THE IMPACT OF PATENTS ON MEDICAL BIOTECHNOLOGY

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Summary

This article considers one of the most widely debated concerns associated with the modern patent system: the impact of gene and related research tool patents on innovation in medical biotechnology. The justification for patents is that they encourage innovation by providing a temporary monopoly to patent owners, allowing them to exclude others from making use of the patented invention for the life of the patent. Patenting of genes with known function and other foundational biomedical research tools is generally allowed provided that they fulfil the usual invention and disclosure criteria specified in national patent laws and international agreements. There is growing concern internationally that the impact of patents on innovation in the medical biotechnology industry could be negative in circumstances where single patents have the capacity to hive off whole areas of research or where there are simply too many patents in a particular area. Gene and research tool patents also have the capacity to negatively impact on foundational public sector research and on the provision of healthcare services. Despite these theoretical concerns, there is limited empirical evidence at present of patents being inappropriately exploited and of research, product development and healthcare delivery being impeded. However, this evidence is not comprehensive and needs to be interpreted with caution. In response to the theoretical concerns in this important area of research and development, a number of initiatives are being developed both nationally and internationally that focus on mechanisms that balance the potentially conflicting needs to guarantee access to patented biomedical technologies and to support the growth of the industry.

1. Introduction

Governments around the world are expressing strong commitments to the development

of indigenous biotechnology industries. In Australia, for example, the federal government puts its commitment to biotechnology in this way:

Consistent with safeguarding human health and ensuring environment protection, that Australia capture the benefits of biotechnology for the Australian community, industry and environment

Like sentiments have been expressed on numerous occasions in other countries. How, then, should the development of indigenous biotechnology industries be facilitated within the regulatory framework of appropriate safeguards for health and the environment? One of the crucial policy issues that national governments need to decide on is the appropriate parameters for intellectual property management, both in terms of what intellectual property rights should be granted and what, if any, limitations should be put on the use of those rights.

In any technology-based industry, the biggest asset of a business is likely to be its intellectual property, particularly its patents [see also– *Inventions, Patents and Morality*]. The main reason for this is that these industries deal in research and innovation, much more intangible resources than the oil or coal or crops of other industries. Tangible end products may only emerge many years after initial investment in research. The purpose of patents is to encourage innovation by creating property rights in the intangible assets of a business. Patent owners are provided with a period of market exclusivity (usually 20 years) in which to develop their innovations and sell their products free from the fetters of competition. However, patents don't just provide an incentive to innovate for the initial innovator, but also for their competitors. As a trade off for the period of market exclusivity, the patent owner is required to fully disclose the invention and the best method of performing it. With this knowledge, competitors are encouraged to work around the patented territory and, once the period of exclusivity has come to an end, move into that territory. Patents may also serve other socially valuable purposes: innovation could lead to improved access to healthcare and better protection of the environment as well as the more obvious economic benefits.

During the period of market exclusivity, patent owners can charge licence fees for use of their innovations, or include a royalty component in the price of products arising out of their innovations, or they might simply decide to sell their patented innovations to other people who are better able to commercially develop them. Without patents, competitors could free ride on the hard work and financial investment put into innovation. Hence, in some areas of technology, if patents were absent, competitors would easily be able to out-compete innovators by manufacturing and selling generic products at prices much lower than the original innovation simply because they are not dependent on recovering the same research and development costs.

The pharmaceutical industry is a case in point: companies need to invest many millions of dollars in taking their new drugs through all of the research and regulatory hurdles to get them to market. The actual costs of manufacturing approved drugs are insignificant when compared with the many millions of dollars put into research and product development. Hence there is an obvious need to build in some mechanism to recoup the cost of research and development. Patents provide such a mechanism, and, as a

consequence, would seem to encourage innovation in the pharmaceutical industry. Whilst it must be recognised that there are complex issues associated with access to patented drugs, particularly in least developed and developing countries, it is difficult to deny that, on the face of it, pharmaceutical patents appear to serve an important social function of encouraging innovators to make new drugs. But it is vitally important to bear in mind that patents could just as easily have a negative effect on innovation if they are improperly granted or improperly used. Policy makers need to take these considerations into account in formulating best practice models for patent management.

