UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.: 05-cv-12237WGY
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.,	)	**REDACTED VERSION**
	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO AMGEN'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS

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Dated: December 28, 2006

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Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully submit this opposition to the Motion to Compel Production of Documents filed by Plaintiff, Amgen Inc. ("Amgen"), on December 14, 2006.

I. Introduction

After serving 224 Requests for Production on Roche seeking a vast array of documents, many bearing no relevance to any claim or defense in this action,[1] and while discovery negotiations are still in their early stages, Amgen now seeks the Court's intervention with a scattershot motion to compel that is both ill-founded and premature. As demonstrated below in chart form, Roche explained its positions at the parties' meet and confer, and for the majority of topics, provided a compromise approach which Roche believes is the proper course for discovery on these issues.

Amgen Requests	Roche's Position	Roche's Compromise
All documents relating to the EPO "component" of the accused drug. (Amgen Requests Nos. 5, 14-24).	MIRCERA™ is the alleged infringing product, not EPO. To the extent Roche uses EPO as a starting reagent, Roche has detailed all this information in its IND and BLA.[2]	In addition to the IND and BLA, Roche agreed to produce documents showing comparison data between MIRCERA™ and EPO.
All documents relating	Amgen has not pled a damages	Because sales and marketing information

[1] See Exh. 1 (Roche's Responses and Objections to Amgen's First Set of Requests for Production of Documents and Things (Nos. 1 to 224)).

[2] Despite Roche's expedited production in the ITC of its highly sensitive Investigational New Drug Applications ("INDs") and Biologics License Application ("BLA") (still pending before the FDA) for MIRCERA™, which comprise over 300,000 pages, in both paper and the OCRed searchable electronic format Amgen specifically requested, Amgen moves for Roche to re-produce the entirety of these voluminous documents, because it now desires the documents in a different electronic format. This notwithstanding Roche's agreement to fill in any missing pages that may have been unintentionally omitted should Amgen identify them. Although Roche views Amgen's requests to re-produce its BLA as well as its INDs as, in large part, unreasonable, Roche has agreed to provide a new paper set for these documents as well as electronic versions in a new format agreed to by the parties in an effort to expedite discovery in this matter.

to the marketing, sales, and pricing of the accused drug. (Amgen Requests Nos. 45-57, 60-64, 69-81, 85, 88-90, 97-98, 100-102, 111, 148-150, 153, 155, 158 and 166).	claim in its complaint, and has not indicated whether it will pursue damages in this case. Until Amgen indicates its damages position, Roche cannot commence wholesale damages discovery.	may be relevant to the issue of a preliminary or permanent injunction, Roche offers to produce: (1) documents sufficient to show actual projected sales figures for MIRCERA™; (2) documents sufficient to show projected market share for MIRCERA™; (3) documents sufficient to identify potential customers for MIRCERA™; and (4) documents sufficient to show current pricing and reimbursement plans for MIRCERA™.
All documents relating to imminent infringement and tracking of imports, and ongoing discussions with the FDA. (Amgen Requests Nos. 158-167).	Amgen has this discovery from the ITC where that judiciary body ruled that there is no infringement because of 35 U.S.C. § 271(e)(1). Moreover, because this Court has already ruled that there is subject matter jurisdiction based on imminence, such discovery is not relevant and is extremely burdensome and disruptive to Roche. Furthermore, this discovery is unnecessary in light of the extensive discovery already undertaken in the ITC.	Roche has agreed that documents relating to clinical studies that have been completed and submitted to the FDA will be produced, but that production of ongoing communications with the FDA would be unduly burdensome to Roche's efforts to gain FDA approval. Moreover, Roche has already indicated that it will update the Court of any significant events before the FDA regarding MIRCERA™, including whether approval is imminent.
All documents relating to Roche's attempts to "design around" cell lines, processes, and DNA sequences. (Amgen Requests Nos. 16-24 and 200-205).	Roche has already produced documents identifying the cell lines, processes, and DNA sequences used to make MIRCERA™. Contrary to Amgen's position, these documents are not relevant to the issues of invalidity or the doctrine of equivalents.	Roche will produce documents showing comparison data between MIRCERA™ and EPO, and Roche will produce documents showing the various constructs used towards the development of MIRCERA™.
All documents relating to the naming of "MIRCERA™." (Amgen Requests Nos. 218-220).	Roche's decision to give its drug a particular trade name is not relevant to any of the claims or defenses in the case.	

