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"Obvious To Try": A New Standard for Biotechnology Inventions?

This Spring, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") handed down a widely anticipated decision pertaining to the biotechnology arts in *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009), which affirmed the finding by the Board of Patent Appeals and Interferences (BPAI) that Kubin et al.'s invention was obvious under 35 U.S.C. § 103.

With this decision, the court addressed the obviousness standard of DNA-based inventions in view of the landmark decision in *KSR Int'l v. Teleflex, Inc*. and the extension of *KSR* to the "unpredictable" arts making up biotechnology.

In doing so, the Federal Circuit in *In re Kubin* effectively overturned its long-time precedent reflected in *In re Deuel,* 51 F.3d 1552 (Fed. Cir. 1995) by now holding that it would have been "obvious to try" under *KSR* to obtain a nucleic acid molecule encoding a known protein coupled with the availability of conventional techniques for obtaining nucleotide sequences. Thus, *In re Kubin* establishes the applicability of the "obvious to try" standard as a proper basis for obviousness of DNA-based inventions.

The main issue considered by the Federal Circuit in *In re Kubin* was whether the BPAI was correct in upholding the Examiner's rejection of obviousness on the grounds that it would have been "obvious to try" to obtain specific DNA sequences of a *known* protein using *known* methodologies. In the past, this standard usually was not applied to biotechnology cases in view of at least *In re Deuel*.

Not surprisingly, the Federal Circuit's decision was not embraced by the biotechnology industry as it renders it more difficult to obtain patents for DNA-based inventions. In addition, the decision illuminates the Federal Circuit's apparent view that biotechnology is quickly becoming a less unpredictable art. As such, the securing and protection of patents in this technology area may grow to be more difficult where subject matter, otherwise patentable, will be increasingly viewed as "obvious to try."

The Kubin Application and the Obviousness Rejection

On September 20, 2000, Marek Z. Kubin and Raymond G. Goodman, filed a patent application entitled "NK Cell Activation Inducing Ligand (NAIL) DNA and Polypeptides, and Use Thereof" ("the Kubin application"). The inventors sought patent protection of isolated nucleic acid molecules encoding NAIL polypeptides, the NAIL polypeptides themselves, and methods for modulating the activity of NK ("natural killer") cells using the NAIL polypeptides and nucleotide sequences.

According to the inventors, NK cells are a major type of immune system component which are involved in killing certain tumors and virus-infected cells and which are also thought to bear an important overall role as regulators of immune responses—mediated through cytokine-releasing activities. The application teaches that human NK cells were previously known to comprise a specific cell surface protein ("p38" or NAIL) that, once activated, provide the NK cells with their cytotoxic and cytokine-releasing properties.

However, neither the amino acid nor the nucleotide sequence of NAIL (or p38) were previously described in the art before Kubin et al.'s invention. The Kubin application specifically describes the isolation and cloning of the cDNA sequence encoding human p38 (NAIL) protein, provides the NAIL sequences and shows that the NAIL protein binds the immune system cell marker CD48, the interaction of which is shown to have potential therapeutic benefits. The Applicants claimed a genus of nucleic acid molecules that encode CD48-binding proteins having 80% sequence identity with amino acids 22-221 of NAIL.

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"...there exists a justifiable concern that as the art of biotechnology continues to mature and progress, the Federal Circuit may possibly expand the reach of In re Kubin into other areas of biotechnology..."

The Examiner rejected the claims as being obvious over the prior art. According to the Examiner, one reference discloses the p38 protein (NAIL), its role in signal transduction and NK cell cytotoxicity, and a monoclonal antibody (C1.7) that specifically binds to p38. The reference does not disclose the DNA or amino acid sequences of p38 (NAIL). Nevertheless, the Examiner argued that conventional methodologies provided both in the specification and in the art could have easily been used to obtain the corresponding p38 (NAIL) cDNA and amino acid sequences using the C1.7 antibody.

The Applicants appealed the Examiner's final rejection to the Board of Patent Appeals and Interferences (BPAI), which upheld the Examiner's rejection of obviousness. The Applicants then appealed to the Federal Circuit, which affirmed the obviousness determination of the BPAI.

The Federal Circuit Decision

The Federal Circuit first addressed and upheld the factual findings made by the BPAI. In particular, the court agreed with the BPAI's finding that Kubin used the same basic conventional methodologies as the prior art to isolate the NAIL cDNA. In addition, the court also agreed with the BPAI's finding that "one of ordinary skill in the art would have recognized the value of isolating NAIL cDNA, and would have been motivated to apply conventional methodologies, such as those disclosed and utilized in in the prior art, to do so.

The court then addressed the BPAI's conclusions on the merits and Kubin's arguments.

In doing so, the Federal Circuit considered the effect of its prior obviousness jurisprudence on the BPAI's conclusion of obviousness, holding that its previous rejection of the "obvious to try" doctrine for certain biotechnological inventions no longer applied in view of *KSR*'s discrediting of *Deuel*.

For over 10 years, Applicants and patentees alike have relied on the Federal Circuit's holding in *In re Deuel* to thwart obviousness challenges to DNA-based claims as "obvious to try." However, this may no longer be a feasible argument or defense. The Federal Circuit, agreeing with the BPAI, points out that the Supreme Court in *KSR* has effectively overruled *In re Deuel*'s "obvious to try" doctrine. In particular, the Federal Circuit, held that "[i]nsofar as Deuel implies the obviousness inquiry cannot consider that the combination of the claim's constituent elements was "obvious to try," the Supreme Court in *KSR* unambiguously discredited that holding. In fact, the Supreme Court expressly invoked *Deuel* as a source of the discredited "obvious to try" doctrine."

