

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AVANIR PHARMACEUTICALS, INC.,
AVANIR HOLDING COMPANY, AND
CENTER FOR NEUROLOGIC STUDY,

Plaintiffs,

v.

ACTAVIS SOUTH ATLANTIC LLC,
ACTAVIS, INC., PAR PHARMACEUTICAL,
INC., PAR PHARMACEUTICAL
COMPANIES, INC., IMPAX
LABORATORIES, INC., WOCKHARDT,
LTD., WOCKHARDT USA, LLC, WATSON
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., AND WATSON
PHARMA, INC.,

Defendants.

C.A. No. 11-704-LPS
(CONSOLIDATED)

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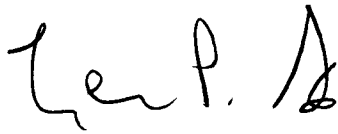
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MEMORANDUM OPINION

October 25, 2013
Wilmington, Delaware.



STARK, U.S. District Judge:

Pending before the Court is Defendants' Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction Based on the Expiration of Asserted U.S. Patent No. RE38,115. (D.I. 371) For the reasons discussed below, the Court will deny the motion.

I. PROCEDURAL BACKGROUND

Avanir Pharmaceuticals, Inc., Avanir Holding Company, and Center for Neurologic Study (collectively, "Avanir" or "Plaintiffs") filed this patent infringement action against Actavis South Atlantic LLC, Actavis, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Impax Laboratories, Inc., Wockhardt, Ltd., Wockhardt USA, LLC, Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (collectively, "Defendants") on August 10, 2011.¹ (D.I. 1) There are three patents-in-suit. United States Patent No. RE38,115 (the "'115 patent") relates to formulations containing dextromethorphan ("DM") and quinidine ("Q"), the active ingredients of Avanir's Nuedexta[®] product. United States Patent Nos. 7,659,282 (the "'282 patent") and 8,227,484 (the "'484 patent") relate to the use of DM and Q for the treatment of a neurological disorder.

On August 5, 2013, Defendants filed a motion to dismiss Plaintiffs' claims arising under the '115 patent. (D.I. 371) After full briefing, the Court heard argument on this motion during the pretrial conference on September 3, 2013. A bench trial was then conducted from September 9 to September 13, with an additional day on October 15, 2013. During the September phase of the trial, both sides presented evidence relating to the motion to dismiss, particularly with respect

¹ Several separate but related actions were consolidated on September 26, 2011. (D.I. 21) The Watson Defendants were added on July 11, 2012. (D.I. 103)

to the prosecution history of the '115 patent. After hearing that evidence, the Court ordered the parties to provide supplemental briefing relating to the motion to dismiss, briefing which the parties completed on September 30, 2013. (*See* D.I. 419 ¶ 6; D.I. 420-26)

II. PROSECUTION HISTORY

The prosecution history related to the '115 patent involves three interrelated lines of filings, consisting of (1) a series of original filings, (2) a series of Patent Cooperation Treaty ("PCT") filings, and (3) a reissuance proceeding.

On June 9, 1992, Dr. Richard Smith filed U.S. Patent Application Serial No. 07/896,053 (the "'053 application"). (DTX 32 at AVAN-0403490) An examiner with the United States Patent and Trademark Office ("PTO") issued a final office action for the '053 application on April 28, 1993, which required a response within three months, by July 28, 2013. (DTX 32 at AVAN-0403617-18) On August 30, 1993, the applicant mailed a petition for a retroactive one-month extension for the '053 application. (DTX 32 at AVAN-0403620) On that same date, the applicant also mailed a conditional express abandonment² of the '053 application (DTX 32 at AVAN-0403619) as well as a continuation-in-part application ("C-I-P") of the '053 application (*see id.*), which became known as U.S. Patent Application Serial No. 08/114,845 (the "'845 application") (DTX 127 at AVAN-0316787). The PTO granted the one-month extension for the '053 application up to August 30, 1993. (DTX 32 at AVAN-0403678) No further extensions were either sought or received. On December 8, 1993, the examiner issued a notice of

² The conditional abandonment stated, "[a]pplicant hereby expressly abandons the above-identified ['053] patent application. This abandonment is conditional upon granting of a serial number and filing date for the enclosed C-I-P application [i.e., what became the '845 application]." (DTX 32 at AVAN-0403619)

abandonment of the '053 application. (DTX 32 at AVAN-0403621) In the meantime, on September 3, 1993, the '845 application was filed. (DTX 127 at AVAN-0316787)

On September 22, 1994, Drs. Richard Smith and Jonathan Licht filed PCT International Application No. PCT/US94/10771 (the "'771 application"). (DTX 638 at AVAN-0207672-710) Subsequently, on September 19, 1996, Drs. Smith and Licht filed a U.S. national stage application of the '771 application, known as U.S. Patent Application Serial No. 08/464,792 (the "'792 application"). (DTX 179 at AVAN-0207665) Neither the '771 application (*see* DTX 638) nor the national stage '792 application (*see* DTX 179 at AVAN-0207667) included priority claims to either the '053 or '845 applications.

