Foreword

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The contribution made to public welfare by biopharmaceutical innovation since the latter part of the last century is undeniable. Indeed, one analyst has calculated that approximately 40% of the two-year increase in life expectancy measured from 1986 to 2000 can be attributed to the introduction and use of new medicines. HIV/AIDS is no longer an untreatable fatal disease. Childhood vaccination has all but eradicated some previously fatal diseases and significantly reduced infant mortality.

Biopharmaceutical innovation takes many forms. It includes the development of first-in-class medicines and vaccines, competitive innovative products which have subtle but medically significant differences from the first-in-class, new combinations displaying synergistic effects and new formulations which may, for example, increase patient compliance.

These advances have taken place in a context where, on average, it takes in excess of 10 years and, according to some, costs in excess of $1.3 billion to bring a new product to market and where less than half of new products launched are profitable. It is trite for those who will be reading this book to say that it is hard to imagine that these welfare benefits would have occurred were it not for the existence of the incentives to invest and take risks provided by robust yet flexible intellectual property systems that provide a period of exclusivity to the innovator for a defined period.

Patents are at the heart of these incentives. It can be argued that patents in the biopharmaceutical industry are of more importance to innovation and of greater value than in any other sector. The relatively recent introduction in many countries of patent term restoration is an implicit acknowledgement of the importance of patents as an incentive to innovate in this sector.

The significance of data exclusivity, which prevents 'piggy-backing' on the extensive data generated by innovators to satisfy regulators that a product is safe and effective, should not be underestimated. It can provide a period of protection from competition from copies (but not other innovative products) in the event that, for whatever reason, the investment undertaken by an innovator does not benefit from effective patent protection.

As is the case in other sectors, trademarks provide the advantages associated with branding. In addition, and importantly, they are a vital tool in the fight against counterfeiting which, in this sector, is a public-health rather than a commercial imperative.

The world has seen remarkable change over the last decade or so, driven to a

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significant degree by globalisation and advances in many fields of technology. Pharmaceutical innovation models and the biopharmaceutical industry have both led and adapted to those changes.

Regulatory hurdles in the developed world have increased, leading to increased R&D costs and decreasing numbers of new molecules being approved. Pressure on prices (exacerbated by the economic crisis) and 'patent cliffs' have constrained the amount of money available in many companies for R&D.

Emerging markets are now seen as key growth drivers for many in the industry.

Personalised medicines, often based on genetic diagnostics, are becoming more and more significant therapeutically and, in respect of some therapy areas, commercially. Advances in the field of biotechnology have been such as to lead to predictions that in the next few years biotech drugs will dominate the league of bestsellers.

An increasing recognition of the importance of science emanating from academia and smaller companies is leading to research models changing to embrace the concept of open innovation. No longer will it be the norm (if it ever was) that a company will 'simply' discover a molecule in its own labs and take it through development to launch and marketing using only its own skills and knowledge. Instead, there is a rapid growth in collaboration between academia and small and large industry in which the talents of key stakeholders are brought together to maximise the efficiency and quality of innovation. As a consequence, new and sophisticated models of sharing intellectual property are developing.

The industry has recognised the moral imperative of improving the access of poorer sectors of society to vital medicines and the need to develop medicines for neglected diseases and has taken significant steps in this direction. Far from being evidence, as some claim, of the international intellectual property system in this field being an obstacle to innovation and access to medicines, this is evidence of the flexibility of intellectual property as a tool for driving innovation and access. Rather than innovation and intellectual property being seen as somehow opposing forces, the innovation driven by intellectual property is a vital part of the continuum that leads to better public welfare.

This book addresses the international intellectual property system, the law in many emerging markets, second generation inventions, specific issues in the areas of biotechnology and collaborative models, in addition to more traditional subjects such as the European framework. As such, it reflects the changes that are taking place in law in this area. It is a welcome contribution to an understanding of the law which helps shape a field of vital public importance.

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An introduction to European intellectual property rights

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1. Patents

1.1 Patentable inventions

The requirements for patentable inventions are set out in Article 52 of the European Patent Convention (EPC). Patentability requires that the invention is new, involves an inventive step and is susceptible of industrial application. An 'invention' is not defined. However, it is clear from EPO case law that inventions must have a concrete and technical character and this is consistent with the non-exhaustive list of 'non-inventions' in Article 52(2) EPC including discoveries, scientific theories, aesthetic creations, business methods and programs for computers. The exclusion of business methods and programs for computers in particular has given rise to an important body of case law (both at the EPO and in the national courts) concerning the scope of these exclusions. Of greater relevance to pharmaceutical patenting are the exceptions to patentability set out in Article 53 EPC, namely that European patents shall not be granted: if their exploitation would be contrary to *ordre public* or morality, for plant or animal varieties or essentially biological processes for the production of plants or animals and methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body (in contrast to other jurisdictions such as the United States, where patents for methods of treatment are allowed).

The exclusion of inventions the exploitation of which would be contrary to *ordre public* or morality (defined by the Technical Board of Appeal in *Harvard/Onco-mouse* T356/93 as "not in conformity with the conventionally accepted standards of conduct pertaining to this culture") and for plant and animal varieties and essentially biological processes has been considered further in the context of the Biotechnology Directive 98/44/EC (see below). The decision of the Court of Justice of the European Union (CJEU) in *Brüstle v Greenpeace* (case C34/10) gave a broad interpretation of the term 'human embryo' and clarified that a process involving the removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of the embryo, is not patentable subject matter. The EPO subsequently issued new examination guidelines in line with the CJEU's ruling (even though the EPO is not formally bound to follow the EPO[1]). However, the impact of this decision is mitigated to a considerable extent by the availability of technologies that

avoid the destruction of human embryos in the production of pluripotent stem cells and also by the other barriers to entry in this highly complex area of biotechnology.[1]

The methods for treatment by surgery or therapy and diagnostic methods set out in Article 53(c) EPC are excluded from patentability as a matter of policy (ie, to protect clinicians and veterinarians from falling foul of patent laws). Previously, this exclusion was expressed on the basis that such methods are not susceptible to industrial application. However, this fiction has been corrected by EPC 2000. The scope of this exclusion, which is to be interpreted narrowly, has been considered in a number of EPO cases (summarised in the EPO Guidelines for Examination).

Importantly, the exclusion of Article 53(c) EPC does not apply to products for use in such methods and thus pharmaceutical products may be patented for multiple uses (ie, a patentable invention may reside in the product itself or the use of a known product for a new medical use). This is set out in the terms of Article 54(4) EPC, which states that the fact that a product may be part of the state of the art "shall not exclude the patentability of any substance or composition ... for use in a method referred to in Article 53(c) EPC, provided that its use for any such method is not comprised in the state of the art". Whereas such second (or further) medical use claims were previously only permitted when drafted in the 'Swiss' style (eg, the use of X in the manufacture of a medicament for the treatment of Y), after the implementation of EPC 2000 this has no longer been necessary and indeed such claims are no longer accepted by the EPO (although old Swiss-style claims remain valid and enforceable).

The patentability of known products for medical use is not restricted to new therapeutic indications. The EPO has held that novelty may also reside in a new dosage regime or means of administration. However, the new use must satisfy the inventive step requirement and must be more than a mere discovery about an already known use. This distinction has been considered by both the EPO and the national courts.

1.2 Industrial application

As indicated above, patents shall only be granted for inventions that are susceptible to industrial application, defined in Article 57 EPC to mean inventions that "can be made or used in any kind of industry, including agriculture". Relative to the other requirements of patentability set out in Article 52 EPC, there is a paucity of decisions on industrial application. This is unsurprising as the term 'industry' is construed broadly and in most areas of technology the mere fact that a patent is worth applying for is of itself an indication that the invention has industrial value. However, for biotechnology inventions in particular the threshold may be harder to satisfy (ie, if the practical use to which the new technology will be put has not been identified at the date of the application).

1 Furthermore, in its recent judgment in *International Stem Cell Corporation* (C-364/13) the CJEU qualified its decision in *Brüstle* by ruling that in order to constitute a 'human embryo' a stimulated ovum must have "the inherent capacity to develop into a human being" and thus parthenotes are not automatically excluded from patentability following *Brüstle* (although it is still possible for national courts to prohibit the patentability of parthenotes).

The European, US and UK law of industrial application was reviewed by the UK courts in *Eli Lilly v Human Genome Sciences* (including an analysis of the following EPO case law: *Max-Planck* T870/04, *Johns Hopkins* T1329/04, *Genentech* T604/04, *ZymoGenetics* T898/05, *Bayer* T1452/06 and *Schering* T1165/06). A number of common principles were identified, including the propositions that 'industry' must be construed broadly, that the industrial application must be derivable from the patent application (read with common general knowledge), the need for a sound and concrete basis for recognising that the contribution could lead to practical application in industry and that "the patentee must make a full disclosure of his invention, including a practical use to which it can be put. It [is] not a hunting licence to find such a use". In this case, in which the invention was the identification using bioinformatics techniques of a novel protein (neutrokine-α) through its homology to the TNF superfamily, the court decided on the facts that an industrial application for the gene sequence had not been made plausible by the specification. Although the UK court (both at first instance and on appeal) approved the EPO's approach to industrial applicability, the EPO Technical Board of Appeal upheld the same patent – an example of different findings of fact leading to different results.

1.3 Novelty

Novelty is dealt with in Article 54 EPC, which provides that "an invention shall be considered to be new if it does not form part of the state of the art". The state of the art comprises everything made available to the public (anywhere in the world) whether by written or oral description, by use or in any other way before the filing or priority date of the application. After the entry into force of EPC 2000, for the assessment of novelty (but not obviousness) the state of the art includes the content of European patent applications having an earlier priority date but published after the application in question (ie, co-pending patent applications). A co-pending PCT application may also form part of the state of the art so long as it has been published in one of the official languages of the EPO or its translation into one of these languages has been filed with the EPO and published and the national fee has been paid.[2] Article 55 EPC provides a limited six-month 'grace period' for disclosures made in consequence of "an evident abuse in relation to the applicant or his legal predecessor" (eg, where the disclosure is made in breach of a duty of confidence owed to the inventor) or for disclosure of the invention at officially recognised international exhibitions.

The onus is on the party seeking to revoke the patent to prove that the disclosure or prior use was made available to the public before the priority date and further that a skilled person would have been able to put the prior art into practice in such a way as to carry out the invention. Interpretation of the disclosure is by reference to the knowledge of the skilled person in the field at the relevant date. Importantly, the purpose of the prior art disclosure is irrelevant for assessment of novelty and thus a disclosure in an unrelated technical field, which may be directed at a completely

2 Rule 165, Implementing Regulations to the Convention on the Grant of European Patents.

different technical problem, may still constitute an 'accidental' anticipation (even if the same disclosure would be irrelevant for assessment of inventive step).[3]

The test for novelty is a stringent one. For a disclosure or prior use to anticipate a claim it must disclose all of the features of the claim (ie, only if the invention disclosed by the prior art would infringe the claim in question, if performed post-grant, will it deprive that claim of novelty). The test is not simply that the prior product or process was available to the public but that the information conveyed by that product or process made the invention available. For example in *G2/88 MOBIL/Friction reducing additives*, the use of the additives in question, which were already known for one use, would necessarily have achieved the new use as well. Although the new use would have been inherent in the old use, this would not have been evident and so the novelty attack was rejected. Further, for a claim to be anticipated, it must be inevitable that following the disclosure of the prior art something within the scope of that claim will result. The test of 'inevitability' is strictly applied (*Union Carbide* T396/89).