Amgen declared its intention to file the present motion to compel less than two days after the meet and confer and while Roche was still negotiating its discovery positions with Amgen by

letter. Amgen's motion violates both the letter and spirit of Local Rule 37.1 by failing to include the proper certification as well as the spirit of that rule by short circuiting the meet and confer process before Roche had an opportunity to respond to Amgen's characterization of Roche's positions.[3] Amgen's hastily cobbled together motion arrived before either party had provided any production in this case. Amgen's motion is also premature insofar as Roche has agreed to provide certain marketing, sales and pricing documents to the extent they relate to the issues surrounding a preliminary or permanent injunction. However, Roche is unable to ascertain the full scope of the relevance of such documents without a clear statement from Amgen as to whether or not it will also seek monetary damages, a possibility Amgen refuses to foreclose, despite the absence of such a claim from Amgen's pleadings. The contested issues relating to an injunction will become clearer as discovery advances such that Amgen could propound more specific and clearly relevant requests to Roche at a later date. Instead, Amgen has decided to press for discovery of an unreasonable and unlimited scope at this early stage.

In so doing Amgen has ignored the tremendous volume of probative and significant discovery that Roche has already provided, including information on future clinical trials, sales, and marketing. In fact, from the ITC proceeding Roche produced close to 400,000 pages of documents, provided 16 deponents in three countries offering more than 100 hours of testimony, and submitted interrogatory responses detailing Roche's production, importation and distribution of MIRCERA™ into the U.S. While Amgen tries to marginalize this effort, among the materials provided by Roche were its crown jewel BLA and INDs for MIRCERA™. These documents alone account for the lion's share of information relating to the development, composition,

[3] See Exh. 2 (12/11/06 Fishman Letter to Suh), Exh. 3 (12/13/06 Fishman E-mail to Suh), Exh. 4 (12/13/06 Suh E-mail to Fishman), Exh. 5 (12/13/06 Suh Letter to Fishman).

characteristics, manufacturing, clinical experience and formulations of MIRCERA™. The question that Amgen avoids is what other information it could possibly require that isn't already in these documents. The truthful answer is precious little concerning the key information about the attributes, formulation and functioning of MIRCERA™. For these reasons and those discussed below Amgen's motion to compel should be denied in full.

II. Documents Relating Solely to EPO Are Not Relevant

Amgen claims that Roche should be required "to produce documents regarding the structure and activity of the EPO contained in its accused product." (Amgen Inc.'s Memorandum of Points and Authorities in Support of its Motion to Compel Production of Documents, "Amgen Br." at 11). As an illustrative example of the type of request Amgen claims is relevant to this issue, Amgen points to its Request for Production No. 5 which seeks documents relating to a host of characteristics for "EPO" only and Roche's Response.[4] However, where Amgen has sought the same information with respect to the accused product MIRCERA™, such as in its Request for Production No. 6, Roche has agreed to produce responsive documents.[5]

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[4] **REQUEST NO. 5**: Documents and things sufficient to characterize accurately the amino acid sequence, molecule weight, structure, spectra, post-translational modification, glycosylation, sialyation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, in vitro or in vivo biological activity, and any other physical or functional characteristic of the EPO from which MIRCERA™ is produced.

RESPONSE TO REQUEST NO. 5: Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have relevance to any claim or defense in this action as EPO is not the accused product in this case. Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™.

[5] **REQUEST NO. 6**: Documents and things sufficient to characterize accurately the amino acid sequence, molecule weight, structure, spectra, post-translational modification, glycosylation, sialyation, acetylation, phosphorylation, sulfation, proteolysis, homogeneity, integrity, purity, specific activity, in vitro or in vivo biological activity, and any other physical or functional characteristic of the EPO from which MIRCERA™ is produced.

(continued...)

This set of Requests is illustrative of many of Amgen's Requests on which it moves to compel production in its motion. One request seeks documents related to MIRCERA™, and the preceding or following request seeks the same exact documents related to "the EPO from which MIRCERA™ is produced." Perhaps this explains, at least in part, the incredible and outrageous number of document requests propounded by Amgen in its First Set of Requests. In any case, Roche responded consistently to these types of requests.

As seen above, in response to Requests Nos. 5 and 6, Roche stated that, subject to certain general objections, Roche would produce documents responsive to the second request concerning MIRCERA™, but objected to producing documents which relate to EPO because EPO is not an accused product in this litigation. In its Amended Complaint, Amgen accuses Roche's MIRCERA™ product of infringing its asserted patents. In response, Roche has asserted an affirmative defense that MIRCERA™ does not infringe, and a counterclaim of non-infringement for MIRCERA™. Thus, the fundamental issue for Amgen's infringement claims is whether Roche's MIRCERA™ product meets the limitations of the asserted claims in Amgen's patents. Documents relevant to show the structure and function of MIRCERA™ may therefore be relevant, and Roche has either already produced or will produce all non-privileged, non-cumulative documents responsive to Request No. 6 concerning MIRCERA™.

