

DJW/1

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

**UNIVERSITY OF KANSAS
CENTER FOR RESEARCH, INC.,**

Plaintiff,

Civil Action

v.

No. 08-2565-JAR-DJW

**THE 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,

and

**CENTOCOR ORTHO BIOTECH
PRODUCTS, L.P., et al.,**

Intervenor-Defendants.

MEMORANDUM AND ORDER

Plaintiff brings this action under United States patent laws to correct the inventorship of two patents. Pending before the Court are the parties' Cross Motions for Protective Order (doc. 131 & 133). For the reasons set forth below, the Court grants each Cross Motion in part. The Court will enter the Protective Order, as modified by the Court, in a separate filing.

I. Nature of the Matter Before the Court

A. Background Information

This case arises under the patent laws of the United States (35 U.S.C. § 256) and concerns the correction of inventorship for United States Patent Nos. 6,713,446 and 6,958,319 (collectively

the “patents in suit”). The following facts have been gleaned from the parties’ pleadings, including the briefing on the instant Cross Motions, Plaintiff’s Amended Complaint, Defendant’s Answer, and the briefing on Intervenor Defendants’ Motions to Intervene.

Plaintiff, the University of Kansas Center for Research (“KUCR”), is a not-for-profit corporation that is related to the University of Kansas. KUCR is charged with applying, improving, and increasing the resources of the University of Kansas for research, advanced instruction, and public service. Defendant, the United States of America, as represented by the Secretary of the Department of Health and Human Services, by and through its agents the National Institutes of Health (“NIH”) and the National Cancer Institute (collectively the “United States”), is the owner of the patents in suit. Dr. Shanker Gupta, an employee of the United States, is the only named inventor of the patents in suit.

KUCR claims that each of the patents in suit includes one or more claims containing significant inventive contributions of Dr. Valentino Stella and Ms. Wanda Waugh. It further asserts that Dr. Stella and Ms. Waugh assigned their ownership rights in those inventive contributions to the University of Kansas, who in turn assigned the ownership rights to KUCR. In addition, KUCR contends that despite the fact that Dr. Stella and Ms. Waugh are rightfully co-inventors of claimed features of the patents in suit, they were inadvertently and without deceptive intent not named as inventors on the patent applications.

One or more claims of the patents in suit cover formulations for, or methods for formulating, the drug VELCADE®, which is a cancer drug currently sold by Millennium Pharmaceuticals, Inc. (“Millennium”). Millennium has exclusively licensed the patents in suit from NIH. Centocor Ortho Biotech Products, L.P. (“COBI”) has a non-exclusive sublicense to develop VELCADE® in the

United States and an exclusive sublicense to commercialize VELCADE® worldwide, except for the United States. Millennium and COBI (“Intervenor Defendants”) have been granted leave to intervene as Defendants

KUCR seeks a declaratory judgment that Dr. Stella and Ms. Waugh are co-inventors of the patents in suit. KUCR also asks the Court to issue an order directing the Commissioner of Patents to add both Dr. Stella and Ms. Waugh as co-inventors of the patents in suit. The United States and the Intervenor Defendants (collectively “Defendants”) deny that Dr. Stella and Ms. Waugh are co-inventors of the patents in suit and ask the Court to enter an order declaring that they are not co-inventors. In addition, Millennium has filed a counterclaim against KUCR, seeking a declaratory judgment that KUCR unreasonably delayed in asserting its claims against Millennium and that KUCR is barred from asserting any ownership rights in the patents in suit. Millennium seeks to enjoin KUCR from asserting or obtaining any ownership rights in the patents in suit.

B. The Proposed Protective Order and Disputed Provisions

Pursuant to Paragraph 2.k. of the October 20, 2009 Scheduling Order,¹ KUCR and Defendants (collectively “the Parties”) attempted to agree to the terms of a joint protective order that would protect the confidentiality of certain documents produced during the course of discovery. They were able to agree to all but two provisions. Consequently, two proposed versions of the Protective Order have been submitted to the Court.²

¹Scheduling Order (doc. 113), ¶ 2.k.

²KUCR’s version of the proposed Protective Order is attached as Exhibit A to Pl’s Mot. for Protective Order (doc. 131). Defendants’ version of the proposed Protective Order is attached as Exhibit A to Defendants’ Memorandum in Support of Defendants’ Cross Motion (doc. 134).

KUCR's version of the proposed protective order includes a provision, Paragraph 6(h), which would allow Dr. Stella, Ms. Waugh, and Dr. Gupta access to a certain subset of technical information that is deemed confidential under the Protective Order. KUCR's version also includes a provision in Paragraph 13(b) that pertains to certain non-testifying consultants. Defendants object to the inclusion of both of these provisions. Except for these two provisions, Defendants' proposed version is virtually identical to KUCR's.

Before discussing the disputed provisions in more detail, the Court will discuss the general framework of the proposed Protective Order to which the Parties agree. The proposed Protective Order applies to the disclosure of "Protected Discovery Material," which is defined as information produced or disclosed by a party to the lawsuit ("Party") or a "Supplying Owner"³ that the Party or Supplying Owner "believes in good faith contains nonpublic confidential, proprietary, commercially sensitive, or trade secret information."⁴ Generally speaking, the Protective Order provides that Protected Discovery Material may be used only for purposes of litigation between any two or more of the Parties concerning the inventorship and/or ownership of the patents in suit and "may not be disclosed to anyone other than a Qualified Person."⁵

The term "Qualified Person" is defined in Paragraph 6 of the proposed Protective Order to include, *inter alia*, employees of the Parties, outside attorneys for the Parties, three in-house attorneys for each Party, designated outside consultants and experts, and the Court. In its proposed

³The proposed Protective Orders define the term "Supplying Owner" to mean "a person or entity who is not a Party and owns or possesses . . . Protected Discovery Material." Proposed Protective Orders, Definitions, ¶ 1.

⁴Proposed Protective Order, ¶ 5.

⁵*Id.*, ¶ 10 (emphasis added).

