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Developments in the patentability of biotechnology in Australia and the United States — Part 1

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Key points

- Decisions by the High Court of Australia and the Supreme Court of the United States have overturned long-established practice in relation to patentable subject matter in biotechnology. Subsequent rulings in the lower courts in the US have interpreted the Supreme Court decision broadly, potentially invalidating vast numbers of patent claims.

- In this two-part article, we provide a brief overview of the historic approach to defining patentable subject matter in Australia and the US, and an analysis of these decisions in this context, with a particular focus on the most recent decision of the Australian High Court.

- These decisions provide a powerful reminder that, while providing flexibility for the evolution of patent law, allowing for the boundaries of patentable subject matter to be judicially determined can be highly disruptive.

Part 1

Introduction

The breathtaking complexity and functional optimisation underpinning living organisms offers an extraordinary resource for humans to build upon in the form of biotechnology. Biotechnology has a vast array of applications, including unparalleled potential to increase lifespan and treat disease. Biotechnology can also represent intellectual property of substantial value. However, the distinction between an invention in this field and the exploitation of some form of life per se has long been debated. Additionally, as is the case for other rapidly developing technology areas, it can be difficult to place developments in biotechnology within the boundaries of existing intellectual property legislation and case law.

Thus, while the importance of defining patentable biotechnology is widely accepted, the manner in which this occurs differs considerably among jurisdictions. In Australia and the United States, what constitutes patentable subject matter in relation to biotechnology (and otherwise) has largely been determined by case law.

Defining patentable subject matter

Australia

In Australia, legislation defines patentable subject matter in broad terms as any “manner of manufacture” according to the Statute of Monopolies. The High Court decision in National Research Development Corp v Commissioner of Patents has been a long-standing authority for what constitutes a manner of manufacture. It had been considered that a patentable invention must be some form of “vendible product”. However, in NRDC, it was held that the scope of patentable subject matter should not be limited in this way, but instead could extend to any “artificial state of affairs” with “economic utility”. In the half-century since NRDC, this precedent has been considered central to defining the scope of patentability in Australia. It has been seen to facilitate a flexible judicial approach, suitable to allow evolving technology to be encompassed within the patent system.

Prior to the High Court decision in D’Arcy v Myriad Genetics Inc (discussed below), it was long-standing practice in Australia to consider “isolated” biological material as patentable subject matter. “Isolated” has been interpreted broadly as a state requiring human intervention. So, for example, pure cultures of microorganisms, and purified antibodies or nucleic acids, have been considered patentable. This practice was subject to legislative consideration, with an Australian Law Reform Commission report recommending against parliamentary intervention to alter it. Additionally, a Private Member’s Bill seeking to provide a statutory exception to the patentability of biological material that
is “substantially identical” to the material as it occurs naturally (even if it is in isolated or purified form) was not passed.12

United States

United States legislation provides four broad categories of patentable subject matter: “process”; “machine”; “manufacture”; and “composition of matter”. Within this framework, “non-statutory” exclusions from patentability have been established by case law. Recognised non-statutory exclusions are “laws of nature”, “physical phenomena” and “abstract ideas”.13 The US Supreme Court’s decision in Diamond v Chakrabarty14 established that biological material, including living organisms, could be patented in the US, provided that some alteration or modification of the material by human intervention has occurred. Following this decision, it was long-standing practice in the United States Patent and Trademark Office to grant patents for isolated biological material, including nucleic acids.

Myriad decisions

Despite examination practice and legislative consideration as noted above, the patentability of isolated nucleic acids has more recently been subject to extensive judicial consideration in both Australia and the US, in respective series of cases involving Myriad Genetics Inc (Myriad).

Australia

Federal Court and Full Federal Court decisions

In Cancer Voices Australia v Myriad Genetics Inc15 (Cancer Voices), the Federal Court determined the validity of three claims, directed to isolated nucleic acids encoding variants of the human gene BRCA1 (which are associated with an increased risk of breast and ovarian cancer). An appeal from Cancer Voices focusing on a single claim, was then decided by the Full Federal Court in D’Arcy v Myriad Genetics Inc16 (D’Arcy FFCA). In these cases, it was accepted by both the Federal Court and, unanimously, by the Full Federal Court that an isolated nucleic acid falls within the scope of an artificial state of affairs as per NRDC, as its production requires human intervention. Notably, arguments that an isolated BRCA1 nucleic acid encodes the same information as the corresponding native human gene were not considered relevant, since the claim was held to be directed to the isolated nucleic acid itself ie as a composition of matter, not to the information embodied in its nucleotide sequence.17

High Court decision

In D’Arcy HCA, the High Court unanimously overturned the decisions of the Federal courts, holding that Myriad’s claims directed to isolated BRCA1 nucleic acids are not a manner of manufacture, and therefore not patentable subject matter in Australia. Separate opinions were provided within this unanimous ruling, with a majority opinion provided by French CJ, and Kiefel, Bell and Keane JJ.

Claims directed to “information”

Central to the majority opinion, and in direct contrast to the decision in D’Arcy FFCA, was the finding that the nucleotide sequence encompassed by the claim “can properly be described as ‘information’”.18 It was considered most appropriate for the claimed compounds to be thought to “embod[y] and convey” the information contained within this sequence, in contrast to being chemical compounds with formulas defined by the sequence, due to the importance of the “informational aspect” to the utility of the claimed invention.19

For this reason, the majority considered that the subject matter of Myriad’s claims was placed at the boundaries of what constitutes a manner of manufacture under Australian law. It was held that, although “in a formal sense”20 the isolated nucleic acids could be considered a product created by human action, this was not sufficient to support characterisation of the subject matter of the claims as a manner of manufacture. Thus, it was ruled that the subject matter of the claims was not patentable, either as directed to nucleic acids that possessed the identical sequence to that of naturally-occurring BRCA genes, or as directed to nucleic acids with non-identical sequence to these genes (such as cDNA, potentially lacking introns) that nevertheless encodes the same information.

Relevance of the NRDC precedent

As noted above, the “artificial state of affairs … with economic utility” formula propounded in NRDC has long been considered a requirement for patentability under Australian law. However, the High Court stated that satisfaction of NRDC’s formula does not “mandate a finding of inherent patentability.”21 It was considered that the court in NRDC could not have seen this to be an absolute definition of manner of manufacture, because it had already denounced such an absolute definition with respect to the pre-existing vendible product rule. As such, while stating that the formula may “suffice for a large class of cases”, it was held that this will not always be so, and that the formula should instead be taken as a guide only.22

The majority opinion went on to state that “when the invention falls within the existing concept of manner of manufacture, as it has been developed through cases”, the requirements of NRDC’s formula will ordinarily be
sufficient to meet the patentability requirement. However, it was held that where an extension of the concept of manner of manufacture was required to encompass “a new class of claim”, as was determined to be the case in this instance, other factors may be relevant.\textsuperscript{23}

**New criteria for assessing patentability**

The majority provided four new factors to be considered in assessing whether the concept of manner of manufacture should be expanded judicially.\textsuperscript{24} These can be summarised as follows:

1. Is according patentability consistent with the Act?\textsuperscript{25}
2. Would according patentability enhance or detract from the coherence of the law?
3. What relevance does according patentability have with respect to Australia’s place in the international community?
4. Would according patentability involve law making of a kind that should be performed by the legislature?

