IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE, LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE, INC. Defendants.	Civil Action No. 05-CV-12237 WGY

ROCHE'S BENCH MEMORANDUM IN RESPONSE TO AMGEN'S BENCH MEMORANDUM CONCERNING THE APPROPRIATE JURY INSTRUCTION ON 35 U.S.C. § 271(g)

In its Bench Memorandum regarding the parties' proposed jury instructions on 35 U.S.C. § 271(g) (D.I. 1321) Amgen makes numerous misstatements regarding this statute, its interpretation by the Courts and its application to this case. Roche submits this reply bench memorandum to correct these fallacies and to support its proposed jury instructions Sections 6.4 - 6.5 (attached hereto as Exhibit A) which accurately set forth the principles of 35 U.S.C. § 271(g) that are applicable to this case.

Pursuant to § 271(g), "[a] product which is made by a patented process will, for purposes of this title, not be considered to be so made after (1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product." 35 U.S.C. § 271(g). "The 'materially changed' exception of § 271(g) requires, at a minimum, that there be a real difference between the product imported, offered for sale, sold, or used in the United States and the products produced by the patented process." *Biotechnology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1560 (Fed. Cir. 1996) (emphasis added).

Thus, despite Amgen's obfuscations in its bench memorandum, the relevant inquiry under § 271(g) in this case is whether Roche's MIRCERA product, if imported into the United States, is materially changed from a direct product made by Roche by a process claimed by Amgen.

The test for material change under § 271(g) is closely related to the test for determining the doctrine of equivalents for product claims, as both look to the substantiality of differences in physical properties. For the same reasons that Amgen cannot establish that MIRCERA is equivalent to the product of the product by process claims of the '933 patent it cannot establish that there is no material difference between MIRCERA and the direct product of its asserted process claims. Much like a *Festo* bar, Amgen's forfeiture of certain structurally and functionally altered compounds in its specification and file history precludes it from claiming products as materially changed as MIRCERA.

Contrary to Amgen's arguments, in the case of a chemical compound such as CERA, the active ingredient in MIRCERA, it is appropriate for the fact-finder to consider evidence such as the creation of distinct and valuable features and different properties relating to basic utility, structural differences such as the addition or deletion of one or more particular chemical groups and the complexity of the subsequent processes as set forth by the district court in *Eli Lilly and Co. v. Am. Cyanamid Co.*, 66 F.Supp.2d 924, 932 (S.D. Ind. 1999). As the Federal Circuit held in affirming the district court in *Lilly*, these factors are probative of whether there has been "a significant change in the compound's structure and properties" to show a material change under 35 U.S.C. § 271(g). *See Eli Lilly and Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1573 (Fed. Cir. 1996). Roche does not argue, as Amgen has misleadingly suggested, that any one such factor is dispositive but rather points out that the fact-finder may consider any of or the confluence of all

of the structural and functional changes and the complexity of the subsequent processes in determining the issue of material change. Accordingly, Roche will adduce evidence that Roche's chemical processes impart significant structural and functional differences to its CERA end product including, but not limited to, differences in molecular weight, size, half-life, binding affinity and dosing intervals.

Amgen's reliance on analogies to mechanical cases in the context of § 271(g) is inapt because chemicals must be considered in the totality of their atoms and bonds. Dr. Lodish testified that a molecule "is a collection of atoms linked together by covalent chemical bonds." (Lodish, 2502:4-6). This is in contrast to machines or mechanical devices, where the individual components are themselves not changed by the addition of other components. Chemical compounds, on the other hand, are not properly considered "components" of other compounds: "we don't usually think of a process protein as a part of another protein, no. I don't like that language." (Lodish, 2341:15-20). When chemical compounds are reacted with other chemical compounds the structure and properties of each starting reagent may be significantly transformed. Thus, contrary to Amgen's bench memorandum, *Oki America, Inc. v. Advanced Micro Devices, Inc.*,[1] involving semi-conductor wafers subjected to additional processing steps in an assembly line fashion is inapposite. Unlike that case, where the additional steps did not "impact the product"[2] of the process, but rather added additional elements, Roche's CERA end product possesses significant functional and structural differences from the actual direct product of any of Amgen's claimed processes. Consistent with the Federal Circuit decisions in *Eli Lilly* and *BTG*, respectively, Roche's jury instructions appropriately allow the jury to consider such

[1] No. C-04-03171, 2006 WL 2711555 (N.D. Cal. Sept. 21, 2006).

