

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	CIVIL ACTION No.: 05-CV-12237-WGY
F. HOFFMANN-LA ROCHE LTD,	)	
ROCHE DIAGNOSTICS GMBH,	)	
and HOFFMANN-LA ROCHE INC.,	)	
	)	
Defendants.	)	

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**ROCHE’S OPPOSITION TO AMGEN’S MOTION *IN LIMINE* NO. 20:  
PRECLUDE ROCHE FROM MAKING STATEMENTS REGARDING  
THE DURATION OF AMGEN’S PATENT PROTECTION**

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*Hoffmann-La Roche Inc.*

## **I. Introduction**

Amgen's motion *in limine* to preclude Roche from referring to the duration of its patent protection ignores long-standing legal precedent concerning the defense of obviousness-type double patenting ("ODP"). An essential element to be proved for double patenting is that the second patent extends the term of the subject matter of the first patent. Therefore, Roche must be allowed to discuss the dates and terms of the patents to prove the necessary elements of its case. The parties already have agreed that the patents-in-suit and the '008 patent are pre-admitted into evidence and, therefore, the expiration dates of the various patents are also in evidence. Thus, Roche should be permitted to explain how the expiration dates of these patents proves its ODP defense.

Amgen's motion also ignores the fact that Roche's ODP defense regarding the '868 and '698 patents were not part of any motion for summary judgment and therefore will be tried to the jury. Moreover, although the Court has held that the '933, '422 and '349 patents are not invalid for ODP over the '008 and '016 patents, Roche will present evidence at trial to show that these patents are invalid over the earlier-expiring '868 and '698 patents.

Furthermore, the terms and expiration dates of the patents-in-suit evidence Amgen's pattern of conduct during patent prosecution, evidence that is critical to Roche's defense of inequitable conduct. Thus, Roche should be permitted to introduce this evidence to meet its burden of proof. Accordingly, Amgen's motion should be denied.

## **II. ARGUMENT**

### **A. Double Patenting Expressly Embraces The Question Of Patent Duration**

The Federal Circuit has repeatedly noted that "the rubric of 'double patenting'" encompasses the concept that "[a] second patent may not improperly *extend the term of*

*protection* for an earlier patented invention.” *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992) (emphasis added); *see also In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997) (“[t]he doctrine of double patenting is intended to prevent a patentee from obtaining a *time-wise extension* of patent for the same invention or an obvious modification thereof”) (emphasis added); *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001) (ODP operates to “prohibit[] a party from obtaining an *extension of the right to exclude*”) (emphasis added); *In re Goodman*, 29 U.S.P.Q.2d 2010, 2015 (Fed. Cir. 1993) (ODP exists “to prevent *extension of the patent right* beyond statutory limits”) (emphasis added); *Perricone v. Medicis Pharm. Corp.*, 77 U.S.P.Q.2d 1321, 1323 (Fed. Cir. 2005) (ODP is designed to “prevent claims in separate applications or patents that ... would effectively *extend the life* of patent protection”) (emphasis added).

Similarly, for years the Patent Office has made clear to patent practitioners and examiners alike that ODP “seeks to prevent the *unjustified extension* of patent exclusivity beyond the term of a patent.” M.P.E.P. § 804 (8th ed. Rev. 5, Aug. 2006) (emphasis added); *see also* M.P.E.P. § 804 (5th ed. Rev. 8, May 1988) (ODP “is primarily intended *to prevent prolongation of the patent term* by prohibiting claims in a second patent not patentably distinguishing from claims in a first patent.”) (emphasis added). Accordingly, in seeking to preclude Roche from referring to the duration of Amgen’s patent protection, Amgen essentially seeks to eviscerate a primary “concept” intertwined in the “rubric” of one of Roche’s invalidity defenses. Amgen’s motion should therefore be denied.

