The “Experimental Use” and “Bolar” Infringement Exemptions in Europe

Andrew Teuten
Sagittarius IP

Introduction

The objective of this paper is to review the “Experimental Use” and “Bolar” Research Exemptions in Europe in terms of their legislative basis, how they have been interpreted in court cases, and what differences of scope appear to exist across the continent. Further legislative changes are afoot and these will also be discussed.

A starting point – the position in the UK

It is convenient to take, as a starting point, the position in the UK. Exemptions from infringement are provided in s60(5) of the Patents Act 1977. For the purposes of the present discussion, subsections (b) and (i) are important:

An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if:

(b) it is done for experimental purposes relating to the subject matter of the invention;...

(i) it consists of (a) an act done in conducting a study, test or trial for and is conducted with a view to the application of... paragraphs 1 to 4 of article 10 of Directive 2001/83/EC [EU generic medicines law], or (b) any other act which is required for the purpose of the application of those paragraphs."

Subsection (b) is the “experimental use” exemption and subsection (i) is the UK implementation of the “Bolar” provision. Subsection (i) also makes reference to acts done in relation to submissions of generic veterinary products (paragraphs 1 to 5 of Directive 2001/82/EC) but this will not be further discussed in this paper.

As will be discussed in more detail later, the expression “experimental purposes relating to the subject matter of the invention” in subsection (b) has been the subject of court interpretation in terms of whether it allows working with or working on an invention. The expression “conducted with a view to the application of... paragraphs 1 to 4 of article 10 of Directive 2001/83/EC” clearly limits the benefit of the “Bolar” provision in the UK to acts done with a view to developing a generic medicine. This is notably different from the scope of “Bolar” provisions in other major jurisdictions, notably the US and Canada.

Variant provisions corresponding to (b) and (i) exist in the other countries of Europe.

A historical perspective – the “experimental use” exemption

The position in the UK

The “experimental use” exemption (s60(5)(b)) that we have in the UK is based on language found in the Community Patent Convention of 1975. Note that this was never brought into effect however the UK law was substantially harmonised with it when revised in 1977 and most European countries also have very similar provisions. The Unified Patent Court agreement of February 2013 that will be
discussed later contains an experimental use exemption (Article 27(b)) with identical wording to that of s60(5)(b).

The key case concerning the interpretation of s60(5)(b) in the UK is Monsanto v Stauffer, Court of Appeal, 1985. This case concerns a claim for an interim injunction by Monsanto concerning field trials that were being performed by Stauffer on a generic plant protection product. The facts of the case are unusual in that since it concerned an application for an interim injunction it was not fully argued at trial and, moreover, the generic product being contested was actually on the market following extensive field trials but further field trials were being conducted to obtain certain post-marketing approvals.

The key passage from the judgment of the Court of Appeal in its finding in favour of Monsanto was as follows:

“trials carried out in order to discover something unknown, or to test a hypothesis, or even in order to find out whether something which is known to work in specific conditions...will work in different conditions can fairly ...be regarded as experiments. But trials carried out in order to demonstrate to a third party that a product works, or in order to amass information to satisfy a third party, whether a customer or a [regulatory] body...that the product works as the maker claims are not to be regarded as acts done for “experimental purposes””.

Practitioners in the UK understand this to mean that experiments “on” the subject matter of an invention with a view to finding some new information (such as a new use for a patented drug, as an example) are exempted whereas experiments “with” the subject matter of an invention (such as clinical trials on a generic medicine) are not exempted.

The position in Germany

During the 1990’s two key cases emerged from the German Supreme Court which have significantly clarified the scope of the experimental use exemption in Germany and have influenced the position elsewhere.

In the first case, known as “Clinical Trials 1” (BGH, 1997), the German Supreme Court decided that the experimental use exemption permitted the carrying out of clinical trials on a patented drug to ascertain its effects on medical indications not mentioned in the patent.

This principle appears similar to the UK “new information” test and, incidentally, was cited with approval in a recent UK case CoreValve v Edwards (Patents Court, 2009).

In the second case, known as “Clinical Trials II” (BGH, 1998), the German Supreme Court went significantly further and held that the experimental use exemption permits the carrying out of clinical trials to ascertain whether the tested product works as well as (or better than) the patentee’s commercial product.

This decision appears to approve the conducting of clinical trials with a view to obtaining a marketing authorisation for a generic product, and therefore extended the scope of the experimental use exemption in Germany far beyond that in the UK.

The “Bolar” exemption in Europe

In 2004, no doubt noting this clear discrepancy between UK and Germany, the European Union decided to clarify and harmonise the law concerning the possibility to perform clinical trials on generic medicines prior to patent expiry by introducing a “Bolar” type provision into EU law. The law
was brought in by means of EU Directive 2004/27/EC amending the EU code relating to medicinal products (Directive 2001/83/EC) and was implemented in the UK in October 2005 and in other member states at around the same time. It is important to note that, unlike in the US, this “Bolar” provision was not a quid pro quo for the patent term extension legislation. Europe’s patent term extension legislation had been brought into effect in 1993 without any “Bolar” provision.

The wording of amended Directive 2001/83/EC section 10(6) is:

> “Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”

Paragraphs 1, 2, 3 and 4 of section 10 of Directive 2001/83/EC concern applications for a generic medicine using the abridged procedure in the EU. Thus the explicit wording of the European “Bolar” provision provides exemption from infringement only for acts done with a view to submission of an application of a marketing authorisation for a generic medicine in the EU. It does not cover acts done with a view to submission of an application of a marketing authorisation of a new (innovative) medicine, nor does it cover acts done with a view to submission of an application of a marketing authorisation outside of the EU.

Readers not familiar with EU law making should note that when the EU introduces law by means of a Directive, this does not have direct legal effect (in this respect the position can be contrasted with that of a Regulation, which does have direct effect). Accordingly, EU member states have some discretion in terms of how the effect of a new EU Directive is implemented. Accordingly, around Europe there were a wide range of different implementations depending on the local culture, the state of existing case law concerning the experimental use exemption (as in Germany) and whether “Bolar” provisions already existed (as in many countries of Eastern Europe).

“Bolar” implementation – UK vs Germany

As noted above, the UK wording of the “Bolar” provision provides an exemption for:

(a) an act done in conducting a study, test or trial for and is conducted with a view to the application of... paragraphs 1 to 4 of article 10 of Directive 2001/83/EC or (b) any other act which is required for the purpose of the application of those paragraphs .”

