IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAYER AG, BAYER HEALTHCARE AG, and BAYER PHARMACEUTICALS CORPORATION, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC., Defendants.	)	Civ. No. 04-179-SLR
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC., Counterclaim Plaintiffs, v. BAYER AG, BAYER HEALTHCARE AG, and BAYER PHARMACEUTICALS CORPORATION, Counterclaim Defendants.	)	

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OPINION

Dated: October 25, 2007
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This action arises out of the filing of an Abbreviated New Drug Application ("ANDA")[1] by Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Reddy") to market a generic version of the antibacterial drug AVELOX® proprietary to Bayer AG, Bayer Healthcare AG, and Bayer Pharmaceuticals Corporation (collectively, "Bayer"). The active ingredient in AVELOX® is moxifloxacin hydrochloride, which is protected by, inter alia, U.S. Patent Nos. 4,990,517 ("the '517 patent") and 5,607,942 ("the '942 patent"). Upon receiving notification of the filing of Reddy's ANDA, Bayer brought this suit for infringement of the '517 and '942 patents pursuant to 35 U.S.C. § 271(e)(2)(A).[2] (D.I. 1) Reddy concedes that its generic moxifloxacin product infringes both patents. (D.I. 69) From August 7 to August 15, 2006, a bench trial was held on Reddy's defense and counterclaim that the '517 and '942 patents are invalid and/or unenforceable due to obviousness, double patenting, and inequitable conduct. (D.I. 123-129) The issues were fully briefed post-trial. (D.I.132-135) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1400(b). Having considered the documentary evidence and testimony, the court makes the following findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).

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[1]No. 76-938

[2]"(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]"

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

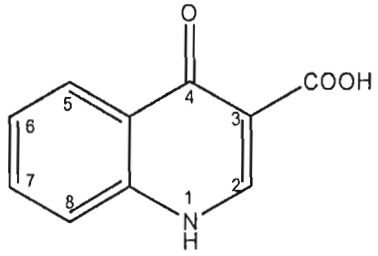
A. The Parties

1. Bayer AG is a German corporation with a principal place of business in Leverkusen, Federal Republic of Germany. (JTX-1 at ¶ 1) Bayer Healthcare AG is also a German corporation with its principal place of business in Leverkusen, Federal Republic of Germany. (Id. at ¶ 2) Bayer Pharmaceuticals Corporation is a corporation organized under the laws of the State of Delaware, with a principal place of business in West Haven, Connecticut. (Id. at ¶ 3)

2. Dr. Reddy's Laboratories Ltd., which has its principal place of business in Hyderabad, India, is a public limited liability company formed under the laws of the nation of India. (Id. at ¶ 4) Dr. Reddy's Laboratories, Inc. is a New Jersey corporation which has its principal place of business in Bridgewater, New Jersey. (D.I. 1 at ¶ 6; D.I. 6 at ¶ 6)

B. Technology at Issue

3. This case involves a class of antibacterial compounds called quinolones, having the following core structure:



4. This core structure has several positions (numbered 1-8 above) at which

atoms or chemical groups (called substituents) may be attached. Such substituents may be "monocyclic" substituents, or a molecular structure with only one ring (a "nonocycle"), or "bicyclic" substituents, which are molecules consisting of two fused rings (a "bicycle").[3] A "5/5" bicyclic substituent has two rings of five atoms; a "5/6" bicyclic substituent has one ring of five atoms and a second ring with six atoms.[4]

C. The Patents

5. The '517 patent and the '942 patent are part of the same patent family, called "Le A 26 108." (PTX-2073) The first application in this family was filed in the German Patent Office and issued on July 15, 1988.[5] Applications claiming priority to this German application were later filed in other countries including the United States; United States Patent Application No. 07/375,434 ("the '434 application") was filed in the United States Patent and Trademark Office ("PTO") on June 30, 1989, and issued as the '517 patent on February 5, 1991. (PTX-1) The application leading to the '942 patent was filed on March 20, 1995 as a divisional application (in a chain of divisionals) claiming priority to the '517 patent, and issued on March 4, 1997. (PTX-3)

6. Claims 1 and 2 of the '517 patent generically claim millions of quinolone compounds, expressed through a generic quinolone formula with multiple variables.

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[3]The ring(s) of the monocycles or bicycles may, in turn, have other substituents attached to them at various places.

[4]A five-membered ring containing one nitrogen atom is called a pyrrolidine.

[5]German Patent No. 3,824,072. (PTX-1; PTX-3) The '517 and '942 patents also list German Patent No. 3,906,365 (March 1, 1989) as an additional priority application.

Each of the quinolone compounds encompassed by the claims have a 5/5 or a 5/6[6] bicyclic substituent at the 7-position. Moxifloxacin[7] was one of many compounds listed in the '517 specification; it had not yet been synthesized at the time the application was filed. (D.I. 133 at 5) The claims of the '942 patent are directed to a specific quinolone and its four stereoisomers, one of which is moxifloxacin. (PTX-3) Moxifloxacin is a quinolone with a methoxy ($O\text{-}CH_3$) group at the 8-position and a 5/6 bicyclic substituent at the 7-position. Moxifloxacin hydrochloride, a moxifloxacin salt, is the active ingredient in AVELOX®.

D. The Prosecution Histories

7. The '434 application was filed on June 30, 1989, claiming priority to German patent documents 38 24 072.6 (July 15, 1988) and 39 24 365.8 (March 1, 1989). (PTX-2 at 529) As filed, the '434 application was 189 pages long and contained 20 claims.

8. On March 23, 1990, the examiner of the '434 application, Bernard Dentz, spoke with patent counsel, Mr. Horn, about a restriction requirement. (Id. at 855) During the call, Mr. Horn made a provisional election with traverse to prosecute the invention which examiner Dentz designated as Group IV.[8] (Id.) An office action was mailed on April 4, 1990 that described nine distinct groups of invention and formalized

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[6]The 5/5 or 5/6 bicyclic substituent containing a pyrrolidine attached to the quinolone core structure.

[7]$C_{21}H_{24}FN_3O_4$

[8]"Claims 1-3, 7-10 and 12-18, drawn to [compounds] wherein R3 is moiety C, classified in Class 546, subclass 113 e.g.." (PTX-2 at 853) With respect to claim 19, the examiner stated that "[i]ntermediate claim 19 is divided into 4 groups below. There are 20 separate [compounds] named in said claim." (Id.)

the restriction requirement. (Id. at 852-57) This office action also contained substantive grounds for rejection of many of the original claims 1-20.[9] Mr. Horn filed a response to this office action containing a formal election of Group IV on July 19, 1990. (Id. at 892-95)

> Applicants affirm their election of Group IV, claims 1 to 3, 7 to 10 and 12 to 18, with traverse. The compounds share a great deal of common structure of utility. They further share R^3 as B, i.e. an amino-pyrrolidine, with A and C which merely have the amino group as part of a further ring but not really so remote structurally.
>
> For the foregoing reason it is submitted [that] the rejection of claims 1 to 3 and 12 to 18 at the bottom of page 6 as being drawn to an improper Markush group should be withdrawn.

(PTX-2 at 893)

9. On August 10, 1990, an examiner interview was held "[t]o cancel non-elected subject matter," including non-elected claims 4-6, 11, 19, and 20, as per an examiner's amendment. (Id. at 1215-17) Two separate notices of allowance were mailed by the examiner on August 27, 1990: (1) a "Notice of Allowability" of elected claims 1-3, 7-10 and 12-18; and (2) a "Notice of Allowance and Issue Fee Due," which contained the boilerplate notification that "Prosecution on the Merits is Closed." (Id. at 1213-14)

10. On September 10, 1990, U.S. Patent Application No. 07/580,906 was filed as a divisional application claiming priority to the '434 application ("the '906 divisional

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[9]Claims 1-3, 10 and 12-18 were rejected under 35 U.S.C. § 102(a) as being anticipated; claims 1-3, 7-9 and 12-18 were rejected under 35 U.S.C. § 102(a) as being anticipated by, or, in the alternative, under 35 U.S.C. § 103 as obvious; claims 1, 12-16 and 18 were rejected under 35 U.S.C. § 112, first paragraph, as non-enabled; and claims 1-3 and 12-18 were rejected for being drawn to an improper Markush group. (PTX-2 at 856-58)

application").[10]

11. The issue fee for the '434 application was paid to the PTO on October 31, 1990. (Id. at 1219) Thereafter, on November 7, 1990, a European search report was issued by the European Patent Office ("EPO") in the prosecution of the European counterpart to the patents in suit. (Id. at 1230) The European search report listed three references as "X" references to claims then pending in that application: (1) European patent application 241,206 to Sankyo (the "Sankyo application") (DTX-28); (2) an article published in the Journal of Medicinal Chemistry, 1984, vol. 27, no. 12 (p. 1543-48) by Egawa et al. ("the Egawa article") (DTX-4);[11] and (3) the translated abstract of Japanese patent 60-126284,[12] assigned to Dainippon Seiyaku Co. Ltd. (DTX-261A)[13] (the "Dainippon abstract").[14] (PTX-2 at 1233-34) The then-pending claims of the EPO application, to which these references were directed, differed from those allowed in the

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[10]The '906 divisional application issued on October 22, 1991 as U.S. Patent No. 5,059,597.