On the other hand, EPO is not an accused product in this case, nor could it be - Roche is not seeking approval to sell EPO in the United States. Documents showing characteristics of

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RESPONSE TO REQUEST NO. 6: Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have relevance to any claim or defense in this action as EPO is not the accused product in this case. Moreover, Roche objects to this Request to the extent it uses terms that may require construction by the Court. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™.

EPO, such as structure and activity, are simply irrelevant to this litigation. Even taking Amgen's premise that one of the starting materials for MIRCERA™ is "EPO", how can the structure and activity of a starting material in any way be relevant to whether MIRCERA™ meets the limitations of Amgen's claims? The structure, function and activity of MIRCERA™ may very well be relevant to this inquiry, but these same characteristics of a starting material are simply not relevant to any issue in this case. Amgen's brief fails to explain how the structure and activity of an alleged starting material is relevant to whether or not MIRCERA™ infringes Amgen's patents.

Further, Amgen's Requests encompass the development and use of EPO in Europe even though Roche is permitted to market and sell EPO free and clear of any Amgen patents in Europe and currently markets an EPO product in Europe under the trade name NEORECORMON®. Clearly Roche's operations in Europe directed to producing and selling EPO products should not be the subject of any discovery in this litigation as they are irrelevant to any claim of patent infringement in the United States by MIRCERA™, a completely different and unrelated product. Amgen's Requests relating to EPO, therefore, are grossly burdensome and not limited to the United States activity that must form the basis for this litigation.

To the extent that by asking for documents related to the structure and activity of "the EPO from which MIRCERA™ is produced," Amgen seeks documents relevant to show how MIRCERA™ is produced; by what process it is produced; from what starting materials it is produced and the amino acid sequence and other characteristics of the protein starting material used in the manufacture of MIRCERA™ (as relevant to Amgen's alleged process claims, for example) this information and data has been and/or will be produced to Amgen.

Every detail about how MIRCERA™ is made, the nature and structure of the starting materials for MIRCERA™, including the amino acid sequence of the protein starting material for MIRCERA™, and details about the structure and activity of MIRCERA™ are required to be detailed in Roche's BLA. The complete BLA was produced to Amgen in the related ITC action soon after it was filed with the FDA on April 18, 2006. In addition, the INDs for MIRCERA™ contain a plethora of information about the structure and activity of MIRCERA™, the starting materials used to make MIRCERA™, and a complete range of data on the pharmacokinetics and pharmacodynamics of MIRCERA™. These documents also were produced to Amgen in the ITC action. In its Response to Request No. 5, Roche referred Amgen to Roche's BLA to the extent information on how MIRCERA™ is made and from what it is made is what Amgen was seeking in this Request.

Amgen also requested documents related to the development of MIRCERA™.[6] Roche has stated that it has or will produce documents responsive to this Request, so to the extent these are the types of documents Amgen seeks in its Requests for documents related to "the EPO from which MIRCERA™ is produced," Roche has indicated it will produce them.[7] Roche has also

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[6] **REQUEST NO. 26:** All documents and things relating to the research and development of peg-EPO including research papers, experiments, and studies conducted to develop peg-EPO.

RESPONSE TO REQUEST NO. 26: Roche incorporates herein by reference its Response to Request No. 25 above. Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading.
Subject to these objections and the General Responses and Objections above, relevant, non-cumulative documents responsive to this Request which are in Roche's possession, custody or control and which are not subject to a claim of privilege or work product immunity or otherwise protected from disclosure, will be produced or made available for inspection and copying.

[7] In addition, Amgen has requested information concerning "the manufacture or attempted manufacture of peg-EPO or EPO by or on behalf of ROCHE in the United States after 1995," documents "relating to the peg-EPO or EPO manufacturing, production or purification process developed or refined by or for ROCHE in the United States." (Amgen Requests Nos. 171 and 173). Roche responded that to the extent the Request relates to the manufacture of

(continued...)

stated that it would produce to Amgen any documents in its custody or control which relate to comparisons between the accused product, MIRCERA™, and erythropoietin or Aranesp®.[8] Thus, any document relevant to the question of whether MIRCERA™ infringes Amgen's patents has been or will be produced. To the extent Amgen's Requests concerning, as Amgen puts it, the structure and activity of "the EPO from which MIRCERA™ is produced" seek documents unrelated to the activity and characteristics of the accused product, MIRCERA™, or the process and materials used to make MIRCERA™, the Requests are overbroad, unduly burdensome, and seek clearly irrelevant documents not reasonably calculated to lead to the discovery of admissible evidence, and Amgen's motion to compel should be denied with respect to Amgen Requests Nos. 5 and 14-24.