By contrast, the German wording of the “Bolar” provision provides an exemption for:

“studies and trials and the resulting practical requirements necessary for obtaining a marketing authorisation to place a medicinal product on the market in the EU or a marketing approval for a medicinal product in the Member States of the EU or in third countries...”

Thus the UK implementation follows the literal wording of the EU Directive (what I will call “narrow Bolar”) and the German wording broadens it to extend the exemption also to innovative drugs and applications for marketing authorisation outside of the EU (what I will call “broad Bolar”).

Overview of “Bolar” implementation around Europe

Various countries have implemented the “Bolar” provision in strict (i.e. narrow) terms, more or less following the wording of the EU Directive. Countries in this situation include: UK, Belgium, Ireland, Greece, Cyprus, Netherlands, Sweden, Spain* and Luxembourg.

*limited to necessary acts for generic drug marketing authorisations, but not limited to EU marketing authorisations
More countries have implemented the “Bolar” provision in broader terms, somewhat like the position in the US, where the exemption is not limited to necessary acts for generic drug marketing authorisations. Countries in this situation include: Germany, Austria, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovak Republic and Slovenia. Switzerland, although not an EU country, has implemented a “Bolar” provision in these terms.

Some more detail on the precise wording of the “Bolar” provision for a selection of EU countries is given below:

Austria: exemption for “studies and trials as well as to the consequential practical requirements, as far as they are necessary to obtain a permission, authorisation or registration for putting on the market pharmaceutical products.”

Belgium: “conducting the necessary studies, test and trials with a view to meeting the conditions and modalities referred to in the intends 1 to 7 of this paragraph [generic medicines law] and all the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates.”

France: exemption for “the studies and tests required for obtaining a marketing authorisation for a medicament, as well as to the acts necessary for their performance and for obtaining the authorisation.”

Netherlands: exemption for “carrying out the necessary studies, tests and consequential practical requirements for the purposes of Article 10(1)-(4) of Directive 2001/83/EC”

Poland: exemption for “the exploitation of an invention to a necessary extent for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorisation, being due to the intended use thereof requisite for certain products to be allowed to be put on the market, in particular those being pharmaceutical products.”

Spain: exemption for “research and tests conducted for the authorisation of generic drugs, inside or outside of Spain, and the corresponding practical requirements, including preparing, obtaining and using the active principle for these purposes.”

Sweden: exemption for “studies, trials and associated measures relating to a reference medicinal substance, to the extent necessary to achieve a marketing authorisation pursuant to section 8(a) of the Medicines Act (1992: 859) or in other processes for obtaining a marketing authorisation based on Art 10.1-10.4 in Directive 2004/27/EC...”

What acts are and are not covered by the “Bolar” provision?

There is very little case law on this subject. We can, however, be informed by guidance issued by the UK Intellectual Property Office. According to guidance issued in 2013, the following activities are covered by the exemption:

- Carrying our necessary pre-clinical tests, clinical and bioavailability trials and stability studies on a medicinal product;
- Manufacture or importation of sufficient quantities of substance for studies, tests and trials;
- Development of the final pharmaceutical composition; development of the final manufacturing process; testing and use of associated analytical techniques for either; and
• Compilation and submission of a marketing authorisation and manufacture and supply to the competent authorities of samples.

It would appear that the following acts are not covered by the “Bolar” provision:

• Stockpiling;
• Commercial supply of an active pharmaceutical agent for “Bolar” use; and
• Manufacture of API for sales outside of the EU.

Concerning commercial supply of an active pharmaceutical agent for “Bolar” use, there has been a recent case in the courts in Poland and Germany between Astellas Pharma and Zakłady Farmaceutyczne Polpharma (“Polpharma”). Polpharma had placed an internet advert for sale of various active pharmaceutical ingredients (APIs), including Astellas’s product solifenacin succinate, together with a notice that read:

“Products subject to patent protection are not offered for commercial purposes in countries where this constitutes an infringement of patent rights. In Poland, patent-protected products are offered solely for experimental purposes or within the confines of the Bolar provision, in strict accordance with Polish regulations relating to intellectual property (in this case, solifenacin succinate).”

In Poland, the Gdansk court (first and second instances) decided that the intended use of the purchaser was irrelevant and that it was established that the defendant had manufactured and sold a patented substance which was infringement. Such sales were said to go beyond the infringement exemption provisions allowable under law. The first instance court in Germany (Dusseldorf) reached an essentially similar conclusion and an appeal decision is awaited.

Legal practitioners in Europe consider that these cases can be distinguished from the case where the manufacture of a drug is commissioned by a generic drug developer who thus employs the third party manufacturer as his agent. In this case the third party manufacturer should benefit from the “Bolar” exemption.

Other national provisions – Belgium, Netherlands and Switzerland

This paper does not contain a review of the wording of national experimental use exemptions since they are largely harmonised (although court interpretation has been different, see the above discussions concerning UK and Germany).

It is, nevertheless, worth commenting that Belgium’s experimental use exemption is notably broader than the consensus wording:

“The rights conferred by a patent shall not extend to acts done for scientific purposes, with or on the subject matter of the patented invention.” (emphasis added)

Since acts “with or on” the subject matter of the invention are allowed, this has been understood by legal practitioners in Belgium to extend to most acts necessary for preparation of a new medicine, including phase I, II and III clinical trials, although there are no cases on the subject.

Taken together with its “Bolar” implementation, Belgium appears to have a comprehensive exemption for acts necessary to file a marketing authorisation for a medicine of whatever sort (as in the US).
By contrast, the Dutch experimental use exemption has a subtly different wording:

“The exclusive right does not extend to acts done exclusively for the purpose of experiments on the patented invention...” (emphasis added)

By virtue of the extra word “exclusively”, it is possible that this exemption might be construed as being narrower than elsewhere. There are two Supreme Court precedents (ICI/Medicopharma, 1992 and ARS/Organon, 1995) which construed the experimental use exemption narrowly and restrictively, however, these relate to “Bolar” type scenarios (i.e. generic drug clinical trials) prior to the implementation of the “Bolar” provision and thus may no longer be considered good law.

Although secondary to the main subject of this paper, it is also worth noting that Switzerland has a compulsory licence provision which applies to patents covering research tools. In case of a dispute as to whether working a research tool patent is working “with or on” the subject matter of the invention (in the author’s personal view, more likely the former) then a compulsory licence would, at least, be available.