In regard to the first factor, the majority considered that according patentability to the claims would not serve the purpose of the Act due to a lack of well-defined boundaries of the claims,\textsuperscript{26} and potentially negative consequences for innovation that may occur as a result. The court did not address the second factor in detail, but implied that according patentability to the claims was not necessary from the perspective of the coherence of the law. The third factor was considered to be of lesser importance;\textsuperscript{27} notwithstanding this, the majority stated that no evidence had been presented that it was necessary based on Australia’s international obligations to accord patentability to the claims.\textsuperscript{28}

With respect to the fourth factor, the majority noted the legislative refusal to provide a statutory exception to the patenting of isolated biological molecules including genes, as had the lower courts. However, it was stated that the appeal was not concerned with “gene patenting” generally, only whether the claims at issue fall within the scope of manner of manufacture under Australian law.\textsuperscript{29} Because it was considered that this was not so, it was stated that according patentability was a matter of inclusion not exclusion, and that the legislative history was not relevant to determining the appeal.\textsuperscript{30}

**Implications of new criteria for patentability**

Certain key observations can be made in regard to the introduction of these new criteria for assessing patentability.

- First, where previously NRDC’s formula had been considered to be, at the very least, a key tool to assist with the evolution of the boundaries of patentable subject matter, introducing these criteria appears to have relegated it to a shorthand representation of material that has already been determined to be patentable subject matter by judicial assessment. If this was not, in fact, the court’s intention, there is no clear guidance to be found within the decision as to how the precedent of NRDC can be of assistance in performing its previous role.
- Strikingly, it would also seem that, in general, the more innovative and distinguished a new technology is from existing technologies, the less likely it would be to be considered suitable for inclusion within the boundaries of manner of manufacture under these guidelines. By way of example, affording patentability to early developments in a new branch of technology that had previously been largely uncontemplated would be likely to create an extensive monopoly;\textsuperscript{31} require new developments in the law that would necessarily be disruptive with regard to settled principles;\textsuperscript{32} and involve policy considerations.\textsuperscript{33} Thus, these guidelines seem in stark contrast with the NRDC formula which, as noted above, has been lauded for offering a flexible approach to allow for new technology to be placed within Australian patent law.

**United States**

*Association for Molecular Pathology v Myriad Genetics Inc (AMP v Myriad)*\textsuperscript{34}

Similar claims to isolated BRCA nucleic acids as those considered in Australia were assessed for patent eligibility in the US. At first instance, the district court rejected Myriad’s claims under the rationale that such material is not “markedly different” from corresponding material as it exists “in nature”.\textsuperscript{35} However, on appeal to the Federal Circuit, in a minority judgment (2:1) it was held that an isolated nucleic acid is markedly different to natural material.\textsuperscript{36} The case was referred back to the Federal Circuit for consideration by the Supreme Court, in view of the decision in Mayo Collaborative Services v Prometheus Laboratories Inc\textsuperscript{37} (discussed below). In response, an almost identical ruling was issued.

On appeal, in *AMP v Myriad*, the Supreme Court unanimously reversed the ruling, and held that an isolated nucleic acid with identical sequence to a human gene is not patentable subject matter. As followed in the majority decision of the Australian High Court, the US Supreme Court focused on the information content of the nucleic acids claimed by Myriad. However, in contrast to the Australian High Court’s majority judgment, the US Supreme Court held that cDNA is patentable, to the extent that it possesses a sequence that is different from the corresponding natural nucleic acid.
In Part 2 of this article, further key United States decisions are addressed, discussion of the developments as a whole, and conclusions are provided.

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Footnotes
1. B Glick, T Delovitch and C Patten Medical Biotechnology American Society of Microbiology 2014.
6. Re GEC’s Application (1942) 60 RPC 1 per Lord Morton.
7. Above n 5, at 277.
13. Diamond v Diehr 101 S Ct 1048 (1981); Diamond v Chakrabarty (Chakrabarty) 100 S Ct 2204 (1980); Parker v Flook 98 S Ct 2522 (1978); Funk Bros Seed Co v Kalo Inoculant Co 68 S Ct 440 (1948).
17. Above n 16, at [194].
18. Above n 10, at [89].
19. Above n 10, at [92].
20. Above n 10, at [94].
21. Above n 10, at [20].
22. Above n 10, at [20].
23. Above n 10, at [28].
25. And in particular:
   - Could this create a large new field of monopoly with potentially negative effects on innovation?
   - Could this create a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee?
   - Would according patentability involve the court in assessing important and conflicting public and private interests and purposes?
26. Above n 10, at [29].
27. Above n 10, at [28].
28. Above n 10, at [32].
29. Above n 10, at [37].
30. Above n 10, at [37].
31. At least specifically because broad claims would be likely to meet other criteria for patentability, assuming the subject matter was considered patent-eligible.
34. Association for Molecular Pathology v Myriad Genetics Inc S Ct 2107 (2013).
Follow-on innovation or evergreening: what is the difference?

Michael Caine DAVIES COLLISON CAVE

Key points

• While the terms “evergreening patent” and “follow-on patent” are both used to refer to patents that protect pharmaceutical formulations, new forms of active agent, processes for manufacturing active agents, new uses for pharmaceutical products, new combinations of active agents, new dosing regimes and the like, the pejorative term “evergreening” is reserved by academics and economists for those patents filed by the originator of the active agent.

• Without a full appreciation of the ingenuity involved in the development of pharmaceutical products, and the importance of effective patent term in driving pharmaceutical companies to invest in these developments, it is very easy for academics, economists and others unfamiliar with the technology involved in developing commercial pharmaceutical products to categorise important “follow-on” patents as mere evergreening patents, since this categorisation avoids completely the need to assess whether or not inventive ingenuity was involved in creation of the patented invention.

• Incremental innovation is recognised by both innovator companies and generic companies as being of critical importance in the development of improved pharmaceutical products and therapies, and follow-on inventions, and the patents that protect them, are important in achieving these outcomes. All patents should be judged on their merits and an originator company should not be criticised, or accused of evergreening, for pursuing patent protection for its inventions any more than generic companies should be criticised for pursuing patents for their inventions.

What is “evergreening” and why has this term gained currency?

The terms “evergreening patent” and “follow-on patent” are both used to refer to:

• patents that protect pharmaceutical formulations;
• new forms of active agent;
• processes for manufacturing active agents;

• new uses for pharmaceutical products;
• new combinations of active agents; and
• new dosing regimes, and the like.

However, the term “evergreening” is reserved for a subset of these patents; namely those filed by the originator of the active agent. But does it serve any useful purpose applying the evergreening label to these originator-owned patents?

An active pharmaceutical agent is not much use if it cannot be produced in a stable form in commercial quantities. It is also not much use if it cannot be formulated in a manner which allows it to be delivered to a patient in a suitable formulation such that it reaches the site of action in the patient’s body where it can exert its pharmaceutical action to treat the patient’s disease or disorder. The active agent will also not be particularly useful if it is delivered in a manner that hits other targets in the patient’s body causing undesirable side effects, or if the agent is metabolised into other compounds that cause toxicity or side effects. It is therefore not surprising that the process of developing an active agent into a commercially successful pharmaceutical product, which is both safe and efficacious, involves overcoming numerous problems which could potentially give rise to patentable inventions. Despite this, academics, economists and others unfamiliar with the technology involved in developing commercial pharmaceutical products have written papers and articles criticising pharmaceutical companies for seeking protection for these inventions. With the exception of the original patent protecting the active agent, these additional patents are pejoratively referred to as evergreening patents in such publications.

