UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION AND FAILURE TO STATE A CLAIM FOR WHICH RELIEF MAY BE GRANTED

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

Leora Ben-Ami
Patricia A. Carson
Thomas F. Fleming
Howard S. Suh
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel. (212) 836-8000

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STATUTES

I. PRELIMINARY STATEMENT

Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche"), respectfully submit this reply memorandum in further support of Defendants' Motion to Dismiss the Complaint of Plaintiff Amgen Inc. ("Amgen") pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) for Lack of Subject Matter Jurisdiction and for Failure to State a Claim for Which Relief May be Granted.

First, Amgen's opposition papers concede that its Complaint has no cause of action based on *current* infringement, and that its only count is directed to declaratory relief based on alleged impending acts of infringement. (Amgen Opposition Brief ("Opp.") at 19). Therefore, as a matter of law, Roche's motion to dismiss Amgen's Complaint based on alleged existing acts of infringement should be granted pursuant to Rule 12(b)(6).

Amgen would have this Court believe that Roche "has performed all of the steps . . . necessary to obtain FDA approval." (*Id.* at 1). By doing so, however, Amgen vastly oversimplifies the complex approval process by the U.S. Food and Drug Administration ("FDA") to a mere routine formality. As Roche demonstrated in its moving papers, the FDA review process is far from certain and often results in delays that extend beyond the 10-month period *goals* that the FDA strives to meet for reviewing applications. Amgen concedes as much by pointing to statistics where the median time for approval for standard applications is nearly 14 months. (*Id.* at 10). In fact, while Amgen accuses Roche of exaggerating the approval period to 22-25 months, these FDA sanctioned statistics are completely consistent with recent approvals by both Amgen and Roche. For example, Hoffmann-La Roche Inc.'s most recently approved Biologics License Application ("BLA") for its recombinant Pegasys® product took 29 months for approval. Amgen's BLA for its second generation EPO product, Aranesp®, took nearly 21 months to approve.

Moreover, Amgen's self-serving threats by its executives against Roche in the media are irrelevant to this issue. Here, Amgen is holding the Damoclean Sword over the heads of potential competitors, who do not even have FDA authority to challenge Amgen's nearly 20 year monopoly on EPO. Therefore, as the patent holder, Amgen cannot unilaterally fabricate an "actual controversy" in the media to support a Declaratory Judgment Action just because it wants one. Where, as here, a party has just commenced the FDA approval process and is therefore immune from infringement under the safe harbor provision of 35 U.S.C. § 271(e)(1), courts have repeatedly declined to initiate declaratory judgment infringement actions or dismissed them outright.

Critically, Amgen's legal arguments rest exclusively on the Federal Circuit's *Lang* and *Glaxo* cases.[1] However, Amgen's reliance on these cases is misplaced for at least the following reasons. First, the Federal Circuit in *Lang* actually affirmed the dismissal of the declaratory judgment complaint because it found that actual infringement was at least 9 months away and therefore too remote and speculative.[2] Second, this Court has already once before declined Amgen's arguments regarding *Glaxo*, when it stated that such declaratory judgment actions "run afoul of the Congressional policy underlying the section 271(e)(1) exception," "have the potential to discourage and hamper" competition, and "could easily become a tool of harassment and intimidation."[3]

Finally, Amgen's plea for discovery rings hollow as nothing more than the kind of harassment and resource draining distraction that § 271(e)(1) was designed to eliminate.

[1] *See Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761 (Fed. Cir. 1990); *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997).
[2] *Lang*, 895 F.2d at 764-65.
[3] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112-13 (D. Mass. 1998) (Young, C.J.).

Amgen's request for discovery should be denied and its Complaint should be dismissed with prejudice.

II. PROCEDURAL HISTORY

Defendants filed their motion to dismiss on April 11, 2006, and Plaintiff Amgen filed an opposition on April 25, 2006.[4] By order, dated April 19, 2006, the Court granted leave to file a reply memorandum by May 1, 2006, and has set a hearing for Defendants' Motion to Dismiss for May 10, 2006.

