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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOGATEKEEPER, INC.

Petitioner,

v.

KYOTO UNIVERSITY

Patent Owner.

Case IPR2014-01286

U.S. Patent No. 8,058,065

PATENT OWNER KYOTO UNIVERSITY'S PRELIMINARY RESPONSE

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In accordance with 35 U.S.C. § 313 and 37 C.F.R. § 42.107, Kyoto University (“Kyoto”) hereby submits its Preliminary Response to the Substitute Petition for *Inter Partes* Review of U.S. Patent No. 8,058,065 (Paper 6) (the “Petition”) submitted by BioGatekeeper, Inc. (“BioGatekeeper”).

I. INTRODUCTION

In 2012, Dr. Shinya Yamanaka, received the Nobel Prize in Physiology and Medicine in large part due to the invention claimed in U.S. Patent No. 8,058,065 (the “’065 Patent”). The ’065 Patent is entitled “OCT3/4, KLF4, C-MYC AND SOX2 PRODUCE INDUCED PLURIPOTENT STEM CELLS.” It includes a single claim invented by Dr. Yamanaka and Dr. Kazutoshi Takahashi.

In its Petition, BioGatekeeper, an enigmatic entity formed less than one week before filing its original petition, alleges that this revolutionary discovery is unpatentable. Unsurprisingly, BioGatekeeper’s Petition is not supported by any expert declaration. Instead, its Petition is solely supported by attorney argument from the same law firm that has brought frivolous defamation lawsuits against Dr. Yamanaka and even the Nobel Prize Assembly itself.

BioGatekeeper’s Petition is defective and fails to satisfy the threshold standard for instituting an *Inter Partes* Review. The Petition fails to properly identify the real party-in-interest, it fails to provide support for its allegations regarding the teachings of the references that it relies upon, and it fails to establish

that one of ordinary skill in the art would have had a reason to combine the disparate teachings of the asserted references. The Petition also fails to address the conspicuous and extraordinary objective evidence of non-obviousness – Dr. Yamanaka’s Nobel Prize. Accordingly, BioGatekeeper fails to establish a reasonable likelihood of prevailing as required under 35 U.S.C. § 314(a). For at least these reasons, Kyoto respectfully requests that the Board deny BioGatekeeper’s Petition.

II. BACKGROUND

A. Dr. Yamanaka

In 2012, the Nobel Assembly awarded the Nobel Prize in Physiology and Medicine to Dr. Yamanaka and Dr. John B. Gurdon for “their discovery that mature, differentiated cells can be reprogrammed to a pluripotent stem cell state.” (Ex. 2001 at 1.) The Nobel Assembly stated that Dr. Yamanaka’s and Dr. Gurdon’s “groundbreaking discoveries have completely changed our view of development and cellular specialization. Textbooks have been rewritten and new research fields have been established. By reprogramming human cells, scientists have created new opportunities to study diseases and develop methods for diagnosis and therapy.” (Ex. 2002 at 5.)

Prior to Dr. Yamanaka’s work, scientists investigated human embryonic stem cells (“ES cells”) because of their pluripotent qualities. (Ex. 1001 at 1:34–38.)

However, as explained by the '065 Patent, the use of human embryos faced ethical controversies. (*Id.* at 1:56–57.) It was also difficult to generate patient-specific or disease-specific ES cells. (*Id.* at 1:57–59.) Moreover, similar to organ transplant rejection, transplanted ES cells could be rejected by the recipient. (*Id.* at 1:42–44.) Other techniques for reprogramming cells were technically unreliable and unsafe. (*Id.* at 2:15–29.) These shortcomings of reprogramming cells persisted until Dr. Yamanaka performed his Nobel Prize-winning experiments.

In awarding the Nobel Prize to Dr. Yamanaka, the Nobel Assembly explained that Dr. Yamanaka's landmark discovery was his selection of transcription factors that he considered candidates to establish pluripotency from somatic cells and his eventual discovery of four transcription factors that successfully established this pluripotency. (Ex. 2001 at 5.) The Nobel Assembly declared:

In a strikingly bold experiment, all 24 genes encoding these transcription factors were introduced in one step into skin fibroblasts and a few of them actually generated colonies that showed a remarkable resemblance to ES cells. The number of genes capable of inducing such colonies were reduced, one-by-one, to identify a combination of only four transcription factors (Myc, Oct3/4, Sox2 and Klf4) that were sufficient to convert mouse embryonic fibroblasts to pluripotent stem cells.

(*Id.*)

This discovery of induced pluripotent stem cells (“iPS cells”) was praised as a “truly fundamental discovery” (*id. at 6*) and “[g]roundbreaking because it raises the possibility of creating any cell in the body much more easily.” (Ex. 2003 at 2.) The Nobel Assembly called it a “paradigm shift in our understanding of cellular differentiation and of the plasticity of the differentiated state.” (Ex. 2001 at 1.) House Minority Leader, Nancy Pelosi declared that “Dr. Yamanaka’s innovative, creative, and potentially life-saving work on cellular reprogramming builds upon a career of scientific excellence.” (Ex. 2004.) In addition to the Nobel Prize, Dr. Yamanaka was elected to the National Academy of Sciences in 2011 for his iPS cell work. (Ex. 2005.) Dr. Yamanaka has received many other awards and honors for this work, including the Albert Lasker Basic Medical Research Award, the Wolf Prize in Medicine, the Millennium Technology Award, the Shaw Prize, the Kyoto Prize for Advanced Technology, the Gairdner International Award, the Robert Koch Award, and the March of Dimes Prize. (Ex. 2006.)