It is hard to find a consistent definition of the term “evergreening” as it is used to describe patents relating to pharmaceuticals. However, it is clear that the term is reserved for the patents filed by originator companies who own the original patent on the particular active agent. If other companies, including generic companies, file patents relating to new pharmaceutical forms, formulations, processes for the manufacture of pharmaceuticals, dosing regimes for pharmaceuticals, they are termed “secondary” patents or “follow-on” patents.
Apparently it is perfectly acceptable for companies other than the originator to file such patents and this action is only objectionable when originator pharmaceutical companies carry out additional work on their own active agents.¹

Without a full appreciation of the ingenuity involved in the development of pharmaceutical products, it is very easy for those who use the term “evergreening” to categorise these important patents as mere evergreening patents, since this categorisation avoids completely the need to assess whether or not inventive ingenuity was involved in creation of the patented invention. In my view it is unhelpful to draw a distinction between evergreening patents and secondary or follow-on patents based on who has filed them. All patents should be judged on their merits and an originator company should not be criticised for pursuing patent protection for its inventions any more than generic companies should be criticised for pursuing patents for their inventions. All patents need to meet the stringent patentability and description requirements imposed by national and regional patent laws. For this reason, if there is any need at all to adopt a term to describe this broad class of patents relating to pharmaceutical products, I prefer to call them all follow-on patents. This term takes into account the incremental nature of pharmaceutical development and biomedical innovation, and draws no distinction based on the commercial activities of the patentee.

**Encouragement for follow-on innovation provided by the patent system**

Those who criticise follow-on patents in any form fail to appreciate that one of the objectives of the patent system is to encourage follow-on innovation. Although it is often said that the quid pro quo for granting a patent is disclosure of the invention to the public in the patent specification, it is important to note that publication normally occurs well before the grant of the patent. One of the risks of filing a patent application is that details of the invention will be published by the Patent Office which may ultimately refuse to grant the patent. The considerable amount of patenting activity in connection with follow-on innovations in the pharmaceutical field is a clear indicator that the patent system is doing its job. This is particularly the case, since most of these follow-on patent applications are filed by applicants other than the originator company.

In 2013 the results of a study were published, carried out in relation to Australian patents associated with 15 of the most expensive drugs sold in Australia over the previous 20 years.² While the study identified a mean of 49 patents associated with each drug, three quarters of the patents were owned by companies other than the drug’s originator. In fact, the majority of the patents identified in the study were owned by companies that do not have a record of developing top selling drugs. In my view, this intensive patent activity around important drugs is an indicator of the amount of ongoing research which is carried out in an effort to improve various aspects and properties of known drugs. In my experience, this work often leads to new pharmaceutical products which have better properties and provide better therapeutic outcomes for patients.

**Distinction between pre- and post-marketing follow-on patents**

Returning now to patents filed by originator companies, I believe it is possible to divide them into two categories:

- those filed prior to the launch of the original product incorporating the active agent; and
- those filed after the launch.

In view of the difficulties associated with developing a promising active pharmaceutical agent into a commercially acceptable formulation, it is not surprising that the original commercial formulation of the active pharmaceutical agent may embody a number of inventions. Not only will it incorporate the novel active pharmaceutical agent, which is likely to be the subject of a patent, the active agent may also be in a particular novel crystalline form which provides the required levels of bioavailability, solubility, stability and the like. If ingenuity was involved in developing this particular form of the active agent then there may also be a patent protecting that form. There may also be a patent protecting the particular formulation which was developed to allow the active agent to be administered to the patient in a form which achieves the required pharmaceutical effect. Formulating active pharmaceutical agents, particularly novel pharmaceutical agents, is not as trivial as some academics and economists would have you believe. In some cases there may also be a patent protecting the particular dosing regime associated with administration of the pharmaceutical agent.

In view of the extensive time required to demonstrate that a new pharmaceutical product is safe and efficacious, most of these follow-on patents will have filing dates well before the date the pharmaceutical product receives marketing approval in Australia. In many cases, the patent filed in respect of the active pharmaceutical agent will have been filed from 10 to 15 years prior to the first marketing approval in Australia, leaving 5 to 10 years remaining of the original 20 year patent term. Patents relating to crystalline forms, methods of manufacture, formulations and dosing regimes associated with the product as originally registered will normally have been filed later, and will normally have more of
their original 20 year term remaining at the time of first marketing approval. Recognising the substantial reduction in effective patent term caused by the lengthy regulatory approval process, Australian patent law provides for patent term extensions of up to 5 years in an effort to provide the patentee with an effective 15 year patent term. Since no more than 5 years additional term is available, a 15 year effective patent term will only be achieved if the patentee manages to obtain regulatory approval for the pharmaceutical product in less than 10 years from the patent filing date.

Although the final marketed pharmaceutical product may embody several inventions, it is not surprising that generic companies often seek to launch generic versions of the pharmaceutical product upon expiry of the active agent patent. However, they can only do this if they avoid the other patents protecting various aspects of the approved pharmaceutical product. Other options available to the generic pharmaceutical companies are to seek to invalidate these additional patents or to wait until all patents protecting the registered pharmaceutical product have expired before entering the market.

There are very few complaints about patentees of non-pharmaceutical inventions obtaining 20 year patents, even when the patentee is able to start deriving commercial benefit from these inventions soon after patent filing. However, despite the huge investment that pharmaceutical companies must make in order to bring a pharmaceutical product to market, usually well in excess of $1 billion, those who use the term “evergreening”, begrudge pharmaceutical companies the effective 15 year patent term that they may be able to obtain under Australian patent law. Such commentators report upon losses to the government, and therefore the taxpayer, associated with paying for these pharmaceutical products while they are protected by a patent. However, it is abundantly clear that it is the “effective” patent term provided for pharmaceutical products which drives research based pharmaceutical companies to invest in and develop new pharmaceutical products. Indeed, in the absence of new pharmaceutical product development there would not be a generic pharmaceutical industry.

In many ways, those patents filed prior to product launch are not follow-on patents at all, since they all contributed to the success of the original product as launched. However, they can be considered follow-on patents to the extent that they build upon the original work done by the originator company to identify the active agent.

The second class of follow-on patents filed by drug originators are those filed after regulatory approval and launch of the original product. The inventions claimed in these patents will not be embodied in the originally approved product, and cannot be used to prevent generic companies from marketing the original product for the original indications when the patents covering the original product expire. Despite what might be suggested by those who use the term “evergreening”, it is not possible to obtain more than 20 years effective patent term for a pharmaceutical product. If originator companies produce new and improved products and make them available to the public at a later date, following additional clinical trials and regulatory studies, then the success or otherwise of the new and improved product will necessarily depend on the benefits associated with the new product. The success or otherwise of a pharmaceutical company in marketing a new and improved product is completely unrelated to the existence or otherwise of a patent on the product, except to the extent that the patent will prevent generic companies from marketing the new product while the patent is in force. However, the new patents will not interfere with the ability of the generic company to sell the original product upon patent expiry.

