

In The
**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.

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

REPLY BRIEF OF APPELLANT

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Dated: August 29, 2013

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CERTIFICATE OF INTEREST

Counsel for Appellant Consumer Watchdog certifies the following:

1. The full name of every party or amicus represented by me is:

Consumer Watchdog

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

NONE

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

NONE

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Daniel B. Ravicher, Sabrina Hassan, Public Patent Foundation

Dated: August 29, 2013

/s/ Daniel B. Ravicher
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INTRODUCTION

The claims at issue here cover human embryonic stem (hES) cells that are not markedly different from those in our bodies. Thus, the claims are invalid under 35 U.S.C. § 101 for covering ineligible subject matter, an issue the Court may and, as a matter of judicial economy and public policy, should address. While WARF conflictingly argues Appellant both could not have raised the issue below and yet somehow also waived it, even WARF does not go so far as to suggest the Court may not address the issue.

Regarding anticipation and obviousness, WARF seeks to distract the Court (like it distracted the Board) with an after-the-fact, hindsight-filled declaration to contradict the plain language of the prior art. When read directly, and not through Dr. Stewart's biased unchallenged one-sided vision, the plain language of Williams expressly taught the use of feeder cells for both derivation and maintenance of ES cells, including hES cells, and Bongso expressly taught selecting hES cells using the previously known way to select mouse ES cells, which even the '913 patent itself says was the proper way to do so. Thus, the Stewart declaration submitted by WARF late in this reexamination, which was relied on by the Board for its findings of patentability, cannot provide the substantial evidence necessary to support its decision. Viewing the prior art without the distraction of the misleading declaration

shows that the Board's original finding that the '913 patent's claims were both anticipated and obvious was correct.

ARGUMENT

I. THE CLAIMS VIOLATE SECTION 101, AN ISSUE THE COURT MAY AND SHOULD ADDRESS

As explained in Appellant's opening brief, the Federal Circuit may, and should, address patent eligibility in deciding whether to uphold the claims before it. While it is indeed true that Appellant could not have raised invalidity under § 101 at the Patent Office during this reexamination, the Court may of course consider the issue considered "threshold" by the Supreme Court. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). Doing so is especially appropriate here given recent developments in the law of patent eligible subject matter.

WARF argues *Comiskey* allowed such consideration only because of the judicial economy that resulted from affirmance on alternative grounds in that case, which saved the Board from rehearing the case only to reach the same conclusion. WARF Br. at 33 (discussing *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009)). But judicial economy similarly results here, because a decision by the Court that the '913 patent claims cover ineligible subject matter will alleviate the need for any separate or further action based on § 101 in light of *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 2013 U.S. LEXIS 4540 (Jun 13, 2013).

Comiskey did draw a distinction between affirmance and reversal, as WARF points out, but the precedent relied on by *Comiskey* on that issue illustrates that the distinction depended upon the appellant raising a new ground for reversal that it could have raised below, and thus had waived. 554 F.3d at 975, n.6 (citing *Boston Sci. Scimed, Inc. v. Medtronic Vascular, Inc.*, 497 F.3d 1293, 1298 (2007), which found that district court did not err in precluding party's presentation of theories on constructive trust and equitable assignment which had not been advanced during the PTO proceeding below).

Here, as WARF correctly points out, Appellant could not have raised the § 101 issue below and thus it cannot be waived. Further, the law has developed in the intervening period, justifying a consideration of the issue by the Court regardless. Contrary to WARF's insinuation that the recent *AMP v. Myriad* decision changed nothing in the law (WARF Br. at 34), the Supreme Court's decision in *AMP* reversed what had been the prevailing rules from this Court's precedents. From July 2011 until June 2013, the binding law of this Circuit stated that isolated DNA molecules were patent eligible under § 101 even if they had an identical nucleotide sequence to molecules in the body because removing them from the body made them different enough from nature to escape the patent eligibility exception for laws and products of nature. *Ass'n for Molecular Pathology v. United States PTO*, 653 F.3d 1329 (Fed. Cir. 2011); *Ass'n for Molecular Pathology v.*

Myriad Genetics, Inc., 689 F.3d 1303 (Fed. Cir. 2012) (*rev'd* by 569 U.S. ____ (2013)). Thus, even though Appellant's attorneys were indeed "aware of [*AMP v. Myriad* and the § 101 issues" it raised (WARF Br. at 34), the Supreme Court's ultimate decision rendered in June 2013 did not provide additional guidance for invalidating the '913 patent claims until very recently. Even this Court recently recognized that the Supreme Court's *AMP v. Myriad* decision changed the landscape of the law enough to warrant reconsideration of the patent eligibility of other patents. *Aria Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Aug. 9, 2013) (remanding to district court for consideration of subject matter eligibility in part "[b]ecause the district court did not have the benefit of *Myriad*"). WARF's allegation of "sandbagging" and suggestion that § 101 is not an appropriate issue for consideration by the Court are, thus, unfounded.