Paragraph 6(h), KUCR seeks to include Dr. Stella, Ms. Waugh, and Dr. Gupta in the list of “Qualified Persons.” KUCR’s proposed Paragraph 6(h) provides as follows:

The term “Qualified Person” shall mean any one of the following:

* * * *

(h) Dr. Valentino Stella, Ms. Wanda Waugh, and Dr. Shanker Gupta, but only with respect to *technical Protected Discovery Material that is relevant to identifying or determining the actual inventor(s) of the patents in suit*. Before disclosing such Material to Dr. Stella, Ms. Waugh, or Dr. Gupta, any receiving Party shall first obtain confirmation from the producing Party or Supplying Owner, on a per document basis, that this subsection applies to such Material. This Court shall resolve all disputes over whether disputed Material constitutes technical Protected Discovery Material that is relevant to identifying or determining the actual inventor(s) of the patents in suit.⁶

In Paragraph 13 of the Protective Order, the Parties address the disclosure of Protected Discovery Material to designated outside consultants or experts (“Consultants”). The Parties agree in Paragraph 13 that each Party must disclose to all other Parties and Supplying Owners the identity of each Consultant who is to be given access to Protected Discovery Material. In Subparagraph 13(b), the Parties agree that “[n]on-testifying Consultants will not be subject to depositions or subpoenaed as witness at trial.” KUCR’s version of the proposed Protective Order, however, includes the following language at the end of the sentence: “except to the extent such Consultant is an employee of a Party or of any entity affiliated with a Party.”⁷

II. Issues

In ruling on the Parties’ Cross Motions for Protective Order, the Court must resolve the Parties’ disputes regarding Paragraphs 6(h) and 13(b). In addition, the Court must examine all other provisions of the Protective Order that the Parties have agreed upon. That the parties have agreed

⁶KUCR’s Proposed Protective Order, ¶ 6(h) (emphasis added).

⁷*Id.*, ¶13(b).

to certain provisions and terms of the Protective Order does not mean the Court will automatically approve those provisions. The Court must examine the Protective Order under Federal Rule of Civil Procedure 26(c), which governs protective orders, in addition to this District's Guidelines for Protective Orders. The Court must decide whether all of the agreed upon terms are proper and whether the parties have demonstrated good cause for the entry of a protective order to protect the confidentiality of certain information produced or supplied to the Parties during the course of this action.

III. Rule 26(c)(1) Protective Order Standards

Federal Rule of Civil Procedure 26(c)(1) provides that “[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense”⁸ The party seeking a protective order has the burden to show good cause for it.⁹ To establish good cause, a party must make “a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.”¹⁰ Furthermore, the Scheduling Order entered in this case provides that any protective order proposed by the parties “shall include . . . a concise but sufficiently specific recitation of the particular facts in this case that would provide the court with an adequate basis upon which to make the required finding of good cause pursuant to Fed. R. Civ. P. 26(c).”¹¹

⁸Fed. R. Civ. P. 26(c)(1).

⁹*Reed v. Bennett*, 193 F.R.D. 689, 691 (D. Kan. 2000).

¹⁰*Gulf Oil Co. v. Bernard*, 452 U.S. 89, 102 n.16 (1981).

¹¹Scheduling Order (doc. 113), ¶ 2.k.

The district court has broad discretion to decide when a protective order is appropriate and what degree of protection is required.¹² The Supreme Court recognizes that “[t]he trial court is in the best position to weigh fairly the competing needs and interests of the parties affected by discovery. The unique character of the discovery process requires that the trial court have substantial latitude to fashion protective orders.”¹³

Generally speaking, there are three kinds of protective orders that courts use to limit the discovery or dissemination of confidential or trade secret information: (1) particular protective orders; (2) blanket protective orders; and (3) umbrella protective orders.¹⁴ “Particular protective orders cover specific, identified information and usually [are] sought by a party prior to disclosing the information for which protection is sought. Umbrella protective orders designate all discovery produced in a particular litigation as protected without any prior review, by either a court or the parties.”¹⁵ In between these two extremes lies the “blanket protective order,” which is the type of protective order proposed by the Parties in this case.

A blanket protective order places upon the parties the initial burden of determining and defining what information is entitled to protection.¹⁶ Typically, a blanket protective order requires counsel for a producing party to review the information to be disclosed and designate the

¹²*MGP Ingredients, Inc. v. Mars, Inc.*, 245 F.R.D. 497, 500 (D. Kan. 2007) (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984)).

¹³*Seattle Times*, 467 U.S. at 36.

¹⁴*Foley v. Signator Investors, Inc.*, No. 03-2099-KHV, 2003 WL 22844110, at *2 (D. Kan. Nov. 25, 2003); *Gillard v. Boulder Valley Sch. Dist.*, 196 F.R.D. 382, 385 (D. Colo. 2000).

¹⁵*Foley*, 2003 WL 22844110, at *2 (citing *Gillard*, 196 F.R.D. at 385).

¹⁶*Id.* (citing *Gillard*, 196 F.R.D. at 385).

information counsel believes, in good faith, is confidential or otherwise entitled to protection.¹⁷ The designated information is then protected from certain uses and disclosure under the terms of the protective order, unless the designation is objected to by an opposing party.¹⁸ If the parties are unable to resolve their dispute regarding the designation, the court may review the designation and determine whether the designated information should be protected.¹⁹ The terms of a blanket protective order, like the terms of the two other types of protective orders, must be approved by the court, since a protective order is, by definition, an order of the court and not merely a stipulation or agreement of the parties.

The Tenth Circuit has observed that blanket protective orders are becoming standard practice in complex cases,²⁰ and has recognized their usefulness as follows:

They allow the parties to make full disclosure in discovery without fear of public access to sensitive information and without the expense and delay of protracted disputes over every item of sensitive information, thereby promoting the overriding goal of the Federal Rules of Civil Procedure, “to secure the just, speedy, and inexpensive determination of every action.”²¹

With these standards in mind, the Court will now examine both the disputed and agreed upon terms of the Parties’ proposed Protective Order.

