No. _____

In the Supreme Court of the United States

CONSUMER WATCHDOG,

Petitioner,

v.

WISCONSIN ALUMNI RESEARCH FOUNDATION,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Does a statute that expressly provides a requester of agency action a right to appeal any dissatisfactory decision of the agency on her request to the courts provide sufficient Article III standing for the appeal, or must additional requirements be satisfied above and beyond the statute?

PARTIES TO THE PROCEEDINGS

Petitioner Consumer Watchdog and Respondent Wisconsin Alumni Research Foundation are the only parties to the proceeding. The United States Department of Justice and the United States Patent and Trademark Office participated as *amicus curiae* at the Court of Appeals after being *sua sponte* asked to do so.

RULE 29.6
CORPORATE DISCLOSURE STATEMENT

Consumer Watchdog has no parent companies, and no company owns ten percent or more of Consumer Watchdog.

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The opinion of the Court of Appeals for the Federal Circuit is reported at 753 F.3d 1258 (Fed. Cir. June 4, 2014). The administrative decision from which appeal was sought is the Decision on Appeal of the United States Patent and Trademark Office, Patent Trial and Appeal Board in Reexamination No. 95/000,154 entered January 22, 2013.

JURISDICTIONAL STATEMENT

The Federal Circuit Opinion and Judgment issued on June 4, 2014. On August 8, 2014 The Chief Justice granted Consumer Watchdog's application (14A162) to extend the time to file a petition for writ of certiorari from September 2, 2014 to October 31, 2014. Jurisdiction is conferred by 28 U.S.C. 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III, Section 2 of the United States Constitution provides in relevant part as follows:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;-- to all Cases affecting Ambassadors, other public Ministers and Consuls;-- to all Cases of admiralty and maritime Jurisdiction;-- to Controversies to which the United States shall be a Party;-- to Controversies between two or more States;-- between a State and Citizens of another State;-- between Citizens of different States;-- between Citizens of the same State claiming

> Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

The version of 35 U.S.C. § 141 that applies to this case provided[1]:

> A . . . third-party requester in an *inter partes* reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision in an appeal to the Board of Patent Appeals and Interferences under section 134 may appeal the decision only to the United States Court of Appeals for the Federal Circuit.

The version of 35 U.S.C. § 315(b)(1) that applies to this cases provided[2]:

> A third-party requester may appeal under the provisions of section 134, and may appeal under the provisions of sections 141 through 144, with respect to any final decision favorable to the patentability of any original or proposed amended or new claim of the patent.

28 U.S.C. § 1295(a)(4)(A) provides:

> The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—of an appeal from a decision of—

[1] This section was amended by the Leahy-Smith America Invents Act ("AIA") in 2011, but that amendment does not apply to this matter. Pub. L. No. 11229, 125 Stat. 284 (2011), Sec. 7(e)(2).

[2] This section was also amended by the AIA in 2011, but that amendment also does not apply to this matter. Pub. L. No. 11229, 125 Stat. 284 (2011), Sec. 6(c)(3)(c).

> the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to a patent application, derivation proceeding, reexamination, post-grant review, or inter partes review under title 35, at the instance of a party who exercised that party's right to participate in the applicable proceeding before or appeal to the Board, except that an applicant or a party to a derivation proceeding may also have remedy by civil action pursuant to section 145 or 146 of title 35; an appeal under this subparagraph of a decision of the Board with respect to an application or derivation proceeding shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;

STATEMENT OF THE CASE

This case concerns Article III standing to appeal agency decisions. Specifically, it asks whether a party expressly identified by statute as having a right to appeal to an Article III court an agency decision made in response to a specific request of the party has standing to do so absent statute-independent injury.

The Administrative Decision

Petitioner Consumer Watchdog (CW) is a not-for-profit organization that provides a voice for taxpayers and consumers in public discourse, government and politics. Petitioner requested *inter partes* reexamination of Respondent's patent on human stem cells because it believes the patent is invalid for several reasons, including that it is a patent on nature as it exists in our bodies.

The Patent Office examiner assigned to the reexamination granted Petitioner's request for a reexamination but upheld the patent as valid. Petitioner appealed the examiner's decision to the Board of Patent Appeals and Interferences[3] within the Patent Office ("Board"), which reversed the examiner's decision and agreed with Petitioner that Respondent's patent was indeed invalid. A-29. Respondent then introduced a new expert declaration from a witness whom Petitioner did not have the opportunity to cross examine. In light of Respondent's new expert testimony, the Board reversed its previous decision and upheld the patent. A-15.

The Statutory Scheme

Two statutes in the Patent Act, 35 U.S.C. §§ 141 and 315, expressly provide Petitioner the right to appeal the Board decision to the Court of Appeals for the Federal Circuit.[4] Section 141 of the Patent Act states, a "third-party requester in an *inter partes* reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision [of the Patent Office Board] may appeal the decision only to the United States Court of Appeals for the Federal Circuit." Referencing Section 141, Section 315 of the Patent Act states, "[a] A third party requester … may appeal under the provisions of sections 141 through 144, with respect to any final

[3] Now known as the Patent Trial and Appeal Board (PTAB).

[4] Both of these statutes were amended by the Leahy-Smith America Invents Act ("AIA") in 2011, but those amendments do not apply to this matter. Pub. L. No. 11229, 125 Stat. 284 (2011), Secs. 6(c)(3)(c) and 7(e)(2).

decision favorable to the patentability of any original or proposed amended or new claim of the patent."

In addition, 28 U.S.C. § 1295(a)(4)(A) provides that, "[t]he United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—of an appeal from a decision of—the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to a … reexamination … under title 35, at the instance of a party who exercised that party's right to participate in the applicable proceeding before or appeal to the Board."

Petitioner timely appealed the decision to the Court of Appeals for the Federal Circuit pursuant to the applicable statutes.

The Appeal.

On appeal, Respondent raised no challenge to Petitioner's standing. The Patent Office chose not to participate in the appeal, leaving it to the parties to resolve the matter. After Petitioner and Respondent fully briefed the merits of the case, the Court of Appeals *sua sponte* ordered both parties to brief the issue of whether Petitioner had Article III standing. A-13. The parties did so, with Petitioner arguing standing existed due to the express language of the applicable statutes and Respondent arguing standing did not lie because Petitioner had not satisfied the requirements needed for a declaratory judgment challenge to the patent.

The Court of Appeals heard argument in the case in December 2013 and focused exclusively on the standing issue. Immediately after oral argument, the Court of Appeals scheduled a second oral argument for March 2014 and asked the United States

Department of Justice and Patent and Trademark Office (collectively the "Government") to participate. A-10. The Government appeared and argued that standing did not lie because one who sought to appeal an adverse decision in an *inter partes* reexamination must meet an intermediate standard of Article III jurisdiction: it need not meet the strict standard required of a declaratory judgment plaintiff, in light of this Court's precedent that relaxes immediacy and redressability requirements in cases dealing with procedural rights, but an injury independent of the statute is nonetheless necessary. After the Government briefed the issue, Respondent abandoned its original position that full declaratory judgment standing is required and agreed with the Government's intermediate standard.

During argument in March, one member of the (ultimately unanimous) panel acknowledged Congress's intent to allow parties like Consumer Watchdog to appeal to the Federal Circuit: "It seems like Congress intended to do exactly what you're saying they intended to do." C.A. Oral Arg. Recording, 35:30- 35:35 (available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2013-1377_3132014.mp3). The central issue is thus not one of statutory interpretation but rather Congress's authority to define an injury sufficient to create Article III standing.

In June 2014, the Court of Appeals decided that Petitioner could not maintain its appeal of the Patent Office's decision to uphold Respondent's patent. It held Petitioner lacked injury sufficient to maintain Article III standing despite the express statutory right to appeal. A-1. Prior to this case, the

Court of Appeals had decided many appeals of *inter partes* reexamination decisions by dissatisfied third-party requesters, never considering whether more was required for standing than the dissatisfactory administrative decision being appealed pursuant to the statutes. Thus the Court of Appeals had never before proffered a standard for determining whether a third-party *inter partes* requester had standing before it decided this case. In its decision here, the Court of Appeals also did not suggest any standard or test for determining standing in future cases where third-party *inter partes* requesters are dissatisfied with the Patent Office's decision. Standing requirements for third-party requesters are thus unknown.

REASONS FOR GRANTING THE WRIT

I. THE DECISION BELOW CONFLICTS WITH SUPREME COURT PRECEDENT

The Court has addressed standing in procedural rights cases numerous times. Broadly speaking, the cases can be divided into two categories.

In the first category, the party seeking judicial review of an administrative action was party to the action and was uniquely identified in the judicial review statute as having the right to judicial review of the action. *E.g.*, "a third party requester in an *inter partes* reexamination proceeding. . . may appeal the decision [on the proceeding it requested]. . ." 35 U.S.C. § 141. In these cases, no injury other than dissatisfaction with the agency response to the request is needed for standing to lie. These are cases where Congress has exercised its "power to define injuries and articulate chains of causation that [] give rise to a case or controversy

where none existed before." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 580 (1992) (Kennedy, J., concurring in part and concurring in the judgment). The Court does not require any additional or separate conditions to find standing. The judicial review statutes at issue in this case, governing review of Patent Office Board decisions following *inter partes* reexamination requested by third parties, fall squarely into this category.

In the second category of cases, the party seeking judicial review of an administrative action was not a party to the action and was not uniquely identified in the judicial review statute under which reversal was sought. E.g., "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." Administrative Procedure Act, 5 U.S.C. § 702. In those cases the Court requires the challenging party to show statute-independent injury to establish standing. *See, e.g. Lujan*, 504 at 559 (finding no standing absent injury to plaintiffs who challenged, under the EPA citizen suit provision, the Secretary's action of promulgating a law narrowing the geographical scope of an environmental regulation); *Sierra Club v. Morton*, 405 U.S. 727, 730 (1972) (finding no standing absent injury to plaintiffs who challenged, under the APA, federal approval of commercial development in the Sequoia National Forest); *Summers v. Earth Island Inst.*, 555 U.S. 488, 489 (2009) (finding no standing absent injury to plaintiffs who, under the APA and ARA, challenged unspecified applications of regulations that exempted certain land sales from the notice, comment and appeal process); *Havens*

Realty v. Coleman, 455 U.S. 363 (1982) (finding standing for black respondent who was lied to about housing availability but not for white respondent who received accurate information, where statute authorized civil suit to enforce discriminatory housing practices).

This case does not fall into the second category because Petitioner here was a party to the contested action and is uniquely identified in the applicable statutes as having the right to seek judicial review. The Court of Appeals decision to the contrary was in error.

A. STATUTES GRANTING RIGHT OF JUDICIAL REVIEW TO THE DENIED REQUESTER OF AN ADMINISTRATIVE ACTION DO NOT REQUIRE STATUTE-INDEPENDENT INJURY

Cases concerning the Freedom of Information Act ("FOIA") and the Federal Election Campaign Act of 1971 ("FECA") deftly illustrate the Court's repeated holdings that Congress can create Article III standing to seek review of specific agency action by statute alone. No independent injury is necessary to appeal administrative decisions under those acts. A party who seeks judicial review of a denied request under FOIA or FECA need demonstrate no more than that she made a request pursuant to the statute and was dissatisfied with the administrative response. She need not show that the dissatisfactory administrative response was harmful to her in any way.

FOIA provides that government agencies must make certain information available to the public (5 U.S.C. § 552(a)), that agencies must make

information available to "any person" upon request (5 U.S.C. § 552(a)(3)(A)), and that, on complaint, the appropriate district court "has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B). Only information included within one of the nine FOIA exemptions (5 U.S.C. § 552(b)) may properly be withheld.

The Court has interpreted FOIA to be a "judicially enforceable public right," *EPA v. Mink*, 410 U.S. 73, 80 (1973) and clarified that no injury beyond denial of the request is required of a person who seeks to enforce that right. *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 221 (1978). The Court reiterated that Article III standing exists for denied FOIA requesters years after *Mink* and *Robbins* in *Public Citizen*:

> As when an agency denies requests for information under the Freedom of Information Act, refusal to permit appellants to scrutinize the ABA Committee's activities to the extent FACA allows constitutes a sufficiently distinct injury to provide standing to sue. Our decisions interpreting the Freedom of Information Act have never suggested that those requesting information under it need show more than that they sought and were denied specific agency records.

Public Citizen v. United States Dep't of Justice, 491 U.S. 440, 449 (1989). Thus, for several decades, Article III standing to seek judicial review under FOIA has required no injury other than denial of a FOIA request. A denial of a FOIA request is not a

refusal to consider it, but rather a decision that the requester is not entitled to all the information she requested.

Any argument that the violation of a substantive legal right to information about the United States government underlies the injury necessary for an unsatisfied FOIA requester to have standing to seek court review of the agency's response is specious. Not only has the Court found standing absent discussion of such a substantive right, but FOIA does not require that a requester even be a United States citizen with any substantive rights whatsoever. "The general rule is that any person—citizen or not—can make a FOIA request." Freedom of Information Act: Frequently Asked Questions at http://www.foia.gov/faq.html#who, last visited 10/14/14. It is implausible that our government should value non-citizens' access to information about the United States enough to bestow upon virtually every non-citizen an enforceable right to such information. Any attempt to justify FOIA standing based on some underlying substantive right is unfounded. It is the statute, and the statute alone, that justifies standing.

Denial of a FOIA request is not only sufficient to confer standing; it is also necessary for standing to lie, as an agency's refusal to provide information outside the FOIA context fails to support Article III standing.

