IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

BONE CARE INTERNATIONAL, LLC and GENZYME CORPORATION,)	
Plaintiffs)) (Cara Na 100 are 1002	
v.) Case No.: 08-cv-1083	
PENTECH PHARMACEUTICALS, INC., and COBREK PHARMACEUTICALS, INC.,) Judge Robert M. Dow, J	Γ.
Defendants.	,))	

MEMORANDUM OPINION AND ORDER

Plaintiffs Bone Care International, LLC and Genzyme Corporation (collectively, "Plaintiffs") brought this patent infringement suit against Defendants Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc. (collectively, "Defendants") for infringement of United States Patent No. 5,206,116 ("116 patent"). Defendants asserted affirmative defenses and counterclaims [227] alleging, *inter alia*, that the '116 patent is unenforceable because of Plaintiffs' alleged inequitable conduct in prosecution of the patent before the United States Patent and Trademark Office ("PTO"). Currently before the Court is Plaintiffs' motion for summary judgment [336] on Defendants' inequitable conduct affirmative defense "D." For the reasons stated below, Plaintiffs' motion for summary judgment [336] is granted.

I. Background

A. Factual Background

The Court takes the relevant facts primarily from the parties' Local Rule ("L.R.") 56.1¹ statements: Plaintiffs' Statement of Facts ("Pls.' SOF") [333], Defendants' Response to Plaintiffs' Statement of Facts and Statement of Additional Facts ("Defs.' Resp. to Pls'. SOF" and "Defs.' SOF") [378], and Plaintiffs' Response to Defendants' Statement of Additional Facts ("Pls.' Resp. to Defs.' SOF") [394].

The '116 patent establishes a method for using the vitamin D compound doxercalciferol to treat patients suffering from hyperparathyroidism secondary to end-stage renal failure. The '116 patent issued from the '488 application, which was the last in a chain of related applications that Bone Care filed with the PTO over the course of seven years. Specifically, the '488 application was filed on April 3, 1995, as a continuation-in-part application of the '895 application, which was filed on September 10, 1993, as a continuation of the '056 application, which was filed on December 17, 1991, as a continuation of patent application No. 596,412,

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¹ Local Rule 56.1 requires that statements of facts contain allegations of material fact and that factual allegations be supported by admissible record evidence. See L.R. 56.1; Malec v. Sanford, 191 F.R.D. 581, 583-85 (N.D. Ill. 2000). The Seventh Circuit has confirmed repeatedly that a district court has broad discretion to require strict compliance with L.R. 56.1. See, e.g., Koszola v. Bd. of Educ. of the City of Chicago, 385 F.3d 1104, 1109 (7th Cir. 2004); Curran v. Kwon, 153 F.3d 481, 486 (7th Cir. 1998) (citing Midwest Imports, Ltd. v. Coval, 71 F.3d 1311, 1317 (7th Cir. 1995 (collecting cases)). Where a party has offered a legal conclusion or a statement of fact without offering proper evidentiary support, the Court will not consider that statement. See, e.g., Malec, 191 F.R.D at 583. Additionally, where a party improperly denies a statement of fact by failing to provide adequate or proper record support for the denial, the Court deems that statement of fact to be admitted. See L.R. 56.1(a), 56.1(b)(3)(B); see also Malec, 91 F.R.D. at 584. The requirements for a response under L.R. 56.1 are "not satisfied by evasive denials that do not fairly meet the substance of the material facts asserted." Bordelon v. Chicago Sch. Reform Bd. of Trs., 233 F.3d 524, 528 (7th cir. 2000). The Court also disregards any additional statements of fact contained in a party's response brief but not in its L.R. 56.1(b)(3)(B) statement of additional facts. See, e.g., Malec, 191 F.R.D. at 584 (citing Midwest Imports, 71 F.3d at 1317). Similarly, the Court disregards a denial that, although supported by admissible record evidence, does no more than negate its opponent's fact statement. In other words, it is improper for a party to smuggle new facts into its response to a party's L.R. 56.1 statement of fact, and the Court will disregard such facts. See, e.g., Ciomber v. Cooperative Plus, Inc., 527 F.3d 635, 643 (7th Cir. 2008).

which was filed on August 17, 1990, as a continuation of the August 2, 1988, '371 application. The '371, '412, '056, and '895 applications are thus "ancestor applications" to the '488 application. PTO Examiner Theodore J. Criares was assigned to review the '412, '056, '895, and '488 applications—which means that he examined all but the original '371 application.

