

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
v.)	Civil Action No.: 05 Civ. 12237 WGY
)	
F. HOFFMANN-LA ROCHE LTD, ROCHE)	
DIAGNOSTICS GmbH, and HOFFMANN-)	
LA ROCHE INC.,)	
Defendants.)	
)	
)	

**DEFENDANTS' MOTION FOR CLARIFICATION ON WHETHER THE
COURT'S PRIOR RULINGS PRECLUDE DEFENDANTS FROM ARGUING
NON-INFRINGEMENT OF '933 CLAIMS 9 AND 12
BASED ON THE MARKUSH GROUP LIMITATION**

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 and HOFFMANN-LA ROCHE INC.**

October 14, 2007

Roche filed a motion for summary judgment of non-infringement of claim 1 of the '422 patent and claims 9 and 12 of the '933 patent with the Court on June 11, 2007 which the Court denied. The Court also granted Amgen's motion for summary judgment of infringement of the '422 patent, claim 1. Roche now seeks clarification of whether the Court's rulings preclude Roche from arguing non-infringement of the '933 claims 9 and 12 based on the fact that Roche's product, MIRCERA, does not meet the limitation "[a] pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier."¹

In its previous motion for summary judgment, Roche argued that under the Court's claim construction, Amgen's limitation, "A pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier," constituted a Markush group that is "closed, i.e., it must be characterized with the transition phrase 'consisting of,' rather than 'comprising' or 'including.'"² As such, Roche contended that this claim covers only pharmaceutical compositions containing one and only one of the specified alternatives, i.e., one diluent or one adjuvant or one carrier, and not, for example, a combination of a diluent and a carrier.

The undisputed evidence in this case remains that MIRCERA cannot be a pharmaceutical composition in accordance with the asserted claims. Dr. Lodish,

¹ In filing this motion, Roche does not concede that its product MIRCERA meets any of the other limitations of the claims at issue. Indeed, MIRCERA (i) is not, and does not contain "human erythropoietin" or its equivalent, (ii) does not contain a "therapeutically effective amount of human erythropoietin" (iii) is not "purified from mammalian cells grown in culture," and (iv) does not contain a "glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin." However, for the purposes of this motion it is not necessary to consider whether MIRCERA meets any of these limitations.

² *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003).

Amgen's own expert, stated that MIRCERA is a pharmaceutical composition that is formulated by adding "a diluent and carrier."

As was detailed in Roche's previous motion for summary judgment, a Markush group is a listing of specified alternatives of a group typically expressed in the form: "a member selected from the group consisting of A, B, and C."³ Unless there is certain qualifying language, a Markush group should be "closed" in the sense that no additional elements can be added to the listed group of alternatives. Here, the claim language construed by this Court, "containing a diluent, adjuvant, or carrier" is thus a closed Markush group in the form "A, B, or C."

Abbott Labs. also requires that when a specified list of alternative claim elements is not modified by qualifying language to include mixtures or combinations of the members of the Markush group, the claim is properly construed to allow for one and only one of the listed alternatives. Here, like in *Abbott Labs.*, there is no qualifying language to indicate that applicant Lin intended to claim a selection of multiple members from the Markush group. Under *Abbott Labs.*, the claim limitation "containing a diluent, adjuvant, or carrier" means that the pharmaceutical composition must contain one and only one member of the group to be selected as part of the claimed invention. The claimed invention cannot cover a pharmaceutical composition with a combination of a diluent and carrier.

Roche now seeks clarification on whether the Court's previous rulings preclude it from arguing that it does not infringe claims 9 and 12 of the '933 patent based on the presence of a diluent and a carrier in MIRCERA, rendering it beyond the reach of claims 9 and 12 of the '933 patent.

³ *Abbott Labs.*, 334 F.3d at 1280.

CONCLUSION

For all of the foregoing reasons, Roche asks for clarification on whether it is precluded from arguing non-infringement of '933 claims 9 and 12 based on MIRCERA's combination of both a diluent and a carrier.

DATED: October 14, 2007
Boston, Massachusetts

Respectfully submitted,
F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH,
and HOFFMANN-LA ROCHE INC.

By its attorneys,

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/s/ Thomas F. Fleming
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