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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MedImmune, Inc., Plaintiff, v. **Genentech, Inc., City of Hope, and Celltech R&D Ltd.** Defendants.	CASE No. CV 03-2567 MRP **MEMORANDUM OF DECISION** RE: Defendant Celltech's Motion for Judgment on the Pleadings and Defendant Genentech's Motion for Summary Judgment (69-1) (56-1)

On September 30, 2003, Plaintiff Celltech R&D Ltd. ("Celltech") filed a Motion for Judgment on the Pleadings. On October 31, 2003, Genentech, Inc. ("Genentech") filed a Motion for Summary Judgment on Plaintiffs' Antitrust Claims. The Court heard oral argument on December 15, 2003 and took these matters under submission.

BACKGROUND

I. SUMMARY OF THE DISPUTE

This dispute deals with patents claiming a method of producing monoclonal antibodies utilizing recombinant DNA technology. Plaintiff MedImmune is a biotechnology company whose most successful product is

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Synagis, a drug used to prevent respiratory syncytial virus in children. The Defendants are two biotechnology companies, Celltech and Genentech, and a nonprofit organization, City of Hope. MedImmune's Synagis product utilizes the monoclonal antibody production techniques covered by the patents at issue. The patent for this technology was originally owned by Celltech, but following the resolution of a priority dispute the technology is now claimed by a patent that has been assigned to Genentech and City of Hope.[1]

MedImmune alleges that Celltech and Genentech illegally resolved the priority dispute between them in a manner that required neither Celltech nor Genentech to give up anything, but that was designed to cause a real loss to others in the industry. Celltech had a patent on the technology at issue that was due to expire in 2006. (Am. Comp. ¶13). As part of their settlement, Celltech ceded priority to Genentech. (*Id.* ¶12). Genentech then obtained a patent over essentially the same technology; that patent is due to expire in 2018. (*Id.* ¶17, ¶123). MedImmune claims that this agreement had the effect of creating a 29-year patent monopoly over this technology. (*Id.* ¶13).

II. UNDISPUTED FACTS

The essential facts are uncontroverted. *See* Plaintiff MedImmune, Inc's Statement of Genuine Issues of Material Fact and Responses to Proposed Conclusions of Law in Opposition to Genentech, Inc.'s Motion for Summary Judgment (filed under seal November 17, 2003).

A. Cabilly and Boss Patents

[1] References to "Genentech" in the remainder of this memorandum refer to both Genentech and City of Hope.

On April 8, 1983 Genentech filed a U.S. patent application; this patent issued on March 28, 1989 as U.S. Patent No. 4,816,567 with Shmuel Cabilly as the first inventor (the "Cabilly" patent). On November 14, 1984, Celltech filed an application that issued as U.S. Patent No. 4,816,397 on March 28, 1989 with Michael A. Boss as the first inventor (the "Boss" patent). Genentech had a continuation application pending that claimed the benefit of its original April 8, 1983 application date (the "New Cabilly application"). This New Cabilly application was amended to restate the claims of the Boss patent.

B. Interference

Genentech advised the United States Patent and Trademark Office (PTO) of the conflict between the Boss patent and Genentech's pending New Cabilly application. On February 28, 1991, the PTO's Board of Patent Appeals and Interferences ("Board") declared Patent Interference No.102,572 between the Boss patent and Genentech's pending continuation application. On August 13, 1998, the Board awarded priority to Celltech. *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (Bd. Pat. App. & Interf. 1998).

C. §146 Action

On October 9, 1998, Genentech commenced an action under 35 U.S.C. §146 ("the §146 action") to overturn the Board's priority determination. During the §146 action, Genentech produced a draft patent application that had not been produced during the interference proceeding before the PTO.

Genentech filed a summary judgment motion in the §146 action. On July 28, 2000 the Honorable Maxine M. Chesney, United States District Judge for the Northern District of California, heard argument on

Genentech's motion for summary adjudication. Judge Chesney denied Genentech's summary judgment motion on the ground that a triable issue of fact existed.

D. Settlement of the §146 Action

On the day of the summary judgment hearing, Judge Chesney stated that the parties should consider alternative dispute resolution or private mediation. Genentech and Celltech engaged in mediation conducted by a retired judge in an effort to resolve the §146 proceeding. Genentech and Celltech entered into the "Settlement Agreement between Genentech, Inc. and Celltech Chiroscience Limited" ("Settlement Agreement") on March 2, 2001. On the same day, Genentech and Celltech also entered into the "Amended and Restated License Agreement between Genentech, Inc. and Celltech Chiroscience Limited" ("ARLA").