On March 10, 1997, during prosecution of the '792 application, the examiner rejected claims 1-4 as obvious under 35 U.S.C. § 103(a) over the Zhang 1992 reference.³ (*Id.* at AVAN-0207773) In response, the applicants did not address the teachings of the Zhang 1992 reference, but instead attempted to claim priority back to the '053 application, whose filing date pre-dated the Zhang 1992 reference. (*See id.* at AVAN-0207864) Specifically, the applicants contended that the '792 application enjoyed a continuous line of co-pendency back to the '053 application through (i) the '845 application and (ii) the '771 application. (*Id.*) On December 19, 1997, the examiner mailed a notice of allowability of the '792 application; no reason for the allowance was provided. (*See id.* at AVAN-0207874-77) On October 7, 1998, the examiner issued an examiner's amendment removing the '053 and '845 applications from the list of cross-referenced patent applications in the first paragraph of the specification of the '792 application and replacing

³ Zhang et al., "Dextromethorphan: Enhancing its systemic availability by way of low-dose quinidine-mediated inhibition of cytochrome P4502D6," *Clin. Pharmacol. Ther.*, 51:647-55 (1992) ("Zhang 1992"). (DTX 60 at AVAN-0207762-70)

them with reference to the '771 application. (*Id.* at AVAN-0207883-84) The '792 application issued as U.S. Patent No. 5,863,927 (the "'927 patent") on January 26, 1999, without any priority claim to the '053 or '845 applications. (DTX 20)

On January 18, 2002, the applicants filed U.S. Patent Application Serial No. 10/052,698 (the "'698 application") for reissuance of the '927 patent. (DTX 180 at AVAN-0209475-77) The applicants sought to claim priority to the '053 and '845 applications. (*Id.*) The examiner issued the '698 application as the '115 patent without a reference to the '053 and '845 applications on the face of the patent; however, the '053 and '845 applications were listed in the first paragraph of the '115 patent specification. (DTX 18)

During the present litigation, on March 26, 2013, Plaintiffs filed an ePetition to revive the '053 application and correct what Defendants allege was a lack of co-pendency with the '845 application. (D.I. 371 Ex. B; *see also* D.I. 397 at 3) Plaintiffs did not file a terminal disclaimer with the ePetition. (*See* D.I. 371 Ex. B) The ePetition was granted on the same date it was filed, March 26, 2013. (*Id.* at 4)

III. LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter. As the question of subject matter jurisdiction under Rule 12(b)(1) is not unique to patent law, it is governed by the law of the regional Circuit, here the Third Circuit. *See Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1380 (Fed. Cir. 2002) ("We review a dismissal for lack of subject matter jurisdiction according to regional circuit law, since it is a procedural question not unique to patent law.").

Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to

the Court's subject matter jurisdiction. *See Gould Elec., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). In reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to those allegations. *See Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions, and testimony, to resolve any factual issues bearing on jurisdiction. *See Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997). Once the Court's subject matter jurisdiction is challenged, the plaintiff bears the burden of proving jurisdiction exists. *See Mortensen*, 549 F.2d at 891.

IV. DISCUSSION

Plaintiffs contend that the '115 patent claims priority to June 9, 1992, the filing date of the '053 application, through the '845 application.⁴ (D.I. 397 at 1-3) This priority claim is predicated on Plaintiffs' assertion that the '053 and '845 applications were co-pending. *See* 35 U.S.C. § 120 ("No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application.")⁵ During the instant litigation, however,

⁴ As discussed above, during prosecution of the '792 application, the applicants also attempted to claim priority through the '771 application. It is unclear, however, whether Plaintiffs are advancing this theory. (*See* D.I. 397, 420; *see also* Trial Tr. at 988 ("I agree that they didn't initially claim priority when they filed the PCT ['771] application") (testimony of Plaintiffs' expert, Mr. Godici))

⁵ In the text of this opinion, the Court quotes and applies the current version of § 120. An earlier version of § 120 was in effect at the time the '845 application was filed, and it provided:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title [35

Defendants advised Plaintiffs that, in Defendants' view, the '053 application was abandoned three days before the '845 application was filed, creating a gap in co-pendency. (See D.I. 423 at 1; D.I. 423-1 Ex. A at 5 (Watson's Invalidity Contentions)) At least in part as a response to Defendants' contentions, on March 26, 2013 Plaintiffs filed an ePetition to revive the '053 application and correct any lack of co-pendency. (See DTX 174; see also D.I. 397 at 3) In Defendants' view, the consequence of Plaintiffs' filing of the ePetition is that the '115 patent retroactively expired on June 9, 2012 – rather than January 26, 2016, which Defendants agree was the '115 patent's pre-ePetition expiration date (D.I. 371 at 2 n.1) – due to the terminal disclaimer Plaintiffs should have filed (but did not) under 37 C.F.R. § 1.137(d)(2). In other words, Defendants assert that, in exchange for revival of the abandoned '053 application, which would allow Plaintiffs to get behind certain prior art, Plaintiffs were required to dedicate the terminal period of their patent term to the public, via a terminal disclaimer. (D.I. 371 at 1) Plaintiffs' failure to file a terminal disclaimer should, Defendants continue, lead to dismissal of Plaintiffs' attempt to enforce the

U.S.C. § 112] in an application previously filed in the United States, or as provided by section 363 of this title [35 U.S.C. § 363], which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120 (1993). There is no material difference, for the purposes of the issues before the Court, between the 1993 version of the statute and the current version. The parties evidently agree on this point, as they do not address the fact that the statute has been amended. Indeed, even Plaintiffs acknowledge that § 120 "***requires that an application claiming the benefit of an earlier filing date be co-pending with the parent application.***" (D.I. 422 at 8) (emphasis in original)

'115 patent, as the Court should "equitably enforce the consequences of Plaintiffs' actions by declaring the '115 patent expired and dismissing all related claims." (D.I. 409 at 10; *see also* D.I. 371 at 9) It follows, as Defendants see it, that the Court lacks subject matter jurisdiction to resolve issues relating to the infringement or validity of this patent.

