EDWARDS ANGELL PALMER&DODGE

Intellectual Property Bulletin

Spring 2009

Court of Federal Claims Allows Patent Infringement Suit Directly Against Government Contractor

A recent ruling by the Court of Federal Claims has qualified a long enjoyed shelter by government contractors, which protected them against infringement suits for activities arising under government contracts. With this ruling, patentees may now sue government contractors directly, when relevant activities occur outside the United States.

The underlying facts and circumstances of the case date back to 1991, when the United States contracted with Lockheed Martin Corporation to design and build the F-22 advanced tactical fighter aircraft. Lockheed subcontracted for two types of silicide fiber products used in the body of the aircraft. The first product was a pre-impregnated material made from fibers partially carbonized and manufactured into sheets in Japan, which were then imported to the United States. The second product was a silicide fiber made from fibers manufactured exclusively in Japan, but processed into mats in the United States. (See *Zoltek Corporation v. United States*, 422 F.3d 1345, 1349 (CAFC 2006)).

> "With this ruling, patentees may now sue government contractors directly..."

Zoltek sued the U.S. government under 28 U.S.C. §1498(a), alleging Lockheed's use of both of the fiber products in the F-22 jet fighter infringed on Zoltek's U.S. Patent No. Re 34,162. The action originated in the U.S. Court of Federal Claims, where it was held that Zoltek could not bring an action against the United States under 28 U.S.C. §1498(a) because §1498(c) bars actions arising in foreign countries. The Court also held, however, that Zoltek could instead assert its claims in an action arising from a Fifth Amendment taking. *Zoltek Corp. v. United States*, 58 Fed. Cl. 688 (2003).

The United States appealed the decision to the U.S. Court of Appeals for the Federal Circuit and Zoltek cross-appealed against the ruling under 28 U.S.C. §1498. The Federal Circuit affirmed the ruling against Zoltek under 28 U.S.C. §1498 and reversed the determination that the Federal Claims Court could assert jurisdiction by treating the action as a Fifth Amendment taking. Later, the Federal Circuit refused to reconsider en banc and the U.S. Supreme Court refused to grant certiorari. On remand, the Court of Federal Claims decided to transfer the case to a district court once Zoltek amended its complaint to name Lockheed instead of the United States. *Zoltek Corporation v. United States*, 2009 U.S. Claims LEXIS 10.

The result is that the patentee, Zoltek, is now able to bring its patent infringement action directly against the government contractor, Lockheed, for activities arising under the government contract. This decision was based on 28 U.S.C. §1498, which governs patent infringement claims involving government contractors. 28 U.S.C. §1498(a) states, in relevant part, "[w]henever an invention described in and covered by a patent of the United States is used ... by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." 28 U.S.C. §1498(c) further

Continued on page 2

In This Issue:

Court of Federal Claims Allows Patent Infringement Suit Directly Against Government Contractor 1-2

The Opposition Procedure before the European Patent Office 2-3

Patentability of Methods of Medical Treatment and Medical Devices in Europe 4-6

Highlights & Congratualtions 7

USPTO Update 8-9

Federal Circuit Update 10-11

EAPD WELCOMES NEW PARTNER AND TEAM

John Olsen joins as co-chair of the firm's International Trademark and Copyright Protection Group.

See page 9 for further details


By Joshua L. Jones and
Scott D. Wofsy
Stamford

For further information contact:

e: JLJones@eapdlaw.com
t: +1 203 353 6870

e: SWofsy@eapdlaw.com
t: +1 203 353 6831

states, "[t]he provisions of this section shall not apply to any claim arising in a foreign country."

28 U.S.C. §1498(a) does two things. First, it waives the sovereign immunity defense of the Unites States in the case of patent infringement suits. Second, it shelters government contractors by requiring infringement actions arising from contractors' activities "for" the United States to be brought against the government itself. It was well established before Zoltek that §1498(c) barred actions against the United States (under §1498(a)) for claims arising in a foreign country. What is new with the latest Zoltek ruling is the notion that §1498(c) also removes the shelter for government contractors, allowing patentees to sue contractors directly, where relevant activities occur outside the United States.

The reasoning of the Court of Federal Claims appears to be that if the relevant activity occurred outside the United States, 28 U.S.C. §1498(c) renders §1498(a) inoperative, both with respect to the sovereign immunity waiver and with respect to immunity for government contractors. Therefore, although Zoltek may not sue the United States government in this instance, Zoltek can directly sue the government contractor, Lockheed. The ruling seems to be mindful that if §1498(c) were a bar to Zoltek's claim against the United Sates under §1498(a), and if Zoltek were not allowed to sue the contractor directly, Zoltek would be precluded from getting its day in court.

This outcome benefits patentees because under this rule the government and its contractors cannot avoid infringement claims under §1498(a) by simply using overseas subcontractors. Government contractors, however, may consider the outcome unfair, since contractors supplying products to the government may now be denied expected shelter from patent infringement liability simply because part of their contract was performed in a foreign country.

