

**INTELLECTUAL PROPERTY AND COMPETITION
REVIEW COMMITTEE**

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1. Introduction

The following comments are restricted largely to the topic of the interaction of applicants' use of the patent system with:

1. the rapid developments occurring in the broad fields of biotechnology, world-wide, and
2. the likely development of a viable industry, based on the tools of biotechnology, in Australia.

The issues raised below, and the comments provided thereon, are not based on legal analysis, review of court decisions, patent attorney views or practice, or theoretical economic analysis. They are instead based on experience in and an understanding of the commercial realities associated with attempting to develop novel products based on biotechnology tools, protect them adequately, and release them into markets world-wide. They are views of one who has been a user of the system, rather than either a disinterested observer and critic of it, or a service provider within it.

2. Primary purpose of providing IP protection

The grant of rights to protect intellectual outputs is predicated on an understanding that the provision of this limited-term exclusivity stimulates innovation. The development of useful marketable products for the benefit of consumers necessitates substantial resources and, particularly when developing new products for new markets, entails significant risks. Private enterprise is unlikely to invest in this kind of high-risk product development unless there is a reasonable assurance that an appropriate return may be realised. This is particularly true of the development of biotechnology-based tools and products.

3. Value of IP protection for biotechnology

Over the coming decades, an increasing range of biotechnology tools may be able to be used to dramatically improve our lives. The potential for revolutionary developments in methods for diagnosing, treating and eventually preventing human and animal disease is enormous. Likewise, advances in our understanding and capability in this field may have major beneficial effects for preventing plant disease, for ensuring sustainable high-value agriculture and for allowing efficient production of sufficient food for the world's population. However, it is unlikely that the kinds of investments required to develop this capability will take place in Australia in the absence of a strong IP protection regime.

The Australian *Patents Act 1990* provides a mechanism whereby appropriate protection for important developments in these fields may be acquired. The fact that this protection is available provides encouragement to researchers in both the public and private sectors to invest the necessary resources to compete in order to find new and better ways of achieving desirable ends. However, the existence of the system is not enough. It must also provide clarity with respect to the nature and scope of the protection available and it must engender, amongst users of the system, a belief in its ability to examine, and assess applications and make grants of rights which consistently conform to their stated clear position. These matters are discussed further in the ensuing three sections.

Note that this submission does not intend to imply that strong IP protection is *sufficient* for the encouragement of a whole new industry. Rather, it is only one of a number of essential drivers: necessary but not sufficient.

3.1 IP protection stimulates innovation

3.1.1 The US biotechnology industry

Biotechnology-based industries have been growing in the US for at least the past two decades. There are now in excess of 2,000 companies in the so-called “biotechnology industry” in the US. At the 1998 and 1999 Biotechnology Industry Organisation’s annual conferences there were in excess of 5,000 delegates, from academia, small and medium R&D and service-oriented enterprises and large pharmaceutical/life science organisations. More than 20 million hectares of land are under cultivation with crops, generated through the use of the tools of biotechnology, displaying improved traits.

In the US, clarity as to the patentability of biotechnology R&D outputs and the new “varieties/strains” of micro-organisms, plants and animals which could be thereby produced was provided relatively early, following the 1980 Chakrabarty case (*Diamond v Chakrabarty* (1980) 447 US 303). Since then, many decisions and debates in the area have occurred which have reinforced the possibility of using the patent system to protect inventions in this latest high-tech field of human ingenuity.

3.1.2 The European biotechnology industry

On the other hand, throughout the '90's in Europe there has been very considerable uncertainty about the extent to which the patent system would be able to be utilised to provide protection for new commercially-useful plants and animals. Oppositions by Greenpeace and others, primarily under the contentious Article 53(b) of the European Patent Convention, appeared to immobilise the European Patent Office. Applications relating to plants and animals generated with the tools of biotechnology piled up at the Office and were not examined for years, pending some clarity about what could and could not be granted. Technical Board Decisions were discouraging and Enlarged Board of Appeal Decisions were slow to come and only provided further doubt.

Companies operating in this field relocated their operations to the US and Canada, where there was support for the technology and clarity as to its protectability. Only in the last 2-3 years, following the passing of the Biotechnology Directive, has significant investment in this technology begun to take place in some European countries: notably Germany, the Netherlands, Belgium and the UK.

Requirement:

An IP system which provides clear and unequivocal support for the patentability of these new technologies.