On March 6, 2001, Genentech and Celltech filed a Notice of Settlement and Joint Request for Entry of Settlement Instruments, a Proposed Order Regarding Resolution of Interference ("Proposed Order"), and a Proposed Judgment. On March 14, 2001, Celltech and Genentech participated in a telephonic status conference before Judge Chesney. Revised versions of the Proposed Order and Proposed Judgment were subsequently submitted by Celltech and Genentech. The Order and Judgment were executed by Judge Chesney on March 16, 2001.

E. Obtaining the '415 Patent

On June 1, 2001, Genentech filed certified copies of the District Court's Judgment with the PTO Board. *Cabilly v. Boss*, 60 U.S.P.Q.2d 1752, 1755 (Bd. Pat. App. & Interf. 2001). The PTO Board directed Genentech's application to be returned to an Examiner.

On September 13, 2001 Genentech, through its lawyer and its patent agent, submitted documents relating to Genentech's pending application to the PTO and participated in an interview with representatives of the PTO on the same subject. Subsequently, Genentech submitted a Supplemental Information Disclosure statement to the PTO and, on October 4, 2001, participated in an additional interview with representatives of the PTO.

On December 18, 2001, the PTO issued Genentech's pending continuation application as United States Patent No. 6,331,415B1 (the the "New Cabilly" patent).

F. MedImmune Files Suit

MedImmune filed its initial Complaint in this case on April 11, 2003. On August 13, 2003, Plaintiff MedImmune, Inc. served its First Amended Complaint ("Am. Comp."); its Initial Disclosures were served on August 21, 2003.

LEGAL STANDARD

Although Celltech's and Genentech's motions both rely on the *Noerr-Pennington* doctrine, Celltech's motion is based on Rule 12(c) of the Federal Rules of Civil Procedure (FRCP), whereas Genentech's is a summary judgment motion made under FRCP Rule 56(c). This Court has considered the same evidence in consideration of each motion, thus both motions will be treated as motions for summary judgment. Rule 12(c) explicitly permits this: "If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment . . .". FRCP, Rule 12(c); *see Hal Roach Studios*, 896 F.2d 1542, 1550 (9th Cir. 1989)("judgment on the pleadings is improper when

the district court goes beyond the pleading to resolve an issue; such a proceeding must properly be treated as a motion for summary judgment").

Summary judgment is appropriate when the submissions show that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as matter of law." FRCP Rule 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-26 (1986). For the purposes of this motion, MedImmune is entitled to all reasonable inferences that may be drawn from the evidence it cites. *Eisenberg v. Ins. Co. of N. Am.*, 815 F.2d 1285, 1289 (9th Cir. 1987)("[T]he non-moving party's evidence is to be taken as true and all inferences are to be drawn in the light most favorable to the non-moving party."). Furthermore, if MedImmune adduces direct evidence of a genuine issue of fact, such evidence may not be weighed against the Defendants' evidence but must be submitted to the trier of fact for resolution. *Id.*

ANALYSIS

The Defendants ask this Court to find that the *Noerr-Pennington* doctrine bars MedImmune from pursuing its federal antitrust claims (Counts 5 and 6 of the Amended Complaint), state law antitrust claims (Counts 8 and 9), and the state unfair competition claim (Count 10).

The parties agree that California law follows *Noerr-Pennington*, and thus that a decision as to the *Noerr-Pennington* issues will resolve the question of immunity to MedImmune's Cartwright Act and unfair competition claims as well as the Sherman Act claims.

Consequently, this discussion focuses on whether the *Noerr-Pennington* doctrine applies to the facts of this case as pled or otherwise established.

I. The *Noerr Pennington* Doctrine

A. State Action Immunity: The Basis for *Noerr-Pennington*

The Noerr-Pennington doctrine essentially grants antitrust immunity to parties engaged in petitioning activities. This doctrine has its basis in the state action immunity doctrine - the idea that the government cannot be held liable for anticompetitive acts because the Sherman Act prohibits only those anticompetitive conditions that are sought to be or are created by "individuals or combinations of individuals or corporations." *Standard Oil Co. v. United States*, 221 U.S. 1, 51-62 (1911). States cannot be held liable under the Sherman Act because "nothing in the language of the Sherman Act or in its history suggests that its purpose was to restrain a state or its officers or agents from activities directed by its legislature." *Parker v. Brown*, 317 U.S. 341, 351 (1942).