This point is evidenced by two contrasting cases in which parties separately sought President Obama's birth certificate. In one case, a party who opposed Obama's candidacy for President sought to compel the production of Obama's long-form birth

certificate in district court. *Berg v. Obama,* 574 F. Supp. 2d 509, 512 (E.D. Pa. 2008), *aff'd*, 586 F.3d 234 (3d Cir. 2009). Berg did not request the certificate through FOIA and, as such, his complaint was correctly dismissed in an opinion calling his status "no more differentiated than that of millions of other voters" and his harm "too vague and its effects too attenuated to confer standing. . ." *Id.* at 519. However, in another case seeking the exact same information, a party who opposed Obama's candidacy for President sought his long-form birth certificate through FOIA and, after being denied, had standing to appeal to the courts. *Taitz v. Ruemmler*, 2011 U.S. Dist. LEXIS 119452 (D.D.C. Oct. 17, 2011), *aff'd*, No. 11-5306, 2012 WL 1922284 (D.C. Cir. 2012) (per curiam). Thus, it was not the failure to provide the birth certificate that provided Article III standing, but rather the denial of a FOIA request and the express statute providing a right to appeal that denial to the courts that confers standing; else *Berg* would have had standing, too.

The FECA statute also gives a party standing to seek judicial review of a denied administrative request without statute-independent injury. Similarly to FOIA, FECA imposes certain regulations (record keeping and disclosure requirements for political committees), empowers a category of individuals to make administrative requests to enforce those regulations ("Any person who believes a violation of this Act . . . has occurred, may file a complaint with the Commission." 2 U.S.C. 437g(a)(1)), and provides a right of judicial review to those whose requests were denied ("Any party aggrieved by an order of the Commission dismissing a complaint filed by such party . . . may file a

petition with the United States District Court for the District of Columbia." 2 U.S.C. 437g(a)(8)(A)).

The Court in *FEC v. Akins* analyzed standing similarly to the FOIA cases. 524 U.S. 11 (1998). In *Akins*, voters complained to the FEC that a particular organization was violating FECA disclosure requirements. 524 U.S. 11, 18 (1998). The FEC dismissed the voters' complaints, and the voters sought judicial review under FECA's judicial review provision. The Court found standing despite the Solicitor General's argument that standing was lacking, stating:

> Congress has specifically provided in FECA that 'any person who believes a violation of this Act . . . has occurred, may file a complaint with the Commission.' It has added that 'any party aggrieved by an order of the Commission dismissing a complaint filed by such party . . . may file a petition' in district court seeking review of that dismissal.

Id. at 19.

Akins further emphasized the importance of the statute in distinguishing the case from another in which a taxpayer lacked standing to obtain information to which he claimed the Accounts Clause entitled him. Explaining the difference, the Court pointed to the existence in *Akins* of "a statute which . . . does seek to protect individuals such as respondents from the kind of harm they say they have suffered . . .." *Id.* at 22 (contrasting *United States v. Richardson*, 418 U.S. 166, 178 (1974)). Standing thus lay because of the statute.

B. THE RELEVANT APPEAL STATUTES DO NOT REQUIRE STATUTE-INDEPENDENT INJURY

The statutory scheme at issue in this case is precisely analogous to the FOIA and FECA statutes above. First, the Patent Act constrains certain government activity by forbidding the grant of patents that don't meet conditions for patentability. 35 U.S.C. §§ 101, 102, and 103. Second, a category of individuals—here requesters of *inter partes* reexamination who have their request for reexamination granted—are allowed to challenge the agency by seeking cancellation of the invalid patent during reexamination to redress the violation of those statutes. Third, for each such challenge, the *inter partes* reexamination requester is provided a right to seek judicial review of any final Patent Office Board decision with which it is dissatisfied.

While the right to judicial review is described in terms of jurisdiction in the FOIA statute (5 U.S.C. § 552(a)(4)(B), declaring that the appropriate district court "has jurisdiction to enjoin the agency . . .") and in terms of an affirmative right of the complainant in the FECA statute (2 U.S.C. 437g(a)(8)(A), declaring that "[a]ny party aggrieved . . . may file a petition . . ."), the three judicial review statutes that pertain to requesters of *inter partes* reexamination define the right in both ways. "A . . . third-party requester in an *inter partes* reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision . . . may appeal the decision only to the United States Court of Appeals for the Federal Circuit." 35 U.S.C. § 141. "A third-party requester may appeal . . . with respect to

any final decision favorable to the patentability of any . . . claim of the patent." 35 U.S.C. § 315(b)(1).

> The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—of an appeal from a decision of—the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to a . . . reexamination . . . , at the instance of a party who exercised that party's right to participate in the applicable proceeding before or appeal to the Board . . .

28 U.S.C. § 1295(a)(4)(A). Thus, with no less than three separate statutes expressing the same desire, Congress' intent to confer standing on parties like Petitioner through legislation is abundantly clear. A member of the Court of Appeals plainly stated as much during oral argument, saying "It seems like Congress intended to do exactly what you're saying they intended to do." C.A. Oral Arg. Recording, 35:30- 35:35 (available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2013-1377_3132014.mp3).

Unlike the FOIA and FECA statutes, Congress enacted the judicial review statutes concerning *inter partes* reexamination against a historical background that already recognized a "judicially enforceable public right" via a judicial review statute that applied to denied requesters of administrative action. *EPA v. Mink*, 410 U.S. 73, 80 (1973). *Inter partes* reexamination was not allowed until 1999, and the right of appeal for third-party requesters (as opposed to patent owners) did not exist until 2002. *See* Changes to Implement the 2002 *Inter Partes* Reexamination and Other Technical Amendments to

the Patent Statute, 68 Fed. Reg. 70996, 70997 (Dec. 22, 2003). By then Congress had a template by which to craft legislation that would similarly create a new right to judicial review.

In every way that is relevant to standing, the statutory scheme Congress created is equal to or stronger than the FOIA and FECA schemes. First, the judicial review statutes here similarly check government behavior rather than protect private interests. *See Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 604 (Fed. Cir. 1985) (observing that "[t]he reexamination statute's purpose is to correct errors made by the government, to remedy defective governmental (not private) action, and if need be to remove patents that should never have been granted"). *Cf. Akins,* 524 U.S. at 14 (stating, "the Federal Election Campaign Act seeks to remedy any actual or perceived corruption of the political process . . ."); *Mink*, 410 U.S. at 80 (opining that FOIA "seeks to permit access to official information long shielded unnecessarily from public view . . .").

Second, if the dissatisfied third-party reexamination requester sought the result it desired (cancellation of the patent) in court without first successfully requesting a reexamination and receiving a final Board decision pursuant to the statute, it would lack standing. *See Boeing v. Commissioner of Patents & Trademarks*, 853 F.2d 878, 88182 (Fed. Cir. 1988) and *Syntex (U.S.A.), Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1573 (Fed. Cir. 1989) (both pointing to the lack of a relevant statute in denying standing to third-party reexamination requesters who sought to challenge reexamination decisions before such statutes existed). *Cf. Berg v. Obama,* 574 F. Supp. 2d. 509*;*

Richardson, 418 U.S. 166. Any creation of a "substantive legal right []" (753 F.3d at 1262) to the requested result is thus founded in the judicial review statute itself. There is no less reason to find a right to cancellation of an invalid patent than a right to information that falls outside FOIA exemptions.

Third, there is no guarantee of the requested result—cancellation of the patent—but merely a guarantee of judicial review of agency decisions in response to the request. Just as a court may determine that information denied under FOIA indeed falls within one of the nine exemptions, *see Taitz*, 2011 U.S. Dist. LEXIS 119452, or that the FEC indeed properly dismissed a complaint, the Court of Appeals in this context may too find that the Patent Office Board indeed correctly upheld the challenged patent.

Fourth, when the third-party requester receives an adverse decision from the Board, it is only that party who may appeal. Just as Petitioner here may not appeal the denial of some third party's FOIA request or the dismissal of that third party's FECA complaint, neither can any such third parties appeal the Patent Office Board decision in Petitioner's *inter partes* reexamination. Only the party who made the request has the statutory right to appeal to the courts.

The Court of Appeals distinguished this case by concluding that FOIA and FECA create substantive legal rights, 753 F.3d at 1262, but it offered no explanation of why statutes could give parties substantive rights to enforce government obligations to provide information that should be public or to prosecute political committees that were violating

disclosure laws but not to cancel invalid patents. Indeed, the only analysis performed by the Court of Appeals was as follows:

> Consumer Watchdog's analogy to the Freedom of Information Act (FOIA) and Federal Election Campaign Act (FECA) is unpersuasive. These acts created substantive legal rights—access to certain government records—the denial of which inflicts a concrete and particularized injury in fact. *See FEC v. Akins*, 524 U.S. 11, 21 (1998). Unlike the plaintiffs in the FOIA and FECA cases, Consumer Watchdog was not denied anything to which it was entitled. Consumer Watchdog was permitted to request reexamination and participate once the PTO granted its request. This is all the statute requires. *See generally* 35 U.S.C. §§ 311–318. Accordingly, unlike the FOIA and FECA cases, the PTO did not abridge any of Consumer Watchdog's rights. *See Lujan*, 504 U.S. at 562 ("[W]hen the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish.") (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)).

A-7. The distinction relied on by the Court of Appeals is not evident in the language Congress used to impose regulations or confer standing in the various statutes. It is not evident in the purpose of the statutes, which is to check government behavior. It is not evident in the procedures, which grant judicial review only to parties who first request

administrative action and are dissatisfied with the response.

Indeed, the Court of Appeals seemed to focus on the fact that the applicable reexamination statutes do not "guarantee a particular outcome favorable to the requester." A-6. But that is true of FOIA and FECA as well. Neither a FOIA/FECA requester nor a reexamination requester is entitled to any particular outcome. They both are only entitled to make a request of an administrative agency and then appeal to the courts any unsatisfactory response the agency makes to their request. If the courts agree the agency was correct in not providing a satisfactory response to the request, so be it. That does not negate the right of the requester to seek court review as provided for by the statute. The Court of Appeals' reliance on that issue in this case, saying that FOIA/FECA requesters are entitled to the response they want, was clear error.

Every reasonable basis for finding standing in the FOIA and FECA cases is at least equally apparent in the statutes at issue in this case. The only distinction is the Court of Appeal's arbitrary decision. Further, as the Court recently stated in *Lexmark Int'l, Inc. v. Static Control Components, Inc.*:

> We do not ask whether in our judgment Congress *should* have authorized Static Control's suit, but whether Congress in fact did so. Just as a court cannot apply its independent policy judgment to recognize a cause of action that Congress has denied, . . . it cannot limit a cause of action

> that Congress has created merely because "prudence" dictates.

134 S. Ct. 1377, 1388 (2014). Similarly, it is not within a lower court's discretion to ignore Congress' explicit addition to a category of statutes the Court has condoned. The decision below is irreconcilable with the Court's precedent.

II. THIS CASE RAISES AN IMPORTANT CONSTITUTIONAL QUESTION

The Court of Appeals decision raises the important Constitutional question of whether Congress and the President have the power to provide for Article III Court review of discrete administrative decisions. The decision will impact more than just the patent system, as its reasoning could limit the power of Congress and the President to provide for court appeal of administrative responses to requests in any field. Indeed, the issue in this case implicates the power of Congress and the President to create Article III standing by statute in any sense, such as for disputes between private parties, or private parties and the government outside of the administrative context.

Just within the patent system, the decision raises Constitutional questions for recently passed statutes not directly involved here, including 35 U.S.C. §§ 319 and 329 and the current versions of 35 U.S.C. §§ 141 and 315, which give rights of appeal to the Court of Appeals for the Federal Circuit to third party requesters of new *inter partes* review and post grant review processes created by the America Invents Act in 2011. The intent of Congress and the President in passing the AIA was to enhance the ability of the public to challenge patents at the Patent Office. *See*

Michael J. Burstein, *Rethinking Standing in Patent Challenges*, 83 GEO. WASH. L. REV. (forthcoming 2015), *available at* http://ssrn.com/abstract=2359873 ("Congress acknowledged the importance of more and better mechanisms for weeding out invalid intellectual property when it enacted new patent review procedures as part of the America Invents Act ('AIA')").

By replacing the *inter partes* reexamination process, the subject of this case, with new, stronger *inter partes* review and post grant review processes, available for any person or entity to use, Congress and the President in 2011 aimed to solve the problem of poor patent quality. *Id.* Included in the AIA were provisions entitling any third party requester of *inter partes* review or post grant review with the same right of appeal to the Court of Appeals for the Federal Circuit as Petitioner has in this case. The Court of Appeals decision in this case, therefore, will curtail those rights similarly. This is contrary to the AIA's language and intent because standing rules that preclude certain parties, including public interest organizations like Petitioner here, from appealing Patent Office decisions in such challenges will discourage the exact challenges Congress and the President meant to encourage. *Id.* Even competitors without a concrete declaratory judgment dispute may not want to risk challenging patent validity through reexamination given the uncertainty that they will be allowed to appeal an adverse decision, especially when there is no doubt that the patent holder would be free to appeal a decision of the Patent Office Board striking the patent. Such one-sided right to appeal (patentees, but not challengers) not only conflicts with the

express language and intent of the applicable statutes, it also violates fundamental fairness and plain common sense.

Thus, the decision below not only affects the standing of parties who have filed *inter partes* reexaminations, like Petitioner here, but also parties that have filed the new *inter partes* reviews or post grant reviews with the Patent Office since passage of the AIA and those who may consider doing so in the future. Beyond the patent system, the rationale of the Federal Circuit could entirely preclude Congress and the President from providing court review of administrative decisions and limit their power to create standing in any context. This obstacle raises severe Constitutional and Separation of Powers issues.[5]

[5] The Court is currently considering another petition for *certiorari* concerning Article III standing based on a statute, the Fair Credit Reporting Act ("FCRA"). Petition for Writ of Certiorari, *Spokeo, Inc. v. Robins*, No 13-1339 (U.S. May 1, 2014). Should the Court decline the *Spokeo* petition, it would leave a circuit split between the Ninth Circuit's decision there (finding standing can lie based on statute alone) and the Federal Circuit decision here (finding standing cannot lie based on statute alone). Should the Court grant the petition in *Spokeo*, an affirmance of that decision by the Court would undermine the Court of Appeals decision in this case, justifying at minimum GVR. A reversal by the Court of *Spokeo*, however, would not resolve this case because *Spokeo* does not involve standing to seek judicial review of a specific agency action. Rather, it involves the right to bring a private cause of action for violation of a statute.