Upon expiry of the original patents covering the original pharmaceutical product, it is not uncommon for generic companies to rely upon patents to protect their own formulations, crystalline forms or methods of administration in connection with the marketed versions of their products. This is not objectionable and is important for many generic companies in their quest to compete with the originator company, and other generic companies.

Examples of follow-on innovation in relation to successful pharmaceutical products

It is useful to consider a number of patents for pharmaceutical products which have drawn the attention of those who use the term “evergreening” to characterise follow-on patenting by pharmaceutical companies. **AstraZeneca’s patent on Losec™**

Commentators who have discussed the so-called “evergreening” problem in Australia have often made reference to AstraZeneca’s patent on Losec™, a pharmaceutical product used to reduce stomach acid containing the active ingredient omeprazole. The validity of the Losec patent was upheld by the High Court of Australia, although the equivalent patent in the United Kingdom was found to be invalid. However, when the background to the development of the Losec formulation is analysed, it is clear that the Australian High Court was justified in upholding the patent’s validity.

Although the first patent application in respect of omeprazole was filed in 1978, it was not until 1985 that AstraZeneca filed a suit that would allow delivery of the active agent to the patient. Various problems had to be overcome in order to
arrive at this formulation. The first problem was that omeprazole is acid sensitive, meaning that it would break down on contact with stomach acid. Another problem which impacts on the bioavailability of omeprazole is that it is sparingly soluble in water. After several years of work, the inventors eventually arrived at a formulation in which the active agent was combined in a central core with an alkaline material, this being coated in a water soluble sub-coat over which there is an applied enteric coat. The enteric coat allows the formulation to pass through the stomach without bringing omeprazole into contact with the stomach acid. After passage through the stomach the enteric coat and the water soluble sub-coat dissolve allowing uptake of the omeprazole in the upper part of the small intestine.

There was no evidence presented at the trial to the effect that omeprazole, or its properties, formed part of the common general knowledge in the art in Australia. There was no evidence that any researchers other than the inventors considered omeprazole was worth developing into a commercial formulation. Despite these factors, for the purpose of assessing whether the Losec formulation possessed an inventive step, the court assumed that the person skilled in the art would have commenced with knowledge of omeprazole and its properties. One of Alphapharm’s witnesses was provided with information regarding omeprazole and its properties and was asked, with prompting from Alphapharm’s lawyers, to outline the steps he would take to develop a suitable formulation. Despite being given information about omeprazole and its properties, and being prompted by Alphapharm’s lawyers, he was not able to arrive at the allegedly obvious formulation claimed in the patent.

It is also important to note that the Losec patent had a filing date well prior to the date Losec received marketing approval in Australia. Accordingly, when combined with the patent previously filed in respect of omeprazole, the effective patent term obtained by AstraZeneca for their Losec product was less than the statutory 20 years. The term “evergreening” should therefore never have been applied to AstraZeneca’s Losec patent.

**Abbott’s patent on Norvir**

Another pharmaceutical product often mentioned in “evergreening” papers is Norvir®, an anti-HIV/AIDS drug marketed by AbbVie which contains the active agent, ritonavir. The complaint against AbbVie, or at least Abbott who originally marketed the drug, appears to be in relation to the number of patents filed to protect the active agent and combinations with other agents. However, sufferers of hepatitis C are particularly happy that AbbVie did not stop its research on ritonavir and combinations with other agents because AbbVie has now developed a new combination of antiviral agents with ritonavir which has recently been approved for the treatment of hepatitis C. According to some reports, this combination of antiviral agents has achieved a 97% cure rate for sufferers of hepatitis C. This cure rate compares well with that achieved by Gilead’s antiviral combination products containing the active agent, sofosbuvir. Again, combinations of the active agent with other antiviral agents have been shown to achieve a better cure rate than the active agent itself.

The development of these combination products for the treatment of hepatitis C is a demonstration of the importance of drug combinations and incremental innovation in the fight against chronic disease. These new products are far superior to the interferon therapies first trialled in Australia in 1989.

The difficulties associated with finding a stable form of ritonavir for use in pharmaceutical products represents a good example of the importance of identifying an appropriate form of an active agent for incorporation into a commercial pharmaceutical product. Commentators on the topic of evergreening often dismiss this important work by referring to these forms of active agent as “minor variations” or “a mere new form”, or similar.

The original form of ritonavir, known as Form I, seemed appropriate at the time for incorporation into Abbott’s Norvir product. At that time this form of ritonavir showed appropriate levels of solubility and stability, and there was no indication that the form was not stable. The drug, which was initially formulated in the form of soft gelatin capsules and as an oral solution, received marketing approval in Australia in 1996.

However, something happened in 1998 in the US manufacturing facility which caused the production of a new crystal form of ritonavir, referred to as Form II. Since Form II was more thermodynamically stable than the original Form I, it was not long before Abbott was unable to produce ritonavir in its original form. It also appears that scientists from the US travelled to the other manufacturing facility in Italy and contaminated the atmosphere in the facility with crystals of new Form II. From that point onwards it was also not possible for Abbott to manufacture ritonavir in its original form in the Italian manufacturing facility. It also turned out that the solubility characteristics of Form II were unsuitable and, as a result, Abbott had to withdraw its product from the market. This obviously caused difficulties and concern for the patients who were on this HIV medication at the time.

Eventually, Abbott was able to find a solution to the stability problem and launch a new formulation of ritonavir which required refrigeration. In more recent times Abbott (now AbbVie) has developed a new form of ritonavir which does not require refrigeration.
New therapeutic indication for Prolia™

As a final example of follow on innovation I refer to the recent announcement by researchers at the Walter and Eliza Hall Institute (WEHI) that they have identified a new pharmaceutical use for the biologic drug, Prolia™ (denosumab), which has been used previously in the treatment of osteoporosis in postmenopausal women and for increasing bone mass in men with osteoporosis or osteopenia. The WEHI researchers have now found that this drug might be useful in targeting and preventing the development of breast cancer in women carrying the faulty BRCA gene. Again, this finding demonstrates the importance of follow on innovation based on known drugs.

Follow-on innovation critical for public health

It is clear from the examples presented above that incremental innovation is of critical importance in the development of improved pharmaceutical products and that follow-on inventions, and the patents that protect them, are important in achieving these outcomes. It is very easy for those not involved in the biomedical research sector to bundle all of these patents into the evergreening bucket without giving any consideration to the ingenuity and inventiveness involved in solving the significant problems encountered in drug development.

In a presentation given in Cape Town on 14 April 2015 at the International Federation of Intellectual Property Attorneys (FICPI) Congress, Dr Fiona Bor, who at that time was the Vice President and Director of IP of the generic pharmaceutical company Mylan, made the following comments about incremental innovation:

During the life cycle of a small molecule product, improvements are likely to be discovered. It is unrealistic to expect innovator companies to keep on producing exactly the same product according to its original formulation, when experiences both in the laboratory and in the clinic may demonstrate that a particular finished dose product (and perhaps the efficiency of its manufacture) can be improved. Incremental innovation in the pharmaceutical industry is therefore inherent and overall it is probably a public good that is to be encouraged!

It therefore appears that all of those actually involved in the manufacture and development of pharmaceutical products realise and appreciate the importance of incremental innovation. One can only hope that academics and economists will come to recognise this as well, and remove the inappropriate and pejorative term “evergreening” from their lexicon.