Plaintiffs respond on multiple grounds. First, Plaintiffs contend that this Court is the wrong forum to address Defendants' contentions, as improper revival and prosecution irregularities are not grounds on which the Court may invalidate a patent. Next, Plaintiffs assert that there was no gap in co-pendency of the pertinent patent applications and, even if there were, the ePetition corrected any resulting problems. Plaintiffs further insist that no terminal disclaimer was required to accompany the ePetition. Finally, Plaintiffs contend that even if they are incorrect on each of the preceding points, Defendants are entitled to no relief, and especially not a judicial declaration that the '115 patent is expired.

The Court considers each of these issues below.

A. Jurisdiction

As a threshold issue, the Court must determine if this Court is an appropriate forum to decide the issues Defendants have raised in their motion. Plaintiffs, relying on the Federal Circuit's decision in *Aristocrat Technologies Australia PTY Ltd. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008), assert that "any determination of whether a terminal disclaimer was required is within the exclusive province of the PTO," so Defendants may only litigate their present contentions via a separate action brought pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, which would have to be filed against the PTO in the Eastern District of Virginia. (D.I. 420 at 6-7) Plaintiffs argue that "[b]ecause *Aristocrat* unequivocally

foreclosed the ability of a party to assert improper revival as a defense to patent infringement in the underlying infringement litigation, the only potential claim Defendants might assert to challenge the grant of the ePetition without a terminal disclaimer is an APA claim that the PTO's grant of the petition was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (D.I. 420 at 7) (internal quotation marks omitted)

While *Aristocrat* holds that "improper revival may not be asserted as a defense in an action involving the validity or infringement of a patent," 543 F.3d at 663, *Aristocrat* did not consider a challenge to a court's subject matter jurisdiction.⁶ That is, *Aristocrat* involved a validity challenge under Title 35 relying on improper revival as a defense to liability, not, as here, an issue as to the jurisdiction of a court to resolve disputes over patent priority and patent term, which is an issue arising under 28 U.S.C. § 1338(a). The fundamental initial question before the Court is whether this Court has jurisdiction, *not* (as in *Aristocrat*) whether the patent-in-suit is invalid because of "improper revival." Nothing in *Aristocrat* precludes this Court from deciding the jurisdictional question. More fundamentally, nothing in *Aristocrat* – nor any other authority to which the parties have cited – trumps the well-settled, general proposition that federal courts

⁶ The Court recognizes that *Aristocrat* contains broad statements as to the non-viability of a defense of "improper revival." See 543 F.3d at 659 ("We conclude that 'improper revival' is not a cognizable defense in an action involving the validity or infringement of a patent."); *id.* at 661 ("We conclude that 'improper revival' may not be raised as a defense in an action involving the validity or infringement of a patent."); *id.* at 663 ("Because the proper revival of an abandoned application is neither a fact or act made a defense by title 35 nor a ground specified in part II of title 35 as a condition for patentability, we hold that improper revival may not be asserted as a defense in an action involving the validity or infringement of a patent."); *id.* ("[I]mproper revival is not a defense . . ."); *id.* at 665 ("[W]e have concluded that 'improper revival' is not a cognizable defense . . ."). However, under the very different circumstances presented here, the implications of *Aristocrat* for the issues confronting this Court are not straightforward. Hence, it will be necessary at various points in this opinion to address how *Aristocrat* does, and does not, apply.

always possess the authority and obligation to examine their own jurisdiction over disputes brought before them. *See, e.g., Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006) ("[C]ourts . . . have an independent obligation to determine whether subject-matter jurisdiction exists, even in the absence of a challenge from any party.").

Therefore, the Court will proceed to the next steps of the analysis.

B. Co-pendency

The Court must determine whether there was a lack of co-pendency between the '053 application and the '845 application. Having considered the evidence of record as well as the parties' arguments, including the trial testimony and extensive briefing, the Court finds that there was a three-day gap between the abandonment of the '053 application and the filing of the '845 application. Specifically, the '053 application was abandoned on August 30, 1993, but the '845 application was not filed until September 2, 1993. (D.I. 127 at AVAN-0316787; *see also* D.I. 397 Ex. B at Par Pharma DEX 0014576)⁷

Plaintiffs' own expert, Nicholas Godici, acknowledges the gap that occurred between the '053 application's abandonment and the '845 application's filing. (D.I. 409 Ex. A at 89 (stating that nothing in file history indicates that '053 application had extension beyond August 30); *id.* at 81 (noting that '845 application has September 2 filing date); Trial Tr. at 1006 (agreeing that '845 application's filing date was September 2); *id.* at 1007 (agreeing generally that there would have