B. Antitrust Immunity for Petitioning Activities

The corollary to the state action immunity doctrine is the idea that the conduct of private individuals petitioning the government for anticompetitive action can not be restricted by the antitrust laws, an idea that is known as the *Noerr-Pennington* doctrine.

1. Establishing Petitioning Immunity

The competition between railroads and the trucking industry over long-distance transportation of freight gave the Supreme Court its

first opportunity to consider whether antitrust liability could result from attempting to influence the government to pass anticompetitive laws. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). In *Noerr* the trucking industry sought relief under the antitrust laws when a consortium of railroad executives conducted a campaign to sully the image of the trucking industry and obtain the passage of laws restricting freight trucking. 365 U.S. at 129-32. The *Noerr* Court recognized that "no violation of the Act can be predicated upon mere attempts to influence the passage or enforcement of laws" and ruled that the railroads could not be held liable for the effects of their campaign. *Id.* at 141-43. The Court held that the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly"). *Id.* at 136.

Although *Noerr* dealt only with petitioning lawmakers, later cases made it clear that petitioning the executive and judicial branches was protected as well: "the right to petition extends to all departments of the Government." *California Motor Transport Co. et al. v. Trucking Unlimited et al.*, 404 U.S. 508, 510 (1972) (applying *Noerr* immunity to petitioning the courts);[2] *United Mine Workers of America v. Pennington*

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[2] In *California Motor Transport*, a group of highway carriers attempted to resist and defeat a competitor group's applications for operating rights by seeking reviews and appeals of agency and court decisions on the applications. 404 U.S. at 509. The Court found that "the right of access to the courts is indeed but one aspect of the right of petition" and thus that "it would be destructive of rights of association and of petition to hold that groups with common interests

et al., 381 U.S. 657, 671 (1965) (applying Noerr immunity to petitioning an executive official).[3]

2. Justification for Petitioning Immunity

The Noerr Court stated two reasons for concluding that Congress did not intend petitioning activities to be regulated by the Sherman Act.

First, the Court noted that "the whole concept of representation depends on the ability of the people to make their wishes known to their representatives." *Noerr*, 365 U.S. at 137. The imposition of antitrust liability for attempts to influence government could chill those communications and would thus be detrimental to democratic government. *Id.* To hold that people cannot freely inform their representatives of their wishes would impute to Congress an attempt to regulate political activity, a purpose that the Court found unsupported by the legislative history of the Sherman Act. *Id.*

Second, the Court recognized that the First Amendment's right of petition could be violated by imposing antitrust liability on petitioning activities. *Id.* at 138. The Court found that it could not

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may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests *vis-a-vis* their competitors." *Id.* at 510-11.

[3] In *Pennington*, the Court considered the legality of a joint effort by a coal workers union and large companies in the industry to obtain establishment from the Secretary of Labor of a minimum wage that would drive smaller companies out of the industry. *United Mine Workers of America v. Pennington et al.*, 381 U.S. 657, 660 (1965). The Court found that *Noerr* made it clear that the union and large companies could not be held liable for any injuries the plaintiff suffered from the action of the Secretary of Labor. *Id.* at 671.

"lightly impute to Congress an intent to invade these freedoms." *Id.*

C. Petitioning for the New Cabilly Patent

The *Noerr-Pennington* doctrine confers immunity where petitioners "attempt to persuade [the government] to take particular action with respect to a law that would produce a restraint or monopoly." *Noerr* 365 U.S. at 136. In this case, the "particular action[s]" that the Defendants sought that would "produce a restraint or monopoly" were the resolution of priority and the issuance of the New Cabilly patent.

As MedImmune suggested in oral argument, there were two basic steps necessary to the issuance of the New Cabilly patent: 1) establishing priority and 2) resolving the other patent issues before the PTO. As is discussed below, this Court finds that petitioning was involved in each of these two steps.[4] Consequently, this Court finds

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[4] Had petitioning been involved in only one of these two steps, immunity would still have been conferred. In prior cases applying the *Noerr-Pennington* doctrine, including *Noerr* itself, only one petitioning activity has been involved. Had only one of the two "prongs" involved petitioning, immunity would still preclude MedImmune's antitrust claims because either through resolving priority or resolving other patent issues, petitioning would still have been involved in obtaining the *New Cabilly* patent. Immunity protects not only the petitioning activity, but other related activity as well:

> The *Noerr* Court also rejected the proposition that petitioning immunity was limited to injuries flowing directly from governmental action. It held that the railroads were also shielded from liability for the harm the truckers suffered in their relationships with their customers. In the Court's view, that injury was 'incidental' to the defendants' campaign to influence legislation. To impose liability for such incidental effects would 'be tantamount to outlawing' the petitioning activity itself.