[2] *Id.* at * 14.

evidence in determining whether "a significant change in the compound's structure and properties" exist and whether there is "a real difference between the product imported, offered for sale, sold, or used in the United States and the products produced by the patented process"

Amgen's bench memorandum also misstates the proper comparison that must be made to determine whether there is a material change under 35 U.S.C. § 271(g). Amgen argues that it is not proper to consider whether the imported product has been materially changed, essentially claiming that the direct product of the process should be compared to the product of the process under 35 U.S.C. § 271(g). (See D.I. 1321 at 7). This unsupported standard does not define at what point subsequent processes may no longer be considered prior to importation. Thus, the standard breaks down to a tautology where the direct product of the process is compared to itself and there could never be a material change. Of necessity, the end product which has been subjected to all subsequent processes up until importation is what must be compared to the direct product of the patented process in order to determine whether a material change has taken place. This is clearly what is required by the cases applying § 271(g). As the *BTG* Court stated the test for material change is whether there exists "a real difference between the product *imported, offered for sale, sold, or used* in the United States and the products produced by the patented process." *Biotechnology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1560 (Fed. Cir. 1996) (emphasis added). The District of Massachusetts has similarly held, stating "[t]o determine whether the 'materially changed' provision applies, the court must look to the substantiality of the change between the product of the patented process and the product that is being imported." *Genentech, Inc. v. Boehringer Mannheim*, 47 F.Supp.2d 91, 107 (D. Mass. 1999). Amgen's reading is thus at odds with the prevailing caselaw. Further, Amgen's reading at worst would render material change a nullity and at best would draw an arbitrary line as to what is considered

a "subsequent process." The proper inquiry, as stated in Roche's proposed jury instructions, is whether Roche's MIRCERA product is materially changed from the direct product of Amgen's patented processes.

Amgen also misleadingly suggests that the "trivial and non-essential component" prong of 35 U.S.C. § 271(g) must be considered in the analysis and that Roche's failure to factor it into its jury instructions is somehow improper. The "trivial and non-essential component" prong is a separate and alternative provision that may be pursued permissively. As the statute unequivocally states, a product made by a patented process will not be considered so made if "(1) it is materially changed by subsequent processes; ***or*** (2) it becomes a trivial and nonessential component of another product." 35 U.S.C. § 271(g) (emphasis added). Thus, a product may be held not to infringe under *either* rationale and an accused party is free to pursue both or only one prong as a basis of non-infringement. Since it is Amgen's burden to prove infringement it must submit evidence that MIRCERA is not materially changed ***and*** that the product of the process is not a trivial component of MIRCERA.

These two prongs are designed to apply to wholly different circumstances. For instance, in the case of a patented bolt which happens to become incorporated into an imported automobile, there may be no indication that the bolt is materially changed by its inclusion in the automobile but it may well be "a trivial and non-essential component" of the automobile such that the automobile does not infringe under § 271(g). Thus, whether or not the "trivial and non-essential component" prong applies in this case has no relevance to whether CERA is materially changed and Amgen is wrong to conflate the two tests. Amgen's insistence on including an instruction relating to "trivial and non-essential component" shows that Amgen wishes to obtain

a prejudicial inference with respect to the "material change" prong. The Court should not countenance this attempt to confuse the jury.

Finally, Amgen includes another "test" which is not a recognized requirement under § 271(g) in order to procure an improper inference. Amgen argues for inclusion in the jury instructions, the proposition that a product will not be considered materially changed if it would not be possible or commercially viable to make that product but for the use of the patented process - a proposition which is not found in the statutory language of 35 U.S.C. § 271(g) and which has not been adopted by the Federal Circuit. This language comes from a House report in the legislative history of § 271(g). In the *Lilly* case, the Federal Circuit did "not find the legislative history dispositive" and in considering this language in particular did not accord it "equal status with the language of the statute itself" which is silent as to the issue of commercially viable alternatives. *See Eli Lilly and Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1574, 1575-76 (Fed. Cir. 1996). The *Lilly* Court specifically commented with respect to the commercial viability language that "the inserted language is not easy to interpret, in part because it purports to identify some products that can "materially be changed" without being "materially changed." *Id.* at 1575. The *Lilly* Court ultimately declined to hold that the legislative history could be applied to determine whether an imported product was materially changed under § 271(g), stating "we cannot claim that the legislative background of the 1988 Act provides a conclusive answer to the question of how the 'materially changed' clause should be construed in general." *Id.* at 1578.

"Resort to legislative history is only justified where the face of the [statute] is inescapably ambiguous." *Holder v. Hall*, 512 U.S. 874, 933 n.28 (1994); *see also United States v. Councilman*, 418 F.3d 67, 87 (1st Cir. 2005). In the absence of a clear statutory requirement or

any authority stating that the legislative history should control and in view of the Federal Circuit's refusal to adopt this standard, Amgen's proposed instruction regarding whether there is a commercially viable alternative to Amgen's claimed processes should be rejected.

In any event, even assuming *arguendo* that this test were to apply it would be Amgen's burden to show a lack of commercially viable alternatives to its patented process. The burden of proof on the issue of material change rests with the patentee where, as here, the process by which the defendant's product is made is known. *Genentech, Inc. v. Boehringer Mannheim*, 47 F.Supp.2d 91, 108 (D. Mass. 1999). However, Amgen has put in no evidence regarding whether commercially viable alternatives to its claimed processes exist. As a result, there would be nothing for the jury to consider on this point and inclusion of this language in the jury instructions would be unduly prejudicial and confusing.

For all the foregoing reasons, Roche respectfully submits that the Court should adopt Roche's proposed jury instructions with respect to the issue of material change and reject Amgen's instructions on this issue.

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Boston, Massachusetts

Respectfully submitted,
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