

ADAMS, J.

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

DAVID HALPERN,)	CASE NO. 1:07CV3040
)	
Plaintiff,)	
)	JUDGE JOHN R. ADAMS
v.)	
)	<u>MEMORANDUM OF OPINION</u>
PERITEC BIOSCIENCES, LTD., et al.,)	<u>AND ORDER</u>
)	[RESOLVING DOC. 3]
Defendants.)	

This action is before the Court upon defendants' Motion to Dismiss (Doc. 3) pursuant to Fed. R. Civ. P. 12(b)(1) and (6). The Court has reviewed the memorandum in support and Exhibits 2 and 3 attached thereto, corrected memorandum in opposition (Doc. 6), and reply memorandum (Doc. 7) and Exhibit 1 attached thereto.¹ Defendants move the Court to dismiss the first nine (9) Claims for Relief for failure to state claims upon which relief can be granted.² Once the First and Second Claims for Relief are dismissed, the defendants contend that all remaining state claims must be dismissed because the Court does not have jurisdiction to hear them.

¹If referred to in a complaint and central to the claim, documents attached to a motion to dismiss form part of the pleadings. *Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999), *overruled on other grounds by Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002); *see also Armengau v. Cline*, 7 Fed.Appx. 336, 344 (6th Cir. 2001).

²This Court concludes that it will not exercise supplemental jurisdiction over the state common law and/or statutory law claims. Therefore, the Court declines to address the arguments regarding the Third through Ninth Claims for Relief. The arguments can be renewed in the state court, if these claims are refiled there.

I. Background

Plaintiff David Halpern (hereinafter “plaintiff” or “Halpern”) was hired by defendant PeriTec Biosciences, Ltd. (hereinafter “PeriTec”) to assist in the design of a catheter delivery system for tissue-lined stents, among other things. Complaint (Doc. 1) at ¶ 5. A letter agreement, dated March 24, 2005 (Doc. 3-4),³ “memorialized” the parties’ “understandings” of their employment relationship. Doc. 1 at ¶ 9. Prior to commencing his employment as “Project Manager” with PeriTec, Halpern also executed “Company documents,” including a Confidential Information and Invention Assignment Agreement (hereinafter, “the Agreement”) (Doc. 3-5).⁴ *See id.* at ¶ 62.

On October 4, 2007, the plaintiff commenced the case at bar by filing a ten-count complaint against defendants PeriTec, PeriTec Biosciences (hereinafter “PeriTec”), Rajesh Khosla (hereinafter “Khosla”), and Timur Sarac (hereinafter “Sarac”) (collectively referred to herein as “defendants”). Plaintiff alleges that this Court has subject matter jurisdiction based on 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1367 (supplemental jurisdiction). *Id.* at ¶ 2.

Plaintiff’s First Claim for Relief is brought pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201. Halpern alleges that he is entitled to “a declaration as to Plaintiff’s non-liability for Defendants’ failure to comply with [Food and Drug Administration (“FDA”)] regulations,” as

³Exhibit 2 to the memorandum in support.

⁴Exhibit 3 to the memorandum in support. Halpern also executed a second Assignment Agreement (Doc. 7-2), which is Exhibit 1 to the reply memorandum. In these two (2) separate assignments, the plaintiff assigned his rights to any designs that he developed while working for PeriTec.

well as “indemnification from Defendants as a result of any suits that may be brought by patients who have already been implanted with . . . PeriTec[’s] tissue-lined stent” by exporting the experimental medical devices for investigational use in humans without proper FDA authorization. Doc. 1 at ¶ 73. Plaintiff bases this claim on the Federal Declaratory Judgment Act insofar as resolution of certain of his claims rests upon the FDCA and regulations promulgated thereunder. *See id.* at ¶ 72. Halpern alleges that “[a]n actual controversy exists pursuant to Article III of the Constitution in that Plaintiff is potentially liable with Defendants as a result of suits that may be brought by patients *who have already been implanted with . . . PeriTec[’s] tissue-lined stent.*” *Id.* at ¶ 74 (emphasis in original). The patients that the plaintiff alleges may, at some point in the future, suffer injury and/or file a lawsuit against the defendants were allegedly operated on in Chile and Brazil. *See id.* at ¶ 49. Finally, with regard to his First Claim for Relief, Halpern’s prayer for relief requests “a declaratory judgment that Plaintiff will not be liable jointly, severally or otherwise for any failure of the PeriTec delivery system as a result of the actions described herein, . . . an Order directing that Defendants be enjoined from any further violations of FDA Regulations; and . . . an order directing Defendants to indemnify and hold Plaintiff harmless for any damages as a result of any such actions.” *Id.* at 26.