Dr. Yamanaka’s revolutionary discovery is embodied in the single claim of the ’065 Patent. Claim 1 recites, *inter alia*, “introducing into the somatic cell one or more retroviral vectors comprising a gene encoding Oct3/4, a gene encoding Klf4, a gene encoding c-Myc and a gene encoding Sox2 operably linked to a promoter.” (Ex. 1001 at 103:53–104:49.) As explained in the ’065 Patent’s specification, “with Examples 13-20 it was shown that iPS cells can be generated

from adult HDF and other somatic cells by retroviral transduction of the same four transcription factors, namely Oct3/4, Sox2, Klf4, and c-Myc.” (*Id.* at 40:22–25.)

B. BioGatekeeper

BioGatekeeper was incorporated in Nevada by a Mr. Jonathan Zhu on August 7, 2014. (Ex. 2007.) The identity of Mr. Zhu and BioGatekeeper remains a mystery to Kyoto and the scientific community at large. (Ex. 2008–2010.) Five days after its incorporation, BioGatekeeper filed its original petition for *Inter Partes* Review. (See Paper 1.)

Based on responses to Kyoto’s inquiries, BioGatekeeper is allegedly “in the business of establishing a U.S. Distribution Company” and is “temporarily based in Los Angeles, California.” (Ex. 2011 at 1.) BioGatekeeper’s address corresponds to a P.O. Box at a UPS Store® in downtown Los Angeles that is designed to appear as a “real street address.” (Ex. 2007; Ex. 2012 at 1 & 3.) BioGatekeeper apparently has no real offices or physical presence anywhere.

BioGatekeeper’s articles of incorporation list Mr. Zhu as holding all of the company’s titles: President, Secretary, Treasurer, and sole member of the Board of Directors. (Ex. 2007 at 1–2.) Mr. Zhu is purportedly “an entrepreneur” and owner of BioGatekeeper. (Ex. 2011 at 1.) Unspecified “[f]amily members of Jonathan Zhu based in China” allegedly funded, directed, and/or controlled BioGatekeeper’s incorporation. (*Id.* at 2.)

BioGatekeeper's lead and backup counsel are from the Ardent Law Group, PC ("Ardent"). (Paper 6 at 2.) In December of 2012, Ardent brought suit on behalf of Dr. Rongxiang Xu against the Nobel Assembly alleging that the Nobel Assembly made false statements regarding Dr. Yamanaka. (Ex. 2013 at 3, ¶ 11.) Mr. Alexander Chang, BioGatekeeper's backup counsel, served as an attorney for Dr. Xu in that lawsuit. (Paper 6 at 2; Ex. 2013 at 1.) The Court dismissed the action for lack of personal jurisdiction. (Ex. 2014 at 1.)

Later, in May of 2013, Ardent brought suit on behalf of Dr. Xu against Dr. Yamanaka himself, alleging that "Dr. Yamanaka's deception has greatly impaired and affected Dr. Xu's reputation in science" (Ex. 2015 at 6, ¶ 14.) Mr. Alexander Chang again served as an attorney for Dr. Xu in that lawsuit. (*Id.* at 1.) The Court dismissed Dr. Xu's meritless action and awarded Dr. Yamanaka his attorney's fees. (Ex. 2016 at 1 & 10.) Dr. Xu lives in Los Angeles, California, the same city where BioGatekeeper is "temporarily located." (Ex. 2015 at 1, ¶ 1; Ex. 2011 at 1.)

III. ARGUMENT

BioGatekeeper's Petition should be denied. The Petition fails to properly identify the real party-in-interest, it fails to support its allegations regarding the teachings of the references that it relies upon, and it fails to establish that one of ordinary skill in the art would have had a reason to combine the disparate teachings

of the asserted references. The Petition also fails to address the conspicuous and extraordinary objective indicia of non-obviousness: Dr. Yamanaka's Nobel Prize for the work embodied in the challenged claim.

A. The Petition Fails to Adequately Identify the Real Party-in-Interest

A Petition for *Inter Partes* Review is required to identify all real parties-in-interest. 35 U.S.C. § 312(a)(2) and 37 C.F.R. § 42.8(b)(1). A real party-in-interest is “the party that desires review of the patent” and in some instances is not the petitioner itself. 77 Fed. Reg. 48759 (Aug. 14, 2012). For instance, the real party-in-interest may be the party at whose behest the petition has been filed. *Id.*

The real party-in-interest requirement “seeks to protect patent owners from harassment via successive petitions by the same or related parties, to prevent parties from having a ‘second bite at the apple.’” *Id.* The naming of the real party-in-interest is essential to establish the entity to whom the estoppel provisions attach. 35 U.S.C. § 315(e). Without enforcement of the requirement to list the real parties-in-interest, a patent challenger could easily circumvent the statutory estoppel provisions by naming a new straw man in every request. *Cf.* Decision Vacating Filing Date at *8, *In re Guan et al. Inter Partes Reexamination Proceeding*, Control No. 95/001,045 (Aug. 25, 2008).