[11]The full title of the Egawa article is "Pyridonecarboxylic Acids as Antibacterial Agents. 4. Synthesis and Antibacterial Activity of 7-(3-Amino-1-pyrrolidinyl)-1-ethyl-6-flouro-1,4-dihydro-4-oxo-1,8-naphthyridine-3-carboxylic Acid and its Analogues." (DTX-4)

[12]Chemical Abstracts, vol. 104, 1986, p. 521.

[13]The translated version of Japanese Patent No. JP60-126284 is attached as DTX-261-T.

[14]The European search report listed the Sankyo application and the Dainippon abstract in reference to claims 1-3, 8, and 9, and the Egawa article in reference to claims 1-4, 8, and 9. (PTX-2 at 1233-34)

A second chemical abstract to a Japanese patent assigned to Dainippon also appears to have been cited as an X reference. (Id. at 1233 (Chemical Abstracts, Vol. 111, 1989, p. 721)) Reddy limits its inequitable conduct case to the three X references discussed above.

'434 application. (Id. at 1335-38; PTX-1)

12. The European search report was received by Bayer on November 9, 1990. (D.I. 125 at 533:15-19) It was transmitted to Mr. Horn's law firm on November 12, 1990. (Id. at 533:23-534:11) A copy was also sent to Dr. Petersen, a named inventor, who provided comments that same day. (Id. at 534:12-15) On November 28, 1990, Mr. Horn sent an Information Disclosure Statement ("IDS") listing the X references to the PTO in connection with the '434 application. (PTX-2 at 1221) With his submission, Mr. Horn stated only that "[t]he enclosed references were cited in the search report of the European Patent Office in the corresponding European application." (Id.)

13. The '434 application issued as the '517 patent on February 5, 1991. On February 11, 1991, examiner Dentz mailed a copy of the November IDS in which the examiner's initials appeared next to each cited reference. (Id. at 1563) The IDS was accompanied by a cover sheet which was entitled "Notice of Allowability," except that this title was crossed out by the examiner. (Id. at 1562) The cover document contained a check in the box next to the statement: "All the claims being allowable, prosecution on the merits remains closed in this application." (Id.) Examiner Dentz noted that the references were considered on February 8, 1991 – three days after the '517 patent issued. (Id. at 1563)

14. On February 19, 2001, Mr. Horn filed an IDS in the '906 divisional application citing the X references. (PTX-11 at 36501-03) In addition to stating that these references were cited by the EPO in the corresponding European application, Mr. Horn provided the following information:

With reference to the accompanying [IDS], particularly the four "[o]ther

> [d]ocuments" at the bottom of the page, Document No. 1 [the Dainippon abstract] does not disclose bicyclic systems for C7, No. 2 [the Sankyo abstract] is substantially the same and additionally has been published too late. It is overcome by the certified translation of applicants' priority document filed in the parent application; should the [e]xaminer wish, a copy can be filed here. . . . Finally No. 4 [the Egawa article] neither discloses bicyclic systems for C7 nor 1-cyclopropyl substituted compounds.

(Id. at 36502)

15. Following a restriction requirement dated February 25, 2001, Mr. Horn elected to pursue only a subset of claims in the '906 divisional application ("Group III"), which were "drawn to compounds wherein [the] R^3 [group] is a moiety [of the second structure identified on page 176 of the specification]." (Id. at 36495-97) The X references did not form the basis for any anticipation or obviousness rejections with respect to these claims. (Id. at 36498-99) The '906 divisional application was allowed on May 17, 1991 and issued on October 22, 1991 as U.S. Patent No. 5,059,597. (Id. *at* 36286, 36518) A third and fourth divisional application were filed in the chain, the latter issuing as the '942 patent in suit.

E. Obviousness

1. Introduction

16. "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." 35 U.S.C. § 103(a). Obviousness is a question of law, which depends on several underlying factual inquiries.

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained;

> and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

KSR Inter'l Co. v.Teleflex Inc., 127 S. Ct. 1727, 1734 (2007) (quoting Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966)). "Because patents are presumed to be valid, see 35 U.S.C. § 282, an alleged infringer seeking to invalidate a patent on obviousness grounds must establish its obviousness by facts supported by clear and convincing evidence." Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 968 (Fed. Cir. 2006) (citation omitted).

17. Reddy's obviousness case is based on several discrete logical steps. Reddy asserts that: (1) a person of ordinary skill in the art would have been motivated to modify a particular monocyclic compound disclosed in the Dainippon abstract (DTX-261), referred to as AT-3295, and/or a monocyclic compound disclosed in the Sankyo application (DTX-28), referred to as Sankyo 1-130, at the 7-position; (2) such a person would have been motivated to use a diazabicyclo octane ("DBO") substituent at the 7-position; (3) through "routine experimentation," a person of skill in the art would have made bicyclic AT-3295 and/or Sankyo 1-130 with the Bayer 5/5 bicycle, which are included within the many compounds covered by the asserted claims. (D.I. 132 at 38-39; D.I. 135 at 31-32)

18. Because it asserts that monocyclic AT-3295 and Sankyo 1-130 and the use of DBO at the 7-position were disclosed by the prior art, Reddy must identify some "reason that would have prompted a person of ordinary skill in the relevant field to

combine the[se] elements" to yield the claimed compounds.[15] KSR, 127 S.Ct. at 1741. In addition to showing that a person of ordinary skill in the art would have had reason to attempt to make the composition, Reddy must demonstrate that such a person "would have had a reasonable expectation of success in doing so." PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007).

2. Facts related to Reddy's invalidity claim

19. Bayer's medicinal chemistry expert, Dr. Taylor, testified that a person of ordinary skill would have been motivated to modify the 7-position substituents of prior art compounds. (D.I. 128 at 1548:10-18) Bayer does not dispute that a great deal of the work on quinolones involved the 7-position. (D.I. 134 at 6, n.5)

20. The Bayer 5/5 bicycle is a DBO substituent. (D.I. 128 at 1546:10-18) DBO refers to a carbon-based two-ring (bicyclic) structure with eight atoms, two of which are nitrogen atoms.

21. Dr. Petersen and Dr. Schenke, another named inventor on the '517 patent, had a prior art application directed to quinolone antibacterial compounds with a particular 7-position substituent. (DTX-161)[16] Each of the 7-position substituents

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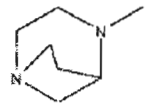
[15]"Reddy argues that combining the art which discloses AT-3295 or Sankyo [c]ompound 1-130 with the art which suggests the use of bicycles at the 7-position would have led the person of ordinary skill as a matter of routine experimentation to make two of the compounds covered by the asserted claims of the '517 patent." (D.I. 135 at 31-32)

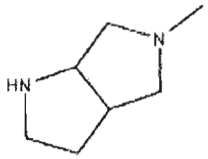
[16]The translated version of this German Patent application (DE 3601567 A1), entitled 7-(azabicycloalkyl)-quinone-carboxylic acid and -napthyridon-carboxylic derivatives, is attached as DTX-161-T.

depicted in DTX-161 is a bridged piperazine,[17] or six-membered ring containing two opposing nitrogen atoms and an ethylene bridge:



These compounds had activity that was as good as, or better than, ciprofloxacin. (DTX-161 at 19 (table); D.I. 123 at 197:10-23; D.I. 124 at 420:21-24)

22. The fused pyrrolidines[18] of the '517 patent are bicyclic molecules wherein two nitrogen atoms are contained on different rings:



23. Piperazines and fused pyrrolidines are both compounds falling within the broad class of DBOs.[19] Both Drs. Schenke and Petersen testified that these structures are quite different; for example, the bridged piperazines of DTX-161 were toxic. (D.I. 123 at 199:24-200:7; D.I. 124 at 420:23-421:5) This toxicity, however, was not disclosed in DTX-161. (Id.)