⁷ As noted earlier, the PTO issued the final office action on the '053 application on April 28, 1993, requiring a response within three months. (DTX 32 at AVAN-0403617-18) On August 30, 1993, the applicant filed a petition for a one-month extension (DTX 32 at AVAN-0403620), which the PTO granted, keeping the the '053 application alive until August 30, 1993 (DTX 32 at AVAN-0403678). No additional extensions were sought or received. The '845 application was filed three days later, on September 2, 1993. (DTX 127 at AVAN-0316787)

been no need to file petition to revive '053 application if it had been co-pending with '845 application))

Plaintiffs offer several, unconvincing arguments for the purported existence of co-pendency. Plaintiffs contend that the "'053 application's abandonment was conditional upon the granting of the filing date for the '845 application." (D.I. 420 at 3; *see also* D.I. 397 Ex. A at ParPharma DEX 0014480) While it seems clear from the prosecution history that the applicant *intended* that the '053 application not be abandoned until after the '845 application was filed, it is nonetheless the case that this is *not* what actually occurred. The undisputed evidence shows that, instead, the applicant prosecuted the '053 application only until August 30, 1993. (DTX 32 at AVAN-0403678) Under these circumstances, the result is mandated by statute: "Upon failure of the applicant to prosecute the application . . . the application shall be regarded as abandoned." 35 U.S.C. § 133.

Plaintiffs next argue that "even if the conditional abandonment of the '053 application was ineffective to initially establish co-pendency, the evidence shows that the PTO exercised its discretion to establish co-pendency and grant the '845 application . . . priority to the '053 application." (D.I. 420 at 3; *see also* D.I. 422-1 Ex. K at AVAN-0316838 (examiner writing that '053 and '845 applications were co-pending)) Essentially, Plaintiffs contend that because the PTO considered the '053 and '845 applications to be co-pending during prosecution (before the ePetition was filed), it is improper for the Court even to question the PTO's decision on this point. In making this argument, Plaintiffs rely again on *Aristocrat*, as well as *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956 (Fed. Cir. 1997), for the proposition that "[a]bsent proof of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules

of patent examination becomes irrelevant after the patent has issued." *Aristocrat*, 543 F.3d at 663 (citing *Magnivision*, 115 F.3d at 960).

Again, however, Plaintiffs read too much into these decisions, which are predicated on the principle that "[t]here is good reason not to permit procedural irregularities during prosecution, such as the one at issue here, to provide *a basis for invalidity*." *Aristocrat*, 543 F.3d at 663 (emphasis added). The issue before this Court, however, is whether, even if the PTO did treat the '053 and '845 applications as co-pending, did co-pendency actually exist? This inquiry is statutorily demanded in determining the correct priority date; for any patent application claiming priority to an earlier application, co-pendency is required under § 120. *Aristocrat* did not concern co-pending applications, and it did not address § 120. In the Court's view, *Aristocrat* does not prohibit a factual inquiry into the existence of statutorily required co-pendency.

Plaintiffs have cited no authority for the proposition that the PTO has "discretionary authority" to treat two applications as co-pending when, as a matter of fact, they were not co-pending.⁸ Section 120 is written in absolute terms – "*No application* shall be entitled to the benefit of an earlier filed application under this section *unless* an amendment containing the

⁸ To the extent that Plaintiffs suggest the prosecution of the '792 application cured any lack of co-pendency between the '053 and '845 applications (*see, e.g.*, D.I. 397 at 8-9), this is incorrect, for reasons including that the '792 application could not claim priority to the '053 or '845 applications. (*See* Trial Tr. at 954-55 (testimony of Defendant's expert, Mr. Carmichael)) MPEP § 1893.03(c) states that for "a national stage application (of international application 'X') to obtain benefit under 35 U.S.C. 120 of a prior U.S. national application, the international application ('X') must include an appropriate reference in the Request to the prior U.S. national application." MPEP § 1893.03(c) (6th ed., Rev. 3, July 1997). The '771 application – the international parent of the national stage '792 application – made no reference to the '053 or '845 applications. (DTX 638) Ultimately, the '792 application issued as the '927 patent with no priority claim. (*Id.* at 953-54)

specific reference to the earlier filed application is submitted at such time *during the pendency of the application.*" – which does not suggest the PTO has such discretion. Even if the PTO has such discretion and exercises it, Plaintiffs have cited no authority for the proposition that a Court faced with determining the proper priority date of a patent-in-suit cannot, nonetheless, consider what may be the actual facts with respect to the non-existence of co-pendency of two applications.

Plaintiffs contend that the issuance of the '115 reissue patent, in which Plaintiffs successfully added the '053 and '845 applications to the language of the specification under "Related Applications" (D.I. 422 Ex E at 1), is dispositive of co-pendency.⁹ (D.I. 422 at 8) But Plaintiffs point to no authority for the proposition that a patent applicant or the PTO can cure a lack of co-pendency through prosecution of a reissue.¹⁰ During reissue proceedings, the statutory