Where the real party-in-interest statement is not facially accurate, or is ambiguous, the Office will inquire as to the identity of the actual real party-in-interest. *Id.* at 6. Ambiguities may be established by extrinsic evidence. *Id.* In *In re Guan*, a petitioner for *inter partes* reexamination was identified as Troll Busters LLC (“Troll Busters”). *Id.* at *1. The extrinsic evidence established that Troll Busters “held out a primary function” to file requests in its name “to maintain the anonymous nature of a party or parties.” *Id.* at *7. Troll Busters later failed to disclose who paid for the *Inter Partes* Reexamination Request. *Id.* at *8. Thus, the proceeding was vacated due to Troll Busters’s failure to unambiguously name the real party-in-interest. *Id.* at *8–9; *see also* Decision Denying Institution of *Inter Partes* Review at *11, *Zoll LifeCor Corp. v. Philips Electronics North America Corp.*, IPR2013-00606 (Mar. 20, 2014) (Paper 13), 2014 WL 1253100 at *4 (stating that “the failure to identify the parent corporation, Zoll Medical, violates the statutory and regulatory requirements that the petition identify *all* real parties-in-interest”) (emphasis in original).

BioGatekeeper’s Petition should be denied because it fails to unambiguously identify the real party-in-interest. The only real party-in-interest identified by the Petition is “BioGatekeeper, Inc.” (Paper 6 at 1), and the evidence demonstrates that BioGatekeeper is likely nothing more than a shell corporation, established solely for the purpose of filing the Petition. For example, BioGatekeeper was only in

existence for five days before it filed the original Petition, and the Petition did not identify any other party as a real party-in-interest. BioGatekeeper was incorporated in Nevada, and the only address listed in its articles of incorporation corresponds to a mailbox at a UPS Store® in downtown Los Angeles that provides a “real street address” for companies that wish to create the appearance of having an actual place of business. (Ex. 2007; Ex. 2012 at 1 & 3.) BioGatekeeper’s Power of Attorney document is executed by a shadowy “Jonathan Zhu,” who alone purportedly serves as the company’s President, Secretary, Treasurer, and sole member of the Board of Directors. (Paper 2 at 2; Ex. 2007 at 1–2.)

Noting the inadequacy of the identifying information in the Petition, Kyoto’s counsel contacted BioGatekeeper’s counsel to request additional information about the identity of BioGatekeeper and Jonathan Zhu. (Ex. 2017.) BioGatekeeper’s counsel tersely responded that BioGatekeeper was “in the business of establishing a U.S. Distribution Company.” (Ex. 2011 at 1.) This “U.S. Distribution Company” was not identified. (*Id.*) The location of BioGatekeeper’s principle place of business was identified as “temporarily based in Los Angeles, California,” a city of nearly 4 million people and 469 square miles. (*Id.*)

In response to Kyoto’s counsel’s request for a detailed description of Mr. Zhu’s professional employment, BioGatekeeper’s counsel simply stated that Mr. Zhu is “an entrepreneur and is the owner of BioGatekeeper, Inc.” (*Id.*) When

asked of any and all parties that funded, directed, and/or controlled the incorporation of BioGatekeeper, Inc., BioGatekeeper's counsel's vague reply was: "Family members of Jonathan Zhu based in China." (*Id.* at 2.)

Thus, the only identifying information about BioGatekeeper is that it was formed five days prior to filing the Petition, is temporarily located in Los Angeles, California, and is owned by Jonathan Zhu. The only information supplied for Jonathan Zhu is that he's "an entrepreneur" and the owner of BioGatekeeper. Notably, it appears that no one in the field of stem cell research has ever heard of either BioGatekeeper or Jonathan Zhu. (Exs. 2008–2010.) Similarly, Kyoto has no knowledge of BioGatekeeper or Jonathan Zhu, and only is aware of BioGatekeeper's attorneys because that same law firm pursued the frivolous lawsuit against Dr. Yamanaka for being awarded the Nobel Prize. (Ex. 2013 at 8.)

BioGatekeeper has simply not supplied enough information to ensure that Kyoto, if successful in this *Inter Partes* Review, will not be subjected to additional petitions by other shell companies headed by other so-called "entrepreneur(s)" with no tangible presence or visible background. The facts of the present proceeding lead to the inevitable conclusion that BioGatekeeper was formed solely for the purpose of challenging the '065 Patent while shielding the real party-in-interest from the estoppel effects of this proceeding. Kyoto has no idea who Mr. Zhu is, or for whom he really works. Mr. Zhu has not provided a resume, a job

history, or even a place of residence. Moreover, Mr. Zhu’s “[f]amily members . . . based in China,” admitted directors, funders, or controllers of BioGatekeeper, are not even identified by name.

In view of the above, Kyoto submits that the Petition should be denied at least because the Petition fails to unambiguously identify the real party-in-interest. *Zoll* at *11, 2014 WL 1253100 at *4. The evidence strongly suggests that BioGatekeeper is a shell company formed for the sole purpose of filing this Petition for *Inter Partes* Review. When asked for additional information, BioGatekeeper’s counsel essentially provided none. A name, “Jonathan Zhu,” and “family members . . . based in China,” are woefully insufficient to ensure that the estoppel provisions will protect Patent Owner from subsequent petitions from other “family members,” shell entities, or straw-men.¹ The Petitioner’s blatant attempt

¹ BioGatekeeper’s back-up counsel, Mr. Alexander Chang, has represented that there is no relationship between BioGatekeeper or Mr. Zhu, on the one hand, and Dr. Rongxiang Xu, on the other hand. (Ex. 2011 at 1–2.) However, these representations are questionable on their face given that BioGatekeeper’s back-up counsel, Mr. Alexander Chang, represented Dr. Xu in lawsuits filed against Dr. Yamanaka and the Nobel Assembly in reaction to Dr. Yamanaka’s Nobel Prize-winning discovery. (Ex. 2013; Ex. 2015.) Kyoto further notes that the allegation

to circumvent the real party-in-interest requirement by using a shell company should not be condoned. *Cf. In re Guan* at *8. Indeed, if such clear efforts to evade the statutory requirement to identify the real party-in-interest were to be tolerated, this case would provide a blueprint for future parties aspiring to conceal the identity of the actual party seeking to challenge a patent.