Plaintiffs and their attorneys submitted the same eight prior art references during prosecution of each of the '371, '412, and '056 applications. Plaintiffs did not re-submit any of these eight references during prosecution of the '488 application. They did, however, indicate in the '488 application itself that it was a continuation-in-part application and list the genealogy of the ancestor applications; they also subsequently submitted an Information Disclosure Statement ("IDS") identifying the '488 application as a continuation-in-part application. On February 11, 1997, the PTO issued the '116 patent on the basis of the '488 application. The patent expires on February 11, 2014.

On April 6, 2000, the FDA approved Plaintiff Genzyme's New Drug Application ("NDA") for doxercalciferol, and Plaintiffs began producing and selling the drug under the brand name Hectorol. Defendant Pentech later submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to manufacture, use, or sell a generic version of Hectorol. Pentech alleged in the ANDA that its application did not infringe on the '116 patent as the patent was invalid and unenforceable.

B. Procedural Background

Plaintiffs filed a complaint against Pentech and Cobrek claiming that Pentech's ANDA infringed on the '116 patent and seeking a declaratory judgment, injunctive relief, litigation costs, attorneys' fees, and, in the event that Defendants proceed with the manufacture, use, or sale of doxercalciferol prior to the 2014 expiration of the '116 patent, money damages. [197]

Defendants asserted affirmative defenses and counterclaims arguing, *inter alia*, that the '116 patent is invalid because Plaintiffs engaged in inequitable conduct during its prosecution. [227]

Plaintiffs moved to dismiss Defendants' inequitable conduct affirmative defenses and counterclaims A-G. [241]. The Court granted in part and denied in part Plaintiffs' motion, dismissing Defendants' affirmative defenses and counterclaims A, B, C, and E, but denying the motion to dismiss as to affirmative defenses and counterclaims D, F, and G.² [327] Plaintiffs now seek summary judgment on affirmative defense and counterclaim D.

II. Legal Standard

Summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

To survive a motion for summary judgment, the non-movant must go beyond the pleadings and "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 250. A mere showing that there is "some metaphysical doubt as to the material facts" is not enough. *Matsushita Elect. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). There must be more than a "mere existence of a scintilla of evidence in support of the [non-movant's] position" that a jury could reasonably find in the non-movant's favor. *Anderson*, 477 U.S. at 252. When the non-movant "fails to make a showing sufficient to establish the

² Plaintiffs moved to dismiss affirmative defense and counterclaim D on the ground that Defendants had not affirmatively explained why the eight prior references it alleged Plaintiff had omitted during prosecution of the '488 application were not cumulative. The Court rejected this argument, holding that Defendants' failure to affirmatively allege non-cumulativeness at the pleading stage was not tantamount to failure to state a claim.

existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," summary judgment is warranted. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

The party moving for summary judgment bears the burden of establishing that the nonmovant has not presented any genuine issue of material fact. See *Celotex*, 477 U.S. at 323. The Court must then "construe the facts and draw all reasonable inferences in the light most favorable to a nonmoving party." Foley v. City of Lafayette, 359 F.3d 925, 928 (7th Cir. 2004).

