NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC. and GENENTECH, INC., Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-4417 (SRC) (MAS) Civil Action No. 08-3065 (SRC) (MAS) Civil Action No. 08-4053 (SRC) (MAS) Civil Action No. 10-6241 (SRC) (MAS) (consolidated with 07-4417 for all purposes) **OPINION**
HOFFMANN-LA ROCHE INC. and GENENTECH, INC., Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., GENPHARM ULC and GENPHARM, L.P., Defendants.	Civil Action No. 07-4661 (SRC) (MAS) Civil Action No. 08-4052 (SRC) (MAS) Civil Action No. 11-0579 (SRC) (MAS) (consolidated with 07-4661 for all purposes)

HOFFMANN-LA ROCHE INC. and GENENTECH, INC., Plaintiffs, v. WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC., Defendants.	Civil Action No. 07-4539 (SRC) (MAS) Civil Action No. 07-4540 (SRC) (MAS) Civil Action No. 08-4054 (SRC) (MAS) Civil Action No. 10-6206 (SRC) (MAS) (consolidated with 07-4539 for all purposes)

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for a preliminary injunction by Plaintiffs Hoffman-La Roche Inc. and Genentech, Inc. (collectively, "Roche") against Defendants: Apotex Inc. and Apotex Corp., (collectively, "Apotex"); Mylan Inc., Mylan Pharmaceuticals Inc., Genpharm ULC and Genpharm, L.P. (collectively, "Mylan"); and Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Watson Pharma, Inc., Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. (collectively, "Watson"). This Court held oral argument on this motion on March 8, 2012. For the reasons stated below, the motion will be denied.

BACKGROUND

The background to this Hatch-Waxman action for patent infringement has been presented in previous Opinions and will not be repeated here. Roche owns U.S. Patent Nos. 4,927,814 (the "'814 patent"), 7,410,957 (the "'957 patent"), and 7,718,634 (the "'634 patent"), which relate to ingredients and treatment methods related to Roche's branded ibandronate product, Boniva®. The '814 patent, which covers ibandronate sodium, expires on March 17, 2012. On February 8,

2012, this Court modified and dissolved its previous Order of November 10, 2010, which had enjoined Cobalt Pharmaceuticals Inc. from marketing or selling a generic version of Boniva®, and in effect lifted the injunction as of the date of the expiration of the '814 patent, March 17, 2012. Roche then moved for the instant preliminary injunction, seeking to prevent Defendants from selling generic versions of Boniva® after the '814 patent expires.

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

"The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008).

As to the requirement that the movant establish that he is likely to succeed on the merits, the Federal Circuit has held:

> [T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. . . .

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citation omitted).

"[A]n issued patent comes with a statutory presumption of validity under 35 U.S.C. § 282." Id.

> If [] the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial. The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence, which of course may include analysis and argument. . . .
>
> [T]he trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings. Then . . . if the trial court concludes there is a 'substantial question' concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.

Id. at 1377-79.

The Federal Circuit then stated definitively the standard that the trial court must apply in ruling on a validity challenge in the context of an application for a preliminary injunction:

> [W]hen analyzing the likelihood of success factor, the trial court, after considering all the evidence available at this early stage of the litigation, must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid.

Id. at 1379.

II. Patent Invalidity due to Obviousness

"A patent is presumed to be valid, 35 U.S.C. § 282, and this presumption can only be overcome by clear and convincing evidence to the contrary." Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1374 (Fed. Cir. 2001) (citations omitted). The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282. "This burden is especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (quotation omitted).

To patent an invention, the subject matter must be non-obvious:

> A patent may not be obtained . . . 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. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

The Federal Circuit has set forth these basic principles to guide the determination of obviousness:

> Obviousness is ultimately a question of law, based on underlying factual determinations. The factual determinations that form the basis of the legal conclusion of obviousness include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, known as objective indicia of non-obviousness.

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1007 (Fed. Cir. 2009) (citations omitted).

