UNITED STATES DISTRICT COURT
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.: 1:05-cv-12237 WGY

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO STRIKE INFRINGEMENT ALLEGATIONS IN AMGEN'S EXPERT REPORTS AND TO PRECLUDE TESTIMONY

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I. INTRODUCTION

Roche's Motion to Strike is based on a false predicate: That the opinions of Amgen's three experts that pegylation was routine and well-known stem from information that "Roche was denied during discovery."[1] This is not true. Roche is well aware that all documents referenced in the paragraphs of Amgen's expert reports that Roche seeks to strike were produced by Amgen (or ***Roche*** in some cases) and/or were publicly available.[2] So overreaching is Roche's motion that it seeks to strike portions of Amgen's expert reports that cite directly to Roche's peg-EPO BLA filings.

Amgen's Experts' Reports Rely on Information Disclosed in Discovery	
contain information based on documents Amgen produced and/or publicly available scientific publications, as well as the experts' knowledge and experience	Lodish ¶¶ 62, 184 Katre ¶¶ 3-5, 16-18, 29-30, 39-40 Torchilin ¶¶ 28, 30, 32-33, 73, 78, 83, 85, 87-89, 91, 95-96, 109-111
contain information based on Roche production of its peg-EPO BLA filings	Lodish ¶ 184 Katre ¶ 29, 40 Torchilin ¶¶ 65, 82, 84-88

Roche concedes that it had access to all of the documents that Amgen's experts rely upon.[3] Faced with this fundamental fact, Roche tries to create an illusion of prejudice and alleged Amgen misrepresentations to the Court that resulted in the Court on January 3 denying Roche's motion to compel production of all of Amgen's research and development documents related in any way to pegylation of any compound ("Motion to Compel").[4] Roche characterizes the subject matter of its earlier Motion to Compel as "pegylation" rather than what it was – Amgen's proprietary research and development of pegylating non-EPO proteins – and uses

[1] Docket 426, Memorandum in Support of Defendants' Motion to Strike Infringement Allegations in Amgen's Expert Reports on Which Amgen Did Not Provide Discovery and To Preclude Testimony ("Roche Mem.") at 9-10.

[2] Ex. 1 to the Declaration of William G. Gaede, III ("Gaede Decl.") is a chart showing the documents the experts cite in the paragraphs at issue, the expert report they were cited in, and the production status/Bates numbers.

[3] Roche Mem. at 8.

[4] Jan. 3, 2007, Order.

Amgen's successful opposition to that motion as a springboard to argue here for a bar to Amgen's experts offering certain opinions.[5]

But the facts do not fit Roche's rhetoric. Amgen opposed Roche's Motion to Compel on the grounds that Roche's unfocused and overbroad document requests calling for all Amgen documents relating to pegylating proteins not at issue were overbroad and unduly burdensome. Amgen never represented to the Court that pegylation generally and the supporting scientific literature that its experts now address were not at issue. To the contrary, and as Amgen clearly stated:

> Unfocused discovery into Amgen's pegylation projects is unwarranted. There can be no dispute that pegylation is a well-known and commonly used technique to increase the serum half-life of therapeutic proteins. Amgen-authored publications cited in Defendants' Memorandum state as much. Defendants' representations in their BLA are not to the contrary.[6]
>
> * * *
>
> ***Defendants admit that pegylation is a standard technique, on which there is extensive scientific literature***. There is no compelling justification to force Amgen to produce the enormous amounts of proprietary information on Amgen's research and development of products other than EPO.[7]

The opinions of Amgen's experts that Roche hopes to strike are directly in line with Amgen's unequivocal statements that pegylation was well-known and common, and that the scientific literature supports this principle. Roche's Motion to Strike rests on mischaracterizing Amgen's opposition to the Motion to Compel.[8]

Moreover, Roche has not shown how it has been prejudiced by this Court's previous Order. Amgen's experts do not rely on information from Amgen's research and development program that was not produced in accordance with that January 3 Order. Roche does not show that its preparation of expert reports was hindered in any way. And the Amgen reports that Roche complains of were responded to fully by Roche in several hundred pages of experts

[5] *See* Roche Mem. at 10.
[6] Docket 201 (Amgen Inc.'s Opposition to Defendants' Motion To Compel the Production of Documents) at 8.
[7] Docket 201 at 10 (emphasis added).
[8] See *id*. at 8-9.

reports served on May 11, 2007. By contrast, striking portions of Amgen's expert reports would materially harm Amgen's ability to present to the trier of fact a full and complete history on what the pegylation scientific literature and Roche's documents show. Roche's Motion to Strike should be denied.

