BoxInterferences@uspto.gov
Tel: 571-272-9797

Entered: January 28, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ashok **Kumar**
and
Nellithanath Thankachen Byju
Junior Party
(Application 14/794,417).

v.

Hong-Bin **Sun**,
Jiaqi Shan, Boyu Zhang,
and
Fang Yuan,
Senior Party
(Patent 8,772,489),

(Patent Interference No. 106,063) (JTM)
(Technology Center 1600)

Before SALLY GARDNER LANE, JAMES T. MOORE,
and DEBORAH KATZ, *Administrative Patent Judges.*

MOORE, *Administrative Patent Judge*.

JUDGMENT - Bd. R. 127(a)

The Board determined that Sun showed entitlement to benefit for Count 1 of PCT/CN2011/000138, filed 28 January 2011; CN2010 1 0624329, filed 30 December 2010; and CN2010 1 0104091, filed 2 February 2010. (Decision, Paper 101). This interference is redeclared to reflect that change. Paper 102.

Kumar's earliest alleged priority date of August 26, 2010 (Paper 34) is after the earliest of these dates. Accordingly, Kumar cannot prevail on priority.

Accordingly,

It is ORDERED that judgment on priority is entered against junior party Kumar as to Count 1, the sole Count, of the interference (Declaration, Paper 1, at 5;

FURTHER ORDERED that claims 1-6, 8-17, 20-29 of Kumar application 14/794,417, which correspond to Count 1, are FINALLY REFUSED. 35 U.S.C. § 135(a);[1]

FURTHER ORDERED that the parties are directed to 35 USC § 135(c) and Bd. R. 205 regarding the filing of settlement agreements;

FURTHER ORDERED that a party seeking judicial review timely serve notice on the Director of the United States Patent and Trademark Office. 37 C.F.R. §§ 90.1 and 104.2. *See also* Bd. R. 8(b). Attention is directed to *Biogen Idec MA, Inc., v. Japanese Foundation for Cancer Research*, 785 F.3d 648, 654–57 (Fed. Cir. 2015) (determining that pre-AIA § 146 review was eliminated for interference proceedings declared after September 15, 2012); and

1 Any reference to a statute in this Judgment is to the statute that was in effect on March 15, 2013 unless otherwise indicated. See Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

FURTHER ORDERED that a copy of this judgment be entered into the administrative records of the involved Sun patent and Kumar application.

cc (via email):

Attorneys for Sun

Thomas O. Hoover, Esq.
Wei Song, Esq.
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston MA 02110
thoover@mccarter.com
wsong@mccarter.com

Richard Torczon, Esq.
Wilson Sonsini Goodrich & Rosati LLP
1700 K Street, N.W., 5th Floor
Washington, DC 20006
rtorczon@wsgr.com

Attorneys for Kumar

Barry E. Bretschneider
Peter J. Knudsen
Charles C. Carson
BAKER & HOSTETLER LLP
1050 Connecticut Avenue, N.W., Suite 1100
Washington DC 20036-5304
bbretschneider@bakerlaw.com
pknudsen@bakerlaw.com
ccarson@bakerlaw.com

BoxInterferences@uspto.gov
Tel: 571-272-9797

Entered: January 28, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Hong-Bin **Sun**,[1]
Jiaqi Shan, Boyu Zhang,
and
Fang Yuan,
Junior Party
(Patent 8,772,489),

v.

Ashok **Kumar**[2]
and
Nellithanath Thankachen Byju
Senior Party
(Application 14/794,417).

(Patent Interference No. 106,063) (JTM)
(Technology Center 1600)

Before SALLY GARDNER LANE, JAMES T. MOORE, and DEBORAH KATZ, *Administrative Patent Judges*.

MOORE, *Administrative Patent Judge*.

DECISION ON MOTIONS
37 C.F.R. § 41.125

---

[1] The real party in interest is identified as Jiangsu Vcare Pharmatech Co., Ltd. Paper 5, 1.

[2] The real party in interest is identified as Ipca Laboratories Limited. Paper 9, 1.

I. Background

An interference was declared under 35 U.S.C. § 135(a)[3] on September 16, 2016. Paper 1. Hong-Bin Sun, Jiaqi Shan, Boyu Zhang, and Fang Yuan ("Sun") were assigned the status of junior party with an initial application filing date of September 18, 2012. *Id.*, 5. Ashok Kumar and Nellithanath Thankachen Byju, ("Kumar") were assigned the status of senior party with an initial application filing date of August 26, 2011. *Id.*, 6.

The interference count is claim 1 of Sun U.S. Patent 8,772,489. *Id.*, 5. The count reads as follows:

> 1. An optically active 2-hydroxytetrahydrothienopyridine derivative, wherein said derivative is (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)- acetate or a pharmaceutically acceptable salt thereof.

Paper 7, 3.

Following a conference call on November 9, 2016, the following motions were authorized by the Board. Paper 23, 2–3.

1. Sun Motion 1 – for benefit of PCT/CN2011/000138, filed 28 January 2011 (translation, EX2002); CN2010 1 0624329, filed 30 December 2010 (translation, EX2004); and CN2010 1 0104091, filed 2 February 2010 (translation, EX2003).

2. Kumar Motion 1 – for benefit of Indian Patent Application No. 2388/MUM/2010, filed August 26, 2010.

[3] Any reference to a statute in the Decision is to the statute that was in effect on March 15, 2013 unless otherwise indicated. *See* Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

Kumar has requested reconsideration (Paper 31) of the single judge denial of its request to file Kumar Proposed Motion 2, which request is denied by the full panel below. Kumar has also filed Miscellaneous Motion 3 to exclude evidence. That motion is denied below.

Although the parties requested oral argument (Papers 79 and 81), the Board deems argument unnecessary to the resolution of the motions presented for decision. Accordingly, the requests for oral argument are denied.

The motions are therefore ready for disposition.

As we find Sun Motion 1 to be dispositive of this interference, we address it first.

II. Sun Motion 1 – Benefit

i. Benefit

To be accorded the benefit of priority of an earlier application, a party must show that the earlier application is a prior constructive reduction to practice by meeting the requirements of 35 U.S.C. § 112, first paragraph, for at least one embodiment within a count. See *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1362 (Fed. Cir. 2006). Sun bears the burden of establishing entitlement to relief, by a preponderance of the evidence.

Count 1, the only count in this interference, is claim 1 of Sun's patent, and recites:

> An optically active 2-hydroxytetrahydrothienopyridine derivative, wherein said derivative is (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)- acetate or a pharmaceutically acceptable salt thereof.

Paper 7, 3.

To prevail, Sun must show by a preponderance of the evidence written description and enabling support for every element of the count in the PCT application and the CN applications.

Factual Background

The compounds contained within the count of the present interference - optically active 2-hydroxytetrahydrothienopyridine derivatives - are said to be useful for inhibiting platelet aggregation. Ex. 2001, abstract. The compounds are said to be converted *in vivo* into pharmacologically active metabolites and therefore to be useful as precursors for the metabolites inhibiting platelet aggregation. Such compounds are also said to be useful for the manufacture of medicine for preventing or treating thrombosis and embolism related diseases. *Id.* It should be noted that no level of pharmacological activity is contained within the count, merely that the compound be optically active. Paper 7, 3.

Arguments

Scope of the Count

As noted above, Count 1, the only count in this interference, is claim 1 of Sun's patent, which recites the following compound: "An optically active 2-hydroxytetrahydrothienopyridine derivative, wherein said derivative is (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate or a pharmaceutically acceptable salt thereof." Paper 7, 3.