ANALYSIS

I. Roche has not demonstrated that it is likely to succeed on the merits.

Defendants' most substantial defense to Roche's claims for patent infringement is that the two patents at issue are both invalid for obviousness. To rule on the motion for a preliminary injunction, then, this Court must weigh the evidence both for and against the validity of the two patents that is available at this preliminary stage in the proceedings. Weighing the evidence, this Court must decide whether it is more likely than not that Defendants will be able to prove at trial, by clear and convincing evidence, that the patents are invalid due to obviousness. As a corollary, to show a likelihood of success on the merits, Roche must show that, in light of the burdens and

presumptions that will inhere at trial, it will likely withstand Defendants' challenges to the validity of the two patents. From the record before this Court at this stage, this Court finds that it is more likely than not that Defendants will be able to prove both patents invalid due to obviousness at trial, and that Roche has not shown that the patents will likely withstand Defendants' challenges to their validity.

At the outset, the Court observes that, although two patents are at issue, none of the parties differentiates the two patents. It is striking that the briefing, while acknowledging that there are two of them, treats them as one. The abstracts of the two patents are identical, word-for-word. No party has asserted that the patented treatment methods claimed in the patents differs in any way that is relevant to the present obviousness inquiry. The key elements of these methods appear to be: 1) oral administration 2) once monthly on a single day 3) of 150 mg of a salt of ibandronic acid.[1] The parties reference the briefs filed in regard to a pending motion for summary judgment that the '634 patent is invalid based on obviousness.

Defendants contend that the prior art disclosed all of the elements of the claimed treatment methods years before. Defendants point in particular to these pieces of prior art:[2]

Defendants point to the article titled "Update: Bisphosphonates" in the Spring 1999 issue of "Lunar News." A paragraph in the article begins: "Researchers are seeking solutions for better compliance. . ." and describes one dosing regimen using alendronate. (PI-2-APP-09654.) The

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[1] In its moving brief, Roche states that the two patents "cover the use of Boniva® brand 150 mg ibandronate sodium oral tablets in a once-monthly dosing regimen." (Pls.' Br. 1.)

[2] Defendants dispute the assertion that the critical date is May 10, 2002, contending that it is May 6, 2003. This Court need not reach this issue because none of the key pieces of prior art was published after May 10, 2002.

article then states:

> Another approach is to use bisphosphonates with high potency yet low irritability, such as zolendronate (Novartis) and ibandronate (Roche) [29, 30]. Oral agents could be given intermittently (once/month, for example) and still be quite potent. The projected mode for ibandronate is injection once every three months. . .

(Id.) Roche posits a reading of these sentences that is distorted and implausible, essentially ignoring the sentence about oral agents being given once per month. Roche contends that, as to ibandronate, the reference discloses only a treatment in which it is injected once every three months. This interpretation might make sense if zolendronate was an oral agent and ibandronate was administered only by injection, but this does not appear to be the case: the '814 patent on ibandronate, issued in 1990, discloses both therapeutic use for the treatment of osteoporosis as well as oral administration in tablet form. '814 patent col.1 ll.30-35, col.6 ll.12-16. Roche does not argue that the skilled artisan in 1999 would not have understood that ibandronate could be used as an oral agent. Roche's attempt to deny that the "Lunar News" reference disclosed oral administration of ibandronate on a once monthly basis is unpersuasive. Furthermore, the article teaches that this monthly dosing regimen, despite its intermittent nature, could be potent.

At the hearing, Plaintiffs' expert, Dr. Bilezikian, opined that the skilled artisan would not read the Lunar News reference to disclose oral monthly dosing with ibandronate, contending that, because the cited footnotes associated with ibandronate in the sentence at issue refer to references in which ibandronate was administered intravenously, the skilled artisan would not have understood ibandronate to be one of the oral agents that could be administered monthly. (3/8/12 Hrg. Tr. 22:13-21.) Yet, on questioning, Dr. Bilezikian conceded that the word "irritability" in the text at issue refers to gastrointestinal complications which are only an issue with oral

administration, and not with intravenous administration, and that irritability is irrelevant to intravenous use. (3/8/12 Hrg. Tr. 23:9-24: 2.) This confirms that Roche's interpretation is inconsistent with the text.