The court then observes that the Supreme Court's analysis in overruling *In re Deuel* was in line with its own prior obviousness jurisprudence expressed in its pre-*Deuel* decision in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), which held that for there to be obviousness, all that is required is a "reasonable expectation of success." One issue the court focused on was the meaning of "obvious to try," which the court noted was often misapplied in two different impermissible situations. First, "obvious to try" should not equate to obviousness where the thing that would have been "obvious to try" would involve trying various adjustable parameters without clear direction as to their significance or effect. Second, "obvious to try" should not equate to obviousness where what was "obvious to try" was a new technology or approach with nothing more than general guidelines for its use or application.

With respect to this earlier decision, the *Kubin* court states that *O'Farrell*'s first impermissible "obvious to try" situation is actually stated in the inverse by the Supreme Court in *KSR* by its holding that "where a skilled artisan merely pursues "known options" from a "finite number of identified, predictable solutions," obviousness under 103 arises." Thus, on the bases that the prior art teaches the protein of interest (p38), includes a motivation to isolate the gene coding for that protein (p38 is a marker on all NK cells), and provides illustrative instructions for cloning cognate genes, the Federal Circuit held under *KSR* that the claimed invention is "the product not of innovation but of ordinary skill and common sense." Or, as the court states under its earlier *In re O'Farrell* analysis, the invention was obvious because "a skilled artisan should have had a resoundingly 'reasonable expectation of success' in deriving the claimed invention" without being impermissibly "obvious to try."

Conclusion

After *In re Kubin*, some things are clearer than others. For instance, on the one hand, *In re Kubin* does not change the fact that, under *KSR* and earlier jurisprudence, the determination of obviousness is still highly fact specific. On the other hand, while *In re Kubin* makes it clear that the "obvious to try" standard can now be applied in the "unpredictable" art of biotechnology under certain circumstances, i.e., known protein and known methods for obtaining nucleic acid and amino acid sequences, the extent that the "obvious to try" standard will be applied to situations outside of the facts of *In re Kubin* remains to be seen.

At a minimum, it would appear that *In re Kubin* will make it more difficult to secure patents covering DNA sequences if the corresponding protein is known or has been previously identified (with or without an amino acid or partial amino acid sequence thereof) and general methods for DNA cloning and sequencing are available that can be used to obtain the claimed DNA sequence.

At least for now, the impact of the *Kubin* decision on biotechnology inventions may likely be limited to claims directed to DNA sequences. However, given the court's view that *KSR* should not be restricted to the "predictable arts" on the basis that the "unpredictable art" of biotechnology can be, in certain instances, "profoundly 'predictable,'" there exists a justifiable concern that as the art of biotechnology continues to mature and progress, the Federal Circuit may possibly expand the reach of *In re Kubin* into other areas of biotechnology, possibly rendering a wider-array of inventions "obvious to try." Only time will tell as to *Kubin*'s ultimate effect on biotechnology inventions as additional factual scenarios are brought before the courts.

The ECJ finds that wine and glasses are not similar

The European Court of Justice (the ECJ) has dismissed an appeal filed by Waterford Wedgwood plc of the decision by the Court of First Instance (the CFI), which rejected Waterford Wedgwood's opposition to the Community Trade Mark (CTM) registration by Assembled Investment (Proprietary) Ltd. (the Applicant) of the figurative mark "WATERFORD Stellenbosch." According to the ECJ, the CFI's assessment that wine and articles of glassware are not similar within the terms of Article 8(1)(b) CTMR was based on sufficient argument.

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Article 8(1)(b) of the CTM Regulation provides that, "upon opposition by the proprietor of an earlier trade mark, the trade mark applied for shall not be registered if, because of its identity with or similarity to the earlier trade mark and the identity or similarity of the goods or services by the trade marks, there exists a likelihood of confusion (including a likelihood of association) on the part of the public in the territory in which the earlier trade mark is protected."

The Applicant filed an application for registration in Class 33 of the "WATERFORD Stellenbosch" figurative mark (represented above) for *"alcoholic beverages, namely wines in the Stellenbosch district, South Africa."*

Waterford Wedgwood plc (the Opponent) opposed the CTM application on the basis of its earlier WATERFORD mark registered for, amongst other things, *"articles of glassware, earthenware, chinaware and porcelain"* in Class 21. The Opposition Division of the Office for Harmonisation in the Internal Market (OHIM) rejected the opposition, but the Opponent successfully appealed that decision. The OHIM First Board of Appeal concluded that wine and articles of glassware were similar on the basis that wine and wine glasses complement each other. As such, in view of the high similarity between the marks, there was a likelihood of confusion within the terms of Article 8(1)(b). The Applicant then lodged an appeal before the CFI, which reversed the OHIM First Board of Appeal's decision. The CFI concluded that the degree of complementarity between wine and articles of glassware was not sufficient for the purpose of Article 8(1)(b). The Opponent asked the ECJ to have the CFI's decision set aside, claiming that the CFI had (i) applied erroneous legal criteria in the assessment of similarity of goods, and (ii) distorted the facts.

The ECJ dismissed the Opponent's appeal on the grounds that the CFI's assessment of the similarity of the goods at issue was sufficiently detailed and based on the factors previously set out in *Canon/Metro-Goldwin-Mayer,* C-39/97. Such factors include the nature of the goods, their intended purpose, their method of use and whether they are in competition with each other or are complementary.

The ECJ referred to the established case law (*Canon*; *Sabel AG/Puma AG*, C-251/95; *Lloyd Schuhfabrik Meyer & Co./Kijsen Handel*, C-342/97) in which the ECJ held that the likelihood of confusion on the part of the public must be assessed globally, taking into account all the relevant factors of the case. Accordingly, a low degree of similarity between the goods or services covered may be offset by a high degree of similarity between the marks, and vice versa. The ECJ noted, however, that the interdependence of those different factors does not mean that a complete lack of similarity can be fully offset by the strong distinctive character of an earlier trade mark for the purposes of Article 8(1)(b). Since the CFI, after carrying out a detailed assessment, found that the goods were not similar, one of the conditions required by Article 8(1)(b) was lacking, and therefore there was no likelihood of confusion.