On April 11, 2006, counsel for Roche and Amgen met and conferred regarding this motion to dismiss. Amgen refused to withdraw the Complaint. Tellingly, later that same day, Amgen filed a complaint with the International Trade Commission ("ITC") against Roche based on the same patents and the same accused product, CERA. (Reply Ex. 1).[5]

III. STATEMENT OF FACTS

A. Even Amgen Admits That It Is Impossible To Predict CERA's Approval

Amgen dedicates most of its opposition to contesting Roche's statement that the average approval period for standard new chemical entities is 22-25 months from filing of a BLA. Not only does Amgen make numerous statements with no support regarding approval periods, Amgen's own brief demonstrates the uncertainty over the FDA approval process by vacillating between approval periods of 12 months, 10 months, 10-13 months, and 13.8 months.[6] This highlights the inherent unpredictability in the FDA approval process.

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[4] On the same day Amgen filed its Opposition, it also filed an Amended Complaint which merely includes the additional information provided by Roche that it had filed its BLA on April 19, 2006. (Docket No. 52). This amendment does not correct the deficiencies addressed in Roche's motion to dismiss, and thus, Roche's motion applies equally to this Amended Complaint.

[5] "Reply Ex." refers to exhibits attached to the accompanying Reply Declaration of Howard S. Suh.

[6] *See, e.g.*, Opp. at 1, 3, 6, 9, 10 and 15.

Amgen makes much of the fact that the financial markets have been closely monitoring this case, as if to absurdly suggest that because Amgen's CEO and CFO have made self-serving threats in the media against Roche and other companies, this makes the alleged infringement imminent and therefore ripe for a declaratory judgment action. However, such threats in the media can normally only trigger declaratory judgment actions by the accused infringer, not the patentee. Amgen would have the law of declaratory judgments turn upside down by arguing that it can unilaterally create a case of controversy and sue competitors for patent infringement based on Amgen's public threats, even when there are no allegations of current infringement, and as demonstrated below, any possibility of allegedly infringing acts could be as distant as 2 years away. Indeed, these same Amgen executives have told the financial community in government regulated documents that the FDA approval process is unpredictable and uncertain. Consider the following:

> In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, it remains costly to maintain. The FDA and other U.S. and foreign regulatory agencies have substantial discretion to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, require changes in labeling of our products, and mandate product withdrawals. (Amgen Form 10Q, Quarterly Period Ending 9/30/05, Reply Ex. 3 at 34).
>
> The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. (Amgen Form 8K, 4/18/06, Reply Ex. 4 at 3).
>
> We cannot take any action to market any new drug or biologic product in the United States until our appropriate marketing application has been approved by the FDA. Even after we have obtained initial FDA approval, we may be required to conduct further clinical trials and provide additional data on safety and effectiveness and are required to gain clearance for the use of a product as a treatment for indications other than those initially approved. In addition, side effects or adverse events that are

> reported during clinical trials can delay, impede, or prevent marketing approval. (Amgen Form 10K, 2005, Reply Ex. 5 at 22).

Moreover, while Amgen is quick to point out that its CEO, Mr. Sharer, feels confident about Amgen's track record in litigation, Mr. Sharer was apparently at a loss for words when asked why the life of the patents-in-suit lasted so long beyond the statutory prescribed periods. He could only answer by confessing, "It's an obvious question; I've had it myself."[7]

B. Recent Experience By Amgen And Roche Before The FDA Only Confirms That The FDA Process Is Uncertain And Unpredictable

Roche has never asserted with certainty that its BLA will take 22-25 months to approve. It could be longer, it could be shorter. Approval itself is not guaranteed. Roche cited these statistics from the FDA's own website to show what past practice has been – not goals, but actual practice. Roche's point, which should not even be seriously contested, is that the FDA approval process cannot be predicted with any certainty, and therefore, approval of Roche's BLA for CERA is not imminent. Amgen, on the other hand, relegates the FDA to a bureaucratic pawn of the pharmaceutical industry, where the approval process amounts to nothing more than a routine formality. This is simply not true.

In fact, if recent practice before the FDA by Amgen and Hoffmann-La Roche Inc. is any indication, this 22- to 25-month approval period is completely realistic. Roche's most recently approved BLA of its Pegasys® product took 29 months to approve. (Reply Ex. 6). Aranesp® and Kineret® are among Amgen's two most recently approved biologics, and the review time for these were 21 and 23 months, respectively. (Reply Ex. 7 at 5-6).