The "Lunar News" article teaches the combination of two of the three key elements of the treatment method presently at issue: 1) oral administration of ibandronate[3] 2) once monthly, for the treatment of osteoporosis. The only key element of the patented methods that is not disclosed in this reference is the 150 mg dose.

Roche makes much of the fact that Defendants have offered no piece of prior art that discloses oral dosing at exactly 150 mg, which is Plaintiffs' strongest point. Defendants contend, however, that:

> A person of ordinary skill applying common sense could have combined any of the oral monthly teachings for ibandronate in, for example, the Spring 1999 Lunar News with prior art teachings relating to dose ranges for ibandronate as taught in Möckel '326 and Daifotis '932 to obtain an appropriate monthly dose for ibandronate.

(Defs.' Opp. Br. 18.)

Defendants also point to the 1996 research report by Ravn et al. in the journal, "Bone." (PI-2-APP-10007-13.) The article describes a "dose finding study" of the effect of ibandronate on women with postmenopausal osteoporosis. (PI-2-APP-10007.) In the experimental groups, patients were administered daily doses in a range of .25 through 5 mg for twelve months. (PI-2-APP-10008.) The study concluded that the 2.5 mg daily dose was the most effective, but that

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[3] No party has asserted that the chemical differences between the various descriptions of the form of ibandronate administered – ibandronate, ibandronate sodium, ibandronic acid, or salt of ibandronic acid – are material to this dispute, nor that the skilled artisan would find such differences material in terms of the issues at hand.

positive outcomes were found in both the 2.5 mg and 5 mg groups. (PI-2-APP-10007, -10012.)

Defendants observe that multiplying the two daily doses found to be effective in the Ravn study by 30 yields monthly doses of 75 mg and 150 mg. Defendants also point to United States Patent No. 6,432,932 ("Daifotis '932"), applied for in 1999, directed to inhibiting bone resorption in mammals by oral treatment with a bisphosphonate using dosing regimens of once every week or once every two weeks. Daifotis '932 col.1 ll.16-24. The patent teaches that certain bisphosphonates, including ibandronate, have "high potency as inhibitors of osteoclastic bone resorption." Id. at col.1 l.60. The patent discloses that bisphosphonates are known for causing adverse gastrointestinal side effects, associated particularly with treatment methods using daily dosing. Id. at col.2 ll.24-26, 65-67. The patent teaches that other treatment methods utilize "a cyclic regimen of treatment and rest periods." Id. at col.2 ll.59-60. It further states:

> In the present invention, it is found that the adverse gastrointestinal effects that can be associated with daily or cyclic dosing regimens can be minimized by administering the bisphosphonate at a relatively high unit dosage according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing. In other words, it is found that the administration of a bisphosphonate at a high relative dosage at a low relative dosing frequency causes less adverse gastrointestinal effects, particularly esophageal effects, compared to the administration of a low relative dosage at a high relative dosing frequency. This result is surprising in view of the teachings suggesting that adverse gastrointestinal effects would be expected to increase as a function of increasing bisphosphonate dosage.

Id. at col.3 l.58-col.4 l.6. The patent also teaches a treatment method involving weekly dosing of ibandronate:

> For once-weekly dosing, an oral unit dosage comprises from about 7 mg to about 100 mg of the ibandronate compound, on an ibandronic acid active weight basis, i.e. calculated on the basis of the corresponding acid. Examples of weekly oral dosages include a unit dosage which is useful for inhibiting bone resorption, and

> treating and preventing osteoporosis selected from the group consisting of 35 mg, 40 mg, 45 mg, or 50 mg.