The ECJ noted that an appeal to the ECJ can lie solely on a particular point of law and, thus, the CFI has exclusive jurisdiction to assess facts and evidence, save where the facts or evidence are distorted. The ECJ ruled that the CFI's conclusion that wine and articles of glassware were not similar within the meaning of Article 8(1)(b) was based on a detailed comparative assessment of the goods in question, which also took into account the evidence submitted by the Opponent. On that basis, the ECJ rejected the Opponent's second ground of appeal that the CFI had distorted the facts. As the CFI did not distort the facts or evidence, the ECJ had no jurisdiction to conduct a new assessment of the facts and evidence of the case.

"The ECJ ruled that the CFI's conclusion that wine and articles of glassware were not similar within the meaning of Article 8(1)(b) was based on a detailed comparative assessment of the goods in question..."

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Strategies for Cost Effectively Securing and Maintaining Foreign Patent Rights

In today's challenging economic environment, for individual inventors or companies, large and small, the decision whether to seek patent rights beyond U.S. borders is a difficult choice to make.

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"The Federal Trade Commission publishes a "priority watch list" that identifies countries that fail to adequately protect intellectual property and violate intellectual property enforcement agreements."

Further, once the decision has been made to pursue protection abroad, the individuals or corporate entities must then decide in which countries pending applications and issued patents should be maintained.

In the context of patent filing, the following foreign filing options are usually available to clients: 1) no foreign protection, 2) file a PCT international application, 3) file one or more regional applications, and 4) file national applications in selected countries. It should be noted that the second through fourth options can be selected individually or in combination. Obviously, if the technology has little present or future economic value, no foreign filings should be made.

The second option listed above concerns the filing of an international application under the Patent Cooperation Treaty (PCT). The PCT established a union for cooperation in the filing, searching, and examination of applications for the protection of inventions. What the PCT does not provide is a patent right. In other words, filing an application under the PCT provides applicants with an understanding of the potential patentability of the disclosed invention (in the form of a search report and written opinion) but does not result in an international patent. Ultimately, after approximately 20 or 30 months from the priority date of the invention, depending on the "contracting state," a separate application must be filed in each of the contracting states in which patent protection is desired.

Over 140 nations are members or "contracting states" of the PCT and, therefore, the PCT application can serve as a mechanism for extending the deadline for filing national applications in many countries and deferring the associated cost. This extension of the national filing deadline provides time for marketing the product and/or identifying a licensee. Additionally, the search and examination that is conducted on the PCT application provide the applicant with an opportunity to amend the claims of the application in order to place the application in better condition for entry into national patent offices.

Certain disadvantages are noteworthy when filing a PCT international application. First, there will inherently be a delay in obtaining the ultimate patent. Because published PCT applications provide at most only provisional claim protection in most jurisdictions, such a delay gives competitors the ability to market and sell competing products during that time period. Additionally, all PCT applications are published 18 months from their priority date. This pre-grant publication provides advance notice to the competition of the applicant's products and potential scope of protection.

One way to reduce the cost associated with filing a PCT application is through the applicant's selection of the International Searching Authority (ISA). On November 1, 2008, the Australian Patent Office (IP Australia) became the fourth agency designated as a competent International Searching Authority (ISA) and International Preliminary Examination Authority (IPEA) under the PCT for applications filed in the U.S. With this addition, U.S. applicants can select the U.S. Patent & Trademark Office (USPTO), the European Patent Office (EPO), the Korean Intellectual Property Office (KIPO) or IP Australia as the ISA or IPEA. Currently the search fees for these agencies differ significantly, as the U.S. and EPO fees are $2080 and $2164, respectively, while the fees charged by IP Australia and KIPO are $1091 and $609, respectively. Thus, an applicant can save roughly $1555 dollars simply by selecting KIPO as the ISR, in lieu of the EPO.

The third option listed above concerns the filing of regional patent applications. Regional patent organizations, such as the European Union, consist of groups of countries (i.e., "members states") that have agreed to apply a unified set of patent laws. As a result, a regional patent application will mature into an issued patent, which then only needs to be validated in the desired members states (countries) in order to obtain full national patent protection in the selected countries. The cost associated with validating the European application can be reduced by selecting a European associate that has offices in the desired member states. Still further, selecting a U.S. law firm with an office in Europe can also reduce filing and prosecution cost by eliminating the need to engage local counsel for the European filing.

The fourth option listed above concerns the direct filing of national patent applications (also called direct convention applications) in the countries of interest or in those countries that are not contracting states of the PCT or member states of a regional patent union. Before a decision is made as to whether to incur the expense associated with one or more direct foreign filings, one must first determine if

foreign protection for the invention is available.

Unlike U.S. law, patent protection is only available in many foreign countries if a patent application was filed prior to any public disclosure. This rule is often referred to as the "absolute novelty" standard.

Once it has been determined that the invention was not publicly disclosed prior to the filing of an initial patent application, the costs associates with filing abroad must be considered. The estimated cost to prosecute a foreign language patent application to issue is approximately $6,000/country. Further, the estimated cost to prosecute a foreign language patent application to issue is approximately $15,000/country, if Asian language translations are required. These costs do not include annual maintenance fees or annuities that each country charges in order to keep the pending application or issued patent alive or in force.

One important factor to consider when determining whether to file abroad is whether there is a licensee for the technology. In other words, if the U.S. rights have been licensed, does the licensee desire foreign protection or does the license require the pursuit of foreign protection and will that party pay for the associated costs? Or, are there foreign entities that need a license?

