UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MERIAL LIMITED and MERIAL SAS, Plaintiffs, v. INTERVET, INC., Defendant.	Civil Action No. 1:07-cv-00630 (HHK)

MERIAL LIMITED'S AND MERIAL SAS' MEMORANDUM IN OPPOSITION TO INTERVET'S MOTION TO DISMISS THE MERIAL PARTIES' COMPLAINT

Defendants Merial Limited and Merial SAS (collectively "Merial") oppose Intervet's Motion to Dismiss their complaint. Because all of the issues in case no. 1:07-cv-00559 ("the 559 case") are also present in case no. 1:07-cv-00630 ("the 630 case"), filed by Merial Limited and Merial SAS against Intervet, Inc.,[1] the 559 case should be dismissed, pursuant to Merial's separately filed in that case and the 630 case should be allowed to proceed.

FACTUAL BACKGROUND

I. U.S. Patent No. 7,192,594.

The patent-at-issue in these actions, United States Patent No. 7,192,594 (the "'594 patent") issued on March 20, 2007 to Merial Limited and Merial SAS. The '594 patent is a continuation-in-part of Merial's U.S. Patent No. 6,368,601 (the "'601 patent"), which,

as described below, is the subject of separate, but related, litigation between Merial and Intervet. By definition, as a continuation-in-part of the '601 patent, the application for the '594 patent repeated a substantial portion or all of the earlier application that matured into the '601 patent and added matter not disclosed in that application. *See Manual of Patent Examination & Procedure, Rev. 5, Aug. 2006, § 201.08.* Prior to Intervet filing its complaint in the 559 case, Merial had never discussed the '594 patent or its application with Intervet, nor had Merial ever asserted that Intervet infringed the '594 patent.

II. Litigation and U.S. Patent No. 6,368,601.

A. Merial's Georgia Action.

On December 15, 2005, Merial Limited filed suit against Intervet in the United States District Court for the Northern District of Georgia (the "Georgia Action") alleging Intervet's Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector infringed the '601 patent. On March 31, 2006, Merial filed a motion for a preliminary injunction against Intervet. Intervet's response to Merial's motion for a preliminary injunction was its first of many attempts to delay resolution of Merial's claims that Intervet infringes the '601 patent.

On April 11, 2006, Intervet filed a Motion to Dismiss Merial Limited's complaint in the Georgia Action alleging that Merial Limited lacked standing to enforce the '601 patent and that there were additional parties who were necessary to the case, but whom Intervet did not seek to add as parties. The Georgia Court found that, despite the agreement of the parties who owned the '601 patent at that time that Merial had the

[1] Intervet admits in its Motion to Dismiss Merial's Complaint in case no. 1:07-cv-00630 (D.I. 13, pp. 1, 2) that the two cases involve the same parties and identical issues.

exclusive right to enforce the '601 patent, Merial lacked standing. The Court dismissed the Georgia Action without prejudice on April 27, 2006.[2]

B. Intervet's Declaratory Judgment Action.

On the same day that Intervet filed its Motion to Dismiss in the Georgia Action, Intervet initiated case no. 1:06-cv-00658 before this Court by filing a Complaint for declaratory judgment of non-infringement and invalidity of the '601 patent (the "'601 Litigation") against Merial and two universities. Upon their motion to the Court, the two universities were dismissed because there was no case or controversy between them and Intervet. Had Intervet truly felt the universities were necessary parties to litigation over their infringement of the '601 patent it could have joined them in the Georgia Action, but instead Intervet pursued a new action in another forum over the very same issues that were present in the Georgia Action. In essence, Intervet transferred the case from Georgia to the District of Columbia, and this change of forum allowed Intervet to (i) delay the resolution of Merial's infringement claims regarding the '601 patent, (ii) deprive Merial of its chosen and home forum, and (iii) make Intervet the plaintiff so it could more easily dictate the pace of the '601 Litigation.

