

DJW/bh

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

GREAT PLAINS LABORATORY, INC.,

**Plaintiff and
Counterclaim Defendant,**

CIVIL ACTION

v.

No. 04-2125-JTM-DJW

METAMETRIX CLINICAL LABORATORY,

**Defendant and
Counterclaimant,**

v.

WILLIAM SHAW,

Counterclaim Defendant.

MEMORANDUM AND ORDER

Pending before the Court is the Motion for Leave to Amend (doc. 170) filed by Defendant Metamatrix Clinical Laboratory (“Metamatrix”). For the reasons set forth below, the Court will grant the Motion.

I. Background Information

This is a patent infringement lawsuit. Plaintiff provides analytical products and services related to nutritional and metabolic testing of medical patients, including autistic patients. Plaintiff alleges that Metamatrix has infringed U.S. Patent No. 5,686,311 (“the ’311 Patent”), which is entitled “Diagnosis of Autism and Treatment Therefor.” In general terms, Patent ’311 purports to

teach a method of diagnosing autism in patients by analyzing the quantities of a limited number of specified organic acids present in bodily fluid samples.

Metamatrix seeks leave to amend its Answer to assert the affirmative defense of inequitable conduct. Metamatrix argues that recent testimony of Counterclaim Defendant Dr. William Shaw, the inventor of the '311 Patent and Plaintiff's President, supports its proposed defense. Metamatrix alleges that Plaintiff committed acts amounting to inequitable conduct by making misrepresentations and omissions of material fact, and submitting false material, to the U. S. Patent and Trademark Office ("PTO") with the intent to deceive.¹

Plaintiff filed its suit against Metamatrix on March 29, 2004. Metamatrix answered and filed a counterclaim against Dr. Shaw on July 30, 2004. Metamatrix asserted several affirmative defenses in its answer, including the affirmative defense of inequitable conduct. On September 3, 2004, Plaintiff moved to strike Metamatrix's inequitable conduct defense. Plaintiff asserted that Metamatrix had failed to plead the defense with the requisite particularity.

Metamatrix conceded in its response to the Motion to Strike that it was required to plead the inequitable conduct defense with particularity, and it withdrew the defense. It stated, however, that it was reserving the right to re-plead the defense. Noting that Metamatrix had withdrawn the defense, the Court granted Plaintiff's Motion to Strike as it applied to that particular defense.² Metamatrix represents in the instant motion that it withdrew the defense with the intention of

¹Seventh Affirmative Defense, Proposed Am. Answer, attached as Ex. A. to Metamatrix's Brief in Supp. of Mot. for Leave to Amend (doc. 172).

²See Nov. 2, 2004 Mem. and Order (doc. 40) at p.2 ("Defendant Metamatrix . . . withdraws that affirmative defense [of inequitable conduct.] Accordingly, the motion [to strike] is granted with respect to the affirmative defense of inequitable conduct.").

conducting discovery to create a formal record regarding Dr. Shaw's inequitable conduct and then seeking leave of court to reassert the defense.

On April 15, 2005, the parties held a *Markman* hearing on claim construction before the late Judge VanBebber. On September 7, 2005, Metamatrix took Dr. Shaw's deposition. Metamatrix contends that during the *Markman* hearing and particularly at his deposition, Dr. Shaw made various admissions that reveal he engaged in inequitable conduct before the PTO when prosecuting his patent.

The case was originally set for trial on December 6, 2005.³ Discovery on claim construction issues was to be completed by February 28, 2005, and all other discovery was to be commenced or served in time to be completed four months following the Court's rulings on claim construction issues.⁴ Motions to amend and/or join parties were to be filed by November 12, 2004.⁵

Following Judge VanBebber's death, the case was reassigned to the Hon. Thomas J. Marten. Thereafter, the Court, on its own motion, vacated the December 2005 trial setting. It became apparent to the Court that an additional *Markman* hearing was necessary. That second hearing was held on July 14, 2006. The Court has not yet made any rulings on claim construction issues. In addition, no new trial date has been set.

³See ¶ IV.c, Scheduling Order (doc. 37) filed Oct. 28, 2004.

⁴*Id.*, ¶ II.b.

⁵*Id.*, ¶ III.a.

II. Standard for Ruling on a Motion to Amend

Rule 15 of the Federal Rules of Civil Procedure allows a party to amend its pleading once as a matter of course before a responsive pleading is served.⁶ Subsequent amendments are allowed only by leave of court or by written consent of the adverse party.⁷ Leave to amend is to be “freely given when justice so requires,”⁸ and the Supreme Court has emphasized that “this mandate is to be heeded.”⁹ The decision to grant leave to amend, after the permissive period, is within the district court’s discretion and will not be disturbed absent an abuse of that discretion.¹⁰

Leave to amend should be denied when the court finds “undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment.”¹¹ In addition, the court may properly refuse leave to amend if a party knew or should have known of the facts upon which the proposed amendment is based but failed to include the allegations in its original pleading.¹² Finally, if the motion is filed after the Scheduling

⁶ Fed. R. Civ. P. 15(a).

