

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.: 05-12237 WGY
	)	
	)	
F. HOFFMANN-LA ROCHE	)	
LTD., a Swiss Company, ROCHE	)	
DIAGNOSTICS GmbH, a German	)	
Company and HOFFMANN-LA ROCHE	)	
INC., a New Jersey Corporation,	)	
	)	
Defendants.	)	
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**AMGEN’S RESPONSE TO ROCHE’S OFFER OF PROOF REGARDING CLAIMS OF  
U.S. PATENT NO. 5,441,868 AND NO. 5,618,698 THAT INVALIDATE CLAIMS OF U.S.  
PATENT NO. 5,547,933, NO. 5,756,349, AND NO. 5,955,422 REGARDING  
OBVIOUSNESS-TYPE DOUBLE PATENTING**

Roche’s Offer of Proof on obviousness-type double patenting filed on September 7, 2007 (D.I. 1020), comes in the middle of trial, greatly expands the issues to be briefed, argued and decided by the Court, and still fails to provide any detail on the positions that Roche was obligated to disclose months ago in discovery. Rather than providing the detailed, claim-by-claim analysis required to support an ODP defense, Roche’s Offer simply recites a new list of claims from the ‘868 and ‘698 patents to be argued as ODP references against the asserted claims of the ‘933, ‘422 and ‘349 patents. Although Roche mentioned only one claim from either the ‘868 or ‘698 patents in the pretrial memorandum, Roche now seeks to inject seven more claims from these patents as ODP references in this case, necessitating 35 additional “patentably distinct” analyses. Amgen renews its request to strike these untimely defenses.

On June 21, 2007, the Court ordered the parties to meet prior to the final pretrial conference “to narrow the issues to be tried.” (D.I. 536, at 1.) The Court ordered the parties to prepare a joint pretrial memorandum setting forth, *inter alia*, “contested issues of fact,” and “issues of law, including evidentiary questions, together with supporting authority.” (*Id.* at 2.) In response to the Court’s Order, Roche disclosed in the parties’ August 10, 2007 Joint Pretrial Memorandum those obviousness-type double patenting defenses that Roche sought to raise at trial. Apart from the ‘008- and ‘016-based ODP defenses that had been the focus of the parties’ expert reports and summary judgment briefing, Roche disclosed only one additional claim from the ‘868 and ‘698 patents as a basis for ODP:

70. Whether subject matter covered by the Asserted Claims is obvious in view of subject matter patented in U.S. Patent No. 4,704,008 (the ‘008 patent).

71. Whether subject matter covered by the Asserted Claims is obvious in view of subject matter patented in U.S. Patent No. 4,667,016 (the ‘016 patent).

***72. Whether subject matter covered by the Asserted Claims is obvious in view of claim 1 of the ‘868 patent.***

(D.I. 807, Ex. B, at 8 (emphasis added).)

Now, having lost most of its ‘008 and ‘016-based ODP defenses on summary judgment, Roche seeks to add several new ODP defenses that it chose to withhold from the Joint Pretrial Memorandum. Specifically, Roche’s September 7, 2007 offer of proof lists seven additional claims from the ‘868 and ‘698 patents as alleged bases for invalidating claims in the ‘933, ‘422 and ‘349 patents. (*See* D.I. 1020, at 1.) Obviousness-type double patenting is determined on a claim-by-claim basis, and each claim in the ‘868 and ‘698 patents constitutes a separate ODP “reference” and necessitates a separate “patentably distinct” analysis. Therefore, Roche’s offer of proof seeks to add no less than 35 additional ODP defenses that were not mentioned in the Joint Pretrial Memorandum.

As explained in Amgen's emergency motion, Roche's new ODP defenses were not mentioned in any interrogatory responses served before the close of fact discovery on April 2, 2007, and were not developed in any of Roche's expert reports. (*See* D.I. 965, at 2-5.) Roche's untimely mention of these defenses in a later supplemental interrogatory response, served after the close of discovery, lacked any detail or any claim-by-claim comparison. (*Id.*) The MPEP section cited in Roche's offer of proof shows how much more detail an Examiner must provide to support an ODP rejection, and highlights just how inadequate Roche's untimely interrogatory response was to support these particular ODP defenses. (*Compare* D.I. 1020, at 1-2, *with* D.I. 994, at 4.)

Amgen already is significantly prejudiced by Roche's tactics. The distraction and burden of responding to Roche's efforts to add these untimely defenses in the middle of trial is substantial. If Roche is allowed to proceed with these defenses, the burden on Amgen will be further compounded. Additionally, Roche's gamesmanship has robbed Amgen's experts of the opportunity to address these defenses, which will prejudice Amgen's ability to fully develop the record for appeal of these issues.

As Roche urged the Court just last week, a party that fails to make the required disclosures should not be permitted to pursue the undisclosed theories at trial. *See* D.I. 1006, at 4 (citing *Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998); *Cytec Corp. v. TriPath Imaging, Inc.*, 2007 U.S. Dist. LEXIS, at \*13-18 (D. Mass. Aug. 22, 2007)). Amgen respectfully requests that the Court put an end to Roche's attempt to expand the invalidity case by ordering Roche's untimely ODP defenses based on the '868 and '698 claims waived or dismissed for failure to comply with the Court's discovery schedule. At the very least, the Court should limit Roche's new ODP defenses to those disclosed by Roche in the Joint Pretrial Memorandum—*i.e.*, ODP based on claim 1 of the '868 patent.

Respectfully Submitted,

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September 10, 2007

**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ Michael R. Gottfried  
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