By Dr. John S. Lloyd
EAPD Innovations, London

The Opposition Procedure before the European Patent Office

In Europe, there is an Opposition procedure which can be used to challenge the validity of granted patents before the EPO. This procedure is centralised, which means that a successful challenge will be effective in all of the European contracting states covered by the granted patent. It has been estimated that Oppositions are filed against about 5% of granted European patents, which corresponds to about 3000 per year. The Opposition procedure is a well used and important tool for attacking a European patent in a cost effective manner.

"A Notice of Opposition must include a written reasoned statement indicating the facts, the evidence, and arguments relied upon."

Grounds for Challenging Validity

A European patent can be challenged on the grounds that, at least: (i) the claimed invention is not patentable (ie. it is not novel and/or inventive); (ii) the patent insufficiently describes how to perform the invention; or (iii) the granted patent contains new matter that extends beyond the scope of the filed application.

Preparing an Opposition

A Notice of Opposition must include a written reasoned statement indicating the facts, the evidence, and the arguments relied upon. An Opposition fee must also be paid. The Notice and fee are due within nine months of the publication of the grant of the European patent. If these requirements are not fulfilled within this time frame, then the opportunity for using the centralised Opposition procedure will be lost. The only option then is to challenge the validity of the patent nationally in one or more of the designated contracting states. This will be much more expensive and time consuming.

Importantly, the Notice of Opposition should also include in it a request for Oral Proceedings in the event that the EPO is not minded to revoke the opposed patent in its entirety. This affords the opportunity for the parties to verbally argue their case at the EPO before a decision is reached.

Evidence and Arguments

The likelihood of success of the Opposition will depend upon the strengths and weaknesses of the arguments that are filed in the Notice. Whilst additional arguments can be filed at a later stage, the Opposition Division may not accept such late arguments and, therefore, all of the arguments and evidence should be contained in the Notice of Opposition.

To attack the patentability of the invention, it is

necessary to submit prior art documents (e.g., journal papers, patent applications, and the like) in order to argue that the alleged invention lacks novelty and/or an inventive step. Often a good source of documents is the prosecution history of corresponding applications in other countries. The patent offices of those countries might also have searched and examined the applications, which may uncover additional documents and/or arguments that have never been considered by the EPO. Internet-based searches and even searches of publicly available company materials may also be useful sources of prior art.

It is also worth carefully considering whether or not the skilled person is enabled to carry out the claimed invention. Whilst insufficiency of disclosure is always a tempting ground for opposing a patent, the EPO has placed the burden of proving this firmly on the opponent and so evidence (e.g., experimental data or supporting documents and the like) will often be required to support such arguments.

A careful review of the prosecution history may also give rise to an attack on the ground of "added matter" within the application. New matter that was not disclosed in the application as originally filed may have been inadvertently introduced into the claims during prosecution in order to secure its grant. This may now provide an invaluable hook upon which to hang an added matter attack. This objection may sometimes be incurable if the only available amendment is one which extends the scope of protection since this is not allowable under the provisions of the European Patent Convention. Thus, this ground may result in the complete revocation of the patent with no way for the patentee to cure the problem. It can therefore be a very powerful ground of attack.

Examination of the Opposition

Assuming that the Opposition is admissible before the EPO, the Opposition Statement will be forwarded to the patentee for comment. An extendable term of four months is normally provided within which counter-arguments and optionally, amended claims, may be filed. The opponent will receive a copy of the patentee's response upon which they may also comment. In fact, any number of further observations from the patentee or the opponent can be filed until such time as the Opposition Division decides that they are able to reach a decision or issue a summons to oral proceedings. This process can take between two and three years.

The summons usually includes a preliminary and non-binding opinion from the Opposition Division, which includes an indication of the issues that they consider should be discussed. The Opposition Division typically comprises three EPO examiners, one of whom is usually the examiner who dealt with the case during its prosecution.

At the Oral Proceedings, after hearing the parties' arguments, a decision will be reached, which will be one of the following: to revoke the patent; to maintain the patent as granted; or to maintain the patent in amended form. After a few months, a written decision outlining the Opposition Division's reasoning for their decision will be issued. This decision can be appealed to the EPO's Board of Appeal by any of the parties adversely affected by the decision. It should be noted that it is possible to file the Opposition anonymously and/or to request acceleration of the proceedings, which may be of importance in certain situations.

Appeals

A Notice of Appeal must be filed within two months of receipt of the EPO's written decision. A fee for appeal must also be paid. A reasoned statement of the Grounds of Appeal must be filed within a further two-month period. The Board of Appeal operates independently from the Opposition Division. Unlike the largely administrative and technical procedure of the Opposition Division, the Board of Appeal tends to focus more heavily on the legal issues and is able to make new case law. This case law develops the practice and procedure of the EPO. The Board of Appeal is able to overturn or uphold a decision of the Opposition Division. If the decision is overturned, then any remaining grounds of Opposition may be remitted back to the Opposition Division for further consideration. If the Board revokes the patent, there is only a very limited opportunity for further appeal.

Enlarged Board of Appeal

It is possible to file a 'petition for review' of the Board of Appeal's decision to the Enlarged Board, which is the highest level of authority within the EPO. The petition for review is a relatively new provision and so the metes and bounds of its applicability have not been broadly tested thus far. It is likely, however, that this provision will only be of use in very limited circumstances – such as an abuse of procedure.