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Footnotes
5. F Bor “Incremental Innovation — a generic industry perspective” (Paper presented at FICPI Congress, Cape Town, 14 April 2015).
Interview with Terri Janke

Sharon Givoni SHARON GIVONI CONSULTING

Terri Janke, a Wuthathi/Meriam woman from Cairns, is founder and Director of Terri Janke and Company. Terry is an international authority on Indigenous Cultural and Intellectual Property (ICIP).

It says on your website that one of your main focuses is on Intellectual Property and Indigenous Culture. What got you into this area?

I had a job at the Aboriginal and Torres Strait Islander Arts Board of the Australia Council and worked with the inspirational Chicka Dixon. Uncle Chicka showed me that arts and culture can deliver similar social and economic objectives as the law. I then understood the importance of the law being a spear, and not just a shield. I learnt about intellectual property law and its relevance to Aboriginal people. It’s the legal protection of ideas and creations of the mind like art, music, film, inventions and knowledge. The advancement of Aboriginal cultural rights via copyright and intellectual property became my focus. I saw Indigenous cultural and intellectual property law as a path of empowerment.

Your firm was founded in April 2000, could you tell us a bit about your background prior to founding the firm?

Before starting the firm, I worked at Michael Frankel & Company (now Frankel Lawyers) which allowed me to gain experience in advising clients on film, arts and business. That was also where I wrote the report Our Culture: Our Future — Report on Australian Indigenous Cultural and Intellectual Property Rights.

Before that, I was the Copyright Information Officer at the National Indigenous Arts Advocacy Association, which involved assisting the legal team in coordinating logistics around the appeal case of Milpurruru v Indofurn and the development of the Aboriginal arts certification mark, the Label of Authenticity.

What would you say is the most rewarding aspect of your work?

There are two aspects that I find are the most rewarding in my work. The first is seeing Indigenous businesses come through our firm and working with them around their contracts and starting up/developing their business. I love being able to share with them things that I have learnt in business and seeing them succeed. The other aspect is having corporate, government or organisations come to us to build their Indigenous Cultural and Intellectual Property Protocols. Being able to develop the protocols to strengthen these relationships and encourage them to grow is inspiring.

Have you had any particularly interesting cases? Has there been much media coverage of these matters?

During the 16 years of operating, we have seen some interesting cases. One was around an artist, Bibi Barba. She googled her name in preparation for a website she was putting together and discovered her name was connected to a Hotel in Domaslaw, Poland. The Hotel Eclipse had used prominent features of her artwork Desert Flowers and Flowers of the Desert in their wood panelling, glass dividers, table tops and art panels in the foyer. A Polish designer had used the works without permission when designing the hotel interior. The case is being pursued in Poland. There has been a lot of media coverage of this particular case.

A different story concerns the Musée du Quai Branly, a museum in Paris, which commissioned eight Indigenous Australian artists to produce works that were incorporated into the architectural skin of the building. Two highly experienced Australian Indigenous curators were brought in — Brenda Croft and Hetti Perkins. They worked with the Australian Installation Architect firm Cracknell & Lonergan to select the artists and consult with them about the creation and installation of the works. The process ensured the control of the community was respected. The artists were paid a fee, but also attended the launch. The contract also included attribution clauses; community recognition clauses; annual reporting provisions; and the Indigenous visual arts protocols guide was translated in French and attached in an appendix. A curatorial guide was created for the Musée so that the care of the works could be properly managed.

Another case that we worked on was the Deepening Histories of Place project. Deepening Histories of Place was a multi-partner project for the collection, recording, storage and use of Indigenous knowledge about place/location. The project included interviewing Indigenous
people, filming interviews (video and sound), recording notes, filming Indigenous land and places. It also used existing copyright and archival material. We created protocols to clearly set out the values of the project and purposes, and that dealt with setting up the framework for the interplay of information and processes for filming on Indigenous lands and national parks; dealing with when people filmed passed away, protocols, copyright and ethics. The most interesting feature about this project was that the ownership of the recordings are vested in the knowledge holders even though the recordings are made by filmmakers and researchers. To cover this, all rights are assigned to the knowledge holder in writing.

Your firm offers a professional development course called True Tracks which trains Australian corporate partners on indigenous culture and intellectual property for business. What has been the response to this program? Do you think the message is getting across?

We get a strong response from the workshop. Usually after attending the True Tracks workshop, we end up working with a lot of the participants. I think it gives them a greater understanding of the impact that culture and intellectual property has in the lives of Indigenous Australians. From this, we can see the message getting across. We teach people the True Tracks 10-steps process for working with Indigenous cultural and intellectual property. This has been really positively received. It becomes a checklist for projects and in-house or industry based protocols.

You run a program called Law Way which assists indigenous entrepreneurs and the corporates and government bodies teaming up with them in response to the IPP (Indigenous Procurement Policy). What first alerted you to the need for this kind of program?

We act for a lot of Indigenous businesses and people wanting to work and joint venture with Indigenous businesses. Clients needed advice on the legal structure, branding, shareholders agreements and protection of IP. We wrote a short guide which was extremely successful and then we developed the videos to make the message accessible. We chose topics and presented them in short 1-minute clips. These have been extremely successful.

Some of the topics include start-up mistakes, joint ventures, choosing the right legal structure, employment, intellectual property, etc.

We also do a face-to-face workshop that covers the IPP and legal issues such as joint ventures, shareholders deeds and contracting with government. We wanted to make sure that the arrangements reflected fair and equitable business principles. The US has had minority procurement policies for over 40 years so we did research on their experiences and the legal needs of the Minority Business Enterprise. There are some good examples and bad examples which give us case studies for the workshop. Learning from these experiences can save us from a lot of the mistakes that have been encountered before.

I also think that the policy is very strong, the increase in government spending around Indigenous business has really changed the way that Indigenous businesses operate and are allowed/encouraged to operate.

What do you see are the biggest challenges facing the protection of indigenous artwork under the current Australian legal regime for copyright law?

One of the biggest challenges I see Indigenous artists face is the reproduction of fake Indigenous artworks. There have been issues where Indigenous artwork is reproduced overseas for reduced prices and then sold over here at low prices. The art is stylised and circumvents copyright laws. These fake works are typically sold in tourist shops. The Indigenous communities are faced with the exploitation of their traditional knowledge and never receive any consultation, royalties or respect. The Fake Art Harms Culture campaign that is being run by the Arts Law Centre is pushing for this change.

The main problem is that this is traditional Indigenous knowledge and it is being used without the permission of the communities. They also lack respect for Indigenous communities and their artwork. Reproducing the artwork without permission causes upset. We submitted a report to IP Australia with comments and suggestions to improve current intellectual property law to better protect Indigenous knowledge and cultural expression, you can find the report here: www.ipaustralia.gov.au/sites/g/files/net856/f/submission__terri_janke_and_company__ip_lawyers.pdf.
You've been a big part of the call for a National Indigenous Cultural Authority. Could you tell us very briefly the role you would like that authority to take in relation to Australia's intellectual property law?

The National Indigenous Cultural Authority (NICA) would set a new framework which would enrich artistic, social and economic lives of Indigenous creators. It would allow for a practical strategy for protecting and managing Indigenous cultural and intellectual property. It would also assist users with contacting and identifying relevant Indigenous owners. This would prevent the misuse of ICIP and allow for Indigenous communities to control the interpretation and understanding. I wrote a guide about NICA, you can read about it in more detail here: http://media.wix.com/ugd/7bf9b4_3346f929752c4f1da9766f83da148c14c.pdf.

