

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SHANGHAI HONGENE BIOTECH CORPORATION,

Petitioner,

v.

CHEMGENES CORPORATION,

Patent Owner.

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IPR2023-00875

U.S. Patent No. 8,309,707 B2

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**PATENT OWNER SUR-REPLY**

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PETITIONER AS PROTECTIVE ORDER MATERIAL-OUTSIDE  
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## TABLE OF CONTENTS

TABLE OF AUTHORITIES .....	iii
EXHIBIT LIST .....	iv
I. INTRODUCTION .....	1
II. CHEMGENES' POSA DEFINITION IS PROPER.....	1
III. DR. BARAN IS BIASED.....	2
A. Hongene and Dr. Baran Withheld Dr. Baran's Significant Business Relationships with Hongene.....	2
B. Hongene's Arguments Regarding Dr. Baran's Bias are Without Merit .....	5
C. Dr. Baran Lacks Significant Experience in P(III) Synthesis .....	12
IV. GROUNDS I AND II .....	14

## TABLE OF AUTHORITIES

### CASES

<i>Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.</i> , 807 F.2d 955 (Fed. Cir. 1986) .....	1
<i>Ferring B.V., v. Barr Labs., Inc.</i> , 437 F.3d 1181 (Fed. Cir. 2006) .....	5, 6

### TREATISES

4 Weinstein Federal Evidence. §607.04 .....	6, 13
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## EXHIBIT LIST

Ex. No.	Description
2001	Expert Declaration of Patrick Hrdlicka, Ph.D.
2002	U.S. Provisional Patent Application No. 61/191,065
2003	Deposition Transcript of Dr. Phil S. Baran (Jan. 22, 2024)
2004	U.S. Patent No. 8,541,569 (Ex. 1001 in IPR2023-00862)
2005	ChemGenes Corporation Catalog, Bio Technology Products & Manufacturer of DNA-RNA Intermediates (1999)
2006-2029	Exhibit numbers not used
2030	Knouse et. al, <i>Unlocking P(V): Reagents for chiral phosphorothioate synthesis</i> , 361 SCIENCE 1234-1238 (2018)
2031	Exhibit number not used
2032	Huang et al., <i>A P(V) platform for oligonucleotide synthesis</i> , 373 SCIENCE 1265-1270 (2021)
2033-2039	Exhibit numbers not used
2040	BioITWorld.com, New expert advisory board appointments set to drive growth and innovation at Hongene (Oct. 25, 2023), available at <a href="https://www.bio-itworld.com/pressreleases/2023/10/26/new-expert-advisory-board-appointments-set-to-drive-growth-and-innovation-at-hongene">https://www.bio-itworld.com/pressreleases/2023/10/26/new-expert-advisory-board-appointments-set-to-drive-growth-and-innovation-at-hongene</a>
2041	LinkedIn.com, Hongene Biotech Corporation post announcement, available at <a href="https://www.linkedin.com/posts/hongene-biotech-corporation_hongene-advisory-board-activity-7123353670590558208-IXFI?utm_source=share&amp;utm_medium=member_desktop">https://www.linkedin.com/posts/hongene-biotech-corporation_hongene-advisory-board-activity-7123353670590558208-IXFI?utm_source=share&amp;utm_medium=member_desktop</a>
2042-2044	Exhibit numbers not used
2045	Dr. Phil S. Baran 9/13/2023 Deposition Transcript from IPR2023-00490 (Ex. 2009)
2046	Email chain between ChemGenes' and Hongene's counsel (1/25/2024-2/5/2024)
2047	Email chain between ChemGenes' and Hongene's counsel (2/7/2024-2/14/2024)
2048	Email chain between ChemGenes' and Hongene's counsel (2/21/2024-3/4/2024)
2049	Email chain between ChemGenes' and Hongene's counsel (3/13/2024-3/14/2024)

## I. INTRODUCTION

ChemGenes respectfully submits this Sur-Reply to Hongene's Reply ("Reply") (Paper 14) to the Patent Owner Response ("POR") (Paper 10). While the issues on patentability under Grounds I and II are now moot, to correct the record, ChemGenes responds to certain unsubstantiated arguments that Hongene made in its Reply.

## II. CHEMGENES' POSA DEFINITION IS PROPER

ChemGenes' POSA definition is proper. It is undisputed that the subject claims are directed to P(III) nucleosides. POSAs should therefore have the experience that ChemGenes proposed in its POR and a background in medicinal chemistry is not necessary. (*See* POR, §V; Ex. 2001, §VII).