II. ARGUMENT

A. ROCHE FAILS TO SHOW THAT IT WAS NOT PROVIDED DISCOVERY ON THE SUBJECT MATTER OF AMGEN'S EXPERT REPORTS

Roche's motion does not rest upon a failure by Amgen to provide discovery on the documents Amgen's experts relied upon; nor could it, as Amgen produced all of the documents cited in the Reports except for three publicly available articles.[9] In other words, Roche is seeking to have the Court strike paragraphs from expert reports on documents that Amgen in fact produced in discovery. There is no basis in equity or law for striking such paragraphs where there has been discovery.

While Roche makes much of Amgen's own research and development of pegylated proteins other than EPO, Roche's motion fails to show and cannot show that Amgen's experts relied upon that research and development program in formulating their opinions. This is ***not*** a case where an expert selectively relied on Amgen's research and development work of certain pegylated proteins to support his opinion (sword) while at the same time Amgen denied Roche discovery into that material (shield).

Indeed, so strained is Roche's argument that it seeks to prevent Amgen's experts from stating certain opinions about Roche's regulatory documents that Roche produced which discuss Roche's peg-EPO product.[10] There is no basis for preventing Amgen's experts from relying on Roche peg-EPO documents, particularly where, as here, Roche produced them and Amgen provided the reciprocal discovery into its peg-EPO research and development work.

[9] Gaede Decl., Ex. 1.

[10] *See* Gaede Decl., Ex. 2 (Torchilin Report ¶¶ 65, 86-88).

Faced with these fundamental facts, Roche mischaracterizes Amgen's representations to the Court in its opposition to Roche's Motion to Compel to justify its motion. Contrary to Roche's position, Amgen did not contend that pegylation was not relevant. Rather, what Amgen contended was that pegylation was well-known and established in that the scientific literature, and the burdensome and unfocused discovery requests aimed at hundreds of thousands of pages of Amgen documents failed to satisfy the requisites of Rule 26. Amgen statements to this Court included:

> "Defendants argue that they are entitled to virtually all Amgen documents relating to pegylation of *any* substance. Defendants elevate "peg" over EPO, in an attempt to divert this Court's attention away from the indisputable fact that their peg-EPO products contains EPO. EPO, not peg, is at the heart of this dispute."[11]
>
> "Unfocused discovery into Amgen's pegylation projects is unwarranted. There can be no dispute that pegylation is a well-known and commonly used technique to increase the serum half-life of therapeutic proteins. ***Amgen-authored publications cited in Defendants' Memorandum state as much***. Defendants' representations in their BLA are not to the contrary."[12]
>
> "Defendants' request, seeking ***all*** documents related to pegylating ***any*** "compound" (the "compounds" are not even limited to proteins) are unreasonably broad."[13]
>
> "***Defendants admit that pegylation is a standard technique, on which there is extensive scientific literature***. There is no compelling justification to force Amgen to produce the enormous amounts of proprietary information on Amgen's research and development of products other than EPO."[14]

Amgen was very clear that pegylation and the scientific literature in general was at issue, but that the relevance of Amgen work on non-EPO pegylated proteins did not justify the overbroad, unfocused and burdensome discovery that Roche sought. The Court agreed, denying Roche's Motion to Compel. All Amgen's experts rely upon is the very scientific literature that both

[11] Docket 201 at 7.
[12] Docket 201 at 8 (emphasis added).
[13] *Id*. at 8-9.
[14] *Id*. at 10 (emphasis added).