3.2 Clarity regarding nature and scope of protection

It is acknowledged that there is considerable controversy surrounding what is regarded as the “ownership of life”. Much of this reflects an emotional reaction based on insufficient understanding of the intellectual property rights regime, its nationally-based jurisdiction, the requirements for patentability, and the limited nature of the rights granted. Nevertheless, this is a matter that must be addressed and resolved, so that biotechnologists can operate in an

environment of clarity and certainty. There are several different parts to this argument some of which are:

- “Life” should not be “owned”;
- Genetic sequences *per se* should not be patentable; only inventive uses thereof; and
- Genetic sequences no longer satisfy non-obviousness test.

The first point reflects a philosophical stance, against which numerous and persuasive contrary arguments can be countered. However, these are beyond the scope of this submission.

3.2.1 Genetic sequences *per se* should be patentable subject matter

The “manner of manufacture” test has served the needs of the patenting system through almost 400 years of innovation in technology. The definition has been able to accommodate developments in many diverse fields through the course of the industrial revolution and the computing and telecommunications revolutions, as well as the present revolution in gene technology. Defining what is or is not patentable in more specific terms, or attempting to put boundaries around it, would only ensure that the definitions needed constant up-dating to take account of the “latest development” in any age. Witness the difficulties with the *Copyright Act 1968* not being able to accommodate readily the new digital age communications technologies.

Biochemical entities – discovered, developed, and/or synthesised by the pharmaceutical industry during drug discovery processes – have been patentable, and patented, in many countries for decades, as have the biologically-active chemical entities (pesticides, herbicides, insecticides, etc.) used in crop protection. Genetic sequences, and the proteins they encode, are also biochemical entities, and can be described in terms of structure, function and commercially-useful applicability in the same way that other biochemical entities can. They may represent, for example, an improved way of treating some of the very same human disease conditions that the presently-used biochemical entities treat, or a better means for a plant to fend off pests and disease than is provided by the present, patent-protected pesticide and insecticide compounds. There would seem to be no reason why some kinds of biologically-active molecules can be patentable subject matter, while others cannot.

From the point of view of a research institution developing new knowledge, the implementation of a policy which provided that only inventive uses of genetic sequences should be patentable, and not the sequences themselves, would severely reduce the value of the research outputs able to be contributed by research scientists. They only rarely have the level of funding required to take an early “invention” far enough through the development phase to demonstrate its ultimate application. Furthermore, it is not generally what research scientists see to be their role. However, incentives for a commercial entity to “deal” with the research institution would be practically eliminated if the initial information were unprotected and freely available to anyone in industry.

Since the stated desire is to encourage increased commercial interactions between the tertiary sector and industry, such a change would be counter-productive. In the first place, whatever small amount of leverage the institution may have had would have been removed. Moreover, the fact of the information’s now being available to anyone may well have the unintended effect of delaying or even eliminating the likelihood of its being further developed by anyone in the industry. That problem comes back to one of the economics of product development and the realities of there being only one blockbuster in 100 leads.

3.2.2 Genetic sequences can satisfy the “non-obviousness” test

Technology Development

In any field of technology development, advances generally occur *via* major breakthroughs and paradigm shifts, followed by:

- initial resistance;
- replication and verification;
- eventual acceptance;
- expanded application; and finally
- incremental improvements,

until such time and the next major breakthrough occurs and the cycle repeats.

In relation to genetic sequences, opponents may argue that we are in the “expanded application” and “incremental improvements” phases and that the same techniques, now well-known and accepted, are being used to locate and isolate sequences which are known to exist. Hence, the argument would run, genetic sequences cannot be regarded as “inventive”.

The nature of research and innovation

This attitude, however, belies a lack of understanding of the nature of research and new technology development. It also fails to recognise that many assumptions about the world around us, including the world of genetics, turn out to be either wrong or incomplete on further investigation. For example, many sequences, which are “known to exist”, prove to be much less than straight-forward to locate and isolate than expected, and considerable inventive thought and experimentation is required before they can be identified. On the other hand, many completely unknown and unexpected sequences may be found during attempts to locate and isolate an altogether different sequence. These sequences can hardly be said to be obvious.

In support of inventive sequences

In some cases, the techniques being used to carry out the locating and isolating of genetic sequences are themselves the subject of either major breakthroughs, or incremental improvements. These “incremental improvements” *are* able to be “non-obvious” under the patent legislation, as long as they satisfy the test requiring a sufficient amount of “inventive step”. However, even in circumstances where relatively straight-forward, routine procedures are used to isolate and characterise a novel sequence, the fact that the methods used may be “obvious” should not be used to argue for the obviousness of the sequence *per se*. Because of the redundancy of the genetic code, as much as for any other reason, it is impossible to predict with certainty what the primary structure of a particular genetic sequence will be – even when the sequence of its product is known. Furthermore, once known-to-exist sequences have been isolated and characterised, they sometimes turn out to have completely unsuspected, additional useful functions, or to be able to be put to very different uses than was originally supposed based on prior knowledge. An isolated sequence might be able to be used in a manner which would be impossible in its *in vivo* state: to manufacture far higher amounts of its gene product, for example.