[7] Pollack, A., "Rivals Laying Siege to Amgen's Near Monopoly in Anemia Drugs," The New York Times, Dec. 23, 2005, Reply Ex. 13 at 2 ("In the United States, Amgen received seven patents. All were based on the work done in the early 1980's by one of its scientists, Fu-Kuen Lin, who isolated the human gene for erythropoietin, or EPO, the protein that makes up the drugs. While the first of these patents expired late last year, the others were not granted until the mid-to-late 1990's and could preserve Amgen's monopoly until 2015 - well beyond the 17 or 20 years contemplated in patent law for an innovation . . . . Even Kevin W. Sharer, Amgen's chief executive, when asked why EPO's patent life lasted so long, replied, "It's an obvious question; I've had it myself.").

The 21-month approval time for Aranesp® is especially significant in view of the fact that this is Amgen's second generation EPO product. Thus, while Amgen argues in its opposition that CERA's approval time should be faster because "the FDA is experienced with the disease state addressed by the BLA" and "understand[s] the clinical end points that must be met" (Opp. at 10), these factors apparently did nothing to accelerate the approval of Aranesp®. After all, Amgen's first generation EPO product, Epogen®, had by then been approved by the FDA for several years and administered to thousands of patients.

Finally, FDA statistics that concentrate solely on BLAs,[8] as opposed to New Drug Applications, corroborate this 22- to 25-month approval period. For example, in 2004, the median time of approval for standard review of BLAs was nearly 20 months. (Reply Ex. 9 at 2). In 2003, it was 30 months. *Id.*

C. Amgen's Interpretation Of The FDA Goals Is Incomplete And Wrong

Amgen's calculated adherence to the 10-month review period set forth in the FDA Prescription Drug User Fee Act (PDUFA) does not tell the complete story. As Roche pointed out in its moving brief, this 10-month benchmark is a goal, not a requirement. More importantly, however, this goal is for a first response, not necessarily an approval. Therefore, this 10-month period includes many applications that are denied or that require further testing or submissions. For example, for Roche's Pegasys® product, the FDA sent Roche a "complete response" letter within 11 months after the filing of the BLA. (Reply Ex. 10). However, Pegasys® was not ultimately approved until another 18 months because of FDA requests for additional data. *Id.*

[8] "In contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized. Biological products, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs. Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." FDA Center for Biologics Evaluations & Research, *available at* http://www.fda.gov/Cber/faq.htm, Reply Ex. 8 at 2.

Similarly, Amgen received a "complete response" letter from the FDA after 13 months of filing its BLA on Aranesp® (Reply Ex. 12), but had to wait another 8 months before FDA approval. (Reply. Ex. 7 at 5).

The PDUFA goal itself requires a response within 10 months for 90% of Standard new chemical entity applications, meaning that 10% of the applications can have a response within an unlimited amount of time and still be in compliance with the PDUFA goal.[9] Even if the FDA meets its PDUFA goal, it is impossible to determine whether Roche's BLA will be in the group that receives a response (including requests for further testing) in 10 months, or in the group that receives a response at some indeterminate period beyond 10 months. Thus, Amgen's suggestion that FDA guidelines require the FDA to act on Roche's BLA within 10 months is both incomplete and misleading.[10]

D. Amgen Disregards The Current FDA Environment

Amgen's opposition completely ignores the fact that the trend in FDA approval times has shown a marked increase in the last several years. As reported in the recent Impact Report of the Tufts Center for the Study of Drug Development, Vol. 7, No. 6, Nov./Dec. 2005, Suh. Decl. Ex. 2,[11] the average approval time for standard new chemical entities for the most recent period for which statistics are available, 2002-2004, was 22 months (1.8 years), which was the longest period since 1993-1995. The study shows a steady increase from 1996-1998 to 1999-2001 to

[9] Amgen repeatedly cites goals for both standard and priority applications despite the fact that Roche made clear in its moving papers that Roche's BLA for CERA is a standard application.