One aspect of novelty that is of particular relevance to pharmaceutical inventions is where the novelty resides not in the product but in its use. As indicated above, 'second (or further) medical use' claims are permissible in Europe and provided that the other requirements of patentability are satisfied novelty may reside in a new indication, dosage regime or means of administering a known product. A second aspect of novelty that often arises in a pharmaceutical context is the patentability of a sub-group from within a previously disclosed class. The EPO approach is that the patented thing only lacks novelty if it is individually disclosed in the prior art, and this is not usually the case where a selection is made from more than one list (or, in the case of a '*Markush* formula', from one list of substituents at one position and another list of substituents at another position, etc).

The old German law used to be that disclosure of a class entailed disclosure of all members of the class, so all members of that class lacked novelty. English law took a similar view but tempered by the concept of selection patents: a selected sub-class was patentable if it enjoyed an advantage (taught in the later patent) not enjoyed by other members of the main class. In recent years the German and UK courts have both rejected the old approach and adopted the 'individualised description' approach of the EPO (ie, distinguishing what is within the scope of the prior art from what has actually been taught). In doing so, the English court also rejected the rules previously applied to selection patents. In *Dr Reddy's v Eli Lilly* the UK Court of Appeal followed the EPO approach, summarised by Lord Justice Jacob as follows: "It regards what can fairly be regarded a mere arbitrary selection as obvious. If there is no more than an arbitrary selection then there is simply no technical contribution provided by the patentee."

The settled EPO jurisprudence that disclosure of a racemate is not (by itself) a novelty-destroying disclosure of the component enantiomers is now followed by

3 Note, however, that 'accidental' anticipations may be the subject of a disclaimer following G1/03. More recent EPO case law has clarified that where the subject matter to be disclaimed is disclosed in the patent (a so-called 'disclosed' disclaimer) the less stringent test set out in G2/10 is to be followed, ie, that after the amendment the skilled person must not be presented with new technical information.

national courts (although in the absence of particular difficulties in resolving the racemate, establishing 'inventive step' (see below) may be difficult).

1.4 Obviousness

Lack of inventive step (also referred to as 'obviousness') is the most common means of attacking the validity of a patent. The approach taken by the EPO to assessing inventive step (followed to a greater or lesser extent by most EPC countries) is the 'problem-solution approach' (ie, identify the 'closest prior art', establish the 'objective technical problem' and then ask whether the claimed invention would have been obvious to a skilled person starting from the closest prior art and the problem to be solved). The approach most commonly followed by the UK courts is the *Windsurfing* test (reformulated in *Pozzoli*), although in recent years the English courts have also shown a willingness to follow the EPO approach. Both are means of applying a structured approach in order to avoid an *ex post facto* analysis and in most cases the 'mechanics' of the approach followed is unlikely to result in a different outcome (save perhaps where identifying the problem is itself part of the invention); whatever the approach followed, the key question remains: 'Is the invention obvious to a person skilled in the art?'

It is established case law of the EPO that the question is whether the skilled person would have arrived at the invention in the expectation of the improvement or advantage actually achieved (not whether he could have done so). However, the weight to be attached to motivation and the expectation of success may vary from case to case.

Until the mid-2000s the English courts were widely perceived as being out of step with the rest of Europe in terms of the approach to obviousness, particularly as applied to pharmaceutical inventions. In recent years the English courts have been adopting a more patentee-friendly approach to 'secondary' patents, and patents to enantiomers, combinations, dosage regimes and new crystal forms have all been upheld, where in the past (until the mid-2000s) one would have expected that these patents would have been revoked for lack of inventive step (on the basis that they were 'obvious to try'). The English court is now more aligned with the rest of Europe in focusing its attention on what the skilled person would have done, taking into account considerations such as the motive to find a solution to a problem, alternative avenues of research, the effort involved and the expectation of success, rather than looking at what (with hindsight) he could have done.

A developing area of the law of obviousness (and one that overlaps with insufficiency issues – considered below) is that a patent which claims classes of things in respect of which no technical effect is disclosed, or where the technical effect is purely speculative, lacks an inventive step (so-called 'plausibility' obviousness). In *Conor v Angiotech*, the English House of Lords approved the European case law of *AGREVO* T939/92 and *Johns Hopkins* T1329/04, ie, that a specification must pass the threshold test of disclosing enough to make the invention plausible.

1.5 Insufficiency

Article 83 EPC sets out the requirement that "the application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art" and this corresponds to the ground for revocation at Article 100(b) EPC. This 'sufficiency' requirement is an important means of maintaining the balance between, on the one hand, encouraging investment in innovation and rewarding invention and, on the other hand, ensuring that others can work the invention after the patent has expired. In combination with Article 84 EPC, the requirement for clarity and that the claims are "supported by the description", Article 83 also addresses the policy requirement that the patentee is only entitled to claim the contribution he has made to the art and taught in the patent. As stated in *Genentech/Polypeptide* expression I T292/85 there is a "general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported or justified".

It is settled law that the disclosure of the application must be sufficient to enable the skilled person to perform the invention across the scope of the claim (eg, *EXXON/Fuel Oils* T409/91). However, where the patentee has taught a principle of general application, teaching one way of performing the invention may be enough, even if the claim is of broad scope. Put at its simplest, the claim scope needs to be commensurate with the technical contribution made.

As at the date of the application the skilled person, having read the application as a whole and in light of the common general knowledge, must be able to put the invention into practice without 'undue effort' (*Genentech/Human* t-PA T929/92). This will be assessed on the facts of the case but a degree of trial and error will be allowed so long as this does not require an inventive step.

It is difficult to point to material differences in the law of insufficiency as applied across Europe. Nevertheless, it remains the case that insufficiency attacks hit the mark with greater frequency in some countries (most notably the United Kingdom) than in others.

1.6 Inequitable conduct

The list of grounds for opposition set out in Article 100 EPC is exhaustive. Unlike in the United States and certain other jurisdictions, inequitable conduct is not a ground to revoke or render unenforceable a patent in Europe. The European Patent Convention does not deal with misrepresentation or fraud.

1.7 Patent infringement

Infringement requires first that a prohibited act is carried out whilst the patent is in force and in the territory of the patent. Furthermore, the product or process that is subject of the act must fall within the scope of the claims.

The infringing acts, which differ depending on whether the claim is for a product or a process, are set out in Article 25 of the Community Patent Convention.[4] Article 25 defines the prohibited acts as:

(a) making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes;

(b) using a process which is the subject-matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the territories of the Contracting States;

(c) offering, putting on the market, using, or importing or stocking for these purposes the product obtained directly by a process which is the subject-matter of the patent.

In respect of infringement by offering (etc) the product obtained directly by a patented process, it is important to note that the requirement that the product is a direct result of the process has been strictly applied, severely curtailing the ability of patentees to take enforcement action where the process is performed abroad and then a product of that process is imported (ie, if the product has been further processed or altered in some way after performance of the claimed method, then its importation and sale in a patent protected country will not be an infringement). For example in the UK case of *Monsantō v Cargill*, the court held that the progeny of a genetically transformed plant were not the direct products of the claimed method for producing a genetically transformed plant.

As well as the primary acts of infringement identified above, Article 26 of the CPC provides for indirect infringement where a party supplies or offers to supply means relating to an essential element of the invention. However, unlike the primary acts of infringement for which knowledge or intention is irrelevant (save for offering a process for use), indirect infringement also requires the patentee to establish that the alleged infringer had the requisite knowledge (ie, that those means are suitable for putting and intended to put the invention into effect). For this requirement the objective knowledge of the reasonable person will suffice. The territorial requirements of indirect infringement also require close attention.

Of course, for there to be an infringement the relevant product or process must fall within the scope of the claims. The extent of protection conferred by the claims is determined by reference to Article 69 EPC and the Protocol on its interpretation. In essence this provides that the description and drawings shall be used to interpret the claims and that a balance must be struck between a very narrow 'literal' interpretation of the claims (that would not give fair protection to patentees) and a broad interpretation in which the claims serve only as a guideline (that would not give third parties a reasonable degree of certainty as to the extent of the patent).

How this guidance has been interpreted by the national courts differs. Whereas in most European countries non-literal infringement is considered by applying a 'doctrine of equivalents', in the UK there is no doctrine of equivalents and Article 69 EPC is satisfied by a 'purposive' construction of the claims.

2. The European patent litigation system

As has been explained in the previous chapter, the EPC establishes the EPO as the granting body for European patents. Once granted, a European patent is to be treated in each of the designated countries as having "the effect of and be subject to the

4 Although all signatory states did not ratify the Community Patent Convention and it never came into force, equivalent provisions are enacted in the laws of a number of European states and the Convention itself remains widely influential in judicial decision making.

same conditions as a national patent granted by that state" (EPC Article 2). Thus a European patent is often equated to a bundle of national patents, each one identical in form and granting the patentee a monopoly right in respect of the invention in question in that particular designated EPC signatory state.[5] That said, it should be noted that post-grant amendments at a national level may result in different designations of the same European patent having different claims.

Patents (whether national or European) only have effect within the borders of that country (although in some cases the decision of one national court may be persuasive in others). Accordingly, if a pharmaceutical company wants to 'clear the way' to launch a new product in Europe it may have to bring proceedings in multiple jurisdictions to revoke a blocking patent. Similarly, if a potentially infringing product is launched across Europe, then infringement suits will need to be brought in multiple jurisdictions. This provides litigants with the opportunity to forum shop (ie, to choose to litigate in the court(s) that best suit that party's commercial objectives).

In practice, for reasons of cost and efficiency, patents are not litigated in every country in Europe. However, it is not uncommon for patents for pharmaceutical products to be litigated in (say) three or four jurisdictions – on the basis that once the arguments have been tested in these countries, a settlement will be reached that will cover the others. The legal, procedural and strategy issues that guide the selection of the countries in which to bring proceedings are of course fundamental to successful litigation. Relevant factors may include: the specialist nature of the court, the precedent value of a decision, the rigorousness of the procedure (including the ability to obtain disclosure and cross-examine witnesses), the value of being able to separate infringement and validity in the bifurcated systems of Germany and Austria, availability of interim remedies (including injunctions), application of the law and the perception of how 'patent friendly' a particular court may be, speed and cost (including the ability to recover legal costs from the other side if successful). It is most common for patent litigation to be brought in one or more of the following countries, in which the court systems are seen as being the most sophisticated when it comes to patent matters: Germany, the United Kingdom and the Netherlands (followed by France and Italy).