⁷ *Id.*

⁸ *Id.*

⁹ *Foman v. Davis*, 371 U.S. 178, 182 (1962).

¹⁰ *Panis v. Mission Hills Bank, N.A.*, 60 F.3d 1486, 1494 (10th Cir.1995); *Woolsey v. Marion Labs., Inc.*, 934 F.2d 1452, 1462 (10th Cir. 1991).

¹¹ *Frank v. U.S. West, Inc.*, 3 F.3d 1357, 1365 (10th Cir. 1993).

¹² *Steinert v. Winn Group, Inc.*, 190 F.R.D. 680, 684 (D. Kan. 2000) (citing *State Distrib., Inc. v. Glenmore Distilleries Co.*, 738 F.2d 405, 416 (10th Cir. 1984)).

Order deadline, as here, the moving party must show good cause for allowing the amendment out of time.¹³

III. Analysis

A. Opposition to the Motion to Amend

Plaintiff and Dr. Shaw oppose Metamatrix's motion, arguing that it is untimely, as it was filed long after the Scheduling Order deadline for filing motions to amend had expired. They also argue that allowing the proposed amendment would be prejudicial and futile. Each of these arguments is discussed in detail below.

B. Timeliness of the Motion

The Scheduling Order deadline for filing motions to amend was November 12, 2004.¹⁴ Metamatrix, however, did not file its motion to amend until a year later, on November 17, 2005. As noted above, when a motion to amend is filed after the Scheduling Order deadline, the moving party must demonstrate good cause for allowing the amendment out of time.¹⁵ To establish good cause, the moving party must show that the deadline "could not have been met with diligence."¹⁶

Metamatrix asserts that it did not learn of most of the specific facts giving rise to the defense of inequitable conduct until it deposed Dr. Shaw on September 7, 2005. Metamatrix contends that Dr. Shaw made several admissions during his deposition that show he engaged in inequitable

¹³*SIL-FLO, Inc. v. SFHC, Inc.*, 917 F.2d 1507, 1518 (10th Cir.1990).

¹⁴*See* ¶ III.a, Scheduling Order (doc. 37).

¹⁵*SIL-FLO*, 917 F.2d at 1518.

¹⁶*Becerra v. Unified Gov't of Wyandotte County/Kan. City, Kan.*, 272 F. Supp. 2d 1223,1226 (D. Kan. 2003) (*quoting Denmon v. Runyon*, 151 F.R.D. 404, 407 (D. Kan. 1993)).

conduct before the PTO when prosecuting his patent, which included making various material misrepresentations and omissions.

Plaintiff and Dr. Shaw argue that Metamatrix was not diligent in deposing Dr. Shaw, and that it could have deposed him prior to the amendment deadline. It also argues that even without that deposition, Metamatrix should have learned of the alleged facts giving rise to the inequitable conduct defense through the numerous written discovery requests that Plaintiff and Dr. Shaw answered prior to the first, April 15, 2005 *Markman* hearing. At the very least, they argue, Metamatrix gained knowledge of the alleged inequitable conduct at the first *Markman* hearing, and Metamatrix should have sought leave to amend shortly after the hearing. They thus argue that Metamatrix unduly delayed in filing its Motion to Amend in November 2005.

Metamatrix counters that it would have been unrealistic to expect Metamatrix to take Dr. Shaw's deposition prior to the November 12, 2004 amendment deadline, when the Scheduling Conference did not even take place until mid-October 2004. Metamatrix also explains that it needed to engage in written discovery before it took Dr. Shaw's deposition. Furthermore, while Metamatrix concedes that it learned some of the facts upon which its defense is based at the first *Markman* hearing on April 15, 2005, it explains that a significant number of the facts giving rise to the defense were not learned until Dr. Shaw's deposition was taken on September 7, 2005.

The Court agrees with Metamatrix's position. This is a complex patent case. It was reasonable for Metamatrix to depose Dr. Shaw after comprehensive written discovery was completed and after the first *Markman* hearing was held. The Court cannot find that Metamatrix was dilatory in conducting discovery or learning of the facts giving rise to its proposed defense. The Court therefore finds that Metamatrix has shown good cause for allowing the amendment out of time.