[10] Amgen also criticizes the 22- to 25-month period because it alleges that this number is not indicative of new applications, such as Roche's BLA, because it includes "previously rejected applications." Opp. at 9. As support, Amgen cites to paragraph 10 of the declaration of Amgen's consultant, Bette A. Goldman. However, Ms. Goldman cites no authority for this proposition, but instead merely repeats the performance goals of the PDUFA, and some unremarkable statistics regarding the different approval times between priority and standard applications. Notwithstanding the fact that CERA's BLA is not a priority application, the Goldman declaration sheds no light on the issue of previously rejected applications.

[11] "Suh Decl. Ex." refers to the exhibits that accompany Roche's moving brief, and not the exhibits attached to the Reply Declaration of Howard S. Suh ("Reply Ex.").

2002-2004. *Id.* This trend is likely to continue in the near future due to the increased scrutiny that the FDA has faced recently, particularly following the reports of deaths and complications tied to use of the drug Vioxx®. As Roche pointed out in its moving brief, since the stories involving Vioxx® were disclosed in late 2004, the FDA has been facing increased pressure to be extremely thorough with regard to safety issues. (Mem. p. 7). This increased pressure is causing the FDA to request more data than in the past, and will likely lead to increased approval times. The Pink Sheet, Vol. 67, No. 45, Nov. 7, 2005 (quoting the director of the Tufts Center for the Study of Drug Development, Kenneth Kaitlin), Suh Decl. Ex. 1. Amgen fails to take any of this into account when it speculates that CERA will be approved in 10 months.

No one, not even the FDA, can say with certainty whether Roche's BLA will be approved or how long this approval will take. By even the most ambitious estimates provided by Amgen, CERA's approval will not occur until at best, mid-2007, while the strong likelihood remains that it will probably take longer to approve. If anything, this demonstrates that both parties accept that approval is not imminent. Anything beyond that is pure speculation.

IV. ARGUMENT

A. Amgen's Allegations Of Current Infringement Should Be Dismissed From The Complaint

Amgen concedes in its opposition brief that its Complaint "sounds in declaratory relief for future infringement" and that "Roche's complaints about Amgen's failure to allege actual infringement . . . are irrelevant." (Opp. at 19). However, even in Amgen's recently filed Amended Complaint, dated April 25, 2006, Amgen preserves such ambiguous statements that Roche "currently infringes" the EPO patents (Reply Ex. 11 ¶ 26), and seeks a declaration that these patents are "currently infringed" by Roche's importation of CERA. (Reply Ex. 11 at 9).

Because Amgen admits that it is not alleging existing acts of infringement, and for the reasons articulated in Roche's moving papers, the Court should dismiss any such claims from this case and strike any suggestion of current infringement from Amgen's pleading.

B. Amgen's Reliance On The *Lang* And *Glaxo* Cases Is Misplaced

Amgen's legal arguments are flawed because the two Federal Circuit cases it relies upon, *Lang v. Pacific Marine & Supply Co.* and *Glaxo, Inc. v. Novopharm Ltd.*, actually backfire against Amgen as they are further authority to dismiss the Complaint.

In *Lang*, the Federal Circuit affirmed the *dismissal* of the declaratory judgment count because it ruled that the plaintiff failed to establish that there was an actual case or controversy. In *Lang*, the accused infringing product was a ship's hull structure. The declaratory plaintiff contended that when construction of this hull was completed, it would infringe certain patents, and therefore, this created an actual controversy to support a declaratory judgment action. *Lang*, 895 F.2d at 763. The Federal Circuit rejected this argument and affirmed the dismissal of the Declaratory Judgment count because it determined that infringement was too remote in view of the fact that the ship's hull would not have been complete for another 9 months from the time of the filing of the complaint. The Federal Circuit held that:

> Here, Lang failed to meet the actual controversy requirement necessary to maintain Count I under the Declaratory Judgment Act. The accused infringing ship's hull would not be finished until at least 9 months after the complaint was filed. . . . As the district court correctly held, "there is no 'substantial controversy . . . of sufficient immediacy and reality to warrant' consideration of [Lang's] claim for declaratory relief."

