

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JEWISH HOSPITAL OF)
ST. LOUIS,)
)
PLAINTIFF)
)
v.)
)
IDEXX LABORATORIES,)
)
DEFENDANT)

Civil No. 95-290-P-H

**ORDER ON IDEXX’S MOTION TO FILE THIRD AMENDED
ANSWER AND COUNTERCLAIM (Docket Item 202)¹**

IDEXX has moved under Fed. R. Civ. P. 15(a) to file a Third Amended Answer and Counterclaim to assert three affirmative defenses: (1) lack of standing or failure to join an indispensable party; (2) patent misuse and unclean hands; and (3) inequitable conduct. I conclude that IDEXX’s proposed amendment is futile because Jewish Hospital does have standing to sue on the ‘275 patent, the United States Government is not an indispensable party, and the remaining affirmative defenses are immaterial. The motion is, therefore, **DENIED**.

¹ IDEXX’s request for oral argument on this motion (Docket Item 213) is **DENIED**. See Local Rule 7(f). The parties addressed the practical implications of this motion at the April 18, 1997, conference, see Tr. of Proceedings (Apr. 18, 1997) at 17-35, and the briefs sufficiently explain the parties’ substantive legal arguments.

STANDARD FOR MOTION TO AMEND UNDER FED. R. CIV. P. 15(a)

Rule 15(a) provides that “a party may amend the party’s pleading . . . by leave of court.” Although Rule 15(a) states that “leave shall be freely given when justice so requires,” the court “need not grant every request to amend, come what may.” Correa-Martinez v. Arrillaga-Belendez, 903 F.2d 49, 59 (1st Cir. 1990). In exercising its discretion to grant or deny leave to amend, a court must consider, among other things, the merits or futility of the amendment. See Foman v. Davis, 371 U.S. 178, 182 (1962). “If the proposed change . . . advances a claim or defense that is legally insufficient on its face, the court may deny leave to amend.” 6 Charles Alan Wright, Arthur R. Miller, et al., Federal Practice and Procedure § 1487 at 637 (1990).

I consider, therefore, the legal sufficiency of IDEXX’s proposed affirmative defenses.

LACK OF STANDING OR FAILURE TO JOIN

IDEXX’s proposed affirmative defenses of lack of standing and failure to join the Government under Fed. R. Civ. P. 19 are based on its contention that title to the ‘275 patent belongs to the Government through what IDEXX characterizes as “automatic transfer” provisions of the Bayh-Dole Act, 35 U.S.C. § 202(c) (“section 202(c)”), and the implementing regulation, 37 C.F.R. § 401.14(d)(1) (“regulation 401.14(d)(1)”). Jewish Hospital only recently acknowledged that the ‘275 patent was obtained in part through the use of funding from the National Institute of Health (“NIH”). See IDEXX Br., Ex. 3 (Letter from John Harvey to the NIH of 03/15/96). Under section 202(c):

Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the [grant recipient] disclose each subject invention to the Federal agency within a reasonable time after it becomes known . . . and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the [grant recipient] make a written election within two years after disclosure to the Federal agency . . . whether the [grant recipient] will retain title to a subject invention . . . provided . . . [t]hat the Federal Government may receive title to any subject invention in which the [grant recipient] does not elect to retain rights or fails to elect rights within such times.

Section 206 empowers the Secretary of Commerce to issue regulations interpreting 35 U.S.C. §§ 201-204. Pursuant to 35 U.S.C. § 206, the Secretary of Commerce has issued a regulation defining the circumstances where title will in fact go to the Federal Government. Specifically, in the event a nonprofit organization like Jewish Hospital fails to disclose the invention to the Federal Government within two months, regulation 401.14(d)(1) provides:

The [grant recipient] will convey to the Federal agency, upon written request, title to any subject invention . . . provided that the agency may only request title within 60 days after learning of the failure of the [grant recipient] to disclose or elect within the specified times.

(Emphasis omitted.)

Neither the statute nor the regulation results in the automatic transfer of title IDEXX asserts. The statute requires funding agreements to provide that the Government “*may* receive title” under certain circumstances. (Emphasis added.) Rather than automatically transferring title to the invention upon late disclosure, the Secretary has provided in regulation 401.14(d)(1) that grant recipients like Jewish Hospital retain title to the invention unless and until the Federal agency meets

two requirements. First, the Federal agency must make a “written request.” 37 C.F.R. § 401.14(d). Second, the Federal agency must make this request “within 60 days after learning of the failure of the [grant recipient] to disclose” 37 C.F.R. § 401.14(d)(1).² Because Congress has given the Secretary authority to issue interpretive regulations, I defer to the Secretary’s reasonable interpretation. See Chevron, U.S.A., Inc. v. National Resources Defense Council, Inc., 467 U.S. 837, 844 (1984) (“We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.”) (footnote omitted). Regulation 401.14(d)(1) is perfectly consistent with the permissive language of section 202(c)(1), which states that “the Federal agency *may* receive title to any subject invention not disclosed to it” within the required time. 35 U.S.C. § 202(c)(1) (emphasis added).³

² Indeed, the very title of regulation 401.14(d) is “*Conditions When the Government May Obtain Title.*” 37 C.F.R. § 401.14(d) (emphasis added).

