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Patent Term Adjustment Updates

On January 21, 2010, the US Patent and Trademark Office (USPTO) and the Department of Justice announced that they will not seek further court review of the Federal Circuit's January 7th decision in Wyeth v. Kappos.

The announcement, published on the USPTO Web site, says applicants and owners are reminded of the requirement to seek review of Patent Term Adjustment determinations within 180 days of patent issuance and the time periods set in the implementing regulations.

The USPTO also indicated that it is preparing guidance for expediting requests for recalculation of patent term adjustments by the USPTO in light of the *Wyeth* decision.

Patents that are likely to have some additional patent-term due to the *Wyeth* decision are those whose prosecution history include: (1) a pendency of more than three years from filing until either the patent issues or the applicant files an RCE, and (2) a delay of more than 14 months from the application filing to the mailing of the first examination notification.

Prior to *Wyeth*, the USPTO treated the beyond three year issuance delay as overlapping with the beyond 14 month notification delays, and such overlaps did not provide any additional term adjustments.

For patents that issued before March 2, 2010, the USPTO has prepared a form to request (without fee) a revised term adjustment calculation based on the *Wyeth* decision. The request must be filed within 180 days of the issue date of the patent to be timely [See Form PTO/SB/131]. This form cannot be used for any patents that issue after that date.

On February 12, 2010, Pfizer and the USPTO filed a joint motion in the US District Court for the District of Columbia to administratively reopen the PTA case filed for US Patent No. 7,544,362 and to remand the case to the USPTO for further proceedings. On March 3, 2010, the court granted the motion and sent the matter back to the USPTO for recalculation and adjustment of the disputed patent term in accordance with the *Wyeth* decision. I expect to see similar motions being filed in pending PTA cases.

New PTA Cases

Plaintiff: Boehringer Ingelheim
Defendant: David Kappos (USPTO)
Patent Number: 7,585,845
Date Filed: 3/5/2010

Plaintiff: Merck Serono S.A.
Defendant: David Kappos (USPTO)
Patent Number: 7,585,840
Date Filed: 3/3/2010

Plaintiff: Boehringer Ingelheim
Defendant: David Kappos (USPTO)
Patent Number: 7,582,770
Date Filed: 2/26/2010

Plaintiff: Amgen Inc.
Defendant: David Kappos (USPTO)
Patent Number: 7,579,168
Date Filed: 2/19/2010

Plaintiff: Boehringer Ingelheim
Defendant: David Kappos (USPTO)
Patent Number: 7,579,449
Date Filed: 2/18/2010

Plaintiff: Arius Two, Inc.
Defendant: David Kappos (USPTO)
Patent Numbers: 7,579,019
Date Filed: 2/16/2010

Plaintiff: Cephalon, Inc.
Defendant: David Kappos (USPTO)
Patent Number: 7,576,206
Date Filed: 2/12/2010

Plaintiff: Merck & Co.
Defendant: David Kappos (USPTO)
Patent Number: 7,572,922
Date Filed: 2/5/2010

Plaintiff: Novartis AG
Defendant: David Kappos (USPTO)
Patent Number: 7,569,337
Date Filed: 1/29/2010

New Time Rules—Federal Rules of Civil Procedure

On December 1, 2009, the Federal Rules of Civil Procedure were amended (22 Rules) and one new Rule was added (Rule 62.1) regarding how the Federal Courts now calculate time periods and deadlines. Nearly all of the Rules with deadlines of 30 days or less were changed so that the deadline is now a multiple of seven days (7-, 14-, 28-days), so that the expiration of the deadline will ordinarily fall on a weekday. The new rules count every day of the week, including Saturdays, Sundays, and holidays, in calculating the deadlines.

Amended Rule 6(a) states that all deadlines are computed the same way. What this means is that if a "forward counted" deadline falls on a Saturday, Sunday, or holiday, the deadline moves *forward*, *i.e.*, to the *following day* that is not one of these. Similarly, if a "backward counted" deadline falls on a Saturday, Sunday, or holiday, the deadline moves *backward*, *i.e.*, to the *preceding day* that is not one of these. Finally, for electronic filings, the last day of every deadline ends at midnight.

Local Rules of the US District Courts have been modified to conform to the new Federal Rules of Civil Procedure. Check your Local Rules for new deadlines—it is likely that some are either longer or shorter than before. For example, in Massachusetts, deadlines that used to be 10 days are now 14 days, while deadlines that used to be 30 days are now 28 days. Deadlines that used to count only business days (*e.g.*, five business days) are now seven days—counting each day of the week.