#### **B. Roche’s Obviousness-Type Double Patenting Defense Is Very Much Alive**

When the parties submitted the Joint Pretrial Memorandum on August 10, 2007, Amgen did not list the current motion in its list of twenty motions *in limine* to be filed prior to trial. (D.I.

807 at 19-21). While Amgen reserved the right to submit additional motions, the absence of the pending motion from Amgen's list, in conjunction with the fact that Amgen has already submitted a substantially similar motion *in limine* regarding the use of the term "monopoly" (D.I. 847), confirms that Amgen's entire motion is based solely on the fact that the Court recently granted summary judgment of no ODP for the '933, '422 and '349 patents.<sup>1</sup>

However, Roche's ODP defense is still very much alive. Amgen is well-aware that the PTO required that process claims for making EPO be prosecuted along with the DNA and host cell claims which eventually issued in the '008 patent. Instead of complying with the PTO's express requirements, however, Amgen voluntarily cancelled Lin's process claims and chose to prosecute the '868 patent and '698 continuation patent with process claims instead. In securing the '868 and '698 patents, Amgen failed to file a terminal disclaimer over the '008 patent. As a result, both the '868 and '698 patents expire in 2012 -- nearly *8 years* after they should have if Amgen had followed the PTO's instructions and prosecuted its process claims in the '008 patent.<sup>2</sup>

The *fact* that Amgen's '868 and '698 patents provide it with years of patent protection beyond that of the '008 is at the very heart of obviousness-type double patenting. As the Federal Circuit explained in *Eli Lilly*:

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<sup>1</sup> Indeed, Amgen plainly states that its argument that "Roche's rhetoric is legally irrelevant" is a "[c]onsequen[ce]" of the Court's granting summary judgment of no ODP for the '933, '422 and '349. (D.I. 887 at 1).

<sup>2</sup> Roche continues to assert that claim 7 of the '349 patent properly would have belonged with the Group II process claims that were filed in the '008 patent and subsequently cancelled by Amgen and prosecuted in the applications that led to the '868 and '698 patents-in-suit. Thus, because claim 7 expires in 2015, the '349 patent likewise results in a time-wise extension of Amgen's patent rights.

The judicially-created doctrine of obviousness-type double patenting cements the legislative limitation by prohibiting a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.... As one of our predecessor courts explained, “the fundamental reason for the rule of obviousness-type double patenting is to prevent the timewise extension of the right to exclude granted by a patent *no matter how the extension is brought about.*”

251 F.3d at 967 (emphasis added; citations omitted). Thus, it is highly relevant for the jury to hear evidence and argument showing that the patents-in-suit result in a timewise extension of the right to exclude that was originally granted to Amgen by virtue of the ‘008 patent. Indeed, for Roche to prevail on its double patenting defense, it “must prove facts supporting a conclusion” that the Amgen patents constitute an improper “time-wise extension.” *Research Corp. Techs., Inc. v. Gensia Labs., Inc.*, 10 Fed.Appx. 856, 860 (Fed. Cir. 2001). Amgen has not -- and cannot -- provide a sound basis for asking this Court to preclude Roche from arguing the predicate facts necessary for finding the patents invalid for obviousness-type double patenting. Accordingly, Roche must be permitted to fully pursue its ODP defense and all the concepts embraced therein, including the duration of Amgen’s patent protection.

Moreover, the Court’s August 28, 2007 Order regarding double patenting in no way affects Roche’s defense that the asserted claims of the ‘933, ‘422 and ‘349 patents are invalid based on ODP over the previously issued ‘868 and ‘698 patents. (*See* Defendants’ First Amended Answer and Counterclaims to Plaintiff’s Complaint, dated March 30, 2007, Sixth Defense (D.I. 344)). The prior art patents at issue in the Court’s Order were limited to the ‘008 and ‘016 patents. Thus, Roche is still permitted to argue that the ‘933, ‘422 and ‘349 claims suffer from an improper time-wise extension because those claims should, at minimum, expire at the same time as the earlier issued ‘868 and ‘698 claims.