Predictably, Intervet has consistently attempted to slow the pace of the '601 Litigation through various scheduling and discovery-related issues and motions. These attempts include, for example, (i) a refusal to agree to any scheduling order which allowed a reasonably prompt resolution of claim construction issues; (ii) a refusal to agree to a protective order in any form common to patent litigations, thereby forcing the

[2] A copy of the April 27, 2006 Order is attached hereto as Exhibit A.

parties to brief this issue extensively before the Court; (iii) delaying responses to Merial's attorneys, sometimes for a month or more, on fairly simple issues when the parties were negotiating a plan for discovery; (iv) taking several unreasonable positions with regard to discovery which forced the parties to undergo extensive negotiation and often brief issues before the Court; and (v) twice moving to amend the case schedule entered by this Court. Intervet's motivation in this regard is palpable: It, not Merial, is the accused infringer, and in that capacity Intervet seeks to delay adjudication of its infringement of the '601 patent so that it can continue to sell its infringing vaccine and garner the considerable profits therefrom. In short, Intervet's conduct and its position as the accused infringer demonstrate that Intervet has no interest in seeing resolution of the '601 Litigation at any time in the near future.

III. Litigation and U.S. Patent No. 7,192,594.

Intervet now has attempted to create a dispute with regard to the '594 patent in an apparent attempt to further delay the resolution of Merial's claims that Intervet infringes the '601 patent. On March 20, 2007, the day the '594 patent issued, Intervet filed—but did not serve—its complaint in the 559 case. When Merial learned of this complaint a few days later, its attorneys contacted Intervet to request service and agreed to waive formal service requirements. In response, Intervet declined to serve its complaint and would not even confirm whether it intended to serve its complaint on Merial at all. Exh. B., 3/28/07 Smith letter to Loughnane. In attempt to overcome Intervet's delay tactics and because Merial could not be sure that Intervet ever planned to serve its complaint,

Merial filed and promptly served on Intervet its complaint for infringement of the '594 patent on April 4, 2007. Only after being served with and having time to review Merial's complaint did Intervet finally serve Merial with the complaint in the 559 case.

ARGUMENT AND CITATION OF AUTHORITIES

Intervet's purpose in filing the complaint in the 559 case was to introduce further delay into the resolution of its infringement of Merial's patents. It is the same Intervet product—Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector—that infringes both Merial patents. An injunction barring infringement of the '601 patent will render an injunction barring infringement of the '594 patent unnecessary. However, in attempt to put itself in the position of plaintiff to control the pace of a suit on the '594 patent and to further slow the '601 patent infringement action, Intervet rushed to file this action on the day the '594 patent issued. In addition to its aim to slow the '601 Litigation, Intervet apparently was determined to once again (i) make itself the plaintiff in a case where Merial is the harmed party and the proper plaintiff and (ii) prevent Merial from filing an action in its home forum.[3] Merial requests that this Court not reward Intervet's procedural fencing tactics.

I. Courts Have Broad Discretion to Decline to Entertain Declaratory Judgment Actions and Have Inherent Power to Control Their Dockets.

This Court has the authority to dismiss the 559 case in favor of this 630 case.

The Declaratory Judgment Act states that "in a case of actual controversy within its jurisdiction . . . any court of the United States . . . *may* declare the rights and other legal relations of an interested party seeking such declaration, whether or not further

relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added). The language of the Act implies, and case law confirms, that a court has "broad discretion to withhold declaratory judgment." *Adair v. Winter*, 451 F. Supp. 2d 210, 215 (D.D.C. 2006). Indeed, the "Supreme Court in Wilton took great pains to emphasize the singular breadth of the district court's discretion to withhold declaratory judgment." *Jackson v. Culinary Sch. of Wash., Ltd.,* 59 F.3d 254, 256 (D.C.Cir. 1995) (referencing *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995). Even where jurisdiction otherwise exists, courts have undisputed discretion not to hear declaratory judgment actions. *Brillhart v. Excess Ins. Co. of Am.,* 316 U.S. 491, 494 (1942); *Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Assocs.*, 16 Fed. Appx. 433, 437 (6th Cir. 2001). Simply because a declaratory judgment action satisfies subject matter jurisdiction prerequisites such that "a court *can* enter a declaratory judgment does not mean that it should." *In re Iraq & Afganistan Detainees Lit.*, 479 F. Supp. 2d 85, 118 (D.D.C. 2007). Even where all other requirements are met, a court may "properly refuse to grant declaratory relief for prudential reasons." *Coalsales II, LLC v. Gulf Power Co.*, No. 06-CV-488, 2007 WL 612252, at *5 (S.D. Ill., Feb. 23, 2007). Cases in which courts properly refuse to grant declaratory relief are largely intellectual property cases. *Id.* Where a declaratory judgment action is filed in anticipation of an infringement action, it is proper for the infringement action to proceed even if it is filed a few days later. *Tempco Elec. Heater Corp. v. Omega Eng'g, Inc.*, 819 F.2d 746, 749 (7th Cir. 1987); *Eli's Chicago Finest, Inc. v. The Cheesecake Factorty, Inc.*, 23 F. Supp. 2d 906 (N.D. Ill. 1998).

