UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY

EDWARD L. ABNEY, BARBARA ALLEN, JAMES DAY, ROBERT GREEN, DELBERT JACKSON, JAMES PUGH, ROGER THACKER, and DANIEL HUNTER WEBSTER,	:	Docket No.: 5:05-254
Plaintiffs,	:	
v.	:	
AMGEN, INC., a Delaware Corporation,	:	
Defendant.	:	A Civil Action

PLAINTIFFS' BRIEF IN OPPOSITION TO THE DEFENDANT'S MOTION TO STAY

I. INTRODUCTION

Edward Abney, Barbara Allen, James Day, Robert Green, Delbert Jackson, James Pugh, Roger Thacker, and Daniel Webster, the plaintiffs in this matter (collectively, "plaintiffs"), by and through their counsel, Alan C. Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A. and Debra Doss of The Law Offices of Debra Doss, respectfully submit this brief in opposition to the motion to stay that has been filed by Amgen, Inc., the defendant in this matter ("Amgen").

In its motion, Amgen posits that, "in the interest of juridical economy," this case should be stayed pending the disposition of an appeal in another case, Robert Suthers and Niwana Martin v. Amgen, Inc. ("Suthers").[1] Its position is predicated upon its contention that the Suthers case and this case possess "extreme similarities," that the appeal in the Suthers case will

[1] See Defendant's Motion to Stay and Supporting Memorandum ("Defendant's Motion"), ¶ 11.

be disposed of quickly by the Second Circuit, and that the plaintiffs "have waited almost ten months since the GDNF study was discontinued to file this lawsuit."[2]

Amgen's position is without merit. Suthers was a case filed in the United States District Court for the Southern District of New York ("Southern District") by two enrollees in the clinical trial at issue. Those two enrollees were being treated by different doctors in New York, and they both signed a different informed consent form than the plaintiffs herein did and brought claims under New York law. On June 6, 2005, the Honorable P. Kevin Castel, U.S.D.J. ("Judge Castel") entered an Order denying those individuals' motion for a preliminary injunction, and, subsequently, those individuals took an appeal from this Order. Although they moved for an expedited appeal, delays have occurred in the case, the Second Circuit has neither ruled on their motion for an expedited appeal nor indicated when it will entertain oral argument on and decide the merits of their appeal.

Predicated upon the foregoing, Amgen's motion must be denied, and the hearing that is scheduled to occur at 10:00 a.m. on Tuesday, July 5, 2005 should proceed as currently scheduled.

II. STATEMENT OF FACTS

A. Suthers and Abney Are Completely Different Cases

In 2003, Amgen sponsored a placebo-controlled Phase II trial involving approximately thirty-four patients at multiple sites, including New York University Downtown Hospital ("NYU Hospital"), University of Chicago Hospital, the University of Kentucky, and Frenchay Hospital.[3] Robert Suthers ("Mr. Suthers"), Niwana Martin ("Ms. Martin"), and the other individuals who enrolled in the trial at the NYU Hospital site were treated by Michael Hutchinson, M.D., Ph.D.,

[2] See Defendant's Motion, ¶ 11.
[3] See Complaint, ¶ 27.

who embodied Amgen to them.[4] By contrast, the plaintiffs herein, as well as the other individuals who enrolled in the trial at the University of Kentucky site were treated by John Slevin, M.D., Byron Young, M.D., Don M. Gash, Ph.D., and Greg Gerhardt, Ph.D., who embodied Amgen to them.[5]

Mr. Suthers, Ms. Martin, and the other individuals participating in the trial at NYU Hospital signed one form of an informed consent document ("New York ICD"); by contrast, the plaintiffs herein signed a different informed consent document ("Kentucky ICD").[6] The New York ICD and the Kentucky ICD differ in at least two critical respects.