Another factor that must be considered when making a determination as to whether foreign protection is desired, is the lengthy pendency of foreign applications. In Europe it is not uncommon for applications to be pending for 5 to 10 years. The application process often takes even longer in Japan. As a result, if the applicant is seeking to patent technology that will be outdated or outmoded by the time a patent grants in a foreign country, it may be advantageous to forgo foreign filings and maintain the technology in confidence as a trade secret.

Once the initial decision to seek protection abroad for the technology has been made, the applicant must determine in what countries protection should be sought or maintained. Business savvy clients will appreciate that protection should be pursued in countries where a substantial market for the invention exists. Obviously, the definition of "substantial market" differs from applicant to applicant, and from technology to technology. Another significant factor for determining where to file abroad is where the applicant and its competitors are doing business or will be conducting business. Dunn & Bradstreet reports and various patent databases can often be used to shed light on a competitor's activities.

Applicants should always first look to protect and maintain their intellectual property in countries where they have a manufacturing facility. Next, for obvious reasons, applicants should consider seeking protection in countries where the competition has manufacturing facilities. For example, if the applicant manufactures tanning lamps, and its biggest competitor has only one factory capable of making tanning lamps and the factory is located in Hungary, the applicant should seek patent protection in Hungary. A Hungarian patent would be effective at restricting the competitor's worldwide sales.

Lastly, an important factor to consider when deciding where to file abroad or whether a foreign portfolio is to be maintained is the ability to monitor and enforce the patent once issued. The world news is littered with articles concerning other governments' lack of intellectual property policing. The Federal Trade Commission publishes a "priority watch list" that identifies countries that fail to adequately protect intellectual property and violate intellectual property enforcement agreements.

In conclusion, foreign filing decisions are not easily made. Such decisions require a complete understanding of many factors, such as the present and future value of the technology, the costs associated with the filings, a competitor's activities, and the enforcement policies of foreign nations.

EAPD Welcomes New Partner & Associates

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Nicholas Bolter (London) has joined the firm in the Intellectual Property Department. Nick focuses his practice on contentious and non-contentious work involving trade marks, trade secrets and confidentiality, passing off, copyright and designs.

Bolter advises clients in the luxury and consumer goods sectors in relation to brand protection and brand enforcement and has experience in organizing and running anti-counterfeiting and enforcement campaigns for some of the world's largest brand owners. He sits on the Eastern European and Central Asia Anti-Counterfeiting Sub-Committee of INTA. In 2007 and 2008 he spent nearly a year in total seconded to The Coca-Cola Company as Acting Trade Marks Counsel for Europe.

Sascha Grimm is one of six newly qualifying trainees in the London office of EAPD who completed their training contracts and are now taking up roles as solicitors. **Mitain Patel** has recently completed his training contract at Field Fisher Waterhouse and now joins EAPD as a solicitor in the London office.

'Experimental Use' and 'Bolar' Exemptions in the EU – How Far DoThese Provisions Extend?

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Patent systems were designed to encourage and reward innovation. A system that prevents research into the subject matter covered by a patent would be inconsistent with such goals, and so the patent systems of most countries contain provisions that exempt from infringement experiments performed relating to the subject matter of a patent. More recently the EU has introduced a 'Bolar' provision into its legislation also. But what effect do these combined exemptions have? How far do these exemptions extend to trials performed for the purposes of seeking regulatory approval and what about other clinical trials? Are research tools and their use exempted under these provisions? In this article, the extent of the exclusion for such acts in Europe, particularly the UK, is discussed. I also consider to what extent these provisions may affect scientific development.

"...an exemption is provided such that 'an act which ... would constitute an infringement of a patent for an invention shall not do so if ... it is done for experimental purposes relating to the subject matter of the invention'."

The UK 'Experimental Use' Exemption

According to the UK Patents Act of 1977, section 60 (1) a patent is infringed if, for instance, a person 'makes or uses' a product covered by the patent within the UK. However, an exemption is provided such that 'an act which ... would constitute an infringement of a patent for an invention shall not do so if ... it is done for **experimental purposes relating to the subject matter of the invention'.** This is commonly referred to as the 'experimental use' exemption and shall be referred to in that manner herein.

UK Case Law

In interpreting the meaning of the terms 'experimental purposes' and 'subject matter of the invention', certain decisions of the UK courts are relied upon. In particular, the case still used for the interpretation of the scope of these terms is *Monsanto/Stauffer* (RPC [1985] 515), which, although nearly 30 years old, still holds. In the case in question, Stauffer wished to undertake field trials using a herbicide that was known to infringe a patent held by Monsanto, in order to obtain regulatory clearance for this product.

This case established the principle that experiments carried out for the purpose of gaining regulatory approval for a product would not be exempt, under the 'experimental use' exemption, from being regarded as acts of infringement in the UK. However, it seems that 'experiments' performed to find out something new – that is, which advance scientific knowledge – may be exempt from being regarded as acts of infringement, in so far as they relate to the subject matter of the invention. Further, it is worth noting that according to this case, an exempt act can have 'an ultimate commercial purpose'.

With respect to the meaning of the term the 'subject matter of the invention', the UK courts currently consider that the nature of the subject matter should be assessed by considering the contents of the patent as a whole. Furthermore, it is considered that the experimental purpose must have a 'real and direct' connection with that subject matter. There is an important distinction between research relating to the invention, which is exempted, and a research using the invention, which is not. For example, use of a patented sequencing technology in an experiment to further develop sequencing technologies might be exempted, but it is very unlikely that the use of the same technology in an experiment to determine the sequence of a nucleic acid would be exempted.