Further, the fact that the patented technology in *Aria* was a method for detecting a fetus' chromosomal abnormalities from maternal blood rather than a composition of any type of nucleic acid flatly refutes WARF's claim that *AMP v. Myriad*'s influence is strictly limited to gene patents. WARF Br. at 34.

WARF argues that, in any event, the '913 claims satisfy the subject matter eligibility requirement because (i) Dr. Stewart, its expert, testified that the cell populations within the ICM and in an established replicating culture are "distinct," (ii) the claimed "*in vitro* cell culture" includes processed ingredients that are not

natural phenomena, and (iii) the PTO found the claims to be directed to patent eligible subject matter during prosecution. WARF Br. at 35-37. None of these arguments is availing.

WARF's first argument relies on a statement of law that is incorrect. The fact that a patented item is "distinct" from its natural source is not the standard of patent eligibility. Rather, it must have "markedly different characteristics from any found in nature." *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980); *see also AMP v. Myriad*, 569 U.S. ____ (slip op., at 11). Here, as discussed in Appellant's opening brief, the claims are directed to *in vitro* hES cell cultures that are not markedly different from *in vivo* hES cells. Appellant Br. at 15.

WARF's second argument, that the claimed "culture medium" contains processed ingredients not found in nature, such as fetal bovine serum and amino acid stock (WARF Br. at 36), is akin to the argument the Supreme Court rejected in *AMP v. Myriad*, where the patentee attempted to distinguish the claimed isolated DNA from DNA in the body by using limitations that did not exist in the claims:

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.

AMP v. Myriad, 569 U.S. ____ (slip op., at 14-15). Similarly here, the claims do not include the proposed limitations on the “culture medium” element that WARF argues should be read into the claims. Indeed, WARF’s attempt to add claim limitations regarding the “culture medium” element at this stage is especially improper in light of the rule that during reexamination claims are to be given their broadest reasonable interpretation. *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); *Larson Mfg. Co. of S.D. v. Aluminart Prods.*, 559 F.3d 1317, 1333 (Fed. Cir. 2009); *In re Swanson*, 540 F.3d 1368, 1377-78 (Fed. Cir. 2008). Thus, the claims here cannot be saved by torturing their construction to incorporate the additional limitations WARF seeks to import from the specification.

WARF’s third argument, that the PTO allowed the claims, is true of every patent later invalidated by the courts. Further, the PTO is not entitled to deference on issues of patent eligibility. *AMP v. Myriad*, 569 U.S. ____ (slip op., at 15-16). Lastly, neither the Examiner nor the Board here had the benefit of the Supreme Court’s *AMP v. Myriad* decision, which was issued well after the Board’s decision. Thus, this argument lacks merit as well.

II. THE CLAIMS VIOLATE SECTIONS 102 AND 103

WARF noticeably avoids directly discussing the prior art that anticipates and renders obvious its claims, instead preferring to distract the Court with a declaration from its hired-gun expert, Dr. Stewart, who opines in favor of

upholding the claims using hindsight reasoning and reference to acclaim received by Dr. Thomson. “As the Supreme Court long ago observed, ‘Experience has shown that opposite opinions of persons professing to be experts, may be obtained to any amount ...’” *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1142 (Fed. Cir. 1986) (citing *Winans v. New York and Erie Railroad Co.*, 21 How. 88, 62 U.S. 88, 16 L. Ed. 68 (1859)). Further, Stewart and Thomson worked together as colleagues in the past. STEM CELL NOW, Christopher Thomas Scott, pp. 4-5 (2006). Thus, to suggest as WARF does that Stewart is some neutral unbiased expert strains credulity.