[3] Merial does not dispute, however, that in light of the '601 patent suit which is pending in this Court, this is also a proper forum for the '594 patent suit.

In addition, every court has the inherent power "to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936); *see also U.S. v. Colomb,* 419 F.3d 292, 299 (2005) ("The Federal courts are vested with inherent power 'to manage their own affairs so as to achieve the orderly and expeditious disposition of cases[,]' include[ing] the power of the court to control its docket[.]").

II. Dismissal of Intervet's Complaint Is Appropriate.[4]

A. Intervet's Behavior Mitigates in Favor of Allowing This Case To Proceed.

Intervet's procedural conduct in this case weighs in favor of this Court allowing this case, rather than the 559 case, to proceed. Specifically, by filing—but refusing to serve—its declaratory judgment complaint on Merial, Intervet engaged in "gamesmanship and procedural fencing." *Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Assocs., Inc.*, 16 Fed. Appx. 433, 438 (6th Cir. 2001). Such "procedural fencing" weighs in favor of dismissing a declaratory judgment action. *Zide*, 16 Fed. Appx. at 438 (holding that a "lack of service" of a complaint after filing it is evidence of "gamesmanship and procedural fencing, factors that [] weigh in favor of dismissing a declaratory action"). Although Fed. R. Civ. P. 4(m) provides that a plaintiff has 120 days to serve its complaint before it will be dismissed for lack of service, courts may dismiss an action during that 120 day period for other reasons, including gamesmanship evidenced by a lack of service after filing. *Zide*, 16 Fed. Appx. at 438. Intervet's refusal to serve Merial, even after Merial contacted Intervet's attorneys to request service, and

especially Intervet's refusal to confirm whether it ever planned to serve Merial, are clear indications that Intervet's rush to file the '594 patent suit was improper "procedural fencing."

Through its discretion with regard to declaratory judgment actions and its inherent ability to control its docket, this Court has the power to dismiss the 559 action in favor of the 630 action. Intervet's procedural fencing, gamesmanship and continued attempts to delay the litigation over its infringing product in both Action No 1:06-cv-658 and in these cases, dictate that it should.

B. The First to File Rule Is Not Applicable.

The first-to-file rule is not applicable here because that rule only applies to cases filed in separate federal courts. *Empagran S.A. v. F. Hoffman-La Roche, Ltd.*, No. CIV.00168, 2001 WL 761360, *7 (D.D.C. June 7, 2001) (stating that "the first-to-file rule would not apply here because the claims are pending in two cases in this court rather than in two different courts")(reversed on other grounds, 315 F.3d 338 (D.C.Cir. 2003)); *Amsouth Bank v. Dale*, 386 F.3d 763, 791 n. 8 (6th Cir. 2004) (finding reliance on first-to-file rule improper because it "only applies to two cases in separate federal courts").[5] Because these actions are pending in the same court, the first-to-file rule does not apply and the decision of this Court regarding which case should proceed is left to its discretion with respect to declaratory judgment actions and its inherent power to control its docket.

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[4] This Court also has the authority to strike Intervet's Complaint under Fed.R.Civ.P. 12(f). *Ortho-Tain, Inc. v. Rocky Mountain Orthodontics, Inc.*, No. 05 C 6656, 2006 WL 3782916 (N.D. Ill. Dec. 20, 2006).