3. Motivation to select references for modification

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[17] $C_6H_{11}N_2$

[18] $C_6H_{11}N_2$

[19] It is not clear to the court that a bridged piperazine is properly considered a DBO (diaza**bicyclo** octane), insofar as it has one ring and one bridge, and not two rings. Bayer does not contest Reddy's characterization of the molecule (D.I. 134 at 9), and the court will accept it as fact.

24. The parties debate whether Reddy is required to demonstrate why a person of ordinary skill in the art would have selected either AT-3295 or Sankyo 1-130 for the modification Reddy suggests. Bayer asserts that Reddy must show that a person of ordinary skill in the art would have selected these compounds as "lead compounds." Although Reddy's argument is premised on the notion that persons of ordinary skill would have started with either compound and modified it with a bicycle at the 7-position, Reddy nevertheess asserts that it need not demonstrate a "motivation to select" either compound as a starting material.

25. In this regard, Reddy argues that "the selection of the prior art compounds relied on by Reddy is simple and straightforward because it is undisputed that AT-3295 is the single most important compound disclosed in the Dainippon [a]bstract and Bayer's expert, Dr. Zhanel, admitted that Sankyo Compound 1-130 is one of the **three** most important compounds disclosed in the Sankyo '206 [a]pplication." (D.I. 135 at 31) (emphasis in original) Reddy points to no testimony that a person of ordinary skill in the art would be motivated to select Sankyo 1-130 from these three compounds.[20] More fundamentally, Reddy proffers no connection between either the Dainippon abstract or the Sankyo application and the problem that the '517 patent sought to overcome. With respect to AT-3295, Reddy points to testimony by Dr. Petersen on cross-examination, wherein he appeared to state that monocyclic AT-3295 could have been a lead

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[20]Dr. Zhanel identified these compounds on cross examination when "forced" to start with six compounds listed in the Sankyo '206 application based on the data on one type of bacterium; he stated that all six were "very poor." Additionally, Dr. Zhanel testified that a person of ordinary skill in the art would not have started with these compounds, since they would be interested in broad spectrum effects (on multiple bacteria). (D.I. 127 at 1271:13-1273:20)

compound pursued by Bayer, but was not since it belonged to a competitor. (D.I. 132 at 38, citing D.I. 123 at 392:7-19[21]) The record does not reflect why AT-3295 would have been desirable to work with in such an instance. Reddy did not present its own evidence tending to indicate that a person of ordinary skill in the art, seeking to build an antibiotic to rival ciprofloxacin, would have sought to modify AT-3295 or Sankyo 1-130.[22] In contrast, Bayer presented expert testimony that, as of June 1988, persons of ordinary skill would target and, in fact, were targeting two compounds, clinafloxacin and its 8-flouro analog, as lead structures because they had the best known activity. (D.I. 127 at 1171:1-22, 1179:14-1184:22; D.I. 128 at 1467:8-1469:12)

26. Having reviewed the record and the parties' submissions, the court finds inadequate evidence to support Reddy's claim that a person of skill in the art would have been motivated to perform 7-position substituent modifications on AT-3295 or Sankyo 1-130 as compared to other prior art quinolones.[23] See Takeda Chemical Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1359-60 (Fed. Cir. 2007) (affirming district court's finding that defendant failed to prove a prima facie case of

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[21]Dr. Petersen stated that "[AT-3295] was not an interesting lead compound for Bayer at the time . . . it could have been a lead compound unless it – isn't our, our compound. But we at that time made other compounds and we did not focus at that time on [AT-3295]." (D.I. 123 at 392:11-18)

[22]Reddy's expert, Dr. LaVoie, testified that a person "interested in developing effective antibacterial agents" would have made modifications to monocyclic AT-3295 and 1-130; this is not equivalent to justifying why such a person would have selected either compound from the prior art for this purpose. (D.I. 126 at 899:18-22; see also D.I. 132 at 39)

[23]Likewise, there is no indication that a person of skill in the art would have been motivated to perform 7-position substituent modifications on AT-3295 or Sankyo 1-130 with any reasonable expectation of success.

obviousness where "the prior art disclosed a broad selection of compounds[,] any one of which could have been selected as a lead compound for further investigation," and defendant did not prove that the prior art would have led to the selection of the particular compound singled out by defendant); Janssen Pharmaceutica N.V. v. Mylan Pharm., Inc., 456 F. Supp. 2d 644, 656-57 (D.N.J. 2006) (finding that defendants did not demonstrate why the hypothetical person would have been motivated to choose a particular compound "as a lead compound for attacking [the] general problem" solved by the patent at issue where "[t]he prior art provided more other likely starting points").

4. Motivation to Modify AT-3295 or Sankyo 1-130 (at the 7-position) with DBO and, in turn, the Bayer 5/5 bicycle

27. Reddy has also failed to demonstrate a motivation to modify AT-3295 or Sankyo 1-130 (at the 7-position) with DBO. Reddy asserts that "references such as DTX-161, DTX-256, DTX-260 and DTX-299 must be considered for all they teach regarding the use of bicycles at the 7-position." (D.I. 135 at 33) Reddy, however, points to no testimony regarding the teachings of three of these references. (Id.; D.I. 132)

28. U.S. Patent No. 4,684,648 to Tone et al. ("the Tone patent") (DTX-260) discloses a quinolone antibacterial compound with a fused bicyclic 7-position substituent. According to Dr. LaVoie, the Tone patent reported "superior antimicrobial activity" compared to compounds with monocyclic 7-position substituents.[24] (D.I. 126 at 908:2-910:18) Only a single comparison in the Tone patent between one monocycle

[24]Pursuant to the court's post-trial briefing rules, uncited testimony is deemed stricken from the record. The court cites certain testimony in this section for the purpose of putting Bayer's counterarguments and the court's analysis into context.

and one bicycle supports this result and, with respect to that example, no positive control (comparison to prior art antibiotic compounds) is present. (Id. at 1037:6-1040:19)

29. The European counterpart to the Tone patent, EP Application 0181521 ("Tone EP") (PTX-41), discloses additional data not found in the Tone patent for the same compounds. As Bayer points out, the data in Tone EP demonstrates that compounds with monocyclic 7-position substituents sometimes outperformed those with bicycles, for example, where a flourine was found at the 8-position. (D.I. 126 at 1046:23-1047:2 (Dr. LaVoie); D.I. 127 at 1199:17-1200:1, 1205:16-1206:18-21[25] (Dr. Zhanel)) Dr. LaVoie himself testified that, while the Tone patent disclosed only favorable results for bicyclic compounds, in some cases, the data in Tone EP was better for monocyclic compounds, sometimes better for bicyclic compounds, with no "dramatic difference" in the comparative analysis. (D.I. 127 at 1043:25-1044:15)

30. DTX-299 is a Japanese patent abstract corresponding to Japanese Patent Application No. 58009874 ("the Hokuriku abstract"). The abstract discloses the structure of a quinolone with a bicyclic 7-position substituent, which is "[u]seful as an antibacterial agent[,] [h]aving high antibacterial action on [g]ram-positive and [g]ram-negative bacteria." (DTX-299) This general disclosure, which contains no data, comparisons or other relevant information, did not impact the research in this area.

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[25]Reddy's expert, Dr. Remmel, did not agree that the pharmacokinetic performance data indicated superior performance by the monocyclic compound; the "raw data" indicated a better performance, however, Dr. Remmel was "concerned [about] the way this experiment was done" because different doses were used. (D.I. 129 at 1674:9-1675:18)

(D.I. 128 at 1463:15-19 (Dr. Taylor))

31. European Patent Application No. 106,489 to Culbertson, et al. (the "Culbertson application") (DTX-256) discloses quinolones with three types of 7-position substituents: monocycles, fused bicycles, and spirocycles. Dr. LaVoie admits that persons of ordinary skill in the art would have considered the monocycles and, second to them, the spirocycles to be the most effective 7-position substituents disclosed in the Culbertson application. (D.I. 126 at 1018:3-24)

32. Neither the Tone patent, the Hokuriku abstract, nor the Culbertson application clearly indicate that bicyclic 7-position substituents were more desirable than other types of substituents; Reddy has not put forward any testimony that could demonstrate otherwise. The court finds these references insufficient to demonstrate that a person of ordinary skill in the art would have been motivated to modify AT-3295 or Sankyo 1-130 with DBO 7-position substituents with any reasonable expectation of success.

