

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR
PATHOLOGY, et al.,

:

:

Plaintiffs,

: 09 Civ. 4515 (RWS)

v.

:

UNITED STATES PATENT AND TRADEMARK
OFFICE, et al.,

:

Defendants.

:

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**DEFENDANT UNITED STATES PATENT AND TRADEMARK OFFICE’S
REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS**

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Preliminary Statement

Defendant the United States Patent and Trademark Office (the “USPTO”) respectfully submits this reply memorandum of law in further support of its motion to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiffs offer absolutely no authority for their claim that they can sue the USPTO to invalidate the patents at issue in this case. The precedent is clear – third parties have no standing to sue the USPTO to challenge previously issued patents except as provided by statute. The fact that plaintiffs object to the patents on constitutional grounds does not alter the analysis. In the absence of a single case in which a court has allowed a third party to challenge the USPTO’s issuance of a patent, on any ground – constitutional or otherwise – the claims against the USPTO should be dismissed.

ARGUMENT

THE COMPLAINT AGAINST THE USPTO SHOULD BE DISMISSED

The law as stated by the Federal Circuit could not be more clear: third parties do not have standing to challenge the USPTO’s issuance of a patent. *Syntex (U.S.A.) Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1573 (Fed. Cir. 1989); *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 938-39 (Fed. Cir. 1991).¹

Plaintiffs insist because they object to the patents on constitutional rather than statutory grounds, they should be able to sue the USPTO to invalidate the patents. But, the fact that plaintiffs allege constitutional claims does not alter the standing analysis. In order to reach

¹ The Federal Circuit applied these settled principles again last week in *Rozenblat v. Kappos*, No. 2009-1278, 2009 WL 2952180, at *1 (Fed. Cir. Sept. 16, 2009) (nonprecedential) (reaffirming that a “challenge to validity cannot be brought in a suit against the Director of the PTO”).

the constitutional claims, the court “must first determine whether the plaintiffs have standing to bring this action.” *Amnesty Int’l USA v. McConnell*, 08 Civ. 6259 (JGK), 2009 WL 2569138, at *8 (S.D.N.Y. Aug. 20, 2009) (finding that plaintiffs lack standing to raise First and Fourth Amendment and Art. III constitutional challenges to amendments to Foreign Intelligence Surveillance Act). Constitutional challenges to government action are routinely dismissed where plaintiffs lack standing to sue. *See, e.g., Warth v. Seldin*, 422 U.S. 490, 498 (1975) (rejecting claims under First, Ninth and Fourteenth Amendments challenging zoning ordinance for lack of standing); *Elk Grove Unified School Dist. v. Newdow*, 542 U.S. 1, 17-18 (2004) (father lacks prudential standing to challenge constitutionality of school policy requiring teacher-led recitation of Pledge of Allegiance); *United Presbyterian Church in the U.S.A. v. Reagan*, 738 F.2d 1375, 1378 (D.C. Cir. 1984) (Scalia, J.) (First, Fourth and Fifth Amendment challenges to Executive Order dismissed on standing grounds). Here, the Federal Circuit has repeatedly made clear that there is no standing. Thus, the Court cannot reach the constitutional claims alleged in the complaint.

Plaintiffs contend that if the USPTO grants a patent that violates the Constitution, it cannot “avoid accountability.” *See* Pl. Opp. at 2. Contrary to plaintiffs’ contention, however, it is not a “bedrock principle of our legal system” that every time “an agency of the government commits an unconstitutional act, private citizens are allowed to seek redress for that violation.” *Id.* Rather, there are numerous examples of constitutional violations that may not be redressed in the courts, including constitutional torts allegedly committed by the federal government or its agencies, *see, e.g., FDIC v. Meyer*, 510 U.S. 471, 478 (1994), alleged First Amendment violations committed by supervisors against federal employers, *see Bush v. Lucas*, 462 U.S. 367

(1983), and constitutional claims that are not reviewable because they are political questions, *see Coleman v. Miller*, 307 U.S. 433, 450 (1939).²

Bush v. Lucas is especially instructive here. In that case, a federal employee, subject to Civil Service Commission regulations, brought a First Amendment claim against his supervisors for retaliatory demotion. *See* 462 U.S. at 367. The Court assumed for purposes of the decision that plaintiff's First Amendment rights had been violated and that "Congress has provided a less than complete remedy for the wrong." *Id.* at 373. The Court further assumed that Congress has neither expressly authorized the remedy requested nor "expressly precluded the creation of such a remedy by declaring that existing statutes provide the exclusive mode of redress." *Id.* After reviewing the civil service remedies available, the Court framed the question as follows:

The question is not what remedy the court should provide for a wrong that would otherwise go unredressed. It is whether an elaborate remedial system that has been constructed step by step, with careful attention to conflicting policy considerations, should be augmented by the creation of a new judicial remedy for the constitutional violation at issue.