The evidence strongly suggests that BioGatekeeper and its counsel are deliberately cloaking the identity of the real party-in-interest – the person or persons who directed the filing of the Petition. At a minimum, such egregious behavior warrants the denial of the Petition.

B. The Petition Fails to Establish a *Prima Facie* Allegation of Obviousness

BioGatekeeper fails to establish a reasonable likelihood that Claim 1 is obvious because the Petition fails to establish Whitehead as prior art. Moreover, BioGatekeeper fails to establish a reasonable likelihood that Claim 1 is obvious because the Petition fails to assess the level of skill in the art, fails to substantiate

in BioGatekeeper’s Petition that “the recited term induced pluripotent ‘stem’ cell is internally conflicting and scientifically misleading” (Paper 6 at 12) is remarkably similar to the allegation in Dr. Xu’s court complaint that “‘pluripotent stem cells induced from somatic cells’ is not only misleading, but has affected the reputation of Dr. Xu” (Ex. 2015 at 3, ¶ 11.)

the alleged teachings of the art to a person of ordinary skill, fails to establish any reason to combine the alleged teachings, and fails to address any secondary considerations. Thus, the Petition should be denied because BioGatekeeper has not provided the Board with sufficient factual bases to substantiate a conclusion that Claim 1 is *prima facie* obvious.

BioGatekeeper's Petition alleges that Claim 1 is rendered obvious under 35 U.S.C. § 103 by U.S. Patent No. 7,682,828 to Jaenisch *et al.* ("Whitehead") (Ex. 1002) in view of N. Benvenisty *et al.*, "An embryonically expressed gene is a target for c-Myc regulation via the c-Myc-binding sequence," *Genes & Development* 6:2513–2523 (1992) ("Benvenisty") (Ex. 1003) and in further view of Y. Li *et al.*, "Murine embryonic stem cell differentiation is promoted by SOCS-3 and inhibited by the zinc finger transcription factor Klf4," 105(2) *Blood* 635–637 (2005) ("Li") (Ex. 1004). (Paper 6 at 9.) However, BioGatekeeper does not establish Whitehead as being prior art, and BioGatekeeper does not carry its burden of showing with reasonably likelihood that Claim 1 would be found obvious.

1. BioGatekeeper Fails to Sufficiently Establish Whitehead as Prior Art

As a preliminary matter, BioGatekeeper fails to adequately explain how Whitehead (Ex. 1002) qualifies as prior art. Because this information was not

provided in the Petition as filed, BioGatekeeper's Petition should be denied. 35 U.S.C. § 314(a) ("the Director may not authorize an *inter partes* review to be instituted unless the Director determines that ***the information presented in the petition***" shows a reasonable likelihood of success (emphasis added)).

The Board can deny trial when a petitioner fails to provide sufficient facts to establish a reference as prior art under the statutory basis that the petitioner chooses to assert. See Decision Instituting *Inter Partes* Review at *18, *Oxford Nanopore Techs. Ltd., v. Univ. of Washington*, IPR2014-00513 (Sept. 15, 2014) (Paper 12). In *Oxford Nanopore*, the Board declined to institute trial for certain claims because the petitioner's sole statutory basis for challenging those claims was under 35 U.S.C. § 102(b), and the asserted reference did not qualify under § 102(b). Thus, it is appropriate to deny an asserted ground of unpatentability when a petitioner's chosen legal strategy and relied-upon evidence fail to establish that a reference qualifies as prior art. see also Decision Denying Institution of *Inter Partes* Review at *18, *L-3 Comm. Holdings, Inc. v. Power Survey, LLC*, IPR2014-00832 (Nov. 14, 2014) (Paper 9), 2014 WL 6468495 at *11 (denying institution of *Inter Partes* Review because of Petition's failure to show that the primary reference qualified as prior art).

Here, BioGatekeeper alleges that Whitehead (Ex. 1002) is prior art under 35 U.S.C. § 102(a) (Paper 6 at 9) and/or "35 U.S.C. § 102(1) [sic]" (*id.* at 16) because

“Whitehead patent issued March 23, 2010, with priority date of November 26, 2003 . . .”. (Paper 6 at 9 & 16.) But Whitehead is not prior art under 35 U.S.C. § 102(a). Whitehead issued March 23, 2010, long after the application that issued as the '065 Patent was filed (June 9, 2009). The priority date of Whitehead is irrelevant to a prior art determination under 35 U.S.C. § 102(a). The other alleged prior art basis, “35 U.S.C. § 102(1),” simply does not exist. Thus, BioGatekeeper’s Petition fails to establish that Whitehead qualifies as prior art under the statutory provisions asserted in the Petition (35 U.S.C. § 102(a) or “35 U.S.C. § 102(1)”).