III. Analysis

Plaintiffs move the Court to issue summary judgment on affirmative defense and counterclaim D. Defendants allege in that counterclaim that Plaintiffs engaged in inequitable conduct that renders the '116 patent invalid by (1) intentionally failing to re-submit eight prior art references in the '488 application that were material to the patentability of the asserted claims, and (2) failing to indicate that five of those eight references were previously used by the PTO to reject similar claims made in ancestor applications.³

A determination of inequitable conduct rests on two threshold findings: (1) that the applicant breached its duty of candor and good faith by failing to disclose material information to the PTO; and (2) that, in so doing, the applicant intended to deceive or mislead the PTO examiner into granting the patent. See Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008) (citations omitted); ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998). Both findings must be established by clear and convincing evidence. Star Sci.,

³ The eight prior art references are: the 1978 Reeve publication, the DeLuca '596 patent, the Baggiolini

^{&#}x27;561 patent, the 1984 Sjoden (Acta Endocrinol) publication, the DeLuca '716 patent, the 1986 EP A 197,514 to Potts, et al. patent application, PDR 43rd Ed. pp. 1746-48 "Rocaltrol", and the Brautbar article.

537 F.3d at 1365. If the evidence supports the threshold findings, then the court must balance the equities to determine whether the patent is invalid. *Id*.

The standard for addressing the first threshold finding upon which a determination of inequitable conduct must rest—a patent applicant's duty of candor and good faith in dealings with the PTO—is set forth in section 1.56 of Title 37 of the Code of Federal Regulations. The duty is satisfied "if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) *** and 1.98." 37 C.F.R. § 1.56. Subsection (b) of section 1.56 defines information material to patentability as that which "is *not cumulative to information already of record* or being made of record in the application." 37 C.F.R. § 1.56(b) (emphasis added). In performance of this duty, applicants must provide to the PTO an IDS that lists all patents, publications, applications, and other information relevant to patentability within three months of the application filing date. 37 C.F.R. §§ 1.97(b), 1.98.

Special statutory and regulatory provisions further define the duty of disclosure in the context of "continuation applications." The term "continuation application" comprises three types of patent applications: continuation applications, continuation-in-part applications, and divisional applications. 37 C.F.R. § 1.53; *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994). A continuation application is one that claims the same invention as an ancestor application. *Id.* A continuation-in-part application is one that discloses a substantial portion of the subject matter disclosed in ancestor applications. *Id.* A divisional application is one that claims an invention independent from an ancestor application. ⁴ *Id.*

⁴ Unless otherwise specified, in this opinion the Court employs the term "continuation application" to refer to the category of applications that includes continuation applications, continuation-in-part applications, and divisional applications.

Section 1.56(e) of the Code specifies that, "[i]n any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability * * * which became available between the filing date of the prior application and the national * * * filing date of the continuation-in-part application." 37 C.F.R. § 1.56(e) (emphasis added). The Manual of Patent Examining Procedure ("M.P.E.P."), which provides guidance to patent examiners, attorneys, and applicants regarding practices and procedures for patent prosecution, further clarifies the scope of an applicant's duty in filing a continuation application. M.P.E.P. § 609.⁵ In 1995 (the year in which the '488 application was filed), M.P.E.P. § 609 stated that "the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application *** and a list of the information need not be submitted in the continuing application unless applicant desires the information to be printed on the patent.⁶ M.P.E.P. § 609, 6th ed. (1995) (emphasis added). Thus, an applicant satisfies the duty of candor in prosecuting a continuation application by disclosing all material information in the ancestor applications that was extant at the time of the ancestor applications, and by disclosing material information that became available after the

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⁵ Although it does not carry the force of law, the M.P.E.P. "is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n. 10 (Fed. Cir. 1995) (citation omitted).

M.P.E.P. § 609 has since been amended to provide that: "Information which has been considered by the Office in the parent application of a continued prosecution application (CPA) filed under 37 C.F.R. § 1.56(d) will be part of the file before the examiner and need not be resubmitted in the continuing application to have the information considered and listed on the patent. The examiner will consider information which has been considered by the Office in a parent application when examining: (A) a continuation application filed under 37 C.F.R. 1.53(b), (B) a divisional application filed under 37 C.F.R. 1.53(b). A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent." M.P.E.P. § 609 ("Information Disclosure Statements in Continued Examinations or Continuing Applications") (8th ed. 2001).

filing of the ancestor application; but the continuation application need not resubmit material information cited in ancestor applications. 37 C.F.R. § 1.56(e); M.P.E.P. § 609.