Against this backdrop there is always the possibility of conflicting decisions in different jurisdictions. Notwithstanding that the underlying law is derived from the EPC, the way in which this has been applied by judges and procedural differences (in particular the greater emphasis placed on disclosure of documents and cross-examination of witnesses in some jurisdictions) means that under the current system there will always be conflicting decisions in different member states. An example of this is the pan-European *Novartis v Johnson & Johnson* contact lens litigation. Novartis' patent was revoked for insufficiency by the English court and for anticipation in Germany, but has been upheld in the Netherlands and France.

In recent years there has been a judge-led move towards harmonisation (either as a stepping stone towards a Community patent or a common European litigation

5 Note that the EPC signatory states are not limited to the European Union but also include, for example, Switzerland, Norway and Turkey. As at March 2015 there were 38 EPC signatory states.

system, or as a reaction to the lack of progress in this direction). For example, a number of recent cases exemplify the rapprochement between the English courts and the EPO, and in the UK Court of Appeal judgment in *Grimme Maschinenfabrik v Scott*, guidance was given on the relevance of decisions of the courts of other European countries. The principle across Europe should be "to try to follow the reasoning of an important decision in another country" and "only if the court of one state is convinced that the reasoning of a court in another member state is erroneous should it depart from a point that has been authoritatively decided there". There is a perception that judges across Europe are paying greater respect both to EPO case law and to the decisions of courts in the other major European patent litigation countries. As a result it is hoped that in future conflicting decisions in respect of the same European patent will become less common.

There are three caveats or points to note in respect of the general applicability of the statement above that, within Europe, patents (whether 'European' or national) need to be enforced or challenged at a national level. These are set out next.

2.1 EPO opposition

The EPC provides that, for a period of nine months following grant of a European patent, the validity of that patent may be challenged in opposition proceedings at the EPO. The result of a successful challenge is that the patent is invalidated in all designated states (in which case the decision of the EPO, once the right to appeal to the EPO Technical Boards of Appeal has been exhausted, is final[6] – ie, the patent cannot be 'resurrected' in proceedings before the national courts). The alternative outcomes are that the patent may be upheld in amended form (typically narrowed in scope), or it may be maintained as granted.[7] In either case the patent may then be challenged at a national level. In contrast, for infringement matters the national courts have exclusive jurisdiction. The EPO will not hear infringement proceedings.

An opposition may be filed by 'any person' (save for the patentee). There is no test for standing. Indeed, an opposition may be brought by a firm of patent attorneys (allowing their client to remain anonymous). The notice of opposition must contain a statement of the extent to which the European patent is opposed (ie, which claims are being challenged) and of the grounds on which the opposition is based, as well as an indication of the facts and evidence presented in support of these grounds (Rule 76(2)(c) EPC). As for the grounds on which the opposition may be based, these are set out in Article 100 EPC:

- that the subject matter of the patent is not patentable within the terms of Articles 52-57 EPC (ie, novelty, inventive step, exceptions to patentability, lack of industrial application and 'non inventions');
- that the invention is not disclosed clearly and completely enough for a person skilled in the art to carry it out; and

6 Save for the possibility of judicial review by the Enlarged Board of Appeal under EPC Article 112a where it is alleged that the outcome of the opposition was influenced by a fundamental procedural defect.

7 According to the EPO's annual report for 2013, in approximately 29% of oppositions the patent was revoked, in 40% of oppositions the patent was maintained in amended form and in 31% of cases the opposition was rejected.

- that the subject matter extends beyond the content of the application as filed.

An opposition will first be examined for its admissibility on procedural grounds. Admissible oppositions will then be the subject of substantive examination. The opposition procedure is *inter partes* and both patentee and opponent(s) have the opportunity to submit their written arguments and to argue their case at oral proceedings. Although expert declarations are allowed, there is no scope for cross-examination of the 'other party's' expert. That said, provided that notification is given, an accompanying person (typically a scientist or inventor) may play an important role at an oral hearing. Another procedural point worth highlighting is that a patent may be amended during opposition in order to meet a ground for opposition. Indeed, it is fairly common for the patentee to use a cascading series of auxiliary requests as a means to advance alternative positions as to the scope of the claims sought (in a way that does not feature to the same extent in most national court systems).

It is inherent in the system that national proceedings will run in parallel with EPO oppositions. Given that the typical EPO opposition may last around three years (five or six years if the decision is appealed), this is not uncommon. Different countries take different approaches to the question of whether national proceedings should be stayed pending resolution at the EPO. Although in certain countries and in certain circumstances this may arise (ie, the national court will exercise its discretion to stay the proceedings), the general trend is towards continuing with the national and EPO proceedings in parallel. The principal exception is in Germany where a nullity action cannot be commenced until the opposition period has lapsed or EPO opposition proceedings have been concluded. There are encouraging signs that the EPO is trying to respond to the criticism it has received over the duration of opposition proceedings and also that the EPO and national courts are prepared to engage with each other and adopt a more flexible approach to timing in order to avoid potentially unnecessary duplication. For example, in the recent case of *Eli Lilly v Human Genome Sciences*, the EPO was prepared to accelerate its procedure in order to hear an appeal within only five months of receiving a request from the UK Court of Appeal (allowing the UK to fix a later hearing date and avoid the possibility of the UK court upholding the patent only for it to be revoked centrally shortly thereafter). The flip-side of the pressure on parties to request acceleration (where appropriate) and the reluctance of national courts to stay proceedings is that it is becoming increasingly difficult to achieve a tactical delay.

The primary advantages of the opposition procedure are certainty – if successful the patent will be knocked out across Europe – and cost, which is low compared with litigation in any one of the major patent litigation jurisdictions.[8] On the other hand, one needs to act quickly in order to file an opposition during the nine-month period

8 Only rarely does the cost of an opposition exceed €100,000. By comparison, the cost of litigating a pharmaceutical patent in the UK High Court will cost at least £500,000 (with the cost of cases in other national courts to be added).

following grant and one needs to be prepared to wait for the opposition procedure to run its course or initiate national proceedings in parallel and accept the risk of inconsistent decisions and unnecessary costs (eg, if a patent is upheld by a national court only to be revoked or narrowed by the EPO).

That said, only a small number of European patents are opposed (less than 5% in 2009). The perception is that the opposition procedure is more commonly used by originator pharmaceutical companies than by generic companies, who because of the lag between patent grant and commercial success of the product will often only identify a target market and blocking patent after expiry of the opposition period.

An important recent ruling was the UK Supreme Court's decision in *Virgin v Zodiac* in July 2013 that where a patent is found valid and infringed but subsequently revoked by the EPO, the alleged infringer can rely on the revocation of the patent when the Court assesses the patentee's damages. The impact of this decision, for example on stays of UK proceedings pending the outcome of EPO oppositions, on preliminary injunctions and in cases where damages have already been paid prior to the finding of invalidity, remains to be seen.

2.2 Cross-border injunctions and 'torpedo' actions

Historically, some national courts (most notably the Dutch and Italian courts) had been prepared to interpret EC Regulation 44/2001 (Brussels I) in such a way as to permit them to decide patent issues outside their own borders (eg, to grant cross-border injunctions against a single defendant or group of related defendants). This was so notwithstanding that the European rules on jurisdiction provide that patent validity (which is almost always raised as a defence to infringement) can only be determined by the national court in the country to which that part of the patent relates (Article 22(4) of EC Regulation 44/2001).

This has, following the ECJ rulings in *GAT/LuK* and *Roche/Primus* in 2006, and *Solvay/Honeywell* in 2011, become a rarity. In GAT/LuK the ECJ held that the validity of a patent cannot be determined by the court in another jurisdiction and that this rule is mandatory and could not be derogated from. Indeed, where a court is seized of a claim that is primarily concerned with a matter over which the courts of another state have exclusive jurisdiction, the seized court is required to decline jurisdiction and as a consequence cross-border injunctions are not possible where validity is raised as a defence.

In *Roche/Primus* the ECJ held that where it is alleged that a European patent is infringed in multiple countries, infringement in all countries cannot be considered by a single court on the basis that there are multiple defendants within the same group (eg, sister companies) and the company domiciled in that country was responsible for determining a coordinated policy of carrying out the same allegedly infringing acts by the others (the 'spider in the web' doctrine). Nevertheless, in certain circumstances the Dutch courts have indicated a continued willingness to grant cross-border injunctions, although the extent of this practice is now considerably diminished.

In *Solvay* the CJEU looked at whether the decision in *GAT/LuK* would block cross-border preliminary injunctions as soon as the inevitable invalidity defence is raised.

operate across national boundaries. Uniform minimum levels of protection in the EU should help them to prevent others from misusing their trade secrets and confidential information. Harmonisation may also assist in the alleviation of information leaks and the resulting disputes caused where former employees use information they have learnt at their previous workplace. Because today's workers are highly mobile, a harmonising trade secrets directive would appear helpful.

A first reading of the Proposed Directive by the EU Parliament in plenary session has been timetabled for September 8 2015, after which the JURI is expected to adopt a draft report that will indicate which proposed amendments to the draft will be taken forward. Once the Proposed Directive has come into force, member states will be required to implement it as part of their national laws. How this will be done will undoubtedly raise new debates within those countries. Both the Council and the CIRE agree that implementation of the directive should not prevent member states from legislating more far-reaching provisions for the protection of trade secrets in the absence of specific provisions in the directive.[16]

16 Proposed amendment to Article 1.

Australia

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1. Small molecules

1.1 Product and process claims

In Australia, product, process and method of treatment claims are all potentially patentable. In addition to base chemical or compound claims, other common types of pharmaceutical claims are:

- salts, esters and solvates;
- enantiomers;
- polymorphs;
- combinations of APIs;
- formulations;
- methods of use;
- methods of manufacture or process claims;
- product-by-process claims;
- release profiles;
- dosage regimes; and
- methods of medical treatment.

1.2 Scope of protection of claims and *Markush* formulae

New, synthetically manufactured compounds are usually delineated in the claims by a generalised structural formula. This is known as a *Markush* claim. The scope of such a claim depends upon which compounds may be created by combining the different alternatives mentioned in the different positions in the formula. That type of claim makes it possible to define a very large number of compounds concisely. *Markush* claims are common in Australia and their scope is determined in accordance with the usual principles of patent claim construction set out below.

Patent Claim Construction

In *Eli Lilly v Apotex Pty Ltd* [2013] FCA 214, Middleton J stated:

It is well settled that the Court should, from the outset, approach the task of patent construction with a generous measure of common sense. The Court must place itself in the position of a person skilled in the relevant art, being the subject matter of the patent. From this perspective, the patent is to be read as a whole, in the context of the specification and in light of the prevailing common general knowledge and state of the relevant art at the priority date.