III. Amgen's Requests For Future Marketing, Sales and Pricing Documents Are Not Reasonably Calculated to Lead to the Discovery of Relevant Evidence

Amgen's motion seeks all manner of documents relating to future marketing, sales, pricing, costs and reimbursement for a product that has not yet been sold or even approved by the FDA and despite the fact that Amgen has not pled a claim for monetary damages relief based on the prospective sales of this product. Thus, the relevance of many of Amgen's Requests remains, at best, hypothetical.

Amgen previously asserted to this Court that it would not seek damages.[9] If this is true -- and Roche contends that Amgen should be estopped from changing this position -- then the far

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MIRCERA™, it would produce, non-cumulative, non-privileged documents responsive to this Request. (Roche Response to Amgen Requests Nos. 171 and 173).

[8] See Exh. 5 (12/13/06 Suh Letter to Fishman).

[9] For instance, at a May, 10, 2006 Motion Hearing on Ortho Biotech Products , L.P.'s Motion to Intervene, Roche's Motion to Dismiss for Lack of Subject Matter Jurisdiction (based on 35 U.S.C. § 271(e)), and Roche Switzerland and Roche Germany's motion to dismiss for lack of personal jurisdiction, in response to a question from Judge Young on whether this is a jury case, Lloyd Day for Amgen responded that "As the claim is currently framed it's an equitable claim, it doesn't require a jury. There's no damage claim." Exh. 6 (Hearing Tr. 5-16-06, 33:15-24).

reaching discovery Amgen seeks into the planned marketing of MIRCERA™ and projected pricing, costs and reimbursement is unfounded. Without a claim for damages and all the associated issues of reasonable royalty and/or lost profits gone from the case, the scope of this discovery must be limited to the factors underlying the determination of a preliminary or permanent injunction hearing.

As Amgen points out, these factors include 1) irreparable injury to the movant; 2) inadequacy of remedies at law, such as monetary damages; 3) a balancing of the hardships of the parties and 4) the impact of an injunction on the public interest. *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006). Critically, and contrary to Amgen's misstatements, Roche has agreed to produce documents as it understands them to be relevant to these factors. This discovery could include documents that are relevant to the issues of how the sale of MIRCERA™ would impact Amgen's market share and pricing, the investments of both Amgen and Roche in the ESA market, and the prospective customers for MIRCERA™ and the benefits they would receive from the drug.

However, the injunctive relief factors do not implicate all the documents Amgen seeks. For instance, to take the same example Amgen uses at page 5 of its memorandum in support of its motion, its Request for Production No. 46 seeks:

> All documents and things generated by or for ROCHE management or any ROCHE organization, group or team since January 1, 2003 that reference or relate to preparations for or the commercial launch, supply, commercialization, promotion, clinical development, current or future pricing, sale or reimbursement of MIRCERA in the United States, including all goals, budgets, forecasts, milestones, minutes, agendas, presentations, tasks lists, schedules and plans of action.

This Request seeks any and all documents and things that relate to pricing, sale or reimbursement without any limitation to the types of information that may tie into a determination of injunctive relief such as projected sales figures, projected and actual market share and actual pricing plans

and other types of specific projections that could illustrate the effects of MIRCERA™'s entry into the market. Instead, this Request and many others, (See Amgen Requests Nos. 48, 50-62, 72-73, 89-103) encompass all types of proposed marketing and sales strategy, general market analysis and competitive intelligence, financial metrics, marketing budgets, manufacturing costs, sales force meetings, recruitment and training, and other areas where any nexus to a factor of injunctive relief is simply too attenuated to justify the scope of the discovery. Such a broad spectrum of information might be implicated by the criteria used to determine the hypothetical negotiated reasonable royalty rate in the damages context, but Amgen has not laid the groundwork for its relevance here. Amgen's blunderbuss approach appears to be designed to procure as much of Roche's sensitive marketing and business information as it can without regard to whether it stands a chance of eliciting information pertinent to the question of equitable relief or any other issue.

Nevertheless, Roche has agreed to produce a narrower subset of documents limited to the injunction factors, which Amgen ignores. Roche's Response to Amgen's Request for Production No. 46 states that:

> Roche will therefore produce such documents only to the extent they relate to the factors considered in a preliminary or permanent injunction determination should those issues arise. To the extent Amgen seeks remedies beyond injunctive relief, Roche reserves the right to supplement its response to this Request. (See Exh. 1).

