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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNIVERSITY OF KANSAS CENTER FOR RESEARCH, INC.,	)	
Plaintiff,	)	
vs.	)	**Case No. 08-2565-JAR**
UNITED STATES OF AMERICA, represented by the DEPARTMENT OF HEALTH AND HUMAN SERVICES, by and through its agents the NATIONAL INSTITUTES OF HEALTH and the NATIONAL CANCER INSTITUTE,	)	
Defendant.	)	

MEMORANDUM AND ORDER

Now before the Court are movant Centocor Ortho Biotech Products, L.P.'s Motion to Intervene (Doc. 26) and movant Millennium Pharmaceuticals, Inc.'s Motion to Intervene (Doc. 36). Defendant United States of America has filed a brief in support of both parties' motions to intervene (Doc. 53). Plaintiff filed a Response (Doc. 54), opposing only movant Centocor Ortho Biotech Products, L.P.'s motion to intervene. Both movants and defendant have filed replies (Docs. 55, 56, 62). The Court does not find that oral argument would materially assist it in the resolution of these motions. The Court has reviewed the record submitted on the briefs and is prepared to rule. Neither party opposes movant Millennium Pharmaceuticals, Inc.'s motion, and the Court finds that intervention is appropriate. As described more fully below, the Court also grants Centocor Ortho Biotech Products, L.P.'s motion.

I. Background

Plaintiff Kansas University Center for Research, Inc. ("KUCR") filed this action on November 12, 2008, seeking correction of inventorship of U.S. Patent Numbers 6,713,446 ("the '446 patent") and 6,958,319 ("the '319 patent") (collectively "the patents-in-suit") under 35 U.S.C. § 256. KUCR filed an Amended Complaint on January 28, 2009 (Doc. 15). On March 2, 2009, the United States filed its Answer (Doc. 19).

Each of the patents-in-suit is currently owned by the United States as represented by the Department of Health and Human Services. Dr. Shanker Gupta is the only named inventor on the patents-in-suit. KUCR seeks to add Dr. Valentino Stella and Ms. Wanda Waugh as co-inventors of the patents-in-suit. On May 4, 2009, prior to any planning meeting or scheduling conference, KUCR filed a Motion for Partial Summary Judgment (Doc. 22), seeking to add Dr. Valentino Stella as an inventor to the '446 and the '319 patents.

The patents-in-suit cover the formulation of bortezomib, sold as VELCADE®. VELCADE® is a first-in-class drug approved in the United States for the treatment of multiple myeloma patients and mantle cell lymphoma patients who have received at least one prior therapy.

Millennium Pharmaceuticals, Inc. ("MPI") has exclusively licensed the '446 and '319 patents from the National Institutes of Health ("NIH"). The drug has been used to treat more than 100,000 patients and clinical trial participants, including the participants in over 200 MPI-sponsored or supported clinical trials. VELCADE® received its first marketing approval in the United States in 2003, and is currently approved in more than 85 countries. In 2008, VELCADE® revenues represented approximately 85% of MPI's total revenues. To date, MPI

and its affiliates have invested significant scientific and business resources, totaling more than $900 million, in the development and marketing of VELCADE®, MPI's main product.

MPI is the assignee of six patents covering bortezomib, all of which are identified in the VELCADE® listing in the Orange Book published by United States Food and Drug Administration ("FDA"). MPI has an exclusive worldwide license to, *inter alia*, make, use, and sell the VELCADE® formulation of its bortezomib drug under the '446 and '319 patents from their sole owner, the United States. Under its license to the patents-in-suit, MPI sells VELCADE® in the United States.