CONCLUSION

For the reasons stated above, the petition for certiorari should be granted.

Respectfully submitted,

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October 31, 2014

APPENDIX

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ENTERED: JUNE 4, 2014

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

CONSUMER WATCHDOG,
(formerly known as The Foundation for Taxpayer and Consumer Rights),

Appellant,

v.

WISCONSIN ALUMNI RESEARCH FOUNDATION,

Appellee.

2013-1377

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Reexamination
No. 95/000,154.

Decided: June 4, 2013

SABRINA Y. HASSAN, Public Patent Foundation Benjamin N. Cardozo School of Law, of New York, New York, argued for appellant. With her on the Brief was DANIEL B. RAVICHER.

KARA F. STOLL, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington,

DC, argued for appellee. With her on the brief were WILLIAM B. RAICH and SARAH E. CRAVEN.

MARK R. FREEMAN, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for amicus curiae. With him on the brief were STUART F. DELERY, Assistant Attorney General and SCOTT R. MCINTOSH, Attorney. Of counsel on the brief were NATHAN K. KELLEY, Solicitor, and SCOTT C. WEIDENFELLER, Senior Counsel for Patent Law and Litigation, United States Patent and Trademark Office, of Alexandria, Virginia.

Before PROST,* *Chief Judge*, RADER,** and HUGHES, *Circuit Judges*.

RADER, *Circuit Judge*.

Consumer Watchdog appeals from the Patent Trial and Appeal Board's decision affirming the patentability of claims 1–4 of U.S. Patent No. 7,029,913 ('913 patent). Because Consumer Watchdog has not established an injury in fact sufficient to confer Article III standing, however, this court dismisses the appeal.

I.

Consumer Watchdog is a self-described "not-for-profit public charity dedicated to providing a voice for taxpayers and consumers in special interest-

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* Sharon Prost assumed the position of Chief Judge on May 31, 2014.

** Randall R. Rader vacated the position of Chief Judge on May 30, 2014.

dominated public discourse, government and politics." Appellant's Br. 1. In 2006, Consumer Watchdog requested inter partes reexamination of the '913 patent, which is owned by Appellee Wisconsin Alumni Research Foundation (WARF). J.A. 106. The '913 patent is generally directed to human embryonic stem cell cultures. *E.g.*, '913 patent abst.

Consumer Watchdog has not alleged any involvement in research or commercial activities involving human embryonic stem cells. Nor has it alleged that it is an actual or prospective competitor of WARF or licensee of the '913 patent. Instead, Consumer Watchdog simply alleges that WARF's "broad and aggressive assertion of the '913 patent has put a severe burden on taxpayer-funded research in the State of California where [Consumer Watchdog] is located." Appellant's Br. 2. Indeed, Consumer Watchdog states that it filed the reexamination request because it was concerned that the '913 patent allowed WARF to completely preempt all uses of human embryonic stem cells, particularly those for scientific and medical research. *Id.* Consumer Watchdog was ultimately unsuccessful in the reexamination, however, and filed the present appeal.

II.

Federal courts do not have authority to entertain every dispute. Relevant to this appeal, Article III only allows the federal courts to adjudicate "Cases" and "Controversies." U.S. Const. art. III, § 2, cl. 1. Ostensibly, these broad terms could cover a wide range of disputes. Over the years, however, the federal courts have developed a variety of doctrines

to clarify that Article III limits the federal courts' jurisdiction to those disputes seeking to "redress or prevent actual or imminently threatened injury to persons caused by private or official violation of law." *Summers v. Earth Island Inst.*, 555 U.S. 488, 492–93 (2009). These doctrines—including standing, ripeness, and mootness—distinguish justiciable disputes from those that are not. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008). Collectively, these doctrines represent a fundamental limitation on the authority of the federal courts. *Hollingsworth v. Perry*, 133 S. Ct. 2652, 2661 (2013).

The present appeal concerns Article III standing. To meet the constitutional minimum for standing, the party seeking to invoke federal jurisdiction must satisfy three requirements. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, the party must show that it has suffered an "injury in fact" that is both concrete and particularized, and actual or imminent (as opposed to conjectural or hypothetical). *Id.* at 560–61. Second, it must show that the injury is fairly traceable to the challenged action. *Id.* at 560. Third, the party must show that it is likely, rather than merely speculative, that a favorable judicial decision will redress the injury. *Id.* at 561.

These constitutional requirements for standing apply on appeal, just as they do before district courts. *Hollingsworth*, 133 S. Ct. at 2661. Accordingly, these requirements apply with equal force to appeals from administrative agencies, such as the U.S. Patent and Trademark Office (PTO), to the federal courts. *See Sierra Club v. E.P.A.*, 292 F.3d 895, 899 (D.C. Cir. 2002). To be clear, although

Article III standing is not necessarily a requirement to appear before an administrative agency, once a party seeks review in a federal court, "the constitutional requirement that it have standing kicks in." *Id.*

That said, where Congress has accorded a procedural right to a litigant, such as the right to appeal an administrative decision, certain requirements of standing—namely immediacy and redressability, as well as prudential aspects that are not part of Article III—may be relaxed. *See Massachusetts v. E.P.A.*, 549 U.S. 497, 517–18 (2007). However, the "requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed by statute." *Summers*, 555 U.S. at 497. That injury must be more than a general grievance, *Hollingsworth*, 133 S. Ct. at 2662, or abstract harm, *City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983).

Indeed, "a disagreement, however sharp and acrimonious it may be" will not suffice for the injury in fact requirement. *Hollingsworth*, 133 S. Ct. at 2661 (internal quotations and citation omitted). Rather, the party invoking federal jurisdiction must have "a personal stake in the outcome." *Lyons*, 461 U.S. at 101. The personal stake in the outcome—and injury in fact—generally will be easier to show where the party seeking to invoke the federal courts' jurisdiction is the object of the complained of action (or inaction). *Lujan*, 504 U.S. at 561. By contrast, where a party is alleging an injury arising from the government's allegedly unlawful action or inaction pertaining to a third party, injury in fact is much more difficult to prove. *Id.* at 561–62.

III.

With these principles in mind, this court turns to Consumer Watchdog's appeal. Consumer Watchdog does not identify any alleged injury aside from the Board denying Consumer Watchdog the particular outcome it desired in the reexamination, i.e., canceling the claims of the '913 patent. Appellant's Br. in Response to United States 3. Consumer Watchdog does not allege that it is engaged in any activity involving human embryonic stem cells that could form the basis for an infringement claim. It does not allege that it intends to engage in such activity. Nor does it allege that it is an actual or prospective licensee, or that it has any other connection to the '913 patent or the claimed subject matter. Instead, Consumer Watchdog relies on the Board's denial of Consumer Watchdog's requested administrative action—namely, the Board's refusal to cancel claims 1–4 of the '913 patent. That denial, however, is insufficient to confer standing.

To be sure, "Congress may enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute." *Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n.3 (1973) (citations omitted). That principle, however, does not simply override the requirement of injury in fact. *Lujan*, 504 U.S. at 578. Here, the Board's disagreement with Consumer Watchdog did not invade any legal right conferred by the inter partes reexamination statute. The statute at issue here allowed any third party to request reexamination, and, where granted, allowed the third party to participate. 35 U.S.C. §§ 311(a), 314(b)(2) (2006). The statute did not guarantee a particular outcome favorable to the requester. *See*

generally 35 U.S.C. §§ 311–318 (2006). Consequently, the Board's denial of Consumer Watchdog's request did not invade any legal right conferred upon Consumer Watchdog.

For this reason, Consumer Watchdog's analogy to the Freedom of Information Act (FOIA) and Federal Election Campaign Act (FECA) is unpersuasive. These acts created substantive legal rights—access to certain government records—the denial of which inflicts a concrete and particularized injury in fact. *See FEC v. Akins*, 524 U.S. 11, 21 (1998). Unlike the plaintiffs in the FOIA and FECA cases, Consumer Watchdog was not denied anything to which it was entitled. Consumer Watchdog was permitted to request reexamination and participate once the PTO granted its request. This is all the statute requires. *See generally* 35 U.S.C. §§ 311–318. Accordingly, unlike the FOIA and FECA cases, the PTO did not abridge any of Consumer Watchdog's rights. *See Lujan*, 504 U.S. at 562 ("[W]hen the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish.") (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)).

Nor is it enough that the inter partes reexamination statute allows a third party requester to appeal decisions favorable to patentability. 35 U.S.C. § 315(b). A statutory grant of a procedural right, e.g., right to appeal, does not eliminate the requirements of Article III. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1386 (2014). To be clear, a statutory grant of a procedural right may relax the requirements of immediacy and redressability, and eliminate any

prudential limitations, *Massachusetts*, 549 U.S. at 517–18, which distinguishes the present inquiry from that governing a declaratory judgment action. But the statutory grant of a procedural right does not eliminate the requirement that Consumer Watchdog have a particularized, concrete stake in the outcome of the reexamination. *Summers*, 555 U.S. at 496 ("[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right in *vacuo*—is insufficient to create Article III standing.").

The estoppel provisions contained within the inter partes reexamination statute likewise do not constitute an injury in fact for Article III purposes. 35 U.S.C. § 317(a), (b). Consumer Watchdog is not engaged in any activity that would give rise to a possible infringement suit. Nor does Consumer Watchdog provide any indication that it would file another request seeking to cancel claims at the Patent Office. In any event, as Consumer Watchdog only has a general grievance against the '913 patent, the "conjectural or hypothetical" nature of any injury flowing from the estoppel provisions is insufficient to confer standing upon Consumer Watchdog. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 344 (2006); *Warth v. Seldin*, 422 U.S. 490, 509 (1975); *see also Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 648 (D.C. Cir. 1998); *cf. also Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1323 (Fed. Cir. 2012) (holding various plaintiffs lacked standing in declaratory judgment action because alleged injuries were too speculative), *rev'd on other grounds sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2114 (2013). The court, however,

leaves it to future panels to decide whether, under other circumstances, the preclusive effect of the estoppel provisions could constitute an injury in fact. In sum, aside from its procedural right to appeal, Consumer Watchdog has only alleged a general grievance concerning the '913 patent. It states that it is a nonprofit consumer rights organization that is concerned about the potential preemptive reach of the '913 patent and the alleged burden it places on taxpayer-funded research in the State of California. Appellant's Br. 1–2. While Consumer Watchdog is sharply opposed to the Board's decision and the existence of the '913 patent, that is not enough to make this dispute justiciable. *Lujan*, 504 U.S. at 577.

IV.

Because Consumer Watchdog has not identified a particularized, concrete interest in the patentability of the'913 patent, or any injury in fact flowing from the Board's decision, it lacks standing to appeal the decision affirming the patentability of the amended claims. The court has considered Consumer Watchdog's remaining arguments to the contrary, but finds them unpersuasive. Accordingly, Consumer Watchdog's appeal is dismissed.

DISMISSED

ENTERED: DECEMBER 4, 2013

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

CONSUMER WATCHDOG (FORMERLY KNOWN AS THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS),
Appellant,

v.

WISCONSIN ALUMNI RESEARCH FOUNDATION,
Appellee.

2013-1377

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Reexamination No. 95/000,154.

O R D E R

The court requests that the United States Patent and Trademark Office (PTO) and the United States provide briefs in *Consumer Watchdog v. Wisconsin Alumni Research Foundation*, No. 13-1377. The court would like the PTO and the United States to address whether Consumer Watchdog has standing to pursue its appeal to this court. The PTO and the United States may submit a joint brief, if they so choose. The brief(s) shall be filed by January 6, 2014.

The Court also requests that the PTO and the United States participate in an oral argument, jointly or separately, to be scheduled in January regarding the same matter.

Consumer Watchdog and Wisconsin Alumni Research Foundation each may file a responsive brief, which shall be filed by January 16, 2014. The parties' briefs are limited to responding to the brief(s) of the PTO and the United States. The parties are also invited to participate in oral argument in January. The argument will be scheduled at a later date.

Accordingly,

IT IS ORDERED THAT:

(1) The PTO and the United States are requested to file brief(s) in this case via electronic case filing, concerning whether Consumer Watchdog has standing to pursue this appeal. The brief(s) are due no later than January 6, 2014. The PTO and the United States are also requested to participate in oral argument, jointly or separately.

(2) The parties may file briefs in response to the PTO's and the United States' brief(s). The parties' responsive briefs are due no later than January 16, 2014. The parties may also participate in oral argument.

(3) Six paper copies of each brief shall also be filed one day after electronic filing.

(4) Oral argument will be scheduled by subsequent order of the court.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

ENTERED: NOVEMBER 14, 2013

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

CONSUMER WATCHDOG,
(formerly known as The Foundation for Taxpayer and Consumer Rights),
Appellant,

v.

WISCONSIN ALUMNI RESEARCH FOUNDATION,
Appellee.

2013-1377

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Reexamination No. 95/000,154.

PER CURIAM.

O R D E R

IT IS ORDERED THAT:

The parties are each directed to submit a brief on the issue of whether Consumer Watchdog has standing to pursue this appeal. Briefs shall be limited to 10 pages in length, and are due by November 25, 2013, via simultaneous filing by ECF.

FOR THE COURT

November 14, 2013
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

ENTERED JANUARY 22, 2013

UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

THE FOUNDATION FOR TAXPAYER &
CONSUMER RIGHTS
Requester and Appellant

v.