Sun asserts that the count's proper scope is when it "is given its broadest reasonable construction in view of the specification from which it originates." Paper 48, 1, citing *DeGeorge v. Bernier*, 768 F.2d 1318, 1321-22 (Fed. Cir. 1985). According to Sun, this means Count 1 requires optical activity but does not specify a degree of optical activity. *Id.* Kumar does not disagree with this statement about

the degree of activity. Paper 73, 3:1–2. Sun's ultimate position is that optical activity would result if the S compound is present in excess amount versus the R enantiomer, and would be maximal when exclusively the S enantiomer is present. Enantiomeric excess (ee) is said to be the difference between the percentage of the major enantiomer in a mixture and the percentage of its mirror image. Paper 48, 1–2, citing Ex. 2015, 282-83.

Kumar, on the other hand, asserts that the count must be interpreted much more narrowly and with respect to claim 1 of Sun's involved patent. According to Kumar, this also requires that when "properly construed, Sun claim 1, and thus the count, requires Sun to show possession of an optically active *and enantiomerically pure form* of the specific (S)-isomer derivative set forth in the claim." Paper 73, 2:3–5 (emphasis added).

We observe that we are not pointed by either party to a location in the specification of Sun's '489 patent where the term "optically active" is defined. We have not been able to locate such a definition in our inspection of Ex. 2001. Sun points us to a description of the various optical purities which should be present. Paper 48, 4:15-18.

Kumar is of the opinion that we must consult the prosecution history to determine the meaning of the term "optically active." Paper 73, 4. Kumar asserts that the term is defined in the prosecution history to mean "the pure enantiomer." *Id.* We are pointed to Kumar's statements of fact 83, 84, 85, 86, and 88 in support of this proposition, and Ex. 2001 as a whole.

Given the importance of this issue to our decision, we reproduce the proposed SFs from 84–89 below:

> 84. Sun responded to the Examiner's rejection by arguing that the prior art did not read on the claimed optically active (S)-isomer: "The '938 patent, the primary reference, does not teach superior activity and less toxicity of *one of the two enantiomers* of antiplatelet compounds." Exhibit 1016 at 12.
>
> 85. In Reasons for Allowance, the Examiner concluded as follows.
>
> > The claimed invention is directed to the pure enantiomer compound (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate and pharmaceutically acceptable salts and compositions thereof. The closest prior art it [sic - is] the cited US patent 5190938 which discloses the racemic compound.
>
> Exhibit 1017 at 3.
>
> 86. Sun acquiesced in and did not refute the Examiner's conclusion. Exhibit 1016, *passim.*
>
> 87. In Sun's involved patent the term "optically active" (S)-isomer is synonymous with enantiomerically pure (S)-enantiomer. Exhibit 2001, *passim.*
>
> 88. Sun's involved patent nowhere defines the degree of enantiomeric purity that is associated with "optically active" (S)-isomer. Exhibit 2001, *passim*.
>
> 89. Sun's involved patent describes the purity of the (S)-isomer as having an ee=98.9%. *Id*. at col. 12, l. 20.

Paper 73, 34–35 (emphases in original).

According to Kumar, the Examiner rejected claims reciting an optically active compound - "The compounds taught by US 5190938 are identical to those of the instant claims except they are racemic mixtures rather than pure compounds. … It would have been obvious to one skilled in the art at the time of the invention to modify the racemic compounds of US 5190938 … to provide the enantiomerically pure compounds of the present invention." Paper 73, 4:21–25, citing FF83 and Exhibit 1015 at 5-6.

Next, Kumar asserts that in response to the Examiner's rejection, Sun argued that the prior art did not teach an optically active (S)-isomer as follows: "The '938

patent, the primary reference, does not teach superior activity and less toxicity of one of the two enantiomers of antiplatelet compounds." Paper 73, 4–5, citing SF84; Exhibit 1019 at 12. Kumar urges that Sun relied on the properties of the compound of Example 5 having an ee=98.9% to distinguish its optically active derivative from the prior art racemic mixture of the '938 patent. Paper 73, 5, citing SF84; SF88; SF89; and Exhibit 1019, *passim.*

Kumar then reasons that the Examiner relied on Sun's argument, and in the Reasons for Allowance concluded that "[t]he claimed invention is directed to the pure enantiomer compound (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate and pharmaceutically acceptable salts and compositions thereof." Paper 73, 5, citing SF85 and Exhibit 1017 at 3. Accordingly, Kumar concludes that Sun acquiesced in the Examiner's statements about the claimed invention (SF86) and may not now argue that the "optically active derivative" of Sun claim 1 is not enantiomerically pure. *Id.*

The basic question concerning the scope of the count raised by Kumar in its opposition is whether (1) the argument made during prosecution by Sun that the S-isomer was unexpectedly less toxic and better, (2) relying on an example of over 98%, (3) the Examiner's statement in the reasons for allowance, and (4) the failure to refute by Sun serve as prosecution estoppel to raise the level of optical activity to enantiomeric purity for the claim, and then also for interpreting the scope of the count.

Initially, we turn to the '489 patent for objective evidence of the meaning of the term "optically active." The '489 patent states that "[t]he present compound of Formula I has an optical purity of 70–100%, preferably 90–100%, more preferably 95-100% and most preferably 98–100%." Ex. 2001, 5:7–10. However, as noted

above, optical purity is not recited in the count (or Sun claim 1) - what is recited is merely that the derivative is "optically active." Optically active, therefore, is in our view likely broader than 70-100% optically pure, unless the term has been limited during prosecution.

It is true that the Examiner did make a finding during prosecution (in a restriction requirement dated September 18, 2012) that it "would have been obvious to one skilled in the art at the time of the invention to modify the racemic compounds of US 5190938 according to the teachings of US 4847265 to provide the enantiomerically pure compounds of the present invention in order to improve potency and toxicity." Ex. 1015, 6. But, that statement was made in regard to claims that were much broader than the instant claims.

In response to that restriction requirement, on July 3, 2013 original claims 1-4 were cancelled and claim 5 amended to recite a single species of derivative. Ex. 1016, 2. Claim 6-10 were cancelled and claim 11 amended also to recite a single species. *Id.*, 5. Further amendments similarly tailored the remaining claims. The arguments then made included one that the species was novel over the art by a modification made to its structure. *Id.*, 8. More specifically:

> The '938 Patent, the primary reference, does not teach superior activity and less toxicity of one of the two enantiomers of antiplatelet compounds. Furthermore, as discussed in Section II, the '938 Patent does not teach or suggest that adding an acyloxy substituent to the 2-position of the thienopyridine ring would improve pharmacological activities of the antiplatelet compounds.

Ex. 1016, 12.

It is fair to say that Sun argued that the superior activity of one of the two enantiomers of modified antiplatelet compounds was not taught, as seen above.

But we do not see where Sun made the argument to the Examiner that it was a "pure" enantiomer. Indeed, such an argument would have been significantly different from the express teachings in the specification that the S-compound optical purity was preferably between 70 -100% and higher. Ex. 2001, 5:7–9.