¹⁷*Id.* (citing *Gillard*, 196 F.R.D. at 385).

¹⁸*Id.* (citing *Gillard*, 196 F.R.D. at 385).

¹⁹*Id.* (citing *Gillard*, 196 F.R.D. at 385).

²⁰*United Nuclear Corp. v. Cranford Ins. Co.*, 905 F.2d 1424, 1427 (10th Cir. 1990) (citing *Manual for Complex Litigation (Second)* § 21.431 (1985)).

²¹*Id.* (citing Fed. R. Civ. P. 1).

IV. Does Good Cause Support the Entry of a Blanket Protective Order?

Before turning to the disputed provisions of the proposed Protective Order, the Court must determine, as a threshold matter, whether the Parties have demonstrated good cause for the entry of a blanket protective order to protect the confidentiality of the information and documents they have labeled “Protected Discovery Material” and to prevent their use except for the purposes of any litigation in the United States between the Parties concerning the inventorship and/or ownership of the patents in suit. The Court holds that the Parties have demonstrated sufficient good cause for the entry of a blanket protective order. The Court will now turn to the particular provisions of the proposed Protective Order that are in dispute.

V. Should the Protective Order Include KUCR’s Proposed Paragraph 6(h)?

A. The Parties’ Arguments

As noted above, KUCR seeks to include a provision, Paragraph 6(h), which would allow Dr. Stella, Ms. Waugh, and Dr. Gupta access to “technical Protected Discovery Material that is relevant to identifying or determining the actual inventor(s) of the patents in suit” (“Inventorship Material”). KUCR’s proposed Paragraph 6(h) further provides that “[b]efore disclosing such Material to Dr. Stella, Ms. Waugh, or Dr. Gupta, any receiving Party shall first obtain confirmation from the producing Party or Supplying Owner, on a per document basis, that this subsection applies to such Material.”

According to KUCR, Dr. Stella, Ms. Waugh, and Dr. Gupta are uniquely qualified to consider and testify about this otherwise protected information because they each have a particular understanding and knowledge of their own respective contributions to the claimed inventions. KUCR argues that “[f]airness requires symmetrical access by all three relevant individuals” to the

Inventorship Material.²² KUCR contends that Defendants have the burden to show good cause for excluding Dr. Stella and Ms. Waugh from accessing this Inventorship Material.²³ KUCR argues that Defendants have not established good cause because: (1) there is a need for Dr. Stella and Ms. Waugh to access this information and that need greatly outweighs any risk to Defendants of inadvertent disclosure; (2) denying Dr. Stella and Ms. Waugh access would give Defendants “an unfair testimonial advantage” that would impair KUCR’s ability to prosecute its claims;²⁴ and (3) Defendants’ concern that the Inventorship Material may affect the trial testimony of Dr. Stella and Ms. Waugh is not a valid reason to prevent their access.

Defendants, on the other hand, argue that they do not have the burden to show good cause to prohibit the disclosure of the Inventorship Material, but rather KUCR has the burden to show that such disclosure is necessary to the action. Defendants argue that Dr. Stella and Ms. Waugh are fact witnesses and not parties; therefore, their only role is to testify regarding events and communications about which they have personal knowledge. Pursuant to Paragraph 12 of the Protective Order, they will be allowed to review any Protected Discovery Material (which would include the Inventorship Material) that they had previous lawful access to or that they currently possess or formerly

²²KUCR’s Mem. in Support of Cross Mot. for Protective Order (doc. 132) at 3-4.

²³KUCR’s proposed Paragraph 6(h) would provide for “symmetrical” disclosure, i.e., Dr. Stella and Ms. Waugh would have access to Defendants’ Inventorship Material, while Dr. Gupta would have access to KUCR’s Inventorship Material. Defendants, however, apparently see no need for Dr. Gupta to have access through Paragraph 6(h), because (1) Dr. Gupta previously had access to much of the Inventorship Material through his work on the patents in suit, and (2) under Paragraph 12 of the Protective Order, he would continue to have access. (*See* footnote 25, *infra*, for the text of Paragraph 12.) Consequently, the Parties focus their Paragraph 6(h) arguments on Dr. Stella and Ms. Waugh. The Court will therefore do the same.

²⁴KUCR’s Resp. to Defs.’ Cross Mot. for Protective Order (doc. 140) at 3.

possessed, independent of its disclosure in this lawsuit.²⁵ Allowing them access to Inventorship Material that they previously have not had access to would improperly taint their trial testimony.

Furthermore, Defendants contend that even if they do have the burden to demonstrate good cause for not allowing Dr. Stella and Ms. Waugh access to the Inventorship Material, they have met that burden by showing there is a significant risk of inadvertent disclosure, particularly since Dr. Stella regularly consults for pharmaceutical companies that compete with Millennium and COBI.

B. The Standard for Rule 26(c)(1)(G) Protective Orders and the Applicable Burden

As a threshold matter, the Court must determine the applicable burden and how it should be applied to this dispute. As noted above, KUCR argues that, pursuant to Rule 26(c), Defendants have the burden to show good cause as to why Dr. Stella and Ms. Waugh should be prohibited from having access to the Inventorship Material. Defendants disagree, and argue that they need only show that the Inventorship Material constitutes confidential research, development, or commercial information under Rule 26(c)(1)(G) and that its disclosure might be harmful. They argue this shifts the burden to KUCR to show that requiring Defendants to disclose that Inventorship Material to Dr. Stella and Ms. Waugh is necessary to KUCR's prosecution of the action.

²⁵The parties agree in Paragraph 12 of the proposed Protective Order as follows:

A recipient of particular Protected Discovery Material, and any Qualified Person, may discuss such Protected Discovery Material with any other person who is not a Qualified Person only to the extent that said person has already had lawful access to such Protected Discovery Material independent of any disclosure in this litigation. This Protective Order shall not prohibit any person from reviewing particular Protected Discovery Material to the extent that said person currently or formerly possessed or had access to such Protected Discovery Material independent of any disclosure of it as Protected Discovery Material in this litigation, provided such possession or access was not obtained by theft or deceit.