The imminent UK law change

As is apparent from the discussion above, the “narrow Bolar” implementation, as applied in the UK and elsewhere, is the minority view. The majority of European nations have a broad implementation exempting acts done in preparation of a marketing authorisation of any drug at all.

Early in this decade, the UK government became concerned that the number of clinical trials performed in the UK has been declining. Attributing this possibly to uncertainty about the legal position for research on innovative medicines, and following an extensive consultation with stakeholders, it announced that it planned to change the law to extend s60(5)(i) to cover the activities required to secure regulatory approval for innovative medicines (including clinical trials) as well as activities necessary for health technology assessment (these activities are normally conducted after regulatory approval is obtained, e.g. to support assessment by the UK government body NICE). The text of the new law, intended to be implemented in 2014, is awaited.

Impact of the Unified Patent Court (UPC) Agreement

The UPC Agreement, which established a court system having jurisdiction of all EU patents and in due course all European patents, was signed in February 2013. The signatories of the agreement include all the EU states except Spain, Poland and Croatia. The UPC Agreement will come into force when the agreement establishing the EU Patent comes into force, which is when the two agreements are ratified by UK, Germany and France plus 10 further signatory states. This will not be before 2015 at the earliest and possibly not until 2017.

Article 27 of the UPC Agreement provides for exemptions to infringement as follows:

“The rights conferred by a patent shall not extend to...

(b) acts done for experimental purposes relating to the subject matter of the invention;...

(d) The acts allowed pursuant to...Article 10(6) of Directive 2001/83/EC...”

As can be seen, Article 27(b) is identical to the “consensus” experimental use exemption in force in most of Europe (not Belgium which is broader – see above) and Article 27(d) corresponds to the “Bolar” provision implemented in its strict (narrow) wording.
In order to avoid the law applying to EU and EP patents differing from that applying to national patents in Europe it is expected that national patent laws will in due course be harmonised with that of the UPC Agreement. Clearly there are discrepancies in all countries which have “broad Bolar” implementation and in Belgium which has a broad experimental use exemption. Although there has been much discussion on this point in interested circles it remains unclear how these discrepancies will be resolved. The author finds it hard to believe that Germany and the countries of Eastern Europe, which have long had a “broad Bolar”-type exemption (whether by case law or statute), and which has significant political and economic associations, will give it up. Meanwhile this conundrum is exercising the UK Intellectual Property Office as it contemplates how to broaden the UK’s presently “narrow Bolar” provision whilst remaining compatible with the UPC Agreement.

Summary

Europe is a continent of many sovereign states, and there are many factors involved in deciding whether and where to do experimental work without infringing third party patents.

If the work concerns development of a generic product to be registered in the EU using an abridged procedure, “Bolar” provisions can be relied upon in all counties of the EU. The law of some countries permits work on the development of a generic product to be registered outside of the EU.

If the work concerns development of an innovative product, it is necessary to consider (a) whether the experimental use exemption can be relied upon (which is likely for early studies, but may include late studies and trials in some countries); and (b) whether the work can be conducted in a country which has a “broad Bolar” implementation.

There has been comparatively little case law concerning interpretation of the experimental use and “Bolar” infringement exemptions in Europe which leads to lack of clarity in a number of areas (particularly in countries with “narrow Bolar” implementation). The signature of the UPC Agreement has created further uncertainty about the future legal position, at least in relation to research work on innovative medicinal products. It is hoped that these uncertainties can be ironed out as soon as possible.

About the author

Andrew Teuten is a Chartered and European Patent Attorney and practises in the chemistry and lifesciences fields. He founded Sagittarius IP (www.sagittariusip.com) in 2002 after working for 10 years for various major pharmaceuticals corporations. The author can be contacted on ajt@sagittariusip.com.

Disclaimer

This paper has been prepared for informational purposes and no liability is accepted by the author for reliance on its contents. Specifically, it is not a substitute for taking appropriate professional advice.
Occasionally, advances in biotechnology yield novel classes of molecule. Monoclonal antibodies represent an early example. Never patented at a class level, structurally defining monoclonal antibodies as a class would have been challenging against the backdrop of polyclonal antibody prior art available at the time – but at least antibodies have common structural characteristics that distinguish them from other substrate-binding proteins.

In the past 20 years several classes of nucleic acid molecule have been identified by developing screens for functional characteristics. Aptamers, identifiable by SELEX, are short nucleic acids characterised by high affinity binding to the selected target. The nucleotide sequence of an aptamer for a target is not predictable and two aptamers to the same target often have unrelated sequences. More recently, screening for transcriptomes has generated structurally diverse pools of nucleic acids having a common functional property. Other examples are siRNA and ribozymes.

At the European Patent Office (EPO), to obtain a product (composition of matter) claim novelty must, of course, be established. During novelty examination the Examiner will consider whether the claim is clear enough for it to be distinguished over the known prior art. When claiming products, a molecule of a known structural type that is characterised by function alone is unlikely to be considered clear enough, particularly where the prior art contains structurally similar molecules not described, or tested, in respect of the function being used to define the claim. Notably, today, antibodies can be an exception but it has taken considerable time for the EPO to reach this position and an antibody analogy can be difficult to deploy if the molecular class at hand does not have a similar distinct structural characteristic.

For example, a claim to a short nucleic acid characterised by binding to target Y, or having gene repressing ability will be assessed against the backdrop of a very large number of short nucleic acids in the prior art for which such functions have not been tested. The EPO can be expected to consider that at least one such molecule in the prior art may inherently have the property at hand and where that probability is not considered to be de minimis can be expected to take the view that the claims are not clear enough to allow novelty to be established and/or that an undue burden is placed on a third party to determine if a nucleic acid in their possession in fact has the property and therefore falls within the claim, i.e. insufficient certainty to determine infringement. Introducing gross structural claim limitations, e.g. non-natural chemical modification, can reduce the extent of prior art to some degree but it can still be a considerable body of art and so the problem may remain.

So, obtaining product protection via the EPO may be very difficult, even impossible. What can be done?

Product by process claims are allowable before the EPO. Although not preferred they may be accepted where there is an inability to define the product satisfactorily by reference to composition, structure of other testable parameter and to deny patent protection would be unfair in view of the contribution made to the art. The product itself must still be new and, therefore, must also be clearly defined under Article 84 EPC. The Boards of Appeal have
acknowledged that the process part of the definition of the product may be used to provide clarity of the claim but the balance of any burden placed on the EPO or third parties to determine if a product (in the prior art or after the filing date) falls within the claim will be made against the desirability to provide fair protection to the patentee to recognise the breadth of contribution made to the art. In my experience, the patentee comes off second best.