ChemGenes' definition does not "exclude[] highly skilled practitioners," as Hongene argues. (Reply, 1). Indeed, ChemGenes expressly stated just the opposite in its POR. (POR, 22 ("This definition **would not exclude** medicinal or other chemists so long as the chemist in question met the above requirements") (emphasis added)); Ex. 2001, ¶65).

Also, contrary to Hongene's assertion (Reply, 1), utilizing a proper POSA definition would be central to the Board's obviousness analysis and could therefore lead to different results. *See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

### **III. DR. BARAN IS BIASED**

#### **A. Hongene and Dr. Baran Withheld Dr. Baran's Significant Business Relationships with Hongene**

Additional information was discovered after the filing of the February 5, 2024 POR, including documents and testimony relating to Dr. Baran's ties to Hongene.

On January 22, 2024, Dr. Baran testified that Hongene initially contacted Dr. Baran in July of 2023 regarding his appointment to Hongene's "Strategic Advisory Board" ("SAB"). (Ex. 2003, 119:6-120:11). It was later discovered, after the filing of the POR, that Hongene contacted Dr. Baran much earlier, on January 20, 2023, the day after Hongene filed its Petition in the related IPR2023-00490 case (the "'885 IPR"), to discuss "work[ing] together." (Ex. 2033 in '885 IPR).

It was also later confirmed, after the filing of the POR, that the contract under which Hongene agreed to pay Dr. Baran \$70,000 per year for his service on its SAB was executed on August 7, 2023. (Ex. 2034 in '885 IPR).

Dr. Baran did not disclose this arrangement during his September 13, 2023 deposition (Ex. 2045) or in his January 19, 2024 Reply Declaration in the '885 IPR (Ex. 1033 in '885 IPR). Dr. Baran also did not disclose the arrangement or update his CV in this case until ChemGenes independently learned about the SAB appointment and pressed for discovery related to it.

Dr. Baran testified during his February 20, 2024 deposition in the '885 IPR that Hongene's counsel "knew about the SAB" but the information was withheld

because “none of us thought it was relevant ....” (Ex. 2035 in ’885 IPR, 121:14-20). Hongene’s counsel erroneously instructed Dr. Baran not to answer follow-up questions on the basis of “privilege[,]” “work product, et cetera.” (*Id.*, 121:21-122:4).

It was also discovered after the filing of the POR that Elsie Biotechnologies (of which Dr. Baran is a co-founder) had been [REDACTED]  
[REDACTED]  
[REDACTED] (*Id.*, 134:9-15, 145:23-146:4; Ex. 2039 in ’885 IPR, HONG\_0000014; Ex. 2038 in ’885 IPR, HONG\_0000017).

It was also discovered that [REDACTED] and Hongene have been engaged in discussions during the pendency of this case regarding evaluation of [REDACTED]  
[REDACTED] for use with [REDACTED] (Ex. 2035 in ’885 IPR, 149:8-150:4). Neither Hongene nor Dr. Baran disclosed this information until ChemGenes pressed for its discovery.

Hongene and Dr. Baran failed to disclose this information despite Dr. Baran being asked direct questions during his January 22, 2024 deposition that invited its disclosure. (Ex. 2003, 114:23-115:8, 160:19-161:7). ChemGenes discovered this information only after requesting and obtaining a limited set of documents and questioning Dr. Baran during his February 20, 2024 deposition in the ’885 IPR.

When asked why he did not disclose this information, Dr. Baran testified he felt it was as relevant as his “favorite color sweater ....” (Ex. 2035 in ’885 IPR, 151:5-21).

Dr. Baran owns approximately “10%” and “3 million” shares of Elsie and testified he would “personally financially benefit if Elsie does well” which is where his “conflict of interest or individual ability to profit comes from.” (Ex. 2003, 85:16-21, 112:5-9; Ex. 2035 in ’885 IPR, 157:20-158:15).

Dr. Baran also testified during his January 22, 2024 deposition that he had no other agreements in place with Hongene and was first contacted by Hongene in July 2023. (Ex. 2003, 120:5-11, 161:16-20). Dr. Baran’s testimony was false, as it was later discovered that Dr. Baran had in fact executed a “CDA” with Hongene on February 9, 2023 and was initially contacted by Hongene on January 20, 2023. (Ex. 2035 in ’885 IPR, 122:12-123:23; Ex. 2036 in ’885 IPR, HONG\_0000030; Ex. 2033 in ’885 IPR).

Despite all of this, Dr. Baran testified during his February 20, 2024 deposition in the ’885 IPR that he has “nothing to hide” contemptuously stating “[y]ou can check my DNA, urine samples, whatever you like, ... I think it’s all funny.” (Ex. 2035 in ’885 IPR, 140:24-141:15, 153:6).