In *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151, Bennett J stated:

... the end point is that the words in a claim should be read through the eyes of the skilled addressee in the context in which they appear. Words used in a specification are to be given the meaning which the person skilled in the art would attach to them, having regard to his/her own general knowledge and to what is disclosed in the body of the specification ... This applies to words used in the claims ... The construction of a specification, including the claims, is ultimately a question of law for the Court ... While the claims define the monopoly claimed in the words of the patentee's choosing, the specification should be read as a whole ... It is not permissible to read into a claim an additional integer or limitation to vary or qualify the claim by reference to the body of the specification ... However, terms in the claim which are unclear may be defined or clarified by reference to the body of the specification ... The language of the claims may have no positive meaning when read apart from the specification but the meaning may become clear and the invention sufficiently defined when read using the body of the specification as a dictionary of the jargon and ascertaining the nature of the invention.

A number of propositions may be gleaned from the foregoing observations:

- a patent is a public instrument which must, if it is to be statutorily valid, define a monopoly which is not reasonably capable of being misunderstood;
- a court, when reading the entire patent specification, must place itself in the position of a person who is skilled in the relevant art, given their general knowledge, and the state of the art that existed before the priority date of the patent;
- the words used in a specification, including the claims, are to be construed from this standpoint in a 'common sense' and not abstract manner;
- what is disclosed in the body of the specification will also assist the skilled person in the art to understand the claims, bearing in mind that a patent is a unilateral document and the patentee has chosen particular words to describe the invention;
- claims define the monopoly claimed in the patent;
- terms which are unclear in the claims may be defined or clarified by reference to the body of the specification;
- language which has no positive meaning in the claims may become clear when the specification is used as a 'dictionary' for the jargon in the claims; and
- that said, given the special function of the claims, it is impermissible to read into a claim an additional integer, or otherwise vary the scope of the claim, by reference to the body of the specification.

It is clear from the above propositions that the use which the court can make of the body of the specification will vary from case to case. There is a fine line between using the specification to construe the claim and using the specification in such a way as to add an impermissible gloss to the claims.

In *Inverness Medical Switzerland GmbH v MDS Diagnostics Pty Ltd* (2010) 85 IPR 525, Bennett J stated:

An essential part of the process of construction involves understanding the nature of the invention described and claimed and the way in which the patentee has used words or phrases in describing and then claiming that invention. Sometimes the patentee provides a clear dictionary in the body of the specification for words and phrases. However, that is not always the case. While a patent is a public instrument which must define a monopoly in such a way that it is not reasonably capable of being misunderstood, it is also appropriate to try and understand what the patentee seeks to convey by the words used, especially where those words convey matters of biological or technological complexity.

The Australian courts have endorsed the concept of the 'purposive' construction of a patent. In *Australian Mud Company Pty Ltd v Coretell Pty Ltd* (2011) 93 IPR 188, the Full Court stated:

To give a purposive construction to a patent specification, and in particular its claims, is not to engage in a process of reasoning that extends the patentee's monopoly to the 'ideas' disclosed in the specification. Nor does it extend the patentee's monopoly to products or processes that the patentee did not, by the claims, define as the invention, even if those products or processes can be seen to perform the same function as the invention or to be based on the patentee's "ideas".

Further, in the *Lundbeck* case cited above, Emmett J stated:

There is no warranty for adopting a method of construction that gives a patentee what it might have wished or intended to claim, rather than what the words of the relevant claim actually say. While such an approach may be appropriate where there is a genuine ambiguity, it is not permissible to read an entire limiting integer into the claim as written, when the claim clearly does not contain it.

1.3 Metabolites

An active metabolite, if novel and inventive and of utility, can be patented separately to the base compound – which then gives rise to the question of whether sales of the original drug substance infringe the patent claiming the active metabolite.

In *Merrell Dow Pharmaceuticals Inc v HN Norton and Co Ltd* [1996] 33 IPR 1 the House of Lords accepted the argument that, although some members of the public had been making the active metabolite by swallowing terfenadine before the date of the metabolite patent, they had not been aware of that fact and thus the prior use was not novelty destroying. However, the disclosure of the terfenadine patent specification itself, by teaching that it could be used as a pharmaceutical if injected, was held to anticipate the claim to the acid metabolite because the specification communicated to the public "information which enables it to do an act having the inevitable consequence of making the acid metabolite".

Although it has not been the subject of final judicial determination in Australia, it is strongly arguable that the reasoning applied by the House of Lords in *Merrell Dow* also holds good in Australia.

For example, in *Apotex Pty Ltd v Sanofi Aventis (No 2)* (2012) 204 FCR 494, Bennett and Yates JJ doubted that the 'inevitable result' cases can be uncritically applied in every case of alleged anticipation. Their Honours drew attention to the statutory test which denies novelty in Australia only in light of information made 'publicly available' (Section 7(1) of the Patents Act 1990). There was no necessity in that case

to explore the matter further. To similar effect, but again without considering the issue in substance, see *AstraZeneca AB v Apotex Pty Ltd* [2014] FCAFC 99.

2. Second-generation inventions

2.1 Combinations

Combinations, including combinations of active pharmaceutical ingredients, are inherently patentable if they are novel, inventive and useful. See *Minnesota Mining and Manufacturing Co (3M) v Beiersdorf* (1980) 144 CLR 253.

Under Section 50(1)(b) of the Patents Act 1990 a patent application may be refused on the ground that the specification claims as an invention a substance which is capable of being used as a medicine and is a mere mixture of known ingredients, or a process producing such a substance by mere admixture.

'Mixtures' embrace not only powders or granules, either loosely or in compacted form, but also mixtures of liquids or gases and include suspensions and solutions.

By 'mere mixture of known ingredients' is meant a mixture exhibiting only the aggregate of the known properties of the ingredients. If the result achieved by the invention is more than might be expected from a mere mixture (ie, synergism is established), the invention is patentable.

For a recent reference to combination patents see *AstraZeneca AB v Apotex Pty Ltd* [2014] FCAFC 99 [508]-[510].

2.2 Enantiomers

Enantiomers are inherently patentable in Australia provided that they satisfy the basic requirements for patentability – novelty, inventiveness and utility.

In the last few years there have been two important decisions, dealing with clopidogrel and escitalopram respectively, which have set out the principles relating to the novelty and inventiveness of enantiomer patents.

In the *Lundbeck*[1] and *Apotex*[2] cases, it was held that the mere disclosure of a compound by exact naming in the prior art was sufficient, of itself, to constitute anticipation. Those were not the facts in the *Lundbeck* case, but it was in *Apotex* in which the court held that the disclosure of a particular enantiomer in the prior art anticipated the later patent which claimed that the enantiomer, notwithstanding the compound consisting only of that enantiomer, had never been made.

The alternative line of authority in Australia, to the effect that a prior art disclosure must be 'enabling' in order to anticipate a later patent, is based on the decision in *Hill v Evans* [1862] ER 365 and of the decision of the Australian High Court in *Olin Corporation v Super Cartridge Co Pty Ltd* [1977] 180 CLR 236. In *Hill v Evans* it had been held that:

> *the prior knowledge of an invention to avoid a patent must be knowledge equal to that required to be given by a specification, namely, such knowledge as will enable the public to perceive the very discovery, and to carry the invention into practical use.*

1 *H Lundbeck A/S v Alphapharm Pty Ltd* [2009] 177 FCR 151.
2 *Apotex Pty Ltd v Sanofi-Aventis* [2009] 82 IPR 416.

The very issue of which strand of authority in relation to anticipation applied in the case of an enantiomer patent was considered in the decision of *Albany Molecular Research Inc (AMR) v Alphapharm Pty Ltd* [2011] FCA 120.

Faced with the apparently conflicting line of authority, the court in that case followed the *Lundbeck* and *Apotex* authorities to the effect that any prior disclosure of the compound anticipates, and it rejected the argument that only an enabling prior disclosure of the compound anticipates. The judge in that case was, however, clearly uncomfortable in the conclusion which His Honour felt bound to reach.

The judge considered the evidence of eminent organic chemists and concluded that the prior-art disclosure relied on did not disclose an effective means of preparing substantially pure fexofenadine, being the compound at issue in that case, and stated:

> *if I am wrong about the law as established in* Lundbeck *and* Apotex, *I would hold that the invention, so far as claimed in the claims which are presently relevant, was not anticipated by [the Carr patents].*

The current thrust of the authorities in Australia is that a prior disclosure must be enabling in order to anticipate a patent. In *Damorgold Pty Ltd v JAI Products Pty Ltd*,[3] Bennett J stated:

> *In order to destroy novelty the information [in the prior disclosure] must enable the notional person skilled in the art at once to perceive, to understand and to practically apply the discovery without the need to conduct further experiments … it is necessary to establish lack of novelty that [the prior disclosure] enabled the person to understand the invention by disclosing the essential integers of it.*

In assessment of the inventiveness of a patent for an enantiomer, the so-called 'worthwhile to try' test has been applied to determine obviousness. This is so because it is often the case, when dealing with an enantiomer patent, that the racemate forms part of the common general knowledge. In *Hässle v Alphapharm Pty Ltd* [2002] 212 CLR 411, the Australian High Court, by majority, approved the restatement of the so-called 'Cripps question' of Graham J in *Olin Mathison v Biorex*[4] which can be expressed in general terms as follows:

> *Would the notional research group, at the relevant date, in all the circumstances, directly be led as a matter of course, to try [the invention] in the expectation it might well produce a useful result?*

A recent application of the 'modified Cripps question' approach to considering inventive step (although not in the case an enantiomer patent) is *Bristol Myers Squibb v Apotex* [2015] FCAFC 2.

2.3 Selection inventions

In Australia, currently, the law in relation to selection patents is unsettled.

In the *Apotex* case referred to above, the trial judge expressed some doubt about the applicability in Australia of the concept of selection patents but nevertheless proceeded to consider the criteria for such a patent as set out in *IG Farbenindustrie* as referred to by the Full Court of the Federal Court of Australia in *Ranbaxy Australia Pty Ltd v Warner-*

3 [2015] FCAFC 31 (March 13 2015).
4 [1970] RPC 157.

Lambert Co LLC [2008] 778 IPR 449. At first instance in the Apotex case the trial judge said that, in his view, and after considering various authorities, the concept of a selection patent does not recognise a special class of patents at all but is merely "a convenient shorthand to pick up the relevant principles concerning anticipation".

The Full Court in *Ranbaxy* set out the principles by which a claimed invention constitutes a selection such that it is not anticipated by the disclosure of a class of compounds of which it is a member. The claimed member of the class must satisfy the following requirements:

- There must be some substantial advantage to be secured by the use of the selected members.
- The whole of the selected members must possess the advantage in question.
- The selection must be in respect of a quality of a special character, which can fairly be said to be peculiar to the group.
- The advantage possessed by the selected members must be clearly disclosed in the specification.

In the *Apotex* case, at first instance, the judge found that, if a selection were available, it would be satisfied by the selection of the d-enantiomer from the class comprising the d-enantiomer, the l-enantiomer and the racemate. The judge concluded that there was a substantial advantage to be secured by the use of the d-enantiomer, as compared with the use of either the racemic mixture or the l-enantiomer. The advantage was that the d-enantiomer was better tolerated or less toxic and as effective as the racemate at a lesser concentration. The trial judge also considered the second and fourth criteria set out immediately above to have been satisfied in that case.

