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# Licensing Markets

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## Biotechnology and Pharmaceutical Licensing

Ernest V. Linek

Pharmaceutical patent owners/licensors and licensees—summer is becoming a memory but, as a continuation of my last column, here are more “spring cleaning” tips for your consideration.

### *Patent Term Adjustments*

Look at your recently issued and licensed patents, and check your patent term adjustment (PTA) totals. If any patent was issued more than three years after filing, you may be entitled to a longer PTA than was calculated by the Patent and Trademark Office (PTO). In other words, the PTA listed on the face of your patent may have been calculated incorrectly by the PTO.

On September 30, 2008, the District Court for the District of Columbia granted summary judgment in favor of the plaintiffs Wyeth and Elan Pharma International Limited, holding that the PTO has been misinterpreting the patent term adjustment statute, 35 U.S.C. § 154 [*Wyeth v. Dudas*, 580 F. Supp.2d 138, 88 U.S.P.Q.2d 1538 (D. D.C. 2008)].

Since the 1999 enactment of the Patent Term Guarantee Act, every US patent has been entitled to a one-day extension of its term for every day that issuance of a patent is delayed by a failure of the PTO to comply with deadlines under 35 U.S.C. § 154(b)(1)(A), e.g., the deadline of 14 months for a first

office action. Delays of this type are called “A delays.”

Likewise, every US patent also has been entitled to a one-day extension for every day greater than three years after the filing date that it takes the patent to issue, with certain exclusions, under 35 U.S.C. § 154(b)(1)(B). Delays of this second type are called “B delays.”

The extensions for A delays and B delays are subject to a statutory limitation concerning “overlap”— “[t]o the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this statute shall not exceed the actual number of days the issuance of the patent was delayed.” [35 U.S.C. § 154(b)(2)(A).]

The PTO had been granting adjustments for the greater of the A delays or the B delays, but not A + B delays. In the PTO’s view, the entire period during which an application is pending is the “B period” for purposes of identifying “overlap.” The district court in *Wyeth* held, however, that overlap in the statute means a day of type A delay and a day of type B delay that occur on the same day.

The *Wyeth* court provided a hypothetical example to illustrate how the PTO has been shortchanging patent owners: Assume a patent application is filed 1/1/02, and the patent issues 1/1/08. Assume that in the six years it takes to

issue, there are two “A periods of delay” by the PTO, each one year long: (1) the 14-month deadline for the first office action is 3/01/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO.

Under the PTO’s interpretation, the patent owner gets only three years of patent term adjustment, i.e., the “B delay” period from 1/1/05 to issuance on 1/1/08.

Under the district court’s holding, the patent owner is entitled to four years of adjustment—the first “A delay” does not overlap the “B delay” because it occurs in 2003-04, not in 2005-07. In contrast, the second “A delay,” which covers 365 of the same days covered by the “B delay,” does overlap and, hence, does not increase the patent term adjustment amount.

A request for PTA reconsideration based on *Wyeth* must be filed within two months of the date each affected patent issued. [37 C.F.R. § 1.705(d).]

A civil action challenging the PTO’s PTA determination must be filed in the District of Court for the District of Columbia within 180 days after the grant of each affected patent. [35 U.S.C. § 154(b)(4)(A).]

The PTO filed a Notice of Appeal to the US Court of Appeals for the District of Columbia Circuit on November 28, 2008. The appeal is pending.

While the PTO’s appeal in the *Wyeth* case is pending, applicants currently prosecuting patent applications should consider taking appropriate action to preserve their rights in the event that the holding in *Wyeth* is upheld.

For example, upon receipt of a Notice of Allowance, the

applicant should calculate the patent term adjustment using the framework set forth in *Wyeth* and request a correction of the adjustment from the PTO under 37 C.F.R. 1.705(b)-(c). If the PTO denies the request for correction and the patent issues, then the patentee may request reconsideration by the PTO within two months from the issue date under 37 C.F.R. 1.705(d). NOTE: A patentee *may not* request reconsideration under 37 C.F.R. 1.705(d) if it has failed to request a correction for issues that were raised, or could have been raised, under 37 C.F.R. 1.705(b)-(c).

In addition the statute includes a deadline of 180 days from the date the patent issues to appeal an unsatisfactory patent term adjustment recalculation to the DC District Court under 35 U.S.C. § 154(b)(4)(A).