It is also possible for the Board of Appeal to remit questions on important points of law to the Enlarged Board of Appeal.

Conclusion

Oppositions before the EPO have become an invaluable and relatively inexpensive tool for attacking European patents, the grant of which may, for example, interfere with a business' plans for access to a particular technology. Furthermore, the possibility of using the Notice of Opposition before it has been filed "as a tool to reach an agreeable solution with the patentee" should also not be overlooked. Similarly, it may be possible to force negotiations with the patentee even during the Opposition proceedings in which case the Opposition may be withdrawn during the proceedings if a settlement is reached. The offensive value of the procedure should therefore not be overlooked. The procedure also reinforces the need to maintain a watch on the patenting activities of competitors in view of the minimal nine month window within which a Notice of Opposition can be validly filed before the EPO.

"Oppositions before the EPO have become an invaluable and relatively inexpensive tool for attacking European patents, the grant of which may, for example, interfere with a business' plans for access to a particular technology."

For further information contact:

e: JLloyd@eapdlaw.com
t: +44 (0)20 7556 4255

By Dr. Antonio Maschio
EAPD Innovations, London

Patentability of Methods of Medical Treatment and Medical Devices in Europe

The European Patent Convention (EPC) proscribes the patenting of methods of medical treatment. The reason for this exclusion, which was present in the original EPC (EPC 1973), is that public health in the member states would be at risk if patent rights could be used to impede physicians in the normal course of practicing medicine. Such an exception to patentability is recognised and permitted under TRIPS in Article 3a under Section 5 (patents). However, the EPC does not proscribe the patenting of products that have medical applications, be they pharmaceuticals or medical devices such as scalpels, staplers, surgical sutures, and stents. This article will discuss the implications of the statutory exclusions on the patenting of methods of medical treatment and medical devices.

Medical Uses

The legislators framing EPC 1973 recognised that the prohibition on patenting methods of medical treatment would make the patenting of medical-related inventions very difficult. According to the general novelty requirements under the EPC, a claim directed to a known chemical compound for a new use (compound X for use Y) would be considered to lack novelty over previous disclosures of compound X, whatever the use. Moreover, for pharmaceutical products, traditional use claims ("use of compound X for purpose Y") were treated as unallowable method-of-treatment claims if purpose Y were a therapeutic or surgical procedure.

This resulted in an imbalance in the scope of patent protection available for chemical compounds. For example, if a known compound were discovered to have an application in paint technology that had previously not been recognised, it would not be possible to apply for a patent directed to the compound for use in paint, as this would be anticipated by the original disclosure of the compound itself, considered "suitable for use" in paint. However, traditional use claims (use of compound X in paint) could be used. Method claims could also be directed to a new method for painting, or a novel method for manufacturing paint, using this compound.

On the other hand, for a newly-discovered pharmaceutical application of a known chemical compound, the method-of-treatment prohibition meant that no corresponding method claims or use claims would be allowable, leaving no route open for patent protection. In view of this, a special exception to the laws of novelty was created for medical uses in EPC 1973. Under this exception, a known chemical compound would not anticipate a claim to that same compound for a medical use, provided that no medical use was known in the art.[1] Thus the first medical use claim, "compound X for use in medicine", was born.

Second Medical Use

The exception to the laws of novelty for existing chemical compounds with no previous medical use did not extend to new medical indications of a known medical compound. Thus, only the first medical use of a known chemical compound could be patented, but not any second or further uses. For example, a known analgesic could not have been patented for use in the treatment of Alzheimer's Disease, no matter how surprising and inventive that application might have been. This problem was recognised by the European Patent Office. In decisions G1/83, G5/83, and G6/83[2] the Enlarged Board of Appeal considered the matter in detail and approved a type of claim that was not directed to a method of treatment, but that still permitted the patenting of novel second and further medical indications. This claim was referred to as the "Swiss" claim, after the then-practice of the Swiss Federal Intellectual Property Office. Also known as a second medical use claim, this claim takes the form "compound X for use in the manufacture of a composition for the treatment of disease Y".

The Swiss claim structure falls into two parts. The first part of the claim, "compound X for use in the manufacture of a composition", removes the claim from the ambit of methods of treatment. It is a claim directed to the manufacture of a product, not any therapeutic or surgical method, and

therefore falls outside the exclusion of Article 53(c) EPC.[3] The owner of such a patent thus only has recourse against the manufacturer or seller of the composition, and not against the physician.

The second part of the claim, which describes the use of that composition, provides the novelty of the claim; if the use is not part of the prior art, the claim is novel. As noted by the Enlarged Board of Appeal, where the medical compound itself is new (for instance for reasons of dosage, formulation, or synergistic combinations) then novelty is not at issue. Where the medical compound is identical to a known medical compound except for the use to which it was being put, the Enlarged Board ruled that it was "justifiable by analogy" to the provisions of Article 54(5) EPC 1973[4] to recognise its novelty of use. However, it also stated that this exception could only be allowed for "claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC".

In EPC 2000, these decisions of the Enlarged Board of Appeal are codified in Article 54(5) EPC, which exempts subsequent medical uses of existing medical compounds from the prohibition on patenting methods of medical treatment. Swiss claims remain an acceptable alternative claim format under EPC 2000.

