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# Practice Areas



## Biotechnology and Pharmaceutical Litigation

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### Patent Term Adjustment Case Update

On January 7, 2010, the US Court of Appeals for the Federal Circuit ruled in favor of Wyeth and Elan Pharma International Ltd. in their more than two year long battle with the US Patent and Trademark Office (PTO) regarding how patent term adjustment calculations must be made under 35 U.S.C. §154. The patents at issue are US Patent Numbers 7,189,819 and 7,179,892. The case is *Wyeth et al. v. Dudas*, case number 2009-1120 in the Federal Circuit.

The case started in August 2007, when Wyeth and Elan sued the PTO requesting an additional 294 and 230 days respectively to the terms of their patents. The companies took issue with the way the PTO counted two of the types of delays in patent prosecution set up by 35 U.S.C. §154(b) that can lead to extended terms.

The statute, 35 U.S.C. § 154(a), establishes the patent term at 20 years from the filing date. Section 154(b) introduces various term

adjustments due to PTO delay. One of the adjustment provisions broadly works toward a “guarantee of no more than three-year application pendency.” The other primary adjustment provision more narrowly focuses on the timeliness of individual PTO actions, such as providing an office action within 14-months.

Subsection (A) lays out certain deadlines that the PTO must meet during the prosecution of the application or else grant a one-day extension of the patent term for each day of delay, while subsection (B) provides a similar extension if the agency fails to issue the patent within three years from the application filing date.

The law also includes a provision limiting the extensions possible under the so-called A and B delays, stating that “to the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.”

The PTO had argued that any delay incurred under the first subsection necessarily overlaps with the three-year maximum pendency delay. Wyeth disagreed, claiming that the agency’s interpretation of the two subsections “does not square with the language of the statute” and that the A and B delays only overlap if they fall on the same dates.

The parties’ different perspectives on an exemplary patent term adjustment (PTA) calculation can be represented schematically as shown in Exhibits 1 and 2 (this example was presented in the District Court’s opinion). Exhibit 1 represents the PTO’s version. Under the PTO calculation, the patentee is entitled to three years of PTA, due to the extensive overlap of the A and B delay periods. Exhibit 2 is the Companies’ version. Under the companies’ calculation, the patentee is entitled to four years of PTA, due to the difference in the time frame when the B delay period should begin to be measured.

On September 30, 2008, the District Court for the District of Columbia granted summary judgment in favor of the companies, determining that the PTO had misconstrued 35 U.S.C. § 154(b)(2)(A), and as a result, had denied the companies a portion of patent term to which each was entitled.

According to the district court’s ruling, “the problem with the PTO’s interpretation is that it considers the application delayed under [the B guarantee] during the period *before it has been delayed.*” The PTO thereafter appealed the district court’s decision to the Federal Circuit.

Exhibit 1

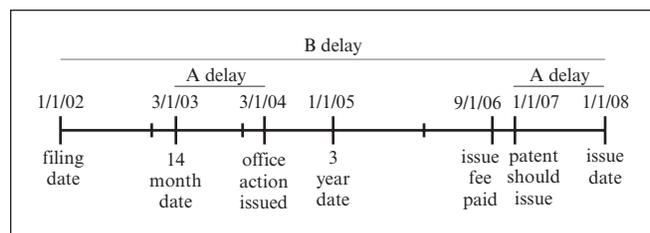
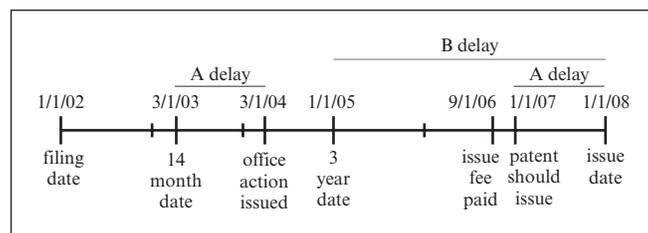


Exhibit 2



In its ruling on January 7, 2010, the Federal Circuit said Section 154(b)'s language is "clear, unambiguous and intolerant of the PTO's suggested interpretation." Calling the PTO's interpretation that the B delay can occur *anytime after the application is filed* "strained" the Federal Circuit further said that:

To the contrary, the language of Section 154(b) does not even permit B delay to start running until three years after the application is filed. The PTO's position cannot be reconciled with the language of the statute.

The Federal Circuit's ruling means that patent applicants and patentees may be entitled to potentially longer patent term adjustments than those previously calculated by the PTO.

A number of PTA cases have been filed in the DC District Court since October 2008, and these cases will now be ready for action in view of this Federal Circuit decision. These cases will be monitored and updates will be reported in later columns.

After the Federal Circuit decision, the PTO placed the following announcement on its Web site:

Wyeth v. Kappos, On January 7, 2010, the Federal Circuit issued a decision in Wyeth v. Kappos, No. 2009-1120, regarding the calculation of patent term adjustments under 35 U.S.C. 154(b). The Federal Circuit's decision rejects the USPTO's interpretation of the "overlap" limitation in Section 154(b)(2)(A). The Solicitor General will determine whether to seek further review of this decision. Pending that determination, the USPTO is in the process of changing the manner it will calculate patent term adjustments under Section 154(b) to conform with the Federal Circuit's decision.