Id. at 388. The Court concluded that given the comprehensive statutory scheme, it should be left to Congress, rather than the courts, to decide whether to create "a new species of litigation" to remedy the violation of plaintiffs' constitutional rights. *Id.* at 389. So too here, given the statutory scheme established by Congress governing the manner in which the validity of patents may be challenged, courts should not create new and unprecedented avenues of attack on existing

² Thus, it is clear that plaintiffs' reliance on *Marbury v. Madison*, 5 U.S. 137 (1803), Pl. Opp. at 2, for the proposition that they must have a remedy for the alleged violation of their constitutional rights, is misplaced. The Supreme Court in *Bush v. Lucas* emphasized that its previous cases "unequivocally rejected" the "extreme" position – represented by *Marbury* – that the judiciary can fashion a remedy for every constitutional wrong. 462 U.S. at 373.

patents that Congress did not choose to provide.

Webster v. Doe, 486 U.S. 592 (1988), which plaintiffs cite for the proposition that where Congress intends to preclude enforcement of constitutional rights its intent must be clear, is not to the contrary. Pl. Opp. at 3. As set forth more fully in the USPTO opening brief, the intent of Congress here is clear as it established a comprehensive scheme that provides a series of mechanisms for challenging patents. *See* USPTO Moving Br. at 1-3, 6-7, 9-10. The scheme plainly does not contemplate third-party challenges to the USPTO's issuance of patents 10-12 years after the fact on any grounds, constitutional or otherwise. In any event, the case is inapposite as *Webster* was an action brought under the Administrative Procedure Act ("APA") to review agency action. The question before the Court was whether the governing statute could be read to preclude constitutional review that was otherwise available under the APA. *Id.* at 602. Here, plaintiffs did not bring an APA action and thus there is no basis for jurisdiction for claims against the USPTO competing against the comprehensive statutory scheme.³ Plaintiffs cannot make an end run around the statutory scheme – which provides the sole mechanisms for challenging patents – by purporting to assert a constitutional violation unmoored to any

³ Nor is an APA action available against the USPTO in a case challenging the validity of a patent. The recent decision in *Pregis Corporation v. John J. Doll, et al.*, Civ. No. 09-467 (GBL) (E.D. Va. August 14, 2009), Hr'g Tr. 55-57 (attached hereto as an appendix), disposes of the question. In that case, the issue before the Court was whether a third party could seek relief under the APA against the USPTO to invalidate a patent. Relying on *Syntex*, the Court dismissed the case against the USPTO, finding that "the APA does not act as a general waiver of sovereign immunity where the Patent Act and its own scheme clearly expresses Congress' intent to preclude putative third party infringers from seeking judicial review of such actions." *Id.* at 56; *see also Animal Legal Defense Fund*, 932 F.2d at 937-38.

jurisdictional grant.⁴

Plaintiffs also inexplicably cite to *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *vacated*, 2009 WL 1916498 (July 6, 2009), claiming that the Federal Circuit permitted suit against the USPTO for violation of constitutional rights. Not only was the case vacated and of no precedential value, *see Socop-Gonzalez v. I.N.S.*, 272 F.3d 1176, 1186 n.8 (9th Cir. 2001), but more importantly, it raised no constitutional claims. Rather, *Tafas* was brought under the APA to challenge four promulgated rules as exceeding the scope of the USPTO's rulemaking authority under 35 U.S.C. § 2, *see* 559 F.3d at 1349 – an indisputably proper application of the APA.