Breach of the duty to disclose material information is necessary, but not sufficient, to show inequitable conduct; as stated above, a second threshold requirement of intent to deceive or mislead the PTO must also be established by clear and convincing evidence. Courts have held that an applicant's failure to disclose material information under the first threshold requirement is not, by itself, clear and convincing evidence of intent to deceive. See, *e.g.*, *Star Sci.*, *Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). However, the converse is not necessarily true. When an applicant has performed his duty to disclose all material information, a court may logically presume that the applicant did not intend to deceive the PTO with respect to the existence of such references. See *ATD Corporation*, 159 F.3d at 547; *Transmatic, Inc. v. Gulton Industries*, 849 F. Supp. 526 (E.D. Mich. 1994), *aff'd in pertinent part, rev'd in part*, 53 F.3d 1270 (Fed. Cir. 1995).

In *ATD Corporation v. Lydall, Inc.*, the Federal Circuit affirmed a grant of summary judgment of no inequitable conduct in the prosecution of ATD's divisional application for its '577 patent. 159 F.3d at 537. Lydall argued that the '577 patent should be deemed invalid because ATD intentionally breached its duty of candor by failing to disclose a material reference during the '577 patent's prosecution. *Id.* at 547. ATD countered that it had fully performed its duty by citing the reference in the '577 patent's ancestor application, and that failure to resubmit it during the' 577 patent process was not clear and convincing evidence of an intent to deceive the PTO. *Id.* The Federal Circuit agreed, explaining that "because the [prior art] reference was of record in the parent * * * application, and because M.P.E.P. § 609 states that the information need not be resubmitted, there was not clear and convincing evidence of material withholding

with intent to deceive." *Id.* In other words, the court found that the first threshold element of a finding of inequitable conduct—failure to disclose material information—was not present, since ATD had in fact disclosed the information in the ancestor application. In light of that disclosure, the court concluded that the second element—intent to deceive—also was not present. And as neither element was present, the court found no inequitable conduct.

In support of its conclusion, the Federal Circuit in ATD cited the district court's decision in Transmatic, 849 F. Supp. 526 (E.D. Mich. 1994). Plaintiffs in Transmatic filed a patent application in 1979. The PTO examiner rejected the plaintiffs' claims on the ground that three extant patents—Schwenkler, Kalt, and Arenberg—rendered the claims obvious. Transmatic, 849 F. Supp. at 538-39. In 1980, Transmatic filed a continuation application, the '415 patent application, that referenced the ancestor application but made no mention of the Schwenkler, Kalt or Arenberg patents. Id. Transmatic later filed an amendment to the application distinguishing its claims from Schwenkler, but at no point during prosecution of the continuation application did it reference Kalt or Arenberg. Id. The PTO ultimately approved the '415 patent application's claims and issued the patent. Id. Gulton argued that Transmatic intentionally misled the PTO by failing to mention or distinguish Kalt or Arenberg. Id. at 540. The district court rejected this argument after an advisory jury trial, finding that, although Kalt and Arenberg were material to patentability of the '415 patent application, Transmatic's failure to resubmit them in the continuation application did not support a finding of intent to mislead, since Transmatic had submitted them in the ancestor application. Id. at 541-42. "Thus," the court held, "[Transmatic's lawyer] had a basis for a good faith belief that he had put [the] Examiner

* * * on notice of Kalt and Arenberg by virtue of the fact that the continuation application clearly referenced the parent application." *Id.* at 542. The district court accordingly found that Transmatic did not engage in inequitable conduct, and that the '415 patent was valid. *Id.* at 543.