It is somewhat incongruous that the Examiner referenced "pure" in the notice of allowability. Now that reference is being urged as an absolute by Kumar. For example, the Examiner refers to claims as being drawn to a "pure enantiomer" when they are not clearly so drawn, except perhaps as regards a content of the "pure" S-enantiomer in the overall composition. Ex. 1017, 2. The issue is made less clear when the Examiner stated "The references, and the prior art as a whole, do not teach or suggest the selection of the racemic compound for further analysis or resolution that would lead a skilled artisan to the enantiomer of the instant invention. Furthermore, the surprising and unexpected pharmacokinetic results obtained with the pure enantiomer relative to the racemate and relative to known compounds with the same utility distinguish the pure enantiomer from the racemate and such related prior art compounds." *Id.*, 3–4.

Perhaps the Examiner was referring to the most pure Example cited, at 98.5%, and not the claim which matured into the count at issue. Such is, in any event, unclear and ambiguous to us. It also is possible that the Examiner was stating that the racemic compound would not be suggested for study (lending credence to the then-applicant's argument on July 3, 2013 that the species itself in the amended claim was novel or nonobvious) and its superior results as contained in the "pure enantiomer" "relative to the racemate" were persuasive. Whether the Examiner was referring to a level of pure enantiomer in a mixture is, again, unclear and ambiguous to us.

One clear statement that exists in the notice of allowance and that is coextensive with Sun's arguments is that the comparison for the determination patentability was a comparison relative to the racemate, in other words, certainly excluding everything up to and including the 1:1 mix of enantiomers.[4]

While we understand Kumar's concern that Sun's statements during prosecution effectively narrowed the claim, we do not conclude under these facts that those statements acted to persuade the Examiner to allow the case because the optically active derivative as a whole composition must be enantiomerically pure. We are, rather, more persuaded by Sun's contention that whatever the somewhat vague one-sided discussion on allowability by the Examiner was, it did not rise to the level of an unambiguous disavowal of claim scope by Sun. *Shire Dev. LLC v. Watson Pharm., Inc.*, 746 F.3d 1326, 1331 (Fed. Cir. 2014). Accordingly, we agree with Sun that optical activity requires that the S enantiomer is present in excess amount versus the R enantiomer in measurable quantity. We therefore reject Kumar's assertion that enantiomeric purity is required by the count.

Disclosures and Priority

A constructive reduction to practice is a described and enabled anticipation under 35 U.S.C. §102(g)(1) within the scope of the count. 37 C.F.R. § 41.201. An earliest constructive reduction to practice must be continuously disclosed through a chain of applications that includes the involved application or patent. *Id.*

Sun asserts that its disclosures occurred as follows:

[4] Dr. Niels H. Anderson is presented as a witness in this interference by Kumar. We find him qualified to testify as to the technical subject matter of this interference. Ex. 1006, ¶ 1 and Ex. 1007. He testifies that a racemic mixture is a 1:1 mixture of enantiomers. Ex. 1019, ¶ 4.

(1) US 8,772,489 B2 was filed as national stage application 13/576,534, with a §371 date of September 18, 2012 (Ex. 2001);

(2) PCT/CN2011/000138 was filed as a PCT application in China on January 28, 2011 (Ex. 2014 (translation Ex. 2002));

(3) CN2010 1 0624329, filed December 30, 2010 (Ex. 2016 (translation Ex. 2004));

(4) CN2010 1 0104091, filed February 2, 2010 (Ex. 2013 (translation Ex. 2003)). Paper 48, 3.

Sun next asserts that it has continuously disclosed an example producing the compound of the count, and points to Ex. 2001, 11:54-12:31 (Example 5); Ex. 2002, 20:1-22 (Example 5); Ex. 2004, 21:8-22:4 (Example 5); and Ex. 2003, 13:16-14:16 (Example 4).[5] Paper 48, 3–4. Sun has also provided an appendix of claim charts which illustrate the compounds said to be within the count. Paper 48, Appendix 3. It is reproduced below, with bolding in the second row of cells added. We have carefully reviewed the cited passages in the Exhibits and find they accurately portray the description found in Exhibits 2002, 2004, and 2003 (through their corresponding translations).

Of note, Kumar does not challenge the description in the PCT application (column 2) or the December 2010 Chinese application (column 3), focusing its challenges only on the inherency aspect asserted by Sun for the February 2010 application, possession, and enablement. Paper 73, 1:10–11. We therefore

[5] Sun provides the declaration testimony of Dr. Timo V. Ovaska, retained as a witness for Jiangsu Vcare PharmaTech Co., Ltd. Ex. 2005. We find Dr. Ovaska to be qualified to provide testimony as to the technical subect matter of this interference proceeding. *Id.*, ¶2–4 and Ex. 2006 (*curriculum vitae*).

conclude, for the reasons noted in the chart provided, that Sun is entitled to priority of the December 2010 Chinese application. We proceed to the February 2010 Chinese application below.

Count 1 (Sun claim 1)	**PCT: EX2002**	**Dec. 2010- EX2004**	**Feb. 2010: EX2003**
An optically active: ---------- 2-hydroxytetrahydro-hienopyridine derivative,	3:22-25, "The present invention discloses an optically active 2-hydroxytetrahydro-thienopyridine derivative…or a pharmaceutically acceptable salt or hydrate thereof"	3:3-5 "The present invention relates … more particularly to optically active 2-hydroxytetrahydro-thienopyridine derivatives"	**[inherent]** ---------- 4:19-23, "novel 2-hydroxythienopyridine derivatives… are first disclosed."
wherein said derivative is (S)-methyl 2-(2-acetoxy-6, 7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate	5:21-24, "Preferred compounds of the present invention are: (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate I-2"	7:5-8, "Preferred compounds of the present invention are: (S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate I-2"	6:4-11, "More preferred compounds are the compounds below…: * * *; (S)-methyl 2-(2-(acetoxy)-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate"
or a pharmaceutically acceptable salt thereof.	3:22-25 "The present invention discloses an optically active 2-hydroxytetrahydro-hienopyridine derivative…or a pharmaceutically acceptable salt or hydrate thereof"	12:4-5, "The compound of the present invention also includes a pharmaceutically acceptable salt of the compound of Formula I"	4:24-25, "A series of compounds represented by general Formula I, or stereoisomers, pharmaceutically acceptable salts or solvates thereof"

As only the optical activity element of the compound of the Chinese February 2010 application is in dispute, we focus our initial analysis there.

Sun asserts that the February 2010 Chinese application identifies the compound of the count "(S)-methyl 2-(2-acetoxy-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate" as a "[m]ore preferred compound[]". Paper 48, 5. We find this to be accurate. Ex. 2003, 6:9–11.

As support for that proposition, Sun cites Ex. 2003, 6:4–11 and 10:22–24 (identifying FIG. 7 as "a ^{1}H NMR spectrum of (S)-methyl 2(2-(acetoxy)-6,7-dihydrothieno[3,2-c]pyridine-5(4H)-yl)-2-(2-chlorophenyl)-acetate"). Sun also cites Ex. 2013, FIG. 7 as showing the structure and NMR data for the compound of the count. Paper 48, 5. Further, Sun asserts that the NMR data for Example 5 in Sun's patent (Ex. 2001) and Example 4 in the February 2010 application (Ex. 2003) are identical for ^{13}C-NMR and essentially the same for ^{1}H-NMR. *Id.* Dr. Ovaska so testifies. Ex. 2005, ¶19. Sun also asserts similarity in electrospray ionization mass spectrometry. Paper 48, 5. We find this evidence to be persuasive and credible. Notably, it is unchallenged. We find that the compound of the February 2010 application is *chemically* the same compound. Kumar does not materially dispute this. Paper 73, *passim*.

