



## I. INTRODUCTION

This case is the latest battle in the continuing war over patent rights in the field of RNA interference ("RNAi"), also known as gene silencing.<sup>1</sup> RNAi is a process whereby a double-stranded RNA molecule inserted into a cell directs the destruction of messenger RNA before it can be translated into a protein. It has great potential therapeutic value.

The University of Utah ("UUtah") brings this Second Amended Complaint against state officials at the University of Massachusetts ("UMass") and other research institutes, alleging that Dr. Brenda Bass, a professor on its faculty, should be named either the sole inventor or a joint inventor on two patents--U.S. Patent No. 7,056,704 and U.S. Patent No. 7,078,196--collectively referred to as the "Tuschl II" patents, named after Dr. Thomas Tuschl, the first named inventor. The complaint requests the Court to order the U.S. Patent and Trademark Office ("USPTO") to correct inventorship, to issue a declaratory judgment, and to require the defendants to cease violating federal patent law by naming Dr. Bass as a sole or joint inventor. The claims of the Tuschl II patents are directed to methods of preparing a particular type of double-stranded RNA molecule that can mediate

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<sup>1</sup> The scientific background is explained in the first patent litigation. See Max-Planck-Gesellschaft Zur Forderung der Wissenschaften E.V. v. Whitehead Inst. for Biomedical Research, 650 F.Supp.2d 114 (D. Mass. 2009). The parties settled those claims right before trial.

RNAi. The molecule has a "3' overhang," a sequence of nucleotides on one end of an RNA strand that hangs over the other RNA strand and make up a double-stranded RNA molecule.

The defendants press two motions to dismiss UUtah's lawsuit. First, the UMass official defendants contend that the Supreme Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. § 1251(a) because the case involves a controversy between instrumentalities of two states: UUtah and UMass, one of the current holders of the Tuschl II patents. Second, all defendants argue that UUtah has failed to state plausible claims for sole or joint inventorship of the patents. After a hearing, the Court **DENIES** the pending motions to dismiss.

## II. ANALYSIS

### A. Subject Matter Jurisdiction

Defendants first contend this Court does not have subject matter jurisdiction over the claims against the UMass state officials because they are barred by sovereign immunity. Generally speaking, "State[s] . . . can[not] be sued as defendant[s] in any court in this country without their consent, except in the limited class of cases in which a State may be made a party in the Supreme Court of the United States by virtue of the original jurisdiction conferred on [the Supreme Court] by the Constitution." Cunningham v. Macon & B. R. Co., 109 U.S. 446, 451 (1883). "Claims against a state official in his official

capacity are treated as claims against the state.” Negron-Almeda v. Santiago, 528 F.3d 15, 21 n.2 (1st Cir. 2008).

The Ex parte Young doctrine is a narrow exception to this rule. The doctrine permits an action in federal court against state officials seeking prospective relief to enjoin a continuing violation of the U.S. Constitution or federal law. “[W]here prospective relief is sought against individual state officers in a federal forum based on a federal right, [sovereign immunity], in most cases, is not a bar.” Idaho v. Coeur D’Alene Tribe, 521 U.S. 261, 276-77 (1997). This exception is predicated on the legal fiction that, when a plaintiff seeks prospective relief and not retrospective monetary relief that would be paid out of the state’s treasury, the suit is only against the state official and not against the state itself. See Pennhurst State School & Hosp. v. Halderman, 465 U.S. 89, 102 (1984). Whether a request for relief is prospective requires a “straightforward inquiry into whether the complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective.” Verizon Md., Inc. v. PSC, 535 U.S. 635, 645 (2002)(internal quotations omitted). A federal court can order prospective relief that has an impact on the state treasury, provided that the impact on the state treasury is only an ancillary result of requiring that the state official conform his or her conduct to the dictates of federal law. See Edelman v. Jordan, 415 U.S. 651, 667 (1974).

The Federal Circuit has held that the Ex parte Young doctrine can be invoked in a patent infringement action against state officials. Pennington Seed, Inc. v. Produce Exch. No. 299, 457 F.3d 1334, 1341-42 (Fed. Cir. 2006); see id. at 1343 n.5 (noting that a state official's refusal to perform a duty can itself be a violation of federal law); Xechem Int'l., Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr., 382 F.3d 1324, 1334-35 (Fed. Cir. 2004)(Newman, J., additional views)(suggesting, but taking no view on whether, the Ex parte Young doctrine may be available in correction of inventorship claims against state university officials).

At oral argument, counsel for defendants for the first time argued that because the relief sought in a correction of inventorship claim under 35 U.S.C. § 256 lies against the USPTO and not the state officials, Ex parte Young does not apply. Section 256 states that to correct inventorship the court "may order correction of the patent . . . and [the Patent Office] shall issue a certificate [of correction]." 35 U.S.C. § 256. Although it is true that the USPTO must correct the patent if plaintiff prevails, the requested relief is still prospective in nature, and does not involve a retroactive remedy. Thus, the Ex parte Young exception may still apply to the request for relief.