**B. Hongene's Arguments Regarding Dr. Baran's Bias are Without Merit**

Hongene and Dr. Baran unjustifiably brush aside Dr. Baran's significant financial relationships with Hongene, and their failure to disclose those relationships, to argue that he is not biased. These arguments are without merit.

First, that Dr. Baran's work on Hongene's SAB is purportedly "separate from his work on this IPR and the related IPRs" is irrelevant. (Reply, 2). Hongene is paying Dr. Baran \$70,000 a year for his service on Hongene's SAB which itself demonstrates a significant financial relationship between Dr. Baran and Hongene and is strong evidence of his bias. Contrary to Hongene's implication, whether the substance of the work for the SAB is allegedly different than the substance of the work at bar bears no relevance to the bias analysis which focuses on financial and business relationships affecting a witnesses' testimony. *See Ferring B.V., v. Barr Labs., Inc.*, 437 F.3d 1181, 1187-88 (Fed. Cir. 2006) ("The general law of evidence has long recognized that the testimony of a witness may be rendered suspect by a past relationship with a party." "A witness's interest is always pertinent to his credibility and to the weight to be given to his testimony.").

Second, the fact that Dr. Baran's payment is separate from his payment in these IPRs is also irrelevant. The fact remains that—above and beyond Dr. Baran's compensation as an expert in this case—Hongene is paying Dr. Baran at least \$70,000 per year for his service on the Hongene SAB. Hongene and Dr. Baran have

also admittedly conferred on other mutual business interests, further demonstrating Dr. Baran's bias.

Third, Hongene provides *no support* whatsoever for its argument that "there is nothing unusual with an expert serving on a company's scientific advisory board and being compensated for it." (Reply, 3). This unfounded argument is directly discredited by established law that holds that an expert's financial and business relationships with the party that the witness is providing testimony for can affect that witness' testimony, bias, and credibility. *See Ferring*, 437 F.3d at 1187. Hongene's argument also glosses over the undisputed fact that Dr. Baran's service on the Hongene SAB and other relationships with Hongene were initially withheld from the record, conduct that the Federal Circuit has found rises to the level of inequitable conduct. *See id.*

Fourth, that Dr. Baran's role on the Hongene SAB is purportedly focused on P(V) chemistry is irrelevant to his financial and business interests which, again, serve to affect his bias in this case. *See id.*; *see also* 4 Weinstein Federal Evidence. §607.04. Furthermore, the testimony that Hongene cites as an example of Dr. Baran being "forthcoming" (Reply, 3-4) regarding the [REDACTED] [REDACTED] and Hongene actually amounts to another instance of Dr. Baran's evasiveness.

For example, during Dr. Baran's January 22, 2024 deposition, he testified as follows:

Q: Would Elsie consider licensing P(V) technology to Hongene?

A: I don't think they legally can. I think that needs to be done like a -- for selling reagents, I think they need to go to work with BMS on that. I don't think Elsie has the right to sublicense things for reagents." (Ex. 2003, 160:22-161:3).

This testimony is not consistent with discovery that was later obtained demonstrating that [REDACTED] and that the [REDACTED]. (Ex. 2035 in '885 IPR, 134:9-15, 145:23-146:4; Ex. 2039 in '885 IPR, HONG\_0000014 (Hongene stating on October 22, 2023 [REDACTED] [REDACTED] [REDACTED]); Ex. 2038 in '885 IPR, HONG\_0000017). Dr. Baran therefore evaded at least this question and withheld these discussions from the record.

As mentioned above, it was also later discovered that [REDACTED] [REDACTED] [REDACTED] [REDACTED], information also not disclosed by Hongene or Dr. Baran until ChemGenes pushed for its disclosure. (Ex. 2035 in '885 IPR, 149:8-150:4).

Accordingly, Hongene and Dr. Baran were not “forthcoming” with this information. It was only discovered *after* Hongene produced emails discussing licensing negotiations between Hongene and Elsie, and *after* additional cross examination of Dr. Baran on these issues occurred.

Fifth, that Dr. Baran submitted his initial declarations across these IPRs (IPR2023-00490, IPR2023-00862, and IPR2023-00875), before his official service on the Hongene SAB allegedly began, does not excuse why Hongene and Dr. Baran decided to withhold this information in these IPRs when they had every opportunity to disclose it. (Reply, 4). It wasn’t until ChemGenes pressed for discovery that this information came to light.