Roche provides the same response to nearly all of the Requests for marketing, sales and pricing documents upon which Amgen bases its motion. (See Exh. 1 at Roche's Responses To Amgen Requests Nos. 45-57, 60-64, 69-81, 85, 88-90, 97-98, 100-102, 111, 148-150, 153, 155, 158 and 166).

Amgen has mischaracterized Roche's position in an attempt to justify its premature motion, by claiming that Roche refuses to produce any documents responsive to such Requests.

Bizarrely, Amgen claims that Roche has represented that it will not produce responsive documents unless and until Roche seeks an injunction or Amgen adds a claim for damages. (See Amgen Br. at 5). Regardless of any misinterpretation Amgen makes about Roche's position set forth in its Responses to Amgen's Requests For Production, the parties' meet and confer and the letters exchanged between the parties, Roche clearly has not made production contingent upon some unspecified injunctive relief it might seek when Amgen is the party seeking a permanent injunction.[10] Instead Roche's position, as repeated throughout its Responses to Amgen's Requests, is that Roche will undertake to produce documents that relate to the factors underlying a preliminary or permanent injunction, to the extent that Amgen can articulate a reasonable connection between such discovery and specific issues in the injunction context.

However, Amgen's Requests are, in general, unreasonably broad and indicate no attempt to tie the discovery into the injunctive relief Amgen seeks. For example, Amgen's Request for Production No. 51 seeks:

All documents and things that comprise or relate to ROCHE's marketing plan for MIRCERA in the United States.

This Request is virtually unlimited in its targeting of all marketing and business information relating to MIRCERA™. Clearly, the type of competitive intelligence and promotional strategy sought by Amgen in this Request exceeds the bounds of discovery designed to shed light on the impact of Roche's market entry on Amgen's sales and the public interest. Again in response to this Request, Roche has agreed to produce documents that are focused specifically on the issues of market impact, balancing the hardships, and the public interest.

[10] See Exh. 5 (12/13/06 Suh Letter to Fishman).

Amgen, on the other hand, has taken the position that it will produce only its future marketing documents (2007 and forward), despite Roche's various antitrust counterclaims directed to Amgen's past and ongoing policies and practices with respect to competition in the markets for treatment of End Stage Renal Disease ("ESRD") and Chronic Kidney Disease ("CKD"). (See Amgen's Responses to Roche's First Set of Requests for Production Nos. 65-66). Thus, Amgen has foreclosed discovery into all of its historical marketing practices that are the focus of Roche's antitrust counterclaims. Additionally, Roche has propounded Requests for documents relating to Amgen's share of total sales of erythropoietin stimulating agents ("ESAs") to ESRD patients and CKD patients, actual or potential market substitutes for ESAs in the treatment of ESRD and CKD, and costs associated with Amgen's Epogen® and Aranesp® ESA products. To all of these Requests, Amgen has responded that it will only produce documents going back to January 1, 2005. (See Amgen's Responses to Roche's First Set of Requests for Production Nos. 61-63, 71-72). Thus, Amgen has also obstructed discovery into documents showing its market power and competitive position before 2005, even though it has been marketing its Epogen® products since 1989.

Roche already has reason to believe that many such documents before 2005 provide information relevant to Roche's antitrust counterclaims. For example, Amgen has produced documents in the ITC from the early 2000's showing Amgen's strategy in vertically integrating the dialysis market by entering into anticompetitive contracts with "key" dialysis providers.[11] In light of these earlier documents, Amgen's position that anything predating 2005 is not relevant to Roche's antitrust counterclaims lacks any credibility.

[11] See e.g., Exh. 7 at AM-ITC00032416, Exh. 8 at AM-ITC00032458.

This discovery is clearly germane to Roche's antitrust counterclaims and Roche has been willing to negotiate with Amgen to circumscribe the bounds of this discovery.[12] However, Amgen remains recalcitrant on this discovery while demanding that Roche produce unlimited marketing and sales documents even though Amgen has not asserted a claim for damages or any other claim that would necessitate discovery of this scope.

Amgen complains that Roche's position with respect to its own marketing and sales documents allows it to selectively determine what is responsive to Amgen's Requests and does not delineate the boundaries of what documents are considered relevant in the context of an injunction. Had Amgen engaged in more than a cursory negotiation with Roche, the parties could have reached an agreement on the types of documents that would likely touch on the issues raised in an injunction hearing. However, to minimize the need for the Court's intervention, Roche offers the following categories as potentially relevant documents that it offers to produce:

- documents sufficient to show actual projected sales figures for MIRCERA™
- documents sufficient to show projected market share for MIRCERA™
- documents sufficient to identify potential customers for MIRCERA™
- documents sufficient to show current pricing and reimbursement plans for MIRCERA™.