Sun admits that the February 2010 application does not describe optical activity or report an enantiomeric excess for Example 4. Paper 48, 6:2–3. In order to prevail, Sun bears the burden of establishing by a preponderance of the evidence that this property was inherently present.

When a specification describes an invention that has certain undisclosed yet inherent properties, that specification may serve as adequate written description to support a subsequent patent application that explicitly recites the invention's

inherent properties. *Yeda Research & Dev. Co., Ltd. V. Abbott GmbH & Co. KG*, 837 F.3d 1341, 1345 (Fed. Cir. 2016). This requires proof that such a property is inherently present in order to show possession of an embodiment within the scope of the count. In order to show anticipation inherently, the disclosure must necessarily include the claimed limitation. *In re King*, 801 F. 2d 1324 (Fed. Cir. 1986); *Agilent v. Affymetrix, Inc.*, 567 F.3d 1366, 13283 (Fed. Cir. 2009).

Sun tested Example 4 for optical activity in support of its motion for benefit. Paper 48, 6. Sun asserts that Dr. Ovaska performed Examples 1–4 in synthesizing the compound and that the S-isomer product had an enantiomeric excess of 91.7%. *Id.*

The process Dr. Ovaska testifies he performed was reproducing Example 1 of Sun's February 2010 Chinese application. He testifies that "(R)-o-chloromandelic acid (5.6 g) was dissolved in 23.1 ml of methanol, 0.12 mL of concentrated sulfuric acid was then added, and the mixture was heated at reflux for 2 hrs……Once the solution had cooled to room temperature, methanol was removed under reduced pressure. The mixture was then dissolved in dichloromethane, and the solution was washed with 10% aqueous potassium carbonate solution (25 mL) and then with water (25 mL). The solution was dried over $MgSO_4$, and the solvent was evaporated to give 5.93 g of (*R*)-methyl-o-chloromandelate as a clear oil, by myself. Yield 98.5 %.....The ^{1}H-NMR and ESI-MS of Example 1 obtained by myself is provided below: ^{1}H-NMR (500 MHz, $CDCl_3$) δ ppm: 3.55(d, *J* = 4.9Hz, 1H), 3.78(s, 3H), 5.57(d, *J* = 4.9Hz, 1H), 7.26-7.30(m, 2H), 7.37-7.41(m, 2H); ESI-MS m/z: 223.2 [M+Na]+." Ex. 2005, ¶¶ 7–8.

Dr. Ovaska then performed Step 2. He testifies "(R)-Methyl o-chloromandelate (5.83 g) was dissolved in 500 ml of anhydrous dichloromethane.

Triethylamine (5.30 ml) was added followed by a catalytic amount of dimethylaminopyridine. The reaction mixture was then cooled to 0°C. A solution of p-nitrophenylsulfonyl chloride (7.08 g) in dichloromethane was added dropwise to the reaction mixture at 0°C. The reaction mixture was then allowed to stir at 0°C for 4 hrs after addition…..Water (200 mL) was then added to the reaction mixture, and the layers were separated. The aqueous phase was extracted with dichloromethane, the organic phases were combined and dried, and dichloromethane was evaporated under reduced pressure to afford a crude product, which was subsequently purified by flash chromatography (petroleum ether: ethyl acetate = 40:5), to obtain 9.4 g of pure (R)-methyl 2-(2-chlorophenyl)-2(4-nitrophenylsulfonyloxy)-acetate, by myself. Yield 84%.....The ^{1}H-NMR and ESI-MS of Example 2 obtained by myself is provided below: ^{1}H-NMR (500 MHz, $CDCl_3$) δ ppm: 3.78(s, 3H), 6.39(s, 1H), 7.20-7.40(m, 4H), 8.06(d, *J* = 8.8Hz, 2H), 8.32(d, *J* = 8.8Hz, 2H); ESI-MS m/z: 408.2 [M+Na]+. *Id.*, ¶¶ 9–10.

Dr. Ovaska then testifies he conducted the third example from Sun's February 2010 application. "2-oxo-5,6,7,7a-tetrahydrothieno[3,2-c]pyridine hydrochloride (4.6 g) was dissolved in acetonitrile, and then 6.5 ml of triethylamine was added, and stirred until the solid was completely dissolved, by myself…..A solution of (R)-methyl 2-(2-chlorophenyl)-2(4-nitrophenylsulfonyl)-acetate (7.71 g) in acetonitrile was added dropwise at 25°C, and then reacted at room temperature for 7 hrs after addition, by myself…….The insolubles in the reaction solution were filtered off, and acetonitrile was evaporated, to give a crude product, which was purified by flash chromatography (petroleum ether: ethyl acetate = 40:7), to obtain 3.96 g of the product, by myself. Yield 59 %.....The ^{1}H-NMR of Example 3 obtained by myself is provided below: ^{1}H-NMR (500 MHz,

CDCl3) δ ppm: 1.80-1.93(m, 1H), 2.30-2.38(m, 1H), 2.56-2.70(m, 1H), 2.95-3.27(m, 2H), 3.70(s, 3H), 3.80-3.93(m, 1H), 4.12-4,19(m, 1H), 4.85(d, 1H), 5.95(d, 1H), 7.22-7.56(m, 4H); ESI-MS m/z: 338.1 [M+H]+. *Id.*, ¶¶ 11–12.

Dr. Ovaska testifies that he performed Example 4: "(S)-methyl 2-(2-oxo-7,7a-dihydrothieno[3,2-c]pyridin-5(2H,4H,6H)-yl)-2-(2-chlorophenyl)-acetate (0.74 g) [1] was dissolved in N,N-dimethylformamide, and then 1.4 ml of acetic anhydride was added. 0.89 mL of triethylamine was added dropwise at 0°C, and heated to room temperature for 1 hr after addition, by myself…..(S)-methyl 2-(2-oxo-7,7a-dihydrothieno[3,2-c]pyridin-5(2H,4H,6H)-yl)-2-(2- chlorophenyl)-acetate (0.74 g)1 was dissolved in N,N-dimethylformamide, and then 1.4 ml of acetic anhydride was added. 0.89 mL of triethylamine was added dropwise at 0°C, and heated to room temperature for 1 hr after addition, by myself…..The ^{1}H-NMR of Example 4 obtained by myself is provided below: ^{1}H-NMR (500 MHz, CDCl3) δ ppm: 2.25(s, 3H), 2.75(m, 2H), 2.83(m, 2H), 3.55(d, *J* = 14.7Hz, 1H), 3.65(d, J = 14.7Hz, 1H), 3.73(s, 3H), 4.85(s, 1H), 6.23(s, 1H), 7.20-7.70(m, 4H); ESI-MS m/z: 380.2 [M+H]+…… The ^{13}C-NMR of Example 4 obtained by myself is provided below: ^{13}C-NMR (500 MHz, CDCl3) δ ppm: 20.69, 24.99, 48.11, 50.30, 52.15, 67.81, 111.9, 125.8, 127.1, 129.2, 129.4, 129.8, 129.9, 133.7, 134.7, 149.5, 167.7, 171.2. *Id.*, 13–15.

Finally, Dr. Ovaska testifies that the product of example four is optically active. He testifies:

> Two samples were tested. The first sample is the corresponding racemic compound, which was provided by Jiangsu Vcare. Under the Chiral HPLC analytical conditions described above, two equal peaks appeared at retention time 18.167 mins and 21.367 mins respectively (Sun Exhibit 2007, page 15). The second sample is the final product I obtained from Example 4.