On June 30, 2003, MPI and Centocor Ortho Biotech Products, L.P. ("COBI") entered into a Collaboration, Distribution, and License Agreement ("the Agreement"). In the Agreement, COBI received, among other rights, a non-exclusive sublicense to develop VELCADE® in the United States and an exclusive sublicense to commercialize VELCADE® worldwide, except for the United States. COBI and its affiliates have spent more than $500 million in testing, marketing, manufacturing, labeling, and distributing VELCADE®. Starting in 2003, COBI and its affiliates devoted substantial resources to obtain regulatory approval to make VELCADE® available to patients to treat certain types of cancer. COBI's development and commercialization efforts have taken place in 86 countries, including the European Union countries, China, and Japan. COBI and its affiliates currently have some 400 employees working on VELCADE® and have approximately 100 ongoing clinical studies. Many cancer patients have benefitted from the efforts of COBI and MPI to develop and commercialize VELCADE®. Approximately 50,000 of the more than 100,000 cancer patients treated with VELCADE® were treated outside the United States with VELCADE® products made available

from COBI.

On May 4, 2009, KUCR requested that the European Patent Office ("EPO") suspend grant proceedings on the European pending counterpart to the patents-in-suit in this litigation, on the grounds that a ruling by this Court that is favorable to KUCR would automatically grant KUCR a co-ownership interest in the claims pending in that application. MPI, COBI, and the United States each opposed the request for suspension. KUCR's request was denied by the EPO on May 14, 2009. COBI filed its motion to intervene in this case on May 19, 2009. On May 21, 2009, MPI filed its motion to intervene.

II. Analysis

Under Rule 24(a)(2), on timely motion, the Court

> *must* permit anyone to intervene who . . . (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.[1]

Even if the Court determines that intervention as of right is not appropriate, the Court may permit anyone on timely motion to intervene under Rule 24(b)(1), who "(B) has a claim or defense that shares with the main action a common question of law or fact," and after considering whether the intervention "will unduly delay or prejudice the adjudication of the original parties' rights."

The parties do not dispute that MPI should be allowed to intervene in this matter but do dispute whether COBI should be allowed to intervene. COBI and the United States maintain that COBI is entitled to intervene as a matter of right, or alternatively, that the Court should permit it

[1]Fed. R. Civ. P. 24(a)(2) (emphasis added).

to intervene under Rule 24(b)(1). KUCR contends that COBI is not entitled to either mandatory or permissive intervention.

A. MPI's Motion

The Court finds that MPI must be allowed to intervene under Rule 24(a)(2). For the same reasons discussed under the Court's analysis of COBI's motion, the motion was timely filed. The Court also finds that MPI claims an interest relating to the patents-in-suit that are the subject of this action. This case seeks to add certain parties as inventors to the patents-in-suit. MPI has exclusively licensed the '446 and '319 patents from the NIH and has invested a substantial amount of money to develop and market VELCADE® in the United States. This interest as an exclusive licensee may be impaired by the disposition of this lawsuit.[2] The Court also finds that MPI's interest cannot be adequately represented by the United States. While the defendant and MPI share the common objective of maintaining the validity of the patent by sustaining the single inventorship of Dr. Gupta, the government's commercial and proprietary interests differ from MPI's. The government has a much smaller financial stake in the outcome of this litigation, as it does not manufacture or sell the drug, while MPI relies on sales of the drug for much of its revenue. Moreover, the government has an interest in the impact of inventorship on its various research and development collaborations, while MPI's interests are commercial in nature. Furthermore, MPI has asserted in its proposed Answer the defense of laches, a defense not asserted by the government.[3] For all of these reasons, the Court finds that the MPI has met

[2]*See Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir. 1997).

[3]*Isr. Bio-Eng'g Project v. Amgen, Inc.*, 401 F.3d 1299, 1306 (Fed. Cir. 2005) (finding that because a laches defense is personal to the defendant raising it, the existing defendant could not adequately represent the intervenor's interest in seeking to assert this defense).

its minimal burden of showing the possibility of inadequate representation.[4]

B. COBI's Motion to Intervene as of Right

The Court must allow intervention as a matter of right if (1) the application is timely, (2) the movant "claims an interest relating to the property or transaction that is the subject of the action,"[5] (3) the movant's interest "may as a practical matter" be "impair[ed] or impede[d],"[6] and (4) the movant's interest is not adequately represented by the existing parties.[7]