Lang, 895 F.2d at 764-65 (internal citations omitted). Amgen accuses Roche of not applying the *Lang* test. (Opp. at 11). In actuality, Roche's entire moving papers are based on the fact that Amgen has failed to meet the actual controversy requirement of the Declaratory Judgment Act, which *Lang* stands for. Ironically, by calling attention to *Lang*, Amgen supports Roche's motion

by highlighting even more Federal Circuit authority supporting dismissal. After all, even under Amgen's best case scenario where Roche's BLA is approved in 10-12 months, the reasoning of *Lang* would still compel dismissal since the Federal Circuit held in that case that 9 months before actual infringement was too remote to constitute an actual controversy.

Amgen's arguments regarding the *Glaxo* case are equally unavailing since the facts of that case are completely inapposite here. First, Amgen fails to mention that the litigants in *Glaxo* had a long history of protracted litigation, where the accused infringer was sued repeatedly by plaintiff for multiple attempts to enter the market with the accused drug. In fact, by the time the Federal Circuit heard the case, the litigants had two bench trials and a previous appellate ruling involving the same patents and product. *Glaxo*, 110 F.3d at 1564-65. This pattern of litigation undoubtedly played a role in the Federal Circuit's decision that the defendant's activities were imminent, especially in view of the fact that the defendant had already filed two previous applications for approval with the FDA. *Id.*

But more importantly, *Glaxo* is an Abbreviated New Drug Application ("ANDA") case. Just as the title suggests, ANDAs are a means for generic drug companies to receive expedited approval based on an abbreviated application to the FDA. Unlike a BLA, ANDAs are filed for the same active ingredient and only require a showing that the generic or "piggy-back" product is bioequivalent to the branded, marketed drug. As the same active ingredient is involved, an ANDA does not require the critical and time consuming safety and efficacy data that the FDA must review before approving a BLA. *See Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877, 879 (D.C. Cir. 2004) ("Enacted to expedite the process by which companies gain approval to sell generic versions of already-approved brand-name drugs, the [Hatch-Waxman] amendments allow companies seeking such approval to submit . . . ANDAs, that 'piggyback' on

the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs."). Filing an ANDA, as opposed to a BLA, "substantially shorten[s] the time and effort needed to obtain marketing approval" which "enable[s] [generic] drugs to be marketed more cheaply and quickly," in particular by "avoid[ing] the costly and time-consuming studies required for a pioneer drug." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). In fact, by statute, the FDA is required to provide immediate action on an ANDA if there are no pending lawsuits after a 180 day waiting period. *See* 21 U.S.C. § 355(c)(3)(C) ("If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent . . . .") (emphasis added).

The immediacy and near certainty of market approval for ANDAs are such that a mere filing of an ANDA constitutes an act of infringement under 35 U.S.C. § 271(e)(2). In *Glaxo*, the parties had a long history involving § 271(e)(2) infringement suits based on the filing of ANDAs. *Glaxo*, 110 F.3d at 1564-65. In fact, the only reason that the defendant in *Glaxo* sought declaratory relief rather than direct infringement was that one of the two patents at issue was directed to a method of manufacturing the drug, which is outside the jurisdictional limits of § 271(e)(2). *Glaxo*, 110 F.3d at 1570. The other patent in the case was a product patent, and as a result, did form the basis of actual infringement under § 271(e)(2). Thus, in the context of ANDAs, a declaratory judgment action provides the same jurisdictional hook necessary for method of manufacture patents as § 271(e)(2) does for product and method of use patents. *See Allergan, Inc. v. Alcon Labs*, 200 F. Supp. 2d 1219, 1227 (C.D. Cal. 2000) ("Section 271(e)(2) therefore provides no new substantive law, but much like the Declaratory Judgment Act, 28

U.S.C. § 2201, merely provides a jurisdictional 'hook' for a patent case"); *Glaxo*, 110 F.3d at 1569 ("§ 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction"). In *Glaxo*, there was no question that the infringement suit was going forward by virtue of the product patent and § 271(e)(2). Unlike the present case, judicial economy was on the side of finding and exercising jurisdiction by allowing the declaratory judgment count to proceed with the method of manufacture patent.

As a result, the facts and reasoning of *Glaxo* are completely irrelevant here. Roche is not a "piggyback" generic but is seeking approval of a new molecule. CERA is not a generic EPO, but a new biologic requiring its own BLA. Roche did not file an ANDA. Roche submitted thousands of pages of safety and efficacy data to the FDA as part of its BLA. Roche's BLA does not get immediate and expedited approval. Amgen has not brought suit against Roche based on § 271(e)(2). Roche and Amgen do not have a history of patent litigation based on the filing of ANDAs. Thus, it is simply disingenuous for Amgen to suggest in a footnote to its opposition that these are not "material difference[s]." (Opp. at 12 n.54).