Furthermore, this is not a situation in which there is no remedy for the alleged wrong. While a challenge to the validity of the patents may not properly be brought against the USPTO, validity of patents may be challenged in an action against the patent holder. One can obtain a ruling regarding the validity of the patents without the presence of the USPTO as a party. Indeed, courts most often invalidate patents in actions in which the USPTO is not a party, including in cases cited by plaintiffs in support of their motion for summary judgment. *See, e.g., Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) (holding that mixture of naturally occurring bacteria was not patentable); *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928) (patent for purified naturally-occurring tungsten found invalid in

⁴ A similar flaw exists in the other cases cited by plaintiffs on this point: *Wright v. City of Roanoke Redevelopment & Housing Auth.*, 479 U.S. 418 (1987), and *Fitzgerald v. Barnstable School Committee*, 129 S. Ct. 788 (2009). In both cases, the question was whether the existing right to sue under 42 U.S.C. § 1983 was precluded by an exclusive statutory scheme. Here, plaintiffs have identified no existing grant of jurisdiction or waiver of sovereign immunity that would provide a comparable basis for suit. Moreover, although those cases did not find that the statute in question provided the exclusive means to challenge an agency action, they recognized that § 1983 could not be used to circumvent established procedures where Congress enacted, as it did here, a “carefully tailored scheme.” *Fitzgerald*, 129 S. Ct. at 795-96.

infringement action).⁵ Once a court declares a patent invalid, the presumption is that the patentee is estopped from asserting the validity of that patent. *See Blonder-Tongue Laboratories, Inc. v. Univ. Of Illinois Foundation*, 402 U.S. 313 (1971). No further action by the USPTO is required to invalidate the patent. Thus, it is not necessary for the USPTO to be a party for plaintiffs to obtain the relief they seek – a holding that the patents are invalid.⁶

Plaintiffs also contend that if the Court found the USPTO policies to be unconstitutional, the Court could “order the USPTO to initiate a reexamination pursuant to 35 U.S.C. § 303, 307.” Pl. Opp. at 7. This is flatly wrong, as the USPTO Director’s ability to initiate a reexamination of a patent is statutorily limited to situations in which prior art patents and publications raise a substantial question that has not previously been considered by the USPTO as to whether the claimed invention is either novel or non-obvious. More specifically, Section 303 limits the Director’s reexamination powers to situations where prior art patents and

⁵ Nor do plaintiffs require the USPTO’s presence as a party in the case to make their constitutional arguments. In an infringement action between private parties, a party is free to argue that a patent is not valid because it runs afoul of the First Amendment or other constitutional provisions. *Cf.* Brief of ACLU as Amicus Curiae, *In re Bilski*, Fed. Cir. No. 2007-1130, 2008 WL 1842266, at *2-14 (filed April 03, 2008) (arguing, in brief filed in support of USPTO, that claim should be held ineligible for patenting based on the First Amendment, or, in the alternative, that “the Court should apply traditional patent doctrines . . . so as to avoid the difficult application of First Amendment doctrines to this situation”).

⁶ Plaintiffs confusingly contend that although the complaint does not so state, their request for relief “includes within it a request that the Court declare the [USPTO’s] policies and practices [with respect to the types of patents at issue here] unconstitutional and enjoin the USPTO from applying its policies and practices with respect to these or any similar claims.” Pl. Opp. at 6 & n.6. Absent a claim under the APA, 5 U.S.C. §§ 702, 706, plaintiffs cannot challenge the USPTO’s “formal, written policy” permitting the patenting of human genes (*see* Pl. Opp. at 1). Thus, they can and do seek nothing more than the invalidation of the patents at issue here. Because, as set forth above, the USPTO is not a proper party to sue to invalidate the patents, plaintiffs fail to meet the redressability prong for constitutional standing and fail to state a claim upon which relief can be granted. *See* USPTO Moving Br. at 8, 13-14.

publications – not court orders – raise “a substantial new question of patentability.” 35 U.S.C. § 303(a); *see also In re Swanson*, 540 F.3d 1368, 1375 n.4 (Fed. Cir. 2008) (“The PTO may . . . instigate a reexamination proceeding on its own motion if it determines that prior art patents or printed publications raise a substantial new question of patentability.”); Manual of Patent Examining Procedure § 2258, at 2200-91 (8th ed., rev. 7, July 2008) (“Rejections will not be based on matters other than patents or printed publications, such as public use or sale, inventorship, 35 U.S.C. 101, conduct issues, etc.”) (citing *In re Lanham*, 1 U.S.P.Q.2d 1877, [1986 Commr. Pat. LEXIS 4] (Comm’r Pat. 1986), and *Stewart Systems v. Comm’r of Patents and Trademarks*, 1 U.S.P.Q.2d 1879, [1986 U.S. Dist. LEXIS 17716] (E.D. Va. 1986)). The Director has no statutory authority to institute a reexamination to consider whether patent claims are unconstitutional or do not claim patentable subject matter pursuant to 35 U.S.C. § 101.