First, the New York ICD only implicitly provided that the patients enrolled at the NYU Hospital site could choose to receive GDNF after the termination of the trial; by contrast, the Kentucky ICD explicitly promised the patients who enrolled at the University of Kentucky site that they could elect to participate in an "extended treatment period" that would last for twenty-four months after the end of the trial.[7] Indeed, the Kentucky ICD stated in boldface print that

> **4. Extended Treatment Period: Starting at week 28 you may elect to continue treatment for up to an additional 24 months. If you elect to continue treatment the procedures listed for week 33 will be done approximately 1 month after the conclusion of the extended treatment period.**
>
> *** * * ***
>
> **If you elect to receive extended treatment, you will be required to visit the Medical Center monthly for the 24-month duration of the extended treatment period.**[8]

Second, the New York ICD provided that "[t]he Principal Investigator may also decide to

---

[4] See Complaint, ¶ 27 and Hutchinson Cert. cited therein.

[5] See Complaint, ¶ 28.

[6] Compare Complaint, Exhibit E (Kentucky ICD) with Complaint, Exhibit V (New York ICD).

[7] See Complaint, Exhibit E, page 2; see also Complaint, Exhibit V.

[8] See Complaint, Exhibit E, page 2 (emphasis in original). The duration of the study itself was approximately "41 weeks." See Complaint, Exhibit E, page 2.

withdraw you from the study under certain circumstances, [including] termination of the study by the sponsor," Amgen; by contrast, the Kentucky ICD provided that "[t]he individuals conducting the study may need to withdraw you from the study "if they find that your being in the study is more risk than benefit to you, if you are not able to follow the directions they give your or if the agency funding the study decides to stop the study early for a variety of scientific reasons."[9] (emphasis supplied) It is clear that Amgen is not the "agency funding the study." Rather, Amgen is, to quote its description of itself on the very first page of the Kentucky ICD, the "sponsor of [the] study."[10] According to Black's Law Dictionary, an "agency" is "[a] governmental body with the authority to implement and administer particular legislation."[11]

If Amgen, whose representatives drafted the Kentucky ICD, had wanted to advise the plaintiffs that Amgen could "decide[] to stop the study early for a variety of scientific reasons," it would have done so by using the language from the New York ICD in the Kentucky ICD.[12] Thus, this case differs markedly from the New York case because here alone Amgen expressly promised that the plaintiffs would receive GDNF for at least twenty-four months after the conclusion of the clinical trial absent one of three events: (1) the Kentucky doctors decided GDNF poses greater risk than benefit, (2) the plaintiffs were not able to follow the directives of the Kentucky doctors or (3) the "agency" funding the study decided to stop it for scientific

[9] See Complaint, Exhibit E, page 15 (emphasis added); see also Complaint, Exhibit V, page 20 (emphasis added).

[10] See Complaint, Exhibit E, page 1 (emphasis added) (providing that "[t]he sponsor of this study is Amgen, Inc. The people in charge of this study are Dr. John Slevin, MD, of Neurology, and Dr. Byron Young, MD, of Neurosurgery.").

[11] See Black's Law Dictionary, 8th ed., Agency.

[12] Cf. Simon v. Cont'l Ins. Co., Ky., 724 S.W.2d 210, 212-13 (Ky. 1995) (reiterating the legal precept that "ambiguities should be resolved against the drafter" of a document).

reasons.[13] None of those events occurred here.

B. ***It is not at all clear that the appeal in Suthers will be resolved quickly.***

On April 26, 2005, Mr. Suthers and Ms. Martin, who were woefully ill, filed a Complaint against Amgen in the Southern District.[14] On the same date, they filed a motion for a preliminary injunction. In their motion, they sought a Court Order directing Amgen to provide the plaintiffs with GDNF on an interlocutory basis in light of their likelihood of success on their breach of contract, promissory estoppel, and breach of fiduciary duty claims.