The Second Claim for Relief is based on alleged patent rights. Plaintiff asserts that the Court has original jurisdiction over this claim pursuant to 35 U.S.C. § 1 *et seq.* and, more particularly, under 28 U.S.C. § 1338(a). In paragraphs 53 through 66 of the Complaint, Halpern asserts rights to two (2) pending U.S. patent applications directed to inventions which stem from projects he worked on while employed as PeriTec’s delivery catheter engineer. He states that “Defendants asked Plaintiff to design a method for compressing the stents.” Doc. 1 at ¶ 55.

Plaintiff also alleges that he alone “invented and reduced to practice a revolutionary ‘cartridge’ method of connecting a compressed stent to the main body of the catheter for delivery into the patient.” *Id.* at 56. Plaintiff asserts that he

did not execute any patent applications, assignments, or other documents granting Peritec, the Defendants, or any other entity, any rights to the stent compressing patent or the cartridge device patent. In fact, these were clearly outside the job description included in the letter agreement.

Id. at ¶ 61.

II. Applicable Pleading Standard

As the Court of Appeals for the Sixth Circuit stated in *Association of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545 (6th Cir. 2007):

The Supreme Court has recently clarified the law with respect to what a plaintiff must plead in order to survive a Rule 12(b)(6) motion. *Bell Atl. Corp. v. Twombly*, --- U.S. ---, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The Court stated that “a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 1964-65 (citations and quotation marks omitted). Additionally, the Court emphasized that even though a complaint need not contain “detailed” factual allegations, its “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true.” *Id.* (internal citation and quotation marks omitted). In so holding, the Court disavowed the oft-quoted Rule 12(b)(6) standard of *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957) (recognizing “the accepted rule that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief”), characterizing that rule as one “best forgotten as an incomplete, negative gloss on an accepted pleading standard.” *Twombly*, 127 S.Ct. at 1969.

Id. at 548.

If an allegation in the complaint is capable of more than one inference, the Court must construe it in the plaintiff’s favor. *Columbia Natural Resources, Inc. v. Tatum*, 58 F.3d 1101, 1109 (6th Cir. 1995), *cert. denied*, 516 U.S. 1158 (1996). The Court may not grant a

Rule 12(b)(6) motion merely because it may not believe a plaintiff's factual allegations. *Id.* Although this is a liberal standard of review, the plaintiff still must do more than merely assert bare legal conclusions. *Id.* To survive a Rule 12(b)(6) motion to dismiss, the plaintiff's complaint must allege either "direct or inferential" allegations regarding all of the material elements necessary to sustain recovery under "some" viable legal theory. *Id.*

A motion to dismiss relying on a paper outside the pleadings is generally permissible only where the complaint refers to that paper. *Weiner v. Klais & Co., Inc.*, 108 F.3d 86, 89 (6th Cir. 1997) (recognizing dismissal as proper when based on "those exhibits submitted by [a] defendant which can properly be considered as incorporated by reference into the complaint"); *see also City of Monroe Employees Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 659 n. 6 (6th Cir. 2005) (permitting papers submitted with motion to dismiss to be considered part of pleadings "if they are referred to in the plaintiff's complaint and are central to the plaintiff's claim") (citation omitted). The purpose of this rule is clearly to avoid unfair surprise and prejudice. *Cf. Yeary v. Goodwill Industries-Knoxville, Inc.*, 107 F.3d 443, 445 (6th Cir. 1997) (noting that where "the defendants had ample opportunity to respond to the plaintiff's affidavits" and "cannot be said [to have] suffered any prejudicial surprise," Court of Appeals need not view motion to dismiss as converted into motion for summary judgment); *United Bhd. of Carpenters & Joiners of Am. v. Ohio Carpenters Health & Welfare Fund*, 926 F.2d 550, 558 (6th Cir. 1991) (noting that where "one party is likely to be surprised by the change [from motion to dismiss to motion for summary judgment,] notice is required").

III. Analysis

Defendants make two arguments in support of their motion to dismiss the First and Second Claims for Relief. First, the First Claim for Relief should be dismissed for failure to state a claim because, by law, as a private individual, the plaintiff can have no claim based on the FDCA. Furthermore, to the extent this claim is based on allegations that Halpern may be subject to future lawsuits by individuals who have potentially been harmed by the defendants' alleged failure to comply with FDA requirements, the plaintiff again cannot state a claim upon which relief can be granted because there is no case or controversy at issue.

Second, according to the defendants, the Second Claim For relief based on alleged patent rights should be dismissed because Halpern assigned any such rights to the defendants upon signing the Agreement, and he has no such rights.

A. *First Claim For Relief*

No private cause of action exists for a violation of the FDCA. *See Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995). As a matter of law, “all such proceedings for the enforcement, or to restrain violations, of this chapter [of the FDCA] shall be by and in the name of the United States.” 21 U.S.C. § 337(a). *See also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000) (noting that no explicit and/or implied private right of action exists under the FDCA); *In re Benedectin Litig.*, 857 F.2d 290, 313-14 (6th Cir. 1988). Moreover, in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), the Supreme Court held that “the congressional determination that there should be no federal remedy for the violation of [the FDCA] is tantamount to a congressional conclusion that the presence of a claimed violation of

the statute as an element of a state cause of action is *insufficiently* ‘substantial’ to confer federal-question jurisdiction.” *Id.* at 814 (emphasis added).