⁹ As a factual matter, it is unclear whether the PTO analyzed either co-pendency or priority during the '115 reissuance proceedings. In their reissue application, the applicants sought to amend the specification to add language about the '053 and '845 applications and allow a priority claim to them. (*See* DTX 180; Trial Tr. at 955) The PTO accepted the change to the specification's language; however, the PTO appears never to have conducted any review of the '053 and '845 applications which formed the basis for the applicants' change in priority. Indeed, the examiner did not check the box indicating acknowledgment of the priority claim (DTX 180 at AVAN-0209537); the Bib Data Sheet for cross-checking of continuity data shows no priority claims to these applications (*id.* at AVAN-0209507); and there is no priority claim to the '053 or '845 applications on the face of the '115 patent (D.I. 426-1). Consequently, the statement added to the specification lists prosecution history but does not necessarily stake out a position on priority date. (*See* Trial Tr. at 955-57)

¹⁰ Plaintiffs cite 37 C.F.R. § 178(a)(2)(iii) (2002, as amended Dec. 28, 2001) (D.I. 422 at 8), which states that "[i]f the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title." While such a reference is necessary to establish priority, nothing in this section suggests that compliance with this single provision is itself sufficient to cure a lack of co-pendency or to establish priority.

requirement of § 120 remains – and, here, it was not satisfied.

Hence, the Court finds, based on the evidence, most of which is undisputed, that there was a lack of co-pendency of the '053 and '845 applications.

C. Terminal Disclaimer

Because there was a lack of co-pendency, and the '053 application was abandoned, the Court must next consider Plaintiffs' attempt to revive that application. Plaintiffs filed a petition to revive; however, Plaintiffs did not include a terminal disclaimer with their petition. The Court agrees with Defendants that, under the circumstances here, a grantable petition to revive would have to be accompanied by a terminal disclaimer.

On March 26, 2013, Plaintiffs filed an ePetition, which sought to claim priority for the '115 patent back to a revived '053 application. (D.I. 371 Ex. B at 3) To determine whether this ePetition required a terminal disclaimer, the Court must apply 37 C.F.R. § 1.137(d)(1) & (2),¹¹ which provides (with emphasis added):

Terminal disclaimer. (1) *Any petition to revive pursuant to this section in either a utility or plant application filed before June 8, 1995, must be accompanied by a terminal disclaimer and fee as set forth in § 1.321 dedicating to the public a terminal part of the term of any patent granted thereon equivalent to the lesser of: (i) The period of abandonment of the application; or (ii) The period extending beyond twenty years from the date on which the application for the patent was filed in the United States . . .*

(2) *Any terminal disclaimer pursuant to paragraph (d)(1) of this section must also apply to any patent granted on a continuing utility or plant application filed before June 8,*

¹¹ Plaintiffs filed their ePetition pursuant to 37 C.F.R. § 1.137(b), which states that a "grantable petition pursuant to this paragraph must be accompanied by . . . any terminal disclaimer . . . required pursuant to paragraph (d) of this section."

1995, or a continuing design application, that contains a *specific reference under 35 U.S.C. 120*, 121, or 365(c) to the application for which revival is sought.

Section 1.137(d)(1) & (2) required a terminal disclaimer to be filed with the ePetition.

With regard to the conditions set out in paragraph (d)(1), (i) Plaintiffs submitted a petition to revive pursuant to § 1.137 (D.I. 371 Ex. B) and (ii) the utility application being revived, the '053 application, was filed on June 9, 1992, predating June 8, 1995. Accordingly, to be grantable, the petition to revive the '053 application required a terminal disclaimer. (*See* 37 C.F.R. § 1.137(b); *see also* Trial Tr. at 958-60)¹² With regard to the conditions set out in paragraph (d)(2), (i) the '115 patent was a patent granted from a continuing utility application; (ii) the '115 patent was filed on September 22, 1994,¹³ predating June 8, 1995; and (iii) the '115 patent contains a specific reference under 35 U.S.C. § 120 to the '053 application, which is the application for which revival is sought. (D.I. 371 Ex. F at ParPharma DEX 0016590-91) It follows that in order for the petition to revive the '053 application to be grantable, the terminal disclaimer required pursuant to (d)(1) "must also apply" pursuant to (d)(2) to the '115 patent. (*See* 37 C.F.R. §

¹² Section 1.137(d)(3) provides, "The provisions of paragraph (d)(1) of this section do not apply to applications for which revival is sought solely for purposes of co-pendency with a utility or plant application filed on or after June 8, 1995, to lapsed patents, to reissue applications, or to reexamination proceedings." None of these exceptions applies here: the '053 application was filed before June 8, 1995 and is not a reissue application, and no lapsed patents or reexamination proceedings are involved here.

¹³ The filing date of the '115 patent is the filing date of the international PCT parent application (the '771 application), which is September 22, 1994. *See* 35 U.S.C. § 252 (reissue is continuation of original patent); D.I. 371 Ex. A at ParPharma DEX 0014599; D.I. 409 Ex. C at ¶¶ 15-16 (stating that application leading to '927 patent – and, ultimately, '115 patent – has filing date of September 22, 1994)

1.37(b); *see also* Trial Tr. at 960-63)¹⁴

Plaintiffs' arguments against this conclusion are unavailing. Plaintiffs contend that the '115 patent does not come within the scope of § 1.137(d)(2) because it is a reissue application and the reissue application's actual filing date is after June 8, 1995. (D.I. 422 at 5) However, the statute provides that "every reissue patent shall have the same effect and operation in law" as the original patent and, further, "shall constitute a continuation thereof and have effect continuously from the date of the original patent." 35 U.S.C. § 252. Plaintiffs cite no authority to contradict the logical conclusion from this statutory language that a reissue application is, indeed, a "continuing . . . application" within the meaning of § 1.137(d)(2). Hence, the '115 reissue patent is, for these purposes, a continuation of the '927 patent, which is traced back to the '771 application, which was filed before June 8, 1995, on September 22, 1994. It follows that Plaintiffs' contention that the applicable application date is January 18, 2002 (D.I. 422 at 5) – the filing date of the '698 reissue application – is incorrect.¹⁵