Moreover, BioGatekeeper fails to allege a substantiated prior art date for Whitehead (Ex. 1002). The Petition asserts that the “Whitehead patent issued March 23, 2010, with priority date of November 26, 2003, and is prior art.” (Paper 6 at 9 & 16.) March 23, 2010 is *after* the filing date of the application that issued as the '065 Patent, and thus cannot serve as a prior art date. November 26, 2003 refers to the filing date of a provisional application to which Whitehead claims priority. BioGatekeeper, as the petitioner, bears the burden to show that Whitehead is entitled to an earlier effective date. See Final Written Decision at *5–7, *Dynamic Drinkware, LLC v. National Graphics, Inc.*, IPR2013-00131 (Sept. 12, 2014) (Paper 42), 2014 WL 4628897 at *3–4; 37 C.F.R. § 42.104(b)(5); *LeVeen v. Edwards*, 57 U.S.P.Q.2d 1416, 1417 (B.P.A.I. 2000). But

BioGatekeeper did not make any effort to show that the provisional application included the relied-upon teachings of Whitehead. Accordingly, BioGatekeeper fails to substantiate November 26, 2003 as an effective filing date for the Whitehead reference.

BioGatekeeper chose to assert that Whitehead (Ex. 1002) is prior art under 35 U.S.C. §§ 102(a) or “102(1)” and chose to rely on Whitehead’s issue date of March 23, 2010 and priority date of November 26, 2003. (Paper 6 at 9 & 16.) The information BioGatekeeper chose to present in its Petition does not establish a reasonable likelihood of successfully demonstrating that Whitehead qualifies as prior art. 35 U.S.C. § 314(a). Thus, BioGatekeeper’s arguments fail to identify a statutory basis for Whitehead serving as prior art and fail to establish that the asserted dates serve as effective dates for Whitehead’s relied-upon teachings. Accordingly, the Petition should be denied because it does not present information and reasoning to establish that Whitehead is prior art to the ’065 Patent. 35 U.S.C. § 314(a); *L-3 Comm. Holdings*, Paper 9 at *18, 2014 WL 6468495 at *11; *Oxford Nanopore*, IPR2014-00513, Paper 12 at *18.

2. **BioGatekeeper Fails to Address the Graham Factual Inquires**

Obviousness under 35 U.S.C. § 103 requires an assessment of (1) the “level of ordinary skill in the pertinent art,” (2) the “scope and content of the prior art,”

(3) the “differences between the art and the claims at issue,” and (4) “secondary considerations” of nonobviousness such as “commercial success, long felt but unsolved needs, failure of others, etc.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). “A party who petitions the Board for a determination of obviousness must show that ‘a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.’” Decision Denying Institution of *Inter Partes* Review at *15, *3D-Matrix, Ltd. v. Menicon Co.*, IPR2014-00398 (Aug. 1, 2014) (Paper 11), 2014 WL 3851279 at *9 (citations omitted). BioGatekeeper fails to present sufficient factual bases to substantiate its allegation that Claim 1 is obvious.

[a] The Petition Fails to Assess the Level of Skill in the Art

BioGatekeeper’s Petition fails to address the required factual findings to determine the appropriate level of ordinary skill in the art. 35 U.S.C. § 103; *Graham*, 383 U.S. at 17. The Petition provides no discussion whatsoever about the level of ordinary skill in the art. Thus, BioGatekeeper’s obviousness allegations lack the minimum factual inquiry necessary to support a conclusion of obviousness.

While the Petition does include a “Technical Background” section (Paper 6 at 6–9), this entire section consists of attorney characterizations of what was allegedly known in the art. These characterizations are not factually supported by any *evidence*. A majority of the characterizations of the state of the art in this “Technical Background” section cite nothing for support. (Paper 6 at 6–9.) For example, page 6 of the Petition does not include a single citation. Where citations are present, they are not pinpoint cites. (*See, e.g., id.* at 9.) Instead, those few citations refer to entire documents – none of which were submitted as Exhibits to BioGatekeeper’s Petition. Moreover, none of the characterizations of what was allegedly known in the art are corroborated by any testimony from one of ordinary skill in the art. Thus, the Petition fails to provide any factual evidence to assist the Board in determining the appropriate level of skill in the art. Accordingly, the Petition’s assertion of obviousness is necessarily and fatally defective, and BioGatekeeper cannot meet its burden of showing that there is a reasonable likelihood that it will prevail in demonstrating that Claim 1 is obvious.

[b] The Petition Fails to Substantiate the Alleged Scope and Content of the Art

The Petition lacks specific cites to the record throughout and makes unsupported characterizations of the art. The rules require that a Petition “specify where each element of the claim is found in the prior art patents or printed

publications relied upon;” and require that the Petition “must include . . . a detailed explanation of the significance of the evidence including material facts[.]” 37 C.F.R. § 42.104(b); 37 C.F.R. § 42.22(a). “The Board may exclude or give no weight to the evidence where a party has failed to state its relevance or to identify specific portions of the evidence that support the challenge.” 37 C.F.R. § 42.104(b)(5). Here, the Petition fails to identify specific portions of the evidence that allegedly support BioGatekeeper’s challenge to Claim 1.

[i] BioGatekeeper’s Description of the Scope and Content of the Prior Art and the Claim Chart Should be Disregarded

The section of the Petition entitled “The Scope and Content of the Prior Art” contains zero citations to the record. (Paper 6 at 4–5.) This entire section refers to Whitehead (Ex. 1002), but never indicates which of the 22 columns of text in Whitehead are being relied upon for support. The Petition also does not substantiate its characterizations of Whitehead with testimony from one skilled in the art. *See e.g.* 77 Fed. Reg. 48763 (“The Board expects that most petitions and motions will rely on affidavits of experts.”). Accordingly, the purported assertions of fact in this section are nothing more than unsupported attorney arguments.