A blanket statement that genetic sequences fail to satisfy the “non-obviousness” test is as likely to be incorrect as a statement that all genetic sequences are non-obvious. The assessment as to inventiveness, or not, must turn on the facts of each particular case. This is another reason why we must ensure that we have properly-qualified examiners (see below), capable of making the necessary determinations in the light of the state of the art, the disclosure and the claims presented.

Requirement:

The acceptability of genetic sequences as patentable subject matter, satisfying the requirement of being a manner of new manufacture.

Clear procedures for examination of inventiveness of genetic sequences, emphasizing that they be examined by the same criteria as are applied to inventions in any other field of technology.

3.3 High quality, consistent examination and grant

3.3.1 Controversy concerning the issue of poorly-examined US patents in the IT area

A debate is currently raging in the US about the extent and quality of patent application examination carried out in the area of computing/software development/IT. Industry observers and participants maintain that, among US Patent Office examiners, there is insufficient capability in this field of art, with the result that patents of questionable validity are issued. It is also maintained that another part of the problem relates to insufficient resources – i.e.: the number of examiners is too few, and their level of training and knowledge in the area is too little. Lastly, the wrong signals/incentives are given, rewarding volume of through-put over quality and accuracy of examination.

3.3.2 Australia's system

The above comment is not intended to be an allegation that any of these conditions necessarily applies in Australia. Rather, the point is that the technologically-advanced fields of information technology and biotechnology demand examiners with comparably-advanced skills in their respective areas. Australia needs to ensure that its standard of examination is sufficient to engender confidence in the system. It is not in users' interests to have invalidly-broad claims granted. This only risks increasing unnecessarily the costs of enforcement of rights, since there is an increased likelihood of challenge. However, it is not always the case that the "error" is corrected – either through the opposition mechanism or subsequent litigation. Instead, the result might be, for example, that:

- potentially-valuable lines of research/application are abandoned because of the risk of infringement; or
- additional expense is incurred through the need of a user to (i) seek clarity from the patent owner, and (ii) pay licence fees which ought not to have been required; or
- potential patentees decide the rigour of the system is too low to justify investing in seeking protection in Australia.

Although it is acknowledged that Australia's system is not the same as the US system in regard to the assumption of validity, this should not be an excuse for a less thorough examination process than is appropriate for this kind of technology. High-level, on-going training of patent examiners working in advanced fields of art would seem to be necessary to ensure that high-quality consistent outcomes can be achieved over time.

A further consideration is the length of the opposition period, presently 3 months in Australia. This contrasts with 6 months under the relatively new, amended Japanese legislation and 9 months under the European Patent Convention. Were an opposition to the grant of a patent to be seriously considered, 3 months is a relatively short time for a decision to be taken to do so

and a case mounted. This might constitute a further impediment to the prevention of grants of invalid claims through the opposition mechanism.

Requirements:

Patent Office examiners with sufficient qualifications, expertise and experience that they are able to determine the novelty and inventiveness – or otherwise – of high-tech biotechnology inventions and provide better-informed and better-argued opinions to applicants. (An obvious corollary of this is that better qualified/trained people cost more money and this cost would have to be recouped somehow. This is a good point and it would be necessary to assess the extent of benefit to be derived from a more certain, rigorous examination process *vs* the additional costs involved in achieving that outcome.)

A pre-grant opposition period that provides potential opponents with the time needed to mount a case: extend from 3 months to 6 months.

3.4 Obligations pursuant to international treaties

It is also relevant to consider the obligations facing Australia as a signatory to various international treaties. In particular, Australia is bound by its obligations under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs Agreement), negotiated as part of the Uruguay round of the General Agreement on Tariffs and Trade, which lead to the formation of the World Trade Organisation. We must have - and we do have - minimum patent laws available for “...any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.” [Article 27]

It is relevant to note that there is another part of this section [Article 27(b)] which is due to be reviewed at forth-coming WTO negotiations. This pertains to the right of Members to:

“..... exclude from patentability.....

- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals

There will be considerable debate on this issue. Without wishing to predict the outcome, it would be severely detrimental to developing biotechnology industries if this were eventually to become an accepted part of international laws, *and* patentability for genetic sequences *per se* were also denied.

Industries - especially fledgling industries trying to develop, such as the biotechnology industries - need a clear, certain legal environment in which to operate. Any steps that Australia can take to harmonise, or cause others to harmonise, laws and regulation in line with acceptable standards would assist this. Moving our laws away from that which is considered to be the minimum standard would certainly not assist.

4. Balancing IP rights with advantages of encouraging competition

Concern about the effect of IP laws on competition generally arises from the belief that the best outcomes for society are provided through competition among many service/product providers in any one market. In some industry sectors, where capital investment is not high and barriers to entry are low, this may well be true. However, different “markets” have neither the same structural characteristics, nor the same drivers for would-be participants. Moreover, biotechnology is a set of tools, and the kinds of inventions that might arise using these tools may have application in a very wide range of different “markets”.

It would be very unlikely that a biotechnology-based “invention” would encompass a product that constituted a one-and-only approach for a particular application, and was the only product of a dominant company in any particular market. There is often an alternative approach and substitute product already on the market, and any new product must prove to consumers that it has the capacity to add the extra value that its price promises. If it cannot do so, this product, like any other, will fail.

The usual perspective on possible anti-competitive effects is the view that, post-grant, there is the potential that IP rights may, contrary to the provisions of the *Trade Practices Act 1974*, lessen competition by providing the patentee with the ability to permanently exclude others from exploiting the invention and sanctioning exclusive dealing.

4.1 Withholding exploitation

To counter this, there are compulsory licensing provisions in the *Patents Act 1990*, which assist in preventing this effect. Even though it is true that they have rarely if ever been used, their existence may serve to encourage commercial parties to deal with each other. This contrasts with the situation in the US where there is no such requirement and where patent owners are therefore at liberty to refuse to allow access, even in situations where the invention is not being “worked” by anyone for the public’s benefit.

In addition, in return for the grant of patent rights a patentee is required to disclose the means for “working” the invention. The best mode of practising the invention must be described and made public. This encourages further innovation by giving potential competitors the where-with-all to invent around the patentee’s protected subject matter; to improve it; or to develop a different way to achieve the same ends in order to avoid infringement. Far from being anti-competitive, this actually may foster a competitive spirit amongst inventors.

4.2 Exclusive dealing

It is unlikely that the kinds of terms which feature in licensing arrangements for patented technology would have the effect of substantially lessening competition in a market - at least, not in the realm of biotechnology.

In the first place, many biotechnology inventions are “pieces” of what is needed to make the eventual product. Many such pieces may be needed to make the product. It is these pieces that are the subject matter of technology licensing contracts, but they do not constitute the relevant “market”. Moreover, it is often in the interests of the owners of these technologies to license them to multiple parties, either non-exclusively for use in the very same field, or exclusively but for use in many different fields of application. While these licences will contain clauses

that are restrictive in terms of, for example, field of application or geography, these restrictions do not usually impact on the competitiveness of a particular market.

Where the patented technology extends to its use in particular fields/applications/products, there are two likely scenarios:

- The product may be a particular plant species, for example (in agricultural biotechnology), exhibiting a specific desirable trait. The trait may provide considerable advantage; nevertheless the variety carrying it is unlikely to be the only available variety on the market - even if we define the “market” in as restrictive a fashion as, for example, the “corn market” rather than the “grains” or “cereals” or “food” market - and so is unlikely to substantially lessen competition.
- The product may be a new drug lead or gene therapy for potential use in treating a particular disease (in human health biotechnology). Again, it is unlikely that the exclusive licensing of the eventual product will have anti-competitive effects in any “market”. There could well be pre-existing treatments, albeit perhaps not as efficacious. Moreover, there are usually “alternative” modes of treatments, which would be competing in the same market.

In the event that it *did* prove to be a completely new treatment for an as-yet-untreatable disease, a judgement would have to be made as to whether or not the product were indeed lessening competition in the relevant market. For example, would a cure for breast cancer be an only product in the “breast cancer” market? Or does it compete in the “cancer” market or the “pharmaceutical” market or perhaps in the “ill-health” market, since there are alternative approaches to the maintenance of well-being? Are there substitutable products in whatever the relevant market is determined to be? However, other considerations which need to be factored in are:

1. the extent to which public good (access to a cure for breast cancer) is outweighed by the cost imposed by any anti-competitive licensing arrangements, and
2. the possibility that the existence of this first “cure” spurs further competition at the R&D level (see below) in order to develop an alternative, or an improved version.

