-days old (the point at which development of the nervous system and potentially human sentience begins).

If Canadian legislators adopt policies that broadly restrict patents on any human-derived products, the Canadian patent system could end up discriminating against a multitude of biotechnology products. Indeed, if the parliament prohibits patent protection for biotechnology therapies containing any material derived 'from human bodies at any stage of development'—as proposed in a report published in February by the Canadian Biotechnology Advisory Committee (see p. 351)—the consequences for Canadian biotechnology could be dire. Certainly, the prospects for Canadian companies intending to develop stem cell therapies (derived from human embryos) look bleak.

The job of the courts is to interpret the law as written. It is appropriate that legislators should tackle larger ethical and societal questions. The decision of the Canadian court to let lawmakers, rather than judges, define the breadth of reach of patent laws is laudable, given widespread public concerns about the commoditization of humans and human body parts. But legislation clarifying the scope of patents on higher forms of life should steer clear of moral and ethical definitions. We need to stick to rational and scientific benchmarks that can be practically applied by patent agencies.

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