BioGatekeeper’s Claim Chart does not include a single quotation from the art of record. (Paper 6 at 15–16.) The Claim Chart includes just one string cite to Whitehead (Ex. 1002), allegedly supporting the teaching of only one portion (part

“(b)”) of Claim 1. (Paper 6 at 16.) There are no cites directed to the alleged teachings of the other portions of Claim 1. (*Id.* at 15.)

The lack of specific support for the alleged teachings of the art alone is sufficient basis to deny the Petition. As the Board has explained, “[a] brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record.” Decision Instituting *Inter Partes* Review at *15–16, *EMC Corp. v. Secure Axxess LLC*, IPR2014-00475 (Sept. 9, 2014) (Paper 10), 2014 WL 4537476 at *8 (citation omitted). In *EMC*, the Board disregarded a claim chart that used only citations to the reference instead of quoting the underlying text of the references. Here, most of the Claim Chart does not even include citations, much less quotations from any Exhibits. (Paper 6 at 15–16.)

Furthermore, no characterization in the claim chart is supported by expert testimony. Instead, almost the entire claim chart is attorney characterization of the references that is unsubstantiated by specific teachings in the references or by expert testimony. Thus, the Claim Chart and the section entitled “The Scope and Content of the Prior Art” should be disregarded because these sections of the Petition fail to specify where each element of the claim is found in the art relied upon. See Decision Denying Institution of *Inter Partes* Review at *11, *Tasco, Inc. v. David Pagnani*, IPR2013-00103 (May 23, 2013) (Paper 6), 2013 WL 5947703, at *5 (“the burden is on the petitioner to establish ‘[h]ow the construed claim is

unpatentable’ by specifying ‘where each element of the claim is found in the prior art patents or printed publications relied upon.’” (quoting 37 C.F.R. § 42.104)).

[iii] BioGatekeeper’s Characterization of Benvenisty Should be Disregarded

Where the Petition does at least provide citations to the record, the characterizations of the cited art are not fair reflections of the text itself and again are not supported by testimony from one of skill in the art. Instead, the Petition improperly advances unsupported attorney argument without any specific factual or evidentiary support. *Cf. 3D-Matrix*, IPR2014-00398, Paper 11 at *12, 2014 WL 3851279 at *8 (holding that a Petition’s attorney argument without specific factual and evidentiary support was insufficient to establish inherency).

For example, the Petition alleges that Benvenisty (Ex. 1003) “teaches c-Myc as a pluripotent gene.” (Paper 6 at 15.) However, BioGatekeeper later acknowledges that it does not: “the Benvenisty article and the Li article do not specifically call the c-Myc gene and the Klf4 gene pluripotency genes.” (Paper 6 at 19.) Benvenisty does not even include the word pluripotent. At best, Benvenisty teaches there has been “considerable speculation, though limited evidence, to suggest that the product of the *c-myc* gene is directly involved in the regulation of gene expression or in DNA regulation.” (Ex. 1003 at 2513, col. 1, ¶ 2.) Even in the absence of “considerable speculation,” the mere mention of c-

Myc potentially having a role in regulating gene expression does not equate to a teaching of pluripotent activity. This is particularly true when BioGatekeeper bears the burden as Petitioner, yet offers this assertion only as attorney argument unsupported by any expert testimony. Accordingly, BioGatekeeper's unsupported characterization of Benvenisty should be disregarded.

Furthermore, without such a teaching by Benvenisty, BioGatekeeper's obviousness theory fails because BioGatekeeper's sole reason to combine Benvenisty with Whitehead is that one of skill in the art would understand that Benvenisty teaches that c-Myc is a "pluripotent gene." Thus, the Petition's obviousness allegation must fail as being nothing more than mere conclusory statements lacking any rational, factually-based underpinning to support the legal conclusion of obviousness. See *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Therefore, BioGatekeeper cannot meet its burden to show that its theory of obviousness can possibly succeed.

[iii] BioGatekeeper's Characterization of Whitehead Should be Disregarded

BioGatekeeper's characterization of Whitehead (Ex. 1002) is similarly unsupported by the Whitehead reference itself or by any expert opinions. BioGatekeeper's characterization of Whitehead is internally inconsistent. For example, the Petition alleges that Whitehead teaches "first *introducing* into the

somatic cell **one or more** retroviral vectors comprising the following pluripotent genes: a gene encoding Oct4, and gene encoding Sox2, and a gene encoding Nanog.” (Paper 6 at 16, citing to, *inter alia*, Claim 9 of Whitehead (Ex. 1002) (emphases added).) Later, the Petition alleges that Whitehead discloses “generating ‘reprogrammed pluripotent somatic cells’ by ***introducing at least two pluripotent genes.***” (Paper 6 at 17, apparently citing to Claim 9 of Whitehead (Ex. 1002) (emphasis added).) Neither characterization of Whitehead is supported by the cited text or any expert testimony.

In fact, the plain reading of Claim 9 of Whitehead is contrary to both of BioGatekeeper’s unsupported characterizations. Claim 9 from Whitehead reads:

A primary somatic cell comprising in its genome a first endogenous pluripotency gene operably linked to DNA encoding a first selectable marker in such a manner that expression of the first selectable marker substantially matches expression of the first endogenous pluripotency gene, wherein the first endogenous pluripotency gene encodes Oct-4 or Nanog, and wherein the cell additionally comprises ***an exogenously introduced nucleic acid encoding Oct4, Nanog, or Sox2*** and operably linked to at least one regulatory sequence.
(Ex. 1002 at 22:1–10 (emphasis added).)