Sessions Tank Liners, Inc. v. Joor Manufacturing, Inc., 17 F.3d 295, 299 (9th Cir. 1994). Even if only one "prong" were held to be protected petitioning activity, the Defendants' involvement in the other "prong" would likely be incidental activity as described in

that the *Noerr-Pennington* doctrine protects the Defendants from antitrust liability. Summary judgment on the antitrust and related state causes of action is therefore **GRANTED** in favor of the Defendants.

II. PRIORITY

In August of 1998 the PTO's Board awarded priority to Celltech. *Cabilly v. Boss*, 55 U.S.P.Q. 1238 (Bd. Pat. App. & Interf. 1998). Overturning this priority decision was a necessary step to obtaining the New Cabilly patent.

A. MedImmune's Proposed Course of Action

MedImmune contends that priority *could* have been resolved without government action and that *Noerr-Pennington* immunity does not attach simply because the Defendants chose to resolve priority through Judge Chesney's Court. According to MedImmune, Celltech needed only to file a disclaimer under 35 U.S.C. §253 to cancel the claims of the Boss patent. Then, according to MedImmune, the PTO would have automatically issued the New Cabilly patent. This argument is both inconsequential and inaccurate.

1. The Availability of Non-governmental Alternatives

MedImmune has failed to cite, and this Court has been unable to find, any law to support the proposition that immunity is unavailable if the anti-competitive result *could* have occurred without government

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Joor.

action, even though the result does not actually occur that way. "[W]here a restraint upon trade or monopolization is the result of a valid governmental action, as opposed to private action, those urging the governmental action enjoy absolute immunity from antitrust liability for the anti-competitive restrain." *Joor*, 17 F.3d at 301 (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 498 (1988), and *Noerr*, 365 U.S. at 136). The antitrust immunity that the government enjoys, and that petitioners who urge government action correspondingly enjoy, is not dependent on their being a non-governmental way to have achieved the anti-competitive result; it depends simply on whether the alleged violation actually involved petitioning.

2. MedImmune's Proposed Alternative

It is simply not true that the New Cabilly patent would have issued in any ministerial way had Celltech utilized §253 to cancel the claims of the Boss patent. Even if Celltech had cancelled its claims, the Board's outstanding priority decision would still have needed to be overturned.[5]

MedImmune argues that had Celltech cancelled the claims of the Boss patent, the patent would have been treated as never having

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[5] As is discussed further in Part II, even if MedImmune's argument were correct and priority could have been resolved without government action, petitioning was still a necessary part of the application for the New Cabilly patent. As is illustrated by the PTO's refusal to obey Judge Chesney's order and issue the New Cabilly patent once Judge Chesney had declared Genentech the winner of the priority dispute, the PTO does not act ministerially in issuing patents, even when priority has been resolved. *Cabilly v. Boss*, 60 U.S.P.Q. 1752, 1756 (Bd. Pat. App. & Interf. 2001).

existed. MedImmune claims that PTO procedure would then have provided for an entry of judgment against Celltech. It is true that when a party involved in an interference claims under §253 such that all claims corresponding to the count(s) at issue in the interference are deleted, the Board *may* enter judgment against the party. 37 CFR §1.662. However, this is still a matter of discretion, and nothing in the regulations suggests that it is done in a ministerial or automatic way.[6]

No law supports MedImmune's contention that *Noerr-Pennington* immunity does not attach to petitioning if the petitioner's desired result could have been accomplished through means not involving petitioning. Even if this proposition had support in the law, it would not help MedImmune in this case because there was simply no non-petitioning means for priority to be resolved, or for the PTO to evaluate other patent issues. The process leading up to the New Cabilly patent necessarily involved petitioning.

As petitioning would have had to have occurred for the New Cabilly patent to issue even if the Defendants had followed the route MedImmune proposed, and as no law suggests that whether non-petitioning alternatives are available is even relevant, the more

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[6] That §1.662 is not ministerial provides further support for the idea that an inquiry into whether non-governmental alternatives are available is meaningless. Even if the §253 procedure had been employed, there is no guarantee that this would have resolved priority. This Court cannot fault the parties for proceeding in a manner that had more certainty - petitioning Judge Chesney for an Order that the Board was willing to accept as determinative as to priority. *See Cabilly v. Boss*, 60 U.S.P.Q.2d 1752, 1757 (2001).

important question is whether the petitioning *actually involved* in resolving priority confers *Noerr-Pennington* immunity.