Medical Devices

Medical science extends to physical devices for use in therapy and surgery, as well as to pharmaceuticals. When such devices are novel, their patentability is generally not affected by the prohibition on patenting methods of treatment; the device can normally be claimed as such, using a standard product claim format. Problems arise however, where the device is already known, but its use is novel. For instance, a suture coated in a specific manner, known for use in heart surgery, might be unexpectedly useful for tendon reattachment in the ankle due to its previously-unappreciated tensile properties.

It is necessary to consider the language of the EPC in detail to appreciate why problems arise in this instance. Article 53(c) EPC states that:

"European patents shall not be granted in respect of:
(c) Methods for the treatment of the human or animal body by surgery or therapy ...; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

Here, we see that product claims specifically do not fall under the exclusion. Thus, it is possible to patent a new drug, or a new surgical device; the medical method-of-treatment prohibition does not apply to products in general, with substances and compositions being a particular example of a product.

Article 54(4) EPC provides the exemption to the normal laws of novelty for first medical uses:

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c)... .

In this case, the exemption applies only to substances and compositions. Therefore, although Art. 53(c) specifically holds that products in general do not fall under the prohibition against patenting medical treatment methods when claimed as products, Art. 54(4) focuses only on compounds and compositions, and so does not extend the exemption of Art. 53(c) to other products, such as medical devices. Art. 54(5) EPC uses the same language in respect of second medical uses.

The same limitations exist in the equivalent provisions of EPC 1973. This was reflected in the Enlarged Board decision G5/83, which noted that the exception to the medical treatment prohibition for the purposes of novelty applied only to "substances and compositions."[5]

Can Uses of Medical Devices be Protected?

The EPC statutory provisions do not provide for the patentability of new medical uses for medical devices. In the revision of EPC 1973 into EPC 2000, the regulatory provisions concerning the EPC were intentionally moved, as far as possible, out of the Articles and into the Rules. The reason for this was that Rules can be changed by the Administrative Council, which is relatively easy. Changing Articles requires a congress of the member states, which is very difficult to arrange. Because the law concerning second medical use inventions was left in the Articles, we can conclude that the drafters did not contemplate that these provisions would change in the foreseeable future. Therefore, it is unlikely that there will be a change in the law that will help in patenting uses of medical devices.

The other avenue for legal change is through the case law of the Boards of Appeal of the EPO. Although the Boards cannot change the law, their decisions can influence its interpretation.

In decision T1020/03 a Technical Board of Appeal of the EPO examined G5/83, and the relevant Boards of Appeal case law since G5/83, in some detail. The decision restates the principles of G5/83, and in particular separates the issue of avoiding the prohibition under Art. 53(c) EPC from the issue of novelty under Art. 54 EPC. According to this decision, it is not necessary for there to be any novel principle involved in the use of a substance for the manufacture of a composition. The novelty may instead lie exclusively in the recited medical use of the composition, as long as that use is one that is permitted by Art. 53(c) EPC.

In the hypothetical coated suture case, the first part

"The other avenue for legal change is through the case law of the Boards of Appeal of the EPO. Although the Boards cannot change the law, their decisions can influence its interpretation."

Continued on page 6

"The EPC does not allow claims directed to methods of surgery or therapy, but it does allow claims directed to the use of substances and compositions in methods of manufacture."

of the claim could read "use of coating composition X in the manufacture of a coated suture." This use in itself is not new, because the coated suture was known in the art. However, the second part of the claim could recite a novel medical application – in this instance, "for use in tendon reattachment in the ankle" – that, according to T1020/02, could be sufficient to impart novelty under Art 54(5) EPC.

Without this Swiss construction, under EPC 2000, the claim would assume the structure: "Coating composition X for use in tendon reattachment in the ankle, wherein the coating composition is applied to a suture ... ." Such a claim, however, may lack clarity under Art. 84 EPC, since the coating composition itself does not perform the reattachment; a Swiss claim formulation might therefore be preferred. The alternative formulation under EPC 2000 ("Coating composition X, and a suture, for use in tendon reattachment in the ankle, wherein the coating composition is applied to the suture ...") is somewhat clumsy and might also attract objections under Art. 84 EPC.

Thus, for medical devices we can avoid the problem by using a Swiss claim, if the medical device includes at least one component that can reasonably be interpreted to be a "substance or composition." But what of a case in which the medical device is, for example, a scalpel, and the invention resides in a new method of using the scalpel in a specific surgical technique?

In order to fit such a claim within the foregoing principles, it would be necessary to recite the manufacture of the scalpel. Following T1020/03, it might be possible to claim, for example, the "use of an alloy of steel and chromium in the manufacture of a surgical implement", with a recitation of the novel surgical technique following this introductory phrase. Although such a claim seems logically sound, there are two problems. The first is that it is unusual for there to be basis in a European application for such a claim, since most applications requiring reformulations of methods of surgery are based on US-filed documents where such approaches are not necessary. The second is that the claim could be construed as being overly-evasive, in that it clearly tries to avoid a prohibition on patenting methods of surgery by choice use of language. On the other hand, however, it is conceptually and structurally no different from the original – and acceptable – second medical use claim.