Rule 26(b)(1), which defines the scope of discovery, is the starting point for the Court's analysis. It states:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter.²⁶

As discussed above, Rule 26(c)(1) provides a mechanism for a party to limit the scope of discovery by applying for a protective order. A party may move for a protective order that would, *inter alia*, forbid the discovery;²⁷ specify the terms, including the place or time, of the discovery;²⁸ or designate the persons who may be present while the discovery is conducted.²⁹ In addition, if the information to be protected is “trade secret or other confidential research, development, or commercial information,” the Court may issue an order under Rule 26(c)(1)(G) that the “information not be revealed or be revealed only in a specified way.”³⁰

²⁶Fed. R. Civ. P. 26(b)(1).

²⁷*See* Fed. R. Civ. P. 26(c)(1)(A).

²⁸*See* Fed. R. Civ. P. 26(c)(1)(B).

²⁹*See* Fed. R. Civ. P. 26(c)(1)(E).

³⁰Fed. R. Civ. P. 26(c)(1)(G). It is well established that “[t]here is no absolute privilege for trade secrets or similar confidential information.” *Fed. Open Mkt. Comm. v. Merrill*, 443 U.S. 340, 362 (1979). A court, however, may issue a protective order when necessary to limit the disclosure of trade secrets and other confidential research, development and commercial information under Rule 26(c)(1)(G). *MGP Ingredients, Inc. v. Mars, Inc.*, 245 F.R.D. 497, 500 (D. Kan. 2007) (deciding case under Rule 26(c)(7), which was the earlier but nearly identical version of Rule 26(c)(1)(G)).

The Tenth Circuit, in the case of *In re Cooper Tire and Rubber, Inc.*,³¹ recently reiterated the standard for issuing a Rule 26(c)(1)(G) protective order. Relying heavily on its 1981 decision in *Centurion Industries, Inc. v. Warren Steurer & Associates*,³² the Tenth Circuit stated:

A protective order may be issued to limit the disclosure of trade secrets. When a party seeks such a protective order, it must first establish that the information sought is a trade secret and then demonstrate that its disclosure might be harmful. If the party makes such a showing, the burden shifts to the party seeking discovery to establish that the disclosure of trade secrets is relevant and necessary to the action.

The need for the trade secrets should be balanced against the claim of harm resulting from the disclosure. It is within the sound discretion of the trial court to decide whether trade secrets are relevant and whether the need outweighs the harm of disclosure. If the party seeking discovery cannot prove that the information is relevant and necessary, then discovery should be denied. However, if the party meets its burden, the trade secrets should be disclosed, unless they are privileged³³

In addition, this Court has held that to establish the requisite harm, the moving party must show that disclosure of the trade secret or other similar information “will result in a clearly defined and very serious injury.”³⁴ To establish this clearly defined and very serious injury, the moving party must “make a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.”³⁵

³¹568 F.3d 1180, 1190 (10th Cir. 2009).

³²665 F.2d 323, 325 (10th Cir. 1981).

³³568 F.3d at 1190.

³⁴*Flint Hills Scientific, LLC v. Davidchack*, No. 00-2334-KHV-DJW, 2001 WL 1718291, at *2 (D. Kan. Dec. 3, 2001) (applying rule in context of Rule 26(c)(1)(G) [formerly Rule 26(c)(7)] motion to protect against disclosure of trade secrets) (internal quotations and citations omitted); *Western Res., Inc. v. Union Pac. R. Co.*, No. 00-2043-CM, 2001 WL 1718370, at *5 (D. Kan. Sept. 12, 2001) (same) (internal quotations and citations omitted).

³⁵*Flint Hills*, 2001 WL 1718291, at *2 (quoting *Gulf Oil Co. v. Bernard*, 452 U.S. 89, 102 n. 16 (1981)); *Western Res.*, 2001 WL 1718370, at *4-5 (quoting same).

Thus, in this case, Defendants must first establish that the Inventorship Material at issue is a trade secret or other confidential research, development, or commercial information, and then demonstrate that its disclosure might be harmful.³⁶ To show that disclosure might be harmful, Defendants must make a particular and specific demonstration of fact that disclosure of the Inventorship Material to Dr. Stella or Ms. Waugh would result in a clearly defined and very serious injury to Defendants. If Defendants meet those requirements, the burden shifts to KUCR to establish that the Inventorship Material is relevant and that its disclosure to Dr. Stella and Ms. Waugh is “necessary to this action.”³⁷ Finally, this Court must balance KUCR’s need to disclose the Inventorship Material to Dr. Stella and Ms. Waugh against Defendants’ claim that they will be injured if the Inventorship Material is disclosed to them.³⁸

C. Have Defendants Met Their Burden?

1. Is the Inventorship Material trade secret information under Rule 26(c)(1)(G)?

The Court holds that Defendants have met their burden to show the Inventorship Material is trade secret information within the meaning of Rule 26(c)(1)(G). Indeed, all Parties agree in the introductory paragraph of the proposed Protective Order that the Protective Order is necessary to protect against unwarranted disclosure “of trade secret or other confidential and proprietary research, development, and/or commercial information regarding the subject matter of the patents.”³⁹ Furthermore, the Parties define “Protected Discovery Material” as material that “contains nonpublic

³⁶See *A Major Difference, Inc. v. Wellspring Prods., LLC*, 243 F.R.D. 415, 416-17 (D. Colo. 2006 (citing *Centurion*, 665 F.2d at 325-26)).

³⁷See *id.* (citing *Centurion*, 665 F.2d at 325-26).

³⁸See *id.* (citing *Centurion*, 665 F.2d at 325-26).