Thereafter, on May 6, Judge Castel signed an Order to Show Cause providing that Amgen was to show cause why a preliminary injunction should not issue. On May 26, Judge Castel entertained oral argument on the issue of whether a preliminary injunction should issue. Ten days later, on June 6, Judge Castel signed a twenty-one page Memorandum and Order, ruling that, under New York law, Mr. Suthers and Ms. Martin were unentitled to preliminary injunctive relief. His decision was unpublished.

The next day, on June 7, a notice of appeal and accompanying papers were sent to the District Court via Federal Express-Overnight Delivery. A few days later, a Motion for an Expedited Appeal was filed with the Clerk of the Second Circuit Court of Appeals. In their motion papers, Mr. Suthers and Ms. Martin sought to make the motion returnable on June 21 and, predicated upon their motion being made returnable on that date, sought a due date of July 5 for their opening brief, a due date of July 18 for Amgen's opposition brief, and a due date of July 22 for their reply brief. Amgen consented to these dates.

Unfortunately, the notice of appeal was mislaid in the Clerk's Office, and it was not filed

---

[13] See Complaint, Exhibit E, page 15 (emphasis added); see also Complaint, Exhibit V, page 20 (emphasis added).

[14] This Court is empowered to take judicial notice of docket entries. See generally Fed. R. Evid. 201.

until last week, at which juncture it was retroactively filed to June 8, 2005. Presumably due to the confusion surrounding the misplaced notice of appeal, the motion was not made returnable on June 21. As a result, counsel wrote to the appropriate individuals at the Second Circuit requesting the dates be pushed back one month, with Mr. Suthers and Ms. Martin's opening brief now being due August 5, 2005, Amgen's opposition brief now being due August 18, 2005, and the appellant's reply brief, if any, now being due August 22, 2005.

III. LEGAL ARGUMENT

As previously stated, Amgen argues that this case should be stayed because the Suthers case and this case possess "extreme similarities," because the appeal in the Suthers case will be disposed of quickly by the Second Circuit, and because the plaintiffs "have waited almost ten months since the GDNF study was discontinued to file this lawsuit."[15] These arguments are non-starters; absolutely no grounds justifying the issuance of a stay exist. As such, Amgen's motion must be denied and the motion for a preliminary injunction must proceed according to schedule.

A. Suthers and Abney Are Completely Different Cases

Amgen first argues that this case should be stayed on the ground that Suthers is similar to it.

This argument fails. As set forth above, though both Suthers and this case involve a Phase II trial of GDNF, the similarities end there. Suthers involved two individuals who enrolled in the trial in the State of New York. Those individuals signed the New York ICD, which only contained an implicit promise that they would be able to continue to receive GDNF, and which Judge Casted held allowed Amgen the right to terminate the trial at its whim. Those individuals sought relief under New York law in a New York court, and an unpublished, non-precedential memorandum opinion and Order resulted. By contrast, this case involves eight individuals who

[15] See Defendant's Motion, ¶ 11.

enrolled in the trial in the Commonwealth of Kentucky. Those individuals signed the Kentucky ICD, which contained an explicit promise that they would be able to continue to receive GDNF for twenty-four months following the trial, and which clearly stated that only some undefined "agency," by contrast to Amgen, had the right to terminate the trial, unless the Kentucky doctors decided the risks outweighed the benefits. Here the Kentucky doctors have testified by certification that the benefits far outweigh the risks.

Even if Suthers and this case involved the same state law, the same location, the same doctors, and the same informed consent document, a stay would still be inappropriate. Judge Castel's memorandum opinion is not entitled to be accorded any precedential value, both by virtue of its status as an unpublished opinion and by virtue of its status as an opinion rendered in a different district.[16] It neither adjudicated nor purported to adjudicate the rights of the plaintiffs in this case.

In sum, Amgen's argument that this case should be stayed on the ground that Suthers is similar to it must fail.