¹⁴ Plaintiffs argue that no patent ever issued from the '053 application, so there is no patent term to disclaim under paragraph (d)(1), and therefore no terminal disclaimer is required under paragraph (d)(2) with respect to the '115 patent. (*See* D.I. 397 at 10) This is not convincing. Because the conditions of (d)(1) are satisfied – even though no term of the '053 application, which is only an application, can be disclaimed – (d)(2) requires a further examination to identify any other patents to which the same terminal disclaimer "must also apply." Here, that includes the '115 patent.

¹⁵ Plaintiffs further argue that "the relevant filing date for purposes of 37 CFR § 1.137(d)(2) is the actual filing date, rather than the effective date." (D.I. 422 at 5) However, Plaintiffs' argument again presupposes that the relevant date is calculated from the *reissue application*, rather than from the *original patent*. As explained above, given the statutory relationship between the original patent and its reissue, the filing date of the '115 reissue application is irrelevant to the analysis. It is the original patent's critical date that governs. Whether the actual filing date of the original '927 patent is used (September 22, 1994) or that patent's effective date (alleged by Plaintiffs to be June 9, 1992) is immaterial here, as both are before June 8, 1995.

Plaintiffs argue no terminal disclaimer was required because the '053 application never issued as a patent and, therefore, the rationale behind terminal disclaimers does not apply, because there is no improper extension of the '053 patent term. (D.I. 397 at 11) As an initial matter, Plaintiffs cite no authority for what they purport to be the rationale for the terminal disclaimer requirement.¹⁶ Further, Plaintiffs' contention is inapposite: the term at issue is the term of the '115 patent, as affected by paragraph (d)(2), not the term of any patent that issued from the '053 application (which would be the subject of paragraph (d)(1)). In any event, to the extent Plaintiffs are correct that "the purpose of a terminal disclaimer is to prevent a patentee from improperly extending its monopoly over patented subject matter" (*id.*), here that rationale *favours* requiring a terminal disclaimer, as without a disclaimer the '115 patent would enjoy a priority date stretching back to June 1992 yet would still retain its full term until January 2016.

Plaintiffs also suggest that if a terminal disclaimer were required, the PTO would have rejected their ePetition, so the PTO's acceptance of the ePetition indicates that no terminal disclaimer was necessary. (*See id.* at 5) This contention overlooks the undisputed evidence that the PTO's automated system automatically granted the ePetition based on Plaintiffs' checking a box indicating *Plaintiffs'* position that a "[t]erminal disclaimer and fee are not required" (DTX 32 at AVAN-0403496), without any independent evaluation of the merits of that position by

¹⁶ The Court has found little discussion of the rationale for a terminal disclaimer, and none arising in circumstances similar to those presented here. For instance, there are decisions addressing terminal disclaimers under 35 U.S.C. § 253, in the context of obvious-type double-patenting. *See, e.g., Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1323 (Fed. Cir. 2007) ("The purpose of the terminal disclaimer [is] to prevent extension of [the] patent term for subject matter that would have been obvious over an earlier filed patent.").

anyone (or even by any computer) (*see* DTX 592; D.I. 409 Ex. C at ¶ 12 (stating PTO automatically grants ePetition "[o]nce all of the items are correctly filled out," without undertaking review on the merits); Trial Tr. at 963-64).

In sum, in order to be properly granted, Plaintiffs' ePetition was required to include a terminal disclaimer, which would have dedicated to the public any portion of the '115 patent's term extending beyond June 9, 2012.¹⁷ It is undisputed that Plaintiffs failed to include such a terminal disclaimer with their March 2013 ePetition.

D. Remedy

Having determined that Plaintiffs' ePetition was required to be accompanied by a terminal disclaimer, which would have resulted in the '115 patent's expiration, and it being undisputed that Plaintiffs did not file a terminal disclaimer, the Court next confronts the difficult matter of discerning the appropriate consequences. Defendants request that the Court either require Plaintiffs to return to the PTO and file a petition accompanied by the necessary terminal disclaimer or, alternatively, simply find that the '115 patent is expired. (D.I. 421 at 8-9)

¹⁷ Pursuant to 37 C.F.R. § 1.137(d)(1)(i) & (ii), the terminal disclaimer

dedicat[es] to the public a terminal part of the term of any patent granted thereon equivalent to the lesser of: (i) The period of abandonment of the application; or (ii) The period extending beyond twenty years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application(s) under 35 U.S.C. 120, 121, or 365(c), from the date on which the earliest such application was filed.

The '053 application was abandoned for more than nineteen years; hence, the period of the required disclaimer is determined pursuant to (d)(1)(ii), and is equal to any patent term beyond twenty years from the '053 application's filing date, i.e., the time between June 9, 2012 and January 26, 2016.