Thus, the patentee should request reconsideration of the term adjustment by the PTO shortly after receiving the Notice of Allowance, and would need to follow up on an unsatisfactory PTO determination by filing a timely action before the DC District Court to avoid loss of rights to additional term (all assuming that *Wyeth* is upheld on appeal).

As shown below, several patentees already have moved the DC District Court to consider the patent term adjustment in view of *Wyeth*. This list is not exhaustive, but is provided to show that this issue is one of great interest in the bio/pharma community.

### ***Pending Wyeth-Based Lawsuits***

Plaintiff: Biogen Idec Inc.  
Defendant: John J. Doll (USPTO)  
Patent Number: 7,442,370  
Date Filed: 4/23/2009

Plaintiff: Hoffmann-La Roche Inc.  
Defendant: John J. Doll (USPTO)

Patent Number: 7,442,776  
Date Filed: 4/24/2009

Plaintiff: Biogen Idec Inc.  
Defendant: John J. Doll (USPTO)  
Patent Number: 7,446,173  
Date Filed: 4/30/2009

Plaintiff: Novartis AG  
Defendant: John J. Doll (USPTO)  
Patent Number: 7,446,175  
Date Filed: 4/30/2009

Plaintiff: Yeda Research and Development Co., Ltd.  
Defendant: John J. Doll (USPTO)  
Patent Number: 7,445,802  
Date Filed: 5/4/2009

Plaintiff: Novartis AG  
Defendant: John J. Doll (USPTO)  
Patent Number: 7,473,761  
Date Filed: 6/30/2009

Plaintiff: Novartis AG  
Defendant: John J. Doll (USPTO)  
Patent Number: 7,470,709  
Date Filed: 6/30/2009

I plan to monitor these cases as well as the appeal of the *Wyeth* case and provide updates in future columns.

### ***Claims to Human Gene Sequences***

Another issue of great interest in the bio/pharma community involves patent claims to human gene sequences. Have you granted or taken a license to a biotechnology patent with claims to a gene sequence? If so, the April 3, 2009, decision of the US Court of Appeals for the Federal Circuit in the case *In re Kubin* (Appeal No. 2008-1184) will be of interest to you.

In *Kubin*, the Federal Circuit affirmed obviousness and written description rejections issued by the USPTO Board of Patent Appeals and Interferences regarding claims directed to classical biotechnology claims; claims directed to the

isolation and sequencing of a gene that encodes a particular protein. Claim 73 is representative:

An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80 percent identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds to CD48.

Kubin revived the O'Farrell analysis of obvious to try:

It is true that this court and its predecessors have repeatedly emphasized that "obvious-to-try" is not the standard under § 103. However, the meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious? [*In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), Fed Cir. Op, p. 14.]

The *O'Farrell* court carved out two factual situations for which the obvious-to-try analysis should not apply:

1. *Throwing darts versus a finite number of identified, predictable known options*: An impermissible "obvious to try" situation occurs where what was "obvious to try" was to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many

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possible choices is likely to be successful.

In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.

2. Exploring new technology versus improving known and predictable technology: An impermissible “obvious to try” situation occurs where what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

[*Id.* at 903.]

The Supreme Court in *KSR International, Inc. v. Teleflex Corp.* [550 U.S. 398 (2007)] affirmed

the logical inverse of this statement by stating that Section 103 bars patentability unless the improvement is more than the predictable use of prior art elements according to their established functions.

In *Kubin*, the court found that neither of the O’Farrell exceptions applied. The invention is old-school biotech—isolating and sequencing a human gene that encodes for a known protein.

The record shows the well-known and reliable nature of the cloning and sequencing techniques in the prior art, not to mention the readily knowable and obtainable structure of an identified protein. Therefore this court cannot deem irrelevant the ease and predictability of cloning the gene that codes for that protein.

[Fed. Cir. Op., p. 16.]

Chemistry and biotech traditionally have been thought of as unpredictable arts. Here, the Federal Circuit has dismantled the art-level distinction in holding that *KSR* equally applies to the unpredictable arts. The sole issue now, regardless of the art, is if the particular invention in question was predictable:

This court cannot, in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.

[Fed. Cir. Opinion, pp. 16–17.]

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