The Future – G2/08

On 30th April 2008, a Technical Board of Appeal referred to the Enlarged Board of Appeal questions concerning the patentability of dosage regimes in a method of therapy. In particular, the Board asked whether it could be possible to patent a new pharmaceutical use, where the disease to be treated was identical to that of the prior art, and the only difference was in the dosage of the medical compound. These were the facts in T1020/03. Moreover, the Enlarged Board has also been asked to comment on any special considerations that it believes should be made when interpreting Art. 53(c) and Art. 54(5) EPC.

In her comments filed on 29th January 2009, the President of the EPO urged the Enlarged Board of Appeal to consider the question broadly, and to comment on the patentability of medical use inventions in general. Unfortunately, there is no requirement that the Enlarged Board extend its comments to medical devices; however, one can hope that the Enlarged Board will make a full and proper analysis of the issues raised in G5/83 and T1020/03, especially in view of the changes that have taken place under EPC 2000.

Practical Considerations

The EPC does not allow claims directed to methods of surgery or therapy, but it does allow claims directed to the use of substances and compositions in methods of manufacture. Moreover, specifically in the medical field, novelty can be obtained by recitation of a novel medical application. Therefore, wherever possible, these types of patent applications should contain the basis for a claim directed to using a substance or composition in manufacturing a medical device for a new and non-obvious medical use, especially if that underlying device is not itself novel.

For further information contact:

e: AMaschio@eapdlaw.com
t: +44 (0) 20 7556 4258

Footnotes:

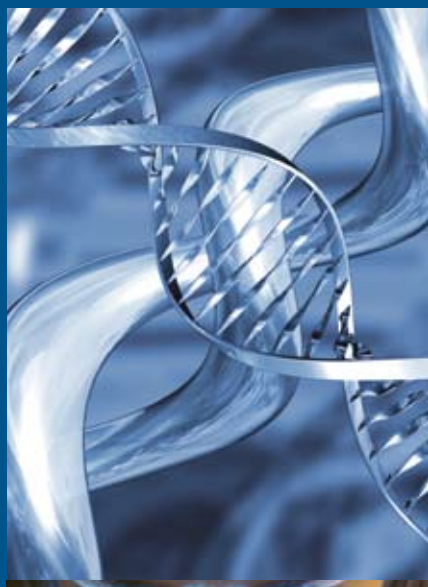
1. See Art. 54(5) EPC 1973. In today's EPC 2000, see Article 54(4) EPC in conjunction with Article 54(2) and 54(3) EPC.
2. The three decisions are fundamentally the same. Decisions of the EPO Boards of Appeal are available online; see www.epo.org.
3. or Article 52(4) EPC 1973.
4. Article 54(4) EPC 2000.
5. See section 21 of the Reasons for Decision in G5/83.