³⁹Proposed Protective Order at 1.

confidential, proprietary, commercially sensitive, or trade secret information.”⁴⁰ The Parties recognize that Inventorship Material is an even *more sensitive* subset of that class of information because, by definition, it is “technical” information which pertains to identifying the inventors of the patents in suit. Thus, the Court concludes that Defendants have met their burden to show that the Inventorship Material is Rule 26(c)(1)(G) trade secret information.

2. *Will disclosure of the Inventorship Material harm Defendants?*

Next, the Court must determine whether Defendants have met their burden to show that disclosure of the Inventorship Material to Dr. Stella and Ms. Waugh would be harmful. The Parties agree in the proposed Protective Order that the information sought to be protected by the Protective Order “has significant commercial value and that disclosure of that information . . . could cause damage to one or more of the parties.”⁴¹ This conclusory recitation alone is not sufficient to satisfy Defendants’ burden under Rule 26(c)(1)(G). Certainly it is not a “particular and specific demonstration of fact” which establishes that disclosure to Dr. Stella and Ms. Waugh would inflict “a clearly defined and very serious injury” on Defendants.⁴²

Defendants go beyond the Protective Order’s recitation and attempt to meet their burden by demonstrating two risks of injury. First, Defendants attempt to show that disclosing the Inventorship Material to Dr. Stella and Ms. Waugh would pose a significant risk of Dr. Stella and Ms. Waugh inadvertently disclosing the information to others. Second, Defendants try to show that disclosing the Inventorship Material to Dr. Stella and Ms. Waugh would likely taint their testimony.

⁴⁰*Id.*, ¶ 5.

⁴¹*Id.* at 1.

⁴²*See, e.g., Flint Hills*, 2001 WL 1718291, at *2; *Western Res.*, 2001 WL 1718370, at 5.

a. The risk of inadvertent disclosure and the harm it would cause Defendants

With respect to the risk of inadvertent disclosure, Defendants assert that Dr. Stella regularly consults for various pharmaceutical companies which compete with Millennium and COBI. Defendants point to two documents in support of this proposition. The first is an undated “Faculty Information” form completed by Dr. Stella, in which he indicates that he consults with 10-30 companies a year regarding drug stability and delivery.⁴³ The second is an “Annual Faculty Portfolio” completed by Dr. Stella, in which he states that he consulted with at least eighteen different pharmaceutical companies in 2007 regarding drug delivery and formulation, an area in which he has expertise.⁴⁴ He further states in the “Portfolio” that he expects to do similar consulting work in the year 2008.⁴⁵ No specific information is included in the record as to his consulting for the year 2009 or 2010; however, KUCR does not dispute that Dr. Stella consults with pharmaceutical companies in the area of drug formulation and delivery.⁴⁶ In addition, Defendants represent that Dr. Stella previously founded two pharmaceutical companies and that he “may opt to compete in the industry again.”⁴⁷ Again, KUCR does not dispute this representation..

⁴³See Ex. A. at 12, attached to Decl. of David C. Currie (doc. 160 & 203). Although this “Faculty Information” form is unauthenticated, Defendants represent that KUCR produced it in discovery in this case, and KUCR does not dispute its authenticity.

⁴⁴Ex. B at. 14, attached to Decl. of David C. Currie (doc. 160 & 203). This document is also unauthenticated, but again, KUCR does not dispute its authenticity.

⁴⁵*Id.*

⁴⁶See KUCR’s Reply (doc. 176) at 7 (“It is good to see that the defendants recognize and confirm that Dr. Stella is one of the world’s leading scientists in ‘drug formulation and delivery’ and consults for various pharmaceutical companies.”).

⁴⁷See Defs.’ Resp. to KUCR’s Submission Regarding Proposed Protective Order (doc. 159) at 12 and Exhibit D attached to Decl. of David C. Currie (doc. 160) (University of Kansas Medical
(continued...)

KUCR does, however, argue that Dr. Stella has worked on various government contracts with the University of Kansas, including the contract under which the patents in suit were invented, and was privy to confidential technical documents and information of the United States similar to the Inventorship Material at issue now. KUCR points out that no one has ever claimed that Dr. Stella improperly or inadvertently disclosed confidential information during any of those contractual relationships. Moreover, there is nothing in the record indicating that Dr. Stella has ever violated any confidential relationship with any entity or that he has ever been accused of misappropriating or improperly disclosing confidential information in any context.

Based on the above, the Court concludes that the danger of Dr. Stella inadvertently, or otherwise, divulging the Inventorship Material to a competitor of Defendants to be quite small. While there certainly exists an *opportunity* for inadvertent disclosure due to Dr. Stella's consulting activities, the potential *threat of disclosure* appears fairly minimal. The United States has already entrusted Dr. Stella with a significant amount of sensitive confidential information regarding the patents in suit and other research. The Court sees no reason why Defendants cannot entrust Dr. Stella with the same type of information now, for use in prosecuting this case.

With respect to Ms. Waugh, Defendants provide no evidence that there is even an opportunity for Ms. Waugh to inadvertently disclose the Inventorship Material to a competitor. Nothing in the record indicates that she currently engages in any consulting work or that she has any contact with any competitor of Defendants. Additionally, as KUCR points out, Ms. Waugh, like Dr. Stella, was privy to confidential technical information of the United States during her work on the patents in suit. Nothing in the record indicates that Ms. Waugh ever improperly or inadvertently

⁴⁷(...continued)
Center Website biography of Dr. Stella indicating he founded two companies, ProQuest and CyDex).

disclosed that information or any other confidential information similar to the Inventorship Material at issue in this case. Accordingly, any risk that Ms. Waugh might inadvertently, or otherwise, divulge the Inventorship Material to a competitor appears extremely small.

In sum, the Court finds that Defendants have failed to make a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements, that either Dr. Stella or Ms. Waugh poses a risk of inadvertently or otherwise disclosing the Inventorship Material to Defendants' competitors.