C. Prejudice

Prejudice under Rule 15 means “undue difficulty” in defending or prosecuting a lawsuit because of a change of tactics or theories on the part of the other party.¹⁷ The party opposing the amendment has the burden of showing prejudice.¹⁸

Plaintiff and Dr. Shaw assert that they will be prejudiced by the amendment because it will divert the court from the genuine issues in this case and spawn unnecessary, satellite litigation. The Court is not persuaded by this conclusory argument. Nothing in the record leads the Court to believe that the proposed allegations of inequitable conduct are spurious or totally unfounded. Moreover, in the context of a motion to amend, the issue is not whether Metamatrix *will prevail* on its inequitable conduct defense, but whether Metamatrix should be given *the opportunity to present evidence* to support its defense. At the close of discovery, Plaintiff and Dr. Shaw will have the opportunity to file a motion for summary judgment if they believe the evidence does not support Metamatrix’s allegations. at that time, the Court can decide—based on a fully developed record—whether the defense has merit.

Plaintiff and Dr. Shaw next argue that granting Metamatrix leave to amend at this stage of the litigation will effectively deprive them of the opportunity to prepare an effective response to the charges of fraud and inequitable conduct made against them. The Court also finds this argument unpersuasive. Plaintiff and Dr. Shaw were put on notice of this defense in Metamatrix’s initial

¹⁷*Acker v. Burlington N. and Santa Fe R. Co.*, 215 F.R.D. 645, 654 (D. Kan. 2003); *Heslop v. UCB, Inc.*, 175 F. Supp. 2d 1310, 1313 (D. Kan. 2001) (citing *LeaseAmerica Corp. v. Eckel*, 710 F.2d 1470, 1474 (10th Cir. 1983)).

¹⁸*Acker*, 215 F.R.D. at 654; *Schmitt v. Beverly Health and Rehab. Serv’s, Inc.*, 993 F. Supp. 1354, 1365 (D. Kan. 1998) (citing *Beeck v. Aquaslide ‘N’ Dive Corp.*, 562 F.2d 537, 540 (8th Cir. 1977)).

answer. They were also aware, when Metamatrix withdrew the defense, that Metamatrix intended to seek leave to re-plead the defense after it conducted discovery. Moreover, to the extent Plaintiff and Dr. Shaw need to conduct discovery into these allegations, there will be ample time for them to do so. Judge Marten has yet to issue a ruling on any claim construction issues. When that ruling is forthcoming, the parties will have four months to conduct discovery.¹⁹ Finally, neither the pretrial conference nor the trial has been scheduled, and no dispositive motion deadline has been set.

In light of the above, the Court finds that Plaintiff and Dr. Shaw should have sufficient time to conduct discovery regarding these allegations of inequitable conduct and to prepare for the pretrial conference and trial. The Court therefore fails to see how allowing Metamatrix to amend its answer at this point in the litigation would deprive either Plaintiff or Dr. Shaw of the opportunity to defend against these allegations. In sum, the Court finds that Plaintiff and Dr. Shaw have failed to meet their burden to show how the proposed amendment would prejudice them.

D. Futility

Plaintiff and Dr. Shaw argue that Metamatrix's motion should be denied because allowing Metamatrix to amend would be futile. They assert that the proposed allegations of inequitable conduct are based on Dr. Shaw's claimed failure to provide information to the PTO regarding the *treatment* of autistic patients. They argue that the *treatment* of autism, however, is not covered by the claims of the '311 patent. Rather, the '311 patent covers only the *diagnosis* of autism. Thus, according to Plaintiff and Dr. Shaw, Metamatrix's proposed allegations cannot give rise to a valid defense of inequitable conduct.

¹⁹See ¶ II.b, Scheduling Order (doc. 37).

Metamatrix counters that the Court has yet to make any rulings regarding claim construction. Accordingly, any assertion that the treatment of autism is not covered by the claims of the '311 patent is premature. The Court agrees, and cannot find, at least at this stage in the litigation, that the proposed amendment would be futile.

IV. Conclusion

The Court does not find that Metamatrix's proposed amendments are futile or that Plaintiff and Dr. Shaw will be unduly prejudiced if amendment is allowed. Moreover, the Court finds that Metamatrix has shown good cause for filing its motion after the expiration of the Scheduling Order deadline. Heeding the mandate that leave to amend should be freely given, the Court will grant Metamatrix leave to amend its answer to plead the affirmative defense of inequitable conduct.

In light of the above, the Court grants Metamatrix's Motion for Leave to Amend (doc. 170). Metamatrix shall file its First Amended Answer and Counterclaims within **ten (10) days** of the date of this Order.

IT IS THEREFORE ORDERED that Metamatrix's Motion for Leave to Amend (doc. 170) is granted. Metamatrix shall file its First Amended Answer and Counterclaims within **ten (10) days** of the date of this Order.

IT IS SO ORDERED.

Dated in Kansas City, Kansas on this 11th day of September 2006.

s/David J. Waxse
David J. Waxse
U.S. Magistrate Judge

cc: All counsel and *pro se* parties