33. As discussed previously, Drs. Schenke and Petersen confirmed that DTX-161 discloses quinolones with bridged piperazine substituents at the 7-position which had a higher activity than ciprofloxacin. (D.I. 123 at 197:10-23; D.I. 124 at 420:21-24; DTX-161 at 19 (table)) It is not clear to the court that this disclosure is akin to a blanket endorsement of any type of DBO substituents at the 7-position. Dr. Petersen and Dr. Schenke's testimony concerns their discovery that bridged piperazine at the 7-position, as disclosed in example 4 of DTX-161, increased the activity of ciprofloxacin; neither inventor characterized their discovery in broader terms, and Reddy apparently did not present its own testimony on the issue. (D.I. 123 at 199:22-200:1, 203:15-204:4; D.I.

124 at 420:9-23, 421:21-422:6) (cited at D.I. 132 at 40) Both Bayer inventors testified that bridged piperazine 7-position substituents and 5/5 pyrrolidine bicycles, such as the Bayer 5/5 bicycle, are completely different molecules (despite their similar chemical nomenclature), as is apparent from their differing chemical structures. (D.I. 123 at 202:11-25, 226:18-227:17, 261:22-263:20; PTX-2071-B) The court finds that DTX-161 provided, at best, a motivation to try DBOs as 7-position quinolone substituents.[26]

34. Even if the inventors' success with a piperazine DBO provided a motivation to use DBOs at the 7-position (beyond a motivation to try), there is no indication that a person of ordinary skill in the art would have actually used the Bayer 5/5 bicycle. Reddy focuses its argument on an "admission" from Dr. Taylor, who confirmed that, if a person of ordinary skill in the art "had been **told** to make a [DBO] substituent derived from [3-]amino 4-methyl pyrrolidine, i.e., the 7-position substituent of Sankyo compound 1-130 and Dainippon compound AT-3295," he "would have made the Bayer bicycle." (D.I. 132 at 41, citing D.I. 128 at 1546:10-17; D.I. 135 at 32 (citing same)) (emphasis added)

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[26]Courts have long recognized the unpredictability of the chemical arts. See, e.g., PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1564-65 (Fed. Cir. 1996) (enablement context); Glaxo Wellcome, Inc. v. Eon Labs Mfg., Inc., No. Civ. A. 00-9089, 2002 WL 1874830, *5 (S.D.N.Y. 2002) (same). The court finds that the evidence of record insufficient to demonstrate either: (1) that the differences between bridged piperazines and fused pyrrolidines are irrelevant to, and do not diminish, any motivation to combine the references; or (2) any reasonable expectation of success.

The court notes that in cases where the evidence demonstrates "a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." KSR, 127 S.Ct. at 1732. In those situations, "the fact that a combination was obvious to try might show that it was obvious under § 103." Id. Because the prior art disclosed a broad selection of DBO compounds which could have been selected for further investigation, and there is no indication that the Bayer 5/5 bicycle was a "predictable solution" for achieving positive antibacterial activity, the evidence is insufficient to demonstrate obviousness.

This is a far cry from establishing an independent motivation. Reddy further relies upon a statement in a "poster"[27] presented by four named inventors of the '517 patent, which stated that

> [b]y **systematic variation** of the 7-amino substituents an amine was found in cis-piperidinopyrrolidine which in combination with various quinolone structures yields outstandingly active quinolonecarboxylic acids.

(DTX-223A at SH_000001-005237 through 5239) (emphasis added) Reddy apparently presented no expert testimony regarding its "routine experimentation" theory. Dr. Taylor testified that a person of ordinary skill in the art, seeking to make bicyclic substituents derived from 3-amino 4-methyl pyrrolidine, would not have been motivated to make a DBO as opposed to a bicyclic substituent with any other number of rings (D.I. 128 at 1576:9-13);[28] if DBOs were used, the Bayer 5/5 bicycle would not have been selected since it does not maintain the functionality of the 3-amino pyrrolidine and the methyl group (as they would have been used to form the ring) (id. at 1489:2-1491:15).[29] Without more, the court declines to conclude, solely on the basis of the inventors' use

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[27]This "poster" appears to be a paper entitled "BAY Y 3118, A Novel 4-Quinolone: Synthesis and In Vitro." The document appears to be undated; the date of its publication was not provided to the court.

[28]Dr. Remmel, an expert for Reddy, confirmed that there are thousands of bicyclic compounds containing two nitrogen atoms. (D.I. 129 at 1657:6-20 (discussing compounds in the context of the Tone patent))

[29]Reddy's proffered evidence regarding a reasonable expectation of success is not convincing. (D.I. 132 at 39-40) For example, Dr. LaVoie stated (on cross examination) that the Tone patent conveys an expectation that a bicyclic 7-position substituent would "not lose at least the antibacterial activity" (D.I. 126 at 1038:12-13); Remmel testified that a person of ordinary skill in the art, after reviewing the Tone patent, would be "left with the reasonable expectation that if you were to use **a bicyclic** at the 7-position, that you'd have a compound that would have useful antibacterial activity." (D.I. 129 at 1638:2-4) (emphasis added)

of the word "systematic variation" without additional context, that the claimed compounds are obvious as a matter of law.[30]

5. Conclusion

35. The court finds that Reddy has not demonstrated, by clear and convincing evidence, that a person of ordinary skill in the art would have had reason to attempt to make the claimed compositions, or that such a person would have had a reasonable expectation of success in doing so. Specifically, Reddy has not demonstrated: (1) a motivation to modify (a) AT-3295 or Sankyo 1-130 as compared to other prior art quinolones; (b) with a DBO (rather than a bicyclic) substituent at the 7-position; (2) an obvious connection between modifying either compound with DBO and arriving at the claimed compounds; or (3) any reasonable expectation of success in making the proffered combination of prior art. The asserted claims of the '517 patent, therefore, are not invalid on this ground.

F. Inequitable Conduct

36. Reddy asserts that both the '517 and '942 patents are unenforceable for inequitable conduct. Specifically, Reddy alleges that the applicants committed inequitable conduct before the PTO by failing to properly disclose four references during the prosecution of the '434 application. These four references include the X references, or the Sankyo application, the Dainippon abstract, and the Egawa argicle.

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[30]In Bayer's words, the court declines to find that the inventors' "systematic variation" of the 7-position substituent could not also have been inventive, insofar as they used substituents which were never before used in the quinolone art (as evidenced by the fact that Reddy did not bring an invalidity defense based on anticipation). (D.I. 134 at 12)

Additionally, Reddy cites an article by Justus Liebigs (the "Liebigs reference"), Justus Liebigs Ann. Chemie 677, 154 (1964) (DTX 218-B). According to Reddy, if inequitable conduct is found with respect to the '517 patent, the '942 (divisional) patent should be rendered unenforceable by reason of the doctrine of "infectious unenforceability."

1. The law of inequitable conduct

37. Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the PTO. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to patent applicants or their attorneys which is material to the examination of a patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Molins, 48 F.3d at 1178.

38. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then the entire patent application is rendered unenforceable. Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). Additionally, "[a] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803-04 (Fed. Cir. 1990).

39. A finding of inequitable conduct is "an equitable determination" and,

therefore, "is committed to the discretion of the trial court." Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001).

40. In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the PTO. Molins, 48 F.3d at 1178.

41. A determination of inequitable conduct follows a two-step analysis. The withholding of information must first meet threshold findings of materiality and intent. Id.

42. The Federal Circuit has recently stated that, prior to 1992, two standards for materiality were in effect: (1) the materiality standard set forth in the present version of PTO Rule 56, 37 C.F.R. § 1.56(b); and (2) the previous version of that rule. See Digital Control Inc. v. Charles Machine Works, 437 F.3d 1309, 1314 (Fed. Cir. 2006). The Court in Digital Control held that the new 1992 iteration of Rule 56 was not intended to replace the broader old Rule 56, and "merely provides an additional test of materiality." Id. at 1316. Therefore, "if a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the 'reasonable examiner' standard or under the older three tests, it is also material." Impax Labs., Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1374 (Fed. Cir. 2006) (quoting Digital Control, 437 F.3d at 1316)).