Dr. Baran’s financial and business relationships with Hongene could and should have been revealed during these matters including during Dr. Baran’s September 13, 2023 deposition in the ’885 IPR (Ex. 2045), during Dr. Baran’s two January 19, 2024 Reply Declarations in the ’885 IPR (Exs. 1033 and 1044 in ’885 IPR), or voluntarily at any time *after* Dr. Baran’s official start-date serving on Hongene’s SAB began on August 7, 2023. Furthermore, while Hongene and Dr. Baran filed an updated CV for Dr. Baran on January 19, 2024, the updated CV *still* did not reveal any of Dr. Baran’s relationships with Hongene, despite containing other updates. (Ex. 1034 in ’885 IPR (*e.g., id.*, 1, showing “September 2023 Richard Lerner Chair of Chemistry” listed on the updated CV but not the original CV)).

Moreover, Dr. Baran admitted that Hongene's counsel actually "knew about the SAB" but both Dr. Baran and Counsel chose to instead withhold this information based on "relevan[ce]." (Ex. 2035 in '885 IPR, 121:14-20). Thus, Hongene's claims of being "cooperative," and "forthcoming" (Reply, 3-4) are belied by the record and this information would not have been revealed absent ChemGenes' efforts.

Seventh, Hongene repeatedly resisted producing narrow categories of documents that ChemGenes requested. For example, ChemGenes requested documents related to Dr. Baran's relationship with Hongene first during Dr. Baran's January 22, 2024 deposition, a second time on January 25, 2024 (Ex. 2046, 5), a third time on January 29, 2024 (*id.*, 3), and a fourth time on February 1, 2024 (*id.*, 2). Hongene finally substantively responded on February 2, 2024, stating, *inter alia*, that "such information is [not] properly discoverable in these IPRs." (*Id.*, 2). After a meet and confer on February 5, 2024, Hongene's counsel again stated on February 8, 2024 that the documents "are not properly discoverable," but agreed to produce the SAB agreement and "related emails." (Ex. 2047, 9).

On February 12, 2024, Hongene emailed ChemGenes stating that "Hongene does not intend to produce the documents without a protective order being in place." (Ex. 2047, 5-6). The Parties reached an agreement on a protective order on the same day. (*Id.*, 2). On February 13, 2024, despite the Parties' agreed upon protective order, Hongene inexplicably produced 13 heavily redacted documents. (*Id.*, 1). On

February 15, 2024, after ChemGenes requested unredacted copies or a good faith basis to support the redactions (*id.*, 1), Hongene finally produced unredacted copies, almost a month after ChemGenes initially requested them.

During Dr. Baran's February 20, 2024 deposition, it was discovered that additional documents evidencing further aspects of the relationship between Hongene and Dr. Baran existed, including emails, a slide presentation, a "CDA" between Dr. Baran and Hongene, and other documents. (Ex. 2035 in '885 IPR, 107:4-108:24, 122:12-123:3, 126:10-127:14, 138:8-139:1, 148:1-149:7). The next day, ChemGenes requested these documents. (Ex. 2048, 5)

On February 23, 2024, Hongene responded in a dismissive manner as follows, further demonstrating its evasiveness in providing full disclosure of the relationship between Hongene and Dr. Baran:

We are surprised and disappointed that ChemGenes is continuing with this irrelevant slideshow, and now evening looking to expand it. Your theory of relevance is false to the point of outlandishness, and would be laughable were it not so offensive to Dr. Baran and so intrusive upon him and Hongene. None of these requests have anything to do with the merits of the IPR. And none satisfy the standards for obtaining the kinds of limited discovery that are available in an IPR. Hongene reserves all rights in connection with this whole sideshow.

(*Id.*, 3-4).

At that time, while Hongene agreed to provide an updated CV and certain emails, it refused to provide any communications, agreements, term sheets or other documents *that it had in its possession* relating to [REDACTED] [REDACTED] on the meritless grounds of alleged third-party confidentiality.

(*Id.*, 4).

On February 26, 2024, Hongene produced a second set of documents, nearly five weeks after ChemGenes' initial request for documents. This production was also not complete, omitting the requested NDA between [REDACTED] and documents with communications between [REDACTED]. On March 4, 2024, ChemGenes again requested these documents. (*Id.*, 1). Hongene waited a week to respond.

On March 13, 2024, Hongene finally responded, refusing to produce these documents based on "third party" confidentiality. (Ex. 2049, 2). The next day ChemGenes explained that such documents should be produced and are fully protected via the protective order in place in this case. (*Id.*, 1). To this day Hongene has never produced the requested documents. Hongene's claim of cooperating with a "voluntary" production is, therefore, baseless.