Functionally defined products are often identifiable by a form of identification/screening method, probably performed in vitro. Patenting that method before the EPO will normally be reasonably straightforward. Where product claims are difficult to obtain, method claims can be valuable. This is because the European Patent Convention provides protection for products that are “directly obtained” by a patented process. This protection is, however, of reasonably narrow scope. The “product” obtained by the method has been construed quite narrowly and a distinction may be made between the crude product of an in vitro screening method and the refined commercial product, the latter not necessarily being “directly obtained” by the patented process.

A related problem is that in the field of nucleic acids, one “product” of the screening method is sequence information, which can be rapidly disseminated across the globe and a new “product” synthesised according to that sequence. Not only does this make reliance on the “directly obtained” provision more complex, but it also raises the issue of infringement of method claims between jurisdictions, e.g. method performed in country X and new product synthesised according to sequence information obtained from that method in country Y, possibly some years later.

Refining the method claim can be considered, e.g. to characterise the method as a method of producing a commercial grade product. The EPO might consider this to drift into reach-through territory, but for a unified class of molecule this problem can sometimes be avoided by noting that the products obtained from the screening steps for formulation in the production steps are not completely open ended but must be of the class.

Another approach used successfully is to frame the claim in terms of production of the commercial grade product starting from sequence information, i.e. a claim to synthesis of the product according to sequence information obtained from the screening method.

Such claims can attract rejection for lack of clarity. In particular, the EPO have moved towards citing the Enlarged Board of Appeal decision G2/88 to formulate an examination Guideline providing the basis to reject such claims as combining irreconcilable types of process. This approach seems open to question, given that the comments in G2/88 would, by common law standards, be considered obiter and not addressing this issue and also clearly state that “there are no rigid lines of demarcation between the various possible forms of claim”.

At this point it is worth noting the particular position taken by the EPO towards product claims for antibodies. For this class of molecule the EPO have become comfortable with the possibility of defining the antibody by providing a functional characterisation of the antigen and this is sufficient where the antigen is new. Where the antigen is known, a further functional characterisation of an antibody sub-genera can be accepted by the EPO, e.g. a functional effect achieved by an antibody of the sub-genera when bound to the antigen. The
EPO appear to have reached this position because they have become comfortable with the idea that an antibody *per se* can be structurally distinguished from other proteins, such that the requirement to afford third parties reasonable certainty as regards their ability to test for antigen binding and any additional functional property recited in the claim may be considered appropriately balanced against the need to afford the patentee fair protection for the invention. That said, this is not a given and even in the antibody field the outcome can be expected to depend on the facts.

Therefore, if the novel molecular class at hand can be defined as having a structure that corresponds with the primary functional property, e.g. target binding, the antibody analogy may be deployed, and certainly should not be overlooked.

I have formulated and deployed strategies of the kind described above over the last ten years. With sufficient effort useful outcomes are possible. Obtaining composition of matter claims will remain an important goal and it is unnatural for many applicants to contemplate that it may not be possible. But there is another way.

This of course is the EPO medical use claim for first or later medical uses. Since the revision of the EPC, both claim types can be thought of as a special type of product claim, limited by its purpose of treatment (or diagnosis) when performed on the human or animal body.

Applying this claim format can make a considerable difference to the problems associated with the “pure” product claims discussed above. The reason is that the intention of the user becomes a relevant factor. That is, when considering the prior art the mere existence of a product of the same structural class, e.g. short nucleic acid, should not be sufficient to raise a novelty concern unless it is indicated for the same medical use. The functional characteristic, e.g. target binding, may also be recited in the claim to add clarity over any prior art that does recite a medical use, and finally a product by process definition may be added to the claim to tip the balance of risk to third parties of uncertainty from a potentially unclear claim against the desire to afford the patentee reasonable protection for the invention.

The result can be a granted claim of broad therapeutic scope and where the products are intended for therapeutic use this may afford meaningful and valid protection in an acceptable prosecution time frame. Of course, the product claims can still be pursued (as can *in vitro* method claims (e.g. for diagnostic uses)) but it may be sensible to do this via a divisional application strategy so as not to delay the issue of enforceable claims.

Later applications may initially identify sub-genera of the functionally defined class and it may be possible to take a similar approach in such cases (and indeed it may become easier to deploy the antibody analogy and get product claims allowed), but as the technology progresses it is reasonable to expect that specific products for specific targets and/or individualised disease treatments will be identified, for which the normal approach to protection of the products and uses should apply.

All of the above is worth considering, if it is possible to do so. No doubt, many readers will be familiar with the EPOs strict and user unfriendly approach to added matter. Unless language for the claim options discussed above appears in the European patent application as filed (for many readers, this will be the PCT application) simply writing admissible claims
of this kind may be impossible, leading to major frustration and expense. Applicants who consult their EP attorney at the drafting stage to seek incorporation of suitable language for the appropriate EP style claims should be rewarded when European prosecution starts!

Richard Clegg is a partner and European patent attorney at Mewburn Ellis LLP in the UK. Richard can be contacted at richard.clegg@mewburn.com. The views expressed are those of the author. They are generalised and do not represent legal advice.

---

2 Article 84 EPC
3 T965/98 Reasons 5
4 e.g. T130/90 at Reasons 3.3
5 e.g. T412/93 Reasons 33
6 Applying the principles of Article 69 EPC and the accompanying Protocol
7 Article 64(2) EPC
8 Pioneer Electronics Capital Inc. and Another v Warner Music Manufacturing Europe GmbH and Another [1997] R.P.C. 757; Medimmune Ltd v Novartis Pharmaceuticals UK Ltd Chancery Division (Patents Court) 2011
9 EP 1564290 B1
10 EPO Guidelines for Examination Part F IV 4.16
11 G2/88 Reasons 2.2
12 EP 0981618 B2
13 Article 69 EPC and the accompanying Protocol
14 EP 0786469 B1
Self-collision in Europe – the poison pill of first to file

Those seeking to obtain patents in Europe should ensure their patent filing and prosecution strategy does not result in “self-collision” when their own applications become novelty destroying prior art against each other. Conversely, those seeking to invalidate European patents should be aware of the opportunities to knock-out European patents presented by the EPO implementation of the first-to-file-system.

