

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UCB, INC. and CELLTECH :  
MANUFACTURING CA, INC., :  
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Plaintiffs, :  
 :  
v. : Civil Action No. 08-223-JJF  
 :  
KV PHARMACEUTICAL COMPANY, :  
 :  
Defendant. :  
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**MEMORANDUM OPINION**

March 9, 2010  
Wilmington, Delaware.

  
**Farnan, District Judge.**

Pending before the Court are six motions in limine, three filed by each side. Plaintiffs UCB, Inc. and Celltech Manufacturing CA, Inc. (collectively "Plaintiffs") filed their Motion In Limine No. 1 To Preclude Defendant From Relying On A Newly-Disclosed On-Sale Bar Defense (D.I. 151), No. 2 To Preclude Defendant From Introducing At Trial Argument Or Evidence Concerning Its New Non-Infringement Theory (D.I. 152), and No. 3 To Preclude Defendant From Introducing Testimony Of Dr. Chambliss At Trial Concerning The Date Of Invention Of The Patent-In-Suit Contrary To The Assumptions In His Expert Report. (D.I. 153.) At the same time Defendant KV Pharmaceutical Company filed its Motion In Limine No. 1 To Hold Plaintiffs To Their 30(b)(6) Testimony Concerning Date Of Invention (D.I. 154), No. 2 To Preclude Testimony Regarding The F2 Similarity Factor (D.I. 155), and No. 3 To Strike The Supplemental Expert Report Of Stephen R. Byrn And Preclude Any Related Testimony. (D.I. 156.) For the reasons discussed, and because the upcoming trial is a bench trial, these Motions will be denied.

## **I. BACKGROUND**

This is a patent infringement action brought by Plaintiffs asserting that Defendant has infringed on United States Patent No. 6,344,215 ("the '215 patent"). The '215 patent pertains to

pharmaceutical dosage forms that provide a modified release of methlyphenidate for the treatment of attention deficit hyperactivity disorder ("ADHD"). Plaintiffs initiated this action in response to Defendant submitting an ANDA to the United States Food and Drug Administration seeking approval to sell a generic version of Plaintiffs' Metadate CD product. (D.I. 128 at 1.) Plaintiffs assert that the Metadate CD product is the commercial embodiment of the '215 patent. The instant suit alleges infringement of only claims 1 and 2 of the '215 patent.

The Court issued its claim construction ruling on August 18, 2009 (D.I. 93, 94) and the parties completed discovery in December 2009. A pre-trial conference was held March 4, 2010 and a bench trial is scheduled to begin on April 12, 2010.

## **II. LEGAL STANDARD ON THE EXCLUSION OF EVIDENCE AND TESTIMONY**

Under Fed. R. Civ. P. 26(a) and (e) parties are required to make a number of disclosures and supplements to disclosures and responses. This standard is further addressed in Fed. R. Civ. P. 37(c)(1) which states that "[i]f a party fails to provide information or identity of a witness as required by Rule 26(a) or (e) the party is not allowed to use that information or witness to supply evidence . . . unless the failure was substantially justified or is harmless."

The Third Circuit and this Court have focused on a series of

factors in evaluating harmlessness and substantial justification:

In determining whether a failure to disclose is harmless courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "Pennypack factors").

Boehringer Ingelheim Int'l GMBH v. Barr Labs. Inc., Civ. No. 05-700-JJF, 2008 U.S. Dist. LEXIS 53475, \*4-5 (D. Del. July 15, 2008) (citing Konstantopoulos v. Westvaco Corp., 112 F.3d 710, 719 (3d Cir. 1997); see also, Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-905 (3d Cir. 1977)). Lastly, "the exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of wilful deception or 'flagrant disregard' of a court order by the proponent of the evidence." Konstantopoulos, 112 F.3d at 719 (quoting Meyers, 559 F.2d at 905).

### **III. PLAINTIFFS' MOTION IN LIMINE NO. 1**

#### **A. Parties' Contentions**

Through its Motion in Limine No. 1 (D.I. 151), Plaintiffs request the Court to preclude Defendant from relying on the on-sale bar defense. Plaintiffs contend that Defendant should be precluded from asserting an on-sale defense bar, under 35 U.S.C. § 102(b), because Defendant did not assert such a defense during discovery. (Id.) Plaintiffs further argue that the untimely

assertion of the on-sale bar defense is both unjustified, because Defendant possessed the relevant discovery long before asserting the defense, and unduly prejudicial because Plaintiffs were unable to properly prepare for the defense. (Id.) Plaintiffs also contend that the fact that they control the relevant documents does not eliminate the prejudice of untimeliness. (D.I. 178.)

Defendant opposes the instant Motion. (D.I. 172.) In doing so, Defendant contends that any delay in the assertion of the on-sale bar defense was a direct result of Plaintiffs' discovery failures. (Id.) Specifically, Defendant argues that Plaintiffs failed to disclose the prior Eurand Litigation and the date of invention. (Id.) Defendant asserts that the supplementation of interrogatories to include the on-sale bar defense was proper as timely following the disclosure of the relevant evidence by Plaintiffs. (Id.) Lastly, Defendant argues that there is no prejudice if the defense is allowed because all of the relevant documents and information are in Plaintiffs' control.