CONCLUSION

For the foregoing reasons and for the reasons set forth in the USPTO’s opening brief, the USPTO’s motion to dismiss should be granted and the complaint against it dismissed.

Dated: New York, New York
September 23, 2009

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INDEX

ARGUMENT BY THE US ATTORNEY	4	24		
ARGUMENT BY FREE-FLOW	26	37	46	
ARGUMENT BY THE PLAINTIFF	9	34	40	52
RULING BY THE COURT	55			

1 The Court doesn't need to credit our
2 demonstrative we thought was helpful or their
3 demonstrative. What counts is the prior art itself.

4 And when you look at the references
5 themselves, we believe under *KSR* there is no issue of fact
6 that on March 8, 1998, which is the critical date here, a
7 person skilled in the art was capable of making this claim
8 subject matter and it was obvious.

9 This is a classic example of the predictable
10 use of pre-existing components. Everything existed, the
11 tube, the film, the configuration, the blocks, the pair of
12 belts, the drive wheel, the planar path, all of it.

13 What's happening here is a competitor is
14 just mixing and matching components and is seeking patents
15 on grounds we've been over with. And we respectfully
16 submit that this is a legal question just like *KSR*. There
17 can't be dispute as to what these documents show. It's
18 just a question of what legal consequences follow from
19 that.

20 THE COURT: Thank you very much.

21 All right, this matter is before the Court
22 on the defendant's motion to dismiss and plaintiff's
23 motion for summary judgment.

24 I'm going to take up the federal defendant's
25 motion to dismiss the claims first, and the question

1 presented is whether the Court should grant the federal
2 defendant's motion to dismiss the claims against him where
3 the plaintiff's claims invoke the Administrative
4 Procedures Act but the Patent Act's comprehensive scheme
5 does not provide a putative third party infringer the
6 right to direct judicial review of the United States
7 Patent and Trademark Office's issuance determination.

8 I'm going to grant the motion because the
9 APA does not act as a general waiver of sovereign immunity
10 where the Patent Act and its own scheme clearly expresses
11 Congress' intent to preclude putative third party
12 infringers from seeking judicial review of such actions.

13 I think the Syntex case is on point. I have
14 considered the argument advanced by the plaintiff that the
15 law has evolved.

16 I do not find the argument persuasive. I
17 realize that this is a novel theory to bring the suit, but
18 I think that the Court is without subject matter
19 jurisdiction here because the APA does not provide a
20 waiver in this context.

21 This would create some new rights for third
22 parties who typically would not have a right to bring a
23 challenge in a district court under this circumstance.

24 Clearly a third party or a competitor here,
25 Pregis, certainly would have the right as it has in a

1 declaratory judgment action if it's threatened with
2 litigation to seek to challenge the validity of the patent
3 or the contents of the patent infringement litigation.

4 But I find that the Syntex case and the
5 structure of the Patent Act sufficiently preclude this
6 action, and so I'm going to grant the motion to dismiss
7 for the federal defendants.

8 As it relates to whether to grant defendant
9 Free-Flow's motion to dismiss the APA claim and to strike
10 associated paragraphs, obviously I'm going to grant the
11 motion to dismiss for lack of subject matter jurisdiction
12 for the same reason I'm granting for the federal
13 defendants. And I will grant the motion to strike as to
14 the paragraphs of the first amended complaint relating to
15 the APA claims because they're immaterial to the remaining
16 claims.

17 As to Pregis's motion for summary judgment
18 on the second, fifth and eight claims under 2201 where
19 Pregis argues that it's entitled to declaration that the
20 patents in issue here are invalid due to obviousness, I'm
21 going to deny that motion.

22 Obviousness is -- is a legal determination,
23 but it rests upon underlining factual inquiries. I think
24 there are factual disputes that remain, and here we have
25 not only competing issues about the -- what do the terms

1 mean but we have underlying factual disputes as well.

2 Clearly, the ultimate judgment of
3 obviousness is a legal determination. But it is dependent
4 upon factual inquiries. And the summary judgment's only
5 appropriate where those factual inquiries into obviousness
6 present no genuine issue of fact.

7 There are three reasons why I'm denying the
8 motion. First is plaintiff has not met its burden of
9 showing its right to summary judgment.

10 A patent is entitled to presumption of
11 validity. And to overcome this presumption, the
12 challenger must present facts supporting the termination
13 of invalidity by clear and convincing evidence under the
14 *Ryko* case.