Federal Rules of Civil Procedure Rule 8—Plausable Pleadings

The Supreme Court first announced this new pleading standard under Rule 8, that a claim must be "plausible on its face" in *Bell Atlantic v. Twombly* [550 U.S. 544 (2007)]. Now the Court has provided a little more guidance for this standard in *Ashcroft v. Iqbal* [129 S. Ct. 1937 (2009)]. "Whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." [*Iqbal*, 129 S. Ct. at 1950.]

One thing is clear, plausibility lies somewhere between possibility and probability. This is because Rule 8(a)(2) "requires a 'showing,' rather than a blanket assertion of entitlement to relief." [*Twombly*, 550 U.S. at 555 n.3.] Thus, factual allegations must be enough to raise "a right to relief above the speculative level." [*Id.* at 555.] However, the standard does not impose a probability requirement, just more than a sheer possibility that a defendant has acted unlawfully. [*Iqbal*, 129 S. Ct. at 1949.]

In a patent infringement action, patent owners may want to identify their patent, claim ownership thereof, identify a specific accused product of the defendant and identify one or more claims that the accused product infringes, and state why the product infringes, thereby providing the required "showing of entitlement to relief."

Inequitable Conduct Update

The duty of disclosure has once again been expanded by the Federal Circuit. In the January 25, 2010, decision in Therasense, Inc. v. Becton, Dickinson & Co., [No. 2008-1511] patent practitioners must now consider citing information from the prosecution of related foreign patent applications.

The Therasense patent at issue claimed technology in the area of disposable blood glucose test strips. The Federal Circuit majority upheld the District Court's inequitable conduct finding based on Therasense's failure to disclose to the USPTO representations made to the European Patent Office (EPO) in a related case which, in the view of the majority, contradicted representations made to the USPTO to secure the US patent. The majority said the undisclosed contradictory statements made to the EPO were material and were withheld from the US Examiner with intent to deceive. In a dissenting opinion, Judge Linn argued that Therasense advanced plausible reasons why it believed the information withheld was not material.

This case follows the disclosure rules mandated by the Federal Circuit's decisions in Dayco Prods., Inc. v. Total Containment, Inc. [329 F.3d 1358 (Fed. Cir. 2003)] and McKesson Info. Solutions, Inc. v. Bridge Med., Inc. [487 F.3d 897 (Fed. Cir. 2007)], which told practitioners that it was prudent to provide an examiner with citations to office actions in related US patent applications.

The Federal Circuit has created what many (this author included) consider to be an unreasonable burden, and only Congress can remove this ever-expanding Rule 56 yoke. If a practitioner cites too little, there is a chance that a court will hold the patent unenforceable due to withholding of one or more later determined "material" references. If the practitioner cites too many references, a court may hold the patent unenforceable because material references were found to have been buried. How can a standard of damned if you do, damned if you don't, be rational? How is the default position of "cite everything," which can entail hundreds (or thousands) of documents, helpful to a patent examiner?

As the Federal Circuit emphasized in Therasense, "if this could be regarded as a close case, which it is not, we have repeatedly emphasized that the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant." The duty of disclosure is to disclose everything. How this "duty" helps a patent examiner is beyond me.

Terminal Disclaimer versus Section 121 Safe Harbor

On January 25, 2010, the Court of Appeals for the Federal Circuit in *Boehringer Ingelheim Int'l GmbH v. Barr Laboratories, Inc.* [No. 2009-1032] overturned a district court decision that Boehringer's patent was invalid for obviousness-type double patenting. The panel majority (Judges Linn & Prost) held that safe harbor provision was available to Boehringer. Judge Dyk dissented.

Patent Number 4,886,812 claims compounds used for the treatment of Parkinson's disease. The patent was granted on an application that was a "divisional of a divisional" of a first Boehringer application.

Barr claimed that Boehringer's patent was invalid for obviousness-type double patenting. In response to this claim, Boehringer filed a terminal disclaimer—*after* the expiration of the first Boehringer patent. The Federal Circuit held that this action could not cure obvious-type double patenting.

However, as a second defense, Boehringer relied on the "safe harbor"

provision of Patent Law Section 121, which protects "true divisional applications" from double patenting claims. Such divisional applications are filed in response to a restriction requirement issued by the patent examiner for pursuit of non-elected claims that the examiner contends define separate inventions.