#### **B. Decision**

The Court concludes that preclusion of Defendant's on-sale bar defense is not warranted when the on-sale bar defense is evaluated under Fed. R. Civ. P. 37 and the Pennypack factors. First, the availability of the necessary information is disputed, as is evidenced further by the ongoing dispute on the date of

invention. The parties have submitted a number of exhibits claiming to show evidence of timeliness and untimeliness, but these documents primarily demonstrate the ongoing discovery disputes between the parties and the statements within them are primarily attorney comments.

However, the Court is able to determine that preclusion is not warranted because Plaintiffs have not shown any actual harm or prejudice they will face if the on-sale bar defense is allowed. Although Plaintiffs argue they were denied discovery regarding the issue, they do not cite to any particular discovery they were unable to complete. The Court finds on the record presented that Plaintiffs are not prejudiced by the late assertion of the defense as seen by their ability to respond to Defendant's Summary Judgment Motion on the issue.

#### **IV. PLAINTIFFS' MOTION IN LIMINE NO. 2 AND DEFENDANT'S MOTION IN LIMINE NO. 3**

Plaintiffs' Motion in Limine No. 2 and Defendant's Motion in Limine No. 3 both relate to the same subject matter, Defendant's non-infringement theory and the supplemental report of Plaintiffs' expert Dr. Byrn.

##### **A. Parties' Contentions**

By their Motion in Limine No. 2, Plaintiffs seek the preclusion of Defendant's non-infringement argument. (D.I. 152.) Plaintiffs contend that Defendant was untimely in presenting the

argument of non-infringement based on the inapplicability of Claim 1 of the '215 patent to the accused product. Plaintiffs further contend that Defendant did not present the argument that the ratio of immediate release and extended release beads was required to be the same in the accused product as in the patent claim in a timely manner. (Id.) Defendant responds that it has long asserted that there could be no infringement because the accused product did not fit within the table that provides the ratios in the '215 patent. (D.I. 173.) Plaintiffs add that if Defendant's argument is permitted, they should be permitted to rely on the Supplemental Report of Dr. Byrn. (D.I. 152.)

Defendant's Motion in Limine No. 3 seeks to strike the Supplemental Report of Dr. Byrn and preclude any related testimony. (D.I. 156.) Defendant contends that Plaintiffs' Expert Dr. Byrn's Supplemental Report, which was issued after a Motion for Summary Judgment filed by Defendant, should be struck as untimely. (Id.) Plaintiffs counter that the supplemental report was necessary and timely because it responded to late opinions raised by Defendant. (D.I. 177.) Plaintiffs also assert that inclusion of the supplemental report is not prejudicial to Defendant because it was presented with adequate time to investigate. (Id.)

#### **B. Decision**

Plaintiffs' Motion in Limine No. 2 will be denied because,

in the Court's view, Defendant has been timely in asserting the instant defense. Defendant has argued since claim construction that its product does not infringe upon the asserted claims of the '215 patent based on the ratios of the table it has long disputed. Plaintiffs have addressed and argued on the issue of the ratio of the beads in the accused product compared to the ratios in the claim language in the context of summary judgment. Thus, although the precise argument of the ratio of beads in the tested accused product may not have been expressly disclosed, the issue of ratios in the context of non-infringement and indefiniteness has long been known.

Defendant's Motion in Limine No. 3 will also be denied. The Court concludes that striking the supplemental report is not warranted because its assertions are consistent with Dr. Byrn's prior statements and it was entered to address Defendant's summary judgment motion. Thus, Defendant will not be prejudiced by the admission of the supplemental report.

In sum, the Court concludes that both Motions in Limine relating to non-infringement will be denied.

#### **V. PLAINTIFFS' MOTION IN LIMINE NO. 3 AND DEFENDANT'S MOTION IN LIMINE NO. 1**

Plaintiffs' Motion in Limine No. 3 and Defendant's Motion in Limine No. 1 both relate to the parties' ongoing dispute about the date of the invention embodied in the '215 patent.

### **A. Parties' Contentions**

Through the instant motions, each side seeks to limit what the other can cite as the date of the invention. By their Motion In Limine No. 3 (D.I. 153), Plaintiffs seek to limit expert Dr. Chambliss to a 1996 date of invention based on assumptions made in Dr. Chambliss' expert report. Plaintiffs contend that, in his expert report, Dr. Chambliss made assumptions regarding prior art related to the '215 patent with both a 1996 and 2000 date of invention, but that Defendant specifically accepted a 1996 date. (Id.) Thus, Plaintiffs contend, Defendant should be limited to a 1996 date of invention. Defendant counters that Dr. Chambliss was merely being prudent in providing prior art information based on both dates because Plaintiffs had not fulfilled their obligation to establish the date of invention at that time. (D.I. 174.)