European practitioners have become familiar with the problem of an applicant’s own applications being citatable against their own later cases. However, there is now also a need to be wary of self-collision within a patent family sharing a common priority claim: in a European Patent Office (EPO) Appeal Board decision (T 1496/11) published earlier this year, it was confirmed that divisional applications derived from the same initial filing can be citable prior art against each other.

Self-collision is a particular issue in the life sciences sector where the presence of one example in a priority application can have the potential to destroy the novelty of an entire patent family.

The European Approach to First to File

Since the coming into force of the European Patent Convention (EPC) in the 1970s, the EPO has operated a first-to-file system. Over the years the system has been refined as the EPO has sought to balance the needs of applicants with legal certainty for third parties. The underlying principle of the EPO’s approach to first-to-file is that, because the applicant is in control of what subject matter is included in a patent specification, the applicant is only entitled to obtain a patent for the subject matter disclosed. There is no justification for giving an applicant the benefit of the doubt to extend the application to cover something not clearly present in the application as filed. Furthermore, the applicant cannot improve its position by adding subject matter not disclosed in the application as filed, even if that new subject matter is narrower than the original disclosure.

The “disclosure test” developed by the EPO to ascertain whether a particular subject matter is disclosed in a document is whether that subject matter can be directly and unambiguously derived from the specification as filed (T 288/92). That test is applied uniformly across all areas where the determination of whether a document discloses a particular subject matter is needed, including whether an application as filed provides basis for an amendment (Art. 123(2) EPC), whether claimed subject matter is entitled to a right to priority from an earlier patent filing (Art. 87(1) EPC), whether an application is entitled to considered as a divisional application divided from an earlier filing (Art. 76(1) EPC) and also concerning what subject matter is disclosed in a prior art document (Art. 54 EPC) (Enlarged Board of Appal decisions G 1/03 - reasons 2.2.2, and G 2/10 - reasons 4.6).

While that approach gives harsh results to applicants in certain situations, such as where an inventor was clearly in possession of an inventive concept but the lack of a direct and unambiguous disclosure of the subject matter they now wish to claim prevents them from obtaining a patent; in other situations it is to their advantage, such as the approach to selection inventions where the rigid assessment of the disclosure of an earlier document enables the later claiming of a combination of features only disclosed in separately in an earlier document.
Status of Unpublished Applications under the EPC

Whilst an advantage of first-to-file system is that it gives legal certainty for third parties, a compromise is needed for earlier filed patent applications that were unpublished at the time a later application was filed.

The approach adopted in the EPC is that only the first European application to disclose a particular subject matter may validly claim that subject matter. All subsequent European patent applications must be novel over the disclosure of that first application, even if that first application was not published at the time the later application was filed. However, the EPC does not prevent the patenting of alternative subject matters that embody the same inventive concept but which are novel, when those alternative subject matters are included in patent applications filed in the period before that the first European application was published. The logic is that as the person skilled in the art did not know of the contents of an application whilst it remained unpublished, the contents of such earlier filed, later published documents are not citable for obviousness.

Accordingly the Articles of the EPC have two categories of prior art:

- **Article 54(2) EPC** - Disclosures of any form before the filing (or priority) date of a patent claim, whether through publication in patent or non-patent literature, prior use, oral presentation or any other public disclosure are part of the state of the art under Article 54(2) EPC, citable against the novelty and inventive step (obviousness) of the later claim.

- **Article 54(3) EPC** - Subject matter disclosed in a European patent application that is entitled to an earlier priority date than the patent claim, but which was unpublished at the priority date of the patent claim is in a special category set out in Article 54(3) EPC.

<table>
<thead>
<tr>
<th>Month</th>
<th>0</th>
<th>12</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action</strong></td>
<td>Provisional filed (e.g. at USPTO)</td>
<td>European application filed</td>
<td>European application published</td>
</tr>
<tr>
<td><strong>Prior art status against later European applications</strong></td>
<td>Art. 53(3) - novelty only, for subject matter contained in the provisional</td>
<td>Art. 53(3) - novelty only, for all subject matter contained in the European application</td>
<td>Full Art. 53(2) prior art – novelty and inventive step, for all subject matter contained in the European application</td>
</tr>
</tbody>
</table>

This special prior art status under Article 54(3) EPC is only afforded to earlier filed, later published, European patent applications. If the earlier European application remains unpublished, it never forms part of the state of the art.

Only European patent applications with an earlier priority entitlement form part of the state of the art under Article 54(3) EPC. Patent applications in all other jurisdictions, including the US and individual European countries, such as the UK and Germany, are not in that category. Furthermore, published international applications that designated Europe, only become Article 54(3) EPC prior art if they validly enter the European regional phase.
Another feature of Article 54(3) EPC is that the whole content of the earlier European application is taken into account, not just the subject matter claimed in the earlier application. This is consistent with the European approach to the first-to-file, in which subject matter may only be protected through the first European application to directly and unambiguously disclose that subject matter. Any future European application directed to the same subject matter will lack novelty. Whether or not the first European application claims the subject matter disclosed therein is irrelevant to the prior art status of the disclosure.

This special category of prior art is only citable against the novelty of subject matter in European applications that is entitled to a priority date before publication of the Article 54(3) EPC prior art document, and is not citable for inventive step (obviousness). Again this is consistent with the approach that two applications can be filed alternative subject matters that embody the same inventive concept, as long as they are not filed for the same subject matter. Thus, even a trivial or obvious modification to the subject matter in an earlier filed but unpublished application will be sufficient to render the later claims patentable in Europe.

Entitlement to Priority

As noted above, the disclosure test is applied to the assessment of whether the subject matter of a patent claim is entitled to the priority date of an earlier patent application. Merely demonstrating that the applicant was in possession of the inventive concept is not sufficient. Only if the subject matter claimed is directly and unambiguously disclosed in the earlier application will the EPO recognise a right to priority for the claim.

Whilst Article 88(2) EPC allows for a patent claim to be entitled to multiple priority dates, enlarged board of appeal decision G 2/98 has clarified that multiple priority dates can only be recognised within a single claim when that claim can be delineated into a limited number of clearly defined alternative subject matters. Where a claim is an “or” claim, each alternative subject matter can be entitled to a different priority date.

Thus, if a claim can be broken down, at least conceptually, to cover subject matter A, B or C, then each of the alternatives A, B and C may be entitled to a different priority date. If the claim cannot be broken down to clearly defined alternative subject matters, then the claim as a whole is only entitled to the filing date of the application which first directly and unambiguously disclosed the subject matter of the claims as a whole.

