Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 1404

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE, LTD, a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No. 05-12237 WGY

ROCHE'S OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* (D.I. 1392) AND BENCH MEMORANDUM (D.I. 1393) TO PRECLUDE ROCHE FROM OFFERING EVIDENCE REGARDING AMGEN'S EFFORTS TO PEGYLATE MOLECULES, INCLUDING EPO, AS IT IS IRRELEVANT TO THE INFRINGEMENT INQUIRY

Amgen's arguments have now reached a new level of incredulity. Amgen's Motion *in Limine* and Bench Memorandum regarding Amgen's efforts to pegylate molecules, including erythropoietin should be denied because:

- Amgen incredibly argues to this Court that pegylation of ERYTHROPOIETIN is NOT relevant but pegylation of compounds OTHER than erythropoietin IS relevant to the infringement inquiry in this case. Such a position not only defies logic, the positions of the parties throughout this case, and the evidence, but is completely disingenuous and improper.

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- The Court has previously ruled that "The Case Involves EPO, Including Pegylated EPO, Not Other Pegylated Compounds."[1] Consistent with this Order, and every issue in the case regarding infringement, testimony and evidence regarding pegylation of erythropoietin is relevant and should be allowed.

Incredibly, Amgen takes the position in its motion *in limine* and bench memorandum that evidence and testimony regarding pegylation of erythropoietin is not relevant to the infringement inquiry in this case. In opposing Roche's motion *in limine* to prevent Amgen from eliciting testimony from Dr. Torchilin regarding pegylation of non-EPO compounds, the nature of pegylation, and whether pegylation was known and routine (D.I. 1371) based on Amgen's failure to produce relevant documents during discovery, Amgen argued that it should not be precluded from introducing evidence of pegylation of non-EPO compounds and that such testimony was relevant. (D.I. 1380). Thus, in the span of less than seven hours, Amgen has taken positions before this Court that pegylation of compounds other than erythropoietin ARE relevant to the issue of whether Roche's accused product infringes, but that pegylation of erythropoietin is NOT relevant to the infringement inquiry in this case. Such a position is absolutely incredible.

With respect to pegylation of non-EPO compounds and whether pegylation is routine and easy, Amgen should be precluded from introducing such testimony because it refused to produce discovery to Roche regarding its efforts to pegylate its non-EPO compounds such as MGDF, NESP and GCSF. Amgen also failed to provide these documents to its own experts, such as Dr. Torchilin, completely undermining the basis of any opinion Dr. Torchilin and Amgen's other

[1] Court's Order dated 1/3/07 on Motion (D.I. 170).

experts might have regarding the ease and routineness of pegylation.[2] With respect to pegylation of erythropoietin, including Amgen's efforts to pegylate erythropoietin, such evidence is clearly relevant to whether Roche's product infringes Amgen's asserted product claims, is made by a process that meets the limitations of Amgen's asserted process claims, is materially changed from the product of those process claims and to infringement under the doctrine of equivalents and reverse doctrine of equivalents. Throughout Amgen's infringement case, the jury has heard Amgen lawyers and witnesses refer to Roche's product as "peg-EPO." Amgen's witnesses have testified that the active ingredient in Roche's product is erythropoietin with a peg molecule attached. The question of how Mircera is made, what starting materials are used, the properties of Mircera such as longer half-life and dosing schedule, are relevant to what Roche's product is and whether it infringes under Amgen's various assertions of infringement. In addition to its other expert witnesses, Amgen's Dr. Torchilin alone has submitted hundreds of pages of expert reports related to pegylation of erythropoietin and how that relates to Roche's accused product. Submission of such reports and every position taken by Amgen in this case prior to today underscore the utter baselessness of Amgen's arguments.

Additionally, evidence specifically regarding Amgen's efforts at pegylating EPO are relevant to the infringement inquiry in this case. Amgen would like to pretend that Roche's product is recombinant human erythropoietin instead of MIRCERA. As Dr. Lodish has already testified, it is not. What pegylation means to erythropoietin, how it changes the EPO molecule, what type of reactions are involved in reacting a peg molecule with an erythropoietin, and whether reacting peg molecules with erythropoietin is easy and routine or a substantial change in the molecules that requires extensive work and material changes are relevant to Amgen's

[2] See D.I. 1371.

infringement claims. In response to Roche's motion to compel production of discovery into Amgen's efforts to pegylate compounds other than EPO, Amgen succeeded in having this Court deny such discovery and issue an order stating that "The Case Involves EPO, Including Pegylated EPO, Not Other Pegylated Compounds."[3] For Amgen to now argue that the Court's order was wrong and this case does not involve Pegylated EPO is utterly without basis and disingenuous.

The Court should deny Amgen's motion *in limine* (D.I. 1392) and bench memorandum (D.I. 1393) to preclude Roche from offering evidence regarding Amgen's efforts to pegylate molecules, including erythropoietin as irrelevant to infringement.

[3] Court's Order dated 1/3/07 on Motion (D.I. 170).

DATED: October15, 2007

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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