McGuffin, Asher S.

From: McGuffin, Asher S.

Sent: Friday, March 8, 2024 12:30 PM

To: Philip.Segrest@huschblackwell.com; Sportel, Nathan; Howe, Steve; Mizerk, Don;

Hitchens, A. Lauren

Cc: WH Merck KGaA Mavenclad ANDA; Whelan, Emily; Geng, Deric; Bassett, David; Ferrera,

Vinita; Kan, Cindy

Subject: RE: TWi v. Merck Serono, IPR2023-00049 & -00050: Dr. Bodor

Counsel,

TWi's threat to move for non-routine discovery in response to Patent Owner's request to engage in a collaborative discussion about how to accommodate its witness's health is not well taken. TWi has not identified anything in Patent Owner's request that is unreasonable but has instead prematurely dismissed Patent Owner's proposal without the benefit of a good faith meet and confer.

TWi has wholly mischaracterized Patent Owner's proposal as refusing to produce Dr. Bodor for cross-examination. That is not so. Patent Owner agrees that cross-examination is routine discovery, and we are attempting to provide TWi the fullest opportunity possible, under the circumstances, to cross-examine Dr. Bodor. However, his health is not routine, and Patent Owner cannot override Dr. Bodor's own medical decisions about his health and the risks he apparently takes in sitting for a deposition. We believe that a combination of reasonable accommodations, including offering to stipulate to the admissibility Dr. Bodor's deposition transcript from IPR2023-00480 and -00481 and, as we have already offered, potentially sitting for a short, remote deposition, would be more than adequate to allow TWi to fully explore Dr. Bodor's testimony. Indeed, Dr. Bodor's testimony is itself limited only to his knowledge of the Ivax/Serono partnership and the disclosures in his patent and corresponding applications—none of which depends on any unique ground or arguments presented by TWi or Hopewell. TWi has not explained how its examination of Dr. Bodor would elicit testimony that is not duplicative of the three hours Dr. Bodor has already been deposed on the issues in his Declaration. Regardless, Patent Owner's proposal that Dr. Bodor sit for an additional hour remotely should be more than sufficient for any such examination.

Moreover, Patent Owner does not agree that use of his prior testimony would be inadmissible hearsay or would violate TWi's right of confrontation. As TWi knows, the right of confrontation does not extend to civil or administrative proceedings. And the sworn prior testimony of an unavailable witness subject to prior cross-examination is admissible under Rule of Evidence 804(b)(1). Nonetheless, consistent with the Board's procedural rules, 37 C.F.R. § 42.51(b)(1)(ii), Patent Owner is committed to offering TWi the fullest opportunity possible, under the circumstances, to depose Dr. Bodor, and we hope TWi will engage with us in discussing reasonable accommodations.

Turning to logistics, as noted in my previous email, the Board's default protective order lays out a protocol for handling allegedly confidential information. Under that protocol, documents produced but not filed, such as Dr. Bodor's prior testimony, can be marked PROTECTIVE ORDER MATERIAL, in which case it should be handled in a manner that preserves its confidentiality. Default Protective Order §§ 2, 5(B). Patent Owner would identify what information in the transcript is confidential and why it should remain sealed sufficiently in advance of the due date for TWi's reply to facilitate filing a motion to seal. § 5(A). We note at this juncture, however, that Patent Owner is merely attempting to facilitate providing information to TWi so that TWi can fully consider Patent Owner's proposal. If it is TWi's position that it is refusing to consider Patent Owner's proposal without adequately meeting and conferring, we will note that for the Board.



Please let us know whether you are willing to confer about potential accommodations, as requested, before we seek relief from the Board.

Thanks,

Asher S. McGuffin | WilmerHale

60 State Street
Boston, MA 02109 USA
+1 617 526 6201 (t)
+1 617 526 5000 (f)
asher.mcguffin@wilmerhale.com

Please consider the environment before printing this email.

This email message and any attachments are being sent by Wilmer Cutler Pickering Hale and Dorr LLP, are confidential, and may be privileged. If you are not the intended recipient, please notify us immediately—by replying to this message or by sending an email to postmaster@wilmerhale.com—and destroy all copies of this message and any attachments. Thank you.

For more information about WilmerHale, please visit us at http://www.wilmerhale.com.