B. Judge Chesney's Order

The route that the Defendants actually chose to resolve priority involved petitioning. MedImmune argues that merely asking a Judge to approve settlement is not petitioning sufficient to confer immunity, but even if they are right on this point of law, those facts are not what occurred in this case. MedImmune further argues that even if approval of a settlement does confer immunity, the availability of immunity depends in some way on the process involved in the approval. That is simply not true. Finally and most importantly, MedImmune contends that misrepresentations to Judge Chesney nullify any immunity that might otherwise have attached. This Court finds that no misrepresentations have been pled that would allow this Court to conclude that the Defendants have lost their right to *Noerr-Pennington* immunity.

1. Approving a Settlement Agreement

The parties seem to agree that a court's stamp of approval will not immunize private anti-competitive agreements; genuine petitioning is necessary for *Noerr-Pennington* immunity to apply. Genentech concedes that settlements that merely require compulsory filings, ministerial agency actions, or inconsequential court orders such as Rule 41(a) dismissals do not raise a *Noerr-Pennington* defense.

This case can be distinguished from those that do not raise *Noerr-Pennington* questions because this is not a case of the

government acting in some way on an agreement that is independently anti-competitive, but the very anti-competitiveness of the agreement depends on the government exercising its discretion to create an anti-competitive result. MedImmune attempts to characterize the settlement agreement itself as anti-competitive, and argues that Judge Chesney's role in approving the settlement cannot immunize it. This is a mis-characterization of the legal effect of the agreement and the role of the government in creating the alleged antitrust violations of which MedImmune complains. This is not a case of an anticompetitive private agreement receiving immunity because it passed through government hands in some ministerial way. Here, the very anti-competitiveness of the agreement depended on the government exercising its independent power to decide priority and issue the New Cabilly patent.[7]

The Defendants in this case did not merely present their settlement to Judge Chesney for approval; they sought a Judgment and an Order as well. The documents that she signed accomplished results, such as overturning the Board's priority decision, that could not have been accomplished through private agreement. It was these documents - the results of the Defendants' petitioning and Judge Chesney's order - that resolved the issue of priority.

2. Judge Chesney's Process

It does not matter whether Judge Chesney ever reached a "considered, substantive judgment," (to use MedImmune's phrase), that

[7] MedImmune makes one antitrust arguement that does not depend on the issuance of the New Cabilly patent. This argument - that Genentech and Celltech engaged in illegal price fixing - is addressed in Part III of this Analysis.

Genentech deserved priority. To evaluate this question would require deconstructing the decision-making process, which is exactly what the Ninth Circuit forbade in *Joor*. 17 F.3d at 300. Whether the decisionmaker involved made a "considered, substantive" judgment has not been evaluated in prior cases applying *Noerr*, and this Court declines to add that requirement to the *Noerr-Pennington* doctrine. It does not matter how or why Judge Chesney reached her decision. It matters only that she had the discretion to resolve priority in favor of Genentech and she did so.

3. Alleged Misrepresentation

MedImmune's most compelling attempt to avoid *Noerr-Pennington* immunity is its claim that misrepresentations to the Court preclude Noerr immunity. Where misrepresentations to a court "deprive the litigation of its legitimacy" they can cause a party to lose Noerr-Pennington immunity. *Kottle v.Northwest Kidney Centers*, 146 F.3d 1056, 1060 (9th Cir. 1998)(noting that misrepresentations to the court may cause litigation to be deemed a sham, and thus fall within an exception to *Noerr-Pennington* immunity). MedImmune alleges three misrepresentations to the Court.

First, MedImmune claims that the Defendant's statement to the Court that Genentech's New Cabilly Patent had priority over the Boss patent was a misrepresentation. This was, however, the key issue in the litigation - any settlement agreement had to make a representation one way or the other on this issue and that representation was sure to be contradictory to a position that one of the parties had taken

earlier in the litigation. *Kottle* indicates that disputed issues from the underlying litigation cannot be recast as misrepresentations. 446 F.3d at 1063.