Co-pending Applications as Prior Art

The interaction between the approach to entitlement to priority and the prior art status of co-pending European patent application under Article 54(3) EPC is such that it is quite possible for the first European application directed to a particular inventive concept to lack novelty over a later filed application for the same concept but which includes subject matter that is entitled to an earlier priority date.

To illustrate, consider the situation in which a first priority filing (P1) included a general inventive concept but did not directly and unambiguously disclose the subject matter claimed in a subsequent
European application (EP1) that claimed priority from the first priority filing (P1). In that case the claim to priority would be invalid and the claim of the subsequent European application (EP1) would only be entitled to the filing date. Between the filing date of the first priority filing (P1) and the filing date of the subsequent European application (EP1), a second European application (EP2) is filed directed to an overlapping subject matter. That second European application (EP2) published sometime after the first European application (EP1) was filed.

There is then the possibility of subject matter contained in the second European application (EP2) depriving the claims of the subsequent European application (EP1) of novelty. The whole contents of the second EP application (EP2) is entitled to a date before the filing date of the claim of the subsequent European application (EP1) and so forms part of the state of the art under Article 54(3) EPC. Therefore, any subject matter in the second EP application (EP2) which falls within the scope of the claims of the subsequent European application (EP1) deprives those claims of novelty. In effect, it is the applicant of the second EP application (EP2) that won the race to the patent office and was the first-to-file for the overlapping subject matter.

General Applicability – Co-owned Applications

The EPC makes no special provisions for applications that are in common ownership or which have common inventors. There is no grace period during which an applicant/inventor’s own European applications are not treated as prior art, nor is there the ability for an applicant to file a terminal disclaimer to negate the prior art effect of a co-owned application. Thus, the applicant’s own European patent applications form part of the state of the art under Article 54(3) EPC when they contain subject matter that is entitled to an earlier priority date than that of a later patent claim.

Poisonous Priorities – Status of Priority Filings

In recent years, the EPO has confirmed that the ability for co-pending applications to self-collide is not limited to family members that share common priority claims, but can extend to collision between a first European filing and the subsequent European application that claims priority from that first European filing (T 680/08).

A patent application filed at the EPO for the purposes of establishing a priority date becomes part of the state of the art on publication. If a later European application includes claims which are not entitled to the date of an earlier European application from which priority is claimed, then the
earlier European application becomes part of the state of the art citable against those claims under Article 54(3) EPC, once published.

If the claims of the later European application can be separated into subject matter contained in the priority document, which is entitled to the priority date, and further, alternative subject matter not entitled to priority, then the publication of the priority document may not be damaging. However, where the claims of later European application cannot be divided into a limited number of clearly defined alternative subject matters, it cannot be separated into parts with differing priority entitlements and the claim as a whole will only be entitled to the filing date (G 2/98). In that circumstance, any subject matter disclosed in the earlier European filing that falls within the scope of the claims of the later European application will deprive it of novelty, the claim to priority being ineffective to avoid self-collision.

In the much-discussed Technical Board of Appeal case T 680/08, the earlier European application disclosed a range of total drive specific energy (SEC) of from 0.325 to 0.415 kWh/kg. A subsequent European application was filed with claims to a revised SEC range of from 0.330 to 0.415 kWh/kg. As the specific end point of 0.330 kWh/kg was not disclosed in earlier application, the new range in the claims of the subsequent European application was held to be not entitled to priority. Furthermore, the new range could not be divided into a clearly defined subject matter that is entitled to priority and another clearly defined subject matter not entitled to priority. Thus, the claim of the later European application as a whole was only entitled to the filing date. On publication the earlier European application became part of the state of the art under Article 54(3) EPC and the SEC range of from 0.325 to 0.415 kWh/kg disclosed in that document deprived the claim of the later European application of novelty.

**Toxic Divisionals – Status of Parent Applications and their Children**

Whilst European practitioners have been aware for some time that the logical conclusion of the European approach to Article 54(3) novelty is that a “parent” application can lack novelty over its own divisional “child”, the EPO Technical Boards of Appeal have until recently shied away from issuing a decision on this point. However, earlier this year decision T 1496/11 was issued confirming that this nightmare situation for applicants can become a reality.

Where a European patent application includes claims that are not entitled to the earliest priority date but includes other subject matter, such as a specific example that is entitled to an earlier priority date than the claims, self-collision will be an issue if a divisional application is filed. Once validly filed, a divisional application is treated as an entirely separate European patent application from its parent and so has the same potential to be part of the state of the art under Article 54(3) EPC as any other European patent application.

Any subject matter contained in the divisional application which is entitled to a priority date which is earlier than the priority date of a claim in the parent application will be citable against the novelty of that claim. For example, a specific embodiment present in each of the priority filing and the divisional application will destroy the novelty of a claim in the parent application, when that claim is not entitled to the priority date and when it encompasses the specific embodiment. Thus, the filing
of a divisional application can be poisonous to the validity of the application from which it was divided. That situation can be inescapable once the divisional application is published.

The case decided in T 1496/11 related to an application directed to a method of verifying a security document. The first application disclosed a self-verification means comprising an optical lens in combination with a security device that comprised a printed or embossed feature. A later filed European application which claimed priority from that first filing omitted the printed or embossed feature in the claims. Using the strict disclosure test, that claim was found to relate to different subject matter from the first filing, being an intermediate generalisation not directly and ambiguously derivable from the first filing. Thus, the claims of the later European application as a whole were not entitled to the priority date.

A divisional application was filed that included an embodiment that was identical to one present in the first filing, and which had the printed or embossed feature. That embodiment is entitled to the priority and so, on publication of the divisional application, that embodiment constitutes part of the state of the art citable under Article 54(3) EPC against the novelty of the claims of the parent application. The fact that that same embodiment was also disclosed in the parent application is immaterial the validity of the claims, as the claims could not be separated into subject matter including the embodiment that is entitled to priority, and a further clearly defined alternative subject matter not entitled to priority. Therefore, the disclosure of the embodiment in the divisional that fell within the scope of the claims of the parent, deprived the claims of the parent of novelty and the patent was revoked.