43. Rule 56 formerly provided that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding

whether to allow the application to issue as a patent." 37 C.F.R. § 1.56 (1990).

44. Currently, Rule 56 is narrower in scope:

> Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
> (i) Opposing an argument of unpatentability relied on by the Office, or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2007).[31]

45. The inquiry presented under the prior "reasonable examiner" standard is whether "a reasonable examiner would have considered such [omitted] prior art important in deciding whether to allow the patent application." Impax Labs., 468 F.3d at 1374 (quoting Digital Control, 437 F.3d at 1314)).

46. The applicable "older three tests" referenced in Digital Control include: (1) the objective "but-for" standard, in other words, "where the misrepresentation was so material that the patent should not have issued;" (2) the subjective "but-for" test, in other words, "where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so;" and (3) the "but it may

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[31]Further,

> [a] prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2007).

have" standard, "where the misrepresentation may have influenced the patent examiner in the course of prosecution." See Impax Labs., 468 F.3d at 1374, n.5 (quoting Digital Control, 437 F.3d at 1315)).

47. After determining that the applicant withheld material information, the court must decide whether the applicant acted with the requisite level of intent to mislead the PTO. See Baxter Int'l, Inc. v. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989). An inference of intent, nevertheless, is warranted where a patent applicant knew or should have known that the withheld information would be material to the PTO's consideration of the patent application. See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

48. Once materiality and intent to deceive have been established, the trial court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct. N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987). The showing of intent can be proportionally less when balanced against high materiality. Id. In contrast, the showing of intent must be proportionally greater when balanced against low materiality. Id.

49. Because a patent is presumed valid under 35 U.S.C. § 282, inequitable conduct requires proof by clear and convincing evidence. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 551 (Fed. Cir. 1990).

2. The X references

a. Disclosure

50. "An applicant can not 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." Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1327 (Fed. Cir. 2000). Bayer asserts that, because there is no dispute that the X references were submitted to the PTO (albeit after prosecution was closed, the receipt of the Notice of Allowability and payment of the issue fee had taken place), the X references cannot form the basis for inequitable conduct. (D.I. 133 at 31)

51. The MPEP in effect in 1988 stated that prior art cited after a Notice of Allowance will be placed in the file, but "will not ordinarily be considered by the examiner" unless the disclosure is accompanied by:

> (a) a proposed amendment cancelling or further restricting at least one independent claim and narrowing the scope of protection sought;
>
> (b) a timety affidavit under 37 C.F.R. 1.131 with respect to the material cited; or
>
> (c) a statement by the applicant or his attorney or agent that, in the judgment of the person making the statement, the information cited
>
> > (1) raises a serious question as to the patentability of the claimed subject matter, or
> >
> > (2) is closer than that of record, or
> >
> > (3) is material to the examination of the application as defined in 35

C.F.R. 1.56(a) and is filed with an explanation as to why the information disclosure statement was not earlier presented **e.g., information recently cited in a corresponding foreign patent application**.

After all claims have been indicated as allowable, there is no duty on the part of the examiner to consider any citation which does not conform to the listed requirements.

(DTX-97, MPEP 5th Ed., 8th Rev., § 609 at 600-66) (emphasis added) Reddy argues that Mr. Horn's failure to cite the X references without the required explanation "was a constructive withholding which supports a finding of inequitable conduct." (D.I. 135 at 15)

52. Examiner Dentz initialed each X reference, but noted that he did not consider them until February 8, 1991, three days after the '517 patent issued on February 5, 1991. In contrast to the cases cited by plaintiff,[32] there is no indication that the X references were either before the examiner or considered during the prosecution of the '517 patent. For these reasons, the court declines to find that the X references were disclosed to the PTO in a manner which would preclude their assertion in an inequitable conduct case.

b. Materiality and cumulativeness

53. The question remains as to whether the X references were material to any claims pending in the application when the European search report was received. See Scripps, 927 F.2d at 1583 ("A reference that is material only to withdrawn claims can

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[32]Compare Molins, 48 F.3d at 1185 (reference of record during prosecution); Litton Sys. v. Honeywell, Inc., 87 F.3d 1559, 1571 (Fed. Cir. 1996), vacated on other grounds, 520 U.S. 1111 (1997) (record was received and considered during reissue proceedings); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1999) (reference cited within another submitted during prosecution) (cited at D.I. 133 at 30-31).

not be the basis of a holding of inequitable conduct") (affirming partial summary judgment of no inequitable conduct); see also Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1457 (Fed. Cir. 1984) (patent applicant's failure to disclose a prior art reference that was only material to originally-filed claims, subsequently cancelled or substantially amended, did not amount to inequitable conduct, as the withheld prior art was not material to any issued claim) (reversing finding of inequitable conduct).[33] The parties do not dispute that the originally-filed claims of the '434 application had several broad generic structures that covered a tremendous number of compounds, several of which were disclosed by the X references. (D.I. 132 at 5; D.I. 134 at 37) These claims were removed from prosecution following the formal election of Group IV on July 19, 1990 (or, at a minimum, the cancellation of non-elected claims on August 10, 1990) and, therefore, were not under examination when the alleged fraudulent act of withholding the European search report was committed – after its

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[33]The Kimberly-Clark court explained:

> In a case such as this, involving an issued patent attacked for breach of the duty of candor only on the basis of nonfeasance consisting of a failure to disclose known prior art, the key issues of materiality and intent should be decided with reference to the claims of the patent. What we see here, however, is an attempt by defendants to build a case of "fraud" by reason of non-disclosure of prior art material only to abandoned claims long since cancelled during prosecution after being rejected by the examiner as unpatentable for reasons not involving the uncited prior art. To base a conclusion of "fraud" on such grounds is to deal with a hypothetical situation, not with reality. Defendants and the trial judge have had little or nothing to say, in discussing the breach of duty to disclose issue, about the limited claims finally patented; they have not shown that non-disclosure of prior art would have had any effect on their allowance. Therefore, defendants have not sustained their heavy burden.

745 F.2d at 1457.

receipt on November 9, 1990. The fact that originally-filed claims may have been anticipated by the allegedly withheld prior art is not relevant to materiality where, as here, the claims were subsequently withdrawn from consideration prior to the time Reddy asserts that the disclosure should have taken place. See Scripps, 927 F.2d at 1583.

54. The X references, by their designation as such, clearly were relevant to the pending claims of the European counterpart at the time they were cited in that application. The parties do not dispute that the X references anticipated and, therefore, were material to originally-filed genus claims in the '434 application. (D.I. 133 at 25) Noticeably absent from Reddy's papers, however, is any comparison between the originally-filed and the issued claims of the '434 patent.[34]

55. Reddy asserts that Mr. Horn admitted that the X references were material to the elected subject matter when, in response to the restriction requirement, Mr. Horn stated that the compounds in the different groups "share a great deal of common structure and utility," have certain common features at the 7-position and are "not really so remote structurally."

56. Mr. Kurt Briscoe, a patent attorney for Bayer, testified that these are "code words to the examiner that what is being argued is unity of invention" (D.I. 126 at 828:10-832:17), which allows for patentably distinct subject matter to be prosecuted in the same application. Reddy puts forward no contrary evidence, and it appears that such arguments are a reasonable response to a restriction requirement. See Jon W.

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[34]Reddy focuses its arguments on intent. (D.I. 132 at 26-29, 64-70)

Henry, Some Comments on "Independent and Distinct" Inventions of 35 U.S.C. § 121 and Unity of Invention (pt. 1), 84 J. Pat. & Trademark Off. Soc'y 745, 771-72 (2002) (cited in Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1354 n.3 (Fed. Cir. 2004) (acknowledging the complexities of restriction practice)).

57. The compounds of the X references have monocycles at the 7-position. As discussed above, the record evidence indicates that monocycles and bicycles are fundamentally different structures. Dr. Taylor testified that the closest prior art to the claims of the '517 patent is the Culbertson patent, which discloses quinolones with fused bicycle 7-position substituents. (DTX-256; D.I. 128 at 1446:12-1447:6[35]) The Culbertson patent appears on the face of the '517 patent, and the U.S. counterpart of the Culbertson patent was cited by the examiner in the first office action. (PTX-2 at 859) A more similar reference does not always render a less similar reference cumulative; a comparison of the two disclosures is required, which was not clearly presented in this case. Although the court finds Bayer's evidence falls short of demonstrating cumulativeness in this regard, it should be noted that Reddy presented no responsive testimony on this point.