parties informed the Court existed and was not at issue in the Motion to Compel the large quantity of Amgen proprietary documents.[15]

Seeking to further bolster its argument, Roche erroneously contends that Amgen's experts' opinions that pegylation is routine are "belatedly presented."[16] Roche has been aware for at least six months that Amgen would contend that pegylation was simple and well known in the art.[17] Amgen likewise provided a 63-line response to Interrogatory No. 9 on January 9, 2007, and supplemented its response to this interrogatory a month later, stating that:

> The addition of one or more peg molecules to EPO does not alter the molecule in any relevant manner, [as] peg-EPO contains the same amino acid sequence, the same glycosylation pattern, the same in vivo biological activity, and the same therapeutic use as the EPO products produced according to Amgen's asserted process claims. Defendants' attachment of polyethylene glycol to the products produced according to Amgen's asserted process claims adds only a single covalent bond out of over 4000 bonds in such products.[18]

Roche was on notice of the basic subject matter reflected in the paragraphs of Dr. Lodisch's, Dr. Torchilin's, and Dr. Katre's expert reports that Roche seeks to strike.[19]

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[15] Roche did not then and has never since articulated any relevance for requests so overly broad and burdensome and did not move for reconsideration.

[16] Roche Mem. at 1-2.

[17] Docket 172 at 2.

[18] Gaede Decl., Ex. 6 at 28.

[19] Roche further mischaracterizes Amgen's statements in an arbitration, contending:

> "Amgen … [in the] proceedings against Ortho/J & J represented that [pegylation] to a molecule could result in major differences and cited its own failed efforts to apply pegylation techniques to MGDF to make a pharmaceutically acceptable composition."

Roche Mem. at 6. The excerpt that Roche cited refers to a cloned gene that Amgen modified by deleting several amino acids from its sequence and states that small changes in the ***amino acid sequence*** of a protein can have monumental consequences. The excerpt clearly indicates that the amino acid changes in MGDF (Megakaryocite Growth and Differentiation Factor), not pegylation, caused a problem requiring cancellation of clinical trials with the compound. (MGDF is not EPO or an EPO analog.) The fact that Amgen also pegylated the MGDF analog is ancillary to why the analog was ultimately not pharmaceutically acceptable. Contrary to Roche's characterization, nothing in the cited excerpt (or elsewhere in the transcript) indicates that Amgen had any difficulty with pegylation.

Roche's Motion to Strike improperly and unconvincingly tries to revise Amgen's position in opposing the Motion to Compel to be that pegylation in general is irrelevant, a position ***never*** taken by Amgen. Rather, Amgen argued that document requests for all of its research and development documents relating to pegylation of any compound failed to satisfy Rule 26.[20] Roche's Motion to Strike is wrongfully aimed at prohibiting opinions of Amgen's experts (1) that are directly in line with Amgen's consistent statements regarding the well-known and common use of pegylation as established in the scientific literature, and (2) that rest on documents Amgen and Roche produced in discovery.

B. AMGEN'S POSITIONS ARE NOT INCONSISTENT AND JUDICIAL ESTOPPEL IS NOT PROPER

1. The Case Law Roche Cites Does Not Support Barring Opinions and Testimony of Amgen's Experts

Although Roche cites several cases in support of its motion, none of them apply to the facts before the Court. For example, Roche cites two cases for the proposition that "courts are empowered to exclude expert opinion that constitutes surprise or a shift in a litigant's previous position."[21] *Thibeault v. Square D. Co.,* 960 F.2d 239 (1st Cir. 1992) and *Freund v. Fleetwood Enterprises, Inc.,* 956 F.2d 354 (1st Cir. 1992). In *Thibeault* the court upheld exclusion of testimony of seven expert witnesses who were identified for the first time only four days before trial. *Thibeault,* 960 F.2d at 241, 246. Similarly, in *Freund*, the court upheld exclusion of an expert's testimony that was first identified, and then only vaguely, four days before trial; the substance of the expert's testimony was not disclosed until a court-ordered deposition in the midst of trial. *Freund*, 956 F.2d at 357-358. Even the version of the facts urged by Roche (which Amgen emphatically disputes) does come close to showing conduct remotely similar to that of the litigants in *Thibeault* or *Freund*.