1. Timeliness

The Court evaluates timeliness "in light of all the circumstances, including the length of time since the applicant knew of his interest in the case, prejudice to the existing parties, prejudice to the applicant, and the existence of any unusual circumstances."[8] KUCR does not argue that COBI's motion to intervene is untimely. The Court easily concludes that the motion is timely. No scheduling order has been entered in this matter; therefore, no deadlines have been imposed for discovery or otherwise. While it appears that discovery has begun in this case, it is still very early in the process. Furthermore, the Court is unable to find that any delay in filing the motion to intervene will prejudice the existing parties.[9] While KUCR has filed a motion for

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[4]*See WildEarth Guardians v. United States Forest Serv.*, –F.3d–, No. 09-1089, 2009 WL 2195790, at *3–4 (10th Cir. July 24, 2009) (explaining the minimal burden of the intervenor and emphasizing that the portion of the lead opinion on the presumption of adequate representation in *San Juan Cty v. United States*, 503 F.3d 1163 (10th Cir. 2007) (en banc) was only joined by three members of en banc court).

[5]*Id.*

[6]*Id.*

[7]*E.g.*, *Utah Ass'n of Counties v. Clinton*, 255 F.3d 1246, 1249 (10th Cir. 2001).

[8]*Id.* at 1250 (quotation omitted); *see also SEC v. Broadbent*, 296 F. App'x 637, 639 (10th Cir. 2008), *cert. denied*, 129 S. Ct. 1323 (2009).

[9]*See Utah Ass'n of Counties*, 255 F.3d at 1250 ("The prejudice prong of the timeliness inquiry 'measures prejudice caused by the intervenor' delay—not by the intervention itself.'") (quoting *Ruiz v. Estelle*, 161 F.3d 814, 828 (5th Cir. 1998)).

partial summary judgment, the response and reply deadlines associated with that motion have been stayed pending resolution of the motions to intervene. KUCR's summary judgment motion does not seek complete relief and was filed prior to any discovery being conducted. Under these circumstances, there is no prejudice to the existing parties in allowing intervention at this early stage of the case.

2. Impairment of Interest

In evaluating both COBI's interest and the impairment of that interest, the Court is mindful that Rule 24(a)(2) requires analysis of the specific circumstances of this case; it is not a mechanical rule.[10] "The central concern in deciding whether intervention is proper is the practical effect of the litigation on the applicant for intervention."[11] The movant must show "only that impairment of its substantial legal interest is possible if intervention is denied. The burden is minimal."[12]

KUCR argues that COBI lacks a sufficient interest in the patents-in-suit because its commercial interests are solely outside the United States. KUCR points to the fact that the sublicensing agreement between MPI and COBI only provides COBI with exclusive commercialization rights outside the United States; COBI is only licensed to "develop" VELCADE® in the United States, which is not a sufficient proprietary interest in the patents-in-suit.

If KUCR is successful in this litigation, it could impact MPI's exclusive license for

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[10]*San Juan Cty v. United States*, 503 F.3d 1163, 1199 (10th Cir. 2007) (en banc).

[11]*Id.* at 1193; *WildEarth Guardians v. United States Forest Serv.*, –F.3d–, No. 09-1089, 2009 WL 2195790, at *2 (10th Cir. July 24, 2009).

[12]*WildEarth Guardians*, 2009 WL 2195790, at *2.