Accordingly, the plain language of Claim 9 relates to exogenously introducing just one of three genes. Regardless, there is no evidentiary support for what the complex language of Claim 9 taught to one of ordinary skill in the art at

the time of the invention. Thus, BioGatekeeper's characterization is not supported by the reference itself or by any expert testimony about what Whitehead taught to one of ordinary skill. Absent this **evidence**, the factual record is completely devoid of any basis to establish that one of ordinary skill in the art would have been directed by Whitehead to perform the method recited in Claim 1. Accordingly, the Petition should be denied because it fails to adequately substantiate the alleged teachings of the art upon which BioGatekeeper's obviousness arguments are premised.

Other unsupported characterizations of Whitehead should likewise be disregarded. For instance, the Petition states that "The Whitehead patent clearly disclosed that its method includes introducing any and all suitable pluripotent genes into a somatic cell." (Paper 6 at 19.) BioGatekeeper's unilateral pronouncement of purported clarity does not make it so. As with BioGatekeeper's other arguments, this allegation is not supported by any citation to the Whitehead patent or any expert testimony. It is simply unsupported attorney argument.

In sum, the Petition should be denied because it lacks sufficient evidence, "in the form of testimony or other probative evidence, regarding what the asserted teachings would have meant to a person of ordinary skill in the art and how they relate to the claim limitation against which they are offered." Decision Denying Institution of *Inter Partes* Review at *10, *Norman Noble, Inc. v. Nutech Ventures*,

IPR2013-00101 (Jun. 20, 2013) (Paper 14), 2013 WL 5970193 at *6. Absent this evidentiary support, it is not possible for BioGatekeeper to establish that there is a reasonable likelihood of demonstrating that the claimed method is obvious.

3. The Petition Fails to Articulate a Reason Why the Cited References Would be Combined

The alleged reason to combine Whitehead (Ex. 1002) with Benvenisty (Ex. 1003) and Li (Ex. 1004) is conclusory and insufficient to amount to a clear articulation of the legal conclusion of obviousness. “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. Rather, there must be “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.* at 418. In other words, to invalidate a patent claim based on obviousness, the evidence must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012). A finding of obviousness may not “be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.”

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 655 F.3d 1364, 1375 (Fed. Cir. 2011) (quoting *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998)).

BioGatekeeper admits that, in contrast to Whitehead, “the Yamanaka patent claims a method that introduces 4 pluripotent genes, Oct4, Sox2, Klf4 and C-myc, into a somatic cell.” (Paper 6 at 5.) BioGatekeeper further explains the differences between the ’065 Patent and Whitehead by stating that Whitehead “does not explicitly disclose also using the Klf4 gene and the c-Myc gene to reprogram a somatic cell.” (Paper 6 at 18.) BioGatekeeper then admits that Benvenisty and Li “do not specifically call the c-Myc gene and the Klf4 genes pluripotency genes.” (Paper 6 at 19.) In the face of these admissions, the Petition – in a concluding unfinished sentence – is entirely silent as to why Benvenisty and Li should be combined with Whitehead: “Although the Benvenisty article and the Li article do not specifically call the c-Myc gene and the Klf4 gene pluripotency genes, [sic].” (*Id.*) Without an articulated reason to combine the applied art, BioGatekeeper’s Petition fails to establish a reasonable likelihood of successfully demonstrating that the claim is obvious. See *KSR*, 550 U.S. at 418 (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (quoting *In re Kahn*, 441 F.3d at 988)).

As discussed above, the Petition alleges that “The Whitehead patent clearly disclosed that its method includes introducing any and all suitable pluripotent genes into a somatic cell.” (Paper 6 at 19.) Even if this allegation were true, BioGatekeeper clearly admits that “the Benvenisty article and the Li article do not specifically call the c-Myc gene and the Klf4 gene pluripotency genes,” and provides no further evidence or explanation of why one of ordinary skill in the art would nevertheless use these genes in the teachings of Whitehead. (Paper 6 at 19.) Thus, BioGatekeeper has not established that c-Myc and Klf4 qualify as “suitable pluripotent” genes that one of skill in the art would select for insertion. Furthermore, BioGatekeeper makes no showing whatsoever regarding the expectation of success that one of ordinary skill in the art may or may not have in combining the references as proposed in the Petition. Therefore, in the absence of a clear teaching in the references, and in the absence of testimony by one skilled in the art, it is not possible for BioGatekeeper to support its alleged combination of references.

At best, the Petition asserts that the cited references are in the same field because they are allegedly directed to pluripotent genes. (Paper 6 at 18.) But, as discussed above, BioGatekeeper affirms that Benvenisty and Li do not include such express teachings. (*Id.* at 19.) Further, the Petition does not rely on the testimony of one skilled in the art to explain this inconsistency. Accordingly,

BioGatekeeper fails to meet its burden of showing obviousness because the Petition does not provide any articulated reason, supported by the factual record, that one of skill in the art would have combined the asserted references.

4. The Petition Fails to Address the Conspicuous and Significant Secondary Considerations

The Petition is silent with respect to any secondary considerations of non-obviousness, even though at least BioGatekeeper's counsel knows about Dr. Yamanaka's Nobel Prize. "[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (citations omitted). Objective indicia of non-obviousness "can be the most probative evidence of nonobviousness in the record, and enables the . . . court to avert the trap of hindsight." *Custom Accessories, Inc. v. Jeffery-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986). Industry praise is evidence of secondary considerations of non-obviousness. *Power One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010).