Practically, what does the 'experimental use' exemption in the UK permit? It is clear that the scope of the exemption is currently interpreted narrowly: experiments that are performed to further scientific knowledge and discover 'something new' can be exempted from being classed as an infringing act, in so far as the experiments performed have a 'direct' connection with the invention described in the patent. However, experiments performed purely for gaining regulatory approval, such as field trials or clinical trials, are, in general not be considered to be exempt from being classed as an infringing act under this provision.

Importantly, however, with the introduction of the new 'Bolar' provisions, discussed in the following section, acts which were previously been considered according to the 'experimental use' exemption are now being addressed under the new 'Bolar provisions' (section 60, subs (5)(i)).

The 'Experimental Use' Exemption in Other Parts of Europe

In other parts of Europe, decisions indicate that the 'experimental use' exemption is being interpreted more generously. For example, the German Supreme Court has held that an exemption permits the carrying out of clinical trials on a patented drug to ascertain its effect in medicinal indications not indicated in the patent (Klinische Versuche (*Clinical trials I* (Germany) [1997] RPC, 623), and in a subsequent decision (Klinische Versuche (*Clinical trial II* (Germany), [1998] R.P.C, 423, tests carried out to ascertain whether another substance falling within the ambit of the patent claim worked as well as (or better than) the patentee's own commercial product were also held exempt. In these two decisions the Bundesgerichtshof emphasised that the only questioned of relevance are whether the acts concerned were in the nature of an experiment which related to the 'subject-matter of the patent'. It was also noted that it was irrelevant whether or not these acts had commercial value.

Although there is no definition of the word 'experimental' it seems appropriate to say that an act may be deemed to be experimental if it seeks to generate new information and the act is not an experiment if it seeks to do no more than verify existing knowledge.

Moreover, a recent decision in France has deemed that under certain circumstances Phase III clinical trials can be exempted from infringement.

European 'Bolar' Provisions

The Pharmaceutical Regulatory Directive

On 11 March 2004 the EU adopted a new European pharmaceutical regulatory directive (Directive 2001/83/EC [2001] OJ EC L311/67 on the Community code for medicinal products for human use). with the aim of facilitating the movement of generic products to the European market. This exemption applies to generic medicinal products and also to non-generics, but only those that are similar to the reference product and which do not fulfil the generic definition for specified reasons.

The directive was implemented into the UK Patents Act by s60(5)(i). This section provides that *'the conduct of tests and trials for the purposes of art.10(1) to (4) of Directive 2001/83 … and the corresponding practical consequences, shall not be regarded as contrary to patent rights for medicinal products'*.

What Does This Mean, in Practice?

This paragraph, in effect, introduces a form of regulatory review or clinical trials defence into UK patent law (i.e., a 'Bolar' exemption). Noteworthy is the fact that this exemption supplements but does not replace the experimental use defence referred to in the preceding section.

The wording of the paragraph is in two sections (i) and (ii). Section (i) exempts *'an act done in conducting a study, test or trial which is necessary for and is conducted with a view to, the application of'* the relevant paragraphs of the appropriate directive; whilst section (ii) in addition exempts *'any other act which is required for the purpose of the application of those paragraphs'*.

The meaning of these terms is rendered clearer by considering the wording of the directive which they implement. Specifically:

'conducting the necessary studies and trials with a view to the application of [the relevant paragraphs] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products'.

Accordingly, in effect a *'consequential practical requirements'* provision has been introduced into the exemption. This seems to relate to the manufacturing, importing and processing of the active material for the necessary studies.

Guidance on how to interpret the provision was issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Patent Office. This guidance is not binding in UK courts, but it is likely that it will be considered and followed in case of doubt.. The MHRA provided a detailed list of exempted activities. These can be summarised as:

- the manufacture or import of active substances and validation of manufacturing process,
- the manufacture or import of finished product and validation of manufacturing process,

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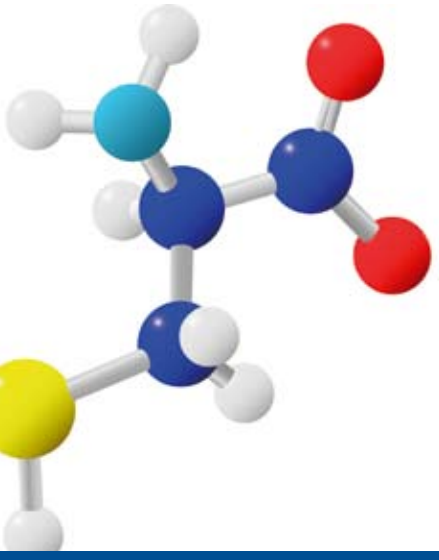
- *Esther Pfaff, International Review of Intellectual Property and Competition Law (2007); 38(3), 258-274: "Bolar" exemptions - a threat to the research tool industry in the US and the EU?*
- *Fiona Bor, European Intellectual Property Review (2006); 28(1) 5-14, 'Exemptions to Patent Infringement applied to biotechnology research tools'.*

"Experimental acts using a patented product may be exempted, in the UK at least, using either the 'experimental use' exemption and/or the 'Bolar' provisions."



- development, testing and use of analytical techniques associated with the manufacture of the active and the finished product,
- conducting pre-clinical tests, clinical and bioavailability trials and stability studies on the medicinal product,
- the compilation and submission of a marketing authorisation and samples of products to regulatory authorities.

The UK approach, like the German version, does not make a distinction with regard to the kind of patents exempted.

Importantly, and in contrast to the US version of the Bolar type exemption, the UK provision has no application to Phase I, Phase II, and Phase III clinical trials on a medicinal product containing a new active substance that has not yet received an authorisation in any medicinal product.

However, as noted above in the clinical trials cases, it appears that in Germany at least, Phase I, II, and III clinical trials may be exempted using the 'use for experimental purposes into the subject-matter of the invention defence'.

It is also worth noting that other member states in Europe have gone further than the UK in their implementation of the 'Bolar' directive. This will be discussed in brief below with respect to Germany.