VELCADE® , which in turn, would effect any exclusive sublicensing arrangement granted to COBI by MPI. The practical effect of such a result would mean that COBI may not continue to have exclusive rights to commercialize VELCADE® outside the United States, which would significantly affect its revenue. The record reflects that COBI and its affiliates have spent more than $500 million in testing, marketing, manufacturing, labeling, and distributing VELCADE® and that they have devoted substantial resources to obtain regulatory approval to make VELCADE® available to patients to treat certain types of cancer. The record also shows that COBI and its affiliates currently have some 400 employees working on VELCADE® and have approximately 100 ongoing clinical studies. "'The threat of economic injury from the outcome of litigation undoubtedly gives a petitioner the requisite interest.'"[13] Given this economic stake in the subject of the litigation, the Court finds that COBI is able to establish that it has an interest in the litigation that will possibly be impaired if intervention is denied.[14]

3. Adequate Representation

The Court has already found that the government would not adequately represent MPI's interests and, for the same reasons, finds the government would not adequately represent COBI's interests. The Court must also consider whether COBI's interests could be adequately represented by MPI. "'An intervenor need only show the *possibility* of inadequate representation.'"[15] COBI argues that it is the only party at risk of losing the right to commercialize VELCADE® in certain foreign countries if KUCR prevails in this litigation. The

[13]*Id.* (quoting *Utahns for Better Transp. v. United States Dep't of Transp.*, 295 F.3d 1111, 1115 (10th Cir. 2002)).

[14]*Id.* at *3.

[15]*Id.* (quoting *Utah Ass'n of Counties v. Clinton*, 255 F.3d 1246, 1254 (10th Cir. 2001) (emphasis added)).

intervenors and the government also argue that their interests may diverge if KUCR prevails, as MPI and COBI may not agree on whether the licensing agreement with the government should be challenged or enforced and because COBI could potentially assert claims against MPI under their Agreement. Finally, COBI points to its affirmative defense of laches, which is personal to the party raising it.[16] The Court finds that all of these reasons establish COBI's minimal burden of showing the possibility that its interests will not be adequately represented by an existing party.[17] Because COBI has established all of the requirements under Rule 24(a)(2), the Court must allow it to intervene.

C. COBI's Motion for Permissive Intervention

COBI urges this Court, in the alternative, to allow it to intervene under Rule 24(b). Even if COBI was not allowed to intervene as of right, the Court would exercise its discretion and allow it to intervene permissively. As discussed above, COBI shares a common defense with the defendants in this litigation, as it seeks to ensure that Dr. Gupta remains the sole inventor of the patents-in-suit. The Court has also determined that the motion is timely and that COBI's interests may not be adequately represented by the government and MPI. Also, KUCR has not made a sufficient showing of undue delay or prejudice if COBI is permitted to intervene. The motion to intervene was timely—it was filed before a scheduling conference was conducted and before discovery had commenced.[18] KUCR's only other claim of prejudice stems from the

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[16]*See Isr. Bio-Eng'g Project v. Amgen, Inc.*, 401 F.3d 1299, 1306 (Fed. Cir. 2005).

[17]*See Utah Ass'n of Counties*, 255 F.3d at 1254.

[18]KUCR complains that the parties had an informal agreement to have the case ready for trial by February 2010. This agreement was never reduced to a scheduling order by the Court, nor will the case be significantly off track as a result of the motions to intervene. The parties conducted some discovery while these motions to intervene have been pending and KUCR's early partial motion for summary judgment apparently required no discovery. Under these circumstances, the Court is unable to find undue delay.

"inefficiency" associated with the fact that COBI has limited knowledge of the events surrounding the inventorship dispute and; thus, intervention would only add "yet another law firm" to this litigation. But the Court agrees with COBI that having to litigate against another party does not constitute prejudice.[19] Accordingly, the Court would allow COBI to intervene in this matter under Rule 24(b).

IT IS THEREFORE ORDERED BY THE COURT that Centocor Ortho Biotech Products, L.P.'s Motion to Intervene (Doc. 26) and Millennium Pharmaceuticals, Inc.'s Motion to Intervene (Doc. 36) are **granted**.

IT IS SO ORDERED.

Dated: September 2, 2009

S/ Julie A. Robinson
JULIE A. ROBINSON
UNITED STATES DISTRICT JUDGE

[19]*See, e.g., Techcapital Corp. v. Amoco Corp.*, No. 99 CIV 5093(AGS), 2001 WL 267010, at *3 (S.D.N.Y. Mar. 19, 2001).