On appeal, the Full Court of the Federal Court of Australia in *Apotex* avoided the issue of selection patents and in so doing stated:

> *It is not necessary to decide whether or not there is a special category of selection patents which, if they satisfy the test in IG Farbenindustrie, may overcome a lack of a claim of lack of novelty. Any such category was not, in our view, intended to exclude from the requirement of novelty a compound (here the d-enantiomer) that was previously disclosed and claimed as one of a class of inventive compounds that demonstrated, or were predicted to demonstrate, particular activity and tolerance at various levels, and the compound was then shown to demonstrate that same activity at a high level, with high tolerance.*

In *Eli Lilly v Apotex Pty Ltd* [2013] FCA 214 (March 15 2013) the court observed that it is not settled that the concept of selection patents forms part of the current law of novelty in Australia. Middleton J stated at [387]:

> *It is clear from the … authorities that patents for selection inventions (if such patents form part of Australian law) are based on the discovery of particularly desirable properties arising from the use of a specific material that has been broadly encompassed by a prior disclosure of a family of related materials. The principle of a selection patent presupposes that there is no novelty in the process of manufacture but that the novelty lies in the selection because it has particular merits (such as fresh or new advantages inherent in that selection) … Thus analysed selection patents encourage improvements.*

> *In ultimately finding the patent novel in that case Middleton J expressly stated that he was applying the selection patent principles 'without purporting to ultimately determine whether they form part of Australian Law'.*

Consequently, currently in Australia, as a matter of law, it is not clear that the courts will recognise the concept of a 'selection patent', whether in a pharmaceutical context or otherwise. The comments of the trial judge in the *Eli Lilly* case would suggest, however, that in the modern context in Australia the concept of a 'selection patent' may no longer find favour – at least as a separate and discernible category of patent but that, rather, considerations of the *IG Farbenindustrie* kind will be taken into account in any consideration of novelty.

2.4 Methods of use and secondary indications

Patents for new methods of use and new indications can be granted in Australia, provided the basic test for patentability is satisfied – in particular the novelty, inventiveness and utility requirements.

In Australia there is currently also a threshold test of patentability, separate to novelty and inventiveness. In order to be patentable, an invention must also be a 'manner of manufacture' within the concept of Section 6 of the Statute of Monopolies 1623 – an ancient English statute given currency in Australia by reason of its adoption into the Australian patent law pursuant to Section 18 of the Patents Act 1990. In *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, the High Court of Australia considered the expression 'manner of manufacture' to require an invention to give rise to an artificially created state of affairs in a field of economic endeavour for it to be patentable.

In the context of pharmaceuticals it is not unusual for an invention to be centred on the concept of a new use or application of a known product. It is commonplace for new uses that are found for known things to be the subject of the claims of a patent. Claims of that type, however, can only be valid where the new use arises from some previously unknown property of the known thing or in some adaptation of the thing to suit the new purpose or in other cases where the adaptation of an old process to a new use involves an inventive step. It was held in *Commissioner of Patents v Microcell Limited* [1959] 102 CLR 232 by the Australian High Court that a use of a known thing that is an exploitation of a known property of that thing is not patentable, notwithstanding that the use may be a new one.

2.5 Methods of treatment

Unlike Europe, for example, methods of medical treatment are directly patentable in Australia. In *Apotex Pty Ltd v Sanofi Aventis* [2013] HCA 50 it was finally determined unequivocally by the High Court of Australia that methods of treatment of the human body are patentable subject matter.

While it is also the practice in the Australian Patent Office for Swiss-style claims to be accepted, they have not been judicially considered in detail in Australia and

5 There was a brief consideration of claims in the Swiss-style form in *Otsuka Pharmaceutical Co Ltd v Generic Health* [2012] FCA 239.

their construction remains an open question.[5] It has been observed by a delegate of the Commissioner of Patents that Swiss-style claims should be interpreted in Australia in the same way that they are interpreted elsewhere – see *Smith Kline Beecham plc v Lek Pharmaceutical and Chemical Company* [2004] 61 IPR 626.

2.6 Formulations and physical forms

A patent is available in Australia for a new, inventive and useful formulation of a pharmaceutical compound. Polymorph inventions are similarly patentable. The most recent decision relating to the latter is that in *Bristol Myers Squibb v Apotex Pty Ltd* [2015] FCAFC 2 in relation to 'aripiprazole'.

2.7 Reach-through claims

In some cases an invention will reside in a method of testing or identifying properties of a particular entity but the claims will be directed to the entity itself, unlimited to that testing environment or any field of use. Such claims are known as 'reach-through' claims.

These reach-through claims are rarely supported over their full scope but, currently[6] in Australia, so long as there is an exemplification of at least one preferred embodiment the Patents Office will not be able to object to a reach-through claim set.

Such claims may, however, lack fair basis. The concept of a 'reach-through' claim contemplates that the underlying entity already existed prior to the testing process and was generated without recourse to it. Invention does not reside in the entity itself but in the consequential uses of the entity (based on the properties ascertained from the inventive method). Claims to the entity *per se*, without further limitation, may therefore be argued to claim matter beyond the subject matter of the invention and if they do that they are not fairly based on the disclosure, in contravention of Section 40(3) of the Patents Act 1990.[7]

3. DNA and biologicals

3.1 Discoveries

The orthodox position in Australia is that mere discoveries, fundamental concepts and principles, which include mathematical algorithms, formulas, calculations, directions for use, or some other form of intellectual information, are precluded from patentability.[8] However, if the application of knowledge in a particular scenario creates an 'artificial state of affairs', then it will be eligible for a patent (supposing it satisfies other criteria). For example, with regard to DNA, the current practice is that a claim to a naturally occurring DNA sequence is a mere discovery, but an isolated and purified sequence is proper subject matter for a patent.[9] At the time of writing,

6 At least for pre-Raising the Bar patents ie, those granted before April 15 2013 or where a request for examination was made before that date.
7 For pre-Raising the Bar patents. For post-Raising the Bar patents, fair basis has been replaced with a requirement that the claims be supported by matter disclosed in the specification.
8 See generally, *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252; *Grant v Commissioner of Patents* (2006) 154 FCR 62.
9 *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115.

there is a pending appeal to the Australian High Court which will finally determine this controversial issue.

3.2 Gene patents and industrial application

A valid Australian patent is required to pass a test of 'utility'.[10] It is akin to 'industrial application' but differs in function. The test requires that the claims, as defined and properly interpreted, are capable of achieving the promise of the patent.[11]

3.3 Stem cells, organic tissue and *ordre public*

Although there is no case in point, the Australian patent examiner's manual reflects the Australian Patents Office practice which permits patents in respect of organic tissue, including totipotent (but not pluripotent/multipotent) stem cells. No objection can be taken to a claim to a new organism on the ground that it is something living;[12] however, 'human beings and the biological processes for their generation' are not patentable.

Although Australia is a signatory to TRIPS, Australian patent law does not, at the moment, expressly include an *ordre public* or other type of morality exclusion. Australian courts are very wary of ethical and social policy concerns, having previously stated that it is an area in which they have no special expertise.[13]

3.4 Bioinformatics systems

Bioinformatics systems are made up of various components and each can attract different intellectual property protection. In Australia, copyright law will protect lines of code, as well as compilations of data.[14] User interfaces and programs can receive patent protection.[15] And for other aspects such as algorithms, which may not otherwise receive intellectual property protection, if it is only known to a small number of people, and is not readily able to be decompiled or reverse engineered then it may be protectable as a trade secret.[16]

3.5 Copyright and sequence information

No Australian case has considered whether nucleotide or peptide sequence information is capable of acquiring copyright protection. However, in light of recent decisions, sequence information would probably be unlikely to acquire copyright protection.[17] Although skill and labour is involved in sequence production, copyright protection is only afforded to effort that is directed to expression itself.[18] Since the

10 Patents Act 1990 (Cth), Section 18(1)(c).
11 Since the enactment of the Raising the Bar changes to the Patents Act, there is an additional requirement that the invention should have a specific, substantial and credible use.
12 Australian Patent Office, Manual of Practice and Procedure (February 22 2006) 2.7.1 and 2.9.2.14.
13 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* 50 FCR 1, 45.
14 Copyright Act 1968 (Cth), Section 10(1) (definition of 'literary work').
15 *International Business Machines Corp v Commissioner of Patents* (1991) 33 FCR 218.
16 *Saltman Engineering Co Ltd v Campbell Engineering Co Ltd* [1963] 3 All ER 413n, 415; *Moorgate Tobacco Co Ltd v Philip Morris Ltd* [No 2] (1984) 156 CLR 414, 437.
17 See generally, *IceTV Pty Ltd v Nine Network Australia Pty Ltd* 239 CLR 458; *Acohs Pty Ltd v Ucorp Pty Ltd* 86 IPR 492; *Telstra Corporation Ltd v Phone Directories Company Pty Ltd* 264 ALR 617.
18 *IceTV Pty Ltd v Nine Network Australia Pty Ltd* 239 CLR 458, 481.

expression of sequence information is primarily dictated by the nature of sequences itself, it is unlikely that sufficient originality would be found to acquire copyright protection.

3.6 Sufficiency issues

The requirement that a patent specification describe an invention fully is the Australian equivalent of sufficiency.[19] Since the Raising the Bar amendments to the Patents Act 1990, a different approach to sufficiency applies depending upon whether the patent was granted before April 15 2013 or upon a pending application in respect of which a request for examination had been made before that date. For pre-Raising the Bar patents, the specification must make it plain, to a hypothetical skilled person in the art, how to create or perform an invention.[20] This requirement is met if the specification discloses how to produce at least *one embodiment* of an invention,[21] even though the patent may claim multiple embodiments of the invention which are not described. For post-Raising the Bar patents, the complete specification must disclose an invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art. This is understood to be a requirement that the invention be enabled across the full scope of the claims.[22]

4. Acts of patent infringement

4.1 Direct Infringement

There is no definition of direct infringement in the Patents Act 1990. However, a patent gives the patentee the exclusive rights, during the term of the patent, to 'exploit' the invention and to authorise another person to exploit the invention.[23]

The rights given are:

- where the invention is a product – to make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or to keep it for the purpose of doing any of those things; or
- where the invention is a method or process – to use the method or process or do any act mentioned in the bullet point above in respect of a product resulting from such use.

The patentee (or any exclusive licensee) may take legal action to prevent infringement of the exclusive rights granted pursuant to a patent. Patent infringement may be either direct or contributory. The infringement is direct if a person, without licence or authorisation, exercises any of the exclusive rights of the patent holder.