Germany

In Germany, a new subsection was introduced into the patent code in order to implement the directive. It translates as:

[the following acts do not constitute infringement]

'Studies and trials and the consequential practical requirements necessary to obtain permission to market [a drug] in the Member States or in third countries according to the effective pharmaceutical regulations'.

The new German 'Bolar' provision is often seen as a continuation of the extension of the Experimental Use Exemption in *Clinical Trials I* and *II* However, as in the U.S., the German 'Bolar' exemption applies not only to the approval of generics but also to drugs in general, unlike the more restrictive UK provisions.

What About Research Tools?

Do They Fall Within These Exemptions?

It is generally accepted that the term 'research tool' in its broadest sense describes the full range of resources that scientists use in the laboratory. This may include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software.

Was it the intention of the European legislature to include within the exemptions the use of research tool patents? There is no hint in the preamble of Directive 2004/27/EC that the legislature intended to include these patents. It only aims at facilitating the access of 'medicinal products' to the market. A strong argument against an inclusion of patents other than those which will be subject to future approval is that the 'Bolar' provision was enacted as part of the Community code relating to medicinal products for human use and not as part of EC Patent Law. Systematically, it is therefore more likely that the European legislature did not want to address any patent involved in the process of drug discovery but only focused on those patents which are going to be subject to future approval.

What is the Practical Effect of This?

The concern that the value of research tool patents could be diminished by exemptions for market approval studies has led to a vivid debate about the scope of 'Bolar' exemptions, naturally, particularly by research tool companies. It will be interesting to watch the debate unfold and we await decisions to guide us in this respect. I do not consider that the legislation intended the use of research tools patents to be exempted by the 'Bolar' provisions. Such an interpretation would be inconsistent with the intention of the patent system to reward and encourage innovation.

Summary

Experimental acts using a patented product may be exempted, in the UK at least, using either the 'experimental use' exemption and/or the 'Bolar' provisions. Experiments designed to elicit new knowledge – that is, which can be considered to advance scientific knowledge – will generally be exempted under the former, whilst experiments and clinical trials using the patented drug and which are designed to obtain regulatory approval will generally be considered for exemption under the 'Bolar' provisions. In the UK at least, these exemptions do not extend to non-generics. In some other EU countries, Germany for example, these provisions have been interpreted more generously.

The importance of a fair interpretation of scope of these exclusions is clear; too broad an interpretation of the exempted acts may lead to a diminution of the value of patent rights for innovative drugs and also the research tools patents involved their production. Effectively, this would discourage the generation of new drugs, whilst at the same time promoting the value in generics. Surely, this is contrary to the goals of the patent system. Conversely, too narrow an interpretation of the exempted acts would confer upon the patent holders of innovative drugs an unfair monopoly and one which would discourage the generic market. The effect? Fewer low-cost generics for consumers. This is certainly not in line with the aims of the EU directives. It will be interesting to see how this area unfolds.

USPTO Update

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USPTO Prior Art Peer Review Program Suspended

On June 15, 2009, the U.S. Patent and Trademark Office (USPTO) announced that the Peer-to-Patent program that allowed third parties to submit and evaluate prior art in pending U.S. patent applications has been suspended indefinitely.

The program originated in June, 2007 as a one-year pilot program, and was extended one year later. However, the USPTO decided to suspend the program this year in order to complete a full evaluation of its impact on the patent examination process.

The Peer-to-Patent program began as an experiment aimed at improving the quality of issued patents by allowing U.S. patent examiners to access prior art submitted by the general public via open network peer review of patent applications. Participation was voluntary, and the program was initially limited to applications in Group 2100 (computer hardware/software), but subsequently expanded to business methods in class 705.

The USPTO reported that 66 Office Actions were issued for applications that underwent peer review, and prior art submitted through the program was utilized by examiners in 18 of those applications. In addition, between 12-21% of examiners reported that prior art obtained through the program was otherwise inaccessible by the USPTO.

The patent community awaits further news on the future of the peer review program, which may be undergoing only a temporary suspension until the review is completed and funding is secured. Previously the program was funded through corporate and foundation grants. It is possible that the incoming USPTO Director, David J. Kappos, will reinstate the program.

USPTO Issues Trademark Guides for Refusals Based on Deceptive Subject Matter

On July 13, 2009, the USPTO issued a notice of new guidelines regarding the examination of trademarks that are considered deceptive under the Lanham Act. The notice refers to Trademark Examination Guides 01-09 and 02-09, issued on May 11, 2009, which list and discuss case law with respect to: elements of a refusal, evidentiary issues with respect to the refusal, and procedures for issuing refusals.

Guide 01-09 provides examination procedures for deceptiveness refusals of non-geographic marks. Guide 02-09 provides examination procedures for refusals of geographically deceptively misdescriptive marks.

In both guides, for example, an inquiry regarding the refusal has been changed from "Is the misdescription likely to affect the decision to purchase?" to: "Is the misdescription likely to affect a significant portion of the relevant consumers' decision to purchase?" The USPTO notice indicates that the guides supersede any inconsistent sections of the Trademark Manual of Examining Procedure (TMEP).

Finland Added to Patent Prosecution Highway

Effective July 6, 2009, the USPTO and the National Board of Patents and Registration of Finland initiated a Patent Prosecution Highway (PPH) one-year pilot program. The U.S.-Finnish PPH is the tenth such program involving the U.S. and foreign patent offices.

Under the Patent Prosecution Highway, applicants who receive a ruling that at least one claim of an application is patentable, in the U.S. or Finland, can request that the corresponding application in the other office receive expedited treatment.