58. Under the current version of Rule 56, the X references could be material if, in combination with other information, they establish a prima facie case of unpatentability of a claim. As discussed above with respect to Reddy's obviousness case, it is not disputed that two of the X references, the Dainippon abstract and the

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[35]"It is the only bicycle in the literature which has a pyrrolidine, a 5-membered ring connected to the quinolone ring, just as the Bayer 5/1 [sic] bicycle does." (D.I. 128 at 1446:20-23)

Sankyo application, disclosed monocycles that could potentially be modified at the 7-position with the Bayer 5/5 bicycle to yield compounds of the issued claims of the '517 patent. Quinolones, such as disclosed in the X references, were known in the art to be effective antibacterial compounds, and the 7-position of such quinolones was undisputably the subject of experimentation prior to the inventions at issue. The novelty of the '517 patent, however, is not simply the selection of particular quinolones; even Bayer admits that claims 1 and 2 "generically claim millions of quinolone compounds" expressed through formulas with multiple variables (D.I. 133 at 5). The invention of the '517 patent was the incorporation of a novel and pharmaceutically important 7-position pyrrolidine ring substituent, yielding combinations that had not been made before. In this sense, the monocycles disclosed in the Dainippon abstract and the Sankyo application are just a few of many available monocycles which could, in theory, undergo modification to result in some of the "millions" of quinolones claimed. Having found that Reddy did not present a prima facie case of obviousness, the court declines to find, absent additional evidence, that either X reference could be used to establish a prima facie case of unpatentability based on the compounds' potential for modification.

59. For the aforementioned reasons, the court finds that Reddy's materiality evidence, consisting of Mr. Horn's statements, does not clearly and convincingly demonstrate materiality under its broadest terms, i.e., that it was substantially likely that the examiner would have considered the X references important in deciding whether to allow the '434 application to issue. The court finds no other independent basis upon which it could conclude the X references are material; having so held, the court need not reach the issue of intent.

3. The Liebigs reference

a. Materiality

60. The Liebigs reference does not discuss quinolones. (D.I. 123 at 128:16-22) Reddy argues that the Liebigs reference was "highly material" to originally-filed claim 19. The Liebigs reference discloses a bicyclic molecule with the nomenclature 2,7-diazabicyclo[3.3.0]octane, or the Bayer 5/5 bicycle. (DTX-218B at 155) Original claim 19 of the '434 application claimed the Bayer 5/5 bicycle. (PTX-2 at BL020-000527; D.I. 124 at 400:24-401:2) Original claim 19 was removed from the case following Mr. Horn's election to prosecute Group IV; it was not the subject of any rejection by examiner Dentz prior to its removal. (PTX-2 at 855-58, 893) The relevant inquiry is whether the Liebigs bicycle was material to any issued claims, not to withdrawn claim 19. See Scripps, 927 F.2d at 1583; Kimberly-Clark Corp., 745 F.2d at 1457.

61. According to Reddy, the Liebigs reference is material because examiner Dentz "could have issued a rejection of issued claim 7[36] of the '517 patent over a combination of the Liebigs reference [which discloses the Bayer 5/5 bicycle] and DTX-341 [which discloses Compound II]." (D.I. 132 at 55) This is because attaching the Bayer 5/5 bicycle at the 7-position to Compound II of DTX-341 would result in the compound claimed in issued claim 7. (D.I. 123 at 207:4-8) Reddy argues that, by including the Bayer 5/5 bicycle in original claim 19, the applicants "explicitly represent[ed]" to the examiner that it was a patentable compound; the examiner "rel[ied] on this representation . . . [and] would [have] certainly conclude[d] that any

[36]Issued claim 7 was originally-filed claim 10. (D.I. 123 at 13:25-14:2)

compound incorporating the Bayer 5/5 bicycle was also patentable." (D.I. 132 at 55)

62. In support, Reddy cites the testimony of Dr. LaVoie, who generally testified about the use of bicycles at the 7-position of prior art quinolones. (D.I. 135 at 5, citing D.I. 126 at 900:19-25) Dr. La Voie confirmed, however, that the Liebigs reference does not disclose or discuss quinolones, such as those claimed in the '517 patent as issued. (D.I. 126 at 938:25-939:1) Nevertheless, the fact that the Bayer 5/5 bicycle (disclosed in Liebigs) can be integrated with Compound II of DTX-341 at the 7-position to yield a compound claimed in issued claim 7 is not disputed. (D.I. 134 at 22)

63. The court finds that the Liebigs reference meets the threshold level of materiality required for inequitable conduct, insofar as it may have influenced the examiner in the course of prosecution of claim 7,[37] and could have formed the basis of an obviousness rejection in combination with DTX-341.[38]

64. The court pauses to discuss the contrast between its holding with respect to the Liebigs reference and its finding that the X references are not material. Both the Liebigs reference and the X references disclose a particular component that, when modified or incorporated with another component, yield a claimed compound. Reddy did not demonstrate a prima facie case of obviousness based on any of the X references; it did not assert the Liebigs reference as part of an obviousness argument. The court finds the Liebigs reference more material, if even by a slight degree, insofar as it discloses the Bayer 5/5 bicycle, which is one of just two pyrrolidine ring structures

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[37] Impax Labs., 468 F.3d at 1374, n.5 (quotation omitted).

[38] 37. C.F.R. § 1.56 (2007). The court finds no occasion to conclude that the Liebigs reference was "highly material" to patentability, as Reddy asserts.

central to the novelty of the claims at issue. In contrast, and as discussed previously, there are millions of quinolone compounds encompassed by the generic formulas of the asserted claims. Because each quinolone encompassed by claims 1 and 2 must contain either the Bayer 5/5 or 5/6 bicycle, the court finds the Liebigs reference more material, insofar as it had greater potential for use in a rejection during prosecution.

b. Intent

65. Prior to filing the '434 application, Dr. Schenke drafted a memo to his colleagues on the Bayer quinolone team that included a drawing of the Bayer 5/5 bicycle, described as a quinolone intermediate disclosed in the Le A 26 108 patent family. (DTX-76 at 5;[39] D.I. 123 at 144:20-145:19) One of the recipients was Dr. Petersen. (DTX-76 at 5) Reddy asserts that this "smoking gun" evidence establishes that Dr. Schenke was aware of the importance of the Bayer 5/5 bicycle to the '434 application and yet did not disclose it, despite the facts that: (1) the Bayer 5/5 bicycle was originally claimed in the '434 application; and (2) Dr. Schenke signed the inventors' declaration in which he affirmed that he had read and understood the content of the application (DTX-74). (D.I. 135 at 7-8)

66. Dr. Petersen, who also signed the inventors' declaration, was "primarily responsible for drafting the claims and specification" of the '434 application. (DTX-76; D.I. 133 at 18 n.4, citing D.I. 123 at 88:13-21, D.I. 124 at 321:25-322:12) Dr. Schenke testified that he drafted the portion of the specification relating to the synthesis of the intermediates he had synthesized, which did not include the Bayer 5/5 bicycle; Dr.

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[39]A translated version of this German document does not appear to be of record.

Schenke stated that this was the responsibility of another co-inventor, Dr. Krebs, who is now deceased. (D.I. 123 at 90:7-91:16, 131:8-11) According to Dr. Schenke, Dr. Krebs synthesized the Bayer 5/5 bicycle using a different method to that espoused in the Liebigs reference. (Id. at 131:2-11)

67. Neither inventor was aware of the Liebigs reference at the time the Le A 26 108 application was filed in Germany, nor at the time the '434 application was filed in the United States. (D.I. 123 at 128:16-131:7; D.I. 124 at 335:21-24, 336:7-10) Both inventors testified that they became aware of the Liebigs reference when Dr. Schenke was working on the Le A 26 686 application, which concerned quinolone intermediates, in contrast to the quinolones of the '434 application.[40] (D.I. 123 at 128:23-129:6; D.I. 124 at 336:11-23) Both inventors relied on their review of the (substantially identical) German application rather than the English version prior to signing the inventors' declaration.[41] (D.I. 123 at 98:11-17, 216:11-217:6; D.I. 124 at 401:20-402:10)

68. Upon discovering the overlap between the Liebigs reference and the claims of the divisional patent application in 1990, Dr. Petersen notified Bayer's patent department. (D.I. 124 at 336:11-339:23) A preliminary amendment was filed in the divisional case prior to any office action on October 1, 1990. (PTX-11 at 36492) The Liebigs reference was disclosed on the first page of the divisional application; Dr.