Id. at col.13 ll.39-46. Thus, Daifotis '932 teaches that a once weekly dose of ibandronate in the amount of 35 mg, 40 mg, 45 mg, or 50 mg is useful for inhibiting bone resorption. The skilled artisan would likely observe that 35 mg per week corresponds to 5 mg per day, which overlaps with Ravn's finding that 5 mg/day was an effective dose. Defendants' expert, Dr. Yates, testified that the skilled artisan reading Daifotis '932 would have determined that a monthly ibandronate dose should be in the range of 150 mg to 200 mg. (3/8/12 Hrg. Tr. 206:18-21.)

Defendants also point to United States Patent No. 6,143,326 ("Möckel '326"), issued on November 7, 2000, which discloses the use of oral ibandronate to treat osteoporosis, and teaches that a single dose of ibandronate should be in the range of .1 mg to 250 mg. Möckel '326 col.1 ll.10-21, col.5 ll.7-11.

Defendants point as well to the research report by Riis et al. published in 2001 in the "Journal of Bone and Mineral Research," entitled, "Ibandronate: A Comparison of Oral Daily Dosing Versus Intermittent Dosing in Postmenopausal Osteoporosis." (PI-2-APP-10026-10033). The discussion section in this reference states: "preclinical data with ibandronate provided evidence that a total dose administered over a defined period provides equivalent results irrespective of the dosing schedule, providing that the dose used is efficacious."[4] (PI-2-APP-10030). The study concluded that "intermittent ibandronate is as effective as the continuous treatment . . ." (PI-2-APP-10032).

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[4] Plaintiffs' expert Dr. Bilezikian agreed that this idea was known as the "total dose concept" and that the skilled artisan would have heard of this concept prior to May of 2002. (3/8/12 Hrg. Tr. 53:3-16.)

Defendants also point to the United States Patent Application No. 2003/0118634 ("Schofield"), descended from a provisional application filed on December 21, 2001. The Schofield reference teaches a method of treating osteoporosis consisting of administering a loading dose of a bisphosphonate, followed by a maintenance dose. (PI-2-APP-09645 at ¶ 0018.) The application states that, during the maintenance period, "a bisphosphonate must be given at least once every three months." (Id. at ¶ 0023.) The reference lists possible dosing frequencies, including once monthly. (Id.) It teaches that ibandronate is a preferred bisposphonate. (Id. at ¶ 0029.) Significantly, Schofield states:

> The oral unit dosage forms of the bone-active phosphonate for the maintenance dose preferably contains from about 2.5 to about 15 mg per day from about 5 to about 10.[5] . . . Equivalent doses can be given every other day, twice a week, weekly, biweekly or monthly.

(Id. at ¶ 0037.) This expresses the total dose concept: one may treat osteoporosis by administering a particular amount of bisphosphonate as a daily dose, or one may administer the proportionately equivalent amount intermittently (monthly, for instance).

The parties do not dispute that the Schofield reference was before the examiner during prosecution of both patents, nor that the patentee overcame an obviousness rejection in view of Schofield during the prosecution of the '957 patent. The rejection was overcome by amending the claim language to exclude use of a loading dose. At oral argument, the experts disagreed over what the Schofield reference would have taught the skilled artisan, with Roche's experts contending, in essence, that it would have taught little of relevance because Schofield requires a

[5] The wording of this sentence in the patent application is confusing. From the surrounding sentences, it appears likely that the word "preferably" was omitted, and that the sentence was intended to express a preference for a range of about 5 mg to about 10 mg per day.

loading dose. This is unpersuasive. Despite the fact that the patentee was able to overcome the obviousness rejection, it seems to this Court that Schofield's treatment method for the maintenance period is very, very close to the treatment method at issue. Schofield discloses that one can maintain osteoporosis treatment by administering once monthly doses of ibandronate which are equivalent to daily doses in the range of 5 mg to 10 mg. As noted above, the 150 mg once monthly dose is equivalent to a daily dose of 5 mg. Furthermore, Dr. Rosini testified that the skilled artisan, reading the Schofield reference, would have had the expectation that using the maintenance period treatment without the loading dose would have helped to treat osteoporosis. (3/8/12 Hrg. Tr. 180:4-10.) This Court finds Defendants' experts to be more persuasive that a skilled artisan, viewing Schofield, would have at least considered trying the maintenance phase without the loading dose, and that the patented treatment method is obvious in view of Schofield's teachings about the maintenance period.