Because of the unique facts in *Glaxo*, it is not surprising that this Court has once before denied Amgen's request to apply *Glaxo* in a non-ANDA setting to commence a declaratory judgment action against alleged infringers. In *Hoechst*, Amgen also relied upon *Glaxo* as dispositive authority in support of its declaratory judgment action against defendants Hoechst and TKT. 3 F. Supp. 2d at 112-13. However, this Court in its discretion declined to exercise declaratory judgment jurisdiction based on the following reasons:

> More important, subjecting the Defendants to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption . . . .
>
> Declaratory judgment actions have the potential to discourage and hamper the very efforts that Congress sought to stimulate, by subjecting potential competitors to the same burdensome litigation

> that Congress sought to eliminate. Although it is true that Amgen seeks only a declaration of its rights, which would not preclude continuing exempt activities, the use of the declaratory action could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition.

Hoechst, 3 F. Supp. 2d at 112-13 (internal citations omitted). All of these factors apply here, especially since Amgen has now brought a second patent infringement suit against Roche before the ITC, and alternatively, as discussed below, seeks broad discovery into Roche's current efforts of gaining FDA approval.

C. Amgen's Request For Discovery Should Be Denied

Amgen's request for discovery betrays its true motives in this district court action. While it claims to seek a "just, speedy, and efficient resolution of this matter" before the Court (Opp. at 18), Amgen's request for broad ranging discovery into CERA's FDA approval process is nothing more than a transparent attempt to harass and distract Roche's attempts to gain regulatory approval. As this Court recognized in *Hoechst*, such resource draining tactics clearly undercut the policy objectives of Section 271(e)(1).

Having realized that Roche was moving to dismiss this first filed action, Amgen raced to the ITC to commence a parallel suit involving the same patents against the same product and seeking similar injunctive relief. Amgen should not be rewarded for its miscalculation and its blatant acts of forum shopping, as it clearly chose this forum knowing that its Complaint was defective and premature.

Moreover, Roche should not be taken to task for information that Amgen should have evaluated before filing this lawsuit. If Amgen did not have the requisite facts to demonstrate an actual controversy for declaratory judgment action, it should not have filed these baseless lawsuits and burden this Court and the ITC. *See Ultra-Temp Corp. v. Advanced Vacuum Sys.*, 194 F.R.D. 378, 383 (D. Mass. 2000) (Collings, M.J.) ("[I]t should be obvious that the

requirement of a pre-filing investigation would be utterly meaningless if a party could file a complaint without having done the requisite investigation, do some discovery, and then file an amended complaint and thereby insulate itself from any possibility of being sanctioned for the failure to conduct a pre-filing investigation before filing the original claim."); *Cuddy v. City of Boston*, 765 F. Supp. 775, 778 (D. Mass. 1991) (Keeton, J.) ("[T]he [First Circuit] has frequently held that where the plaintiff fails to state a claim, he is not entitled to discovery merely to find out whether or not there is a factual basis for his claim."). Instead, Amgen now attempts to harass Roche's efforts to gain FDA approval because of Amgen's own shortcomings.[12]

V. CONCLUSION

Based on the foregoing, Roche respectfully requests that the Court grant its Motion to Dismiss Amgen's Complaint and Amended Complaint and deny Amgen's request for discovery.

DATED: Boston, Massachusetts
May 1, 2006

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

By its attorneys,

/s/ Julia Huston

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
jhuston@bromsun.com

[12] That this Court permitted discovery against the accused infringers in *Hoechst* is of no moment here. After all, those discovery requests were directed to Amgen's allegations of current infringement where Amgen argued that these activities fell outside of the safe harbor provision of § 271(e)(1). Here, Amgen concedes that there is no allegation of actual infringement in this case, and therefore, discovery into these matters is moot.

Of Counsel:

Leora Ben-Ami
Patricia A. Carson
Thomas F. Fleming
Howard Suh
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

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/s/ Julia Huston

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