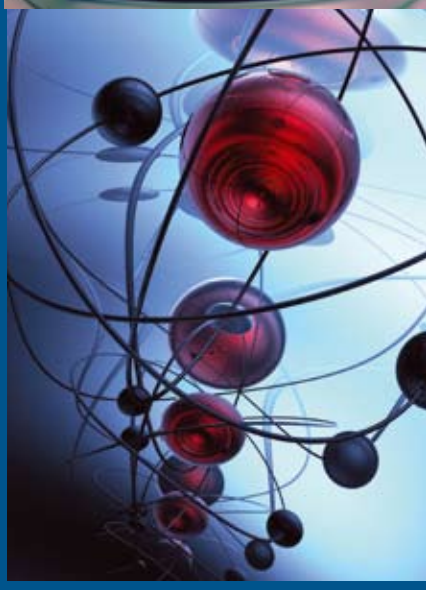
Highlights

- **Jeffrey Hsi** (Boston) was named to the Board of Trustees of Kalamazoo College in the Fall of 2008.
- **John Lloyd, Candi Soames** and **Antonio Maschio** (London) attended the Genesis Biotechnology Conference at the Queen Elizabeth II Conference Centre in London on December 9, 2008.
- **Peter Schechter** (New York) was on the faculty for PLI New York Center, New York, on January 12–13, 2009. The title of the seminar was *"Handling Intellectual Property Issues in Business Transactions 2009"*. A full description of the program can be found on the web at: http://www.pli.edu/product/seminar_detail.asp?id=48500
- **Candi Soames** (London), was a speaker at the 2nd Annual Recombinant Antibodies Conference (Examining the Latest Developments in the Field of Antibody Engineering) held at BSG House in London on January 22–23, 2009. Candi discussed protein claiming strategies: USPTO and EPO requirements; distinguishing known antibodies and novel antibodies; impact of current IP on the future of binding ligands (dabs, scaffolds, framework and CDR shuffling).
- **John Penny** (Boston) attended the AIPLA Japan Practice Committee Pre-meeting at the mid-winter Annual AIPLA conference in Miami, Florida on January 27–28, 2009, during which recent developments in IP Law in Japan and the U.S. were discussed.
- **Howard Gitten** (Florida) presented *"Business Method Patents: Will You Still Be Able To Get Them?"* at the University of Central Florida Incubator on January 28, 2009.
- **Glenn Pudelka** (Boston) attended the Copyright Society of the U.S.A. mid-winter meeting in San Francisco, California on February 5–7, 2009.
- **Carrie Webb Olson** (Boston) was selected as an oral argument judge for the Saul Lefkowitz Moot Court Competition, Eastern Regional Semi-Finals, which took place in New York City on Saturday, February 7, 2009. The Lefkowitz competition is the premiere trademark moot court competition in the country, sponsored by INTA, and draws law schools from throughout the country to compete on challenging and varied issues involved in trademark and unfair competition law.
- **Peter Schechter, Kelly Talcott** and **David Greenbaum** (New York) were speakers at a complimentary webinar hosted by EAPD on February 12, 2009. The webinar briefing is designed for business executives and owners, in-house counsel, product managers, and research and development directors, and focused on how companies can identify their IP assets and protect them from loss, infringement, or theft.
- **EAPD** (Boston) hosted, on behalf of Paul Capital Partners, a seminar titled *"Strategies for Growth in a Downward Recession"* and networking session at their 111 Huntington office on March 17, 2009.
- **Colleen McKiernan** (Boston) presented at the Thirteenth Annual Women in Science Conference for Worcester Public Middle School Girls on March 21, 2009. It was held at the EcoTarium in Worcester. Colleen presented a workshop on careers in patent law entitled *"What's So Special About That? Science and Patent Law"*.
- **Antonio Maschio** (London) and **Kathleen Williams** (Boston) were speakers at BioTrinity 2009 held at The Quadrangle at Kassam Stadium in Oxford, UK on April 2–3, 2009. Drs. Maschio and Williams presented *"How to Streamline IP Strategy for Dual US and European Patent Protection and Enforcement,"* on Thursday, April 2, 2009. **EAPD Innovations** were also sponsors of the conference.
- **Richard Smith, Kathleen Williams** and **George Neuner** (Boston) attended the Pharmaceutical Strategic Outlook Conference in New York City on April 13–15, 2009. EAPD was the exclusive sponsor of this conference. Richard Smith moderated a panel titled *"Does Biotech Venture Capital Need a Plan B?"*

Congratulations

- Congratulations to **Brian Gaff** and **David Cotta** (Boston) in making Partner, **George Chalas** (Providence) being named Counsel.
- Congratulations to **Melissa Hunter-Ensor, Christopher Cowles, Amy DeCloux** and **Elizabeth Spar** (Boston), on passing the Massachusetts Bar and to **Catherine Toppin** (Boston) on passing the Patent Bar.





USPTO Update

By Steven M. Jensen
Boston

USPTO Delays New Rules for Patent Appeals

On December 10, 2008, the U.S. Patent and Trademark Office (USPTO) announced that new rules for patent appeals would not become effective until a later date.

The new rules, if implemented, would add new substantive and procedural requirements for appeal briefs and reply briefs that are expected to increase the time and effort required for preparation of these documents. However, until further notice, appeal briefs and reply briefs will be accepted under the old format.

2009 Patent Reform Bills Include Some Changes

On March 3, 2009, H.R. 1260 and S. 515 were introduced in Congress. These bills are similar to patent reform legislation introduced, but not enacted, in prior years. Both bills include provisions for transition from a "first to invent" to a "first to file" system.

Importantly, each bill includes a post-grant review procedure, similar to past legislation, but which is limited to review within 12 months of the issue date of a patent. In other words, no "second window" of review would be available when an accused infringer is notified of potential infringement after one year has passed.

Other provisions include changes to the manner in which courts calculate damages in patent infringement cases, thus requiring in most circumstances that a reasonable royalty be calculated based on a value attributed to the claimed invention's specific contribution over the prior art, instead of considering the entire market value. Also, a willfulness determination would be required to satisfy specific criteria and could be defeated based on a defendant's good faith belief that a patent was invalid, unenforceable, or not infringed. Additional provisions include changes to venue requirements and interlocutory appeals.

Administration and Legislators Agree on Fee Retention

On February 26, 2009, it was announced that the Obama Administration's budget includes language permitting the USPTO to retain all of its collected fee revenue for operational expenditures. Also, the U.S. House of Representatives separately passed an appropriations bill which allows the USPTO to retain its collected fees with no diversion.

The issue of fee diversion has been controversial in recent years. Previously, the government had diverted user fees collected by the USPTO for other governmental purposes. In recent years, it has been recognized that for the USPTO to operate more efficiently, it must be permitted to utilize fee revenue to improve operations. This year's agreement on fee diversion is a positive development; however, since fee revenue is considered on an annual basis by Congress, it is possible that a change in political climate could result in reinstatement of fee diversion in future years.

An explanatory statement in the appropriations bill directs the USPTO to take action to reduce duplication of work performed by other patent offices, thus seemingly endorsing the multi-jurisdictional work-sharing arrangements that have been pursued by the USPTO recently.

Korea and Singapore Participating in Patent Prosecution Highway

In two separate announcements in January 2009, the USPTO indicated that the Korean Intellectual Property Office (KIPO) will participate in the Patent Prosecution Highway (PPH) on a full-time basis, and the Intellectual Property Office of Singapore (IPOS) will participate in a trial initiative of the PPH.