Plaintiffs' case for the validity of the patents at issue was weakened when, at the hearing, Plaintiffs' expert, Dr. Harris, made a number of important concessions. He conceded that the Lunar News reference provided a motivation to investigate therapy with monthly doses of bisphosphonates. (3/8/12 Hrg. Tr. 98:22-99:17.) Moreover, Dr. Harris agreed that "in the 2000-to-2002 time frame, the art was trending away from daily therapy of bisphosphonates and towards longer interval dosing." (3/8/12 Hrg. Tr. 100:16-20.) He also agreed that, as of May 6, 2002, the skilled artisan would have had reason to investigate treatment with monthly ibandronate. (3/8/12 Hrg. Tr. 109:9-12.) Dr. Harris admitted that, at his deposition, he had stated that, "once one chooses a particular treatment agent and one chooses a particular dosing time interval, that determining a dose within the broad therapeutic range is a routine, is a

relatively routine matter." (3/8/12 Hrg. Tr. 111:2-10.)

Crucially, Dr. Harris testified as follows:

> Q. And as of May 6, 2002, without the '957 or the '634 patents but in view of all the other references that came before, would a person of ordinary skill in the art have had a reasonable expectation that a 150 mg dose of ibandronate taken orally would inhibit bone resorption to some degree in postmenopausal women?
>
> A. One would have an expectation for some degree of inhibition for some period of time.

(3/8/12 Hrg. Tr. 113:12-19.) Roche's expert thus conceded that, as of the critical date, the skilled artisan would have expected that the patented treatment method would have had some effectiveness. This suggests that Defendants have a very strong case for invalidity of the patents at issue due to obviousness.

One of Roche's main points in rebuttal to Defendants' obviousness case is that the prior art taught away from the inventions in the patents at issue. On this record, Roche has failed to persuade this Court that the prior art taught away from the patents at issue. To the contrary, considering the main pieces of prior art cited by the parties, while there is evidence of uncertainties in the field, the field as a whole appeared to be moving toward osteoporosis treatment regimens involving intermittent dosing with bisphosphonates, and periods between doses of a month or more were well-known. Roche claims as well that it is prepared to further rebut Defendants' obviousness case with evidence of secondary considerations indicative of nonobviousness, but it has not detailed its position on secondary considerations in briefing the instant motion, nor substantively pointed out such evidence.[6]

[6] As Defendants observe in the briefing on the associated motion for summary judgment of invalidity due to obviousness, evidence of commercial success is unlikely to be of much

Another aspect of the Roche's "teaching away" argument relies on the idea that osteoclasts have roughly a 14-day life cycle, and that it was widely believed in the art in 2002 that the dosing frequency therefore needed to be every two weeks or more frequently. (Pls.' Br. 5.) Defendants' expert Dr. Rosini pointed out, however, that Plaintiffs' expert Dr. Harris co-authored a paper published in 1990 in which etidronate was effective using an intermittent dosing regimen which included periods of 72 days without a medication dose. (PI-APP-07624-07631.) Dr. Rosini stated that this study showed that etidronate worked beyond the life cycle of osteoclasts. (3/8/12 Hrg. Tr. 174:6-12.) On the current record, Roche appears unlikely to prove that the osteoclast life cycle theory played an important role in teaching away from monthly dosing in 2002.