Numerous courts have cited ATD for the proposition that a failure to re-cite material references in a continuation application—whether it be a continuation, continuation-in-part, or divisional application—that were cited in ancestor applications does not constitute inequitable conduct. See *eBay*, *Inc. v. IDT Corp.*, 2009 WL 2706395, at *3 (W.D. Ark.) (Aug. 24, 2009) (granting motion to dismiss counterclaim of inequitable conduct where patentee had failed to resubmit in continuation application material information originally cited in ancestor application); Avocent Huntsville Corp. v. Clearcube Technology, Inc., 443 F. Supp. 2d 1284, 1370 (N.D. Ala. 2006) (granting motion for partial summary judgment of no inequitable conduct where patentee did not resubmit in continuation-in-part application material reference disclosed in ancestor application); Intex Recreation Corp. v. Team Worldwide Corp., 390 F. Supp. 2d 21, 25-26 (D.D.C. 2005) (granting motion to dismiss inequitable conduct claims where patentee disclosed material reference in ancestor application but not continuation application); Syringe Development Partners, LLC v. New Medical Technology, Inc., 2001 WL 403232, at *62-*63 (S.D. Ind. Feb. 9, 2001). In Syringe Development, the court granted summary judgment of no inequitable conduct for failure to resubmit material information in the continuation-in-part application for patent '952 that the applicants previously had submitted in the ancestor '115 application. During prosecution of SDP's '115 application, the PTO examiner rejected a claim on the basis that it had been anticipated by the Gaarde patent and other prior art. Id. at *4. SDP submitted a response to the PTO arguing that its claims were distinct from the Gaarde patent—an argument that, according to NTM, was premised on a misleading description of that patent. *Id.*

at *62. SDP then filed the continuation-in-part application that eventually issued as the '952 patent. The continuation-in-part application re-cited some prior art that applicants had previously cited in the '115 application, but did not re-cite the Gaarde patent. *Id.* SDP argued that, as in *ATD*, they did not have an additional duty to reference previously disclosed prior art in a continuation-in-part application. *Id.* Although the court found the evidence that applicants may have misrepresented the Gaarde patent "troubling," it nonetheless agreed with SDP. *Id.* at *63. Emphasizing that the Gaarde patent was cited at least once previously to the PTO, the court held that defendants failed to show facts sufficient to support a finding of intent to deceive. *Id.* The court thus granted summary judgment on the inequitable conduct issue. *Id.*

Plaintiffs here similarly rely on *ATD* in asserting that they satisfied their duty of candor by citing the eight material references in the ancestor applications and bore no additional duty to re-cite those references in the '488 application. Although submission of the references alone is sufficient to satisfy the duty of candor pursuant to 37 C.F.R. § 1.56, Plaintiffs have proffered additional evidence that the PTO was even more likely to be on notice of the prior disclosures because Examiner Criares had considered the eight references in reviewing the '412 ancestor application, as indicated by his initialing each of the eight citations for the references in the IDS for that application.

Defendants assert that the Plaintiffs breached their duty to disclose the references because the PTO examiner was not on actual or constructive notice regarding the '488 application's ancestor applications. Defendants fail to set forth any facts in support of this assertion. Indeed, Defendants acknowledge that the IDS for the '488 application identified '488 as a continuation-in-part application, and that the application itself listed each of the ancestor applications. They further admit that the eight references in question were cited in the ancestor applications. And

they acknowledge that Examiner Criares reviewed the ancestor applications—initialing the eight references in one of them—as well as the '488 application. Defendants thus fail to show any genuine issue as to whether the PTO was on notice with respect to the ancestor applications.

Defendants next assert that, notwithstanding identification of the '488 application's ancestor applications, Examiner Criares "had no memory of having reviewed the eight references or the fact that five of them had been relied upon to reject similar claims in the ancestor applications." In support of this assertion, Defendants reference the number of applications that each PTO examiner reviews each year to show that Examiner Criares presumably had a heavy caseload. These statistics are not a sufficient basis for concluding that Examiner Criares failed to review the prior art references disclosed in the '488 patent's lineage. Even if, *arguendo*, this allegation were sufficient to show that Examiner Criares was very busy, it does not necessarily follow that he was too busy to recall the references cited in the '488 application's ancestors. More importantly, even if he did not recall those references off-hand, Examiner Criares was on notice of the '488 application's ancestor applications, and was required by the M.P.E.P. to review those ancestor applications. M.P.E.P. §§ 609, 707.05. Defendants fail to provide any evidence that he failed to do so.