In addition, Defendants fail to explain in any meaningful detail the nature of the harm they would suffer if the particular Inventorship Material were inadvertently disclosed to a competitor or to one of the companies for whom Dr. Stella does consulting work. Defendants only make conclusory statements about Dr. Stella doing consulting work and previously founding two pharmaceutical companies. They fail to explain how they would be harmed if the particular subset of confidential information at issue in Paragraph 6(h), i.e., Protected Discovery Material "that is relevant to identifying or determining the actual inventor(s) of the patents in suit," were inadvertently or otherwise disclosed to their competitors or other third parties. Defendants' lack of detailed explanation to support their position does not satisfy their burden to show a "clearly defined and very serious injury."⁴⁸

⁴⁸See *MGP*, 245 F.R.D. at 501 (holding in patent case that defendants failed to meet their burden of proving that the lack of a two-tiered protective order would result in harm where defendants made conclusory arguments that they would be harmed by the disclosure but failed to discuss in detail how they would suffer the nature or degree of harm claimed); see also *Flint Hills*, 2001 WL 1718291, at *3 (holding that moving party's allegation that defendants might use the trade secret information within certain documents to attack the scope and validity of a patent to be a conclusory declaration of anticipated action that fell short of the showing a "clearly defined and very serious injury").

b. The risk of tainted testimony and the harm it would cause Defendants

The Court will now address Defendants' argument that allowing Dr. Stella and Ms. Waugh access to the Inventorship Material would improperly affect or taint their testimony. Defendants argue that because Dr. Stella and Ms. Waugh are merely fact witnesses and not parties, their only role is to testify regarding events and communications from the relevant time period and about which they have personal knowledge. Defendants argue that disclosing Inventorship Material that neither Dr. Stella nor Ms. Waugh was privy to during the course of their work on the patents in suit creates "a high likelihood" that the disclosure will "consciously or unconsciously affect their testimony."⁴⁹

The Court is not persuaded by this argument. Defendants have the burden to show how disclosure of this particular confidential information would be harmful, and they must meet this burden by making a specific demonstration of fact, as distinguished from stereotyped and conclusory statements. Defendants fail to provide such support for this argument. They also fail to show how such testimony would result in a clearly defined and serious injury to them.

3. Conclusion as to Defendants' burden

In light of the above, the Court concludes that Defendants have failed to show that disclosure of the Inventorship Material to Dr. Stella or Ms. Waugh would be harmful to Defendants. Because Defendants have failed to carry their burden of showing harm, the Court's inquiry may end at this step of the analysis.

⁴⁹Defs.' Resp. to KUCR's Submissions Regarding Proposed Protective Order (doc. 159) at 13.

D. Has KUCR Met Its Burden?

Even if the Court were to hold that Defendants had met their burden to show harm and the Court shifted the burden to KUCR to demonstrate that the Inventorship Material is relevant and that its disclosure to Dr. Stella and Ms. Waugh is necessary to this action,⁵⁰ the Court would find that KUCR has carried that burden. It is undisputed that this information is relevant, since Inventorship Material is, by definition, technical information “that is relevant to identifying or determining the actual inventor(s) of the patents in suit.”⁵¹ Whether Dr. Stella and/or Ms. Waugh are co-inventors is the ultimate issue in this action. Thus, KUCR has met its burden to show that the Inventorship Material is relevant.

The Court also finds that KUCR has met its burden to show that disclosing the Inventorship Material to Dr. Stella and Ms. Waugh “is necessary to this action.” In making this determination, the Court looks to what a plaintiff must prove to correct inventorship under 35 U.S.C. § 256. Patent issuance creates a presumption that the named inventors are the true and only inventors.⁵² To rebut this presumption, the plaintiff must show, through clear and convincing evidence, that the alleged unnamed inventor was in fact a co-inventor.⁵³ Only then will the court correct inventorship.⁵⁴

To be considered a co-inventor, “an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured

⁵⁰*Cooper Tire*, 568 F.3d at 1190 (citing *Centurion*, 665 F.2d at 325-26).

⁵¹KUCR’s Proposed Protective Order, ¶ 6(h).

⁵²*Israel Bio-Eng’g Project v. Amgen, Inc.*, 475 F.3d 1256, 1263 (Fed. Cir. 2007); *Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004).

⁵³*Caterpillar*, 387 F.3d at 1377; *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350 (Fed. Cir. 1998).

⁵⁴*Caterpillar*, 387 F.3d at 1377; *Pannu*, 155 F.3d at 1350 (Fed. Cir. 1998).

against the dimension of the full invention.”⁵⁵ In addition, the alleged inventor must have had “some open line of communication during or in temporal proximity to their inventive efforts.”⁵⁶ Finally, “an alleged co-inventor’s testimony, standing alone, is not sufficient to provide clear and convincing evidence. An alleged co-inventor must supply evidence to corroborate his or her testimony.”⁵⁷

In light of the above, the primary focus of this suit will be on the contributions, if any, that Dr. Stella and Ms. Waugh made to the conception of the inventions at issue, and those contributions must be “measured against the dimension of the full invention.” Consequently, the Court finds it critical that Dr. Stella and Ms. Waugh be allowed access to those materials which relate to the entire contribution, and not just to each of their own respective contributions. In other words, Dr. Stella and Ms. Waugh must be granted access to *all* information and documents that fall within the definition of Inventorship Material and not just those materials that they were privy to during their work on the inventions.⁵⁸ Indeed, the Court believes it would be crippling to KUCR’s case to prevent Dr. Stella and Ms. Waugh from reviewing all Inventorship Material. If they are denied access, they would be excluded from every discussion of the very information that would be essential to present KUCR’s legal arguments and evidence to the Court or trier of fact. They would also be excluded from strategy sessions with KUCR and its counsel. Moreover, they would be

⁵⁵*Caterpillar*, 387 F.3d at 1377 (quoting *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997)).

⁵⁶*Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1373 (Fed. Cir. 2006) (quoting *Eli Lilly & Co. v. Aradigm*, 376 F.3d 1352, 1358-59 (Fed. Cir. 2004)).