[5] Although Intervet cites the *SAS Inst.* case for the proposition that the first-to-file rule should apply even when both cases are filed in the same district court, this is not the generally accepted position on this issue, as even the *SAS* Court acknowledged. *SAS Inst., Inc. v. PracticingSmarter, Inc.*, 353 F.Supp.2d 614 (M.D.N.C. 2005) (noting that application of the first to file rule has historically been in cases where two distinct federal courts have concurrent jurisdiction over actions embracing the same issues).

Even if these cases were filed in different courts, the first-to-file rule should still not apply because equity dictates that the Court should ignore the first-to-file rule in this situation. "District Courts have the discretion to dispense with the first-to-file rule where equity so demands." *Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Assocs.*, 16 Fed. Appx. 433, 437 (6th Cir. 2001). "[T]he first-filed Rule is not a strict rule and much more often than not gives way in the context of a coercive action filed subsequent to a declaratory judgment." *Amsouth Bank v. Dale*, 386 F.3d 763, 791 n. 8 (6th Cir. 2004).

Intervet's suit is an anticipatory filing, which weighs against enforcement of the first-to-file rule. *Zide*, 16 Fed. Appx. at 437 ("Factors that weigh against enforcement of the first-to-file rule include extraordinary circumstances, inequitable conduct, bad faith, anticipatory suits, and forum shopping"). Intervet first rushed to the Court and filed its complaint on the day that the '594 patent issued, without any discussion of this patent with Merial or any threat by Merial that the '594 patent would be enforced. Intervet then proceeded to withhold service until after Merial commenced its own action against Intervet based on infringement of the '594 patent. Intervet's suit was clearly a preemptive strike against Merial. Where a declaratory action is brought to preempt suit by the other party in another forum, the declaratory judgment plaintiff does not deserve the protection of the first-to-file rule. *Lewis v. National Football League*, 813 F. Supp. 1, 4 (D.D.C. 1992). "[A] plaintiff, even one who files first, does not have a right to bring a declaratory judgment action in the forum of his choosing." *Zide,* 16 Fed. Appx. at 437 (quoting *Tempco Elec. Heater Corp. v. Omega Eng'g. Inc.*, 819 F.2d 746, 749-50 (7th Cir. 1987)). Here, Intervet was trying to prevent Merial from filing in its home forum

and from assuming its natural role as plaintiff in a suit over the infringement of a Merial patent. Intervet's failure to serve—and subsequent failure to confirm (or refute) its intent to serve—only exacerbate its inequitable conduct.

For the reasons discussed in detail above, Merial respectfully requests that the Court decline to entertain Intervet's declaratory judgment action and instead proceed with Merial's patent infringement action.

C. Merial Is the Proper Plaintiff.

Because identical issues are presented in both of these cases, a dismissal of Intervet's complaint in the 559 case would have the same effect as consolidating these cases into one in which Merial is the plaintiff. To the extent that one of these cases is better suited to go forward, i.e., has the correct posture, it is the 630 case in which Merial is the plaintiff.

Where one party claims injury by another, the party claiming injury is the "natural plaintiff." *BASF Corp. v. Symington*, 50 F.3d 555, 557 (8th Cir. 1995). Even where there may be "actual and substantial ancillary or secondary issues to the primary issue, the parties should be aligned in accordance with the primary issue in an action." *United States Fid. & Guar. Co. v. Thomas Solvent Co.*, 955 F.2d 1085, 1089 (6th Cir. 1992).

The primary dispute in this action is Merial's assertion of patent infringement claims against Intervet. *See* 6 Donald D. Chism *Chism on Patents* § 19.01 (1), at 19-14 (1993) ("In traditional terms, infringement constitutes the case-in-chief of the patent owner.") All of Intervet's claims in this action are generally considered defenses in an infringement action brought by a patentee. *See* 35 U.S.C. § 282 (designating noninfringement, unenforceability, and invalidity as defenses to patent infringement).