As discovery progresses these categories may be refined or altered as the parties bring the issues of a preliminary or permanent injunction into sharper focus, but since no production has yet taken place it is premature for Amgen to argue that they are inadequate.

To the extent that any uncertainty remains as to what other types of documents are legitimately relevant to injunctive relief and what types are only relevant to monetary damages, it

[12] In particular, Roche has offered to move the floor for sales and costs documents up to 1997. See Exh. 9 (12/13/06 Suh Letter to Gaede).

is the product of Amgen's attempting to have it both ways on this issue. In the face of its complaint seeking only injunctive relief and its representations to the Court, Amgen now maintains that it may seek damages at some unspecified time. If Amgen does seek damages, then Amgen must say so definitively in order for Roche to determine the proper scope of relevant documents responsive to Amgen's Requests. Instead, Amgen holds the threat of damages over Roche's head like the sword of Damocles. Aside from the other prejudice it causes to Roche's case, it is also unfair for Amgen to hold the door open to massive, possibly irrelevant, discovery by refusing to eliminate the possibility of damages. Amgen's unfettered Requests for any and all marketing, sales and pricing documents far beyond the realm of injunctive relief serve no legitimate purpose at this juncture of the case and should be denied.

A. Documents Relating to Imminence and Tracking Imports Are No Longer Relevant

Amgen also attempts to justify its unlimited demands for marketing, sales and pricing documents on the ground that they are relevant to issues of the imminence of approval and commercial launch for MIRCERA™ and also to Roche's accounting for all current uses under 35 U.S.C. § 271(e)(1). This argument is a red herring because these issues no longer require any discovery. Amgen behaves as if it were still hunting for non-exempt uses in the ITC investigation. Indeed many of Amgen's Requests relating to importation, tracking shipments and accounting for inventory of MIRCERA™ seem to be mere leftovers from the ITC investigation and are obsolete in this action. (See Amgen Requests For Production Nos. 158-167). However, the ITC fully adjudicated these issues and found that no Roche use of MIRCERA™ fell outside the § 271(e)(1) safe harbor for uses related to obtaining FDA approval. Later, this Court decided that irrespective of § 271(e)(1), approval and commercial launch of MIRCERA™ were sufficiently imminent to confer jurisdiction over this case. At that point, all questions of both the

§ 271(e)(1) safe harbor and imminence became academic. Thus, Amgen has no basis for seeking documents concerning importation or inventory or the predicted time for FDA approval.

Amgen's Request for Production No. 164 is illustrative of the type of overly broad, painstaking and abusive discovery that Roche already withstood in the ITC to lay to rest Amgen's claims of current non-exempt uses.[13] Based on the Court's determination that this case will go forward on the grounds of future uses outside the safe harbor, there is simply no justification for repeating this exhaustive discovery into every movement of the accused product around the world. In any case, if Amgen seeks to relitigate what is now a non-issue, it still has the benefit of the complete discovery into Roche's importation and inventory of MIRCERA™ from the ITC, deemed by agreement of the parties to be produced in this case, which numbers hundreds of thousands of pages.

As to further Requests relating to the issues of imminence of FDA approval and the time to commercialization of MIRCERA™, these issues too were decided at the hearing on Roche's motion for dismissal of this case. Amgen's Request for Production No. 50 is exemplary of such Requests:

All documents and things relating to any forecast, plan or study of the time required to commence distribution or sale of MIRCERA in the United States following FDA approval.

[13] Amgen's Request for Production No. 164: For each instance of importation into the United States of any EPO product, including (without limitation) peg-EPO, EPO, or any non-PEG component of peg-EPO, documents and things sufficient to separately describe and account for each importation of such product, including (without limitation) (a) The location(s) where the EPO or peg-EPO is manufactured;(b) The date(s) of each importation; (c) The ROCHE entity that contracted to ship the product to the United States; (d) The commercial carrier for each importation; (e) The ROCHE entity that delivered the product to such carrier; (f) The unit(s) and volume(s) of product(s) imported; (g) Any customs agent or broker for such importation; (h) The ROCHE entity receiving the imported product(s);(i) The port of entry for the imported product(s); (j) The disposition of all imported product(s) after importation, including (without limitation) identifying each recipient of such product(s), the unit(s) and volume(s) of such product(s) provided to each recipient, the date(s) such product(s) was provided to each recipient, and all purposes for which such product was provided to each recipient; (k) All uses of such product(s) including the date(s) of use and the unit(s) and volume(s) used; and (l) All documents recording or reflecting any purpose(s) and use(s) for which any product was consumed or used by ROCHE or any recipient.