⁵⁷*Caterpillar*, 387 F.3d at 1377 (citing *Ethicon, Inc. v. U. S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998)).

⁵⁸Pursuant to Paragraph 12 of the proposed Protective Order, Dr. Stella and Ms. Waugh would be allowed to review any Inventorship Material that they previously had lawful access to while working on the inventions.

unable to assist in the preparation of cross-examination of Dr. Gupta, who would testify about the scope of his contributions and, presumably, about the alleged limited scope of Dr. Stella and Ms. Waugh's contributions.

In addition, the Court finds that Dr. Stella and Ms. Waugh's access is crucial to their own testimony and presentation of evidence at trial. No witnesses other than Dr. Stella and Ms. Waugh will be able to provide testimony on behalf of KUCR regarding each of their respective contributions to the inventions. Without documentation, however, their testimony will be insufficient to prove their contributions, because, as purported co-inventors, they must present evidence to corroborate their testimony.⁵⁹ Consequently, the Court holds that the Inventorship Material is necessary to KUCR's prosecution of this case.

E. Balancing Test

The Court now turns to the balancing test. The Court finds that what harm might flow from disclosure of the Inventorship Material to Dr. Stella and Ms. Waugh is so small that it does not outweigh KUCR's critical need to make a full and fair presentation of its case. Moreover, what risk of disclosure there is can be mitigated through certain safeguards and restrictions contained in the Protective Order.

Two of those safeguards are set forth in Paragraph 6(h) itself. Under that paragraph, before KUCR may disclose any Inventorship Material to either Dr. Stella or Ms. Waugh, KUCR is required to obtain confirmation from the producing Party (one of more of Defendants) or Supplying Owner that the material actually falls within the definition of Inventorship Material.⁶⁰ This will prevent the

⁵⁹See *Caterpillar*, 387 F.3d at 1377 (citing *Ethicon*, 135 F.3d at 1460).

⁶⁰Paragraph 6(h) provides that "[b]efore disclosing such Material to Dr. Stella, Ms. Waugh, or Dr. Gupta, any receiving Party shall first obtain confirmation from the producing Party or
(continued...)

disclosure of Protected Discovery Material that is not relevant to identifying or determining the inventors. In addition, Paragraph 6(h) indicates that the Court will resolve all disputes that may arise as to whether certain information constitutes Inventorship Material which may be disclosed to Dr. Stella and Ms. Waugh.⁶¹

Finally, under Paragraph 11 of the Protective Order, Dr. Stella and Ms. Waugh will each be required to sign an “Acknowledgment,” under which they acknowledge that they have read the terms of the Protective Order and agree to be bound by its terms.⁶² With these protections in place, the Court believes the potential for harm will be minimized.

F. Conclusion as to Paragraph 6(h)

Based upon the balancing of the potential risk of harm to Defendants against KUCR’s need for the Inventorship Material, the Court holds that KUCR’s proposed Paragraph 6(h) should be included in the Protective Order.

VI. Which Version of Paragraph 13(b) Should Be Included in the Protective Order?

As noted above, the parties agree in Paragraph 13(b) of their proposed Protective Order that “Non-testifying Consultants will not be subject to depositions or subpoenaed as witnesses at trial.” KUCR, however, adds the following language to its proposed order: “except to the extent such consultant is an employee of a Party or of any entity affiliated with a Party.”

⁶⁰(...continued)

Supplying Owner, on a per document basis, that this subsection applies to such Material.”

⁶¹Paragraph 6(h) states that “[t]his Court shall resolve all disputes over whether disputed Material constitutes [Technical Inventorship] Material that is relevant to identifying or determining the actual inventor(s) of the patents in suit.”

⁶²A form “Acknowledgment” is attached to the proposed Protective Order.

Defendants strenuously object to including this additional language. KUCR states it included this language only because Defendants “demanded” it be part of the Protective Order.⁶³ KUCR states, however, that it “will agree to which ever of the defendants’ two versions of Paragraph 13(b) the defendants ultimately chose.”⁶⁴

It is clear from the briefing that Defendants want to exclude this additional language. Accordingly, the Court will delete this language.

VII. Are the Agreed Upon Provisions of the Proposed Protective Order Appropriate?

The Court will now examine the other terms and provisions of the proposed Protective Order to which the parties have agreed. As noted above, the mere fact that the parties have agreed or stipulated to certain provisions is not dispositive of whether they should be included in a blanket protective order. The Court must still find the provisions appropriate, not only under Rule 26(c)(1) standards, but under the Court’s Guidelines for Agreed Protective Orders.⁶⁵

A. Paragraphs 25 and 26—Filing Documents Under Seal

Paragraph 25 provides as follows:

The Court shall have access to all Protected Discovery Material. The Clerk of this Court is directed to maintain under seal all documents or things which are filed with the Court and which have been designated as Protected Discovery Material. The Clerk shall permit access to such documents or things only to this Court, personnel of the Court authorized to have access, and the attorneys of record.⁶⁶

Paragraph 26 states:

⁶³Pl.’s Resp. to Defs.’ Mot. for Protective Order (doc. 140) at 11.

⁶⁴*Id.*

⁶⁵The Court’s Guidelines for Agreed Protective Orders are found at <http://www.ksd.uscourts.gov/guidelines/protectiveorder.pdf>.

⁶⁶Proposed Protective Order, ¶ 25.

In the event that Protected Discovery Material is included in any filed document, the Party filing such Protected Discovery Material shall seek leave to file it under seal. If the Protected Discovery Material is filed electronically, the Party shall seek to file it under seal pursuant to local rule 5.4.6. All other documents filed with the Court containing Protected Discovery Material shall be filed in sealed envelopes or other appropriately sealed containers on which shall be endorsed the caption of this litigation, the words “CONTAINS PROTECTED DISCOVERY MATERIAL” and “SUBJECT TO PROTECTIVE ORDER” as an indication of the nature of the contents.⁶⁷

The Court does not approve Paragraphs 25 and 26 for several reasons. First, they are inconsistent with one another. Paragraph 25 implies that the Clerk must seal any Protected Discovery Material that is filed with the Court, regardless of whether the filing party has been granted leave under D. Kan. Rule 5.4.6 to file the material under seal. Additionally, Paragraph 25 does not comply with Guideline 3 of the Court’s Guidelines. That Guideline requires a party desiring to file confidential information under seal to first file a motion for leave to seal and be granted leave to do so. Furthermore, Paragraph 26 conflicts with D. Kan. Rule 5.4.6, which provides that a party whose motion for leave to seal is granted “shall” file the documents electronically. In other words, there is no option to file documents conventionally merely because leave has been granted to file them under seal.