While secondary *indicia* are an important part of the obviousness analysis, they play no role in an anticipation analysis, and an obviousness inquiry is not a popularity contest, asking who received public attention for a certain milestone. Rather, the correct legal inquiry asks whether the claimed subject matter was obvious in light of the prior art. Dr. Stewart’s opinions, which were not subjected to cross-examination and which conflict with the plain language of the prior art, can not provide substantial evidence to support the Board’s finding that the claims of the ’913 patent are valid. *See Leo Pharma. Prod., Ltd. v. Rea*, 2013 U.S. App. LEXIS 16610, at *21 (Fed. Cir. Aug. 12, 2013) (finding that there was not substantial evidence to support the Board’s factual finding underlying its obviousness determination). When the prior art is viewed directly, without the

broken lens of Dr. Stewart's paid-for opinions, it is apparent that the claims here are anticipated and obvious and that the Board's conclusion to the contrary was not supported by substantial evidence.

A. The Express Language Of Williams Teaches Feeder Cells For Derivation

Dr. Stewart's skewed interpretation of Williams can not change Williams' express teaching. WARF cites Dr. Stewart's declaration, not the Williams patent itself, to support its argument that Williams does not disclose the use of feeder cells in deriving hES cells. WARF Br. at 39. Appellant trusts that the Court can interpret Williams' plain language without the assistance of Dr. Stewart to determine whether Williams discloses the use of feeder cells during derivation. A1847-1858.

Appellant acknowledges that Williams discusses culture medium for both the derivation and maintenance aspects of the invention, as the two statements in Williams that culture medium "may or may not contain feeder cells" refer once each to derivation and maintenance, in that order. Appellant Br. at 18. It is WARF's position that Williams does not teach feeder cells for derivation of hES cells that conflicts with the reference itself, which is discussed at length in Appellant's opening brief. Appellant Br. at 18-20.

B. Bongso Succeeded In Deriving And Identifying hES Cells

WARF again cites Dr. Stewart's declaration to support the argument that Bongso did not derive ES cells from human blastocysts. WARF Br. at 39. WARF

then uses the supposed Bongso failure as a basis to dispute both anticipation and obviousness. WARF Br. at 39, 45. But Bongso does not refute anticipation or obviousness, because Bongso actually did not fail at deriving hES cells or maintaining those cells. A1471 (“Embryos were grown and allowed to hatch on passaged human Fallopian tubal epithelial monolayers which acted as feeder layers.”) Indeed, following what Williams taught, Bongso clearly described using feeder cells in the *isolation* of hES cells. *Id.*

Thus, the claim that Bongso failed to identify the correct cell colonies for isolation because Thomson hadn’t yet described their morphology as “flat” is false. WARF Br. at 45. Bongso did indeed isolate hES cells and maintain those cells. Even the Examiner recognized this. A547 (“Bongso ‘94 apparently succeeded in isolating human ES cells. These ES cells were isolated from pre-implantation embryos and exhibited the presence of alkaline phosphatase, stem cell-like morphology, and normal karyotype.”).

The only thing Bongso did not teach was maintaining the cells for a sustained period. *Id.* (“ However, as the Patent Owner points out, Bongso failed to go further and to maintain said ES cells in long term culture, presumably because he failed to culture the human ES cells on embryonic fibroblast feeder layers without LIF. The human ES cells of Bongso continued in culture for only two cultures in the presence of human LIF before differentiating.”). This is why the

claims at issue here recite the limitation “will proliferate in an in vitro culture for over one year in an undifferentiated state without the application of exogenous leukemia inhibitory factor.” A101. The only difference between Bongo and the claims is the amount of time the isolated hES cells were capable of being maintained. Bongo did not fail at identifying and isolating hES cells.

Similarly, in withdrawing his obviousness rejection, the Examiner nonetheless noted that, “[Williams] describes human ES cells prophetically as being isolatable using the same method that was used to isolate murine ES cells.” A550. Therefore, Thomson’s description of the cells as “flat” was not necessary, as WARF argues, to teach later researchers which cells to select, because both Williams and Bongso were able to identify and isolate hES cells without Thomson’s additional commentary that the colonies were “flat”.

Even WARF’s own characterization of the facts admits that Bongso *isolated* hES cells. “[Bongso’s] method produced cell colonies that resembled mouse ES cell colonies: the cells displayed a typical stem-cell morphology, and they formed tightly packed (or compact) colonies in which individual cells were difficult to recognize.” WARF Br. at 12, citing A1474. WARF’s description of the cells Bongso isolated is perfectly consistent with Thomson’s description in the ’913 patent: “Colonies demonstrating ES-like morphology are individually selected, and split again as described above. The ES-like morphology is defined as compact

colonies having a high nucleus to cytoplasm ratio and prominent nucleoli.” A1860-61 (8:65-9:1).