In further support of the assertion that Examiner Criares did not remember the prior art references, Defendants cite expert testimony that "there is no basis to presume the examiner was able to recall prior art references in the '488 application from earlier related applications." (Decl. of Mona Gupta in Support of Defs. Mem. in Opp. To Pls.' Mot. for Summ. J. on Affm. Def. and Ctrclm. D, Ex. B, ¶¶ 31, 32). [379] Defendants' attempt to infer from this statement that Examiner Criares did not recall the references is not persuasive: the absence of a basis to prove recollection is not synonymous with disproving recollection.

In any event, proof that an examiner recalled prior art references cited in an ancestor application is not necessary to defeat a claim of inequitable conduct based on failure to disclose prior art in a continuation application. The M.P.E.P. provides clear guidance that examiners reviewing continuation applications should review ancestor applications—presumably because it would be unreasonable to expect an examiner to recall the procedural history of and citations included in an ancestor application. M.P.E.P. §§ 609, 707.05. Indeed, the applicable regulations presume that some material information that previously was disclosed need not be resubmitted because that information remains "of record" (37 C.F.R. § 1.56(b)) and thus presumably available to the examiner. As Defendants submit no evidence to the contrary, the Court presumes that Examiner Criares fulfilled his duty as an examiner to review the ancestor applications and the references contained therein. The Court further notes that, even if the Examiner failed to review the ancestor applications, such failure would not taint Plaintiffs' performance of its duty, as an applicant, to disclose the references. TM Patents L.P. v. Int'l Business Machines Corp., 121 F. Supp. 2d 349, 372 (S.D.N.Y. 2000).⁸ This argument thus also fails to raise a genuine issue of material fact as to disclosure of the prior art.

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Relying on *TM Patents*, Plaintiffs state the general rule that if an examiner breaches his duty under the M.P.E.P. to review ancestor applications during prosecution of a continuing application, that breach cannot be imputed to the applicant. Although it is unnecessary to their summary judgment motion, Plaintiffs suggest that the Examiner presumably did review the ancestor applications in compliance with M.P.E.P. rules. Nevertheless, Plaintiffs assert as a caveat that had Examiner Criares failed to do so, Plaintiffs should not be penalized for that failure. Defendants submit that Plaintiffs' mere reference to the *TM Patents* rule amounts to "an admission that the applicants and their attorneys knowingly and wrongfully sought to take advantage the [sic] examiner's dereliction of duty, which in itself is a failure of the applicant and its attorneys to comply with the duty of candor and good faith." (Defs.' Resp. to Pls.' SOF 11.) [378] Defendants' contention is not well taken, and the Court finds no factual basis for assertion of intentional exploitation of the Examiner.

⁸ Defendants cite to *KangaROOS U.S.A.*, *Inc. v. Caldor*, *Inc.*, 778 F.2d 1571 (Fed. Cir. 1985) in arguing that *TM Patents* was wrongly decided. *KangaROOS* was factually distinguishable from *TM Patents*, however, and did not compel a different result in the latter case. In *KangaROOS*, the district court granted summary judgment against KangaROOS upon finding that there was no genuine issue that KangaROOS had intended to deceive the PTO in claiming priority to an ancestor application pursuant to

Having failed to present any evidence showing that Plaintiffs did not disclose the prior art references in the ancestor applications or that Examiner Criares failed to review them, Defendants' brief in opposition to summary judgment motion launches into a legal argument that Plaintiffs, along with the Federal Circuit in *ATD*, err in stating that there is no duty of candor in prosecution of a continuation application. In so doing, Defendants misapprehend Plaintiffs' argument and the controlling case law upon which it relies. Plaintiffs have never argued that they had no duty to disclose material references in ancestor applications. Nor have they argued, as Defendants suggest, that M.P.E.P. § 609 should be construed to negate the duty of disclosure set forth in 37 C.F.R. §§ 1.56, 1.97, and 1.98. Rather, Plaintiffs assert that they satisfied their duty to disclose material references by supplying the relevant references to the PTO in the ancestor applications. Citing *ATD*, Plaintiffs argue that they bore no *additional* duty to re-submit the references in the '488 application. In other words, Plaintiffs argument is not "no duty," but "no breach."