**Self-collision in Summary**

There is no special treatment for members of the same patent “family” in Europe, with each patent application being assessed individually regardless of whether they were derived from the same first filing. The priority date is determined for each patent claim and then an assessment made as to whether the claimed subject matter is novel over each piece of Article 54(2) and 54(3) EPC prior art, followed by an assessment of whether the claim involves and inventive step (is non-obvious) over all Article 54(2) prior art. If subject matter disclosed in one patent application in a patent family is entitled to a priority date that is earlier than the priority date of a patent claim in another patent application in the same patent family, that subject matter will be citable against the novelty of the later claim.

Accordingly, the way Europe approaches co-pending applications can be a dangerous trap for applicants. In many respects, an applicant’s own earlier filings are more dangerous than those of their competitors. Whilst third party filings can often be circumvented using a trivial amendment, it can be more difficult to identify an amendment that achieves novelty over an application from the same stable, where the same drafting style is likely to have been employed and the same “boilerplate” list of desirable features included in the specification. This is especially true in the chemical field. A single example present in a patent filing may embody the entire invention of a series of cases. If the claims of a European application lose their entitlement to priority, the disclosure of that molecule in co-pending cases in the series can deprive the claims of novelty and be very difficult to amend around.
A Permanent Reality or Passing Nightmare?

This is an evolving area of practice in Europe and it remains to be seen whether the recent “toxic divisional” and “poisonous priority” decisions T 1496/11 and T 680/08 are a high-water mark from which the EPO will retreat, or whether those decisions are to be universally accepted.

The general consensus in the European profession is that those decisions represent the logical conclusion to the EPO’s interpretation of the way the European Patent Convention (EPC) implements a first-to-file system. Whilst the outworking of the EPO’s approach is often harsh on applicants and can be criticised for not fulfilling the intentions of the Paris Convention, there is internal consistency in the way the EPO entitlement to priority, added matter and the disclosure of a prior art document and that does result in a workable system.

Some Boards of Appeal (such as in T 1222/11) have suggested that the strict approach to the assessment of entitlement to priority is incorrect and a claim can be separated into parts with different dates even when it cannot be divided into clearly defined alternatives. As a result the harsher effects of self-collision can be mitigated against, for example, by determining that the part of a claim that reads onto a specific embodiment is entitled to the priority date of the first application to disclose that embodiment, regardless of whether the embodiment is clearly defined in the claim. However, relaxation in that area would be a departure from the coherent approach that has been developed by the EPO and could result in inconsistencies within the system.

Mitigation Against Self-Collision

The only way of fully mitigating against the self-collision of members of the same patent family is to ensure that all parts of a European application are entitled to the earliest priority date, i.e. by making no changes to the first filing during the Paris Convention year. Of course, in practice that is not always possible. When changes are made, the possibility for self-collision is lessened where the subject matter from earlier filings is included in the final application in such a way that enables the claim to be rewritten as a list of clearly defined alternatives, each of which can be assigned their respective priority date.

The claiming of priority from a provisional application that is nothing more than the inventors’ invention record is to be avoided in Europe. The prospect that such an “invention record” provisional filing will entitle a claim in a later European application to be afforded an early priority date is minimal. However, the subject matter from that first “invention record” provisional filing can provide a disclosure that is part of the state of the art under Article 54(3) EPC citable against the claims of all European applications in the patent family that are not entitled to the priority date of that first filing. As claiming priority from incomplete or poorly drafted first filings is potentially toxic in Europe, it is often better not to include the claim to priority in the later European application.

If applications are filed at the EPO for the purpose of establishing a priority date, it is important that they are withdrawn before publication to prevent them becoming part of the state of the art under Article 54(3) EPC and citable against the novelty of subsequent applications in the same patent family.
Finally, it is important to think carefully before filing divisional applications in Europe. A full assessment of the priority situation is important before any action is taken. It has been common practice to file the whole of a parent case text as the specification for a divisional, but that may not always be the best approach. In many cases it is possible to avoid a divisional application becoming novelty-destroying prior art against its parent by omitting some subject matter from the earlier filings in the divisional application. Filing a divisional application at the last minute without careful consideration of the consequences for self-collision should be avoided.

A Magic Bullet for Invalidity Actions?

Of all the ways of attacking a European patent, self-collision is one of the most potent and troublesome for the patent proprietor. However, not all European practitioners have woken up to the possibilities that self-collision offers to invalidate entire patent families.

Before challenging a European patent, it is always worth checking the file for other family members that could be used as Article 54(3) EPC prior art. If it is determined that the claims of an application are not entitled to the earliest priority date and the patent family includes further European applications, it is highly likely that there will be self-collision.

Dr. Matthew Fletcher, MChem, PhD, European Patent Attorney, Chartered UK Patent Attorney

Matthew Fletcher is a partner in Abel & Imray’s Bath office in the south west of England. Matthew has a background in chemistry, with a degree from Oxford University and PhD from the University of Bristol in organic chemistry. He has been representing clients before the European Patent Office (EPO) for the last 11 years, including a two year secondment to the in-house patent department of a major pharmaceutical and consumer healthcare company. He has particular expertise in the pharmaceutical area, in drafting, prosecution and freedom-to-operate work worldwide and regularly represents clients in opposition and appeal proceedings before the EPO. His patent work includes small chemical entities, drug formulations, biochemistry, printing inks, polymer technology, contact lenses, food technology and packaging. A large proportion of Matthew’s case load is for US corporations.

Abel & Imray is a modern firm with a long history of IP work in the pharmaceutical, bioscience and chemical sectors. We have a focus on representing non-UK corporate clients before the European Patent Office and OHIM, for patent, trade mark and design work and aim to give excellent quality representation by experienced attorneys at acceptable cost. We have three offices in the south of the UK, including our main office in central London.
USPTO's New Ethics Rocket Docket For Attorney Discipline

Law360, New York (October 30, 2013, 6:25 PM ET) -- The U.S. Patent and Trademark Office regulates the recognition and ethical conduct of attorneys and patent agents who practice before it. The Office of Enrollment and Discipline (OED) is charged with administering the rules of admission to practice before the USPTO and ensuring that the conduct of both registered patent attorneys and agents, as well as nonregistered attorneys who practice before the office in nonpatent matters, complies with the USPTO’s ethics rules. Significantly, regardless of whether their conduct runs afoul of the ethics rules of any state or federal bar, attorneys who are registered by, or practice before, the USPTO fall within the ethical jurisdiction of the USPTO and its administrative arm, the OED. See 35 U.S.C. § 32.

One significant change in USPTO ethics law is procedural in nature, but it is proving to have a substantial impact on attorneys and patent agents who are subject to the ethical jurisdiction of the OED. This procedural change addresses the amount of time the USPTO has between when it learns of an ethics violation to when it initiates formal discipline.