Second, MedImmune asserts that the Defendants' statement that the New Cabilly patent did not have defects that should bar its issuance was a misrepresentation. It is not clear from the facts that this statement was a misrepresentation - the fact that the PTO issued the New Cabilly patent suggests that it was at least not a gross misrepresentation. Even if MedImmune could establish that this was a misrepresentation, it would not change the result. The PTO did not rely on Judge Chesney's determination that the New Cabilly patent should issue, thus MedImmune could not have sustained injury from this order. The Defendants consequently have no reason to claim immunity for petitioning for this order, and there is therefore no consequence to a determination that a misrepresentation precipitated the order.

Third, MedImmune alleges that the Defendants misrepresented the law by suggesting to Judge Chesney that Genentech should be granted priority if it demonstrated conception. As students learn in the first days of any patent law class, priority is awarded to the first to reduce to practice, unless the first to conceive works diligently to reduce the idea to practice. This Court must assume that Judge Chesney was not misled by any statement to the contrary. *Walton v. Arizona*, 497 U.S. 639, 653 (1990)("Trial judges are presumed to know the law and to apply it in making their decisions"), *cited in Beaty v. Stewart*, 303 F.3d 975, 986 (9th Cir. 2002).

II. PTO PROSECUTION

The parties agree that attempts to obtain the issuance of a patent from the PTO are ordinarily covered by *Noerr-Pennington*. However, a patentee may be subject to antitrust liability for enforcing a patent obtained through knowing and willful fraud on the patent office. *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965); *Nobelpharma AB, et al. v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (discussing *Walker Process* fraud and the sham exception to *Noerr-Pennington* as two ways a patentee could be found liable in antitrust).[8] MedImmune argues that in this case the Defendants committed fraud on the patent office that prevents *Noerr-Pennington* immunity from attaching. This argument fails because in its Amended Complaint, MedImmune does not plead fraud.

MedImmune's *Walker Process* theory is not supported in the pleadings. Although MedImmune argues that it "asserts with reference to specific facts, at least forty times, that Genentech's omissions and misrepresentations were intentionally made with deceptive intent," Opposition at 18, a review of the Amended Complaint reveals that it is inequitable conduct, not fraud, that appears in the pleadings. Fraud (as that term is meant in *Walker Process)* and inequitable conduct are different legal concepts, and it is simply not the case that

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[8] Neither party has alleged that the sham exception to the *Noerr-Pennington* doctrine applies in this case. MedImmune does allege that the Defendants made misrepresentations to Judge Chesney, and misrepresentations can make litigation into a sham, *Kottle*, 146 F.3d at 1060, but Part I(C) of this Analysis explains that misrepresentations have not be adequately alleged.

inequitable conduct pleadings can be read as affirmatively pleading fraud for all purposes. MedImmune has not pled facts sufficient to support *Walker Process* fraud.

A. Distinguishing Inequitable Conduct from Fraud

There is a significant difference between *Walker Process* fraud and inequitable conduct, a state of law that was highlighted to this Court by Plaintiff earlier in this litigation.[9] The Federal Circuit discussed this distinction in *Nobelpharma*, where it noted that "inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a Walker Process counterclaim," and that "[i]nequitable conduct in fact is a lesser offense than common law fraud, and includes types of conduct less serious that "knowing and willful" fraud. 141 F.3d at 1069; *see also Norton v. Curtiss*, 433 F.2d 779, 793 (C.C.P.A. 1970)(contrasting inequitable conduct with conduct "sufficiently reprehensible so as to carry with it the consequences of technical fraud").

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[9] When filing its Amended Complaint, MedImmune assured this Court that it was making changes to its inequitable conduct claim to "make it consistent with the Court's Order dated August 11, 2003." The August 11, 2003 Order to which MedImmune refers granted Genentech's Motion to Dismiss an inequitable conduct claim but allowed MedImmune leave to amend it. In defending against this Motion to Dismiss, MedImmune argued that the heightened pleading standard of FRCP Rule 9(b) applied only to fraud claims. MedImmune took pains to distinguish its inequitable conduct claim from a fraud claims. *See* Plaintiff MedImmune, Inc's Opposition to Motion by Defendant Genentech, Inc. to Dismiss the Third and Eleventh Causes of Action (filed July 14, 2003) at 9. It now appears that MedImmune is trying to argue that in amending its inequitable conduct claim, it converted it into a fraud claim. This argument is both disingenuous and, as is discussed in more detail above, not supported by the pleadings.