There are new intangible heritage laws that have very recently been introduced in Victoria in the Aboriginal Heritage Act 2006 (Vic). These are aimed at protecting Aboriginal cultural knowledge, artistic traditions, stories and other cultural heritage. Is there anything similar on the horizon in New South Wales?

The Vic Aboriginal Heritage Act allowed traditional owners to register their intangible heritage and then permission must be sought for commercial use of the intangible heritage. In this way, it allows Indigenous groups to stop misappropriation of their culture. In NSW, I am not aware of any similar laws, though in the past, there were discussions about a NSW Aboriginal Heritage Act — we have a very different heritage regime. It would be good to have something like that here and in other states. See the WIPO Draft Articles for Traditional Cultural Expression (TCEs): www.wipo.int/tk/en/igc/draft_provisions.html.

New Zealand’s patent and trade mark laws include specific provisions for the protection of mātauranga Māori (Māori knowledge) which prevent the registration of trade marks or granting of patents that would be considered offensive by Māori or contrary to Māori values. Does Australia need to develop similar intellectual property laws for the protection of its indigenous culture?

Yes. I definitely think there is a need for similar provisions. I think the NZ provisions strike a good balance of protecting cultural interests but allowing commercial use where appropriate. IP Australia should consider this and put together an Indigenous Advisory Group that can develop guidelines for examiners and applicants.
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The defence of innocent infringement of copyright in Australian Copyright Law

Ian Robertson and Sarah Butler HOLDING REDLICH

Keypoints

• Publishers should clear — ie obtain permission for — the reproduction of all pre-existing work.
• In order to infringe copyright, the reproduction of a work must be substantial and defences of fair dealing may sometimes be available.
• To rely on the limited protection of “innocent infringement” a publisher must prove that it was not aware, and had no reasonable grounds for suspecting, that the act constituting the infringement would be an infringement of copyright.

Introduction

Businesses operating in the communications industry, including publishers, screen producers and advertising agencies, here referred to generally as publishers, should be aware of the serious consequences of infringing copyright, even if the infringement occurs unwittingly, and put in place procedures to ensure infringements of copyright do not occur.

The ease with which images, illustrations, audio-visual material and other works in which copyright subsists can be located, modified and reproduced makes it essential that publishers put in place procedures to identify every pre-existing work which is being reproduced in a new work to be published by the publisher.

Even where appropriate procedures are in place there remains a risk that a publisher may unknowingly infringe copyright and receive a claim from the copyright owner as a result. Australian courts generally take a robust view of copyright infringement and the need to protect the rights of the copyright owner. This article considers the protection available to “innocent infringers” under s 115(3) of the Copyright Act 1968 (Cth) and the approach of Australian courts to the interpretation of that limited defence.

Practical steps to identify possible copyright infringement

• It is essential for publishers to have in place simple and practical procedures which identify pre-existing material which is to be reproduced in a new work to be published by the publisher.
• Once pre-existing material has been identified, consideration must be given as to whether its reproduction will infringe copyright. In order to infringe copyright the reproduction must be substantial and there may also be defences of fair dealing available. However, the defences of fair dealing are narrow and are usually of limited use in circumstances of commercial publication.
• Publishers must be alert to common misconceptions. For example, to only reproduce 10% of a pre-existing work may still amount to infringement in many situations — copyright is generally concerned with the quality rather than the quantity of what is reproduced. Further, because material is widely available on the internet and on services such as YouTube, does not mean it may be freely reproduced without infringing copyright.
• If permission has been obtained to reproduce material, it is important to consider the limitations of the specific permission. For example, photographs in respect of which permission has been obtained to reproduce them in an advertising pitch or internal concept development may usually not be communicated to the public at large without obtaining a further appropriate licence.
• The safest rule for publishers to adopt is to clear — ie to obtain permission — for the reproduction of all pre-existing work. This is the approach usually followed by Australian book publishers and screen producers.
• Publishers should be wary of placing significant reliance on third party assurances as to copyright ownership and clearances. Attempts to claim ignorance or rely entirely on third party assurances of
clear copyright may fail in circumstances where there are reasonable grounds to suggest otherwise.

Innocent infringement of copyright

The exclusive rights of a copyright owner are the right to reproduce (or copy), publish and communicate their work to the public using any technology, as well as to perform and adapt their work. Section 36(1) of the Copyright Act provides that copyright in a literary, dramatic, musical or artistic work is infringed when someone other than the owner of the copyright, or their licensee, does any act comprised in the copyright, including reproducing the work or a substantial part of the work, in material form.

Innocent infringement provides a limited defence to copyright infringement, although a person who infringes copyright innocently has nevertheless still infringed copyright. Section 115(3) of the Copyright Act provides that no damages can be awarded to a plaintiff in a case of innocent infringement and specifically provides:

Where, in an action for infringement of copyright, it is established that an infringement was committed but it is also established that, at the time of the infringement, the defendant was not aware, and had no reasonable grounds for suspecting, that the act constituting the infringement was an infringement of the copyright, the plaintiff is not entitled under this section to any damages against the defendant in respect of the infringement, but is entitled to an account of profits in respect of the infringement whether any other relief is granted under this section or not.

Reliance on the defence of innocent infringement

[In order to] obtain the protection of s 115(3), a defendant must establish: (i) an active subjective lack of awareness that the act constituting the infringement was an infringement of the copyright, and (ii) that, objectively considered, he or she had no reasonable grounds for suspecting that the act constituted an infringement.1 [Emphasis added.]

The relevant suspicion is that the performance of the act in question would constitute a breach of copyright.

In order to rely on the protection of s 115(3), the alleged infringer must be able to establish that reasonable enquiries were made as to the existence of any copyright.2 The Copyright Act does not require that the infringer know the specific identity of the copyright owner,3 but a deliberate choice not to enquire as to the existence of copyright may be taken to imply the existence of the relevant suspicion.4

Where these thresholds are met, the defendant will be protected against a claim for damages in respect of what is deemed to have been an innocent mistake. However, this does not preclude a court from making an order for an account of profits, where the defendant has derived a benefit from the infringement and regardless of any other relief provided under s 115 of the Copyright Act.

Limitations of innocent infringement as illustrated by Australian case law

Two recent cases provide guidance on what will, and will not, constitute reasonable grounds for suspicion and reasonable enquiries into the existence of copyright.

Corby v Allen & Unwin

The 2013 Federal Court case of Corby v Allen & Unwin Pty Ltd5 was brought by the sister, brother and mother of Schapelle Corby against Allen & Unwin, the publishers of a book called Sins of the Father written by Eamonn Duff. There were 37 photos in total published in the book, five of which formed the basis of the proceedings. The publisher claimed that all images were either given to Mr Duff or the media in general for publication and that it had the benefit of implied licences from the respective owners of the copyright. It further asserted that, to the extent that this was not the case, it was an innocent infringer of the copyright under s 115(3) of the Copyright Act.6

The applicants asserted that the family members who took the photos would not have given specific permission for the use of the images at any price7 and, further, that no permission was sought or granted in relation to the five specific photos.