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[40]Reddy does not contest Bayer's characterization of Le A 26 686 as an "application related to a method for synthesizing bicyclic compounds for use as starting materials for quinolones." (D.I. 133 at 20)

[41]The court does not find that the trial testimony justifies granting Reddy, at this extremely late stage, leave to assert a new theory of inequitable conduct based on the submission of a false inventors' declaration. (D.I. 132 at 60-61)

Schenke helped to ensure that the claims of that application excluded the Bayer 5/5 bicycle. (PTX-15 at 42556; D.I. 123 at 130:7-20)

69. The court finds the aforementioned circumstantial evidence insufficient to support a finding of inequitable conduct. As an initial matter, although Dr. Schenke's memo demonstrated that the inventors were aware of the relevance of the Bayer 5/5 bicycle intermediate to the '434 application, the evidence does not demonstrate that either Dr. Schenke or Dr. Petersen realized that the Bayer 5/5 bicycle was disclosed in the Liebigs reference prior to the time original claim 19 was removed from prosecution.[42] When they later became aware of the reference, each took steps to disclose the Liebigs reference in the divisional case where it was most relevant – actions that the court finds inconsistent with an intent to deceive the PTO or, at a minimum, that militate against a finding of a high level of culpability.

70. Reddy asserts that Mr. Horn acted with an intent to deceive when he submitted the Liebigs reference in the divisional application but not the '434 application. Reddy argues that either Mr. Horn deliberately did not look to see if the Liebigs reference was relevant to any pending claims in the '434 application, intentionally avoiding the discovery that the Liebigs reference was material to issuing claim 7, or that Mr. Horn did check and, therefore, deliberately withheld disclosure. (D.I. 132 at 63)

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[42]Dr. Schenke was aware that the bicycle was in the prior art in 1989 when he signed the inventors' declaration (D.I. 123 at 163:13-18); Reddy has failed to tie this knowledge to the Liebigs reference.

As previously noted, the '434 application was 189 pages long and contained 20 claims; even after restriction and election, the '434 application remained tremendously lengthy and claimed a multitude of compounds. It is easy to envision how Drs. Schenke and Petersen and Mr. Horn could have failed to make the connections Reddy asserts.

Reddy's argument precludes the possibility that Mr. Horn reviewed the pending claims and did not appreciate that the Bayer 5/5 bicycle, an intermediate, was material to issuing claim 7. As Reddy acknowledges, "Mr. Horn is deceased and cannot tell us whether or not he satisfied [his] duty" to investigate the materiality of the Liebigs reference vis-a-vis claim 7. (Id. at 64) Both possibilities being equally probable, the court does not draw this distinction in Reddy's favor absent additional evidence.

71. Further, since examiner Dentz examined both the divisional and '434 applications, the amendment in the divisional application informed the examiner of the Liebigs reference prior to the time the '517 patent issued.[43]

72. The level of intent to deceive necessary to demonstrate inequitable conduct in this case is significant. See GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1273 (Fed. Cir. 2001) ("The more material the omission, the less culpable the intent required, and vice versa.") (citation omitted) (cited at D.I. 132 at 53). Based on the foregoing, the court finds that Reddy has not met its burden in the case at bar with respect to Dr. Schenke, Dr. Petersen, or Mr. Horn. The court finds neither the '517 patent nor the '942 patent unenforceable for inequitable conduct.

G. Double Patenting

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[43]Reddy asserts, without support, that "the division application ended up being before the 'same examiner' only after the '517 patent had safely issued." (D.I. 135 at 14) There is no indication in the record of when the PTO assigned examiner Dentz to the divisional application. Reddy does not contest the evidence that usual PTO procedure is to assign divisional cases to the same examiner handling the parent. (D.I. 126 at 849:17-850:8) There is no evidence to suggest that Mr. Horn expected otherwise. Nor is there a legitimate dispute that the applications were both assigned to examiner Dentz and were copending at the time of the October 1, 1990 preliminary amendment.

73. The double patenting doctrine generally prevents a patentee from receiving two patents for the same invention. There are two forms of the proscription against double patenting. With respect to the first form,

> [s]tatutory, or "same invention," double patenting is based on the language in § 101 of the Patent Act mandating "a patent" for any new and useful invention. 35 U.S.C. § 101 (2000); In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) ("If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. § 101 because an inventor is entitled to a single patent for an invention.") (citations omitted).

Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 1372-73 (Fed. Cir. 2005). Thus, a second patent may not issue on an "invention drawn to identical subject matter." In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985) (citation omitted).

74. The second form, or "obviousness-type" double patenting (non-statutory double patenting), is a "judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectually extend the right of patent protection." In re Metoprolol Succinate Patent Litigation, 494 F.3d 1011, 1016 (Fed. Cir. 2007) (citing Perricone, 432 F.3d at 1373).

> Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.

Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968 (Fed. Cir. 2001).

75. Reddy asserts that the '942 patent is invalid for double patenting over the '517 patent pursuant to In re Schneller, 397 F.2d 350 (C.C.P.A. 1968), in light of the

parties' stipulation that each asserted claim of the '942 patent cannot be practiced without infringing at least one claim of the '517 patent. (D.I. 132 at 44-45, citing JTX-1 at ¶ 40[44]) Alternatively, Reddy asserts that the '942 patent is invalid for obviousness-type double patenting over claims 4 and 5 of the 517 patent. (Id. at 48)

1. Statutory double patenting

76. The crux of Reddy's argument is that "Bayer should not be rewarded [with an extension of the right to exclude] for its failure to include specific claims directed to the subject matter of the later '942 patent in the earlier '517 patent." (D.I. 135 at 41-42) It is the claims, not the disclosures, of the two patents that form the basis of the court's analysis. Claims 1 and 2 of the '517 patent are genus claims that encompass a multitude of compounds, including moxifloxacin. Claim 1 of the '942 patent claims moxifloxacin. Although claim 1 and/or 2 of the '517 patent may dominate claim 1 of the '942 patent, domination is not per se double patenting.[45]

77. In In re Schneller, the United States Court of Customs and Patent Appeals affirmed a decision by the Patent Office Board of Appeals ("the Board") rejecting claims

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[44]"Each of claims 1, 2, 3, 4, 5, and 7 of United States Patent 5,607,942 cannot be practiced without infringing at least one claim of United States Patent 4,990,517."

[45]"Domination" is the phenomenon

> which grows out of the fact that patents have claims, whereunder one patent has a broad or "generic" claim which "reads on" an invention defined by a narrower or more specific claim in another patent, the former "dominating" the latter because the more narrowly claimed invention cannot be practiced without infringing the broader claim. . . This commonplace situation is not, per se, double patenting[.]

In re Kaplan, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986) (stating that "[d]omination is an irrelevant fact" vis-a-vis the inquiry of whether the latter invention was validly patented).

on the ground of double patenting, where the patentee's

> first application disclosed ABCXY and other matters. He obtained a patent claiming BCX and ABCX, but so claiming these combinations as to cover them no matter what other feature is incorporated in them [by virtue of the term "comprising"], thus covering effectively ABCXY. He [then], many years later, s[ought] more claims directed to ABCY and ABCXY. Thus, protection he already had would be extended, albeit in somewhat different form, for several years beyond the expiration of his patent, were we to reverse.

397 F.2d at 355-56. Having "shown no justification for such extended protection," the court affirmed the decision of the Board. Id. at 356.