Defendants contend that the Ex parte Young doctrine does not apply in this case because it is within the Supreme Court's

original and exclusive jurisdiction over all controversies between two or more states. 28 U.S.C. § 1251(a). In defendants' view, because the real party in interest here is UMass, a co-owner of the patent, this case involves a battle between two state entities, and there is a sufficient remedy in an alternative forum, the Supreme Court. Cf. Seminole Tribe v. Florida, 517 U.S. 44, 73-74 (1996)(holding it was "the carefully crafted and intricate remedial scheme set forth [by Congress]" that barred Ex parte Young relief). However, Utah chose to sue the state officials in federal district court, and to drop the state as a party to preclude exclusive jurisdiction in the Supreme Court. In an analogous situation, the Second Circuit held that the plaintiff has the right to choose whether to name the state or state officials as defendants and "to enjoy (or suffer) the jurisdictional consequences of that decision." Connecticut ex rel. Blumenthal v. Cahill, 217 F.3d 93, 98 (2d Cir. 2000). In Cahill, Connecticut sued New York state officials for allegedly enforcing an unconstitutional state statute forbidding nonresident commercial permit-holders from lobstering in an area of New York. Id. at 96. Because Connecticut chose to sue only New York state officials, but not the state itself, the case could proceed in district court. Id. at 99; but see id. at 105-12 (Sotomayor, J., dissenting)(concluding that the Supreme

Court has exclusive jurisdiction over Connecticut's dispute with New York because New York state was the real party in interest).

Defendants also claim that the relief Utah seeks is retrospective, not prospective, because its effect will be to deprive the state of Massachusetts of its intellectual property. Defendants are correct that such relief would have a financial impact on UMass, as it would lose either a whole or partial interest in the patents, which have been licensed to pharmaceutical companies. Plaintiff argues that such effect is merely an ancillary effect of prospectively correcting inventorship of the patent. See Papasan v. Allain, 478 U.S. 265, 278 (1986) (Ex parte Young doctrine applies "even though [prospective relief may be] accompanied by a substantial ancillary effect on the state treasury"). This case is not like the Supreme Court's decision in Coeur D'Alene Tribe. There, the Court held that Ex parte Young did not apply because the relief the Native American tribe sought "would diminish, even extinguish, the State's control over a vast reach of lands and waters long deemed by the State to be an integral part of its territory." 521 U.S. at 282. Unlike that case, a state's interest in patents does not "uniquely implicate sovereign interests." Id. In the absence of a "core sovereign interest," a state's injunction suit against state officers "may properly proceed in a district court." Cahill, 217 F.3d at 100; see id.

at 104 (holding state of Connecticut may sue New York state officials for declaratory and injunctive relief in federal district court in suit over lobster rights); Oregon v. Heavy Vehicle Elec. License Plate, Inc., 157 F. Supp. 2d 1158, 1164 (D. Or. 2001) (holding federal district court had subject matter jurisdiction over dispute between state of Oregon and Arizona corporation because it was "not the sort of core sovereign interest that warrants the Supreme Court's original and exclusive jurisdiction . . . [but] rather, exactly the sort of quarrel over money and technology that the district courts hear frequently when brought by private litigants."). Unlike disputes over lakes, rivers, and state boundaries, a quarrel over patent rights does not implicate core sovereign interests. Accordingly, this court has jurisdiction over the action against the UMass state officials under the Ex parte Young doctrine.

Defendants further claim that the entire case must be dismissed because UMass is an indispensable party under Fed. R. Civ. P. 19 and must be joined. The Second Amended Complaint does not name UMass as a defendant in this lawsuit, and UMass has not sought to intervene. To determine whether a party is indispensable under Rule 19, "the court must determine [in its discretion] 'whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed.'" Picciotto v. Cont'l Cas. Co., 512 F.3d 9, 18 (1st

Cir. 2008)(quoting Fed. R. Civ. P. 19(b)). The Rule specifies the following four factors to consider:

[F]irst, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

Fed. R. Civ. P. 19(b). Considering the factors, I conclude that UMass is not an indispensable party. On the first two factors, a judgment rendered in UMass' absence will not prejudice UMass or the other parties. UMass' interests are well represented by the other defendants, internationally renowned research institutions and a university, as well as the state officials themselves. Indeed, in the earlier litigation, UMass was an active participant in this court when it was a co-defendant with the Whitehead Institute, among others. A vigorous joint defense was mounted. All defendants are also represented by the same counsel, one of the leading IP law firms in the United States, and there is no apparent conflict of interest. See Dainippon Screen mfg. Co. v. CFMT, Inc., 142 F.3d 1266, 1272 (Fed. Cir. 1998)("[P]rejudice to an absent party is mitigated when the interests of that party are adequately protected by those who are present.")(internal quotations omitted). On the third factor, a declaratory judgment rendered in UMass' absence regarding the inventorship of the Tuschl II patents will provide an adequate

remedy since the USPTO is the entity which corrects the patent. On the fourth factor, while plaintiff would have a remedy against University of Massachusetts in the Supreme Court if this action were dismissed under Rule 12(b)(1), it is unclear whether the Supreme Court would take jurisdiction over the other parties. In any event, this factor is significantly outweighed by the other factors. Accordingly, in equity and good conscience, the action should proceed among the parties before it, and the motion to dismiss is denied. See Dainippon Screen mfg. Co., 142 F.3d at 1272.