Merial Limited's and Merial SAS' affirmative position and status as the harmed parties makes them the natural plaintiffs in this suit, while Intervet's defensive position makes it the natural defendant. *See Plumtree Software, Inc. v. Datamize LLC,* No. C-02-5693 VRW, slip. op. at 7-8 (N.D. Cal. Oct. 6, 2003). Accordingly, the parties should be aligned in accordance with their natural positions on the primary issue in this action, and case No. 1:07-cv-00630 should be allowed to proceed.

III. Merial Acted Properly In Filing Its Complaint In Case No. 1:07-cv-00630.

Intervet asserts that Merial acted improperly and that it should have answered the Complaint in the 559 case even though Intervet had refused to serve it. In support of this assertion Intervet cites to Fed. R. Civ. P. 3 and *Howell v. Tribune Entm't Co.*, 106 F.3d 215, 217 (7th Cir. 1997). Even if these sources did support Intervet's assertion that the Federal Rules permit a defendant to file an answer before being served with a complaint, which these authorities emphatically do not, there is still no support for Intervet's assertion that Merial acted improperly.[6] Even if defendants were "permitted" to file an answer before being served with an answer this hardly means they are "required" to do so. Especially here, where Intervet refused to serve Merial and also would not confirm that it ever intended to serve Merial, Merial actions in filing a separate action that should take precedence are fully justified.

[6] Tellingly, Intervet ignores Fed.R.Civ.P. 12(a)(1) which provides that answers are served in response to service of a summons and complaint, not in response to the filing of a summons and complaint.

CONCLUSION

Merial respectfully requests that Intervet's complaint against it in the 559 case be dismissed, Intervet's Motion to Dismiss Merial's complaint in the 630 case be denied, and the 630 case be allowed to proceed.

Respectfully submitted, this 30th day of May, 2007.

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EXHIBIT A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MERIAL LIMITED and MERIAL SAS, Plaintiff, v. INTERVET INC., Defendant.	CIVIL ACTION NO. 1:05-CV-3168-CAP

O R D E R

This matter is before the court on Intervet's motion to dismiss or, in the alternative, to transfer [Doc. No. 16].

Factual Background and Procedural History

This is a patent infringement action dealing with allegedly competing vaccines used to combat Post-Weaning Multisystemic Wasting Syndrome.

A. Post-Weaning Multisystemic Wasting Syndrome and Porcine Circovirus

Post-Weaning Multisystemic Wasting Syndrome ("PMWS") is a slow, progressive disease in young pigs that is characterized by difficulty breathing, weight loss, and death. PMWS affects roughly 5% of U.S. herds. Mortality in acutely affected herds varies from 5% to 50%, and chronically infected herds may sustain average losses of 15% from weaning to slaughter.

PMWS was first recognized in 1996 in Canada. Since then, hundreds of swine farms in Canada and Europe have been affected. The disease has also spread to swine farms in the United States.

While PMWS is the clinical disease, one co-factor responsible for causing PMWS is the porcine circovirus ("PCV").[1] There are two known "serotypes" of PCV called Type 1 and Type 2. Type 1 does not cause a known disease. Type 2 strains, however, can be found in the lesions of PMWS-affected pigs.

Scientists and veterinarians believe that piglets are most susceptible to PCV and subsequent PMWS after they have been weaned from their mothers when they are about 3-10 weeks old, hence the name "Post-Weaning Multisystemic Syndrome." Protecting piglets from PCV and subsequent PMWS can be done in two ways: by vaccinating a sow (an adult female pig) just before or during pregnancy, and thereby inducing a transfer of maternally derived antibodies to the piglets, or by vaccinating the piglets themselves.

Both Merial and Intervet have developed vaccines to combat PCV Type 2 ("PCV-2") and subsequent PMWS. These vaccines are the subject of this patent infringement suit.

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[1] PCV received its name because its DNA is in the form of a ring.

B. Merial's CIRCOVAC Vaccine

Plaintiff Merial Limited ("Merial") develops, produces, and sells veterinary pharmaceuticals and vaccines for livestock, pets, and wildlife. Merial SAS is a wholly-owned subsidiary of Merial.