> Under the same Chiral HPLC analytical conditions, a small peak appeared at retention time 18.250 mins, and a major peak appeared at retention time 21.267 mins (Sun Exhibit 2007, page 16).
>
> The HPLC spectra I obtained are consistent with the results demonstrated in the JMC paper at pages S66-68 (Sun Exhibit 2008). Specifically, the undesired *R*-isomer has an earlier retention time (about 18.7 mins) and the desired *S*-isomer (i.e., same as Example 4) has a retention time of about 21 mins. Thus, it can be concluded that in the HPLC spectrum of Example 4 product, the peak at 18.25 mins is corresponding to undesired *R*-isomer, and the peak at 21.267 mins is corresponding to the *S*-isomer.
>
> As such, the ee value is calculated as (*S*-isomer Area %– *R*-isomer Area %)/(*S*-isomer Area % + *R*-isomer Area %)= (95.85-4.15)/(95.85+4.15)=91.7%.

Ex. 2005, ¶ 16.

Dr. Ovaska testifies that the data in paragraph 16 of his declaration "demonstrates that the final product of Example 4 is optically active." *Id.* 20. Kumar did not cross-examine Dr. Ovaska on this testimony.

Kumar urges that this evidence is insufficient because, *inter alia,* Dr. Ovaska did not provide evidence persons skilled in the art would have been able to identify the S isomer peak without having the "JMC paper" before him. Paper 73, 2. Kumar also urges that Sun has failed to show possession of the subject matter of the count. *Id.,* 8. We address these issues below.

Possession

Kumar first asserts that a comparison of Sun's February 2010 application with its later applications and patent shows that the Sun inventors did not have possession in February 2010 of the subject matter of Sun claim 1, the count. Paper 73, 8. More specifically, Kumar asserts that the Sun February 2010 application contains no disclosures that "[r]ecrystallization from ethanol afforded a white solid, mp: 73-75° C., ee=98.9%[.];" "explains that the derivative should

have 'an optical purity of 70-100%, preferably 90-100%, more preferably 95-100%, and most preferably 98-100%;" and "Example 5 produces a product with an enantiomeric excess (ee) of 98.9%;" *Id.* 8–9.

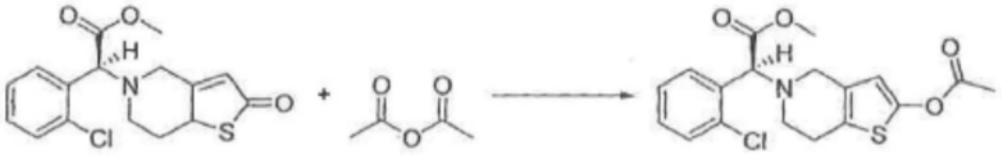
As a consequence, Kumar alleges that this shows it is as likely as not that Sun had possession of the invention of the count. *Id.* 9. We are not persuaded by this contention, which is attorney argument comparing the disclosures of the applications, when the focus in this instance is on the description in the February 2010 application. The precise factual issue to be determined is whether Example 4 in the February 2010 application inherently has the required optical activity, not the December 2010 or PCT applications.

We think the discussion contained within the February 2010 application is more telling. It describes, albeit in the related art section, that "Clopidogrel is a thienopyridine anti-platelet aggregation agent, has one chiral carbon atom, and is an optically active compound. The pharmacological test suggests that S-clopidogrel has the anti-platelet aggregation activity, but R-clopidogrel does not; moreover, after R-clopidogrel is administered to rats, a side effect, convulsion, occurs in the rats (*Perspect Drug Discov Des*, 1994, I: 521)." Ex. 2003, 1:26–2:4. The relationship between chirality and activity in the precursor drug was therefore, established. At page 6, lines 4–11, the February 2010 application states more preferred compounds include: "(S)-methyl 2-(2-(acetoxy)-6, 7 -dihydrothieno[3,2-c]pyrid in-5(4H)-y 1)-2-(2-fluorophenyl)-acetate; (S)-methyl 2-(2-(acetoxy)-6, 7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate…"

Example 4 in the February 2010 Chinese application is central to this issue. It is reproduced below:

Example 4

(S)-methyl 2-(2-(acetoxy)-6, 7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate



(S)-methyl 2-(2-oxo-7,7a-dihydrothieno[3,2-c]pyridin-5 (2H,4H,6H)-yl)-2-(2-chlorophenyl)-acetate (35 mg) was dissolved in N,N-dimethylformamide, and then 0.067 ml of acetic anhydride was added. 0.042 ml of triethylamine was added dropwise at 0°C, and heated to room temperature for l hr after addition. The reaction solution was poured into a large amount of water, the aqueous phase was extracted with ethyl acetate, and the organic phase was dried and evaporated to dryness, to give a crude product, which was purified by flash chromatography (petroleum ether: ethyl acetate =40:3), to obtain 27 mg of pure (S)-methyl 2-(2-(acetoxy)-6, 7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate. Yield 71.1 %. ^{1}H-NMR (500 MHz, CDC1$_3$) 8 ppm: 2.26(s, 3H), 2.77(d, 2H, *J* = 5.4Hz), 2.89(d, 2H, *J* = 5.0Hz), 3.54(d, lH, *J* = 14.2Hz), 3.65(d, lH, *J* = 14.2Hz), 3.72(s, 3H), 4.91(s, lH), 6.26(s, lH), 7.25-7.69(m, 4H); ^{13}C-NMR (300 MHz, CDC1$_3$) 8 ppm: 20.2, 24.5, 47.6, 15 49.8, 51.6, 67.3, 111.5, 125.3, 126.6, 128.8, 128.9, 129.3, 129.4, 133.3, 134.2, 149.1, 167.2, 170. 7; ES I-MS m/z: 380.0 [M+H]+.

Ex. 2003, 13:15–14:16.

On its face, the description of the Sun February 2010 Chinese application states it obtained 27 mg of pure (S)-methyl 2-(2-(acetoxy)-6, 7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate. The evidence of record is strong that this text in Ex. 2003 is a description of the compound of the count, but for a description of its optical activity, which is known to be of importance. The question left for us is whether this description necessarily and inevitably results in a composition that is optically active.

Dr. Ovaska testifies that determination of optical purity by use of high pressure liquid chromatography ("HPLC") was a well-established technique.

> 27. Prior to February 2, 2010, HPLC was a well-established technique for separating enantiomers. Organic chemists routinely identified suitable conditions for effecting these separations. Although Sun's February 2010 Chinese application provides neither the optical purity of Example 4, nor the HPLC conditions for determining optical purity, determining optical purity was not difficult. Organic chemists routinely used a chiral column to determine the optical purity of a chiral compound like Example 4. Indeed, determining optical purity by chiral HPLC is such a standard practice that many authors of peer reviewed scientific articles do not even provide the HPLC conditions in their publications.

Ex. 2005, ¶ 27. We find this testimony to be both reasonable and credible.

Dr. Ovaska testifies that he used a chiral HPLC technique to test the product of Example 4 for optical activity.