15 And whereas here the plaintiff has not
16 overcome that presumption or that presumption of validity
17 because it's from -- obvious that the PTO has considered
18 the same prior art in which a challenger relies, the
19 challenger bears an even heavier burden in proving the
20 invalidity under the *Metabolite Labs* case.

21 Plaintiff failed to satisfy its burden. It
22 attempts to satisfy this burden by pointing to the claims
23 that challenge patents and illustration of prior art.

24 However, there is not a sufficient analysis
25 of the patents by one skilled in the art, and they cannot

1 meet its burden in this fashion.

2 Second, plaintiff has asked the Court to
3 grant summary judgment without determining the proper
4 construction of the claims.

5 And generally the first step in validity
6 analysis is claims construction under *Lemelson versus*
7 *General Mills* case. And it's elementary in patent law
8 that in determining whether a patent is valid and if
9 validly infringed, the first step is to conduct meaningful
10 scope of the claims in suit.

11 And obviously claim construction is a legal
12 determination made by the Court after intrinsic evidence
13 of the record including the patent itself, the claims, the
14 specifications and prosecution history.

15 The words, of course, are given their
16 ordinary and customary meaning. But what we're being
17 asking to do here is to accept plaintiff at its word that
18 the claimed inventions were disclosed by prior art. And I
19 do not have the analysis that would allow me to determine
20 that by one who is skilled in the art to assist me in
21 construing the claims.

22 Plaintiff cannot meet its burden by simply
23 pointing to the patents in the picture and illustrations
24 in the Troy or Larson patents. The FPI has raised several
25 issues of fact as to the scope and contents of the

1 patents, the difference between those patents, the claimed
2 inventions.

3 The first factual dispute exists as to
4 whether Troy disclosed an elongated guide member and
5 recite in the Fuss 2008-2009 Perkins patents. The Fuss
6 2008 and 2009 both recite an elongated guide member for
7 guiding the film and is fed along the path.

8 According to Dr. Kazerooni, the short pipe
9 disclosed in the Troy why it cannot perform this important
10 guiding function and will not prevent the film from
11 drifting off its intended path. That's his declaration.
12 Further he states that he did not believe it would be
13 obvious to use the elongated member in the Troy patent.

14 The second factual dispute exists as to
15 whether Troy disclosed the heating through the belt as
16 recited in the Fuss 2008-2009 patents.

17 FPI contends that one of ordinary skill in
18 the art would interpret heating through the belt as just
19 recited and Fuss' meaning that the heat transfer occurs
20 through the thickness of the belt localized to the
21 immediate areas of the heating blocks where the film was
22 sealed.

23 Unlike in Troy, the heat is not stored and
24 retained in the belt. It was immediately applied through
25 the blocks providing consistency of heat transfer forming

1 the seal, Dr. Kazerooni's declaration, paragraph 41.

2 FPI contends this approach is more efficient
3 and it would not be obviously used such as the sealing
4 mechanism in Troy. And other factual dispute as to
5 whether Troy discloses, one, a channel drawn through
6 inflation sealing and slitting mechanism; second, a
7 channel guiding along the path; third, a planar path and
8 fourth, a belt carrying film material past the source of
9 heat.

10 To respond to the issues of fact identified
11 by FPI, plaintiff again only pointed to language of the
12 claim and provided no analysis by one skilled in the art.

13 So for those reasons I'm going to deny
14 summary judgment.

15 Thank you for the quality of your
16 presentations. We're in recess.

17 (Proceeding concluded at 11:58 a.m.)
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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

Pregis Corporation,)	
)	
Plaintiff,)	
)	
v.)	Case No. 1:09cv467(GBL)
)	
John J. Doll,)	
)	
Acting Under Secretary)	
for Commerce for)	
Intellectual Property)	
and Acting Director of)	
the United States Patent)	
and Trademark Office,)	
et al.,)	
)	
Defendants.)	

ORDER

THIS MATTER is before the Court on Federal Defendants' Motion to Dismiss Claims Against Federal Defendants. For the reasons stated in open court on Friday, August 14, 2009, it is hereby

ORDERED that Federal Defendants' Motion is GRANTED.

The Clerk is directed to forward a copy of this Order to counsel.

Entered this 14th day of August, 2009.

Alexandria, Virginia

08/ 14 /09

/s/
Gerald Bruce Lee
United States District Judge