78. The In re Schneller case is distinguishable from the case at bar on its facts. Absent Federal Circuit support for the proposition, the court declines, as Reddy suggests, to find that In re Schneller sets forth a third, controlling legal test for double patenting that includes requirements that look beyond a comparison of the claims.[46] See gen. Ex Parte Davis, 56 U.S.P.Q.2d 1434, 1436 n.5 (Bd. Pat. App. & Interf. 2000)[47] ("[I]t is our view that Schneller does not set forth another test for determining 'obviousness-type' double patenting. In that regard, it is clear to us that the court in Schneller was concerned with whether or not the invention claimed in the patent was **independent and distinct** from the invention of the appealed claims.") (emphasis in

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[46]Reddy's iteration of the "Schneller" test, unrecognized by any court, is an evaluation of whether: "(a) the subject matter claimed in the later patent was disclosed in the earlier patent; (b) the subject matter claimed in the later patent is covered by claims in the earlier patent; and (c) there is no reason why the patentee was prevented from presenting the claims of the later patent for examination in the prosecution of the earlier patent." (D.I. 132 at 44) Reddy's proffered test runs afoul of In re Schneller itself, in which the Court of Customs and Patent Appeals recognized that "only the claims of the patent can be considered as support for [a double patenting] rejection." 397 F.2d at 1378.

[47]U.S. Patent and Trademark Office Board of Patent Appeals and Interferences No. 1999-1924, found at 2000 WL 1901388.

original); MPEP § 804 (2007) ("The decision in In re Schneller did not establish a rule of general application and thus is limited to the particular facts set forth in that decision.").

79. Reddy does not specifically argue that claim 1 of the '942 patent is not patentably distinct from claim 1 or claim 2 of the '517 patent. (D.I. 132 at 16-17, 44-48) The parties' stipulation that claims 1, 2, 3, 4, 5, and 7 of the '942 patent cannot be practiced without infringing at least one claim of the '517 patent indicates that there is overlapping subject matter; this is not an admission that the sets of claims are not patentably distinct from one another. (JTX-1) For the aforementioned reasons, the court finds that the '942 patent is not invalid under In re Schneller.

2. Obviousness-type double patenting

80. During prosecution of the application which issued as the '942 patent, the claims were rejected "under the judicially created doctrine of double patenting over claims 1-2, and 8-12 of [the '517 patent]." (PTX-4 at BL020-002070) The examiner noted that the application claimed the same "specific quinolone compounds . . . [T]heir compositions and methods of treatment" were claimed in the '517 patent.[48] (PTX-4 at BL020-002070) In response, the applicants argued that the subject matter claimed in the pending application was a separate invention to that previously claimed; "if a stranger discovered the special characteristics of the instant compound and the prior art

[48]Citing In re Schneller, the examiner also noted that "there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent." (PTX-4 at BL020-002070 through 2071) Applicants responded that, prior to the publication of several Board decisions following the issuance of the '517 patent, it was not clear that they were permitted to claim the purified moxifloxacin enantiomer which had not been "actually depicted either by name or structural formula" in the '517 patent specification. (Id. at BL020-002165 through 2169)

was the **claims** of [the '517 patent] . . . such [a] stranger [could] obtain a patent for his discovery[.]" (Id. at BL020-002163) (emphasis in original) Following an interview with the examiner, the application was allowed. It was noted in the interview summary record that a "[s]howing of unexpected results overc[ame] the obviousness-type rejection." (Id. at BL020-002171) Reddy essentially asks the court to revisit this decision; Reddy has stipulated that the '942 patent claims are valid if the court finds, as a matter of law, that unexpected desirable properties are relevant to the determination of obviousness-type double patenting.[49] (D.I. 132 at 50)

81. The court need not reach this legal issue, however, as it finds that Reddy has not set forth clear and convincing evidence that the '942 patent claims are obvious variants of the '517 patent claims under the two-prong test set forth in Eli Lilly & Co.. 251 F.3d at 968. The only difference between claims 1 and 2 of the '942 patent and claims 4 and 5 of the '517 patent is the 8-position substituent. (D.I. 132 at 49) Claims 1 and 2 of the '942 patent have a methoxy group,[50] claim 4 of the '517 patent has a

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[49]The parties highlight what appears to be a conflict between the Federal Circuit's statement in a footnote in Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC, 349 F.3d 1373 (Fed. Cir. 2003), that "[t]he distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include . . . [that] [o]bviousness requires inquiry into objective criteria suggesting non-obviousness [while] nonstatutory double patenting does not," id. at 1378 n.1, with the Court's precedent in which it looked to unexpected properties in the double patenting context. See In re Emert, 124 F.3d 1458, 1462 (Fed. Cir. 1997) ("Absent some indication of unexpected properties, the combination [A and B] rendered B1 obvious."); In re Longi, 759 F.2d 887, 896-97 (Fed. Cir. 1985) ("Contrary to appellants' arguments, the Albazzati declaration fails to provide the unexpected results necessary to rebut the prima facie case of obviousness. . . . There is nothing to show that the results attested in the declaration were unexpected.").

[50]Claim 1 of the '942 patent is directed to one of the four stereoisomers claimed in claim 2.

flourine, and claim 5 of the '517 patent has a chlorine at the 8-position. (Id.) The question at bar is whether claims 4 or 5 of the '942 patent, containing a halogen at the 8-position, are patentably distinct from claims 1 and 2 of the '517 patent, containing a methoxy group at that position.

82. Reddy asserts that the Sankyo application "plainly" directed persons of ordinary skill in the art to use a methoxy group at the 8-position because, according to Dr. LaVoie, the thirteen most preferred compounds disclosed in the Sankyo application contained 8-position methoxy substituents. (D.I. 132 at 49, citing D.I. 126 at 892:13-18, 922:18-923:18) Dr. Taylor acknowledged this and observed that the Sanyko application "say[s] something about the worthwhileness of methoxy at the 8-position." (D.I. 128 at 1519:17-1520:2) This evidence, however, is insufficient to demonstrate that the compounds are obvious variants of each other. Noticeably absent from Reddy's argument is any evidence regarding the interchangeability of, or chemical similarities between, halogen and methoxy functional groups. Further, aside from Dr. LaVoie's conclusory statements regarding the structures disclosed in the Sankyo application, there is no discussion of the teaching of that reference with respect to the 8-position, the conventional wisdom in 1988 regarding 8-position substituents, or any rationale that would justify a person of skill in the art's selection of methoxy as an equivalent 8-position substituent.[51] For all of these reasons, Reddy has not met its burden to

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Methoxy refers to a functional group consisting of a methyl group bound to oxygen. It has the formula $-O-CH_3$.

[51]Compare In re Longi, 759 F.2d at 896 (finding the claimed subject matter unpatentable, despite structural difference in claimed compounds, where the prior art suggested to one of ordinary skill in the art that the newly-claimed compounds would

demonstrate, by clear and convincing evidence, that the claimed inventions are "so alike that granting both exclusive rights would effectively extend the life of patent protection." Perricone, 432 F.3d at 1373 (citation omitted). The court need not reach Bayer's rebuttal evidence; the '942 patent is not invalid for double patenting.

V. CONCLUSION

83. For the reasons discussed above, the court concludes that Reddy has failed to prove, by clear and convincing evidence, that: (1) the '517 and '942 patents are unenforceable due to inequitable conduct; (2) the '517 patent is invalid for obviousness; or (3) the '517 or '942 patent is invalid for double patenting.

84. The effective date of any approval of Reddy's ANDA will be no earlier than March 4, 2014, the later of the expiration dates of the '517 and '942 patents. 35 U.S.C. § 271(e)(4)(A) (2007).

85. The court shall enter appropriate injunctive relief.[52] 35 U.S.C. § 271(e)(4)(B) (2007).

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have utility) (affirming decision of the Board holding the claimed subject matter unpatentable for obviousness-type double patenting).

[52]Reddy did not take issue with Bayer's request for an injunction should the court find in its favor. (D.I. 135)

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAYER AG, BAYER HEALTHCARE AG, and BAYER PHARMACEUTICALS CORPORATION, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC., Defendants.	)	Civ. No. 04-179-SLR
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC., Counterclaim Plaintiffs, v. BAYER AG, BAYER HEALTHCARE AG, and BAYER PHARMACEUTICALS CORPORATION, Counterclaim Defendants.	)	

ORDER

At Wilmington this 31st day of October, 2007, consistent with the opinion issued this same date;

IT IS ORDERED that:

1. The effective date of any approval of Reddy's ANDA will be no earlier than March 4, 2014.

2. Reddy shall not manufacture, use, offer for sale, or sell within the United States, or import into the United States, moxifloxacin hydrochloride or any compound or drug product within the scope of claim 1 or 2 of the '942 patent, prior to March 5, 2014.

3. On or before November 23, 2007, the parties shall submit a joint proposed order of judgment for the court's signature.

United States District Judge