Buchanan J found that there was no effort made by Mr Duff or Allen & Unwin to obtain the consent of the relevant owners of copyright to the reproduction in the book of any of the five photographs.8 Further, there were no reasonable grounds upon which the author or publisher could have concluded that they had any benefit of the licence from the owner of the copyright to reproduce any of the photographs.9

The court accepted the argument of the Corby family, and Buchanan J awarded each of the relevant family members between $500 and $5,000 in compensatory damages pursuant to s 115(2) of the Copyright Act, and $45,000 by way of additional damages pursuant to s 115(4) for the “deliberate” and “studied” disregard of the applicants’ copyrights.10 Allen & Unwin was also ordered to destroy all remaining copies of the book held by the publisher and to ensure that any future editions exclude the five photographs.

In relation to the publisher’s submissions in respect of s 115(3) of the Copyright Act, his Honour concluded that Allen & Unwin had failed to successfully establish that it was an innocent infringer because:

• Simple unawareness as to the owner of the copyright does not constitute “innocence”.11

• In early 2013, although the litigation had commenced, the publisher printed further copies of the book as demand required further stock. Buchanan J found it was “impossible to claim the benefit of s 115(3) once present litigation was underway”.12
Tamawood v Habitare Developments

More recently, in the 2015 case of Tamawood Ltd v Habitare Developments Pty Ltd (Admin Apprd); Mondo Architects Pty Ltd v Tamawood Ltd; O’Mara v Tamawood Ltd, the Full Court of the Federal Court provided further guidance on the defence of innocent infringement.

In this case, Tamawood Limited (Tamawood) prepared building plans (Plans) for a developer, Habitare Developments Pty Ltd (Habitare). Habitare submitted the Plans for city council approval (with Tamawood’s consent). Following council approval and a breakdown in the relationship between Habitare and Tamawood, Habitare engaged Mondo Architects Pty Ltd (Mondo) to prepare construction plans “generally in accordance with [the Plans]”. Mondo duly prepared the construction plans, following which Habitare engaged Bloomer Constructions (Qld) Pty Ltd and Wayne Bloomer (together, Bloomer) to construct the developments.

Tamawood commenced proceedings against Mondo, Habitare, two of Habitare’s directors and Bloomer, alleging that the preparation of, and construction in accordance with, the Plans infringed Tamawood’s copyright in the Plans. Mondo and Habitare claimed that their use of the Plans was authorised by a licence granted by Tamawood. Bloomer denied that it had infringed Tamawood’s copyright and asserted that, in the alternative, any infringement was innocent and attracted s 115(3) of the Copyright Act.

The judge at first instance found Bloomer to be an innocent infringer for the purposes of s 115(3) the Copyright Act, however found that Mondo was not.

The decision at first instance was appealed on nine grounds to the Full Court of the Federal Court, including in relation to the application of s 115(3). In its decision, the Full Court of the Federal Court upheld the primary judge’s application of the defence. In doing so, their Honours noted the following:

- That Mondo, having been alerted to the earlier role and potential interests of Tamawood in the Plans, nevertheless failed to make reasonable enquiries as to the existence of copyright in the Plans. Its unquestioning reliance on Habitare’s assurances as to copyright fell substantially short of establishing that Mondo had no reasonable grounds to suspect its acts would infringe the copyright in the Plans, particularly given their extensive industry experience.
- That Bloomer, having had no involvement in the original planning and approval process, being unaware of the potential infringement where there was no reference to Tamawood on the later Mondo plans and noting construction had already commenced at the point of their involvement, was entitled to the protection afforded by s 115(3).

In dismissing Mondo’s claims under s 115(3), the court observed while Mondo’s reliance on Habitare’s assurances was sufficient to satisfy their parallel misleading and deceptive conduct claim against Habitare, it did “not come close to establishing … Mondo had no reasonable grounds for suspecting its acts would infringe Tamawood’s copyright”. The court was clear in distinguishing factual findings made in the context of a misleading conduct claim, and those with respect to claims for innocent infringement.

Conclusion

In summary, it is essential that publishers have in place practical procedures to identify possible infringements of copyright that might result from the reproduction of pre-existing material in which copyright subsists. Best practice requires that the right to reproduce all pre-existing material, regardless of the magnitude of the reproduction, should be cleared.

The defence of innocent infringement of copyright requires the publisher to prove that it was not aware, and had no reasonable grounds for suspecting, that the act constituting the infringement would be an infringement of copyright. Publishers should avoid placing too much reliance on what is a very limited defence and instead seek to avoid an infringement in the first place.

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Footnotes


4. Tamawood Ltd v Habitare Developments Pty Ltd (Admin Apptd) (Recs and Mgrs Apptd); Mondo Architects Pty Ltd v Tamawood Ltd; O’Mara v Tamawood Ltd (2015) 112 IPR 439; [2015] FCAFC 65; BC201504223.


6. Above n 5, at [23].

7. Above n 5, at [24].

8. Above n 5, at [21].

9. Above n 5, at [21].

10. Above n 5 at [27].

11. Above n 5 at [25].

12. Above n 5 at [25].


19. Above n 4, at [55] (Jagot and Murphy JJ).

20. Above n 4 at [54] (Jagot and Murphy JJ).

21. Above n 4 at [67] (Jagot and Murphy JJ).

22. Above n 4, at [55] (Jagot and Murphy JJ).
Brexit through the gift shop — the UK referendum and its implications for IP owners

Chris Bird and Natasha Dixon ALLENS PATENT & TRADE MARK ATTORNEYS

Practical tips

• There have been no significant changes to the UK and European Union (EU) IP landscape overnight, yet it is important that Australian companies (and, indeed, all those who do business in Europe) begin to think about the ways in which the Brexit decision may affect relevant IP registrations and IP strategies in Europe.

• Consider any relevant IP agreements that will be in place after the Brexit process is complete, such as licences or co-existence agreements, and assess whether any rights or obligations under those agreements are defined by reference to EU rights or the territory of the EU. Similarly, if drafting new agreements, any reference to such rights or territory should be avoided.

• The most significant change for IP will likely be seen in trade marks and designs, as the EU community rights will cease to be enforceable in the UK. While the authors predict that transitional regimes will be negotiated to address the issues arising from this, the form of such a regime is uncertain. As such, if a company is relying on EU community trade marks (CTMs) to protect, for example, a trade mark critical to its business in the UK, consideration should be given to registering a parallel national UK trade mark without delay.

• Brexit may also have an impact on IP enforcement strategies in the EU. EU-wide remedies will not be available from UK courts and EU-wide remedies granted by an EU court will not apply to the UK. As such, it may be necessary to develop parallel enforcement strategies in both European courts and the UK.

The legal implications of the UK’s vote to leave the EU are as uncertain as they are sprawling. Exactly what the exit will mean for just about every area — from data privacy to tax law to IP — will depend on the arrangements worked out between the UK and the EU, and negotiations about starting those negotiations have not even commenced yet. While lawyers across all areas of business are doing their best to prepare their clients for what to expect, the truth is that, at this early stage, it is impossible to know quite how this will play out.

But, with reference to the wise words of Blaise Pascal, “il n’est pas certain que tout soit incertain” (it is not certain that everything is uncertain), this article endeavours to provide guidance on what are the key IP issues to watch out for, and to offer at least some suggestions on where the authors think these issues are likely to end up. Safe to say that we thank the reader for indulging the unavoidable crystal ball-gazing throughout this article!