[20] Docket 201 at 8-9.
[21] Roche Mem. at 7.

Roche's judicial estoppel cases advance its cause no further. In two of the four cases, the First Circuit found that judicial estoppel did not apply. *See Intergen N.V. v. Grina*, 344 F.3d 134 (1st Cir. 2003); *United States v. Levasseur*, 846 F.2d 786 (1st Cir. 1988). The facts in the remaining two cases demonstrate the clearly inconsistent positions a party must take for a court to find judicial estoppel. In *Alternative System Concepts, Inc. v. Synopsys, Inc*., 374 F.3d 23 (1st Cir. 2004), the court invoked judicial estoppel when plaintiff ACS, in order to avoid the statute of frauds, asserted in opposition to a motion to dismiss that it was claiming breach of agreement to negotiate in good faith, ***not*** breach of an agreement to enter a long term contract, then in opposition to a motion for summary judgment asserted that its breach of contract claim related to a permanent oral agreement. *Id*. at 27. In *New Hampshire*, the Supreme Court held judicial estoppel barred New Hampshire from asserting in one proceeding that its boundary with Maine was the middle of the Piscataqua River's main navigable channel, then asserting in a subsequent proceeding that the boundary ran along the Maine shore. *New Hampshire v. Maine,* 532 U.S. 742, 745 (2001).

2. The Factual Requisites for Judicial Estoppel Are Not Satisfied

In contrast to the foregoing cases, Amgen has consistently and candidly presented to the Court and to Roche its views on pegylation in general, and that full-blown discovery into Amgen's research and development on pegylation of non-EPO compounds is not warranted here. Under such circumstances, judicial estoppel barring Amgen's experts from discussing pegylation generally is not warranted.

The Supreme Court established a three pronged approach to analyze judicial estoppel claims:

> First, a party's later position must be 'clearly inconsistent' with its earlier position. … Second, courts regularly inquire whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create 'the perception that either the first or the second court was misled.' …A third consideration is whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.

New Hampshire, 532 U.S. at 750-51 (citations omitted). Courts generally preclude a party from asserting a position "when a litigant is 'playing fast and loose with the courts,' and when 'intentional self-contradiction is being used as a means of obtaining unfair advantage.'" *VLT, Inc. v. Power-One, Inc.*, 2003 U.S. Dist. LEXIS 81 at *8 (D. Mass. 2003) (quoting *Patriot Cinemas, Inc. v. General Cinema Corp.*, 834 F.2d. 208, 212 (1st Cir. 1987)). Amgen has not played "fast and loose" or intentionally contradicted itself. "Where 'there is no indication of deliberate dishonesty . . . nor . . . prejudice to judicial proceedings or the position of the opposing party,' estoppel is not proper." *VLT*, *Inc*., 2003 U.S. Dist. LEXIS at *9 (quoting *Desjardins v. Van Buren Community Hospital*, 37 F.3d 21, 23 (1st Cir. 1994)).[22]

Roche's effort to mischaracterize Amgen's positions as "clearly inconsistent" evokes the facts in *VLT*, *Inc*., 2003 U.S. Dist. LEXIS *1. There the District Court of Massachusetts rejected a request by defendant Power-One to preclude plaintiff VLT from asserting that its patents covered the accused product. *Id*. at *2. In a prior patent litigation, VLT had argued that its patent covered a specific process of "zero-voltage switching." *Id*. at *5-6. Power-One argued in the subsequent action that its accused product did not exhibit "zero-voltage switching" and that VLT should therefore be precluded from arguing that its patent covered Power-One's product. *Id*. VLT denied that it ever asserted "that its patent claimed only zero-voltage switching," and the court agreed that VLT's positions were not "clearly inconsistent." *Id*. at *6, *11.