On April 9, 2002, the United States Patent and Trademark Office issued U.S. Patent No. 6,368,601 entitled "Porcine Circovirus Vaccine and Diagnostics Reagents" (the "'601 Patent"). The '601 Patent relates to strains of the PCV-2 virus. The '601 Patent is assigned to Merial SAS, the Queen's University of Belfast ("Belfast"), and the University of Saskatchewan ("Saskatchewan").

On February 6, 1998, Belfast, Saskatchewan, and Merial SAS entered into an agreement concerning PCV research that leads to patents (the "Tripartite Agreement"). In particular, the Tripartite Agreement granted Merial an "exclusive and worldwide right and license for industrial and commercial exploitation" of any patents obtained as a result of work done in connection with the Tripartite Agreement. Merial SAS was also given the right to grant sublicenses covering the patents to its affiliates.

In exchange for this grant, as well as royalties on the net sales of products manufactured under the covered patents, Belfast and Saskatchewan were granted the right to dispose of the patents to carry on any internal scientific, research, or teaching works. The Tripartite Agreement specifically prohibits Belfast and

Saskatchewan from exploiting the patents commercially or industrially or granting any right or license to any third party. The '601 Patent was obtained as a result of work done in connection with the Tripartite Agreement and is, therefore, covered by the Tripartite Agreement.

On April 14, 2006, Merial SAS, Merial's wholly-owned subsidiary, granted Merial the exclusive right to conduct "any and all activities world-wide relating to the filing, prosecution, and enforcement of" the '601 Patent in the United States. Merial claims that this written license agreement merely memorialized Merial SAS and Merial's prior oral agreement.

Merial SAS manufacturers a PCV vaccine derived from the '601 Patent called CIRCOVAC. CIRCOVAC is designed to be used in pregnant sows. It works by producing high concentrations of Maternally-Developed Antibodies ("MDA") that can be passed to the piglets through the colostrum in order to provide them protection from the PCV-2 virus. Because the sow passes the MDAs to her piglets, Merial's CIRCOVAC provides passive immunization to the piglets.

CIRCOVAC is approved for use in Europe and Canada.[2] Although Merial is seeking authorization to market CIRCOVAC in the United

[2] CIRCOVAC was introduced into the Canadian market on March 20, 2006.

States, the United States Department of Agriculture ("USDA") has not yet granted Merial authorization to do so.

C. Intervet's PCV Vaccine

Similar to Merial, defendant Intervet researches, develops, and manufactures animal health products, such as veterinary vaccines and pharmaceuticals. Intervet currently offers four different swine pharmaceutical products and 23 different types of swine vaccines in the United States.

On February 13, 2003, Intervet gave notice to the USDA that it was developing a vaccine product to help halt the spread of PMWS associated with PCV infection. Approximately two and a half years later, on October 13, 2005, the USDA granted Intervet a conditional veterinary biological product license for the manufacture and distribution of its circovirus vaccine entitled "Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector" ("Intervet PCV vaccine"). The USDA issued the conditional license because it found there was a "need for the product to aid in the protection of disease caused by Porcine Circovirus." According to the conditional license, Intervet's PCV vaccine is manufactured in Delaware.

Intervet's PCV vaccine is labeled for use in pigs three weeks of age or older, the point at which the piglet's passive immunity has declined and the piglet can respond to the vaccine and develop

its own active immunity. Unlike Merial's CIRCOVAC vaccine, Intervet's PCV vaccine provides active immunization to the piglets in that, it is designed to stimulate a piglet's immune system to develop protection from the PCV-2 virus.[3]

Absent USDA approval of Merial's CIRCOVAC vaccine, Intervet's PCV vaccine is the only PCV-2 vaccine available to U.S. swine producers.

D. This Lawsuit

On December 12, 2005, Merial instituted this patent infringement action against Intervet claiming that Intervet has infringed, contributed to the infringement of, and/or actively induced the infringement of at least one of claims 9, 16, 32, 33, and 35 of the '601 Patent by making, using, selling, and/or offering to sell its PCV vaccine. Although no affidavit of service is present in the record, Intervet claims that it was served on March 10, 2006.