19 Patents Act 1990 (Cth), Section 40(2)(a).
20 *Patent Gesellschaft AG v Saudi Livestock Transport and Trading Company* (1997) 37 IPR 523, 530.
21 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274, 297.
22 Patents Act 1990 (Cth), Section 40(2)(a).
23 Patents Act 1990, Section 13.

4.2 Contributory infringement

By virtue of Section 117 of the Patents Act, contributory infringement occurs where there is a supply of a product the use of which would constitute infringement of the patent.

The supply of a product will only amount to contributory infringement if one of the following conditions is satisfied:

- where the product is capable of only one reasonable use, having regard to its nature or design – supply for that use; or
- where the product is not a staple commercial product – supply for any use of the product, if the supplier had reason to believe that the person would put it to that use; or
- in any case – supply for the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.

4.3 *Bolar*-type provisions

In Australia, Section 119A of the Patents Act provides a *Bolar*-type defence to infringement.

This section was added to the Patents Act 1990 in 2006 and provides an exemption from infringement of a 'pharmaceutical patent', at any time during the term of such a patent, if the acts done are solely for obtaining regulatory approval in Australia or elsewhere. (A 'pharmaceutical patent' is defined as one which claims a pharmaceutical substance or a method, use or product relating to one. A pharmaceutical substance is, in turn, defined, in effect, as a substance for therapeutic use.)

The exemption does not apply to permit export of goods from Australia, unless the term of the patent has been extended and the goods contain a pharmaceutical substance *per se* (or have been produced by a process that involves the use of a recombinant DNA technology) (Section 119A(2)).

4.4 Experimental-use exemptions

The Raising the Bar amendments to the Patents Act introduced a new Section 119C, which provides a defence to infringement acts done for experimental purposes. 'Experimental purposes' are defined to include, but are not limited to, the following:

- determining the properties of the invention;
- determining the scope of a claim relating to the invention;
- improving or modifying the invention;
- determining the validity of the patent or of a claim relating to the invention;
- determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

4.5 Infringement of Second Medical Use Patents

Australia is one country that offers incentives for the development of new uses for known drugs by permitting such developments, where they are novel and inventive,

to be patented. The decision in *National Research Development Corp v Commission of Patents* (1959) 102 CLR 252 made this clear. In permitting patents to be granted for second medical uses of known drugs, problems can arise when a generic manufacturer is required to adopt fully the product information leaflet of the originator's product, in order to obtain marketing approval:

- the generic company's product information leaflet may be required to include all the medical indications for which the originator's product is registered, including patented indications;
- this could give rise to secondary patent infringement. If the patented indication is a second medical use for a known drug product and the first use is not patented, the result may be a *de facto* extension of the originator's first patent monopoly;

The Australian Therapeutic Goods Administration requires the sponsor of a generic pharmaceutical product to include a product information leaflet with the product. This must be in substantially the same form as the product information leaflet for the originator product (*Section 23(2)(ba) Therapeutic Goods Act 1989 (Cth) and Guidance 8: Product Information*, available at www.tga.gov.au). However, it does permit the generic sponsor to 'carve-out' specific indications. This practice is sometimes referred to as 'skinny labelling'.

The more controversial issue in Australia is not whether second medical uses of a known drug should be patentable, but in what circumstances a patent for a second medical use of a known product is infringed.

In Australia, there are three potential ways in which a patentee may argue that the supply of a generic is an infringement of a method of treatment claim:

- *Section 117 of the Australian Patents Act 1990*. This is commonly known as the 'contributory infringement' section of the Patents Act.
- *Principles of joint tort feasorship*. The company marketing the generic, by the act of supply, is aiding, inducing or procuring the infringement of the patent, by patients who use the products according to the patented method.
- *Authorisation*. The company supplying the generic is authorising the use of the product when the Patents Act gives the patentee the exclusive right to authorise other persons to exploit the invention during the patent term.

In Australia, there have been three recent cases, each dealing with the issue of 'skinny labelling' where a generic pharmaceutical company has attempted to launch a pharmaceutical product for a non-patented indication by carving out the patented indication from the relevant product information leaflet. The cases involve Leflunomide, Rosuvastatin and Pregabalin respectively.[24]

Despite the decision of the Australian High Court in the Leflunomide case, which appeared to give some hope to generic pharmaceutical companies seeking to launch a generic product in Australia with a 'skinny label', the subsequent Full Federal Court

24 *Apotex Pty Ltd v Sanofi-Aventis Pty Ltd* [2013] HCA 50; *AstraZeneca AB v Apotex* [2014] FCAFC 99; and *Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCAFC 59.

decisions in respect of Rosuvastatin and Pregabalin have signalled a judicial retreat from that high watermark.

The difficulty for a generic pharmaceutical company wishing to rely upon a 'skinny label' to avoid patent infringement in Australia is Section 117(2)(b) of the Patents Act, which makes it an infringement to supply a product to a person if the use of the product by that person would infringe a patent. The subsection deems the use of a product (which is not a staple commercial product) to be an infringement if the supplier had reason to believe that the person would put it to an infringing use.

In the Pregabalin case, the parties were agreed that, while the registered indications and approved product information documents were highly relevant for the purpose of determining whether infringement had occurred under Section 117(2)(b) of the Patents Act, they were not necessarily determinative, and it might be possible to establish the requisite reason to believe by reference to other evidence or the drawing of appropriate inferences. The court accepted that the reason to believe must be that of the supplier and might be subjective in the sense of an actual belief or, alternatively, objective in the sense that there are reasonable grounds so to believe.

In the Pregabalin case, Apotex amended its product registration and its product information leaflet to confine its registration to the use of Pregabalin for adjunctive therapy in adults with partial seizures. Warner-Lambert had a patented indication for the use of Pregabalin to treat neuropathic pain. The issue was whether Apotex had reason to believe that Pregabalin would be prescribed and used in the treatment of neuropathic pain, notwithstanding the carve-out of that indication from its product registration and product information leaflet.

The Full Court of the Federal Court emphasised the evidence given that the seizure indication market was practically non-existent and that doctors and pharmacists may well prescribe Apotex' bioequivalent product 'off-label' for neuropathic pain, notwithstanding the Apotex limited registration and proposed letters to prescribers warning against such off-label use.

The Pregabalin decision demonstrates that if there is clear and convincing evidence that the supplier had 'reason to believe' that the supplied pharmaceutical product would be put to an infringing use, then product registration limitations, product information leaflet carve-outs and announcement letters to doctors and pharmacists may not be enough to prevent the patent holder discharging the evidentiary burden necessary to establish contributory patent infringement.

4.6 Submitting authorisations and offers to supply

The mere filing of an application to list a therapeutic product on the Australian Register of Therapeutic Goods (ARTG) does not amount to an infringement of a patent relating to that product.

In Australia there is no linkage between the obtaining of marketing approval of pharmaceutical products and patents akin to the US Orange Book procedure. However, as a result of the Australia–US Free Trade Agreement, which took effect on January 1 2005, an applicant applying for the listing or registration of a therapeutic good on the ARTG must provide a certificate to the Australian Therapeutic Goods

11. Hot topics

Patentability of claims relating to dosage schedule is a hot topic in the light of the decision of the Paris Court of Appeal of January 30 2015 in *Merck v Actavis and Tiefenbacher* (as to which, see section 2.5 above).

Another hot topic is the patentability of stem cells in the light of the ruling handed down by the CJEU on December 18 2014 in the *International Stem Cell Corporation* case (as to which, see section 3.3 above).

Germany

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1. Small molecules

1.1 Product and process claims

Patent protection is possible for compounds (product claims) and processes (process claims). The scope of protection is, however, different with regard to the acts that can be prohibited (see section 4.1 below).

Use claims – in particular, purpose-limited product claims – form another possible type of claim. Although product claims protect any kind of use to which the claimed product may be put, use claims (in particular, those for a second medical use) only cover the use of the product for the specified purpose. Product-by-process claims, which relate to describing a product by reference only to the manner in which it has been manufactured or processed, are considered to be product claims.

1.2 Scope of protection of claims and *Markush* formulas

The scope of protection is determined on the basis of the wording of the claims by taking into consideration the specification, including the cited prior art, the examples and drawings and the general knowledge of the person skilled in the art at the priority date (Section 14 of the German Patent Act). The specification and the examples do not, however, limit the scope of protection if the claim language is broader than the explanations given in the specification and examples – and in such a case, insufficiency arguments should be considered: see section 3.6 below.

In principle, any compound falling under a *Markush* formula would therefore be within the scope of protection of a patent. It should, however, be noted that such a patent might not be a suitable basic patent for subsequently receiving protection under Regulation (EC) 469/2009 (codified version) concerning the supplementary protection certificate for medicinal products (the SPC Regulation) if the specific compound contained in the medicinal product to which the SPC relates is not covered by the claims of the patent.[1] Furthermore, a *Markush* formula does not of itself contain a novelty-destroying disclosure for any compound falling under the scope of the formula; this arises only if the relevant compound is recognisably individualised in the document.[2]

1 The old German case law (German Federal Supreme Court, GRUR 2002, 415 – *Sumatriptan*, January 29 2002) is no longer applicable following the decision of the Court of Justice of the European Union (CJEU), in *Medeva*, C-322/10, November 24 2011.

2 Federal Supreme Court, GRUR 2009, 382, at 385 – *Olanzapine*, December 16 2008.

1.3 Metabolites

In a decision of 1993 the Munich Appeal Court[3] considered the question of whether the utilisation of the drug terfenadine after the expiry of patent protection for that drug constituted infringement of a patent protecting terfenadine's active metabolite, MDL 16455.[4] The court held that the scope of a patent is not infringed where a pharmaceutically active ingredient was made and applied in accordance with an expired patent, even though that ingredient, once in the patient's body, is converted to a compound protected under a new patent.

2. Secondary patents

2.1 Combinations

Combinations of known substances are patentable in accordance with the general rules – ie, if the combination is new and implies an inventive step. In particular, if the combination creates synergistic effects that go beyond the mere addition of the effects of the combined substances, this can be an indication of an inventive step. However, so-called 'bonus effects' (ie, additional effects) do not imply an inventive step if the combination was obvious for the person skilled in the art even if the bonus effects are unexpected and surprising for the given combination of known substances.[5]

2.2 Enantiomers

Providing an enantiomer from a compound previously only known as racemate (ie, a mixture of enantiomers) can imply an inventive step even if the existence of enantiomers has been obvious from the prior art. The crucial factor for the assessment of the inventive step is the question of whether there was an obvious way to achieve the single enantiomer for the person skilled in the art at the priority date.[6]

2.3 Selection inventions

In principle, the same requirements applicable to novelty and inventive step regarding the above-mentioned enantiomers apply to selection inventions as well. In so far as the prior art does not yet disclose a specific compound – eg, when only a *Markush* formula has been known – identification of a compound might be novel (see section 1.2 above). Furthermore, the intentional selection from a larger range can be considered as inventive, while an arbitrary selection of a smaller range from a larger range is in itself rather an obvious decision for the person skilled in the art.[7]

3 6 U 5155/92 – *Terfenadine*, June 3 1993.
4 It should be noted that because of the bifurcated system in Germany, whereby nullity and infringement proceedings are decided separately, this decision relates only to infringement.
5 German Federal Supreme Court, X ZR 68/99, GRUR 2003, 317 – *Kosmetisches Sonnenschutzmittel I*, February 12 2002; Xa ZR 130/07, GRUR 2010, 123 – *Escitalopram*, September 10 2009.
6 *Escitalopram* (note 6 above).
7 German Federal Supreme Court, X ZR 7/00, GRUR 2004, 47 – *Blasenfreie Gummibahn I*, September 24 2003; X ZR 56/03, GRUR 2008, 56 – *Injizierbarer Mikroschaum*, May 22 2007.