**B. Motion to Dismiss under Rule 12(b)(6)**

Defendants have also filed a motion to dismiss the claims of joint and sole inventorship. Utah asserts a claim for sole inventorship under 35 U.S.C. § 256.<sup>2</sup> Section 256 "provides a

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<sup>2</sup> Section 256 states:

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

35 U.S.C. § 256.

cause of action to interested parties to have the inventorship of a patent changed to reflect the true inventors of the subject matter claimed in the patent. [The Federal Circuit has] interpreted § 256 broadly as a 'savings provision' to prevent patent rights from being extinguished simply because the inventors are not correctly listed." Larson v. Correct Craft, Inc., 569 F.3d 1319, 1324 (Fed. Cir. 2009).

Section 256 provides a mechanism to correct two types of inventorship errors: misjoinder and nonjoinder. Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1553 (Fed. Cir. 1997) ("Stark II"). Misjoinder occurs when a person who is not an inventor is mistakenly listed as an inventor. Id. at 1553. Section 256 allows for deletion of a misjoined inventor "whether that error occurred by deception or by innocent mistake." Id. at 1555. Nonjoinder occurs when a person who is an inventor mistakenly has not been listed as such where "the error [does not] involve any deceptive intention by the nonjoined inventor." Id. at 1553. "[S]ection 256 allows complete substitution of inventors as long as the true inventors are without deceptive intent." Id. at 1556. "If a patentee demonstrates that inventorship can be corrected as provided for in section 256, a district court must order correction of the patent, thus saving it from being rendered invalid." Pannu v. Iolab Corp., 155 F.3d 1344, 1350 (Fed. Cir. 1998).

The Second Amended Complaint sufficiently alleges facts stating a claim for complete substitution, contending that Dr. Bass of Utah was the sole inventor of the Tuschl II patents. The complaint states that Dr. Bass conceived the invention "that the RNase III enzyme Dicer was the key agent of [RNA interference], and hence, that the resultant molecule would have . . . a 3' overhang, by treating multicellular animals with dsRNA corresponding to *C. elegans*<sup>3</sup> Dicer." Compl. ¶ 32. It also alleges that she conceived "treating mammals, including humans, using dsRNA of 21-23 nucleotides with a 3' overhang." Id. ¶ 33. The complaint describes in detail the chronology explaining how she conceived of those inventions and combined them with the prior art, allegedly making her the sole inventor of the patents. Id. ¶¶ 34-43, 50-56, 70, 74-77.

Defendants contend that Utah is really making a claim for priority of invention, not sole inventorship, and such a claim is not actionable under § 256. Their reliance on Rubin v. Gen. Hosp. Corp., 2011 WL 1625024 (D. Mass. Apr. 28, 2011) is misplaced. In Rubin, the district court allowed summary judgment on a complete substitution claim where there was no evidence of "even the most minimal relationship of interaction with the named inventors." Id. at \*12. Here, there are allegations of interaction between Dr. Bass and the named inventors. Further,

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<sup>3</sup> *C. elegans* is a type of worm about 1 mm in length.

although the district court points out that some district courts have not permitted complete substitution under § 256 where there is no collaboration at all between the inventors, § 256 does not require collaboration as a prerequisite for complete substitution. Stark is not so stark. Rather, it permits sole inventorship claims "as long as the true inventors are without deceptive intent." Stark II, 119 F.3d at 1556.

The Second Amended Complaint also alleges a sufficient "quantum of collaboration or connection" to meet the requirements of joint inventorship under 35 U.S.C. § 116. Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917 (Fed. Cir. 1992); see Compl. ¶¶ 40-61. It alleges that Dr. Bass contributed in "some significant manner to the conception of the invention." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Dr. Bass published an article explaining the capability to mediate RNAi in mammals with dsRNA fragments having a 3' overhang. Compl. ¶¶ 42-43. The named inventors read her article, and incorporated her work. Id. ¶¶ 46-48, 60. She also discussed her conception with the named inventors at two conferences and over dinner. Id. ¶¶ 51-53, 57-58. See Kimberly-Clark, 973 F.2d at 917 ("For persons to be joint inventors under Section 116, there must be some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing

another's suggestion at a meeting."). Federal Circuit caselaw is clear that there is "no bright-line standard" in determining joint inventorship. Fina Oil, 123 F.3d at 1473. Accordingly, the motion to dismiss is denied.

**III. ORDER**

Defendants' motions to dismiss (Docket No. 54 & Docket No. 57) are **DENIED**.

/s/ PATTI B. SARIS  
PATTI B. SARIS  
United States District Judge