From: Segrest, Philip < Philip. Segrest@huschblackwell.com>

Sent: Tuesday, March 5, 2024 3:27 PM

To: McGuffin, Asher S. <Asher.McGuffin@wilmerhale.com>; Sportel, Nathan <Nathan.Sportel@huschblackwell.com>; Howe, Steve <Steve.Howe@huschblackwell.com>; Mizerk, Don <Don.Mizerk@huschblackwell.com>; Hitchens, A. Lauren <Lauren.Hitchens@huschblackwell.com>

Cc: WH Merck KGaA Mavenclad ANDA <WHMerckKGaAMavencladANDA@wilmerhale.com>; Whelan, Emily

<Emily.Whelan@wilmerhale.com>; Geng, Deric <Deric.Geng@wilmerhale.com>; Bassett, David

<David.Bassett@wilmerhale.com>; Ferrera, Vinita <Vinita.Ferrera@wilmerhale.com>; Kan, Cindy

<Cindy.Kan@wilmerhale.com>

Subject: RE: TWi v. Merck Serono, IPR2023-00049 & -00050: Dr. Bodor

EXTERNAL SENDER

Counsel,

Petitioner TWi does not consider the proposal regarding cross-examination of Dr. Bodor as a fact witness reasonable and does not agree. Cross-examination of the other side's declarants is routine discovery, and Dr. Bodor's deposition in another IPR by different party represented by different counsel asserting its own grounds of invalidity for obviousness is hearsay and does not adequately protect Petitioner's TWi's right to confront and cross-examine witnesses on its own behalf. Consolidated Trial Practice Guide at 23; 37 C.F.R. § 42.51(b)(1)(ii); 35 U.S.C. § 315(a)(5)(A); Samsung Elecs. Co., Ltd. v. Nucurrent, Inc., No. IPR2019-00860, Paper 27 at 2, 2020 WL 3965912, at *1 (P.T.A.B. July 13, 2020) ("Cross examination is ordinarily allowed in each separate proceeding as a matter of routine discovery."). In Samsung, the Board denied patent owner's request to prevent Petitioner Samsung from deposing Patent Owner's declarants where Patent Owner argued that "that these proceedings have been consolidated (or effectively consolidated with the alignment of due dates)." Id. Here there has been no such consolidation or alignment. If Dr. Bodor is unable or unwilling to sit for cross-examination in the United States the Patent Owner should not submit or rely on direct testimony from him in these proceedings.

Even if the cross-examination of declarant Dr. Bodor were not "routine discovery" for these proceedings, cross-examination of the declarant would be required as "additional discovery" here in the interests of justice. 37 C.F.R. § 42.51(b)(2)(i); 35 U.S.C. § 315(a)(5)(A); Arkema Inc. v. Honeywell Int'l Inc., No. PATENT 9,157,017 B2, 2020 WL 439969,



Mr. Posillico in this case is in the interest of justice."). Moreover, if Dr. Bodor submits such a declaration, it would here be appropriate (and the interest of justice would also require) as additional discovery the production of documents including, for example, all communications between Dr. Bodor and Patent Owner or counsel for Patent Owner. From Patent Owner's description and from declaration previously filed in Hopewell Pharma Ventures, Inc. v. Merck Serono SA, IPR2023-00480 and -00481, Dr. Bodor is being offered as a fact witness, not an expert, and his communications with counsel for Patent Owner are not privileged.

Also, our understanding is that no provision in IPR practice (unlike district court litigation) supports Patent Owner's suggestion that an entire cross-examination deposition may be "designated PROTECTIVE ORDER MATERIALS." See Argentum Pharms. LLC v. Alcon Rsch., Ltd., No. IPR2017-01053, 2018 WL 495204, at *1 (P.T.A.B. Jan. 19, 2018) ("We are mindful that, in district court, a party routinely will determine (by marking or stamping a document 'confidential') whether a document is produced under the terms of a district court protective order. By contrast, in an inter partes review, 'the default rule is that all papers ... are open and available for access by the public.'") (quoting Garmin Int'l v. Cuozzo Speed Techs., LLC, Case IPR2012-00001, Paper 34 at 2, 2013 WL 8696523 (PTAB Mar. 14, 2013)); Corning Optical Communications RF, LLC, v. PPC Broadband, Inc., Case IPR2014-00440, Paper 46 at 3, 2015 WL 1523712 (PTAB April 6, 2015) ("With respect to Exhibits 2106, 2107, and 2108, the Motion to Seal states merely that Patent Owner has identified the information as subject to a protective order in either a Civil Action before a U.S. District Court or an Investigation before the U.S. International Trade Commission (ITC)....That is insufficient. The parties do not represent that the District Court or the ITC has ruled that any such information would be presented for trial in a "sealed" status. We already are at trial."). Our understanding regarding confidential materials is discussed more extensively in our other email today concerning motions to seal and protective orders in IPR practice. If Patent Owner contends that some information in Dr. Bodor's cross-examination is confidential to Patent Owner (even though Dr. Bodor is not an employee of Patent Owner and even though his declaration in that proceeding was not considered confidential), then Patent Owner should propose redactions of the allegedly confidential information, not seek to file the entire routine discovery cross-examination deposition under seal.