**C. Dr. Baran Lacks Significant Experience in P(III) Synthesis**

Other than conclusory statements, the record does not show Dr. Baran has significant experience in *P(III) nucleoside chemistry and synthesis*, as neither Hongene nor Dr. Baran identify specific papers, companies, consultancies, awards, patents, or other facts that demonstrate he does. Nonetheless, Dr. Baran repeatedly belittles this complex and unpredictable technology as “simple,” “trivial,” “undergraduate,” “pedestrian,” and “beneath the skills of our group.” (Ex. 2003, 185:2-19; Ex. 2045, 161:6-12).

Hongene responds to the fact that Dr. Baran has less experience in P(III) nucleoside chemistry and synthesis chemistry by pointing to Dr. Baran’s accolades as a synthetic organic chemist and experience in P(V) chemistry. (Reply, 1-2). But this is misplaced because, as ChemGenes and Dr. Hrdlicka explained, P(V) chemistry is a fundamentally different synthesis platform than the P(III) chemistry at bar, for which Dr. Hrdlicka has significantly more experience. (POR, 19-21; Ex. 2001, ¶¶60-63).

The fundamental differences between P(III) and P(V) chemistry are discussed in Dr. Baran’s own publications. (Ex. 2045, 109:4-6 (“Q. But the focus of this paper [Ex. 2032] is on P(V)? A. The focus of this paper is awakening people to the difference between P(V) and P(III).”); Ex. 2030, 1 (Dr. Baran et al. describing “P(V)-based reagent platform[s]” as “as a fundamentally different approach” as

compared to “phosphorus(III)-based reagent systems.”); *also see* Ex. 2032, 1268-69 (disclosing P(V)-based oligonucleotide synthesis not involving phosphoramidites, and instead using completely different “PSI” reagents in a “fundamentally” different process, such differences including different reagents, solid supports, nucleobase protecting groups, coupling reagents, and no oxidation step as otherwise required by P(III) SPOS); Ex. 2001, ¶60).

Hongene does not rebut in its Reply the fact that P(III) and P(V) chemistry are fundamentally different. Indeed, Hongene admits as much when it argues that Dr. Baran is not biased because “his role on the Hongene Advisory Board has focused on P(V) chemistry, not these IPRs,” which concern the fundamentally different P(III) chemistry. (Reply, 3).

Dr. Baran’s financial and business interests with Hongene, Hongene and Dr. Baran’s failure to disclose those interests, and Dr. Baran’s lack of experience in P(III) synthesis, should be strongly considered in the event the Board or any other body of competent jurisdiction evaluates the weight of Dr. Baran’s testimony and his bias. *See, e.g.*, 4 Weinstein’s Federal Evidence §607.04 (“the trier of fact must be sufficiently informed of the underlying relationships [(including “business” relationships)], circumstances, and influences operating on the witness to determine whether a modification of testimony reasonably could be expected as a probable human reaction.”).

This all contrasts with Dr. Hrdlicka who has spent his entire career in P(III) nucleoside chemistry and synthesis, is and was a POSA in the 2009 timeframe under any definition, is an objective witness with no affiliation to ChemGenes other than as an expert for this case, and his opinions should therefore be given more weight in the event the Board or any other body of competent jurisdiction evaluates the weight of testimony submitted in this matter. (POR, 20-21; Ex. 2001, ¶¶61-63).

#### **IV. GROUNDS I AND II**

ChemGenes' POR, and this Sur-Reply, are submitted without prejudice or disclaimer. ChemGenes reserves all of its rights to the patentably distinct compounds claimed by Claim 1's and Claim 2's Markush Groups, or disclosed in the '707 Patent, including, but not limited to, as may be pursued through reissue proceedings or otherwise under applicable law.

Dated: June 3, 2024

Respectfully submitted,

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## **CERTIFICATE OF COMPLIANCE**

The undersigned certifies that this Patent Owner Sur-Reply complies with the type-volume limitations of 37 C.F.R. § 42.24(a)(1)(i). This Patent Owner Sur-Reply contains 2,970 words as calculated by the “Word Count” feature of Microsoft® Word for PC Version 2401 Build 16.0.1723.20194, the word processing program used to create it. Pursuant to the Trial Practice Guide (November 2019), the page and word count do not include the table of contents, table of authorities, mandatory notices under § 42.8, certificate of service, or appendix of exhibits or claim listings. The undersigned further certifies that this Sur-Reply complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and typestyle requirements of 37 C.F.R. § 42.6(a)(2)(iii). This Patent Owner Sur-Reply has been prepared in a proportionally spaced typeface using Microsoft Word 365 in Times New Roman 14-point font.

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**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the foregoing PATENT OWNER SUR-REPLY was served on June 3, 2024, to the following counsel for Petitioner via electronic mail at Hongene@procopio.com:

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