We reproduce this testimony below:

> 16. Characterization of product of Example 4 – Optical Activity (ee)
>
> The HPLC condition is the same as the condition disclosed in the JMC paper at page 3348, lines 20-23, left column. Sun Exhibit 2008. Chiral HPLC analytical conditions: Chiralpak IC, 4.6 mm × 250 mm, eluting with 92% nhexane + 8% THF + 0.1% Et_2NH, flow rate 0.5 mL/min, oven temperature 25 °C, detection UV 254 nm.
>
> Two samples were tested. The first sample is the corresponding racemic compound, which was provided by Jiangsu Vcare. Under the Chiral HPLC analytical conditions described above, two equal peaks appeared at retention time 18.167 mins and 21.367 mins respectively (Sun Exhibit 2007, page 15). The second sample is the final product I obtained from Example 4. Under the same Chiral HPLC analytical conditions, a small peak appeared at retention time 18.250 mins, and a major peak appeared at retention time 21.267 mins (Sun Exhibit 2007, page 16).
>
> The HPLC spectra I obtained are consistent with the results demonstrated in the JMC paper at pages S66-68 (Sun Exhibit 2008). Specifically, the undesired *R*-isomer has an earlier retention time (about 18.7

> mins) and the desired S-isomer (i.e., same as Example 4) has a retention time of about 21 mins. Thus, it can be concluded that in the HPLC spectrum of Example 4 product, the peak at 18.25 mins is corresponding to undesired *R*-isomer, and the peak at 21.267 mins is corresponding to the *S*-isomer.
>
> As such, the ee value is calculated as (*S*-isomer Area %– *R*-isomer Area %)/(*S*-isomer Area % + *R*-isomer Area %)= (95.85-4.15)/(95.85+4.15) =91.7%.
>
> ee value: 91.7%.

Ex. 2005, ¶ 16. Looking at this evidence, it appears that Dr. Ovaska has established that the process outlined in Sun's Chinese Patent Application from February, 2010 results in an optically active compound.

Kumar asserts that there are unexplained evidentiary gaps and jumps in logic in Sun's motion that cause it to fall short of its required evidentiary showing. Paper 73, 9. More specifically, Kumar urges that Dr. Ovaska did not rely on information that was publicly available in February 2010 to identify the (S)-isomer. *Id.,* 10, citing Exhibit 1019 at¶ 41. Instead, it is urged that he relied on the JMC paper published two years later and information and standards provided by his client. *Id.*, citing Exhibit 1019 at ¶ 13.

As Ex. 2008, the "JMC paper," was published in 2012, it is further urged that Ex. 2008 is not evidence of the state of the art. Paper 73, 10. Kumar then asserts that the only way he could know which was the optically active S-isomer was by access to information as the R-isomer was also optically active. *Id.,* 11. According to Kumar, "Without the knowledge Dr. Ovaska gleaned from the JMC paper, there is no evidence that Dr. Ovaska would have been able to, or did, distinguish the desired S-isomer from the undesired R-isomer based on what was publicly known in February 2010. Dr. Ovaska says nothing else on the state of public knowledge in February 2010." *Id.*

This argument is ultimately not persuasive. We fail to see the relevance of the publication date of the method used to determine the existence of the optical activity of the compound. The fact of optical activity can be demonstrated by any number of accepted techniques, including testing for optical rotation. Kumar's witness, Dr. Andersen, provided testimony on this point during cross examination by counsel for Sun:

> Q. Very good. Do you see on page 2, lines 9 and 10, a sentence starting "for the purposes of my analyses"?
> A. Yes. I do see that.
> Q. And that's where you've defined the level of skill in the art, correct?
> A. Right. A practicing pharmaceutical chemist.
> Q. For purposes of this examination, can we assume that we are talking about a pharmaceutical chemist in February 2010?
> A. Yes.
> Q. Very good. Would such a pharmaceutical chemist have been able to determine whether a compound was optically active without using chiral HPLC?
> A. Yes.
> Q. Would a pharmaceutical chemist have considered optical rotation an indication of optical activity?
> A. That was the method I was thinking of. Yes. That's how they would do it.

Ex. 2024, 13:5–23.

In short, the question we seek an answer to is whether the compound produced by Example 4 possessed the required optical activity. How optical activity is assessed is not particularly relevant so long as the compound being assessed is prepared in the manner described in the Sun February 2010 description.

Kumar also asserts that Dr. Ovaska did not show that the invention of the count is necessary and inevitable. Paper 73, 7. Rather, it is urged that he only

testified that he followed the examples and "this is what I got." *Id.* We disagree with this incomplete assessment of the evidence before us. We find Dr. Ovaska's testimony to be both credible and sufficient. He stated the tests he performed and the results of those tests, which we find to confirm optical activity. There is no meaningful and persuasive evidence to the contrary, merely attorney argument and speculation.

Kumar also asserts that without knowledge of the later-published JMC article, the HPLC peak of the S-isomer could not have distinguished the S-isomer from the also active R-isomer. Paper 73, 11. Dr. Andersen testifies that "[t]o show optically active, enantiomerically pure (S)-isomer by the methods of Examples 1-4, it is necessary to rely on chiral HPLC." Ex. 1019, ¶ 42. Dr. Andersen testifies that in 2010 it was no trivial matter to identify chiral chromatography peaks, and a person of skill could not know it was enantiomerically pure without significant experimentation. *Id.*, ¶ 46.

We think this position is misdirected. Whether one of ordinary skill in the art would have had difficulty determining the physical characteristics of Example 4 in February 2010 is not the appropriate inquiry. The inquiry is whether Example 4 as described produced the optically active compound of the count. On balance, Sun has produced sufficient evidence to show that it does.

Enablement

Sun asserts that, as regards enablement, Dr. Ovaska was "able to reproduce Examples 1-4 of the February 2010 Chinese application "application to obtain the compound (S)-methyl 2-(2-15 (acetoxy)-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl)-2-(2-chlorophenyl)-acetate, using materials and methods that would have been conventional before February 2010 and without resorting to undue

experimentation." Paper 48, 12, citing Dr. Ovaska's testimony in Ex. 2005, ¶25. Among other assertions testified to by Dr. Ovaska is that the compound he produced is optically active (*Id.,* ¶ 23); "the skills needed to reproduce the examples in the Sun disclosures to have been well within the ordinary skill of a practicing synthetic organic chemist at that time." (*Id.,* ¶ 26); and "the product of his experiments is the same as that disclosed in the involved patent." *Id.*, ¶ 24.

Sun asserts that in terms of the relevant *Wands*[6] factors, (1) little or no experimentation was necessary to replicate the disclosed product, (2) due to the ample guidance presented, (3) detailing specific working examples, (4) for the synthesis of a well-characterized compound, (5) that was an analog to a then-known prodrug, (6) where only ordinary skill would have been required of a practicing synthetic organic chemist, (7) because the steps required only then-conventional techniques and produce consistent results, and (8) only a single compound needs to be made for a constructive reduction to practice. Paper 48, 11–12.

Kumar, on the other hand, asserts that Sun has not established enablement by a preponderance of the evidence. As to *Wands* factor 1, Kumar asserts that Sun's 2010 application contains no disclosure of how to show the product of Example 4 is the (S)-isomer of the count by chiral HPLC. Kumar also asserts that Sun failed to test Examples 1–3 but relied upon the JMC paper, which was not disclosed in the February 2010 application. Paper 73, 13–14.

Dr. Ovaska testified that it was a "trivial" matter for a person of ordinary skill in the art to identify suitable conditions to separate by HPLC the enantiomers

[6] *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)(addressing factors to consider when dealing with a question of enablement).

of the compound of Example 4. Exhibit 2005, at ¶ 21. Dr. Andersen testifies that it was "not trivial" to select an appropriate column, produce the compounds, and separate then. Ex. 1019, 48. We agree with Dr. Andersen on the point that the exercise was more than trivial. However, even though the task was complex, we do not doubt that it was within the skill of a person of ordinary skill in the art. In other words, we credit the testimony of Dr. Ovaska more on this overall point. This factor weighs towards enablement.