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

For further information contact:
e: SJensen@eapdlaw.com
t: +1 617 517 5531

EAPD Welcomes New Partner and Team

John Olsen

Intellectual Property (London)

John Olsen (London) has joined the firm in the Intellectual Property Department. A noted trademark practitioner, John was previously with Field Fisher Waterhouse (FFW) where he was head of the Trademark and Brand Protection Group. He will join **Maria Scungio** (New York) as co-chair of the firm's International Trademark and Copyright Protection Group.

Joining with John from FFW will be a team of 14 including: Associates - **Colin Sawdy, James Dunne, Paolo Andreottola, Victoria Strelcova, Ina Brinkmann**; Paralegals, PAs and support staff - **Sophie Magson, Tracey Gilbert, Sarah Kamara, Sharon Del Espino, Claire Houvet, Yoshimi Ando, Gwyneth Rolph, Kathryn Walton**; and **Pat Mitchell** who is a freelance consultant. The entire team will be located in the London office.

John and the team represent a wide range of companies and firms, including Elizabeth Arden, Mastercard, Tumi and a host of other well known brands worldwide.

This is a very exciting development for EAPD's Intellectual Property Department as we further leverage capabilities in our trademark practice and our ability to service clients in the US and Europe.

For further information contact:

e: JOlsen@eapdlaw.com
t: +44 (0) 207 556 4350


By Kathleen B. Carr and Elizabeth Anderson Spinney
Boston

Federal Circuit Update

Federal Circuit Upholds Significant Fee Award Stemming from "Baseless" Invalidity Claims

Takeda Chemical Industries Ltd. v. Mylan Laboratories Inc. **549 F.3d 1381 (Fed. Cir. 2008)**

In one of the most significant rulings on attorneys fees in patent litigation, the Federal Circuit affirmed a $16.8 million attorneys' fee award for Takeda Chemical Industries Ltd., the manufacturer of Actos, a market leader in the treatment of Type 2 diabetes. Mylan Laboratories Inc. and Alphapharm Pty. Ltd. filed abbreviated new drug applications ("ANDAs") for generic versions of the active ingredient in Actos 1/µ, pioglitizone 1/µ, pursuant to the Hatch-Waxman amendments to 21 U.S.C. §355(j) et. seq., seeking approval from the FDA to produce generic versions of the drug. As part of their ANDAs, defendants made certifications under 21 U.S.C. §355(j)(2)(A)(vii)(IV), certifying that the Takeda's patent was invalid for obviousness. As the Paragraph IV filings constitute technical acts of infringement, Takeda sued both companies. The district court held Takeda's patent was valid and enforceable and, finding it was an exceptional case, awarded Takeda attorneys' fees totaling $16.8 million. In addressing the defendants' appeal of the fees award, the appellate court found support for the district court's statement that the Paragraph IV filings for generic pioglitazone were "so devoid of merit and so completely fail[ed] to establish a prima facie case of invalidity that [they] must be described as "baseless"." The court further agreed that the defendants made these filings in bad faith and engaged in vexatious litigation. The Court noted, "[g]iven the court's specific articulation that its ruling was directed toward baseless ANDA filings and litigation in bad faith, we decline to disturb the court's finding of an exceptional case as potentially chilling non-frivolous ANDA filings under the Hatch-Waxman Act." The Court added that the district court "left no doubt as to its opinion of the litigation and work performed by counsel". Indeed, the [district] court indicated that an even higher award would have been justified.

Combining Claims From Separate References Obvious to Try Under KSR

Ball Aerosol and Specialty Container Inc. v. Limited Brands Inc. **555 F.3d 984 (Fed. Cir. 2009)**

A patent claim on a candle holder was obvious in light of two prior art references whose combination was "obvious to try" under the U.S. Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex Inc.*, the Federal Circuit held. The Plaintiff-Appellee, Ball Aerosol, holds a patent for a candle holder that combines allowing the cover to be removed and used as a base and putting feet on the bottom of the candle holder, all to protect a resting surface from potential damage. Ball Aerosol sued Limited Brands Inc., claiming that the travel candle it markets in some of its retail stores infringes Ball Aerosol's patent. After the lower court granted Ball Aerosol's motion for summary judgment, the Federal Circuit reversed, holding that the claims at issue were obvious as a matter of law. The Court noted that prior art disclosed all of the limitations of the patent, and that the function of preventing damage to the surface below was "well known." Applying KSR, which stated, "[i]f a person of ordinary skill can implement a predictable variation, [35 U.S.C.] §103 likely bars patentability," the Federal Circuit found that, "putting feet on the bottom of the candle holder and using the cover as a base for the candle holder was a predictable variation." The Federal Circuit faulted the lower court for looking for an "explicit motivation to combine," adding that it misapplied KSR. Instead, what the U.S. Supreme Court meant in KSR when it said that in determining obviousness, the "analysis should be made explicit," was that the court's analysis, not the motivation, must be explicit. The Federal Circuit also concluded there was no infringement because the claimed configuration was not applied in the accused device, even though that configuration was possible.