Amgen cannot offer any compelling reason as to why it requires such discovery when the Court has already decided that whatever the prediction of time until approval and launch, the ultimate sale of MIRCERA™ is imminent enough to confer jurisdiction. When Amgen couches its Requests solely in terms of the imminence issue as it argues in its motion, it is again flogging an issue no longer in play. Amgen's Requests for documents allegedly relating to § 271(e)(1) and imminence are unwarranted and should be denied.

B. Roche's Purported Hiring of Amgen Employees or Recruitment of Amgen Customers is Not Relevant

Amgen also seeks documents relating to Roche's purported recruitment of Amgen employees and solicitation of Amgen customers in connection with the launch of MIRCERA™ on the ground that these documents somehow also relate to the issues of injunctive relief. (See Amgen Br. at 9-11, Amgen Requests for Production Nos. 116-122). Roche does not concede that its hiring of sales and marketing personnel, medical liaisons, or reimbursement specialists related to MIRCERA™ has been in any way targeted at Amgen employees. However, even if Roche were attempting to recruit competent professionals that included Amgen employees, as well as other workers with relevant pharmaceutical, government or economic training, Roche fails to see how this is particularly relevant to Amgen's claims of infringement and injunctive relief. Further, Amgen seeks documents relating to its own customer lists, business directories and instructional materials when it clearly has all this material itself and Roche's possession of it has no bearing on whether MIRCERA™ infringes Amgen's patents. (See Amgen Requests Nos. 119-122). Unlike Roche, Amgen has not alleged any claim of tortious interference with its employee or customer contracts and therefore Amgen cannot support its need for discovery of these types of materials based on vague intimations of some type of misconduct in the market.

Further, these Requests are far too generalized and detached from any concrete allegation of harm for Amgen to honestly claim that they are pertinent to the factors underlying an injunction.

IV. Documents Post-Dating Filing of BLA and Ongoing Clinical Trials

Roche has notified Amgen in its Responses to Amgen's Requests as well as in the parties' meet and confer and by letter that it will produce responsive, relevant and non-privileged documents relating to completed clinical trials for MIRCERA™ as well as the regulatory approval process in connection with Roche's BLA and IND's for MIRCERA™ up until the date the BLA was filed on April 18, 2006. Roche submits that this is a reasonable time frame for discovery since it is already a full 13 months since Amgen filed its complaint and it encompasses all the final clinical and preclinical data underlying the IND's and the BLA which itself includes all the information concerning the properties, structure, activity and efficacy of MIRCERA™ which Amgen has sought. Amgen is well aware that the product which it has accused of infringement must be fully described in the BLA and that neither the product itself nor the process by which it is produced may be changed without supplementing or amending the BLA. Thus, Roche has agreed to produce any supplements, amendments, updates or other filings related to the BLA when they are completed and submitted to the FDA as well as all relevant underlying data. This discovery scheme allows for full disclosure of all the characteristics and indications for which Roche will seek approval to sell the accused product while avoiding unnecessary and disruptive production of incomplete data from which Amgen cannot form any relevant conclusion anyway. Nothing generated after the filing of the BLA can support a definitive description of MIRCERA™ unless and until it is submitted to the FDA and therefore it cannot be used to support any claim of infringement by Amgen.

For these reasons also, Amgen's Requests relating to any unfinished or future clinical study of MIRCERA™ should be denied. Further, any ongoing or future studies were judged by

the ITC to be within the scope of the 271(e)(1) safe harbor.[14] Nevertheless, Roche agrees that it will produce any relevant documents relating to these studies upon their completion. However, ongoing studies are both highly sensitive and complex and Amgen has not shown good cause to disrupt them with overly broad discovery requests. Requests for unfinished and unanalyzed raw data from these studies are not reasonably calculated to lead to the discovery of any information relevant to whether the finished MIRCERA™ product infringes Amgen's patents. Only if and when these studies are completed and the data is processed for submission to the FDA will they become the subject of legitimate discovery and at that time Roche will produce any responsive associated documents.