2.4 Methods of use and secondary indications

A second medical use may be patentable provided that the secondary indication is novel, involves inventive step and is susceptible to industrial application. Second-medical-use claims can, in particular, cover a new therapeutic use, a new dosage regime, a new mode of application or a new patient subgroup.

Although the German Federal Supreme Court in the *Carvedilol II* case was reluctant to accept the patentability of so-called 'pure dosage suggestions', it accepted the patentability of claims requiring that the medicament is 'prepared' for the said dosage.[8] In a more recent decision, the court clarified that these reservations are in particular not applicable in relation to purpose-limited product claims.[9]

2.5 Methods of treatment

According to the exception stated in Section 2a(1)(2) of the German Patent Act, patents are not granted for methods of treatment of the human or animal body by surgery or therapy. The act clarifies that this exception does not apply to products – in particular, substances or compositions – for use in such methods. As a matter of principle, exceptions are to be construed narrowly.

2.6 Formulations and physical forms

With regard to combinations or second-medical-use claims, formulations and physical forms can be patented if they are new and imply an inventive step. Within the assessment of the inventive step, it will be of particular importance whether the person skilled in the art, having sufficient motivation based on the prior art to apply a known measure to a known substance, had a reasonable expectation of success for solving the technical problem.[10]

2.7 Reach-through claims

'Reach-through' claims are claims directed to a chemical compound (or the use of that compound) defined only in functional terms with regard to the technical effect it exerts on one of the molecules. Patent protection is not possible if the claims are directed to merely functionally defined chemical compounds that are to be found by means of a new kind of research tool (eg, by using a new screening method based on a newly discovered molecule or a new mechanism of action) because they are directed to future inventions.[11] If the subject-matter of the claims can be limited to the actual contribution to the art, it can be patented. Nevertheless, sufficiency of the technical disclosure typically needs careful consideration.[12]

8 German Federal Supreme Court, X ZR 236/01, IIC 2007, 479 – *Carvedilol II*, December 19 2006.
9 German Federal Supreme Court, X ZB 6/13 – *Kollagenase II*, February 25 2014.
10 German Federal Supreme Court, X ZR 98/09, GRUR 2012, 803 – *Calcipotriol-Monohydrat*, May 15 2012.
11 European Patent Office (EPO), Technical Board of Appeal, T 1063/06 – *Reach-Through Claim/Bayer Schering Pharma AG*, February 3 2009.
12 German Patent Court, 3 Ni 5/10 – *Filamentous bacteriophage particles*, January 24 2012. See also section 3.6 later in this chapter.

3. DNA and biologicals

3.1 Discoveries

A finding or discovery merely explains the biological processes underlying the efficacy of the substance for treating a specific condition and can therefore not be patented, unless the finding or discovery leads to some novel teaching involving, for example, a new indication of use or dosage regimen or application to a new patient group.[13]

3.2 Gene patents and industrial application

According to Section 1(2) of the German Patent Act, patent protection is also possible if the subject matter concerns a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used. Biological material that has been isolated from its natural environment or produced by means of a technical process may be the subject matter of an invention even if it had previously occurred in nature.

The human body at its various stages of formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute a patentable invention (Section 1a(1) of the German Patent Act). However, an element isolated from the human body or otherwise produced by means of a technical process (including the sequence or partial sequence of a gene) may constitute a patentable invention even if the structure of that element is identical to that of a natural element (Section 1a(2) of the same act). Such isolated elements could be, for example, gene sequences, partial sequences, peptides, proteins, membranes and adult stem cells.

For patentability it is furthermore necessary that the industrial application of a sequence or a partial sequence of a gene is specifically disclosed in the application by indicating the function fulfilled by the sequence or partial sequence (Section 1a(3) of the same act).

3.3 Stem cells, organic tissue and public order

Patent protection for inventions is not permitted in principle if their commercial exploitation would be contrary to public order or morality. Such a contravention may not, however, be deduced simply from the fact that such exploitation is prohibited by law or administrative regulation.

In particular, by virtue of Section 2(2) of the German Patent Act, patents cannot be granted for:

- processes for cloning human beings;
- processes for modifying the genetic identity of the germ line of human beings;
- uses of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals, where such processes are likely to cause those animals suffering without any substantial medical benefit to man or animal; and
- animals resulting from such processes.

Germany's Protection of Embryos Act is also relevant in this regard.

It has been decided judicially that precursor cells received from human embryonic stem cells could not be patented where the patent description specified that stem cell lines and stem cells received from human embryos should be used as a starting point. It would, however, be acceptable to delimit the patent claim in such a way that precursor cells are derived from human embryonic stem cells, provided that no embryo is destroyed for their production.[14]

3.4 Bioinformatics systems

Bioinformatics systems – ie, genomics and proteomics computer systems for identifying drug targets based on gene and protein sequences – can be patentable on the basis of the general requirements, ie, where there is a novel and inventive technical invention. In particular with regard to the technical character of the invention, European Patent Office (EPO) case law on computer-implemented inventions should be considered.

3.5 Copyright and sequence information

There is no case law in Germany in this regard.

3.6 Sufficiency issues

Under Section 21(1)(2) of the German Patent Act (which corresponds to Article 138(1)(b) of the European Patent Convention), a patent is to be revoked if the invention is not disclosed sufficiently clearly and completely for it to be carried out by a person skilled in the art. According to German case law, an invention is not 'sufficiently disclosed' if the person skilled in the art could not derive the contribution of the patent to the state of the art from the full disclosure of the patent without having to apply inventive thoughts.[15] It is not, however, necessary to disclose any possible way to carry out the teaching of the patent, but disclosure of one feasible possibility is usually considered to be sufficient.[16] On the other hand, if the person skilled in the art has to apply a trial-and-error approach, the patent lacks sufficient disclosure.[17]

However, the German Federal Supreme Court recently decided[18] that the applicant may in principle generalise certain features of the claim in order to achieve a fair scope of protection with regard to the patent's contribution to the art. Apart

13 German Federal Supreme Court, X ZR 68/08, GRUR 2011, 999 – *Memantin*, June 9 2011; X ZR 40/12, GRUR 2014, 54 – *Fettsäuren*, September 24 2013.

14 German Federal Supreme Court, X ZR 58/07 – *Neurale Vorläuferzellen II*, November 27 2012. See also CJEU, C-34/10, GRUR 2011, 1104 – *Oliver Brüstle / Greenpeace eV*, October 18 2011.

15 German Federal Supreme Court, GRUR 2010, 414 – *Thermoplastische Zusammensetzung*, February 25 2010; Federal Patent Court, GRUR 2011, 905 – *Buprenorphinpflaster*, November 23 2010.

16 German Federal Supreme Court, GRUR 2001, 813 – *Taxol*, May 3 2001. See also section 21 item 31 of Busse and Keukenschrijver, *Commentary on the Patent Act*, 7th edn, de Gruyter, 2012.

17 *Buprenorphinpflaster* (note 16 above).

18 German Federal Supreme Court, X ZB 8/12 – *Dipeptidyl-Peptidase Inhibitors*, September 11 2013.

from confirming the general permissibility of generalisations, the court stressed that the admissibility must always be considered in view of the particular circumstances of the case.

4. Acts of patent infringement

4.1 Direct infringement

Acts of patent infringement depend upon the nature of the patented claim.

- In the case of a product claim, the right holder can prohibit the manufacture, offer, putting on the market, or use of a product that is the subject matter of the patent, or the import or possession of the product for such purposes (Section 9(2)(1) of the German Patent Act).
- In the case of a process claim, the right holder can prohibit the use of the process that is the subject matter of the patent as well as the offer of the process for use within Germany, where the person offering the process knows, or it is obvious from the circumstances, that the use of the process is prohibited without the consent of the patentee (Section 9(2)(2) of the same act).
- Furthermore, offering, putting on the market, using or importing or possessing for such purposes the product obtained directly by a process which is the subject matter of the patent can be prohibited (Section 9(2)(3) of the same act).

4.2 Contributory infringement

A patentee can prohibit any person from supplying or offering to supply, within Germany, a person, other than a person entitled to exploit the patent, with means relating to an essential element of such invention for exploiting the invention, where such person knows or it is obvious from the circumstances that such means are suitable and intended for exploiting the invention (Section 10 of the German Patent Act). See also section 4.5 below.

4.3 National treatment of *Bolar*-type provisions

The so-called *Bolar* exemption was implemented in Germany in 2005 by Section 11(2b) of the German Patent Act, which implemented Article 10(6) of Directive 2001/83/EC (the Recast Medical Device Directive). It states that the effects of a patent do not extend to studies and trials and the resulting practical requirements necessary for obtaining a marketing authorisation to place a medicinal product on the market in the European Union or marketing approval for a medicinal product in the member states of the European Union or elsewhere.

There is no distinction between marketing authorisations for generic and innovative drugs, and the exemption applies regardless of whether these authorisations are obtained in Europe or elsewhere. The provision covers studies and trials and the resulting practical requirements – ie, the making, import, possession and use of patent protected substances – if and in so far as it is necessary for obtaining marketing approval in a certain jurisdiction.

The German courts recently had to decide whether a third party supplying an active pharmaceutical ingredient (namely, API) could benefit from the *Bolar* exemption if the delivery was made for the sole purpose of allowing the generic manufacturer to undertake the studies and trials in order to obtain a marketing authorisation with the supplied amount of the API. At first instance, the Düsseldorf District Court decided that such a third-party supply was only exempted by the *Bolar* provision under very restrictive conditions, namely when the supplier was co-organiser of the tests and studies carried out by its customer and thereby allowed under the *Bolar* exemption.[19] The Düsseldorf Court of Appeals disagreed and referred the question to the CJEU. According to the Düsseldorf Court of Appeals, third-party supply can be allowed under certain conditions – in particular, if the supply is aimed at the privileged purposes.[20] The supplier must ensure, for example by applying contractual penalties, that the delivered API is only used for purposes falling within the *Bolar* exemption. Unfortunately, the case was settled before the CJEU could render a decision, and so the requirements for exemption of third-party suppliers remain unclear.