Kappos Sworn In as New Director of USPTO

On August 13, 2009, David J. Kappos was officially sworn in by U.S. Commerce Secretary Gary Locke as director of the U.S. Patent and Trademark Office (USPTO) and under secretary of commerce for intellectual property. Kappos formerly served as the top intellectual property attorney for IBM. Kappos was unanimously confirmed by the U.S. Senate on August 7, 2009, the confirmation coming only one day after the Senate Judiciary Committee approved his nomination by voice vote. Kappos had received bipartisan support at the committee level, and in particular, was urged by committee members to address issues such as patent pendency and the backlog of unexamined patent applications.

In remarks delivered during the swearing-in ceremony, Kappos indicated that he intends to improve operations of the USPTO by reducing the backlog of unexamined patent applications, reducing pendency time of patent applications, working off the backlog of appeals, and improving re-examination procedures. Kappos also remarked that a high priority is to place the USPTO on more sustainable financial footing in both the short term and long term.

Revenue Shifting by USPTO Approved to Avert Patent Layoffs

On August 7, 2009, President Obama signed into law H.R. 3114, which provides the USPTO with the authority to transfer funds collected with regard to trademark applications to fund its patent operations.

The legislation aims to avoid possible layoffs or furloughs of patent examiners due to reduced fee collections on the patent side. Under the legislation, the USPTO can shift revenue to support patent operations until June 30, 2010, under the authority of the USPTO director. Any transferred funds must be repaid by no later than September 30, 2011. The total amount borrowed from trademark operations cannot exceed $70 million. Notably for patent applicants, the USPTO has been granted authority to repay any amounts borrowed by establishing a surcharge on patent fees.

In remarks delivered during his swearing-in ceremony, Director Kappos praised the work done to make these funds available, but indicated that he would prefer not to use the authority.

Federal Circuit Update

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" When issued a covenant not to sue without a specific restriction on sales, however, a competitor is likewise granted permission to make, use, or sell products free of the patentee's claims."

Federal Circuit Vacates Decision Regarding PTO Rulemaking Authority

***Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *decision vacated, appeal reinstated and rehearing en banc granted*, 91 U.S.P.Q.2d 1153 (Fed. Cir. 2009)**

The Federal Circuit recently vacated and granted a rehearing in an earlier, closely-followed decision holding that a certain set of rules regarding patent applications are procedural, and so therefore were within the authority of the Patent and Trademark Office. The PTO issued the disputed rules in August 2007. One of those rules, Final Rule 78, set a limit of two continuing patent applications, and another, Final Rule 114, set a limit of one request for continued examination (RCE). A third rule, Final Rule 75, permits a patent applicant to file only 5 independent claims and 25 dependent claims, and to request additional claims the applicant must provide an examination support document (ESD) to support the claim for patentability. The last rule, Final Rule 265, establishes requirements for the ESD. Appellants Tafas and GlaxoSmithKline argued that these rules were beyond the PTO's rulemaking authority and improperly restricted patent applicants' rights. In its original decision, the court noted that the PTO does not have substantive rulemaking authority, but also found that the rules were not substantive, but procedural in nature. Consequently, the court found that only Rule 78 limiting the number of continuing applications was inconsistent with the rights to which applicants are entitled under the Patent Act. Upon petition by the appellees, the court vacated this decision, agreed to a rehearing en banc, and granted motions for leave to file briefs as amici curiae. The result of the upcoming hearing will have a significant impact on the PTO's rulemaking authority and the corresponding rights of patent applicants, and it will be announced in an upcoming edition of this column.

Infringement Conflict for Product-by Process Claims Resolved

***Abbot Laboratories v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009)**

In a consolidated case on appeal from two separate jurisdictions, the Federal Circuit overruled an earlier decision to resolve a conflict regarding product-by-process infringement claims. The seventeen-year conflict was the result of two conflicting opinions in the Federal Circuit. In one of those opinions, *Scripps Clinic & Research Foundation v. Genentech, Inc.*, the court refused to limit product-by-process claims to the product prepared by the process claimed in the patent. In the other, *Atlantic Thermoplastics Co. v. Faytex Corp.*, the court held that process terms that define the product of a product-by-process claim serve as enforceable limitations to a patent claim. The court in *Sandoz* overruled *Scripps* and, citing several U.S. Supreme Court decisions, adopted the holding in *Atlantic Thermoplastics*. Specifically, the court noted that even if the products of an alleged infringer and a patentee are similar, they are not sufficiently defined until it can be shown that they are made by the same process. In Sandoz, the patentee argued that the language "obtainable by" in the process claim introduced merely an optional process. The court found that it did not, as to find otherwise would mean that the patent could claim a product obtained by a process other than those explicitly recited in the claims. Therefore, the court found, even though the accused product was bioequivalent to the patentee's product, the process described was a limitation to the asserted claims that must be applied in the infringement analysis. Because of this limitation, the patent was not broad enough to encompass the alleged infringers' products produced using an alternate process.

Covenant Not to Sue Equals Authorization to Sell

***Transcore, LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009)**

When parties to a settlement agreement engaged in an infringement dispute, the Federal Circuit found that the patentee's covenant not to sue in the agreement authorized all acts that would otherwise constitute infringement. Authorized acts included, therefore, selling devices covered by the patent, which in this case was an automated toll collection system. The court emphasized that a patentee is given the right to exclude others from making, using, or selling devices covered by the patent. Noting that a covenant not to sue is indistinguishable from a license, the court stated that a competitor does not have to wait to obtain a specific license to sell an otherwise infringing device, because not even the patentee is granted the right to sell, and therefore can not pass that right to another. When issued a covenant not to sue without a specific restriction on sales, however, a competitor is likewise granted permission to make, use, or sell products free of the patentee's claims.