Similarly, Defendant seeks to limit Plaintiffs to a 2000 date of invention based on the testimony given in the 30(b)(6) deposition. (D.I. 154.) Defendant argues that because the 30(b)(6) witness stated that Plaintiffs did not know the date of invention and only that it was within the disclosed documents, Plaintiffs should be held to the constructive date of invention of 2000 based on the date the patent application was filed. (Id.) Plaintiffs counter that Defendant's attempts to obtain the date of invention in the context of a 30(b)(6) deposition were

improper and should have been saved for the deposition of an expert, and that Defendant accepted a 1996 date of invention through its Motion For Summary Judgment based on the on-sale bar. (D.I. 175.)

### **B. Decision**

The presumed date of invention is the date the patent application is filed, however, an earlier date of invention can be established. See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 585 F. Supp. 2d 568, 575 (D. Del. 2008) (noting the rebuttal presumption that the date of invention is the filing date). In establishing a pre-filing date of invention, a patent holder has the burden of production, but a party challenging the patent has the burden of proof. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1576 (Fed. Cir. 1996).

There is no surprise to either party that two dates of invention were potentially at issue in this litigation and will now require proof at trial. In the circumstances presented, neither party is prejudiced, and therefore, the motions of each will be denied.

### **VI. DEFENDANT'S MOTION IN LIMINE NO. 2**

The F2 similarity factor is a test used to compare the dissolution profiles of pharmaceuticals. Plaintiffs contend that the F2 similarity factor can be used to prove that the accused

product infringes on the '215 patent.

Defendant's Motion in Limine No. 2 (D.I. 155) seeks to preclude Plaintiffs from using testimony concerning the F2 similarity factor. Defendant argues that the F2 similarity factor is inappropriate in the context of evaluating infringement and contrasts with Plaintiffs' and the Court's construction of the claim term "approximately." (Id.) Also, Defendant contends that Plaintiffs did not disclose their intention to use the F2 similarity factor in a timely fashion. (D.I. 182.) Plaintiffs counter that the F2 similarity factor is an appropriate and widely accepted method of comparing dissolution rates and that they disclosed the intent to use the method as early as the first expert reports. (D.I. 176.)

In the Court's view, Plaintiffs' intention to use the F2 similarity factor as proof of infringement was brought in a timely manner. It was addressed in Plaintiffs' first expert report by Dr. Byrn. (See D.I. 176 Ex. 1.) Second, the use of the F2 similarity factor is not inconsistent with the claim term "approximately." Although the terms "approximately" and "similarity" may not be synonyms, they are not mutually exclusive terms. Thus, it is possible that the F2 similarity factor could be used in demonstrating infringement in the scope of Claim 1 as it has been construed. Lastly, Defendant's contentions on the probative value of the F2 similarity factor do not warrant the

exclusion of the test all together. Thus, Defendant's Motion will be denied.

## **VII. CONCLUSION**

For the reasons discussed, Plaintiffs' Motion In Limine No. 1 To Preclude Defendant From Relying On A Newly-Disclosed On-Sale Bar Defense (D.I. 151), No. 2 To Preclude Defendant From Introducing At Trial Argument Or Evidence Concerning Its New Non-Infringement Theory (D.I. 152), and No. 3 To Preclude Defendant From Introducing Testimony Of Dr. Chambliss At Trial Concerning The Date Of Invention Of The Patent-In-Suit Contrary To The Assumptions In His Expert Report (D.I. 153) will be denied. Additionally, Defendant's Motion In Limine No. 1 To Hold Plaintiffs To Their 30(b)(6) Testimony Concerning Date Of Invention (D.I. 154), No. 2 To Preclude Testimony Regarding The F2 Similarity Factor (D.I. 155), and No. 3 To Strike The Supplemental Expert Report Of Stephen R. Byrn And Preclude Any Related Testimony (D.I. 156) will also be denied.

An appropriate order will be entered.

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 :

**ORDER**

At Wilmington, this 9 day of March 2010, for the reasons set forth in the Memorandum Opinion issued this date;

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Plaintiffs UCB, Inc. and Celltech Manufacturing CA, Inc.'s (collectively "Plaintiffs") Motion In Limine No. 1 To Preclude Defendant From Relying On A Newly-Disclosed On-Sale Bar Defense (D.I. 151) is **DENIED**;

2. Plaintiffs' Motion In Limine No. 2 To Preclude Defendant From Introducing At Trial Argument Or Evidence Concerning Its New Non-Infringement Theory (D.I. 152) is **DENIED**;

3. Plaintiffs' Motion In Limine No. 3 To Preclude Defendant From Introducing Testimony Of Dr. Chambliss At Trial Concerning

The Date Of Invention Of The Patent-In-Suit Contrary To The Assumptions In His Expert Report (D.I. 153) is **DENIED**;

4. Defendant KV Pharmaceutical Company's Motion In Limine No. 1 To Hold Plaintiffs To Their 30(b)(6) Testimony Concerning Date Of Invention (D.I. 154) is **DENIED**;

5. Defendant's Motion In Limine No. 2 To Preclude Testimony Regarding The F2 Similarity Factor (D.I. 155) is **DENIED**; and

6. Defendants Motion In Limine No. 3 To Strike The Supplemental Expert Report Of Stephen R. Byrn And Preclude Any Related Testimony (D.I. 156) is **DENIED**.

  
UNITED STATES DISTRICT JUDGE