4.4 Experimental use exemptions

Section 11(2a) of the German Patent Act exempts acts done for experimental purposes relating to the subject matter of a patented invention. In principle, an experimental purpose arises if the normally infringing act only serves the purpose of acquiring new knowledge about the patented subject matter. According to the German Federal Supreme Court, it is not required that the experiments should serve exclusively scientific purposes.[21] Commercial activities are also exempted, in particular if a patented substance has been used to find out whether and in what form it can be used to cure other diseases, or for clinical experiments designed to acquire new knowledge for a pharmaceutical application, or for activities which seek to overcome uncertainty about the effect and the tolerance of a patented substance. Such acts are also considered to fall within the scope of 'experimental purposes'.

4.5 Infringement of second medical use patents

Infringement of second-medical-use claims requires a 'manifest arrangement' for the use claimed in the patent.[22] This is usually the case if a drug is marketed with a labelling or package leaflet which refers to the specific indication of use. There are only a few, but well established, cases in Germany on the question of infringement of second-medical-use patents. In most cases, a party has marketed the drug with instructions on the label that describe the patented use. Such a party may be liable for direct infringement because by adding these instructions, the drug is manifestly arranged for the use claimed in the patent. Such manifest arrangement is, however, not necessarily made by the instructions on the label, although this is the most

19 Düsseldorf District Court, 4a O 282/10 – *Solifenacin*, July 26 2012.
20 Düsseldorf Court of Appeals, I-2 U 68/12 – *Solifenacin*, December 5 2013.
21 German Federal Supreme Court, X ZR 99/92, NJW 1986, 782 – *Klinische Versuche*, July 11 1995.
22 German Federal Supreme Court, NJW 1984, 663 – *Hydropyridin*, September 20 1983; GRUR 2001, 730 – *Trigonellin*, March 20 2001.

frequent way; other ways may include formulating, dosing or providing ready-to-use preparations of a drug, provided that it is done to achieve the patented purpose.

A 'manifest arrangement' requires, however, that the purpose of use is closely linked to the product as marketed. It has been found in recent cases that information about a drug in marketing material and flyers, as well as explanations made by salespeople, are not sufficiently attributable to the product, so that infringement was denied.[23] The courts held that the drug had been marketed as such – ie, in a way not covered by the second-medical-use patent. As the flyers, marketing material and explanations were not directly linked to the product, it is not certain that the customer would have taken them into consideration at all, so it is not clear that the patented purpose of the second-medical-use patent would have been fulfilled.

In the *Ribavirin* decision,[24] it was held that contributory infringement of second-medical-use claims could only arise if the essential means, such as the API, were offered or distributed for the purpose of being manifestly arranged. The offer or distribution for the use of the manifestly arranged product as such does not contributorily infringe. In more recent decisions,[25] contributory infringement has not been alleged by plaintiffs and therefore has not been decided upon by the courts. In a preliminary injunction proceedings in 2015 the District Court of Hamburg deviated from *Ribavirin* case law by stating that there is contributory infringement of the generic manufacturer if a drug marketed under 'skinny' labelling – ie, where the patented use is deleted from the labelling or product leaflet – is sold by a pharmacist to a customer for use for the patented indication, because German social law requires automatic substitution of the originator product by the generic product if there is only one overlapping indication.[26]

4.6 Submitting authorisations and offers to supply

(a) Marketing authorisation

Applying for a marketing authorisation as a preparatory measure can create a risk of future infringement if the patent underlying the medicament will not expire reasonably soon after the grant of the authorisation or within a reasonable period before the authorisation expires.[27]

(b) Offer to supply before the expiry of the patent

Every manufacture, sale, offer, putting on the market, use (or the like) of a product in Germany by unauthorised parties before the expiry of the relevant patents is a patent infringement. When assessing the question of patent infringement, the German courts do not differentiate whether the actual sales will occur before or after the expiry of a patent. Every offer, tender, advertisement, sales agreement or the like

23 Düsseldorf Court of Appeals, 2 U 54/11, – *Cistus Incanus*, January 31 2013; Düsseldorf District Court, 4a O 145/12, – *Chronic Hepatitis C*, March 14 2013.
24 Düsseldorf District Court, GRUR-RR 2004, 193, at 196 – *Ribavirin*, February 24 2004.
25 *Cistus Incanus* (note 25 above); *Chronic Hepatitis C* (note 25 above).
26 Hamburg District Court, 327 0 67/12 – *Pregabalin*, April 2 2015.
27 Düsseldorf Court of Appeals, I-2 U 44/12, GRUR-RR 2013, 241 – *HIV Medikament*, September 20 2012.

relating to the product before the expiry of the relevant patents – even if the actual delivery or sale takes place only after the expiry – will be regarded as a patent infringement in Germany.

In the *Simvastatin* case, the German Federal Supreme Court explicitly stated that the listing in the Lauer-Taxe[28] before the expiry of the lifetime of the patent/SPC was to be considered as a patent-infringing 'offer' of the product, even though it was clear that the product would only be delivered after expiry of the patent.[29] The reason for this is that the announcement of the future launch of the product might influence potential customers and have an effect on sales of the patented product.

4.7 Other activities that may constitute infringement

See the previous text in section 4.6 above.

5. Patent enforcement

As a result of Enforcement Directive 2004/48/EC, remedies are substantially similar throughout the European Union.

5.1 Obtaining information on the infringer and the infringement

The infringer can be obliged to render detailed information – eg, on the numbers of items manufactured, distributed, sold, imported, exported etc, the names and addresses of suppliers and customers, and purchase and sales prices. Furthermore, the infringer can be required to submit order confirmations, delivery receipts or invoices.

5.2 Preliminary relief

Preliminary relief is of particular importance in the life sciences industry. In the event of market launches, German courts easily grant preliminary injunctions – and even order recall from the market on a preliminary basis – if the generic manufacturer has not cleared the way sufficiently before the launch.

In addition to demonstrating a clear case of infringement and the balance of convenience, the validity of the patent must in principle be secured. In preliminary proceedings, this is to be proved by the patent owner. The validity of a patent is regarded as secured if the patent has survived contentious proceedings, such as opposition or nullity proceedings, or if there were third-party observations during patent prosecution, which are considered equivalent to contentious proceedings. In cases of generic launches, however, the most frequented courts of Düsseldorf at least make an exception from the requirement of secured validity and require the generic company to clear the way before the launch because of the typical risk of a significant price drop of the pharmaceutical following a generic launch.[30]

5.3 Springboard/post-patent expiry injunctions

Damages can be granted in 'springboard'/post-patent expiry cases. However, as set

28 Lauer-Taxe is the database in which all pharmaceutical products sold by pharmacies in Germany must be listed.
29 German Federal Supreme Court, X ZR 76/05, GRUR 2007, 221 – *Simvastatin*, December 5 2006.
30 Düsseldorf Court of Appeals, GRUR-RR 2013, 236 – *Flupirtin-Maleat*, January 17 2013.

out in a 2014 decision,[31] there are high requirements for substantiation and evidence that damage indeed occurred as a result of the patent infringement.

5.4 Joining health authorities

Recently, public health insurances have been obliged by the German Cartel Office[32] to repeat generic tenders with the obligation to respect the fact that certain indications are patent-protected. Reciprocally, the Hamburg District Court[33] found generic manufacturers liable for contributory patent infringement because they had participated in a tender without ensuring that the skinny-labelled generic product is not sold for the patented indication. The background of these decisions is that German social law permits – and, under certain conditions, even requires – the automatic substitution of originator products by less expensive generic versions if this had not been explicitly excluded by the physician prescribing the drug.

5.5 Unjustified threats

Using court proceedings – as unfounded as a claim might be – is in principle not illegal, as the defendant can use its procedural rights to defend itself. Only if the commencement of proceedings could be considered as an intentional immoral injury under Section 826 of the German Civil Code would it constitute illegal behaviour and could give rise to a claim for damages. This is, however, a very exceptional case.

Unjustified threats out of court – in particular, by means of unfounded warning letters containing the request to give a declaration to cease and desist within a certain deadline – are considered to be an interference with the established business of the recipient under Section 823(1) of the German Civil Code, and the person sending such unfounded warning letters may be found liable for damages.

5.6 Remedies

(a) *Permanent injunctive relief*

The most important remedy is injunctive relief under Section 139(1) of the German Patent Act. Provided that there is a risk either of imminent infringement or of the repetition of infringing acts, such relief is usually granted by German courts automatically after finding the patent infringed – ie, without applying additional considerations on the appropriateness of injunctive relief in the specific case.[34]

(b) *Destruction and recall from the market*

The injured party may request the destruction of infringing goods under Section 140a(1) of the German Patent Act, as well as their removal from the market under Section 140a(3) of that act. In the life sciences in particular, the latter remedy is important in

31 Düsseldorf District Court, 4c O 113/13 – *G-CSF-Polypeptid*, October 10 2014.
32 German Federal Cartel Office, VK 2 – 7/15, March 16 2015.
33 Hamburg District Court, 327 0 67/12 – *Pregabalin*, April 2 2015.
34 For a detailed explanation and case law, see Lunze in *Cepl/Voß, Prozesskommentar zum Gewerblichen Rechtsschutz*, 2015, paragraph 707 item 20.

order to ensure that the infringing products are removed from pharmacies. Recall from the market has even been granted in preliminary proceedings.[35]

(c) *Damages*

Following the rendering of information and account by the infringer, the injured party is free to choose one of three methods of calculating damages:

- reasonable royalty fee;
- infringer's profits; or
- lost profits of the injured party.

The Düsseldorf Court of Appeals recently asked the CJEU to clarify the methods for calculating a reasonable royalty, in particular whether and to what extent an infringer's surcharge could be required.[36]

6. Compulsory licensing

Compulsory licensing is in principle possible under Section 24 of the German Patent Act, which requires that:

- the person seeking a compulsory licence must have tried unsuccessfully to obtain a contractual licence from the patentee within an appropriate time period and subject to reasonable and fair conditions; and
- the grant of the licence must be in the public interest.

This provision has, however, no practical relevance at all.

7. Ownership, inventors and compensation

Employee inventions are considered to belong to the employer if the employer does not formally release the invention to the employee within four months after being notified of the invention.[37] The employee–inventor needs to be appropriately compensated by the employer for the use of the invention in accordance with the mandatory German Employee's Invention Act. Inventors employed by universities have specific publication rights and rights to use their invention in the course of their academic research and work, pursuant to Section 42 of the German Employee's Invention Act.

8. Branding and designs

8.1 Trademarks in life sciences

As trademark law is substantially harmonised in the European Union, this section focuses on aspects in which German law or practice differs from that at an EU level.

The registration procedure for German national trademarks differs to some

35 Munich Court of Appeals, 6 U 1560/12, June 28 2012.
36 Düsseldorf Court of Appeals, I-15 U 21/14, October 16 2014; for more details, see Bröker at www.taylorwessing.com/synapse/ti_infringer_surcharge.html.
37 This applies to inventions notified to the employer since October 1 2009. For all inventions notified before that date, the employer had to claim the invention formally within four months after the notification, otherwise the invention would have been released to the employee. As this was a major source of conflict, the GEIA was amended with effect from October 1 2009.