And in the portion of Bongso’s cell description that WARF failed to reference, the author states, “The cells had an epithelioid morphology with large nuclear to cytoplasmic ratios. Each cell was small, with a large nucleus and minimal cytoplasm (Figure 5) and the nuclei contained one or more prominent nucleoli.” A1474. Thus, reading Bongso directly, instead of just adopting Dr. Stewart’s misleading interpretation of Bongso, shows that it indeed managed to derive hES cells and select the appropriate colonies for isolation. A1470-1477. WARF’s argument to the contrary is, and the Board’s reliance on that argument was, without substantial evidence.

C. WARF Seeks To Collapse Obviousness Into Anticipation

Under the pretext of arguing that the ’913 claims are non-obvious, WARF merely makes arguments that counter a finding of anticipation. For example, under its section on non-obviousness, WARF stresses that “the cited prior art teaches *mouse* ES cell cultures and methods of making *mouse* ES cell cultures” rather than human cell cultures and suggests that therefore means the prior art cannot render hES cells obvious. WARF Br. at 48. However, as discussed in Appellant’s opening brief, the prior art’s teaching of a method for isolating and maintaining mouse ES cells, when combined with the motivation to isolate human ES cells and the limited

predictable set of culture conditions to try, rendered the claims obvious, even if hES cells had not previously been derived and maintained in culture for over a year. Appellant's Br. at 20-23. The prior art need not have actually cultured hES cells for over a year to render the '913 patent claims obvious. Indeed, if the prior art had taught hES cells that were cultured for over a year (which Appellant maintains Williams did in fact teach), that teaching would render the claims anticipated, and there would not need to be any obviousness analysis. WARF's argument that something is not obvious if it had not been done before is a suggestion to delete section 103 from the Patent Act. Such a request for judicial activism is properly rejected.

Regarding whether using feeder layers and not LIF to culture hES cells for over a year as claimed in the '913 patent was obvious to try, WARF strains credibility to characterize the finite number of identified, predictable options for cell culture conditions taught in the prior art as "numerous." Indeed, WARF can only name two options that were available in the prior art: feeder cells and LIF-supplemented culture medium. WARF Br. at 49. If two options to try is so "numerous" as to be unpredictable, according to WARF, then nothing could ever be obvious to try. In reality, there was not a large number of unpredictable ways to maintain a hES cell culture as WARF suggests. There were in fact only two options, and one of ordinary skill in the art would have been motivated to try both.

This is the essence of the “limited parameters” that underlie a *KSR* obvious-to-try finding. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

The supposed failure of “others” WARF references also does not support a finding of non-obviousness, as there is only one “other” it points to as having worked with human blastocysts and failed in an attempt to maintain them. That other was Bongo who, as discussed above, did not fail to isolate hES colonies. Instead, Bongo merely did not maintain such cultures for an extended period of time. This was due to Bongo’s use of LIF rather than feeder cells in the culture medium to maintain the cells (WARF Br. at 16, A1479) – and WARF has already admitted that Williams taught the use of feeder cells in the maintenance of ES cell colonies. A1756, WARF Br. at 40. Thus, had Bongo used the only other known way to maintain hES cells (i.e. the feeder layers taught by Williams), then he would have accomplished exactly what Thomson did.

Lastly, if WARF is so proud to repeat Dr. McMahon’s statement that “harvesting and maintaining a line of stem cells from *any* animal is ‘not routine at all’” (WARF Br. at 17, 51 (emphasis original)), and given the strong motivation for scientists throughout the world to culture hES cells (A77), it seems that WARF should easily be able to identify many more than just one scientist who failed at maintaining a hES cell culture. But WARF can only cite one, and the one they cite was not a failure at all as WARF misleadingly suggests. Thus, WARF’s discussion

of “failure of others” does not support non-obviousness because there was no “failure”, nor were there “others”. At most, WARF’s disrespectful description of Bongso merely demonstrates that it did not anticipate the ’913 patent, which Appellant concedes.