Defendants also argue that *ATD* misstated the holding in *Transmatic* and, as a result, erroneously created a "no duty" rule. Contrary to the *ATD* court's interpretation, Defendants submit, *Transmatic* was not a "no duty" case, but rather a "no intent to deceive" case. As noted

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³⁵ U.S.C. § 120. KangaROOS, 778 F.2d at 1573. On appeal, the Federal Circuit held that "if the claim for priority met the elements of fraud, or was so grossly negligent as to support an inference of fraud or inequitable conduct, lapse on the part of the examiner [in reviewing entitlement to the priority filing date] does not excuse the applicant." Id. at 1576. The Court then reversed the district court's grant of summary judgment upon finding that there was a genuine issue as to whether KangaROOS in fact possessed such intent to deceive. Id. at 1578. By contrast, TM Patents held that an applicant had not breached its duty to disclose material references or misled the examiner when it provided those references in an ancestor application but not in a continuation application. TM Patents, 121 F. Supp. 2d at 372. Unlike KangaROOS, TM involved inequitable conduct with respect to disclosure of prior art references, not a More importantly, the rule in KangaROOS—that if an applicant attempts to claim to priority. intentionally defraud an examiner by misrepresenting a claim to priority, the examiner's later failure to correct that misrepresentation and subsequent determination regarding the priority date does not excuse the applicant—simply does not apply to the facts here. Defendants present no evidence that Plaintiffs intended to defraud the examiner in failing to re-cite previously submitted prior art. Their reliance on KangaROOS in an effort to cast doubt on the holding in TM Patents is thus misplaced.

above, the court in *Transmatic* found that the applicants satisfied their duty of candor in disclosing material references in an ancestor application. *Transmatic*, 849 F. Supp. at 541-43. Insofar as the applicants performed their duty to disclose, the court found that they lacked intent to deceive the PTO by omitting disclosures. *Id.* Similarly, *ATD* held that the continuation applicant performed its duty by disclosing material references in an ancestor application, and that in light of that disclosure there was no intent not to disclose. *ATD*, 159 F.3d at 547. *ATD* and *Transmatic* are thus consistent in holding that there is no additional duty to resubmit information in a continuation application, and, correspondingly, that an applicant that has performed its initial duty to disclose does not breach that duty by later failing to resubmit the disclosures.

Finally, Defendants argue that applicants breached their duty to disclose the PTO examiner's rejections of certain claims in the ancestor applications that were similar to claims in the '488 application. Defendants correctly state the rule in *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367-58 (Fed. Cir. 2003), that an applicant must reveal to an examiner an adverse decision of the same claims made by another examiner in a copending application. Defendants also acknowledge the key facts in *Dayco* that distinguish it from the present case—namely, that *Dayco* concerned copending patent applications reviewed by different examiners.

In *Dayco*, the plaintiffs filed two sets of patent applications with substantially similar claims: the '196 application and the '023 and related applications. *Dayco*, 329 F.3d at 1360-61. The two sets of applications were prosecuted simultaneously before the PTO, and were assigned to different examiners. *Id.* at 1361. The examiner assigned to the '196 application was aware of the copending '023 application, but there was no evidence that the '023 examiner was aware of the '196 application. *Id.* The examiner assigned to the '196 patent rejected certain claims, citing

the extant Wilson patent as grounds for the rejection. *Id.* Although the rejected '196 claims were substantially similar to those of the '023 application, plaintiffs did not advise the '023 examiner of the rejection, nor did they call to the examiner's attention the Wilson patent. *Id.* at 1361-62. The Federal Circuit reviewed the lower court's grant of summary judgment against the patentee as a case of first impression on the issue of "whether the prior rejection of a substantially similar claim in a copending United States application is material under the reasonable examiner standard." *Id.* at 1367. In a preface to its discussion of the issue, the Court noted that:

Patent disclosures are often very complicated, and different examiners with different technical backgrounds and levels of understanding may often differ when interpreting such documents. Although examiners are not bound to follow other examiners' interpretations, knowledge of a potentially different interpretation is clearly information that an examiner could consider important when examining an application.

Id. Citing the lower court's finding that "it was important for [an examiner] to know that another knowledgeable Patent Examiner had carefully examined and rejected all claims of [another] application, including claims that were directly related to claims in the [present] application," the Court ruled that the rejected '196 claims were material to the patentability of the '023 application. Id. at 1368. The Court then found that, contrary to the lower court's determination, a genuine issue existed as to whether plaintiffs had intent to deceive in failing to disclose the rejected claims, and remanded the case for trial on that issue. Id. Thus, although Dayco established a new rule as to materiality of prior rejections of substantially similar claims, it clearly limited that rule to situations in which different examiners review copending applications, and subsequent cases addressing the issue have not extended Dayco's reach. Id. at 1367-69; see McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)

(finding inequitable conduct where examiner of one application was not apprised of adverse decisions by a different examiner in a copending application).

Unlike *Dayco*, this case involves a continuation-in-part application—not a copending application—that Plaintiffs clearly identified to the PTO as relating to a string of ancestor applications. In addition, the same examiner, Examiner Criares, reviewed all but the first of the ancestor applications as well as the continuation-in-part application in question. In so doing, Examiner Criares was responsible for and exercised his discretion in rejecting certain claims in the ancestor applications. As such, the concern in *Dayco*—that different examiners with different technical backgrounds or understandings of similar claims should benefit from one another's interpretations in simultaneously reviewing those claims—is not present here.

Anticipating this fundamental distinction between *Dayco* and the present case, Defendants state that there is no guarantee that a continuation application will be reviewed by the same examiner who reviewed the ancestor applications, and that Plaintiffs did not know at the time of the filing of the '488 application that Examiner Criares would review it. That Plaintiffs were unaware that Examiner Criares would be assigned at the time that the application was filed is irrelevant, however, as they presumably learned during prosecution of the application that he had been assigned. Defendants again assert that Examiner Criares "was unlikely to remember the details of the ancestor applications," especially as the sheer number (four) of ancestor applications would be burdensome for him to review. But, as Plaintiffs point out, the number of ancestor applications that Examiner Criares himself had reviewed if anything would tend to support—not negate—an inference that Examiner Criares would recall the subject matter and procedural history at issue in the '488 application. The Court thus declines to extend the *Dayco* rule regarding disclosure of rejected claims in copending applications to the instant case.

Finally, Defendants argue that Plaintiffs had an obligation under Dayco to disclose the

rejection of claims in a counterpart of the '488 application that was filed in the United Kingdom.

Defendants state that the rejected claims were material to claims made in Group II of the '488

But Plaintiffs cancelled the Group II claims during pendency of the '488

application. The Federal Circuit has held that an applicant's failure to disclose information that

is material only to cancelled claims does not constitute inequitable conduct. Kimberly-Clark

Corp. v. Johnson & Johnson, 745 F.2d 1437, 1457 (Fed. Cir. 1984). As such, as a matter of law,

Plaintiffs cannot be found to have engaged in inequitable conduct by failing to disclose the

rejected claims that since have been cancelled.

IV. Conclusion

For the reasons stated above, Plaintiffs' motion for summary judgment [336] on

affirmative defense and counterclaim D is granted.

Dated: September 17, 2010

Robert M. Dow, Jr.

United States District Judge

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