Additionally, it is undisputed that there is no case or controversy at issue in the case at bar. In a case addressing the Federal Declaratory Judgment Act, the Supreme Court stated:

A “controversy” in this sense must be one that is appropriate for judicial determination. A justiciable controversy is thus distinguished from a difference or dispute of a hypothetical or abstract character; from one that is academic or moot. *The controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character*, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Aetna Life Ins. Co. of Hartford, Conn. v. Haworth, 300 U.S. 227, 240-41 (1937) (emphasis added; citations omitted). Halpern points to no harm and/or damages that have given rise to any claim by any individual patient that the plaintiff claims has been harmed by the defendants. He alleges that “Plaintiff is potentially liable with Defendants as a result of suits that may be brought by patients *who have already been implanted with . . . PeriTec[’s] tissue-lined stent.*” Doc. 1 at ¶ 74 (emphasis in original). This allegation, however, is hypothetical and seeks relief on claims that either do not exist or are not ripe for this Court’s review. *See Crown Equipment Corp. v. Pace Membership Warehouse, Inc.*, 910 F. Supp. 346, 348 (N.D. Ohio 1995) (“Both the Constitution’s Article III and the Declaratory Judgment Act . . . allow a district court to exercise jurisdiction only over ‘actual’ controversies. No actual controversy exists until a potential injury is sufficiently immediate and real.”).

B. Second Claim For Relief

Plaintiff’s claims relevant to alleged patent rights must be dismissed because Halpern, as a matter of law, has no right in any patents or patent applications that relate to the work that he

was hired to perform and/or the assignment to which he admits agreeing. On March 29, 2005, the plaintiff executed the Agreement as a condition of his employment. It provides in pertinent part:

Assignment of Inventions. Without further compensation, I hereby agree promptly to disclose to the Company, and *I hereby assign and agree to assign to the Company or its designee, my entire right, title, and interest in and to all Inventions which I may solely or jointly develop or reduce to practice during the period of my employment or consulting relationship with the Company which (a) pertain to any line of business activity of the Company, (b) are aided by the use of time, material or facilities of the Company, whether or not during working hours, or (c) relate to any of my work during the period of my employment or consulting relationship with the Company, whether or not during normal working hours.* I acknowledge a permanent obligation promptly to execute assignments of Inventions covered by conditions (a), (b), or (c), herein, to the Company even after my relationship with the Company has been terminated. Without limiting the foregoing, if I am a consultant, any Inventions which would otherwise be assigned pursuant to this Agreement and which constitute copyrightable subject matter shall be deemed “works made for hire” as that term is defined in the United States Copyright Act. No rights are hereby conveyed in Inventions, if any, made by me prior to my employment or consulting relationship with the Company. . . .

Doc. 3-5 at 1, ¶ 5 (emphasis added). The Agreement contradicts the plaintiff’s assertion that he did not execute any patent assignments, *see* Doc. 1 at ¶ 61, and it highlights the basic fact that Halpern has absolutely no right in the pending patent applications filed for the cartridge device and stent compressing process and/or patents to which he alleges he has rights. Assuming *arguendo* that the plaintiff does have rights in the applications, he should proceed through the U.S. Patent and Trademark Office for the relief he currently seeks from this Court. *See E.I. Du Pont de Nemours & Co. v. Okuley*, 344 F.3d 578, 584 (6th Cir. 2003) (holding that the district court lacked jurisdiction to review the inventorship of an unissued patent), *cert. denied*, 541 U.S. 1027 (2004).

“When an employee is hired to devote his efforts to a particular problem, to conduct experiments for a specifically designed purpose, and an invention results from the performance of that work, it belongs to the employer.” *Shook v. United States*, 238 F.2d 952, 954 (6th Cir. 1956), *cert. denied*, 353 U.S. 924 (1957); *see also* 2 R. Callmann, *Unfair Competition, Trademarks & Monopolies* § 14:18 n. 8 (4th ed.) (collecting cases). Therefore, the Court holds that the plaintiff has failed to state a claim upon which relief can be granted on his Second Claim for Relief because (1) he voluntarily assigned his rights in all inventions, including any patents or patent applications, to which he now alleges he has an interest, and (2) the inventions to which he claims rights were inventions that he was admittedly hired to develop.

IV. Conclusion

For all the foregoing reasons, the First and Second Claims for Relief will be dismissed because the plaintiff has failed to state claims upon which relief can be granted.

Defendants’ Motion to Dismiss (Doc. 3) is GRANTED IN PART.

IT IS SO ORDERED.

August 13, 2008
Date

/s/ John R. Adams
John R. Adams
U.S. District Judge