Another important consideration is that these new technologies will often not be taken up and further developed, by a company or investor with sufficient resources to undertake the development, unless that company/investor is offered exclusive access to the technology. In the absence of exclusivity, there is insufficient incentive for it to take the risks involved and make the substantial commitment required to take the technology through the very long commercial development procedures and regulatory hurdles which precede market launch. In this event the public would be denied the obvious benefits that derive from research and innovation.

Moreover, there may be seen to be benefit in there being two different parties engaged in the innovation stage (the inventing of new technology) *v* its commercialisation (further development and commercial release). The fact that an arms-length contractual arrangement has to be negotiated between two different parties could be argued to assist in maintaining a competitive research, development and commercialisation process.

4.3 Encouraging competition in R&D

From a different perspective, it is possible to recognise the *positive* effect of stimulating competition in R&D which, it can be argued, results from the fact that only the first to make a new invention derives the considerable benefits which may accrue. The risk of losing the race is very real. Because of the minimum 18-month delay between the filing of a patent application and its publication, it is possible that a great deal of effort and time will be directed at something which is also the focus of another party. It may turn out that the other party wins the race to develop the innovation and file the patent application. One *might* regard this as a lot of wasted and duplicated effort. An alternative view, however, is that this is exactly the kind of competition that is desirable, and that the drive to be “first-to-invent” demonstrates the process is truly competitive. It spurs research, fosters innovation, promotes a competitive spirit within the public and private industry sectors addressing markets and community needs, and lures investors to risk substantial sums of private capital with a view to generating useful and successful outcomes for consumers.

The competitive nature of being the first with a new invention is so enticing that people even risk seeking patent rights a little too early in the innovation process, in order to be sure they establish the earliest possible priority date for their rights. Researchers sometimes risk filing a provisional application as soon as they have the first data set, a gamble being taken that the strategy will be shown to be robust. In addition, companies are sometimes driven to do likewise in order to increase their list of patent assets and hence attract shareholders and investors. These may not necessarily be seen as desirable outcomes, but they nevertheless demonstrate the competitive nature of the research and innovation process.

Furthermore, the existence of the exclusions in Part IV s51 (3) of the *Trade Practices Act 1974* could also be regarded as actually *encouraging* innovation and the further development of new technology, as they provide certainty for patentees with respect to their dealing with these technology rights. They obviate the need for expensive investigations into the acceptability, or not, of particular negotiated positions reflected in licensing agreements.

The need for a research institution, or even a small start-up company, to undertake this kind of competition analysis each time it entered into an agreement for early-stage technology licensing would constitute a considerable additional cost burden which might have the effect of precluding the deal. Moreover, at the early stages at which this technology is sometimes licensed, it would be very difficult to ascertain whether or not its eventual exploitation might have the effect of substantially lessening competition in any market.

One final and more general comment is that the exclusions in section 51(3) ought to operate clearly with respect to all relevant forms of IP including, for example, Plant Breeder’s Rights. At present rights pursuant to the *Plant Breeder’s Rights Act 1994* are not included in the exemptions.

5. A viable biotechnology industry in Australia?

An important consideration is the likelihood of being able to foster a biotechnology-based industry in this country – in line with both Federal and State Governments’ objectives – in the *absence* of the limited-life protection provided by the grant of patent rights. With the extremely long lead-times involved in development of marketable products, there is little

enough term of protection left as it is. Removing it or diluting it may cause the demise of any further R&D in these risky areas in this country.

It is agreed among venture capitalists, technology developers and technology commercialisation managers alike that the two most important, essential-though-not-necessarily-sufficient requirements for the successful development of biotechnology-based products are (i) a good management team, and (ii) effective, clear IP protection. It is the considered view of the writer that, in the absence of the latter:

- little or no investment in this technology would occur;
- little or no commercially-focussed innovation would be engendered;
- no advanced, novel biotechnology would be adopted in a commercial setting for the development of products useful for public consumption (due to the very high costs and risks involved), and
- no viable biotechnology-based industry would have a chance in being able to be established in Australia.

In an environment in which the stated policy objectives are to foster a biotech industry, and in which other government initiatives are aimed at strengthening the possibility for innovation:

- to occur;
- to be recognised and considered valuable;
- to be protected;
- to be invested in;
- to be developed *in Australia* to the point of substantially-increased value, and
- to be commercialised,

it would indeed be counter-productive to reduce the level of IP protection afforded such R&D outputs.