Plaintiffs, understandably, oppose both of these proposed remedies. Plaintiffs observe that, had the PTO determined that the March 2013 ePetition required a terminal disclaimer, the PTO's response would have been to dismiss the petition and provide Plaintiffs the *option* to refile. (D.I. 397 at 1; *see also* Trial Tr. at 994 (testimony of Plaintiffs' expert, Mr. Godici)) Defendants appear to agree that this is what would have occurred.

It follows, in the Court's view, that Plaintiffs should not be left with something less than they would have had if the PTO had reviewed the ePetition on its merits and determined that a terminal disclaimer was required. Defendants cite no authority for the proposition that the Court is obligated to order Plaintiffs to refile their petition with a terminal disclaimer or to declare the '115 patent expired. Nor do Defendants make a convincing case for the Court exercising whatever equitable discretion it has to accomplish such a result.

Unfortunately, Plaintiffs' proposed "remedy" is untenable as well. Plaintiffs ask the Court to do nothing, allowing them to retain the '115 patent's term until January 26, 2016 while also obtaining a priority date back to June 9, 1992. (*See* D.I. 422 at 10) For this conclusion, Plaintiffs rely again on *Aristocrat*, but again their position is unavailing. In *Aristocrat*, the defendants sought to invalidate the '215 patent, contending the original '215 application was abandoned by an improperly granted petition to revive and that this, alone, was sufficient grounds for a defense of invalidity. *See* 543 F.3d at 660.¹⁸ Indeed, since the '215 patent relied on only a single

¹⁸ The *Aristocrat* defendants argued, "Plaintiffs abandoned their '215 Application by: (1) failing to timely file the national fee that was due on January 10, 2000 under 35 U.S.C. § 371; (2) failing to timely file a response to the PTO's June 5, 2001 notice reaffirming abandonment under 35 U.S.C. § 133; and (3) failing to make an adequate 'showing' in their Petition to Revive that their delays were 'unavoidable,' as specifically required under Sections 133 and 371." *Aristocrat Technologies Australia PTY Ltd. v. Int'l Game Tech.*, 491 F. Supp. 2d 916, 923 (N.D. Cal. 2007) *rev'd*, 543 F.3d 657 (Fed. Cir. 2008).

application, the defendants' improper revival argument, if accepted, would have eliminated the only basis for the '215 patent's existence. *See id.* Here, by contrast, the Court's finding of abandonment of the '053 application simply affects the priority date; it does not itself directly form the grounds for "a defense that the patent is invalid." The prosecution history here is far more complicated than the history in *Aristocrat* and, here, there are several other applications to which Plaintiffs can claim priority.¹⁹

Aristocrat is further distinguishable on other grounds as well. In reaching its holding in *Aristocrat*, the Federal Circuit observed that improper revival is not a defense that is found either in § 282 or elsewhere in the Patent Act. The Court further reasoned that it could reject recognition of the proposed improper revival defense because it did not, in *Aristocrat*, confront a situation in which the "failure to impose invalidity for violation of the statute would encourage noncompliance." 543 F.3d at 664. The Court could "discern no legitimate incentive for a patent applicant to intentionally abandon its application, much less to attempt to persuade the PTO to improperly revive it." *Id.* Specifically, the Court concluded that because "patents filed *after enactment of the Uruguay Round Agreements Act* [*"GATT"*]²⁰, like the patents at issue here,

¹⁹ A finding that the priority date of the '115 patent is after the Zhang 1992 reference does not automatically invalidate any claim of the '115 patent. Plaintiffs have had an opportunity at trial to present evidence as to the non-obviousness of the patent claims. The Court has not yet made any findings as to the validity of the '115 patent and will not do so until after receiving and reviewing the parties' post-trial briefs.

²⁰ The General Agreement on Tariffs and Trade ("GATT") is the basis for the June 8, 1995 date called out in § 1.137(d). Patents that issued from applications filed *after* June 8, 1995 receive a 20-year term from the date of filing of the application. *See* 35 U.S.C. § 154(a)(2). Patents claiming priority to applications filed *before* June 8, 1995, however, have a patent term which is the greater of 20 years from the date of the filing of the application or 17 years from the date of the grant of the patent, subject to any terminal disclaimers. *See id.* § 154(c)(1).

generally have a term that runs twenty years from the filing date (instead of seventeen years from issue) . . . abandoning the application would only serve to shorten the applicant's right to exclude." *Id.* (emphasis added).

Here, by contrast, the '115 patent relates to a *pre-GATT filing*, giving rise to a situation in which the disincentives present in *Aristocrat* do not exist. Instead, under the circumstance here, an applicant receives a term of 17 years from *issuance*. Because the patent term is not governed by the filing date, the patent term "clock" does not start "ticking" during prosecution, which provides an opportunity for an applicant to abandon the application and stretch out prosecution without consequences for the patent term. In turn, the automated ePetition process provides an opportunity for the applicant to revive the application to obtain an earlier priority date from an abandoned application and simply check the "terminal disclaimer not required" box to avoid dedicating a terminal part of the patent term to the public. The result is, as the present case illustrates, that an applicant may stretch back the priority date to avoid prior art while keeping a full patent term. Thus, unlike the post-GATT filings involved in *Aristocrat*, abandonment of a pre-GATT filing in no way "shorten[s] the applicant's right to exclude" – *unless* a terminal disclaimer is required. Hence, under the circumstances here, a failure to enforce the terminal disclaimer requirement *would* encourage noncompliance with prosecution procedures.