D. Secondary Indicia Here Do Not Provide Substantial Evidence To Support The Board’s Non-Obviousness Finding

Appellant of course does not dispute WARF’s argument that secondary indicia of non-obviousness are an important part of the obviousness analysis. Appellant also does not dispute that Dr. Thomson was the first to successfully isolate and maintain hES cells for an extended period of time or that he deserves acclaim for that accomplishment. Neil Armstrong was the first man to walk on the moon, and he deserves to be heralded as a national hero for doing so, but he did not invent the moon or even how to walk. As discussed above and in Appellants opening brief, the prior art fully taught how to achieve Dr. Thomson’s milestone, and while he deserves credit for getting there first, his achievement was not the result of his having created a patentable invention.

While the law mandates consideration of secondary indicia, it does not permit factors such as acclaim, commercial success, and failure of others to overcome the direct evidence of prior art teachings and common sense, common knowledge, and motivation to try. *KSR*, 550 U.S. 398. As the Court has repeatedly recognized, it is identifying the problem that can often render the solution obvious.

Leo Pharma. Prod., Ltd. v. Rea, 2013 U.S. App. LEXIS 16610, at *11 (Fed. Cir. Aug. 12, 2013) (“an invention can often be the recognition of a problem itself”).

When the problem is widely recognized and motivation exists, delay in trying obvious solutions is often caused only by limits on access to the necessary resources (raw materials and financial support). Thomson admits that is exactly what happened with hES cells in, for example, his 1998 Science article:

For ethical and practical reasons, in many primate species, including humans, the ability of ES cells to contribute to the germ line in chimeras is not a testable property. Nonhuman primate ES cell lines provide an accurate in vitro model for understanding the differentiation of human tissues.

A5079. As further described in his article, Thomson acknowledged that he was only able to perform his hES cell work because,

Fresh or frozen cleavage stage human embryos, produced by in vitro fertilization (IVF) for clinical purposes, were donated by individuals after informed consent and after institutional review board approval.

Id. Thus, Thomson would not have been able to achieve his accomplishment without the donation of human embryos from an IVF clinic, which is why others were not able to achieve the milestone before Thomson; they did not have the benefit of donated raw materials to start with.

In this case, everyone knew what the problem was and no one skilled in the art was surprised by the way in which Dr. Thomson derived and maintained for an extended period of time hES cells. Rather, it was Thomson’s ability to overcome

the pragmatic obstacles created by the scarcity of human embryos and funding for politically controversial hES cell research at the time of the '913 patent that resulted in the acclaim he received. It was those resource limitations, not ignorance of the problem or unpredictability of the solution, that caused other ES cell researchers to not be first to culture hES cells as Thomson did. Thus, in light of at least the teachings of Williams, Robertson, Piedrahita and Hogan (Appellant Br. at 4-6) and ES researchers' strong motivation to culture hES cells at the time, Thomson's accomplishment was indeed obvious and the Board's conclusion to the contrary lacked substantial evidence.

Lastly, WARF points to supposed commercial success as a factor supporting the Board's finding of non-obviousness, but admits its terms are now quite relaxed. Indeed, after the filing of this reexamination, WARF dramatically changed its licensing terms and now licenses the challenged patent for free to academics. WARF Br. at 18. Its commercial agreements are for material transfer of hES cell cultures and a license to any entire portfolio of ES cell patents. Thus, this "success" is not correlated to any recognition of inventiveness in the '913 patent itself. Rather, the commercial success WARF is receiving is due to its position as one of the only sources of hES cell cultures, not its position as the '913 patent owner. If the Court strikes the '913 patent, as it should, WARF will not lose any of its commercial success, because it will still be one of the only places in the United

States from which to get hES cell cultures and it will still have the other patents in its portfolio to license. If the '913 patent was such a commercial success, we would expect WARF to show that it has been independently licensed, by itself, without attendant material transfer. It has not and, thus, there is no commercial success with a nexus to the '913 patent's claims that justifies a non-obviousness finding.

CONCLUSION

Each claim of the '913 patent covers ineligible subject matter and was anticipated by and obvious in light of the prior art. The Board's decision to the contrary was without substantial evidence. The Court should thus rule each claim of the '913 patent invalid.

Dated: August 29, 2013

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that, on this the 29th day of August, 2013, I electronically filed the foregoing with the Clerk of Court using the CM/ECF System, which will send notice of such filing to the following registered users:

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I further certify that, upon acceptance and request from the Court, the required paper copies of the foregoing will be deposited with United Parcel Service for delivery to the Clerk, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, 717 Madison Place, N.W., Washington, D.C. 20439.

The necessary filing and service were performed in accordance with the instructions given to me by counsel in this case.

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August 29, 2013

/s/ Daniel B. Ravicher

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