B. It is not at all clear that the appeal in Suthers will be resolved quickly.

Amgen then argues that this case should be stayed on the ground that the appeal that has been filed in the Suthers case will be resolved quickly.

This argument fails as well. Neither Amgen, nor the plaintiffs here, nor the plaintiffs in Suthers can predict when the Second Circuit will resolve the appeal of Judge Castel's Order. This is especially true in the light of the misplacement of the notice of appeal and the resulting delay in the calendaring of the motion for an expedited appeal. Even if briefing were to be

[16] See, e.g., Kentucky Resources Council, Inc. v. Babbitt, 997 F. Supp. 814 (E.D.Ky. 1998) (citing Brown v. Crowe, 963 F.2d 895, 897 n.2 (6th Cir. 1992)). Moreover, Amgen has not contended that Judge Castel's opinion is entitled to weight by virtue of res judicata principles, nor can it.

closed by July 18, there is no telling when the Court of Appeals would choose to entertain oral argument and when it would choose to rule.

In fact, even if the Second Circuit were scheduled to rule on July 6, there would still be no a justification for a stay to be issued in this case. As has been made clear, this case is distinct from the Suthers case in a number of important ways. The eventual ruling of the Second Circuit will in no way affect this case, because the Second Circuit will be reviewing Judge Castel's decisions regarding New York law, the promises made by Amgen to the New York enrollees, and the New York ICD. By contrast, this Court is considering Kentucky law, the separate and distinct promises made by Amgen to the Kentucky enrollees, and the Kentucky ICD.

In sum, Amgen's argument that this case should be stayed on the ground that the appeal that has been filed in the Suthers case will be resolved quickly must fail.

C. The plaintiffs' alleged "delay" in bringing this suit is not a ground for a stay.

Finally, Amgen argues that this case should be stayed on the ground that the plaintiffs delayed in bringing this case. This argument is not only meritless, it flies in the face of what Amgen knows to be the truth. As soon as Amgen unilaterally decided to stop providing the lifesaving GDNF, plaintiffs and their family members – and, remarkably, the Kentucky doctors and their institution – tried every means possible to get the company to reverse the decision. They wrote letters, signed petitions, sought the help of Parkinson's support groups, wrote to Congress, appeared on national television, and established a website explaining their case; in short they begged and pleaded with Amgen to give them the only drug that offered hope and a real chance to live their life. Only when their efforts failed did they resort to the courts.

In any event, no authority holds or even suggests, and Amgen has cited no authority holding or suggesting, that a motion for a preliminary injunction should be stayed because the party seeking the motion allegedly delayed in bringing suit. Amgen is free to raise this defense

at the hearing, and the plaintiffs are prepared to refute it in its entirety. This defense, however, is no ground for a stay.

D. Conclusion

The plaintiffs intend to demonstrate at the hearing on their motion for a preliminary injunction that they are entitled to receive GDNF at this juncture on the basis that Amgen committed breach of contract and breach of fiduciary duty and the basis that Amgen is liable on a promissory estoppel theory. The plaintiffs are in need of relief now, as opposed to at an indeterminate point of time in the future after the appeal of an unrelated case is resolved. Absolutely no legal, equitable, or ethical grounds exist for consigning them to that fate.

In sum, this Court should deny Amgen's motion for a stay and allow the hearing to proceed as scheduled on July 5, 2005.

Dated: Thursday, June 30, 2005

Alan C. Milstein - Admission Pending
Sherman, Silverstein, Kohl,
Rose & Podolsky, P.A.
Fairway Corporate Center
4300 Haddonfield Road, Suite 311
Pennsauken, NJ 08109
Telephone: 856-662-0700
Facsimile: 856-488-4744
E-Mail: AMilstein@sskrplaw.com

Debra Doss
The Law Offices of Debra Doss
108 Pasadena Drive, Suite 200
Lexington, KY 40503
Telephone: 859-260-1980
Facsimile: 856-260-1310

Attorneys for the Plaintiffs