Here, the Federal Circuit held that the "safe harbor" provision of Section 121 applied, even though the challenged patent was granted on a "divisional of a divisional application." The Federal Circuit held that the safe harbor provision applied as long as applications in a "divisional chain" followed the lines of demarcation drawn by the examiner in the original restriction requirement.

Written Description versus Enablement

In my opinion, a patent application should: (1) identify the claimed invention; (2) teach how to make and use the claimed invention, including the best mode thereof; and (3) conclude with claims directed to this same invention. To me, this is consistent with 35 U.S.C. § 112, paragraph 1, which states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Unfortunately, not all patent applications are written following this simple format.

On December 7, 2009, the Court of Appeals for the Federal Circuit, sitting en banc, heard oral arguments in Ariad v. Eli Lilly, a case that questions "whether 35 U.S.C. § 112, ¶1, contains a written description requirement separate from an enablement requirement" and, "if so, what is the scope and purpose of the written description requirement."

The Federal Circuit took up the question in the context of a method of treating diseases by regulating a protein in human cells. Although the invention is in the bio/pharma technology field, and specifically entails lowering the activity of a protein, the Federal Circuit's decision in this case likely will cut across all technology fields.

Prior to the rehearing en banc, Federal Circuit panel of three of its judges held the specification did not demonstrate that the inventors "possessed" the invention by "sufficiently disclosing molecules capable of reducing [protein] activity." The panel determined the patent contains no working examples, or even "prophetic" examples, of reducing protein activity, or a description of the synthesis of hypothetical molecules that could be used for this purpose. The panel noted the patentee "chose to assert claims that are broad far beyond the scope of the disclosure provided in the specification."

Although framed as a subsidiary issue by the Court, much of the oral argument on December 7th focused on policy considerations underlying the written description requirement, as well as its historical treatment by the courts.

Eli Lilly described the written description requirement as "corroboration" of what a particular inventor actually invented. In response to questions from Judge Rader on whether courts have previously limited the application of the requirement to first-to-invent disputes, Lilly maintained that the requirement should be available to challenge patent validity in whatever context the challenge may arise.

Ariad criticized the Federal Circuit's "possession" requirement as lacking any support in the Patent Act. Ariad urged that the patent law requires only that the specification "identify" the invention and teach how to make and use it. According to Ariad, policy considerations are satisfied as long as persons skilled in the art are able to actually practice inventions based on the guidance provided in patent specifications, as he asserted was true in the specific case at issue. Ariad agreed, however, that a specification disclosing a single embodiment would not provide an adequate written description for a broad claim when other embodiments were inoperable.

The US Government, as *amicus curie*, argued that the Court should maintain the separate written description requirement. The Government explained the requirement is an important tool for patent examiners to reject excessively broad patent application claims during patent examination. In its brief, the government described the requirement as "crucial to" and "essential to the operation of" the patent system.

During the oral arguments, several of the judges seemed skeptical that the statute contains a written description requirement separate from the enablement requirement. Judge Moore, on the other hand, questioned whether stare decisis alone justified maintaining existing law. As all patents and patent applications are required to meet the statutory mandate of 35 U.S.C. § 112, ¶1, this case will be watched closely to see whether the Federal Circuit makes a sweeping change in how patent applications are obtained and enforced, or whether the Federal Circuit will limit its decision to the narrow bio/pharma nature of the case.

Patent False Marking Update

In its recent decision in *Forest Group v. Bon Tool*, the Court of Appeals for the Federal Circuit expanded patentee liability for mismarking patents under 35 U.S.C. 292(a). The Federal

Circuit adopted a per article interpretation of "offense" creating the potential for significant damages, given the statutory fine of "not more than $500 for every such offense."

Mismarking must be done with intent to deceive the public in order to violate the statute. However, false patent marking can occur under a variety of circumstances, and anyone may sue for the alleged mismarking of an unpatented item.

Since the *Forest Group* ruling, numerous companies have been sued because expired patent numbers remain on products. More of these suits are expected as plaintiffs seek to take advantage of this ruling.

Ernie Linek is a principal shareholder of Banner & Witcoff, LTD. This column is for educational and informational purposes only and should not be construed in any way as legal advice. It reflects the opinion of the author and should not be attributed to the firm Banner & Witcoff or to any of its clients.

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