**C. The Duration Of Amgen's Patent Protection Is Highly Pertinent To Roche's Inequitable Conduct Defense**

In addition to being intricate to the defense of obviousness-type double patenting, the duration of Amgen's patent protection is pertinent to Roche's inequitable conduct defenses.

For Roche to prevail on its inequitable conduct defenses, it must prove that the "applicant, with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submit[ted] materially false information to the PTO during prosecution." *McKesson Info. Solutions v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007). The requisite intent "need not, and rarely can, be proven by direct evidence," and is "generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Ferring BV v. Barr Labs. Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).

Roche's evidence of intent consists in part of circumstantial evidence supporting Amgen's and Messrs. Borun, Odre and Watt's determination to exploit the rules of patent prosecution to extend the life of Amgen's patent protection. For example, the evidence at trial will show that after Amgen was unable to keep competitor Chugai out of the marketplace following proceedings in the ITC and the district court based on the '008 patent, Amgen misrepresented and failed to disclose material facts to the Examiner of the '179 application to bring the '868 patent to issuance. In making such misrepresentations, Amgen and its attorneys were motivated to "extend the life" of its patent protection and ensure that competitors like Chugai were kept out of the market upon the expiration of its '008 patent. Because the 17 year protection promised to Amgen from 1987 to 2004 through the '008 patent proved effectively useless in litigation, it decided to exploit all avenues to reward itself with additional patents with full patent terms and failed to file the proper terminal disclaimers tied to the '008 patent. In doing so, Amgen also exploited a 1995 change in law increasing the term of patent protection

from 17 years to 20 years for certain applications as evidenced by Amgen's sudden filing of multiple continuation applications in June 1995. This activity is part and parcel of Amgen's strategy in patent prosecution and is accordingly pertinent to Roche's evidence of a pattern of conduct to support an inference of intent to deceive. *See Ferring*, 437 F.3d at 1194 (a pattern of conduct, even if not itself inequitable conduct, "can heighten the effect" of alleged instances of inequitable conduct). Given that Epogen<sup>®</sup> "accounted for approximately 80% of Amgen's total revenues" (Amgen 1991 10-K, p. 4 (AM-ITC 00254288)), Amgen clearly had reason to exclude all competitors from the U.S. for as long as possible. Accordingly, Roche must be able to present evidence regarding the duration of Amgen's patent protection to support its required showing of an intent to deceive.

**D. Roche, Not Amgen, Is The Only Party That Will Be Prejudiced**

Amgen's argument that the duration of its patent protection is "misleading and highly prejudicial" is baseless. The evidence that Amgen seeks to exclude consists of simple and basic facts about its patents -- namely, that Amgen has seven patents that, for the most part, issued and expire at different times, affording Amgen patent protection on its drug Epogen<sup>®</sup> from 1987 to 2015. Amgen offers no basis to conclude that the introduction of *facts* relating to its patent coverage is unfairly prejudicial -- the patents-in-suit and the duration of each patent term is already in evidence.

On the other hand, if the Court grants Amgen's motion, it will be Roche that is severely prejudiced. After all, Amgen's requested relief would preclude Roche from presenting fundamental evidence required by the law to support its defenses and is tantamount to granting summary judgment. The Court has explicitly stated that the time of filing summary judgment motions has passed. (July 17, 2007 Summary Judgment Hearing Tr. at 2:16-17 ("No more

motions of this type are going to be entertained after today by this Court”). Moreover, the Court has already ruled against Amgen on its motion for summary judgment of no inequitable conduct. Accordingly, the only potential prejudice here is to Roche.

### III. CONCLUSION

For the foregoing reasons, the Court should deny Amgen’s motion to preclude Roche from offering evidence and statements regarding the duration of Amgen’s patent protection and the current law regarding the term of patent protection.

Dated: August 31, 2007  
Boston, Massachusetts

Respectfully submitted,

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s/ Nicole A. Rizzo

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