Additionally, here, unlike what was attempted by the defendants in *Aristocrat*, the Court is not permitting Defendants to argue that improper revival, or any other prosecution irregularity, invalidates the '115 patent. Instead, under the circumstances here, the Court is faced with issues relating to the determination of a priority date, and the Court's resolution of the parties' dispute does not mandate invalidation of the patent. Therefore, the Court is not permitting "procedural

irregularities . . . to provide a basis for invalidity," *Aristocrat*, 543 F.3d at 663; instead, the Court is considering the entirety of the prosecution history for purposes of determining the correct priority date for a patent-in-suit.²¹

Having rejected both parties' positions with respect to an appropriate remedy, the Court must determine what to do. The resolution to this question begins from the premise that had the PTO dismissed the ePetition, while the '115 patent would not expire until January 26, 2016, the '115 patent also would not claim priority to the '053 application filing date; rather, the '115 patent could only claim priority to the '845 application, which was filed on September 2, 1993 and was not abandoned. Under the circumstances, the Court concludes that the '115 patent may either (i) claim priority back to June 9, 1992 – the '053 application's filing date – and then its terminal period must be disclaimed, pursuant to § 1.137(d)(2), meaning the '115 patent would have expired on June 9, 2012; or (ii) claim priority to September 2, 1993 – the '845 application's filing date – and would not expire until the end of its full term, on January 26, 2016.²² Plaintiffs, then, have options, and the Court sees no reason to foreclose Plaintiffs from making an election to

²¹ Plaintiffs cite to *Promega Corp. v. Applied Biosystems, LLC*, No. 12-3333, D.I. 274 at 14 (N.D. Ill. Apr. 4, 2013) (*see* D.I. 420 at 4-5), in which Judge Posner, citing *Aristocrat*, stated that "[t]he fate of protection for intellectual property . . . should not be allowed to turn on a slip of scheduling of a single day, over twenty years ago." There, Judge Posner would have rejected a defense argument relating to priority date that was based on an alleged one-day break in co-pendency in the chain of patent applications that occurred back in February 1991. *See id.* The *Promega* court's statement was dicta, as the court found both that there was no break in co-pendency and that defendants' argument to the contrary had been waived. *See id.* In any event, notwithstanding *Promega*, this Court concludes that, in the circumstances presented by the instant case, the prosecution history here does impact the priority date (although no finding has yet been made with respect to validity).

²² Pursuant to 35 U.S.C. § 154(c)(1), the '115 reissue patent's term is calculated from the issuance date of the original '927 patent, which is January 26, 1999 (DTX 20).

pursue whichever is their preferred option.

Accordingly, the Court concludes that Plaintiffs' ePetition to revive the abandoned '053 application was inoperative,²³ due to Plaintiffs' failure to comply with the terminal disclaimer requirements of 37 C.F.R. § 1.137(d)(1) & (2). In turn, the '053 application remains abandoned and, pursuant to 35 U.S.C. § 120, Plaintiffs cannot claim its priority date. At present, the '115 patent can only claim priority back to the '845 application's filing date, which is September 2, 1993. Alternatively, Plaintiffs may seek to refile their petition to revive the '053 application, accompanied this time by the required terminal disclaimer, which would result in an earlier priority date as well as an earlier expiration date.

At this point, the '115 patent continues to enjoy a presumption of validity, *see* 35 U.S.C. § 282; *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 93 n.15 (1993), and has not been determined by either the PTO or this Court to have expired. It follows that the Court continues to have subject matter jurisdiction over the parties' disputes relating to the '115 patent.

Accordingly, the Court will deny Defendants' motion to dismiss.

V. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' Rule 12(b)(1) motion to dismiss. An appropriate Order follows.

²³ Plaintiffs agree that if a terminal disclaimer was required, "the remedy would be, at most, that the ePetition is inoperative." (D.I. 422 at 6)

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AVANIR PHARMACEUTICALS, INC.,
AVANIR HOLDING COMPANY, AND
CENTER FOR NEUROLOGIC STUDY,

Plaintiffs,

v.

ACTAVIS SOUTH ATLANTIC LLC,
ACTAVIS, INC., PAR PHARMACEUTICAL,
INC., PAR PHARMACEUTICAL
COMPANIES, INC., IMPAX
LABORATORIES, INC., WOCKHARDT,
LTD., WOCKHARDT USA, LLC, WATSON
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., AND WATSON
PHARMA, INC.,

Defendants.

C.A. No. 11-704-LPS
(CONSOLIDATED)

ORDER

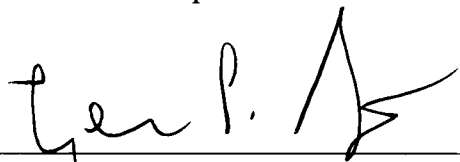
At Wilmington, this **25th** day of **October 2013**,

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. Defendants' Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction Based on the Expiration of Asserted U.S. Patent No. RE38,115 (D.I. 371) is **DENIED**.

2. The Court will reconsider its subject matter jurisdiction with respect to the '115 patent should it be advised by the parties that Plaintiffs hereafter file a petition to revive the '053 application accompanied by a terminal disclaimer.


UNITED STATES DISTRICT JUDGE