The considerations that policy makers need to take into account are even more complex in the biotechnology industry than the pharmaceutical industry. In part, the reason for this is that the risks are even greater in terms of the cost of research, the failure of many products during commercialisation and the time lag between discovery and commercialisation. Another reason why the biotechnology industry raises complex questions with regard to patent management policy is because of the cumulative nature of research and development. Pharmaceutical companies produce drugs: products that they can sell to consumers and charge monopoly prices for. But most research organisations and biotechnology companies do not produce saleable end products as such. What they are producing are ideas, techniques and materials for use by other industry participants. Unless these 'products' are protected by patents, they can be readily copied and have little value in economic terms, deterring investment in the industry.

On the one hand, it seems logical that, if investment in the biotechnology industry is to be fostered, the provision of appropriate patent protection is a desirable policy objective. But on the other hand, if the protection afforded by patents is too strong, then, rather than opening up the biotechnology market and encouraging innovation, it could create a barrier for entry to new players into the market and threaten the survival of existing players. Although the justification for patents is that they enable innovations in biotechnology to be commercialised, they could, at the same time, be used to block others from innovating. Put simply, the dilemma is that:

- if biotechnology industry participants are unable to get access to essential research tools and techniques as a result of the exercise of patent rights by other participants in the industry, this will be a significant impediment to their ability to innovate and their survival in the marketplace; but
- if, at the same time, industry players are unable to adequately protect and exploit their own patents, then this too will be a significant impediment to their market position.

It is not clear how patents are actually operating in the biotechnology industry as a whole at the present time: whether they actually encourage or discourage innovation. An added difficulty in this area, particularly in the medical biotechnology sector, is that patents have the capacity to affect on other socially desirable goals, including freedom of research and scientific discovery and access to healthcare. Thus, it is important to evaluate whether patenting and patent management strategies for biotechnology inventions do indeed achieve the goal of encouraging innovation and whether, in attempting to achieve this goal, these other public interests might be compromised.

This article considers one of the most widely debated concerns associated with the modern patent system: the impact of gene and related patents on innovation in medical biotechnology. Such patents could affect innovation in all sectors of the medical biotechnology industry, from the most upstream public sector biomedical research, through to the value-adding innovations carried out by small to medium sized medical biotechnology companies and beyond to the downstream supply of biomedical healthcare products to consumers. There is growing concern internationally that these patents could prove detrimental to innovation rather than having a positive effect. Owners of patents claiming broadly applicable foundational technology could refuse to license or license on a restrictive basis, blocking off whole areas of downstream innovation. And if the patent landscape is too cluttered, necessitating entry into licence negotiations over multiple patents, innovation could be further impeded or delayed, creating what has become known as a tragedy of the anticommons. Such negative impacts on innovation would be likely to have flow on effects in terms of consumer access, and could extend to basic upstream research as well.

This article starts by explaining the legal position with regard to the patentability requirements, particularly focusing on the law relating to gene patenting. Theoretical concerns and empirical research on the impact of gene and related research tool patents are then considered in the next two sections of the article. It will be seen that practical means are being found to work around the negative aspects of patenting in the medical biotechnology industry. In particular, broadly applicable innovations tend to be widely licensed for small fees. Nevertheless, these findings need to be interpreted with some caution: they should not be seen as signalling that all is well with the industry. Account also needs to be taken of other social policy considerations in medical biotechnology, particularly with regard to healthcare and basic public sector research. These issues are canvassed in sections 5 and 6 of the article. This analysis illustrates that policy makers must continue to engage with researchers, industry participants and end users in assessing the best way for ensuring that the medical biotechnology industry can move forward and fulfil its great promise. Options for achieving this goal are canvassed in section 7.

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