Patent of WISCONSIN ALUMNI RESEARCH
FOUNDATION
Patent Owner and Respondent

Appeal 2012-011693
Reexamination Control 95/000,154
Patent 7,029,913
Technology Center 3999

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON,[1] *Administrative Patent Judges.*

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This is new decision under 37 C.P.R.§ 41.77([) in response to 1) the Patent Owner's Request to Reopen Prosecution after a decision by the Board which

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[1] Jeffrey B. Robertson has replaced Romulo H. Delmendo who participated in the original Board decision.

instituted new grounds of rejection; and 2) the Examiner's subsequent determination under 37 C.P.R.§ 41.77(d) that the new rejections have been overcome.

The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We withdraw the rejections set forth in the Board Decision dated January 29, 2010 and affirm the Examiner decision in the Answer dated July 30, 2009 confirming the patentability of claims 1-3 of US Patent 7,029,913.

STATEMENT OF THE CASE

The patent in dispute in this appeal is U.S. Patent No. 7,029,913 (issued Apr. 18, 2006) ("the '913 patent"), assigned to the Wisconsin Alumni Research Foundation ("WARF"). Dr. James Thomson is listed as the sole inventor. The claims are drawn to human embryonic stem (hES) cells.

The '913 patent is the subject of an inter partes reexamination. After reexamination before the Examiner, the Examiner found all the pending claims allowable. (Action Closing Prosecution (mailed Feb. 25, 2008) & Right of Appeal Notice 80 (mailed Jun. 8, 2008)). The Third Party Requester appealed that determination to the Board.

In the Board decision on the appeal dated April 29, 2010 ("Decision"), we reversed the Examiner's determination not to adopt certain rejections of claims 1-3 of the '913 Patent and designated the new rejections as new grounds of rejection, entitling Patent Owner to re-open prosecution.

The new rejections are as follows:

1. Claims 1-3 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C.

§ 103(a) as obvious based on, Williams[2] (Examiner's Answer ("Ans") 6);

3. Claims 1-3 under 35 U.S.C. § 103(a) as obvious based on Robertson '83,[3] Robertson '87,[4] Williams, and Hogan[5] (Ans. 9);

4. Claims 1-3 under 35 U.S.C. § 103(a) as obvious based on Piedrahita,[6] Williams, and Hogan (Ans. 12); and

5. Claims 1-3 under 35 U.S. C. § 1 03(a) as obvious based on Robertson '83, Robertson '87, Piedrahita, Williams, and Hogan (Ans. 13).

In response to the new grounds of rejection, WARP filed a Request to Reopen Prosecution ("Req. Reopen") accompanied by an amendment and new evidence. The amendment amended Claims 1-3 and added claim 4. The Third Party Requester did not file comments subsequent to the Board decision or subsequent to WARF's Request.

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[2] Robert L. Williams et al., U.S. Patent No. 5,166,065 (issued Nov. 24, 1992).

[3] Elizabeth J. Robertson et al., Isolation, Properties, and Karyotype Analysis of Pluripotentiality (EK) Cell Lines from Normal and Parthenogenetic Embryos, in *Teratocarcinoma Stem Cells* (L.M. Silver et al., ed.), 10: 647-663 (1983).

[4] Elizabeth J. Robertson, Embryo-Derived Stem Cell Lines, in *Teratocarcinomas in Embryonic Stem Cells: A Practical Approach,* Ch. 4: 71-112 (1987), Oxford: IRL Press.

[5] Brigid L. M. Hogan, U.S. Patent No. 5,690,926 (issued Nov. 25, 1997)

[6] Piedrahita et al., *On The Isolation of Embryonic Stem Cells:Comparative Behavior of Murine, Porcine, and Ovine Embryos,* 34 Theriogenology 879, 879-901 (1990).

The Examiner reviewed all evidence of record anew and determined that claims 1-3 and new claim 4 are patentable over the cited prior art of record as set forth in Rejections 1 and 3-5 (Examiner's Determination under 37 CPR ¶ 41.77(d), p. 17).

We agree with the Examiner's determination.

1. ANTICIPATION BY WILLIAMS

Initially, we reversed the Examiner's determination that Williams did not anticipate the claims to human embryonic stem cells. First, we found that Williams disclosed human embryos in a list of animal embryos that could be used as a source of embryonic stem cells (FF5) (Decision 10). Second, we determined that Williams was enabling to make human embryo stem cells (Decision 11-14). WARF had argued that Williams was not enabling, but we found that WARF did not provide persuasive evidence that the Williams' method would not work when applied to human embryos *(id.* at 12).

To address the new grounds of rejection, WARF provided a second declaration by Colin Stewart, D. Phil. (Second Stewart Declaration (2nd Stewart Decl.), filed June 29, 2010). Dr. Stewart states in his declaration that he obtained a doctorate in Mouse Embryology and that his "research career has centered on the development and application of genetic manipulation techniques to studying embryogenesis, stem cells and disease formation in mammals using the mouse as a model organism." (2nd Stewart Decl.¶ 1.) Dr. Stewart is therefore qualified as an expert in the subject matter of this appeal.

Dr. Stewart testified in his written declaration that the Williams patent is not enabled to produce human embryonic stem cells. Dr. Stewart stated that Williams' method of isolating stem cells without feeder cells did not work when applied to human embryo cells (2nd Stewart Decl. ¶¶7-11). Dr. Stewart testified:

> 8. Williams discloses two methods for isolating murine embryonic stem (ES) cells from a blastocyst. The first requires the direct plating of a murine blastocyst onto a plastic tissue culture dish in the presence of the cytokine (growth factor) LIP. The second involves performing immunosurgery on a murine blastocyst and then subsequently plating the resulting inner cell mass (ICM) on a plastic tissue culture dish in the presence of LIP. While these methods are suitable for murine ES cells, the do not work when applied to human blastocysts or human ICMs.
>
> 10. The reason that neither Williams method will work to isolate hES [human embryonic stem] cells is that hES cells can only be isolated by plating a human post-immunosurgery ICM on a feeder layer of cells. The addition of LIP to the culture will have no effect on helping to isolate hES cells.

As evidence of this, Dr. Stewart cited the Bongso publication, published after the filing date of the '913 patent:

> 13. My position is supported by the report of Bongso who followed the Williams ICM [inner cell mass from human blastocysts] method and plated human post-

> immunosurgery derived ICM onto a tissue culture dish that contained LIP, but the dish did not contain a feeder layer of cells. Bongso noted that this method failed to isolate a replicating in vitro cell culture of pluripotent hES cells. This failure was reported by Bongso et al. in 1994 (Human Reproduction 9: 2110-2117; "Bongso"). This supports my position that hES cells can only be isolated by plating a post-immunosurgery derived ICM on a feeder layer of cells.

WARF's evidence is persuasive (Req. Reopen 7-10).

First, the evidence supports WARF's position that Williams does not describe using feeder cells to isolate embryonic stem cells. As argued by WARF, the instances in which feeder cells are utilized by Williams, the feeder cells were used to maintain ES cells, but not to derive them (Williams, col. 2, ll. 54-59; 2nd Stewart Decl. ¶ 11).

In addition, we agree with WARF that Bongso reported negative results without feeder cells. Bongso wrote:

> Our preliminary studies prior to this report demonstrated clearly that, in the absence of an initial feeder layer and subsequent HLIF, the ICM cells were difficult to sustain or always differentiated into fibroblast-like cells.

Bongso, pp. 2115-2116.

As WARF has provided persuasive evidence that Williams did not enable one of ordinary skill in the art, at the time the invention was made, to make

human embryonic stem cells as claimed, we withdraw the anticipation rejection of claims 1-3 over the Williams patent.

2. OBVIOUSNESS REJECTIONS

In the Decision, we reversed the Examiner's determination that claims 1-3 were not obvious under 35 U.S.C. § 103(a) over 1) Williams; 2) Robertson '83, Robertson '87, Williams and Hogan; 3) Piedrahita, Williams and Hogan; 4) Robertson '83, Robertson '87, Piedrahita, Williams and Hogan. In reaching this conclusion, we grouped all the rejections together, since they involved the same set of facts and issues (Decision 20). After considering all the evidence of record, we stated that "it would have been *obvious to have tried* the known mouse protocols on human embryos, and because such protocols would have resulted in human stem cells, we conclude that the claimed human embryonic stems would have been obvious to persons of ordinary skill in the art" (Decision 38 (emphasis added)).

The so-called "obvious to try" standard is applicable when there is a finite number of identified, predictable solutions" available to one of ordinary skill in the art that would have routinely led to the claimed invention.

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and

> common sense. In that instance the fact that a combination was *obvious to try* might show that it was obvious under § 103.

KSR International Co. v. Teleflex Inc.

Whether an invention is "obvious to try" is just another factor to be considered in making an obviousness determination. As made clear by the Supreme Court, and subsequently by the Federal Circuit, there is no one test or single standard for determining obviousness. Rather, all the evidence of record must be considered:

> This court cannot, in the face of *KSR,* cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.

In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009).

While we acknowledged in the original Decision that there was uncertainty as to whether the prior art stem cell technology would work in human embryos, we found this outweighed by the strong reason to make human embryonic stem cells ("obvious to try") and the prior art technology to do so (Decision 36). However, WARF has now cited evidence that identifying human embryonic stem cells was not routine because human stem cells do not have the same morphology as mouse embryonic stem cells and thus it would not have been known which cells to select during the stem cell derivation process.

Dr. Stewart testified that Dr. Thomson "succeeded in part" in isolating hES cells "because he was the first to identify the particular morphology of primate ES cells" (2nd Stewart Decl. 34).

> 35. As noted in my previous Declaration dated May 29, 2007 at paragraph 19, the primate ES cell colonies that Dr. Thomson selected for further study were compact and flatter than mouse ES cell colonies. Mouse ES cell colonies are distinctly different in that they are compact, often tear-drop shaped mounds. Flat, compact colonies of hES cells had not been described at any time before Dr. Thomson's invention. It should be remembered that at this stage in the process, the culture dish contains a heterogeneous mixture of cells and debris, a plethora of colonies, and it would not have been apparent what cells/colonies to choose for further study without the insight exhibited by Dr. Thomson.

Dr. Stewart's testimony is consistent with the disclosure in the '913 Patent. The '913 Patent described the isolation of primate ES cells:

> The colony morphology of primate embryonic stem cell lines is similar to, but distinct from, mouse embryonic stem cells. Both mouse and primate ES cells have the characteristic features of undifferentiated stem cells, with high nuclear/cytoplasmic ratios, prominent nucleoli, and compact colony formation. The colonies of primate ES cells are flatter than mouse ES cell colonies and individual primate ES cells can be easily distinguished.

'913 Patent, col. 9, ll. 57-64. Thus, a preponderance of the evidence supports WARF's argument that Dr. Thomson, in deriving embryonic stem cells from human embryos, did more than just follow the path that had already been taken in the mouse (Decision 34). Rather, the invention took innovation by Dr. Thomson.

As discussed above, whether an invention is obvious because it is "obvious to try," must be weighed against other evidence of nonobviousness in the record. In this case, WARF provided new rebuttal evidence of repeated failures to make rat embryonic stem cells using the available stem cell technology. The Buehr[7] publication was cited by WARF as

> ... conclusive evidence that the path was not so definite [for isolating human embryonic stem cells], the landmarks not so explicit, and the solutions not so predictable. Buehr discloses, for the first time, in 2008, twenty-seven years after the first isolation of murine ES cells, the isolation of rat ES cells. All of the attempts to make rat ES cells that occurred before Buehr failed.

Req. Reopen 20. The failure, until2008, to make rat stem cells using the available stem cell technology is another factor which militates against a finding of obviousness.

Consistently, in a post-filing date publication on stem cell science that appeared in the *Harvard*

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[7] Buehr et al., "Capture of Authentic Embryonic Stem Cells from Rat Blastocysts," *Cell,* 135: 1287-1298, 2008.

Magazine, July-August 106(6):36-45, 37 (2004), it was stated:

> Nevertheless, harvesting and maintaining a line of stem cells from any animal is "not routine at all," explains Andrew McMahon, professor of molecular and cellular biology. No one has been able to derive stem cells from rats, for example, even though mice and rats are closely related. So it was an astounding breakthrough when, in 1998, University of Wisconsin researcher James Thomson successfully established and sustained several human stem-cell lines in culture.

Dr. Thomson's isolation of hES was characterized as a "breakthrough" in the *Harvard Magazine* article. To further support this statement, WARF cited numerous examples of recognition and accolades by the lay and scientific community of Dr. Thomson's work with human embryonic stem cells (Req. Reopen 28-29). Thus, the invention of human embryonic stem cells by Dr. Thomson was highly praised by scientists.

In the original Decision, we had recognized the shortcomings in the prior art for making stem cells of certain animal species, including rat, but we had found this offset by the evidence of record, including a declaration by Dr. Douglas Melton that that human ES cells were successfully isolated "by simply following those methods taught for deriving mouse, rat, pig and sheep ES cells" (Decision 37).

WARF provided new evidence in the Request to Reopen Prosecution that Dr. Melton's declaration should be given less weight. We agree. WARF noted that Dr. Melton had said in his declaration that "we

have successfully isolated human ES cells in our lab by simply following these methods taught for deriving mouse, rat, pig and sheep ES cells. We did so without recourse to Dr. Thomson's publications or patents" (Melton Decl. 13). However, WARF provided Dr. Melton's own scientific publication in *The New England Journal of Medicine* in which he described the isolation of hES cell lines (Cowan et al. 2004, *New Eng. J. Med.* 350 (13) 1353-1356; Req. Reopen 25). WARF states:

> In that paper, Dr. Melton refers to Dr. Thomson's seminal paper in Science in 1998 ... as guiding the isolation of their (Cowan and Melton's) hES cells. For example, ... the authors state that "97 inner cell masses were isolated, and 17 individual human embryonic stem-cell lines ... were derived according to published protocols that we modified in terms of medium composition, enzymatic disassociation, and procedures for freezing and thawing ... ,"citing to Thomson et al. *supra.*
>
> Even more probative is the fact that in this very same publication, Dr. Melton nowhere credits Robertson '83 or Robertson '87, or Piedrahita, references that according to Dr. Melton in his Declaration submitted in the present proceedings, informed him as to how to isolate his hES cells "without recourse to Dr. Thomson's publications or patents." Declaration of Melton, paragraph 13.