³ IDEXX’s reliance on FilmTec Corp. v. Hydranautics, 982 F.2d 1546 (Fed. Cir. 1992), cert. denied, 510 U.S. 824 (1993), is misplaced.

FilmTec involved completely different federal funding statutes, the Saline Water Conversion Act (“SWCA”) and the Federal Nonnuclear Energy Research and Development Act (“FNERDA”), with completely different language. Unlike the permissive and conditional language of the statute and regulation here, FNERDA clearly provides that “title to any invention made or conceived under a FNERDA contract ‘*shall vest*’ in the United States.” 982 F.2d at 1550 (emphasis added). Therefore,

when the invention was conceived by [the inventor-grant recipient], title to that invention immediately vested in the United States by operation of law [T]he statute had divested [the inventor-grant recipient] of all his interest [T]he Administrator could have waived title to the invention, or granted an exclusive or partially exclusive license to any party However, the Administrator has not done so. The result, therefore, is that title remained vested in the United States.

982 F.2d at 1553-54. The Federal Circuit based its decision on the fact that the very intent of Congress in enacting SWCA and FNERDA was to create inventions that would automatically belong to the United States. 982 F.2d at 1550-51; see also id. at 1553 (stating that this was also the parties’ intentions). The statute and regulation at issue here, however, contemplate exactly the opposite. Section 202(c)(1) and regulation 401.14(d)(1) specifically allow the grant recipient to retain ownership of the invention until, in certain circumstances, the Federal agency properly elects to acquire such title. Unlike the statutes at issue in FilmTec, the purpose of the Bayh-Dole Act, under which Jewish
(continued...)

IDEXX does not suggest that the NIH has made a written request pursuant to regulation 401.14(d). At this time, therefore, Jewish Hospital retains title to the invention and the ‘275 patent.⁴

Since Jewish Hospital retains title to the ‘275 patent, it has standing to pursue this suit. Furthermore, because the NIH has not elected to acquire title to the ‘275 patent, the Government is not an indispensable party under Rule 19. The Government’s absence from the lawsuit does nothing to expose IDEXX to potential litigation,⁵ nor does it impede any legitimate interest.⁶

PATENT MISUSE AND INEQUITABLE CONDUCT

Finally, IDEXX proposes to assert the affirmative defenses of patent misuse, unclean hands and inequitable conduct based upon the delay in Jewish Hospital’s disclosure to the NIH. Simply put, I fail to see how the allegations of improper delay, even if true, are at all material to this patent infringement case. These allegations concern the Jewish Hospital-NIH funding contract and its procurement. But whether Jewish Hospital misled the NIH has no bearing on any legitimate issues

³ (...continued)

Hospital obtained its grant from the NIH, is not to provide Government-owned patents. See 35 U.S.C. § 200 (stating the policy and objectives of the Bayh-Dole Act).

⁴ I do not decide whether Jewish Hospital has yet made an adequate disclosure to NIH. Whether the 60-day period for NIH to request title has run or not, title at this point stays with Jewish Hospital. IDEXX’s further argument that Jewish Hospital has forfeited any right to exclusive ownership under 37 C.F.R. § 401.14(e)(1) adds nothing, since this provision only applies if the Government has properly received title. Whether Jewish Hospital improperly licensed the patent to Mallinckrodt under the small-business licensing preference of 37 C.F.R § 401.14(k)(4) is a decision for the Secretary of Commerce, see id., and has no bearing on this lawsuit or its current parties.

⁵ IDEXX’s fear of “potential multiple suits,” IDEXX Br. at 7, is unfounded. Any interest the Government may obtain by some later transfer would simply put the Government in the shoes of Jewish Hospital.

⁶ The fact that IDEXX would prefer to defend this suit against the Government rather than Jewish Hospital, see Tr. of Proceedings (Apr. 18, 1997) at 27, is not a legitimate interest for purposes of Rule 19 analysis.

in IDEXX's answer or counterclaims. IDEXX cannot benefit from potential disputes between Jewish Hospital and the NIH arising under the contract and procurement process.

CONCLUSION

Because all of the defenses in the proposed amendment are futile, IDEXX's motion for leave to file a Third Amended Answer and Counterclaim is **DENIED**.

SO ORDERED.

DATED THIS 12TH DAY OF JUNE, 1997.

D. BROCK HORNBY
UNITED STATES CHIEF DISTRICT JUDGE