In 2012, Dr. Yamanaka, received the Nobel Prize in Physiology and Medicine in large part due to the invention claimed in the '065 Patent. (Ex. 2001 at 1.) The Nobel Prize itself is evidence of extremely high praise in the industry. (Ex. 2018 at 3–4.) Moreover, the Nobel Assembly specifically noted that Dr.

Yamanaka's discovery included the "combination of only four transcription factors (Myc, Oct3/4, Sox2 and Klf4) that were sufficient to convert mouse embryonic fibroblasts to pluripotent stem cells." (Ex. 2001 at 5.) This combination is embodied by claim 1 of the '065 Patent. (Ex. 1001 at 103:50–104:53.) Thus, there is a nexus between the praise awarded by the Nobel Assembly and the claim at issue here. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

The Nobel Assembly called this work a "paradigm shift in our understanding of cellular differentiation and of the plasticity of the differentiated state." (Ex. 2001 at 1.) House Minority Leader, Nancy Pelosi declared that "Dr. Yamanaka's innovative, creative, and potentially life-saving work on cellular reprogramming builds upon a career of scientific excellence." (Ex. 2004.) Dr. Yamanaka's work was further praised as a "truly fundamental discovery" (Ex. 2001 at 6) and "groundbreaking." (Ex. 2003 at 2.) Accordingly, the praise by the industry for the invention of Claim 1 of the '065 Patent supports the non-obviousness of the claim. *See, e.g.*, Decision Denying Institution of *Inter Partes* Review at *16, *Omron Oilfield & Marine, Inc., v. MD/Totco, a division of Varco, L.P.*, IPR2013-00265 (Oct. 31, 2013) (Paper 11), 2013 WL 8595961 at *10.

It is untenable that anyone having sufficient interest in challenging the '065 Patent would be unaware of Dr. Yamanka's Nobel Prize. In any event, BioGatekeeper's counsel knew about the statements from the Nobel Assembly

because the same counsel filed a lawsuit against Dr. Yamanka for winning the Nobel Prize. Nevertheless, BioGatekeeper made a deliberate strategic decision to not to even mention this compelling secondary consideration in its Petition. Such a failure to address known secondary considerations can support denial of the Petition. Decision Denying Request for Rehearing at *3, *Omron Oilfield*, IPR2013-00265 (Feb. 13, 2014) (Paper 14), 2014 WL 2864246. In the present instance, the highly compelling and well-known secondary considerations weigh heavily in the final determination of obviousness. Failure to address this evidence is a defect that, on its own, supports a denial of the Petition. *Id.*

C. Claim Construction

BioGatekeeper's proposed claim constructions are unsupported and conclusory.

1. "Introducing"

BioGatekeeper's entire "analysis" for its first proposed construction of "introducing" is simply that one of skill in the art would understand the term "to mean *incorporating by nuclear re-programming*." (Paper 6 at 10 (emphasis in original).) This construction is allegedly "consistent with the specification" of the '065 Patent. (*Id.*) These two lines are unsupported by any expert testimony and do not include any discussion further illuminating the meaning of "incorporating by

nuclear re-programming.” Thus, BioGatekeeper fails to provide sufficient basis to adopt this construction.

2. **“Induced Pluripotent Stem Cell”**

BioGatekeeper’s proposal to give the phrase “induced pluripotent stem cell” no weight is similarly unsupported and conclusory. The Petition includes the allegations that the use of the term “induced pluripotent ‘stem’ cell” is “conflicting and misleading because ‘embryonic stem cell-like cells’ or ‘ES-like cells’ were known in the art at the time of the Yamanaka patent, and it was known that although such cells are ‘like’ embryonic stem cells, they are NOT synonymous with the term ‘stem’ cells.” (Paper 6 at 12 (emphasis in original).) However, these assertions are not supported by any citations to evidence of what was “known in the art at the time of the Yamanaka patent.” (*Id.*) Further, these assertions are unsupported by testimony from one skilled in the art. These bare assertions provide no guidance to the Board on the proper construction of the claim.

Notably, a complaint filed by BioGatekeeper’s counsel against Dr. Yamanaka included a similar accusation; stating that the phrase “pluripotent stem cells induced from somatic cells” was misleading because Dr. Yamanaka’s research allegedly had nothing to do with stem cells. (Ex. 2015 at 5, ¶ 11.) Regardless of the motivations behind BioGatekeeper’s proposed constructions, the

constructions should be given no weight because they amount to unsupported attorney argument that does not assist the Board.²

IV. CONCLUSION

For the above reasons, Kyoto respectfully requests that the Board deny BioGatekeeper's Petition for *Inter Partes* Review of the '065 Patent in its entirety.

Respectfully submitted,

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Dated: November 25, 2014

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² Kyoto's position with respect to BioGatekeeper's proposed claim constructions is not to be taken as setting forth any position regarding the appropriate scope to be given the claims by the Board in this matter, or by any court or other adjudicative body in any other matter under the claim interpretation standards that may apply in such proceedings.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PATENT OWNER KYOTO UNIVERSITY'S PRELIMINARY RESPONSE** is being served on November 25, 2014, via email pursuant to 37 C.F.R. § 42.6(e) per agreement of the parties, to counsel for BioGatekeeper, Inc., at the addresses below:

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