Req. Reopen 26.

Thus, despite Dr. Melton's statements to the contrary, in his own research in making human

embryonic stem cells, Dr. Melton credited Dr. Thomas's published work.

In sum, while there was a strong reason to have made human embryonic stem cells, the closest prior art cited in this proceeding –the Williams patent - did not make them or enable making them because it did not describe utilizing feeder cells to derive them or describe which cells in the derivation culture were the human embryonic stem cells.

There was reason to try other available prior art methods for making human embryonic stem cells. However, strong evidence of non-obviousness outweighs the countervailing evidence of obviousness. This nonobviousness evidence includes:

• The isolation of human embryonic stem cells required innovation;

• The failure to make stem cells from closely related species, particularly rat;

• Those (Melton) making human embryonic stem cells followed Thomson's work; and

• Acclaim by both the lay and scientific community.

CONCLUSION

Upon reconsideration of the new evidence provided by WARF, the rejections set forth in the Board Decision dated January 29, 2010 are withdrawn and we affirm the Examiner decision in the Answer dated July 30, 2009 confirming the patentability of claims 1-3 of US Patent 7,029,913.

AFFIRMED

ack

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ENTERED: APRIL 29, 2010

UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

THE FOUNDATION FOR TAXPAYER &
CONSUMER RIGHTS

Requester and Appellant

v.

Patent of WISCONSIN ALUMNI RESEARCH
FOUNDATION

Patent Owner and Respondent

Appeal 2010-001854
Reexamination Control 95/000,l54
Patent 7,029,913
Technology Center 3999

Decided: April28, 2010

Before DONALD E. ADAMS, ROMULO H. DELMENDO, and RICHARD M. LEBOVITZ, *Administrative Patent Judges.*

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal by the Third Party Requester from the Patent Examiner's confirmation of the patentability of claim 1-3 in an Inter Partes Reexamination of US Patent 7,029,913. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We reverse the Examiner.

STATEMENT OF THE CASE

The patent in dispute in this appeal is U.S. Patent No. 7,029,913 (issued Apr. 18, 2006) [hereinafter '913 patent], assigned to the Wisconsin Alumni Research Foundation [hereinafter WARF]. WARF is the patent owner and "Respondent" in this proceeding.

The named inventor of the '913 Patent is James A. Thomson. The '913 patent shares ancestry with two other related patents- U.S. Patent No. 5,843,780 (issued Dec. 1, 1998) and U.S. Patent No. 6,200,806 (issued Mar. 13, 2001) - both which were subject of separate reexamination proceedings, each culminating with the issuance of a Reexamination Certificate confirming the patentability of the claims.

The claims of the '913 patent are drawn to pluripotent human embryonic stem ("ES") cells. As explained in the patent:

> stem cells are undifferentiated cells which can give rise to a succession of mature functional cells. For example, a hematopoietic stem cell may give rise to any of the different types of terminally differentiated blood cells. Embryonic stem (ES) cells are derived from the embryo and are pluripotent, thus

> possessing the capability of developing into any organ or tissue type or, at least potentially, into a complete embryo.

('913 patent, col. 1, ll. 28-35.) Because of their ability to produce many different cell types, "[s]cientists already believe that human ES cell research will produce new ways of not just treating, but preventing, a wide range of diseases, including AIDS, diabetes, Parkinson's, Alzheimer's and heart disease." Request for Inter Partes Reexamination 2 (filed July 17, 2006).

The Foundation for Taxpayer & Consumer Rights [1] [hereinafter Third Party Requester] filed a Request for Inter Partes Reexamination on July 17, 2006 under 35 U.S.C. §§ 311-318 and 37 C.P.R.§ 1.913 of every claim of the '913 Patent as invalid under 35 U.S.C. § 103.

They asserted a substantial new question of patentability on the basis the following publications said not to be of record during prosecution of the '913 patent (Request for Inter Partes Reexamination at 3-4):

• Elizabeth J. Robertson et al., Isolation, Properties, and Karyotype Analysis of Pluripotentiality (EK) Cell Lines from Normal and Parthenogenetic Embryos, in *Teratocarcinoma Stem Cells* (L.M. Silver et al., ed.), 10: 647-663 (1983), New York: Cold Spring Harbor [hereinafter Robertson '83];

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[1] The Request stated that on "behalf of the Foundation for Taxpayer & Consumer Rights ('FTCR'),... the Public Patent Foundation ('PUBP AT') respectfully requests *inter parte* reexamination" (Request for Inter Partes Reexamination at 1).

• Elizabeth J. Robertson, Embryo-Derived Stem Cell Lines, in *Teratocarcinomas in Embryonic Stem Cells: A Practical Approach,* Ch. 4: 71-112 (1987), Oxford: IRL Press [hereinafter Robertson '87]; and

• Piedrahita et al., *On The Isolation of Embryonic Stem Cells: Comparative Behavior of Murine, Porcine, and Ovine Embryos,* 34 Theriogenology 879, 879-901 (1990) [hereinafter Piedrahita].

The Request was granted (Order Granting Request for Inter Partes Reexamination (mailed Sept. 29, 2006)) and reexamination proceedings commenced. A set of anticipation and obviousness rejections under 35 U.S.C. § 102 and§ 103, respectively, were instituted by the Examiner, but ultimately the Examiner withdrew all rejections and found claims 1-3 allowable (Action Closing Prosecution (mailed Feb. 25, 2008) [hereinafter ACP] & Right of Appeal Notice 80 (mailed Jun. 8, 2008) [hereinafter RAN]).

The Third Party Requester appeals from the Examiner's decision in finding all the claims allowable and contends that the rejections were improperly withdrawn. The Examiner's favorable patentability determinations with respect to the following withdrawn rejections are appealed:

1. Claims l-3 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious based on, Williams (U.S. Patent No. 5,166,065 (issued Nov. 24, 1992) [hereinafter Williams]) (Ans. 6);

2. Claims 1-3 under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious based on, Hogan (U.S. Patent No.

5,690,926 (issued Nov. 25, 1997) [hereinafter Hogan]) (Ans. 8);

3. Claims 1-3 under 35 U.S.C. § 103(a) as obvious based on Robertson '83, Robertson '87, Williams, and Hogan (Ans. 9);

4. Claims 1-3 under 35 U.S.C. § 103(a) as obvious based on Piedrahita, Williams, and Hogan (Ans. 12); and

5. Claims 1-3 under 35 U.S.C. § 103(a) as obvious based on Robertson '83, Robertson '87, Piedrahita, Williams, and Hogan (Ans. 13).

The Third Party Requestor also appeals the Examiner's decision not to adopt the following rejection:

6. Claims 1-3 under 35 U.S.C. § 103(a) as obvious based on Robertson '83, Robertson '87, and Piedrahita (Request for Inter Partes Reexamination 11).

Claim 1 is the only independent claim on appeal. Claim 1 was amended several times during the reexamination proceeding. (Amendments dated May 30, 2007; Oct. 1, 2007; Oct. 2, 2007; & Oct. 4, 2007.) The amendments are indicated by underlining and brackets in claim 1, as reproduced below. The only other pending claims, claims 2 and 3, depend on claim 1; as they were not separately argued, claims 2 and 3 fall with claim 1. 37 C.P.R. § 41.31(c)(1)(vii).

Claims 1 reads as follows:

> 1. (Amended) A replicating in vitro cell culture of <u>pluripotent</u> human embryonic stem cells <u>derived from a pre-implantation embryo, wherein the stem cells</u> [comprising cells

which] (i) [are capable of proliferation] will proliferate in an in vitro culture for over one year in an undifferentiated state without the application of exogenous leukemia inhibitory factor, (ii) maintain a karyotype in which the chromosomes are euploid through prolonged culture, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are inhibited from differentiation when cultured on a fibroblast feeder layer.

WILLIAMS -ANTICIPATION

The Third Party Requester appeals the Examiner's determination to withdraw the rejection of claims 1-3 under 35 U.S.C. § 102(b) as anticipated by Williams.

Statement of the Issues

There are two issues to be decided in this rejection:

1) Whether Williams described and enabled human embryonic stem cells derived from a pre-implantation embryo, the subject matter of claim 1?

2) Whether Williams' disclosure of human ES cells is negated by facts disclosed in the Cherny article?

Principles of Law

"[A] prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art." *Impax Labs., Inc. v. Aventis Pharms., Inc.,* 468 F.3d 1366, 1381 (Fed. Cir. 2006).

> We think the Karrer patent, as a printed publication, describes to one skilled in this art not only the broad class but also this much more limited class within that broad class, and we think it is immaterial that Karrer did not expressly spell out the limited class as we have done here. It is our opinion that one skilled in this art would, on reading the Karrer patent, at once envisage *each member* of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here.
>
> A simple calculation will show that, excluding isomerism within certain of the R groups, the limited class we find in Karrer contains only 20 compounds. However, we wish to point out that it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved ... it is of no moment that each compound is not specifically named or shown by structural formula in that publication.

In re Petering, 301 F.2d 676, 681-682 (CCPA 1962) (emphasis added).

> . . . although he did not actually premedicate the patients himself, anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art. *Donohue,* 766 F.2d at 533, 226 USPQ at 620 ("It is not, however, necessary that an invention disclosed in a publication

> shall have actually been made in order to satisfy the enablement requirement.").

Bristol-Myers Squibb Co. v. Ben Venue Labs. Inc., 246 F.3d 1368, 1379 (Fed. Cir. 2001).

Findings of Fact ("FF")

The Williams patent

1. "Embryonic stem (ES) cells, the pluripotent outgrowths of blastocysts, can be cultured and manipulated in vitro and then returned to the embryonic environment to contribute normally to all tissues including the germline" (Williams, col. 1, ll. 9-13).

2. "However, it is known that ES cells ... will only retain the stem cell phenotype in vitro when cultured on a feeder layer of fibroblasts (such as murine STO cells ...) or when cultured in medium conditioned by certain cells" *(id.* at col. 1, ll. 43-59).

3. "In work leading to the present invention, it has been found that LIP [leukaemia inhibitory factor] has the capacity to substitute for, or be added to, feeder layers (or conditioned medium) in supporting the maintenance of pluripotential ES cells in vitro." *(Id.* at col. 1, ll. 58-62.)

4. Williams described the "present invention" as "directed to a method for the isolation and maintenance of embryonic stem (ES) cells from animal embryos in vitro which method comprises deriving and/or maintaining said ES cells from said embryos in culture medium containing an effective amount of leukaemia inhibitory factor (LIP), for a time and under conditions sufficient for the derivation and/or maintenance of said ES cells." *(Id.* at col. 3, ll. 28-35.)

5. "The animal embryos may be isolated from a number of animal species such as humans, mice, birds (e.g. chickens), sheep, pigs, cattle, goats and fish." *(Id.* at col. 3, ll. 35-38.)

6. For supporting the growth of ES cells, the "culture medium may or may not contain feeder cells and LIP may be used to substitute for, or add to, said feeder cells." *(Id.* at col. 3, ll. 62-64.)

7. Williams described isolation of ES cells from murine blastocysts using two methods. *(Id.* at col. 6, l. 59 to col. 7, l. 4.)

8. The media contained LIP *(id.* at col. 6, l. 56).

9. "In the first method the blastocysts were allowed to attach to the culture dish and approximately 7 days later the outgrowing inner cell mass picked, trypsinised [sic] and transfered [sic] to another culture dish in the same culture media. ES cell colonies appeared 2-3 weeks later with between 5-7 individual colonies arising from each explanted inner cell mass." *(Id.* at col. 6, ll. 59-65.)

10. "The second method for isolation of ES cell lines used the immunosurgery technique (described in Martin, G. R. (1981) Proc. Natl. Acad. Sci. USA 78:7634-7638) where the trophectoderm cells are destroyed using anti-mouse antibodies prior to explanting the inner cell mass." *(Id.* at col. 6, l. 66 to col. 7, l. 3.)

11. "[B]lastocysts were treated by immunosurgery (as described in Martin, G. R. (1981) Proc. Natl. Acad. Sci. USA 78:7634-7638). The blastocysts were allowed to hatch from the zona pelucida, and then treated with antimouse antibodies and destroyed by the addition of complement. The exposed inner cell

mass was then left to attach to a tissue culture dish and again treated with anti-mouse antibodies and complement. Within a few days pluripotential stem cell colonies appeared and were dissociated and trypsinised [sic] as described above." *(Id.* at col. 8, ll. 22-31.)

Cherny

12. Cherny disclosed that "[i]nitial research into the isolation of domestic animal ES cells in our and other laboratories attempted to repeat the work carried out in mice by isolating cell lines directly from cultured preimplantation embryos." (Robert A. Cherny, *Strategies for the Isolation and Characterization of Bovine Embryonic Stem Cells,* 6 Reprod. Fertil. Dev. 569, 571 (1994) [hereinafter Cherny].)

13. "Published reports of such studies in pigs, cattle and sheep, together with our own research, indicated that cells which displayed some ES characteristics could be identified but the isolation of proven pluripotential ES cell lines remained elusive" *(id.*).

14. "The murine model for totipotential stem cell isolation is yet to prove applicable to domestic animals. However, criteria used in the identification of murine ES cells can serve as guidelines." *(Id.* at 574.)