Applicants and Patent Owners dissatisfied with a patent term adjustment determination by the agency are reminded of the requirement to seek review of that determination within 180 days of patent issuance and the time periods set in the implementing regulations. See 35 USC 154(b)(4) and 37 CFR 1.705.

The statute puts the duty of calculating the patent term adjustment exclusively in the hands of the PTO. Thus, anyone claiming additional patent term under Section 154(b) may only do so based on a PTA determination made by the Director. That theory is bolstered by the statutory limitation of 180-days for filing a civil action based on dissatisfaction with the PTA determination.

### Practice Tip

Thus, anyone whose patent is about to issue or whose patent has issued in the last 180-days should quickly determine whether additional patent term is due. It is unclear if the PTO will go-back and recalculate PTA for those cases.

In addition, it is unlikely that the PTO would be willing to re-calculate the PTA for patents issued more than 180 days ago. However, given the fact that the statute has now been clarified by the Federal Circuit, there is a potential that the DC District Court could disregard the 180-day limitation, based on a doctrine such as equitable tolling. If the properly recalculated patent term is large, it may be prudent to seek redress from the PTO and/or the DC District Court.

### Recently Filed PTA Cases

Plaintiff: Keurig, Inc.  
Defendant: David Kappos (USPTO)  
Patent Number: N/A—Allowed Case—USSN 10/658,925  
Date Filed: 12/11/2009

Plaintiff: Transtech Pharma, Inc.  
Defendant: David J. Kappos (USPTO)  
Patent Number: 7,544,699  
Date Filed: 12/4/2009

### Fed. R. Civ. P. 50

In district court litigation, a motion for judgment as a matter of law (JMOL) is a motion made by a party, during trial, claiming the opposing party has insufficient evidence to reasonably support its case.

Rule 50(a) of the Federal Rules of Civil Procedure states that a JMOL motion made before submission of the case to the jury "shall specify the judgment sought and the law and the facts on which the moving party is entitled to the judgment." The purpose of the requirement is to afford the opposing party an opportunity to cure the defects in proof that might otherwise preclude the party from taking the case to the jury.

If the court does not grant the original JMOL motion, Rule 50(b) allows the party to renew the motion after the verdict. A post-verdict, renewed JMOL motion *may not be made on grounds not included in the earlier JMOL motion*.

On December 22, 2009, the US Court of Appeals for the Federal Circuit issued its decision in *i4i Limited Partnership v. Microsoft Corporation* (Appeal No. 2009-1504). While this case is not a bio/pharma patent case, it does serve to remind all litigators about the *strict requirements* of Rule 50.

Here, the patent owner, i4i, brought suit against Microsoft, alleging that the custom XML editor in certain versions of Microsoft Word software, infringed i4i's patent. After a seven-day trial, the jury found Microsoft liable for willful infringement. The jury awarded i4i \$200 million in damages. The district court further awarded \$40 million in additional damages for willful infringement. It also granted i4i's motion for a permanent injunction.

Microsoft had filed Rule 50(a) and Rule 50(b) motions for JMOL and motions for a new trial. The district court denied these motions for JMOL and motions for a new trial, finding that Microsoft had waived its right

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to challenge, among other things, the validity of the patent based on all but one piece of prior art and the sufficiency of the evidence supporting the jury's damage award.

In this case, Microsoft has waived its right to challenge the factual findings underlying the jury's implicit obviousness verdict because it did not file a pre-verdict JMOL on obviousness for the Rita, DeRose and Kugimiya references.

Fed. R. Civ. P. 50(a), (b).

On appeal, the Federal Circuit affirmed the district court ruling on the JMOL and damages, but modified the injunction. The Federal Circuit confirmed that a party must file a pre-verdict JMOL motion on all theories, and with respect to all prior art references, that it wishes to challenge with a post-verdict JMOL.

Accordingly, Microsoft's pre-verdict JMOL on anticipation, based on one reference (S4), was insufficient to preserve its right to post-verdict JMOL on a different theory, namely

obviousness, or on different prior art (Rita, DeRose, Kugimiya).

Thus, the Federal Circuit was unable to even consider whether the evidence presented at trial was legally sufficient to support the jury's verdict that the patent claims were not obvious. The jury found all of the asserted claims not invalid. This means that the jury must have believed that there were differences between the prior art and asserted claims, and that a person of ordinary skill would not have been motivated to combine the references.

Microsoft also objected to the size of the damages award during the appeal. However, the Federal Circuit rejected these arguments, because that issue was not presented to the district court in a pre-verdict JMOL. Commenting on this, the Federal Circuit said:

Although Microsoft now objects to the size of the damages award, we cannot reach that question because Microsoft did not file a pre-verdict JMOL on damages. ... Though Microsoft could have similarly filed a pre-verdict JMOL, for whatever

reason, it chose not to. *See* Fed. R. Civ. P. 50(a). On appeal, what that strategic decision means for Microsoft is that we cannot decide whether there was a sufficient evidentiary basis for the jury's damages award.

In an appeal, the court can only review those errors that have been properly preserved for review by the appellate court. More importantly, during an appeal, the court must view the evidence in the light most favorable to the verdict. Accordingly, all of these questions were resolved against Microsoft, and in favor of i4i.

Microsoft has requested the Federal Circuit to grant en banc review of the panel decision. This case will be monitored for future columns.

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

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