The *Nobelpharma* court contrasted the nature of the claims and the remedies available for fraud, as that term is meant in *Walker Process*, with the claims and remedies for inequitable conduct. The court noted that inequitable conduct is an equitable defense, whereas fraud is an affirmative claim. 141 F.3d at 1070. It also compared the treble damages available in antitrust with the remedies of patent unenforcability and possibly attorney's fees that are available for inequitable conduct. *Id.*

B. Pleading Fraud

MedImmune alleges that Genentech acted fraudulently by 1) failing to alert the PTO to the enablement problems relating to the refolding aspect of the claimed invention, 2) failing to disclose its prior inconsistent position with respect to a material prior art reference known as the Vallé reference, 3) failing to disclose certain anticipatory prior art about which it allegedly knew and 4) burying anticipatory prior art in the voluminous documents that composed its submission. Even if this Court were willing to look past the disingenuousness of MedImmune's assertation that what the parties and this court were told was an inequitable conduct claim has morphed into a fraud claim, MedImmune's pleadings do not allege facts that, if proved, would allow this Court to conclude that the elements of *Walker Process* fraud had been satisfied.

In *Norton*, the court that preceded the Federal Circuit explained the elements of what the *Nobelpharma* court called "'fraud' as that term was used by the Supreme Court in Walker Process," 141 F.3d at 1069:

> traditionally, the concept of "fraud" has most often been used by the courts, in general, to refer to a type of conduct so reprehensible that it could alone form the basis of an actionable wrong (e.g., the common law action for deceit.) That narrow range of conduct, now frequently referred to as 'technical' or 'affirmative' fraud, is looked upon by the law as quite serious. Because severe penalties are usually meted out to the party found guilty of such conduct, technical fraud is generally held not to exist unless the following indispensable elements are found to be present: 1) a representation of a material fact, 2) the falsity of that representation, 3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), 4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and 5) injury to the party deceived as a result of his reliance on the misrepresentation.

Norton, 433 F.2d at 792-93, *cited in Nobelpharma*, 141 F.3d at 1069-70.

To fulfill the requirements of *Walker Process*, "a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent." *Nobelpharma*, 141 F.3d at 1070. This standard is a difficult one to meet, as the *Nobelpharma* court explains:

> A finding of Walker Process fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct, . . . a finding of Walker Process fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent. Rather, it must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e. that the patent would not have issued but for the misrepresentation or omission.

141 F.3d at 1070-71 (internal citations omitted). MedImmune's pleadings fail to fulfill the requirements of *Walker Process* fraud,

because they suggest neither "independent or clear evidence of deceptive intent" nor that "the patent would not have issued but for the misrepresentation or omission" (i.e. reliance).

In fact, the PTO is presumed to be aware of the references before it, which would include the court documents discussing enablement problems, the Vallé reference, and the other prior art that was submitted, even if it was buried. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984) (noting that a PTO examiner is presumed to have considered the documents submitted). Even inequitable conduct cannot be found on the basis of a reference that was cited to the examiner. *Fiskars, Inc. v. Hunt Manufacturing Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000)("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner").

As for references that were not before the PTO, omissions cannot be fraudulent absent evidence of fraudulent intent. *Nobelpharma* states: "for an omission such as failure to cite a piece of prior art to support a finding of Walker Process fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the PTO will not suffice." 141 F.3d at 1071. MedImmune does not plead facts that would support a finding of fraudulent intent.

MedImmune cannot show that the PTO relied on alleged misrepresentations about references that were before it because the examiner is presumed to have independently considered the references,

and MedImmune cannot base a *Walker Process* claim on the omission of references without alleging independent evidence of deceptive intent. Thus even if each of the allegations of MedImmune's Amended Complaint were true, they would be insufficient to support a claim of *Walker Process* fraud.

III. PRICE FIXING

MedImmune has one antitrust argument that does not implicate *Noerr-Pennington* considerations. This argument is based on the ARLA between Celltech and Genentech, and essentially claims that the ARLA was an illegal price fixing agreement. The ARLA provides that Celltech will receive royalty payments from Genentech that are to be paid from the royalties that Genentech obtains from third parties, including MedImmune. Because the ARLA provides that Genentech will "use best efforts" to charge these third parties at least certain minimum royalties, MedImmune asserts that the ARLA is a price-fixing agreement.