Analysis

Claim l is drawn to a "replicating in vitro cell culture of pluripotent human embryonic stem cells derived from a pre-implantation embryo." The claim requires the stem cell culture to possess certain properties as recited in claim limitations (i) through (iv). The Third Party Requester contends that the

Williams patent described human embryonic stem cells which would possess the claimed properties, anticipating the subject matter of claim 1.

Working examples

Respondent contends that "Williams is without any specific working example other than the mouse, and therefore could not establish a *prima facie* case of anticipation" of the claimed human embryonic stem cell culture (Res. App. Br. [2] 18).

Specific working examples are not necessary to establish anticipation. Anticipation has been found when the scope of embodiments described in a prior art publication were so limited in number that one of ordinary skill in the art could at once envisage the subject matter which is claimed. *In re Petering,* 301 F.2d at 681-82; *Bristol-Myers,* 246 F.3d at 1379.

In this case, human embryos are explicitly recited in a list of animal embryos that can be used as a source of embryonic stem cells (FF5). A species which is specifically disclosed in a prior art reference is anticipatory even though it appears "without special emphasis in a longer list." *Perricone v. Medicis Pharm. Corp.,* 432 F.3d 1368, 1376 (Fed. Cir. 2005).

"[A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." *Bristol-Meyers,* 246 F.3d at 1379. For these reasons, we conclude

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[2] Second Amended Respondent's Brief (filed June 17, 2009) [hereinafter Res. App. Br.] (The response by WARF, the Respondent in this proceeding, to the Third Party Requestor's Appeal Brief).

that Williams described human embryonic stems, as claimed, despite its failure to disclose a working example in which human ES cells were actually made. There would have been reasonable basis to believe that such stem cells would possess properties (i) through (iv) recited in claim 1 because the Williams ES cells were derived from a pre-implantation embryo, the same source of cells required by the claim. *In re Best,* 562 F.2d 1252, 1255 (CCPA 1977).

Respondent also argued that mouse ES cells have different cell markers than expressed in human ES cells and therefore can not anticipate the claimed human cells (Res. App. Br. 18). This argument is not persuasive. The rejection is based on Williams' disclosure of ES cells derived from human embryos (FF5), not Williams' description and exemplification of mouse cells.

Enablement

An anticipatory reference must be enabling. Respondent contends that Williams did not enable persons of ordinary skill in the art to make human embryo stem cells. As evidence of this, Respondent provided a declaration by Dr. Colin Stewart (Declaration of Dr. Colin Stewart (May 29, 2007) [hereinafter Stewart Dec.]) and the Cherny publication which listed the same Dr. Williams as a co-author who was an inventor of the Williams patent.

Dr. Stewart testified in his declaration that "Williams does not disclose a method for isolating primate/human ES cells" (Stewart Dec. ¶ 18).

Dr. Stewart stated:

> When Dr. Thomson [the named inventor of the '913 patent] isolated his primate/human ES cells, he used a method that is not taught in Williams. Dr. Thomson isolated the inner cell mass (ICM) from the blastocyst by immunosurgery, a procedure that removes the trophoblast cells that enclose the ICM.

(*Id.)*

Williams described two methods of isolating ES cells. The second method involved treating blastocysts "by immunosurgery" to destroy trophectoderm cells (FF l 0-ll). Thus, the evidence supports the finding that Williams described immunosurgery in a method of isolating ES cells, the same technique Dr. Stewart testified was used by Dr. Thomson (Stewart Dec.¶ 18).

Dr. Stewart also testified that Williams did not describe the "meticulous series of methods" utilized by Dr. Thomson (Stewart Dec. ¶ 18):

> He plated the isolated ICMs on mouse feeder layers and was very explicit in how the explanted ICMs were cultured, gently disassociated, replated on feeder layers to form colonies, and then expanded on feeder layers to maintain their stem cell characteristics to prevent their differentiation ('780 patent columns 7, 8 [sic] and 9).

(*Id.*)

This argument is not persuasive for several independent reasons. First, Dr. Stewart has not provided evidence that the Williams' method would not work when applied to human embryos. Even

assuming differences between the method used by Williams to derive ES cells and Dr. Thomson's method for producing the claimed human ES cells, these differences do not alone establish that the Williams method would not succeed in isolating embryonic stem cells from human embryos. ES cells are claimed, not a method of making them. Consequently, differences in the isolation method do not alone distinguish the claimed cells from those produced using the Williams methods nor establish that the claimed subject matter was not enabled by the Williams patent.

Secondly, it appears that the method steps described by Dr. Stewart as unique to Dr. Thomson (Stewart Dec. ¶ 18) were broadly described in the Williams patent. Feeder cells were known in the art to have been utilized for deriving stems (FF2) and Williams says feeder cells can be used in its methods (FF6). Williams discloses dissociating cells within days after immunosurgery and after the inner cell mass had been left to attach to the culture plate (FF9-ll).

With respect to the Cherny publication, the Respondent contends that the "Examiner correctly interpreted Cherny as demonstrating the failure or limited success of the Williams procedure for isolating mouse ES cells on ES cells of domestic animals." (Res. App. Br. 18). As evidence, Respondent cited Cherny's statement that the "murine model for totipotential stem cell isolation is yet to prove applicable to domestic animals." (FF14; Cherny at 574, col. I.) Respondent concluded that Williams' disclosure of human ES cells is therefore "negated by the Cherny article" (Res. App. Br. 19).

Cherny's statement about the inapplicability of the murine model to "domestic animals" does not "negate" the explicit disclosure in Williams of human ES cells. Respondent has not introduced evidence that Cherny's reference to a murine model was to the same murine model described in the Williams patent. For example, the inventors of the Williams patent are not the same as those listed as authors of the Cherny publication[3] Therefore, there is insufficient evidence to conclude that Cherny's remarks about a murine stem cell model were a commentary on deficiencies in the Williams patent.

In addition to this, the Cherny publication involved domestic animal species, not humans or primates. Cherny stated that the "murine model" was "yet to prove applicable to domestic animals," not human pre-implantation embryos as claimed.

Finally, even if the Cherny statement was taken in a broader context to criticize the applicability of the murine model to other species, it does not "negate" the explicit disclosure of human embryonic stems in the Williams patent. "A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." *Celeritas Techs., Ltd.. v. Rockwell Int'l Corp.,* 150 F.3d 1354, 1361 (Fed. Cir. 1998); *see also Impax Labs., Inc. v. Aventis Pharms. Inc.,* 468 F.3d 1366, 1382 (Fed. Cir. 2006). Disparaging comments

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[3] The authors of the Cherny publication were Cherny, Stokes, Merei, Lorn, Brandon, and Williams. The listed inventors of the Williams patent are Williams, Gough, and Hilton. The only common scientist to both is Dr. Williams.

therefore do not necessarily negate an explicit enabling disclosure of a claimed invention.

LIF

Respondent contends that "Williams was principally directed towards researching the ability to use LIP to maintain murine ES cells without feeder layers" and that "[u]sing LIP in the absence of a feeder layer is contrary to" the claimed invention (Resp. App. Br. 18). Dr. Colin Stewart, a scientist having research experience with mouse embryonic stem cells, testified on behalf of Respondent that "while LIP has been established by Williams as a component of the feeder layer that enables long term undifferentiated culture of mouse ES cells, LIP does not have the same effect on the long term undifferentiated culture of primate/human ES cells" (Stewart Dec. ¶ 23).

Claim l recites that the pluripotent human embryonic stem cells, derived from a pre-implantation embryo, "will proliferate in an in vitro culture for over one year in an undifferentiated state without the application of exogenous leukemia inhibitory factor." We interpret this limitation, as did the Examiner, as an "intended use" of the claimed cells. (Office Action in Inter Partes Reexamination at 5-6 (mailed Mar. 30, 2007).) That is, the claimed embryonic stem cells must be able to proliferate in an undifferentiated state without exogenous LIP. However, the claim does not exclude the ES cells from having been derived in the presence of LIP nor is the claim limited to particular method of ES cell production. Rather, the claim is a product claim, not a method of producing embryonic stem cells.

The PTO does not have the ability "to manufacture products or to obtain and compare prior art products." *In re Best,* 562 F.2d 1255. Thus, once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 911 F.2d 705, 708 (Fed. Cir. 1990).

In this case, Williams described human ES cells. Because the PTO has no way of proving that the cells would not possess the claimed LIP property, the burden properly shifted to the Respondent to prove otherwise. Dr. Stewart testified that LIP does not have the "same effect" on human ES cells as on mouse ES cells, but he did not establish that human ES cells derived from Williams methods would not have the claimed property of "proliferat[ing] in an in vitro culture for over one year in an undifferentiated state without the application of exogenous leukemia inhibitory factor" or any of the other properties recited in the claim.

Summary

Williams described and enabled human embryonic stem cells derived from a pre-implantation embryo, anticipating the subject matter of claim l. Claims 2 and 3 were not separately argued, and therefore fall with claim l. 37 C.P.R. § 41.37(c)(l)(vii).

HOGAN - ANTICIPATION & OBVIOUSNESS

The Third Party Requester appeals the Examiner's determination to withdraw the rejection of claims l-3 under 35 U.S.C. § 102(b) as anticipated

by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over, Hogan.

Statement of the Issue

The issue in this rejection is whether Hogan's description of ES cells derived from germ cells anticipated the claimed ES cells derived from a preimplantation embryo?

Principles of Law

"It has long been the case that an old product is not patentable even if it is made by a new process .... However, a new product may be patented by reciting source or process limitations so long as the product is new and unobvious." *Amgen Inc. v. F. Hoffmann-La Roche Ltd.,* 580 F.3d 1340, 1366 (Fed. Cir. 2009).

> A product-by-process claim is "one in which the product is defined at least in part in terms of the method or process by which it is made." ... While the patent statute does not provide for product-by-process claims, the courts have long recognized the appropriateness of such claims .... The purpose of product-by-process claims is to allow inventors to claim "an otherwise patentable product that resists definition by other than the process by which it is made."… hus, an inventor will not be foreclosed from the benefits of the patent system simply because a product is difficult to describe in words, or its structure is insufficiently understood.

SmithKline Beecham Corp. v. Apotex Corp, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (citations omitted).

> Product-by-process claims, especially for those rare situations when products were difficult or

> impossible to describe, historically presented a concern that the Patent Office might deny *all* product protection to such claims. *See In re Butler,* 17 C.C.P.A. 810, 813 37 F.2d 623 (1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modem context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case- a product defined by sophisticated PXRD technology - suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection.

Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1294 (Fed. Cir. 2009).

Findings of Fact

15. Hogan described "human, pluripotential embryonic stem cell[s]." (Hogan, at col. 2, ll. 29.)

16. Hogan stated that the "invention further provides a method of making a pluripotential embryonic stem cell comprising culturing primordial germ cells, embryonic ectoderm cells and/or germ cell progenitors ... under cell growth conditions, thereby making a pluripotential embryonic stem cell." *(Id.* at col. 2, ll. 38-46.)

17. Hogan taught that "[p]rimordial germ cells (PGCs) in the mouse are thought to be derived from a small population of embryonic ectoderm (epiblast) cells set aside at the egg cylinder stage prior to gastrulation (Lawson and Pederson, 1992), or even earlier (Soriano and Jaenisch, 1986)." *(Id.* at col. l, ll. 18-22.)

18. Dr. Stewart testified that Hogan "describes the isolation of embryonic germ (EG) cells from primordial germ cells obtained from post-implantation embryos." (Stewart Dec. 7: ¶ 26.)

19. Aflatoonian discloses that human embryonic germ cells (hEG) express SSEA-1 cell surface marker, but this marker is absent from undifferentiated human ES (hES) cells (Behrouz Aflatoonian & Harry Moore, *Human Primordial Germ Cells and Embryonic Germ Cells, And Their Use in Cell Therapy,* 16 Current Opinion in Biotechnology 530, 532 first column (2005) [hereinafter Aflatoonian]). "Notably, hEG cells express SSEA-1 cell surface marker ... This marker is absent from the inner cell mass of the human blastocyst ... and absent from undifferentiated hES cells and only detected on cells following differentiation" *(id.).*

Analysis

Claim l is directed to pluripotent human embryonic stem cells "derived from a pre-implantation embryo." The phrase "derived from a pre-implantation embryo" is a product-by-process limitation. A product-by-process limitation defines a claimed product in terms of how it is made. Product-by-process limitations are typically used to claim "a product whose structure is either not fully known or

too complex to analyze." *Abbott Labs.,* 566 F.3d at 1294. When the way a product is made imparts some structural, chemical, or other characteristic on the product which distinguishes it from products made by other processes, the product-by-process limitation may serve as a basis for patentability. *Id.; see also Fiers v. Revel,* 984 F.2d 1164, 1169 (Fed. Cir. 1993).

Hogan's cells were derived from germ cells; the claimed cells were derived from pre-implantation embryos. The sources of the stem cells are therefore different. The pivotal question in this rejection is whether derivation from a pre-implantation embryo confers some structural or other characteristic on the human stem cell that makes it different from the stem cells described in Hogan derived from germ cells.

Evidence was provided that human embryonic germ cells express SSEA-1 as a cell surface marker, but that human ES cells derived from human preimplantation embryos do not (FF19; Resp. App. Br. 18-19). The Examiner reasonably inferred from this teaching that Hogan's cells, produced from germ cells, or the epiblast cells from which the germ cells are derived (FF17), would express the SSEA-1 marker, but that human ES cells from pre-implantation embryos would not. The Requester did not establish error in the factual finding that SSEA-1 was differentially expressed in germ-derived versus pre-implantation-derived ES cells. Accordingly, we conclude that the product-by-process limitation that the human ES cells are "derived from a pre-implantation embryo" imparts a structural characteristic on the cells which distinguishes them from the cells described in Hogan. The anticipation

rejection of claims l-3 by Hogan was therefore properly withdrawn by the Examiner.