Patents

Interestingly, the UK Intellectual Property Office (UK IPO) has been one of the first government bodies to release an official statement addressing Brexit. In relation to patents, the UK IPO has emphasised the point that the move does not and will not impact the existing system for the grant and enforcement of European patents covering the UK, as it is established by the European Patent Convention, well outside the remit of the EU.

However, Brexit is likely to have an effect on the new Unitary Patent System, which is set to allow the grant of a single European patent. The UK IPO recognises that UK’s position in relation to the Unified Patent Court (UPC) is now uncertain, stating only that there will be “no immediate changes” and that the UK will, for the time being, remain a Contracting Member State of the UPC and continue to attend and participate in UPC meetings in that capacity.

For those who wish to obtain patent protection across Europe (or at least in 25 out of 28 member states), the benefits to a Unitary Patent System are numerous. A unitary system would result in reduced costs, due to the current many and varied translation requirements and the ability to renew patent rights with a single fee. If the UK leaves the EU without joining the Unitary Patent System, the benefits of the new system will be reduced for all users, not just for UK applicants.

Very importantly, the new regime will create a single UPC system for litigation in the participating EU states for both traditional European patents and EU unitary
patents. Participation in this court is contingent upon being a member of the EU. Thus, the UK will no longer be eligible to participate. It follows that European patent holders may need to run separate national proceedings in the UK alongside unitary patent litigation in the rest of Europe.

Should Britain’s exit from the EU result in the need to exclude the UK from the Unitary Patent System, it is likely that there will significant delay to the start of the system which, prior to Brexit, was intended to come into force mid-2017. Particularly problematic is the fact that London is named in the UPC Agreement as the “Life Sciences” seat. In order to unravel all this, there will need to be an agreement on the new location, an amendment to the UPC and a further round of re-ratifications.

However, there is a glimmer of hope here. Since the Brexit decision, there has been discussion around whether it will be possible for the UK to remain part of the Unitary Patent System following its exit from the EU. On this note, we consider that if the UK ratifies the EU Patent Court Agreement prior to leaving, only minor amendments would be required to enable the UK to participate. Given the fact that Brexit will take at least 2 years to be formalised, this does seem to be a possibility, and would go some way in addressing the issues outlined above.

Trade marks

The biggest impact for the world of IP may well be in trade marks. With the UK ceasing to be part of the EU’s community trade mark regime, unitary protection across Europe will no longer be possible. Ultimately, this could also lead to notable divergence between the trade mark systems of the UK and the EU, and will result in trade mark owners needing to file separate applications to gain protection in both jurisdictions.

On this point, the UK IPO has provided some words of reassurance to UK rights holders, emphasising that while the UK remains a member of the EU, CTMs will continue to be valid in the UK. It has also, unsurprisingly, confirmed that following the UK exit from the EU, UK businesses will still be able to register an EU trade mark which will cover all remaining EU member states.

These words of reassurance were not coupled with any meaningful statement regarding the form or approach that the government will be taking to address how, if at all, CTMs will be recognised in the UK in the post-Brexit world. However, in an attempt to calm the concerned throngs, the IPO observed that the UK remains a member of the Madrid system for the international registration of trade marks. The Madrid system is an international trade mark system which facilitates the registration of trade marks in up to 113 countries, including EU member states, with the need to file a single application and pay a single fee.

The UK IPO has also foreshadowed that it will be conducting consultations on options for a transitional regime. But no further details have been forthcoming as to timing or what options are under consideration, and the future of the CTM therefore remains uncertain. The authors believe that transitional provisions are likely to be negotiated to allow rights that are currently provided under the CTM system to continue as UK rights post-Brexit. However, for a company’s critical brands, a conservative course of action should be followed.

In particular, trade mark owners relying on CTMs for protection should consider the importance of the UK market, and file separate UK trade mark applications sooner rather than later, at least for their most important marks. Similarly, for new trade marks, thought should be given to securing both UK and CTM registrations.

Designs

Similarly with trade marks, owners of Registered Community Designs in the EU will not immediately lose protection of their rights. However, unless there is an agreement to the contrary, the UK will no longer be part of the unitary designs systems, meaning that designers in the UK are at risk of losing a strong (and relatively low cost) IP right to defend their designs. Again, this will be a slow process and will likely consist of a transitional regime and a substantial notice period.

In light of this, it is clear that new strategies will need to be adopted by those looking to register designs for protection in both the EU and the UK. Further, if particular designs are of central importance to the owner, consideration should henceforth be given to filing applications in both jurisdictions.

We think it quite possible that there will be a shift to rely on international regimes to fill the legislative void following Brexit. In its statement, the UK IPO voiced its intention to ratify the Hague Agreement in a national capacity, which would provide a practical business solution for registering up to 100 designs in over 65 territories through filing a single international application. This regime will hopefully be introduced within the next year.

Of additional concern for designers in the UK is the status of unregistered design rights. The UK IPO has emphasised that the current protection for unregistered designs will continue to exist through the UK unregistered design right. However, national UK design legislation offers different protection from that offered by the unregistered community right, in that the UK right protects the shape or configuration of objects and the community right protects the appearance of a
product resulting from the features of the lines, contours, colours, shape, texture or materials of the product.

The UK government recently conducted a review of the country’s unregistered design regime and decided to maintain the UK right on the basis that it supplemented the EU right. Based on the latest comments from the UK IPO, it does not appear that the scope of the UK right will be reconsidered. As such, the features protected by the community right will no longer be protected in the UK without registration.

In view of this, designers and other rights owners relying on unregistered design protection in either the EU or the UK would be well advised to give consideration to adopting new strategies in relation to the protection of their IP. For any critical new designs, registered rights should be obtained, as businesses operating in the UK will ultimately no longer necessarily qualify for unregistered community design protection, and vice versa.

Copyright

Copyright, as a territorial right, will likely be the intellectual property right least affected by Britain’s exit from the EU. The authors note that the UK is a member of a number of international treaties and agreements that mean that UK copyright works are protected around the world, a fact that will not change following Brexit.

Furthermore, copyright law has largely been harmonised at a European level in numerous respects, for example, the term of protection, the acts amounting to infringement, performers’ rights and the qualifying criteria for protection. Additionally, the liability of ISPs is also provided under EU legislation which will no longer be applicable to the UK following the formalisation of Brexit.

Many of the directives flowing from the EU legislation have been incorporated into UK national law and as such will not be immediately affected by Brexit unless expressly repealed by the UK government.

However, the extent to which EU and UK law will diverge over time is unclear, which creates some uncertainty for copyright owners in Europe. For example, the European Commission has been pursuing a Digital Single Market strategy, which aims to reform and harmonise copyright law across the EU. If member states eventually implement a set of unitary copyright law reforms, such laws would not apply to the UK, which could lead to a divergence in copyright law between the UK and EU.

Enforcement and licensing

The UK IPO also addressed the issue of enforcement of IP rights, confirming that the UK will continue to play a part in the EU Intellectual Property Office’s Observa-
any updates as to the timing and progress of negotiations between the UK and EU, and react accordingly. After all, as English philosopher Jeremy Bentham mused: “The power of the lawyer is in the uncertainty of the law.”

![Chris Bird](image)

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