V. Attempts to "Design-Around" Are Not Relevant

Amgen also moves to compel documents regarding Roche's "attempts - including its failures - to design around Amgen's patents," and "the cell lines, processes and DNA sequences considered or evaluated by Roche to make the EPO component of MIRCERA." (Amgen Br. at 18). According to Amgen, this includes Amgen's Requests for Production Nos. 16-24 and 200-205. (Amgen Br. at 18-19). Roche objects to many of these Requests to the extent they call for cell lines and DNA sequences other than those used to create Roche's MIRCERA™ product for which commercial approval is sought in Roche's BLA No. STN 125164/0. (See, e.g., Exh. 1 at Roche Response to Request No. 19).

MIRCERA™ is the accused product in this case - the issue is whether MIRCERA™ or the process by which it is made meets the limitations of Amgen's asserted patent claims. Roche

[14] To the extent that Amgen argues that these planned or ongoing studies bear any relevance to 271(e)(1) in this case, which Roche disputes, Amgen has still received extensive discovery related to Phase III(b) studies in the ITC and Roche refers Amgen to those documents for information sufficient to identify current proposed MIRCERA™ studies.

has produced and will produce documents related to the characteristics of MIRCERA™, and the process by which MIRCERA™ is made, including Roche's BLA referenced in response to many of these Requests. Documents related to compounds or products other than MIRCERA™, including cell lines and DNA sequences of other molecules are completely irrelevant to this issue and are not a proper subject of discovery in this case. Likewise, Roche's attempts to "design-around" Amgen's patents, including failed attempts are also completely irrelevant to whether MIRCERA™ infringes.

Amgen states, without explanation, that these documents are relevant to Roche's defense of invalidity based on obviousness. (Amgen Br. at 20). A patent is obvious "if the differences between the subject matter sought to be patented and *the prior art* are such that the subject matter as a whole would have been obvious *at the time the invention was made* to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103 (emphasis added). Documents related to attempts to "design-around" Amgen's patents some 20 years *after* the claimed invention date of Amgen's patents are hardly relevant to whether those inventions were obvious at the time of invention.[15] Likewise, Roche's alleged attempts to "design-around" Amgen's patents are not relevant to infringement under the doctrine of equivalents despite Amgen's unsupported statements.[16] (Amgen Br. at 20). Amgen's motion to compel the production of documents related to molecules other than the accused product or constructs used

[15] Amgen's two cases in support of its argument are inapposite. *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272 (Fed. Cir. 2000), deals with whether failure of an accused infringer to develop a *working* product, *at the time the invention was made*, without surreptitiously obtaining the inventor's formulas and photographing a prototype of the invention, is relevant to non-obviousness of the later patented invention. 212 F.3d at 1285-6. *Dow Chemical Co. v. American Cyanamid Co.*, 816 F.2d 617, (Fed. Cir. 1987) deals with failed attempts of the accused infringer to develop the claimed invention prior to the successful effort of the patentee, not efforts to design around the claimed invention long after a patent issues.

[16] Experimentation by an accused infringer is not relevant to infringement under the doctrine of equivalents because intent plays no role in the application of the doctrine of equivalents. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 36 (1997); *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1334 (Fed. Cir. 2001).

to develop the actual accused product, or Roche's attempts to "design-around" Amgen's patents in response to Requests Nos. 16-24 and 200-205 should be denied.

VI. Documents Related to Naming MIRCERA™ Are Not Relevant

Finally, Amgen also moves to compel Roche to produce documents showing the names by which Roche refers to MIRCERA™. (Amgen Br. at 13-14). Amgen's only explanation for why it contends that documents relating to what Roche has called MIRCERA™ are relevant to this litigation is because "It is Roche, not Amgen, that has put Roche's naming efforts at issue by alleging that MIRCERA™ is a different chemical entity than peg-EPO, and that it is not comprised of EPO." *Id.* This argument defies belief. MIRCERA™ is whatever it is - documents concerning its characteristics, nature, properties, etc., regardless of what it is called, have been produced to Amgen and will further be produced.

Amgen's Request Nos. 218-220 recall Shakespeare's question, "[w]hat's in a name?, that which we call a rose, by any other word would smell as sweet."[17] The name by which Roche calls MIRCERA™ does not affect the drug, its ingredients, characteristics, or most importantly, whether it infringes Amgen's asserted patents. Documents related to naming MIRCERA™ and other names by which Roche or anyone else calls MIRCERA™ are completely irrelevant. Amgen's motion to compel should be denied with respect to Amgen Request Nos. 218-220.

VII. Conclusion

For all the foregoing reasons, the relief sought in Amgen's Motion to Compel Production of Documents filed on December 14, 2006 should be denied in full.

[17] *Romeo and Juliet*, Act II, Scene II.

Dated: December 28, 2006
Boston, Massachusetts

Respectfully submitted,

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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

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