Because there is no evidence that Hogan's embryonic stem cells could be converted into ES cells derived from a pre-implantation embryo, the alternative rejection of claims 1-3, as obvious in view of Hogan, was properly withdrawn, as well.

OBVIOUSNESS REJECTIONS l, 3, 4, & 5

The Third Party Requestor appeals the Examiner's decision to withdraw the following rejections of claims l-3 under 35 U.S.C. § 103(a) based on:

l. Williams;

3. Robertson '83, Robertson '87, Williams, and Hogan;

4. Piedrahita, Williams, and Hogan; and

5. Robertson '83, Robertson '87, Piedrahita, Williams, and Hogan.

Statement of the Issues

The obviousness rejections (l, 3, 4, & 5) over the Williams, Robertson '83, Robertson '87, Hogan, and Piedrahita publications involve the same set of facts and issues. Consequently, the rejections have been addressed together.

The Third Party Requester contends that the Examiner erred by imposing an improperly high standard of obviousness when making the determination that claim l would not have been obvious to persons of ordinary skill in the art in view of the cited prior art. The issue to be decided in these rejections is therefore, what is the proper standard

of obviousness to be applied to the subject matter of claim l, and whether claim l, under the proper obviousness standard would have been obvious to persons of ordinary skill in the art. Claims 2 and 3 were not separately addressed by the Third Party Requester and therefore stand or fall with claim l. 37 C.F.R § 4l.37(c)(l)(vii).

Principles of Law

In *KSR,* the Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under§ 103. 550 U.S. at 421, 127 S. Ct. 1727. This approach is consistent with our methodology in *In re O'Farrell,* 853 F.2d 894 (Fed. Cir. 1988). *See Procter & Gamble Co. v. Teva Pharms. USA, Inc.,* 566 F.3d 989, 996-97 (Fed. Cir. 2009); *In re Kubin,* 561 F.3d 1351, 1359, (Fed. Cir. 2009). *O'Farrell* observed that most inventions that are obvious were also obvious to try, but found two classes where that rule of thumb did not obtain.

First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *O'Farrell,* 853 F.2d at 903. This is another way to express the *KSR* prong requiring the field of search to be among a "finite number of identified" solutions. 550 U.S. at 421, 127 S. Ct. 1727; *see also Procter & Gamble,* 566 F.3d at 996; *Kubin,* 561 F.3d at 1359. It is also consistent with our interpretation that KSR requires the number of options to be "small or easily traversed." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.,* 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Second, an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *O'Farrell,* 853 F.2d at 903. This expresses the same idea as the KSR

> requirement that the identified solutions be "predictable." 550 U.S. at 421, 127 S. Ct. 1727; *see also Procter & Gamble,* 566 F.3d at 996-97; *Kubin,* 561 F.3d at 1359-60.

Bayer Schering Pharma AG v. Barr Labs., Inc., 575 F.3d 1341, 1347 (Fed. Cir. 2009).

> The district court acknowledged that the prior art suggested that there would be concern about the dissolution of a poorly water soluble acid-sensitive drug, but found that the prior art generally suggests that micronization could improve the dissolution of drospirenone. It concluded that a person having ordinary skill would have seen it as a viable option.
>
> . . . Bayer's own expert, Dr. James McGinity, testified that micronization is the first choice solution because it presents the best chance for success. So there remains adequate support for the conclusion that micronization was a viable option.

Bayer Schering, 575 F.3d at 1348.

Scope and content of the prior art

Robertson '83

20. Robertson '83 describes isolation of pluripotential cells from fertilized "delayed" blastocysts from female mice (Robertson '83, p. 649).

21. Robertson '83 describes an isolation procedure that involves: explanting blastocysts into tissue culture dishes, removing the inner cell mass (ICM) derived cell clumps after several days, disaggregating the ICM clumps using trypsin

enzyme, transferring to tissue culture wells containing a layer of preformed inactivated fibroblast cells, and repeating disaggregation after a further 4 days *(id.*).

Robertson '87

22. Robertson '87 taught that "[t]wo methods were originally described to recover stem cells" (Robertson '87, p. 84).

23. "The technique given here is based on the first of these which was described initially by Evans and Kaufman (l). The overall strategy is to transfer intact blastocysts into culture and allow them to continue growth, for a limited period, until they achieve a stage which is equivalent to the early post-implantation embryo. The embryonic portion is then dissociated and culture of the cells is continued under conditions designed to be amenable to cell growth while encouraging stem cells to maintain the undifferentiated phenotype." *(Id.)*

24. The second "technique described by Martin (2) is slightly more complicated in two respects. Firstly the inner cell mass (ICM) of the embryo has to be selectively isolated by immunosurgical removal of the trophectoderm cells prior to culture. Secondly, culture takes place in medium which has been conditioned by exposure to a culture of EC cells. However, if attempts are to be made using this technique it is relevant to note that a comparative study (16) has shown that conditioned medium has no significant effect on the overall efficiency of isolation of stem cells." *(Id.)*

25. "Of the two techniques the method of Evans and Kaufman (l) is the simpler and in the author's

experience has been found reliably to give rise to stem cells at an acceptably high frequency (10-30% of embryos)." *(Id.)*

26. "The procedure for the derivation of stem cells from blastocysts is divided into two stages. During the first stage the embryos are transferred into tissue culture and left undisturbed to attach and grow. The second stage involves the mechanical disruption of the embryos and the culture of the embryo-derived cells." *(Id.)*

27. Robertson '87 provided an extensive description of protocols for blastocyst culture *(id.* at 85-86) and disaggregation of the inner cell mass *(id.* at 86-91; Ans. l 0).

28. Robertson '87 taught that feeder cell layers "are absolutely essential for both the isolation of stem cell lines from embryos and for the routine maintenance of established cell lines" (Robertson, '87, at p. 75).

Piedrahita

29. Piedrahita described protocols for isolating ES cells from murine, ovine (sheep), and porcine embryos.

30. "While murine isolated ICM or intact embryos plated on STO or HEF feeders gave rise to cell lines with embryonic stem cell-like (ES-like) morphology, ovine embryos did not." (Piedrahita, at p. 879).

31. "The results of this study show that conditions which allow isolation of ES cells from murine embryos allow the isolation of porcine embryo-derived cell lines sharing some, but not all, the characteristics of murine ES cells." *(Id.)*

32. "Recently it has been shown that ES cells can be isolated from hamster embryos using feeders composed of murine primary embryonic fibroblasts (19)." *(Id.* at 880.)

33. "Evans et al. (20) have reported the isolation of porcine embryo-derived cell lines with ES-like morphology and a limited ability to differentiate invitro." *(Id.)*

34. Piedrahita acknowledged that previous "[a]ttempts at isolating ovine ES cells by culturing embryos on ovine skin fibroblasts in the presence orabsence of Buffalo rat liver (BRL) conditioned media have been unsuccessful (21)." *(Id.)*

35. Piedrahita's method involve isolating the ICM (e.g., using immunosurgery, mechanically, or with calcium ionophore), plating on feeder cells, dissociating with trypsin/EDT A, and transferring to fresh feeder cells *(id.* at 882; Ans. 12).

36. "The sequence of events leading to the production of embryo-derived colonies was found to be different for the three species examined." (Piedrahita, at p. 884.)

37. Table l shows that ES-like cells lines were obtained from murine and porcine embryos, but not ovine *(id.* at 886).

38. "Attempts to induce porcine embryo-derived cell lines withES-like morphology to differentiate in vitro did not result in obvious morphological changes. It is not clear why differences are observed between porcine and murine ES-like cell lines in the extent of in vitro differentiation. One explanation is that the trigger for induction of differentiation varies with species. Evans et al. (20) reported induction of in

vitro differentiation with porcine embryo-derived cells in media devoid of FBS and β_2-mercaptoethanol." *(Id.* at 896.)

39. "Whether the difficulties encountered in the isolation of ES cells from porcine and ovine embryos were due to inherent species differences, which make such isolation feasible, or whether the difficulties were due to inappropriate culture conditions or source of embryonic material (e.g. , embryos that were too young or too old) remains to be determined." *(Id.* at 897.)

Moore

40. The Moore publication was received by the journal on Oct. 9, 1995, accepted Jan. 8, 1996, and published in volume 33 of *In Vitro Cell. Dev. Biol.* having a date of 1997.

41. "Isolation of ES cell lines have been attempted in the rat (16), mink (34), rabbit (12), hamster (6, 25), primates (37), sheep (14, 24), cattle (9, 27, 28, 32), and swine (1, 9, 11, 21, 23, 24, 33, 35). Varying degrees of pluripotentiality have been demonstrated for each, yet only the mouse and rat have produced chimeric animals, with mouse ES cells being the only cells lines to date conferring germline transmission." (Karen Moore & Jorge A. Piedrahita, *The Effects of Human Leukemia Inhibitory Factor (HLIF) and Culture Medium on In Vitro Differentiation of Cultured Porcine Inner Cell Mass (PICM),* 33 In Vitro Cellular Biology- Animal62 (1997) [hereinafter Moore].)

42. As to porcine ES cells, Moore stated that "[p]luripotentiality varies, but inability to maintain

cell lines for extended periods of time and lack of chimera production are common to all." *(Id.)*

Brook and Gardner

43. The Brook and Gardner publication was received by the journal for review on Feb. 21, 1997 and published in the May 1997 issue of the Proceedings of the National Academy of Science.

44. Brook and Gardner stated that "ES cell lines of proven ability to colonize the germ-line have been obtained at very low frequency in only a few mouse strains other than 129 [strain] and, as yet, no other species of mammal (1)." (F. A. Brook & R. L. Gardner, *The Origin and Efficient Derivation of Embryonic Stem Cells in the Mouse,* 94 Proceedings of the National Academy of Science- Developmental Biology 5709 (May 1997).)

Brook

45. The Brooks publication was published in the January 2003 issue of Diabetes.

46. Brooks taught that "derivation of embryonic stem (ES) cells from the NOD mouse has proved to be extremely difficult." (Frances A. Brook et al., *The Derivation of Highly Germline-Competent Embryonic Stem Cells Containing NOD-Derived Genome,* 52 Diabetes 205 (Jan. 2005).)

Iannaccone

47. Iannaccone described "the derivation of diploid rat embryonic stem cells" which "can differentiate extensively *in vivo"* and produced chimeras with rat blastocysts (Philip M. Iannaccone et al., *Pluripotent Embryonic Stem Cells from the Rat are Capable of*

Producing Chimeras, 163 Developmental Biology 288 (1994) [hereinafter Iannaccone]).

48. Iannaccone taught that "[p]luripotent cells have been isolated from mink... , pig ... , and hamster ... but so far there are no published accounts of chimera formation with stem cells from species other than mouse." *(Id.* at 290.)

Ouhibi

49. Ouhibi described isolation of ES-like cells, RES C-Ol, from rat embryo (Nadia Ouhibi et. al., *Initial Culture Behaviour of Rat Blastocysts on Selected Feeder Cell Lines,* 40 Molecular Reproduction and Development 311 (1995)).

50. Ouhibi reported that they "have not been able to obtain cultures [of the RESC-01 cells] beyond passage 4" *(id.* at p. 317).

Brenin

51. Brenin was published in volume 29 of Transplantation Proceedings, dated 1997.

52. Brenin taught that while "ES cells from other species have been isolated …, the entire process, including the production of functional gametes from ES cells, has not been established in mammals other than the mouse." (D. Brenin, *Rat Embryonic Stem Cells: A Progress Report,* 29 Transplantation Proceedings 1761 (1997).)

53. Brenin described "exhaustive application of standard mouse methodology" to produce rat ES cells *(id.* at 1762).

54. Brenin reported that the rat RESC-01 ES-like cell (of Iannaccone) "shows no evidence of mouse in

cell culture preparations," but produced no chimeras when injected into hosts *(id.* at 1764).

55. However, Brenin reported that, when injected into nude mice, the DNA isolated from the one tumor that arose was of mouse origin, implying "a stable low level contamination with mouse ES cells persists in this population." *(Id.)*

56. Brenin concluded that the rat ES cells derive from rat blastocysts were possibly not pluripotent *(id.* at 1765).

57. However, Brenin stated that "populations with undifferentiated ES morphology andES markers can be grown, for at least twelve passages from the rat" *(id.),* beyond the number originally described by Iannaccone.

Doetschman

58. Doetschman described "the establishment and maintenance of hamster ES cell lines and show[ed] they are highly pluripotent." (Thomas Doetschman, *Establishment of Hamster Blastocyst-Derived Embryonic Stem (ES) Cells,* 127 Developmental Biology 224 (1988).)

59. The hamster ES cells "appear to have a normal chromosome count" and "had been in culture for at least 25 passages" *(id.* at 227).

60. Doetschman stated they "are presently carrying out experiments to determine if the hamster ES cells can colonize the germ line when introduced back into hamster blastocysts." *(Id.)*

Talbot

61. Talbot taught isolation of pluripotent epiblasts from bovine blastocysts, but found that the "cells ...

all differentiated or senesced indicating that standard conditions for mouse embryonic stem cell culture do not maintain bovine epiblast cells in an undifferentiated state." (Neil C. Talbot, *In Vitro Pluripotency of Epiblasts Derived From Bovine Blastocysts,* 42 Molecular Reproduction and Development 35 (1995).)

The '913 patent

62. "Pluripotent cell lines have also been derived from preimplantation embryos of several domestic and laboratory animals species ...." ('913 patent, col. 3, ll. 50-59).

63. "Whether or not these cells lines are true ES cells [sic] lines is a subject about which there may be some difference of opinion." *(Id.* at col. 3, ll. 60-62).