Similar to the facts in *VLT, Inc*., Amgen never argued that the pegylation of non-EPO proteins and pegylation in general are irrelevant. Rather, Amgen argued a narrower position, that Roche's unfocused and burdensome discovery into Amgen's research and development of pegylated proteins other than EPO did not satisfy Rule 26. Like *VLT*, *Inc.*, Amgen's positions are not "clearly inconsistent."

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[22] Amgen is not advocating inconsistent positions by drawing a distinction between the relevance of its research and development related to pegylated proteins other than EPO and the relevance of produced and publicly available information relating to pegylation in general and the state of the art of pegylation. Before judicial estoppel can be invoked, it must be shown that "the estopping position and the estopped position [are] directly inconsistent, that is, mutually exclusive." *Alternative System Concepts*, 374 F.3d at 33. Both positions taken by Amgen peacefully coexist.

Moreover, Amgen did not mislead the Court in opposing Roche's Motion to Compel. It clearly stated its position, and the fundamental problem with Roche's Motion to Compel was one of its own doing, namely it sought to enforce overbroad and unduly burdensome document requests.

Finally, as it must, Roche acknowledges that Amgen's experts have not relied on documents or information withheld from Roche,[23] and thus there is no unfair advantage to Amgen here. Judicial estoppel should not apply to bar Amgen's experts from offering opinions based on information that has been produced or is publicly available. None of the elements required to establish estoppel exist in this case. *See New Hampshire*, 532 U.S. at 751.

C. THE OPINIONS OF AMGEN'S EXPERTS DO NOT IMPOSE UNFAIR DETRIMENT ON ROCHE

Roche's arguments of prejudice are similarly unavailing. Roche complains that it was unable to get discovery from Amgen that it believes *might* exist that "*could* provide crucial rebuttal evidence"[24] (emphasis added). But Roche does not point to any actual evidence that Amgen possesses, or that Amgen has used, that would have aided Roche's expert reports had it been produced – despite having information on Amgen non-EPO pegylation programs as reported in the scientific literature.[25]

The contradictions in Roche's Motion to Strike eliminate any credible claim of prejudice. Roche unabashedly asserts that "Amgen has ambushed Roche with new arguments in its expert reports" and as a result, "Roche is . . . doubly prejudiced."[26] At the same time, Roche admits that it "anticipated that Amgen might argue that pegylation did not result in a materially changed compound with new structural and functional characteristics."[27] Moreover, Roche stated to this

[23] Roche Mem. at 8.
[24] Roche Mem. at 8.
[25] For example, Roche complains in its Motion to Strike that Amgen witness Graham Molineaux was instructed not to answer some of the questions related to an unpublished manuscript on Amgen's peg-GCSF, which the witness testified contained no information relevant to the pegylation of EPO. Roche Mem. at 4-5.
[26] *Id*. at 10.
[27] Roche Mem. at 5.

Court over six months ago that it was aware of Amgen's argument that pegylation of proteins in general is a common and simple procedure.[28] Roche was aware of and able to "anticipate" Amgen's arguments about pegylation because Amgen has repeatedly made Roche and the Court aware of its position – unaltered – on pegylation. There is no ambush here except by Roche at this late stage attempting to hamstring Amgen's experts.

Roche asserts that the paragraphs of Amgen's expert reports that should be struck "unfairly rely on information Roche was denied during discovery."[29] This claim has ***no*** basis in reality.[30] For example, Roche objects to paragraphs in Dr. Katre's report that discuss her twenty years of experience in research and development of proteins, including pegylated proteins.[31] Roche objects to paragraphs in all three reports that discuss documents and information that was produced by Amgen or was publicly available.[32] Inexplicably, Roche even objects to paragraphs in Dr. Torchilin's report that discuss documents produced or identified by ***Roche***.[33] The facts do not support the rhetoric.