Historically, the USPTO took the position that its disciplinary proceedings were not subject to any statute of limitations. After contrary court decisions in the late 1990s, however, the USPTO modified this stance and confirmed it was bound by the general federal statute of limitations, under which it had five years to initiate disciplinary action. See 28 U.S.C. § 2462 (“an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued”).

Even with this (relatively) generous five-year limitations period, however, the OED was criticized for “not expeditiously complet[ing] investigations of complaints against patent practitioners in time to avoid triggering the five-year statute of limitations.”[1] Indeed, in a 1998 report, the Office of Inspector General of the U.S. Commerce Department noted a general decline in the OED’s disciplinary work and a “growing inventory” of ethics complaints that were barred by the five year statute of limitations.[2] At the OIG’s suggestion, the USPTO sought to address this backlog by hiring more staff attorneys dedicated to investigating disciplinary complaints and investigations.

While the five-year limitations period and increased staffing helped the OED to reduce the inventory of backlogged cases, significant pressure has been placed on the office as a result of the Leahy-Smith America Invents Act. Indeed, while the AIA introduced significant changes to the U.S. patent statute, one change that appears to have received relatively little public fanfare is the amended statute of limitations for the PTO to commence disciplinary proceedings. Under the new statute of limitations, the USPTO must commence a disciplinary proceeding “not later than the earlier of”: (1) 10 years after the misconduct occurred, or (2) one year from when the misconduct forming the basis of the proceeding “is made known to an officer or employee” of the PTO. 35 U.S.C. § 32.
Exactly when the clock starts running for purposes of applying the USPTO’s new ethics statute of limitations depends largely upon when and how the USPTO discovers the alleged “misconduct.” While the 10-year rule seemingly provides the office a much longer cushion for investigating and filing disciplinary actions in certain cases, this increase may be illusory. Indeed, in many cases of professional discipline, the time for instituting a disciplinary proceeding will likely be governed by the one-year statute of limitations.

The reason this is so is because the USPTO provides a very broad definition for how misconduct is “made known” to the agency. For example, pursuant to 37 C.F.R. § 11.22(a), the OED director may initiate an investigation regarding possible grounds for discipline whenever the director “receives a grievance, information or evidence from any source suggesting possible grounds for discipline.” A “grievance, information or evidence” is not simply limited simply to client or third party complaints expressly made to the OED (although such complaints frequently form the basis of an OED investigation).

On the contrary, the OED can, and typically does, rely upon its receipt of information through external news sources as the basis for a “grievance, information or evidence.” Common sources of such nonclient-originated “grievances” include published decisions in patent and trademark journals, popular blogs and daily publications such as IP Law360. The receipt by the USPTO of any such “information” is arguably sufficient, based on the broad definition applied by the office, to commence the one-year statute of limitations.

For example, the OED staff typically monitors (or is informed by other USPTO employees) about significant, or newsworthy, decisions from federal district courts. Those actions may involve conduct that could implicate one or more rules of ethics. For example, an article about a district court decision finding that a practitioner committed inequitable conduct, was sanctioned, or was disqualified, puts the office on notice of possible grounds for an ethics charge and arguably triggers the one-year statute of limitations for the OED to institute a disciplinary action against a practitioner.

Since adoption of the AIA statute of limitations, the OED appears to be taking the conservative route and assuming that such public/published “notice” triggers a one-year statute of limitations. Consequently, the OED has established a practice of moving extremely quickly (by bar counsel standards) in making its determination as to whether it is going to charge a practitioner with an ethics violation.

In fact, under the one-year limitations period, and unless the USPTO and the practitioner under investigation agree to toll the limitations period, the OED has only one year to: (1) initially screen the “grievance, information, or evidence” to determine if a further investigation is warranted; (2) prepare a detailed letter to the practitioner outlining the alleged facts, areas of inquiry, and information requested; and (3) send the practitioner its written request for information, which usually requires a 30 to 60 day response time. The practitioner then has an opportunity to respond in writing to the request for information and to present evidence and argument as to why no ethics violation has occurred and to otherwise respond. See 37 C.F.R. § 11.22(d)-(f).

Considering the time between when the OED first learns about the possible ethics violation until it receives a response to the request for information, the OED, in reality, only has around six to nine months to analyze the evidence and otherwise to complete its investigation. Furthermore, if after completing the investigation the OED director believes probable cause may exist for filing disciplinary charges, then the director must present the matter to the Committee on Discipline — a body at the USPTO that acts as a kind of ethics grand jury. Upon the approval of the Committee on Discipline, the OED director may, at that point, institute formal ethics charges against the practitioner. See 37 C.F.R. § 11.22(h). It is the institution of formal charges which is the act that must be completed within one year.

The AIA’s one-year statute of limitations has resulted in the OED becoming a kind of “rocket docket” for
matters of professional discipline. Unless the office wishes to risk a statute of limitations bar, it is statutorily required to move quickly in completing its investigation and, ultimately, instituting formal charges. This one-year time period forces the agency to make its decisions far more quickly than it would have under the previous five-year statute of limitations. At the very least, the speed at which the USPTO operates forces the practitioner under investigation to work quickly in preparing their responses to a USPTO request for information. Since disciplinary actions are rarely reported, it is difficult to say whether the USPTO’s “need for speed” in filing disciplinary charges has had an adverse impact on practitioners who are faced with possible discipline.

Moreover, the one-year time limit to bring charges stands in stark contrast to many state bars. In fact, while state bars share concurrent ethical jurisdiction over patent attorneys and non-patent attorneys who practice before the USPTO, as a practical matter, most state bars have much longer limitations periods, or no limitations period at all.

For example, in Virginia, no statute of limitations applies for filing ethics charges against an attorney. Thus, in cases involving unethical conduct by a patent or trademark practitioner, a state bar with concurrent jurisdiction may simply decide to allow the USPTO disciplinary process run its course. State bars may prefer to preserve their own resources and allow the OED to do the heavy lifting. If the attorney ultimately is found, by clear and convincing evidence, to have violated one or more of the USPTO’s disciplinary rules, the attorney would then be subject to reciprocal discipline by his or her state or federal bars.

--By Michael E. McCabe Jr., Funk & Bolton PA

Michael McCabe is a partner in Funk & Bolton’s Baltimore office.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.


[2] Id. at 3-4

All Content © 2003-2013, Portfolio Media, Inc.