Rules for Transferring Cases Clarified

***In re Volkswagen of America, Inc.*, 566 F.3d 1349 (Fed. Cir. 2009)**
***In re Genentech Inc.*, 566 F. 3d 1338 (Fed. Cir. 2009)**

In two separate opinions, the Federal Circuit clarified the rules for transferring cases from the Eastern District of Texas, which has become known as a patentee-friendly forum. In both cases, the party seeking transfer did so on the basis of *forum non conveniens*, which means that a transfer is warranted for the convenience of the parties and witnesses, in the interests of justice. In the first case, *In re Genentech*, the Federal Circuit granted a petition for mandamus to direct the Eastern District of Texas to transfer the case to California. In doing so, the court held that a motion to transfer venue should be granted when the transferee venue is clearly more convenient than the venue chosen by the plaintiff. The court added that there is no requirement, when seeking a transfer for the convenience of parties and witnesses, that a transferee court have jurisdiction over the plaintiff, only that it have jurisdiction over the defendant.

A court also need not evaluate the significance of an identified witnesses' testimony when considering the convenience of witnesses, but need only determine whether the testimony is relevant and material to the case. In this case, the court also added that there were no witnesses or relevant documents in Texas, which also weighed in favor of transfer. In addition, the court noted that in a patent infringement case, the majority of relevant evidence belongs to the accused infringer, and so the location of the defendant's documents weighs in favor of a transfer to that location.

Finally, unless all else is equal, the courts' relative congestion is not a determinative factor. While denying a petition for a writ of mandamus, the Federal Circuit in *In re Volkswagen* noted the applicability of the factors outlined in *Genentech*. In *Volkswagen*, however, two other cases involving the same patents were also pending in the district. The court concluded that judicial economy was best served by having the same district court try all of the cases, adding that this was a "paramount consideration" when determining whether the transfer would serve the interests of justice.

Highlights

- **Brian Landry** (Boston) participated in the International Trademark Association Roundtable entitled *"Managing Trademark Costs in a Down Economy – Opportunities and Obstacles for Brand Owners"* in April. The roundtable was co-hosted at EAPD's Boston office.
- **Kathleen Williams** (Boston), **Antonio Maschio** and **Candi Soames** (Southampton) presented a workshop on dual EU and US patent strategy at the BioTrinity Conference which took place in Oxford, UK in April.
- **John Olsen** (London), **Maria Scungio**, **David Weild**, **Peter Schechter**, **Ye-won Min**, **David Greenbaum** (New York), **Barry Kramer** (Stamford), **John Ottaviani** (Providence), **Howard Gitten** (West Palm Beach) and **Pat Concannon** (Boston) attended the International Trademark Association (INTA) Annual Meeting that took place in May, in Seattle, WA. During the Annual Meeting, EAPD hosted a private cocktail reception at the Harbor Club and John Olsen (London), presented awards at the World Trademark Review Awards ceremony.
- **Jeff Hsi**, **Peter Lauro**, **Kathleen Carr**, **Nat Gardiner**, **Kathleen Williams**, **Richard Smith**, **Jon Lourie**, **Melissa Hunter-Ensor** (Boston), **Antonio Maschio**, **John Lloyd** (Southampton) and **Mark Arnold** (West Palm Beach) attended the Biotechnology International Organization (BIO) annual conference that took place in May in Atlanta, GA.
- **Glenn Pudelka** (Boston) attended the Copyright Society of the U.S.A. (CSUSA) annual meeting that took place in Bolton Landing, NY in June. At the meeting, Glenn was named a trustee of the CSUSA.
- **Kathleen Williams** (Boston) was a speaker at "The Business of Genomics: Bridging the Gap from Concepts to Realization Symposium" held in June in San Francisco, California. The title of one presentation was *"RNAi: The Intellectual Property Landscape – Early and Evolving."* Kathy also presented "Protecting Your IP and Commercializing Your Technology: The Devil is in the Details," as part of the Intellectual Property Symposium: Navigating the Legal Landmine session.
- **Candi Soames** and **Antonio Maschio** (Southampton) presented at the 16th Forum (European Edition) on Biotech patenting, which took place in Munich, Germany in June. The title of their presentation was *"The Changing Requirements for Inventive Step in Europe."*
- **John Olsen** (London), **David Weild** and **David Greenbaum** (New York) attended the IP Business Congress 2009 conference in Chicago, IL in June. John was on a panel titled, *"Brand Management: Valuing Brands: The Impact of the Downturn; Managing Brands in a Globalized Economy; New Business Models for Private Practice."* EAPD was a sponsor of the conference.
- **Candi Soames** (Southampton), **Kathleen Williams** and **Richard Smith** (Boston) attended Euro-Biotech Forum 2009 in Barcelona, Spain in June. EADP was the exclusive law firm sponsor of the Forum.
- **Catherine Toppin** (Boston) gave a lecture on Intellectual Property basics to a group of Boston Public School students at an agency called Tech Boston In July.
- **John Ottaviani** (Providence) attended the American Bar Association Annual Meeting in Chicago, IL in August.

For further details on any of these highlights please contact Imelda Kenny at: IKenny@eapdlaw.com.

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The Intellectual Property Department of Edwards Angell Palmer & Dodge has significant experience in the various scientific disciplines of biotechnology, computer software and hardware, chemistry, electronics, and mechanical arts. That depth of experience extends as well to all substantive areas of law connected with intellectual property procurement, protection, enforcement, and licensing. Our practice includes patent litigation, prosecution, interference, reexaminations and reissues; trademark clearance, litigation, registration, oppositions and cancellations; trademark portfolio management; copyright registration, and litigation. We also provide advice and opinions concerning all phases of intellectual property, patentability and infringement studies, due diligence analyses, licensing and trade secret protection. Please feel free to contact any Edwards Angell Palmer & Dodge attorney.

We hope you find this publication useful and interesting and would welcome your feedback. For further information and additional copies please contact Imelda Kenny, Editorial Assistant at IKenny@eapdlaw.com.

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