New Rules for Design Patent Infringement

Egyptian Goddess Inc. v. Swisa Inc. **543 F.3d 665 (Fed. Cir. 2008)**

In a unanimous en banc decision, the Federal Circuit ruled that the test that views design patent infringement from the perspective of the "ordinary observer" is the sole test for determining whether the patent has been infringed. The "ordinary observer" test was originally set forth by the Supreme Court in 1871 in *Gorham Co. v. White,* but was later modified by the more recent "point of novelty" test. Returning to the former standard, the "ordinary observer" test determines whether an ordinary person, familiar with the prior art, would be deceived into thinking that the accused design is the same as the patented one. In this case, Egyptian Goddess holds a design patent for an ornamental nail buffer. The asserted point of novelty was a four sided design with pads on three of the four sides. Prior art included three-sided designs, and the defendant's product was a four-sided design with pads on all four sides. Affirming the district court's decision granting the defendant's motion for summary judgment of non-infringement, the Federal Circuit said that "when the claimed design is close to the prior art designs, small differences between the accused design and the claimed design are likely to be important to the eye of the hypothetical ordinary observer." Under this test, said the Court, infringement will not be found unless the accused article "embod[ies] the patented design or any colorable imitation thereof." The Court found that the defendant's buffer, although it was the same shape as the patented design, did not infringe because it had pads on all four sides.

"In a unanimous en banc decision, the Federal Circuit ruled that the test that views design patent infringement from the perspective of the "ordinary observer" is the sole test for determining whether the patent has been infringed."

Scope of Appellate Jurisdiction Under Rule 54(b) Narrowly Defined

iLOR LLC v. Google Inc. **550 F.3d 1067 (Fed. Cir. 2008)**

In a case of first impression, the Federal Circuit ruled that the fact that a district court's order states that an "action" is dismissed with prejudice and that there is "no just cause for delay" does not mean that the judgment is final and that all of the issues in the case are immediately appealable under Fed. R. Civ. P. 54(b). In this case, iLOR LLC sued Google alleging that its Google Notebook infringed iLOR's patent for a "method for adding a user selectable function to a hyperlink." The method allows a user to perform a variety of functions with a hyperlink without having to open the hyperlink. The lower court denied iLOR's motion for preliminary relief as to the disputed patent claim, granted Google's motion for summary judgment of noninfringement on that claim, and ordered that iLOR's claims be dismissed with prejudice. When iLOR appealed, the Federal Circuit ruled that only the preliminary injunction ruling was available for appeal. Noting that the lower court dismissed the "action" with prejudice, the Federal Circuit stated that the use of the word "action," when viewed in context, meant only that iLOR's case was dismissed, not Google's counterclaims. Stating that the bare recitation of the "no just cause for delay" standard of Rule 54(b) is not enough to certify a case for appeal, the Court added, "it must be apparent, either from the district court's order or from the record itself, that there is a sound reason to justify departure from the general rule that all issues decided by the district court should be resolved in a single appeal of a final judgment."

Patentable Subject Matter for Business Methods Clarified

In re Bilski **545 F.3d 943 (Fed. Cir. 2008)**

The Federal Circuit, affirming a decision by the Board of Patent Appeals and Interferences, clarified what constitutes eligible subject matter under a method patent. The Court concluded that a process directed to managing the consumption risk costs of a commodity is not patentable subject matter under 35 U.S.C. §101 because the process encompassed purely mental steps without the aid of a computer or other device. Although the ruling could narrow the availability of patent protection for business methods, the court refused to apply "categorical exclusions" of business method claims. The Court reaffirmed the principle that business method claims are subject to the same patentability requirements as any other process or method.

For further information contact:

e: KCarr@eapdlaw.com
t: +1 617 951 3326

e: ESpinney@eapdlaw.com
t: +1 617 951 2265

Edwards Angell Palmer & Dodge
111 Huntington Avenue
Boston, MA 02199-7613

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.

Editors:

Christine C. O'Day
e: CODay@eapdlaw.com
t: +1 617 517 5558

Howard M. Gitten
e:HGitten@eapdlaw.com
t: +1 561 820 0230/ +1 954 667 6130

Kelly D. Talcott
e: KTalcott@eapdlaw.com
t: +1 212 912 2810

Glenn G. Pudelka
e: GPudelka@eapdlaw.com
t: +1 617 239 0371

John E. Ottaviani
e: JOttaviani@eapdlaw.com
t: +1 401 276 276 4605/+1 617 517 3375

A list of our offices and contact numbers are below. Further information on our lawyers and offices can be found on our website at www.eapdlaw.com.

Boston, MA	t: +1 617 239 0100
Fort Lauderdale, FL	t: +1 954 727 2600
Hartford, CT	t: +1 860 525 5065
Madison, NJ	t: +1 973 520 2300
Newport Beach, CA	t: +1 949 423 2100
New York, NY	t: +1 212 308 4411
Providence, CT	t: +1 401 274 9200
Stamford, CT	t: +1 203 975 7505
Washington, DC	t: +1 202 478 7370
West Palm Beach, FL	t: +1 561 833 7700
Wilmington, FL	t: +1 302 777 7770
London, UK	t: +44 (0)20 7583 4055
Hong Kong (associated office)	t: +852 2116 3747

EDWARDS ANGELL PALMER & DODGE

eapdlaw.com