Defendants argue that Roche's arguments regarding obviousness copy ones made by Merck and rejected by the Federal Circuit in Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005). This is an overstatement, but the instant case does have significant common ground with Merck, which dealt with a defense of invalidity due to obviousness with regard to claims in a 1999 patent directed to once-weekly bisphosphonate dosing to inhibit bone resorption. Id. The Federal Circuit found the claims invalid due to obviousness in view of two 1996 "Lunar News" articles. Id. at 1377. At issue was whether the prior art would have motivated the skilled artisan to formulate a once-weekly dose at a multiple of seven of the prior art daily doses, and the Federal Circuit concluded that it would have. Id. at 1375.

Defendants are correct that Roche's argument in the instant case – that there was

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significance in this case, for two reasons: 1) the commercial success of Boniva® may have been due to the invention in the prior '814 patent; and 2) Roche spent heavily on promoting Boniva®.

something inventive about determining the monthly dose of 150 mg, when effective daily doses of 2.5 and 5 mg were known in the prior art – is similar to that made by Merck and rejected by the Federal Circuit. Roche attempts to distinguish Merck by saying that, in that case, the weekly dose was known in the prior art. (Pls.' Reply Br. 9.) Even if this is true, it does not help Roche: if it was known in the art that an effective weekly dose was equivalent to seven daily doses, would this not suggest to the skilled artisan that an effective monthly dose would be equivalent to 30 daily doses? Despite important differences between the facts of Merck and the instant case, it is very difficult to read Merck and then be persuaded that it was not obvious to come up with a 150 mg monthly dose.

Conspicuously absent from Roche's briefing and hearing presentation are claims about what the inventors of the two patents at issue invented. Patent attorneys defending patent validity in Hatch-Waxman cases are generally given to highlighting the ingenuity of the inventors, at a minimum. Not so here. To the contrary, at no point in the briefing nor at the hearing did Roche point out in the patents at issue what seems to be any genuine discovery by the inventors. The clearest claim made by Plaintiffs was that the inventors had discovered the safety and efficacy of the 150 mg dose. As discussed above, Defendants have persuaded this Court that they are likely to prove that the 150 mg dose was obvious in view of the prior art.

In a similar vein, this Court notes that neither party, either in the briefs or at the hearing, substantively differentiated the two patents. Rather, they were uniformly lumped together and treated as one patent. On the whole, the record raised numerous questions about the extent to which the patents differed from each other and from the prior art. Differences from the prior art are crucial to patent validity under 35 U.S.C. § 103.

Weighing in favor of Plaintiffs is the undisputed fact that all of the prior art brought forward by Defendants on this motion was before the examiner during prosecution of the patents. Also weighing in favor of Plaintiffs is the presumption of validity accorded to issued patents, and the fact that Defendants must prove invalidity at trial by clear and convincing evidence. Weighing the evidence in this record, nonetheless, this Court finds that Defendants have made a strongly persuasive case for invalidity due to obviousness, and that Plaintiffs have offered little to rebut this case apart from the presumptions which favor the owner of a valid patent. On this record, it appears more likely than not that, for both patents at issue, Defendants will be able to prove invalidity due to obviousness by clear and convincing evidence at trial. Put another way, having considered the record in light of the burdens and presumptions that will inhere at trial, this Court finds that Defendants have raised a substantial question regarding the validity of the patents at issue, and Plaintiffs have not shown that this question lacks substantial merit. As a result, Plaintiffs have failed to show a likelihood of success on the merits in defending the validity of the patents at issue at trial.

Defendants have presented a strong challenge to the validity of the patents at issue, and Roche has failed to show that the patents are likely to withstand this validity challenge. Despite the presumption of validity of issued patents, Defendants have persuaded this Court that it is more likely than not that they will be able to prove the patents at issue to be invalid due to obviousness, by clear and convincing evidence, at trial. Because Roche has not shown a likelihood of success on the merits, this Court need not reach the three other preliminary injunction factors. Roche's motion for a preliminary injunction will be denied.

CONCLUSION

For the reasons stated above, this Court finds that Roche has failed to show that it is likely to succeed on the merits at trial. Because a party cannot obtain a preliminary injunction in the absence of showing a likelihood of success on the merits, Roche's motion for a preliminary injunction is denied.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: March 14, 2012