In light of the above, the Court combines Paragraphs 25 and 26 into one paragraph (Paragraph 25), and modifies them to read as follows:

In the event a Party seeks to include any Protected Discovery Material in any filed document or to otherwise file the Protected Discovery Material, the Party shall file a motion seeking leave to file under seal the particular piece of Protected Discovery Material, and shall follow the procedures set forth in D. Kan. Rule 5.4.6. If the motion to seal is granted, the filing Party shall then electronically file the Protected Discovery Material under seal. The Clerk shall permit access to such documents or things only to this Court, personnel of the Court authorized to have access, and the attorneys of record, except for pro hac vice attorneys, who must obtain the sealed documents from local counsel.

⁶⁷*Id.*, ¶ 26.

B. Paragraph 31—Application to Parties Who Are Later Added to the Action

Paragraph 31 states as follows:

In the event that a new party intervenes, is added, substituted, or brought in, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.⁶⁸

The Court will delete this paragraph from the Protective Order. Any new party to the lawsuit must be given to the opportunity to review the Protective Order and decide whether to join in the Order.

C. Paragraphs 33 and 34—Amendments to the Protective Order

Paragraph 33 states that the Protective Order may be amended with leave of Court or by express order of the Court. It further states that it “may be amended as to particular Protected Discovery Material as a need may arise by agreement of the Parties and Supplying Owner(s) without prior leave of the court.”⁶⁹ The Court cannot approve this latter sentence, because all modifications to the Protective Order, just like the initial entry of the Protective Order, must be approved by the Court. The Court will therefore delete this sentence from Paragraph 33 (which will now be numbered Paragraph 31).

The Court will also delete Paragraph 34, which states that “[a]ny modification to this Agreement must be agreed upon in writing by each Party to the Agreement.”⁷⁰ Because all modifications or amendments to the Protective Order must be approved and entered by the Court, this provision is superfluous.

⁶⁸*Id.*, ¶ 31.

⁶⁹*Id.*, ¶ 33.

⁷⁰*Id.*, ¶ 34.

D. Paragraph 35

Paragraph 35 explains that “[t]he terms of this *Agreement*” are binding on the parties and their officers, etc.⁷¹ The Court will substitute the word “Protective Order” for the word “Agreement” in what will now be numbered Paragraph 32.

E. Acknowledgment of Protective Order

An “Acknowledgment” is attached at the end of the Order. The Acknowledgment is a form agreement under which a non-party agrees to abide by the terms of the Protective Order. Such acknowledgments and agreements are allowed under the Court’s Protective Order Guidelines. The last sentence of this particular Acknowledgment, however, must be deleted. That sentence indicates that the non-party submits to the jurisdiction of this Court for purposes of enforcing the Order. Such a provision is invalid, however, as it is well settled that parties may not create jurisdiction—either by acquiescence or stipulation—where jurisdiction does not otherwise exist.⁷²

VIII. Conclusion

The Court holds that the Parties have shown good cause for the entry of a blanket protective order to protect the confidentiality of the information and documents the Parties have labeled “Protected Discovery Material.” In most respects, the Court approves the Parties’ proposed Protective Order. To the extent the Parties have a dispute as to Paragraph 6(h) proposed by KUCR, the Court grants KUCR’s Cross Motion. The Court will allow Inventorship Material to be disclosed to Dr. Stella and Ms. Waugh, as well as Dr. Gupta, as set forth in KUCR’s proposed Paragraph 6(h).

⁷¹*Id.*, ¶ 35 (emphasis added).

⁷²*See Ins. Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982) (“No action of the parties can confer subject-matter jurisdiction upon a federal court. Thus, the consent of the parties is irrelevant.”); *Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1231 n.1 (10th Cir. 2006) (“[Jurisdiction] cannot be conferred upon a federal court by consent, inaction or stipulation”) (quoting *Basso v. Utah Power & Light Co.*, 495 F.2d 906, 909 (10th Cir. 1974)).

The Court finds that KUCR's need for the Inventorship material outweighs any risk of harm to Defendants. The Court will therefore include KUCR's proposed Paragraph 6(h) in the Protective Order.

With respect to KUCR's proposed additional language in Paragraph 13(b), the Court denies KUCR's Cross Motion. The dispute over that language was the result of apparent confusion between the Parties.

With respect to the other provisions of the proposed Protective Order, i.e., the provisions to which all of the Parties have agreed, the Court will make certain modifications to proposed Paragraphs 25, 26, 31, 33, 34, and 35, and to the Acknowledgment, as set forth in detail in Part VII, *supra*. The Court will enter the Protective Order, as modified to conform to this Memorandum and Order, in a separate filing.

IT IS THEREFORE ORDERED that Plaintiff's Cross Motion for Protective Order (doc. 131) is granted in part and denied in part, as set forth herein.

IT IS FURTHER ORDERED that Defendants' Cross Motion for Protective Order (doc. 133) is granted in part and denied in part, as set forth herein.

IT IS FURTHER ORDERED that the Court will enter a Protective Order consistent with this Memorandum and Order in a separate filing.

IT IS FURTHER ORDERED that each party will bear its own expenses and fees incurred in connection with the filing of these Cross Motions for Protective Order.

IT IS SO ORDERED.

Dated in Kansas City, Kansas on this February 12th day of January 2010.

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

cc: All counsel and *pro se* parties