Kumar asserts, as to *Wands* factor 2, that Sun's February 2010 application "provides no guidance for how to demonstrate the optical activity of the compound produced in Example 4 or that it was, in fact, the (S)-isomer. Dr. Ovaska had to rely on the JMC paper provided by his client to reach the conclusion that he had produced the optically active (S)-isomer of the count." Paper 73, 14. This assertion by Kumar's counsel impliedly assumes that guidance is needed in order to confirm optical activity. We agree with Sun that an artisan would have been able to confirm optical activity by 2010 by simply measuring optical rotation. Dr. Andersen admitted such. Ex. 2024, 13:12–14:9 and 26:16-23. Likewise, this factor weighs towards enablement.

As regards *Wands* factor 3, Kumar asserts that "Sun's February 2010 application provides no examples showing how to demonstrate that the S-isomer was produced in Example 4. The other examples in the application describe NMR and biological activity, which do not distinguish S isomer from the R isomer or a racemic mixture. Dr. Ovaska's ability to reproduce the disclosed results of Examples 1-4 does not demonstrate that the disclosure of Examples 1-4 necessarily and inevitably produces an optically active (and enantiomerically pure) (S)-isomer.

Paper 73, 14–15, citing Ex. 1019 at ¶ 41. We are unpersuaded by this contention as there existed methods for assessing optical activity known in 2010, noted above.

Kumar also asserts that "in the absence of known materials for use as standards along with a known chromatographic method, it would not have been possible to identify an unknown enantiomer or measure whether it was enantiomerically pure." Paper 73, 14-15. We question Kumar's assertions that (1) the enantiomer was unknown, (2) the requirement for purity. In any event, we have considered Kumar's additional arguments on this factor, but find that one of ordinary skill in the art could follow the example given in the February 2010 application with the specific precursors, separate the resulting isomers and test for optical activity. We credit Dr. Ovaska's testimony in this regard. Ex. 2005, *generally.* This factor weighs in favor of enablement.

For Factors 4–6 Kumar urges, without elaboration, that Sun Motion 1 fails to show optical activity and enantiomeric purity, the prior art shows only racemic compositions and not the pure (S) isomer, and a person of ordinary skill in February 2010 would not have been able to determine Example 4 fell within the count. Paper 73, 15. We are unpersuaded by these assertions, for reasons noted above. Accordingly, we find these elements to weigh in favor of enablement.

For Factor 7, Kumar asserts that conditions for separating *S*- and *R*- isomers were unpredictable. *Id.* This argument is supported by the allegation that there are a wide variety of chiral HPLC columns available in 2010, and there is no disclosure of which column or solvent systems to use. *Id.,* 16. While, as noted above, we agree that separation is not necessarily trivial and would require some work, we disagree that such work was beyond the level of ordinary skill. Indeed,

we find that the existence of multiple chiral HPLC columns is an indicator of its prevalence in the art. We find this factor to weigh towards enablement.

For Factor 8, Kumar asserts that "Sun had to show that the information disclosed in its February 2010 application was sufficient to enable a person skilled in the art to make that very (S)-isomer and not something else. *Sun* provided no evidence on this *Wands* factor." Paper 73, 16. This position ignores the persuasive testimony of Dr. Ovaska. We therefore find that this factor weighs in favor of enablement as well.

Accordingly, as Sun has met its burden of showing entitlement to priority, we grant Sun Motion 1.

IV. Kumar's Request for Rehearing (Paper 31)

Among the motions initially sought to be filed by Kumar was Kumar Proposed Motion 2. Kumar Proposed Motion 2 was a proposed motion seeking judgment that Sun's claims designated as corresponding to the count are unpatentable to Sun under 35 U.S.C. § 102 over Pereillo et al., Drug Metabolism and Disposition, vol. 30, No. 11 at 1288-95 (2002) ("Pereillo") or under 35 USC § 103(a) over one or more of Pereillo, Savi et al., Thromb Haemost vol. 84, pp. 891-896 (2000); Lau et al., "Contribution of Hepatic Cytochrome P450 3A4 Metabolic Activity to the Phenomenon of Clopidogrel Resistance, Circulation, 109:166-171 (2004); Gurbel et al., "Combination Antithrombotic Therapies," Circulation, 121:569-583 (2010); Gurbel et al., Circulation, 107:2908-2913 (2003); Savi et al., Biochem Pharmacol 44 pp. 527–532 (1992); and Savi et al., Thromb Haemostasis 72 pp. 313–317 (1994). Paper 19, page 1.

The Administrative Patent Judge ("APJ") managing the interference, APJ James T. Moore, did not permit the motion to be filed as it would "not materially advance the determination of priority." Paper 23, 3 (November 15, 2016).

Kumar seeks panel rehearing of that decision in Kumar Miscellaneous Motion 1. Paper 31. According to Kumar, it was an abuse of judicial discretion to refuse authorization for Kumar's motion for judgment over prior art, even though Sun had been authorized to file a motion for unpatentability of Kumar claims in a related interference, Interference No. 106,029 (the "first interference"). *Id.*, 1. It is further urged that the "APJ in charge of this interference was fully aware of the first interference and the issues involved in it because he was the APJ who authored the Board's decision on motions in the first interference. The APJ overlooked the first interference, of which he was personally aware, and rendered a decision denying authorization for Kumar's motion for judgment on the prior art for a reason that makes no sense in light of the Board's handling of a very similar motion in the first interference." *Id.*, 1–2.

In the first interference, Sun was authorized to file Proposed Motion 2, seeking a judgment of unpatentability over the single Pereillo reference, on alternative anticipation or obviousness grounds, of all Kumar's involved claims. Ex. 2003, 4 (Interference 106,029 Paper 35, 4). Sun Motion 2, as it was filed in Interference 106,029, sought entry of judgment that Kumar's involved claims were unpatentable under 35 U.S.C. § 103 on a single ground - as obvious over Pereillo. Interference 106,029, Paper 140. Sun Motion 2 was granted in Interference 106,029, based upon that *single* obviousness ground over the *single* reference Pereillo.

Interferences are principally undertaken for the determination of priority, and the Board "may determine questions of patentability." 35 U.S.C. § 135(a). There is no requirement that the Board undertake similar patentability determination in any given case, it being discretionary.

Kumar asserts that the first interference was overlooked when motions were authorized in the second interference and that the decision makes no sense. This is factually incorrect. The motion proposed by Kumar in this interference relied on a more complex grouping of references, albeit including the same art previously permitted. Thus, the decision to deny authorization for the later motion is not in and of itself an abuse of discretion. Moreover, if Sun's Motion 1 were to be granted, it appears possible that not all of the cited new art would necessarily be prior art (Gurbel having a date of 2010).

Additionally, as the principal object of the interference statute is the determination of priority of invention, we do not find that the denial of the requested motion for the APJ's plainly stated reason – no material advancement of the determination of priority - was an abuse of discretion, as the rationale unambiguously follows the intent of the statute. *See* Order, Paper 23, 3.

Finally, Kumar has other avenues available to it to challenge the patentability of Sun's claims other than during the pendency of this interference. Accordingly, Kumar's request for rehearing is denied.

IV. Kumar's Motion to Exclude

Kumar has moved to exclude Exhibits 2005, 2008, 2009, 2010, 2011, 2012, and 2025. Paper 80, pages 2–6.