If Patent Owner intends to approach the Board for relief or to request a conference call concerning the cross-examination of Dr. Bodor then TWi will also ask for a conference with the Board to discuss its request additional discovery including the production of documents discussed above. Please send us a copy of what Patent Owner will submit to the Board, and we will add a brief statement of what Petitioner also wants to discuss in that conference.

Philip D. Segrest, Jr. (he/him/his)

Partner

Direct: 312-526-1548 Mobile: (312) 805-0314

Philip.Segrest@huschblackwell.com

From: McGuffin, Asher S. < Asher. McGuffin@wilmerhale.com>

Sent: Thursday, February 29, 2024 2:31 PM

To: Segrest, Philip < Philip.Segrest@huschblackwell.com >; Sportel, Nathan < Nathan.Sportel@huschblackwell.com >; Howe, Steve < Steve.Howe@huschblackwell.com >; Mizerk, Don < Don.Mizerk@huschblackwell.com >; Hitchens, A. Lauren < Lauren.Hitchens@huschblackwell.com >

Cc: WH Merck KGaA Mavenclad ANDA <WHMerckKGaAMavencladANDA@wilmerhale.com>; Whelan, Emily

<Emily.Whelan@wilmerhale.com>; Geng, Deric <Deric.Geng@wilmerhale.com>; Bassett, David

<<u>David.Bassett@wilmerhale.com</u>>; Ferrera, Vinita <<u>Vinita.Ferrera@wilmerhale.com</u>>; Kan, Cindy

<Cindy.Kan@wilmerhale.com>

Subject: TWi v. Merck Serono, IPR2023-00049 & -00050: Dr. Bodor

[EXTERNAL EMAIL]

Counsel,



We anticipate submitting a declaration from Dr. Nicholas Bodor in connection with our Patent Owner Response in IPR2023-00049 and -00050. Dr. Bodor's declaration will be substantively the same as his declaration previously filed in *Hopewell Pharma Ventures, Inc. v. Merck Serono SA*, IPR2023-00480 and -00481.

Dr. Bodor, who is 85 years old and suffers from chronic health conditions, has expressed serious concerns about his health following his deposition in IPR2023-00480 and -00481. To address his health concerns, we are reaching out in advance of filing our Patent Owner Response to discuss options to minimize the burden on Dr. Bodor that would be agreeable to both parties if TWi intends to depose Dr. Bodor.

To that end, provided TWi consents to entry of the PTAB's default protective order, Patent Owner is willing to produce a copy of Dr. Bodor's deposition transcript from IPR2023-00480 and -00481, which is designated PROTECTIVE ORDER MATERIAL in those matters, in IPR2023-00049 and -00050. Once TWi has had a chance to review the transcript, we would like to meet and confer about whether TWi intends to depose Dr. Bodor again and, if it does, what reasonable accommodations the parties can agree to that would protect Dr. Bodor's health in view of his recent deposition on substantially the same declaration.

If TWi does not agree to reasonable accommodations, such as submitting Dr. Bodor's prior transcript here and either forgoing a second deposition or limiting any deposition to no more than one more hour fully remote, then we will need to approach the Board for relief.

Please let us know if you are open to this proposal.

Thanks,

Asher S. McGuffin | WilmerHale 60 State Street Boston, MA 02109 USA +1 617 526 6201 (t) +1 617 526 5000 (f) asher.mcguffin@wilmerhale.com

Please consider the environment before printing this email.

This email message and any attachments are being sent by Wilmer Cutler Pickering Hale and Dorr LLP, are confidential, and may be privileged. If you are not the intended recipient, please notify us immediately—by replying to this message or by sending an email to postmaster@wilmerhale.com—and destroy all copies of this message and any attachments. Thank you.

For more information about WilmerHale, please visit us at http://www.wilmerhale.com.