There are at least two problems with MedImmune's theory: 1) price-fixing is not pled in the Amended Complaint and 2) MedImmune would not have standing to make this price-fixing claim even if it were in the Amended Complaint.[10]

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[10] In addition to these two preliminary problems, this Court's review of the ARLA leads to the conclusion that price-fixing is not a part of the agreement. Section 3.02 of the agreement lists "Royalties Payable by Genentech for Third Party Products." The first five sub-parts of §3.02 list specific products for which Celltech was receiving royalties under the Boss patent, and specifies the royalty rate that Genentech would pass-through for sales of that product once Genentech owned the patent to the technology. ARLA §3.02(a)-(e), Winters Declaration, Ex. 14, pp. 11-14 (filed under seal October 31, 2002).

MedImmune's price-fixing theory does not appear in the Amended Complaint. The Amended Complaint does state that the settlement is "illegal and anticompetitive" under either the per se or rule of reason theory. Am. Comp. ¶¶9, 170-72. It does not, however, allege price fixing in any less general way. MedImmune has not alleged facts in its Amended Complaint that would, if true, suggest that the settlement involved price fixing.

The paragraph about which MedImmune complains provides:

> Genentech shall be obligated to pay Celltech the royalties specified in paragraphs 3.02(a)-(e) on Net Sales by a third party licensee or sublicensee of a particular Antibody product only if the amount of payments received by Genentech in a Calendar Quarter from its third party licensee or sublicensee for such product, after deduction of the portion thereof that Genentech is obligated to pay to the City of Hope, equals or exceeds the royalty owed to Celltech in such Calendar Quarter for such Net Sales. Genentech shall, and Genentech shall require that its Affiliates shall, i) use best efforts to impose upon all third parties which are the licensees and sublicensees with respect to the Antibody products referred to in paragraphs 3.02(a)-(e) an obligation to pay to Genentech (or the relevant Affiliate) an amount at least sufficient to meet the royalty obligations set out in paragraphs 3.02(a)-(e), and ii) use reasonable and diligent efforts in good faith to collect such amounts from such third parties.

ARLA §3.02(f), Winters Dec. Ex. 14 pp.14. The paragraph continues on to make provisions that would take effect if Genentech did not collect from third parties royalties in the amounts promised to Genentech. This include passing-through the lesser royalty amount and accruing the remainder for payment at a later time. *Id.* at pp. 14-15. This paragraph requires Genentech to attempt to maintain at least the royalty rates that Celltech was receiving so that Celltech receives the consideration it is expecting from ceding priority, but it does not set a minimum royalty rate at which a license to the Cabilly Patent will be set. Although this Court declines to decide the price fixing issue because of the pleading and standing problems discussed in the text, it is unlikely that such a claim would be successful.

Even if MedImmune had alleged price-fixing in the Complaint, it is difficult to see how the paragraph about which MedImmune complains (see n.8) affects MedImmune. The only MedImmune product affected by the §3.02 of the ARLA is Synagis, and the parties agree that MedImmune signed a license agreement with Genentech regarding Synagis prior to entering the settlement agreement or the ARLA. As MedImmune's royalties for Synagis are established by this licensing agreement, MedImmune would be unaffected by any price-fixing in the ARLA even if it were adequately alleged. MedImmune claims to be worried about its other "pipeline products" but the plain language of the ARLA and Genentech's representations in oral argument make it clear that §3.02 of the ARLA does not cover any MedImmune product, current or future, other than Synagis.

MedImmune has not pled price-fixing, and has no standing to plead that §3.02 of the ARLA constitutes price-fixing. Consequently, MedImmune can not establish a antitrust claim based on price-fixing.

CONCLUSION

Where a plaintiff "fail[s] to prove that its injuries result from anything other than governmental action," *Noerr-Pennington* immunity will attach. *Joor*, 17 F.3d at 296. With the exception of the price fixing argument dismissed in Part 3 above, MedImmune has not pled an injury that was the result of the Defendants' settlement agreement. In the absence of government action in resolving priority and issuing the New Cabilly patent, MedImmune would have suffered no harm from the Defendants' settlement. Because the alleged "restraint upon trade or monopolization is the result of valid governmental action, as opposed

to private action," *Noerr-Pennington* immunity applies. *Joor*, 17 F.2d at 301.

Based upon the fact that *Noerr-Pennington* immunity bars MedImmune's antitrust and related state claims, and in light of MedImmune's failure to adequately plead any antitrust violation (such as price-fixing in the ARLA) that is not barred by *Noerr-Pennington*, summary judgment for the Defendants is hereby **GRANTED** with respect to the fifth, sixth, eighth, ninth, and tenth causes of action in the First Amended Complaint.

IT IS SO ORDERED

DATED: December 22, 2006

Mariana R. Pfaelzer
Honorable Mariana R. Pfaelzer
United States District Judge