Finally, and tellingly, in Roche's five expert reports[34] submitted that address pegylation, not one of the Roche experts opines that his or her opinion was hampered or rendered incomplete through the Court's Order denying Roche discovery into Amgen's research and development documents of non-EPO pegylated proteins. Indeed, Roche's opening expert report by Dr. Langer devotes 23 paragraphs to discussing aspects of pegylation of non-EPO proteins and pegylation in general – the very subject matter that Roche now seeks to strike from Amgen's expert reports.[35] The only prejudice foisted on Roche by Amgen's experts is the truth and accuracy of their opinions.

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[28] *See* Docket 172 at 2.
[29] Roche Mem. at 9-10
[30] The specific paragraphs identified in Roche's Motion to Strike are attached as Exs. 2-4 to Gaede Decl.
[31] Gaede Decl., Ex. 3 (Katre Report ¶¶ 3-5, 39-40).
[32] Gaede Decl., Exs. 1-4 (Torchilin Report ¶¶ 28, 30, 32-33, 73, 78, 89, 91, 95, 96); (Katre Report ¶¶ 16-18); (Lodish Report ¶¶ 62 and 184).
[33] Gaede Decl., Ex. 2 (Torchilin Report ¶¶ 65, 82-88)
[34] Roche served one opening and four rebuttal reports addressing pegylation.
[35] Gaede Decl., Ex. 5 (Langer Report ¶¶ 25-47).

D. ROCHE SHOULD NOT RECEIVE THE WINDFALL OF ALLOWING ITS EXPERTS TO OPINE ON PEGYLATION WHILE BARRING AMGEN'S EXPERTS FROM DISCUSSING THE SAME SUBJECT MATTER

The only actual prejudice associated with Roche's Motion to Strike will land squarely on Amgen if the Court grants Roche's motion. Amgen's experts could not opine on (1) what the general pegylation arts teach, and (2) what certain Roche regulatory peg-EPO documents show, while leaving Roche's experts unfettered in these areas. For example, Roche seeks to strike the following paragraph from Dr. Katre's Report:

> 16. Many of the first proteins produced by recombinant DNA technology were interleukins, cytokines, and growth factors. A number of these proteins were pegylated between the mid 1980's and '90's, such as, Interleukin-2, Interferon-β, TNF, CSF-1, G-CSF, GM-CSF, hGH, Interferon-α, and EPO. (Exs. 2-4, Katre 1993; Delgado et al., 9 CRIT. REV. THERAPEUT. DRUG CARRIER SYS. 249 – 304 (1992); Bailon et al., 1 PHARMACEUT. SCI. TECHNOL. TODAY 352-356 (1998).) While at Cetus, my group pegylated Interleukin-2, Interferon-β, TNF, and CSF-1 using several different linking chemistries. In the context of pegylation, linking chemistry refers to the chemistry used to attach PEG to the protein.

Or consider the following from Dr. Torchilin's Report:

> 28. Currently, there exist many chemical approaches to synthesize derivatives of PEG that may be coupled to proteins. (Exs. 18-19, Nektar 2003; Nektar 2004.) A common site of attachment on proteins for PEG was and is the amino groups (NH_2) of a protein's lysine residues and its N-terminus. Such PEG derivatives, which attach to proteins via amide linkages at the protein's lysines or N-terminus amino groups, have been known and in use since the '70s. Today, Nektar sells a variety of mPEGs combined with different linkers. Some of these linkers have a terminal ester group that can in turn be activated by various chemistries. An appropriately activated mPEG-linker molecule can then react through its activated ester with a primary amine of the protein (at the lysine or N-terminus in amino acid residues) to form an amide linked PEG conjugate.

As the foregoing shows, Roche's overreaching motion would even prevent Amgen from explaining to the trier of fact the basic pegylation technology and its background. Nothing on the facts here justifies prejudicing Amgen in this fundamental manor.

III. CONCLUSION

For all the foregoing reasons, the Court should summarily reject Roche's requests to strike portions of Amgen's expert reports and should reject Roche's request to preclude Amgen from offering testimony that refers to pegylation in general, or to pegylated non-EPO proteins.

DATED: May 15, 2007

Respectfully Submitted,

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