64. "True ES cells should: (i) be capable of indefinite proliferation in vitro in an undifferentiated state; (ii) maintain a normal karyotype through prolonged culture; and (iii) maintain the potential to differentiate to derivatives of all three embryonic germ layers (endoderm, mesoderm, and ectoderm) even after prolonged culture." *(Id.* at col. 3, ll. 62-67).

65. "Strong evidence of these required properties have been published only for rodents [sic] ES cells including mouse ... [,] hamster ..., 1988), and rat..., and less conclusively for rabbit ES cells ...." *(Id.* at col. 3, l. 67 to col. 4, l. 7; citations omitted.)

66. "However, only established ES cell lines from the rat ... and the mouse... have been reported to participate in normal development in chimeras." *(Id.* at col. 4, ll. 8-12; citations omitted.)

Level of ordinary skill in the art

67. Persons of ordinary skill in the art, as evidenced by findings l-66, were familiar with cell culture technology, mouse ES derivation, and able to apply mouse techniques to embryos from other species.

Analysis

Prior to the filing date of this application, scientists had produced pluripotent embryonic stem cells from mice which proliferated in culture for long periods of time in the undifferentiated state and, under suitable conditions, were able to differentiate into any organ or tissue type ('913 patent, col. 1, ll. 28-35). The techniques for producing mouse ES cells had been applied, with varying success, to other mammals (FF30-34, 37-39, 41, 42, 44, 47-50, 52, 56-58, and 61-66). Based on the numerous disclosures of the application of embryonic stem technology in mice and other mammals, the Examiner, in a non-final Office Action, rejected the claims to human ES cells as obvious to persons of ordinary skill in the art under 35 U.S.C. § 103. (Non-Final Office Action (mailed Mar. 30, 2007).)

Although the Examiner initially determined the claims were obvious, the Examiner subsequently withdrew all the obviousness rejections in view of evidence that persuaded him that there would not have been a reasonable expectation that the mouse techniques for producing stem cells would succeed in humans *(see* ACP & RAN).

The Third Party Requester in this proceeding contends that the Examiner erred in withdrawing the rejection by applying an improper standard of obviousness. The Requester contends that "the

Examiner required the expectation of success to be an absolute certainty in order for it to be considered 'reasonable.'" (Second Amended Third Party Requester's Appeal Brief at 4 (filed May 21, 2009) [hereinafter Br.]). The Requester also contends that the Examiner "concluded that since human embryonic stem cell cultures as claimed had not existed before, they were not obvious. This effectively eviscerated the non-obviousness requirement by collapsing it into ... [an] anticipation inquiry." *(Id.* at 5).

Under 35 U.S.C. § 103, "[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." This determination is made, inter alia, after determining the scope and content of the prior art and the level of ordinary skill in the art to which the invention pertains. In *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418 (2007), the Supreme Court warned against confining the obviousness analysis to a "formalistic" approach, but rather encouraged the analysis to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." Thus, while the requirement that there be a "reasonable expectation of success" *(Procter & Gamble Co. v. Teva Pharmaceuticals USA Inc.,* 566 F.3d 989, 996 (Fed. Cir. 2009)) may be one useful standard in assessing the obviousness of an invention, it is not the only standard to be applied when making a patentability determination under Section 103.

The Supreme Court has held that an invention may be proved obvious by showing that a combination of elements was "obvious to try." Where "there are a finite number of identified, predictable solutions" within the "technical grasp" of the ordinary skilled artisan, the invention "is likely the product not of innovation but of ordinary skill and common sense." *KSR,* 550 U.S. at 421. A solution is not "predictable" when "the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Bayer Schering,* 575 F.3d. at 1347 (quoting from *In re O'Farrell,* 853 F.2d 894, 903 (Fed. Cir. 1988)). The "obvious to try" standard focuses on the predictability of a solution as a "viable option" to solve a problem. *Bayer Schering,* 575 F.3d at 1348. A solution which had been known to work when applied to one system might, in some circumstances, be obvious to try in another. If the solution succeeded, the invention likely would have been obvious to persons of ordinary skill in the art.

In this case, the prior art explicitly taught two principal ways to produce embryonic stem cells. In one technique, blastocyst "were allowed to attach to the culture dish and approximately 7 days later the outgrowing inner cell mass picked, trypsinised [sic] and transfered [sic] to another culture dish in the same culture media" (FF9). The second method involved treating the blastocyst with antibodies to destroy trophectoderm- called "immunosurgery" - and then performing dissociation and trypsinizing steps (FF10-11). Both Williams (FF9-11) and Robertson '87 (FF23-24) described the same basic techniques. Piedrahita also appeared to apply a

similar strategy, involving immunosurgery and trypsin dissociation (FF35).

Based on these familiar techniques, the path to deriving human ES cells had a definite starting point with explicit landmarks along the way. A person of ordinary skill in the art, highly skilled in cell culture technology (FF67), was not required to design new protocols or explore new approaches, but rather would follow a path already taken in the mouse. In sum, there were a "finite number of identified" and "predictable" solutions which would have been readily applied by one of ordinary in the art to produce human embryonic stem cells. *KSR,* 550 U.S. at 421.

An invention is not obvious to try when an inventor would have had to attempt all the possibilities in a field, vary all parameters, and try numerous possible choices "'where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful ....'" *Bayer Schering,* 575 F.3d at 1347. Respondent argued that the claimed invention was not "obvious to try" because of the complexity of the prior art and the lack of predictability (Resp. App. Br. 13 & 15-16). Respondent provided some evidence to support this position, which we review in more detail below.

Testimony in the form of a written declaration was provided by Dr. Colin Stewart, a scientist with expertise in embryonic stem cells. Dr. Stewart, testified about Dr. Thomson's claimed invention involving primate/human ES cells (Stewart Dec. ¶ ll). Dr. Stewart stated:

> Dr. Thomson isolated the inner cell mass (ICM) from the blastocyst by immunosurgery, a procedure that removes the trophoblast cells that enclose the ICM. He plated the isolated ICMs on mouse feeder layers and was very explicit in how the explanted ICMs were cultured, gently disassociated, replated on feeder layers to form colonies, and then expanded on feeder layers to maintain their stem cell characteristics to prevent their differentiation ('780 patent columns 7, 8 and 9). This meticulous series of methods is not described in Williams.

*(Id. a*t ¶ 18.)

Dr. Stewart's testimony does not convince us that it would not have been obvious to apply mouse techniques to human embryos. Immunosurgery had been described as part of isolation protocols described in Williams, Robertson '87, and Piedrahita (FF10, FF11, FF24, & FF35). Feeder cells were also recognized as part of standard protocols (FF2, FF6, FF21, FF28, & FF32); and cells were dissociated in the prior art protocols to produce ES cells (FF11, FF2l, FF23, FF27, & FF35). Respondent has not established that the protocol followed by Dr. Thomson necessitated him to "try all possibilities in a field unreduced by direction," but rather the evidence of record points to significant guideposts that would have led the skilled worker in the right direction to successful isolation of human ES cells.

Dr. Stewart also testified in his declaration that the human embryonic stem cell colonies observed in human cell cultures were "distinctly different" than mouse ES colonies and "it would not be immediately

apparent what cells/colonies to choose for further study without the insight exhibited by Dr. Thomson." (Stewart Dec. ¶ 19). A person of ordinary skill in the art, having followed the protocols described by Williams and Robertson '87, would have recognized that differences between species had been observed during ES cell production (FF36) and common sense would have directed her or him to pick different colony types to determine which possessed ES properties.

Respondent has devoted considerable resources to the argument that there was "a high degree of unpredictability" in the mammalian stem cell field (Resp. App. Br. 4). Respondent contends that this unpredictability translated into a lack of reasonable expectation of success that "puts this invention on the patentable side of any obvious-to-try-analysis under *KSR." (Id.* at 13). Respondent asserts there "was no evidence to predict how different cells would respond to different variations in culturing methods, or predict what characteristics the cells would display in culture." *(Id.)*

We have considered the evidence provided by Respondent, including numerous pre- and post-filing publications. There is no doubt from the evidence that the techniques for producing embryonic stem cells from mouse embryos had varying success in other species.

Despite the shortcomings described for ES cells derived from certain mammalian species, isolation of pluripotent stem cells had been reported in rat and hamster (FF4l, FF42, FF50, & FF56-59). Consistently, the inventor, Dr. Thomson, explicitly acknowledged in the '913 patent that there was

strong published evidence that ES cells had been produced from rat and hamster cells (FF65). Therefore, even were there uncertainty as to whether the mouse ES techniques would achieve success when applied to a particular mammalian species or strain, this would not have changed the determination that it would have been obvious to have tried these techniques on human embryos. As in *Bayer Schering,* there were a small number of known options to make embryonic stem cells. These options were known to work, albeit not in every species in which they had been tried, and therefore remained "viable" and "obvious to try" techniques to derive human embryonic stem cells.

Dr. Thomson recognized there had been various published attempts described in the scientific literature at making ES cell lines from domestic and laboratory animal species, but there was "some difference of opinion" as to whether they were true "ES cells" (FF63 & 64). These differences in opinion have played out in this proceeding. The parties dispute the extent to which ES cells had been obtained from porcine, ovine, bovine, and rat embryos (e.g., as described in FF12-14, FF29-42, & FF47-61). However, when Dr. Thomson, himself- an expert in embryonic stem cell technology could not resolve this question, the Board is in no position to determine an answer. Nonetheless, the fact that certain evidence "cut both ways," as it does here, did not preclude the court in *Bayer Schering,* 575 F.3d at 1350, from determining that the claimed invention would have been "obvious to try" in view of the predictable options explicitly taught in the prior art for making ES cells.

The facts support Dr. Thomson's statement that stem cells had been obtained in hamsters and rat. Stem cell technology therefore worked in at least some species in which it had been applied. Cherny, despite limited success in domestic animals, was not dissuaded that the mouse stem cell protocols would be useful to follow in other species. Cherny explicitly concluded that "criteria used in the identification of murine cells can serve as guidelines." (FF14).

It is undisputed that interest in producing human embryonic stem cells was high. According to testimony by Drs. Melton and Cowan, both scientists with expertise in cell culture, human ES cells were successfully isolated "by simply following those methods taught for deriving mouse, rat, pig and sheep ES cells." (Declaration of Dr. Douglas A. Melton at ¶ 13 (June 29, 24007); *see also* Declaration of Dr. Chad Cowan at ¶ 14 (June 29, 2007)). Because it would have been obvious to have tried the known mouse protocols on human embryos, and because such protocols would have resulted in human stem cells, we conclude that the claimed human embryonic stems would have been obvious to persons of ordinary skill in the art.

The Examiner improperly withdrew the rejections of claim 1 as obvious in view of Williams; Robertson '83, Robertson '87, Williams, and Hogan; Piedrahita, Williams, and Hogan; and Robertson '83, Robertson '87, Piedrahita, Williams, and Hogan.

OBVIOUSNESS REJECTION 6

The Third Party Requestor appeals the Examiner's determination to not to adopt its proposed rejection of claims 1-3 under 35 U.S.C. §

103(a) as obvious based on Robertson '83, Robertson '87, and Piedrahita.

The Examiner stated that the rejection would not be adopted because the Requester had improperly relied upon a declaration by Dr. Jeanne F. Loring as providing motivation. Communication to Third Party Requester 7, dated Mar. 30, 2007.

We agree that the Examiner's decision not to adopt the rejection was correct, but for a different reason. The prior art cited in this rejection is redundant to the art in rejections 1-5, but rejection 6 did not rely on Williams as did rejections 1-5. Williams taught human embryonic stem cells and provided additional evidence of the techniques utilized to isolate stem cells. Accordingly, the scope and content of the cited prior art is not as complete as it was for rejections 1, 3, 4, & 5.

SUMMARY

The Examiner's decision to withdraw the following rejections of claims l-3 under 35 U.S.C. § 103(a) is reversed:

l. Williams;

3. Robertson '83, Robertson '87, Williams, and Hogan;

4. Piedrahita, Williams, and Hogan; and

5. Robertson '83, Robertson '87, Piedrahita, Williams, and Hogan.

The Examiner's decision not to adopt the proposed rejection of claims l-3 under 35 U.S.C. § 103(a) as obvious based on Robertson '83, Robertson '87, and Piedrahita is affirmed.

NEW GROUNDS OF REJECTION

37 C.P.R. § 41.77(a) states that "[t]he reversal of the examiner's determination not to make a rejection proposed by the third party requester constitutes a decision adverse to the patentability of the claims which are subject to that proposed rejection which will be set forth in the decision of the Board of Patent Appeals and Interferences as a new ground of rejection …." Accordingly, for the reasons given above, we enter the following new grounds of rejection of claims l-3 under 35 U.S.C. § 103(a) based on:

l. Williams;

3. Robertson '83, Robertson '87, Williams, and Hogan;

4. Piedrahita, Williams, and Hogan; and

5. Robertson '83, Robertson '87, Piedrahita, Williams, and Hogan.

37 C.P.R.§ 41.77(b) states:

(b) Should the Board reverse the examiner's determination not to make a rejection proposed by a requester, the Board shall set forth in the opinion in support of its decision a new ground of rejection; or should the Board have knowledge of any grounds not raised in the appeal for rejecting any pending claim, it may include in its opinion a statement to that effect with its reasons for so holding, which statement shall constitute a new ground of rejection of the claim. Any decision which includes a new ground of rejection pursuant to this paragraph shall not be considered final for judicial review. When the Board makes a

new ground of rejection, the owner, within one month from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal proceeding as to the rejected claim:

(1) *Reopen prosecution.* The owner may file a response requesting reopening of prosecution before the examiner. Such a response must be either an amendment of the claims so rejected or new evidence relating to the claims so rejected, or both.

(2) *Request rehearing.* The owner may request that the proceeding be reheard under § 41.79 by the Board upon the same record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.P.R. § 1.956. *See* 37 C.P.R. § 41.79.

REVERSED; 37 C.P.R. § 41.77(b)

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