Exhibit 2005 (and Exhibit 2018)

Kumar asserts that this exhibit(s) is/are inadmissible under FRE 703[7] because it/they relies/rely upon Exhibit 2008. Kumar asserts Exhibit 2008 is not admissible as evidence of what persons skilled in the art knew as of the February 2010 filing date of Sun's first Chinese application.

More specifically, Kumar asserts that the Board should exclude all of Dr. Ovaska's testimony to the extent it relies on Exhibit 2008 for his opinions. In particular, Kumar asserts that paragraph 16 of Exhibit 2005 should be stricken as improperly relying on the disclosure in Exhibit 2008 of the characteristics of the R-isomer, without which there is no evidence Dr. Ovaska could have been able to find that the product of Example 4 of Sun's February 2010 application was the S-isomer of the count. Paper 80, 3.

We are not persuaded that this request for relief should be granted. It appears to us that Exhibit 2008 was relied upon to show that the results of Dr. Ovaska's reproduction of Examples 1-4 included the S-isomer. Kumar has not materially questioned the efficacy of the actual chiral HPLC test in determining whether a composition is a selected isomer. We therefore are without basis to

---

[7] Rule 703. Bases of an Expert

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

(Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1937; Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

exclude the test as it appears experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject.

To the extent we understand Kumar to be objecting to, and moving to exclude, Ex. 2005 as it relies upon exhibit 2008 as being presented as showing the state of the art in 2010, we do not perceive Exhibit 2008 as being presented for or reflective of that state of the art. Rather, we see Exhibit 2008 as representing a more recent test capable of showing the properties of the composition prepared as described in Examples 1–4 of Sun's applications.

We therefore deny the motion as it relates to Exhibit 2005.

Exhibit 2008 Kumar appears to move to exclude this exhibit under FRE 402[8] and 403[9] for lack of relevance and FRE 901(a)[10] for lack of

[8] Rule 402. General Admissibility of Relevant Evidence
Relevant evidence is admissible unless any of the following provides otherwise: the United States Constitution; a federal statute; these rules; or other rules prescribed by the Supreme Court. Irrelevant evidence is not admissible. (Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1931; Apr. 26, 2011, eff. Dec. 1, 2011.)

[9] Rule 403. Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons
The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence. (Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1932; Apr. 26, 2011, eff. Dec. 1, 2011.)

[10] Rule 901. Authenticating or Identifying Evidence
(a) In General. To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding

authentication/foundation. Kumar asserts that Exhibit 2008 is indicated on its face as having been published in 2012, long after the accorded or sought benefit dates of either party. According to Kumar, Exhibit 2008's relevance is not apparent from its face, which does not show that Exhibit 2008 is evidence of what persons skilled in the art as of Sun's February 2010 application filing date. Paper 80, 4.

As noted above, we do not see this exhibit as being relied upon to establish the knowledge of a person of skill in the art in 2010. We also see it as relevant to establish that the testing performed by Dr. Ovaska showed the S-isomer was present in his reproduced examples. Accordingly, we deny this motion as it relates to Exhibit 2008.

Exhibit 2009

Exhibit 2009 is a Supplemental Declaration, filed in Interference No. 106,029. Kumar moves to exclude this exhibit under FRE 602[11] as not being based on the personal knowledge of the declarant, who has not been qualified as an

---

that the item is what the proponent claims it is. (Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1943; Apr. 26, 2011, eff. Dec. 1, 2011.)

[11] Rule 602. Need for Personal Knowledge
A witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may consist of the witness's own testimony. This rule does not apply to a witness's expert testimony under Rule 703. (Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1934; Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Apr. 26, 2011, eff. Dec. 1, 2011.)

expert witness pursuant to FRE 702[12] and 703. Kumar also asserts that it is hearsay under FRE 802[13] as the exhibit was created for another proceeding. Paper 80, 4–5.

As we did not rely upon or refer to this exhibit, we dismiss this motion as it pertains to Exhibit 2009.

Exhibit 2010

Kumar moves to exclude Exhibit 2010, which is a Supplemental Declaration filed in Interference 106,029. Kumar moves to exclude this exhibit under FRE 602 as not being based on the personal knowledge of the declarant, who has not been qualified as an expert witness pursuant to FRE 702 and 703. Kumar also appears to move to exclude this exhibit under FRE 402 and 403 for lack of relevance, and 802 as hearsay. Paper 80, 5.

As we did not rely upon or refer to this exhibit, we dismiss this motion as it pertains to Exhibit 2010.

[12] Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. (Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1937; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

[13] Rule 802. The Rule Against Hearsay

Hearsay is not admissible unless any of the following provides otherwise: a federal statute; these rules; or other rules prescribed by the Supreme Court. (Pub. L. 93–595, §1, Jan. 2, 1975, 88 Stat. 1939; Apr. 26, 2011, eff. Dec. 1, 2011.)

Exhibit 2011

Exhibit 2011 are documents supporting a declaration filed in Interference 106,029. Kumar appears to move to exclude this document under FRE 901(a) for lack of foundation as not being offered by a witness who has been shown to possess personal knowledge of the matters set forth therein. Kumar also appears to move to exclude this exhibit under FRE 1002 and 1003, stating that the exhibit appears to be both an original in the Chinese language and a translation of portions thereof, making it impossible for Kumar to ascertain what the actual original Chinese-language document is to determine if the translated portions are accurate. Kumar also asserts that the exhibit constitutes hearsay under FRE 802. Paper 80, 5–6.

As we did not rely upon or refer to this exhibit, we dismiss this motion as it pertains to Exhibit 2011.

Exhibit 2012

Exhibit 2012 is a collection of documents supporting a declaration filed in Interference 106,029. Kumar appears to move to exclude this exhibit under FRE 602 and 901(a) for lack of foundation as not being offered by a witness who has been shown to possess personal knowledge of the matters set forth therein and as hearsay under FRE 802. Paper 80, 6.

As we did not rely upon or refer to this exhibit, we dismiss this motion as it pertains to Exhibit 2012.

Exhibit 2025

Exhibit 2025 appears to be Exhibit 1053 from Interference No. 106,029. Kumar appears to move to exclude Exhibit 2025 under FRE 801 and 803 as hearsay. Paper 80, 6.

As we did not rely upon or refer to this exhibit, we dismiss this motion as it pertains to Exhibit 2025.

We therefore DENY Kumar Motion 3 as it pertains to Exhibits 2005, 2008, and 2009, and DISMISS Kumar Motion 3 as it pertains to Exhibits 2010, 2011, 2012, and 2025.

IV. Judgment

Kumar filed a Priority Statement that indicated that its earliest corroborated conception, coupled with diligence is after the priority date now accorded Sun. Paper 34, 1.

Accordingly, this interference shall not proceed to priority. Judgment against Kumar accompanies this decision on motions.

cc (via email):

Attorneys for Sun

Thomas O. Hoover, Esq.
Wei Song, Esq.
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston MA 02110
thoover@mccarter.com
wsong@mccarter.com

Richard Torczon, Esq.
Wilson Sonsini Goodrich & Rosati LLP
1700 K Street, N.W., 5th Floor
Washington, DC 20006
rtorczon@wsgr.com

Attorneys for Kumar

Barry E. Bretschneider
Peter J. Knudsen
Charles C. Carson
BAKER & HOSTETLER LLP
1050 Connecticut Avenue, N.W., Suite 1100
Washington DC 20036-5304
bbretschneider@bakerlaw.com
pknudsen@bakerlaw.com
ccarson@bakerlaw.com