On March 31, 2006, before Intervet answered Merial's complaint, Merial filed a motion for a preliminary injunction [Doc. No. 13]. At the time that Merial filed its motion for a preliminary injunction, Merial was aware of the fact that Intervet

[3] Because Intervet's vaccine is designed to be used on piglets who are three weeks of age or older, by definition, it provides no protection for piglets who are less than three weeks old or who have not been weaned.

was taking orders for its PCV vaccine in Canada and that Intervet had obtained a conditional license to sell its PCV vaccine in the United States. Merial claims it did not know Intervet was selling its PCV vaccine in the United States.

Approximately two weeks later, on April 10, 2006, Merial filed a motion for a temporary restraining order against Intervet [Doc. No. 14]. Merial claims that the motion for a temporary restraining order was necessitated by the fact that Intervet had begun selling its PCV vaccine in the United States.

One day later, Intervet filed suit in the District Court for the District of Columbia against Merial, Merial SAS, Belfast, and Saskatchewan seeking a declaratory judgment of non-infringement and invalidity of the '601 Patent. On the same day that Intervet filed its declaratory judgment action, Intervet also filed the present motion to dismiss or, in the alternative, to transfer this case to the District Court for the District of Columbia.

Six days after Intervet filed its motion to dismiss, on April 17, 2006, Merial amended its complaint to add Merial SAS as a plaintiff.

Legal Analysis

In its motion to dismiss, Intervet argues that the court should dismiss the action because Merial did not have standing to sue for patent infringement at the time that it filed suit and has

failed to join necessary parties. In the alternative Intervet asks the court to transfer the case to the District Court for the District of Columbia, where Intervet filed a patent infringement action against Merial and all three owners of the '601 Patent.

Standing to sue is a threshold requirement in any federal lawsuit. Sicom Systems Ltd. v. Agilent Technologies, Inc., 427 F.3d 971, 975 (Fed. Cir. 2005). Standing must be present at the time the suit is brought. Id. at 976. The party bringing the action bears the burden of establishing that it has standing. Id.

The requirement of standing is both a constitutional limitation on federal court jurisdiction and a prudential limitation on its exercise. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 112 S. Ct. 2130, 2136 (1992). The constitutional requirements for standing emanate from Article III of the United States Constitution, which states that federal courts may only adjudicate cases or controversies. Allen v. Wright, 468 U.S. 737, 750-51, 104 S. Ct. 3315, 3324 (1984). Constitutional standing requires only that the plaintiff have suffered an injury in fact, that there be a causal connection between the injury and the defendant's conduct, and that the injury be redressable by a favorable court decision. Lujan, 504 U.S. at 560, 112 S. Ct. at 2136.

In addition to constitutional standing, standing to sue for patent infringement is also controlled by the Patent Act, which provides that a "patentee shall have remedy by civil action for infringement of his patent." Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1376-77 (Fed. Cir. 2000) (citing 35 U.S.C. § 281 (1994)). Thus, standing to sue for infringement of a patent generally rests with the patent owner(s) or the owner's assignees and not a bare licensee. Sicom Systems, 427 F.2d at 976; Waterman v. Mackenzie, 138 U.S. 252, 255 (1891).

"While a licensee normally does not have standing to sue without joinder of the patentee, an exclusive license may be tantamount to an assignment for purposes of creating standing if it conveys to the licensee all substantial rights to the patent at issue." Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336, 1340 (Fed. Cir. 2006). Whether a transfer is an assignment or a license does not depend upon the name by which it calls itself but upon the legal effect of its provisions.

To determine whether an agreement to transfer rights to a patent amounts to an assignment, the court must ascertain the intention of the parties and examine the substance of the rights granted in the agreement. Id. At its heart, the question is, "Who owns the patent? Does the transfer or retention of certain rights amount to an assignment of the patent or not? A key factor has

often been where the right to sue for infringement lies." Aspex Eyewear, 434 F.3d at 1342.

Merial first argues that its relationship and agreements with Merial SAS conferred upon it the right to bring suit against Intervet. In particular, Merial argues that it had standing to bring suit because Merial SAS is a wholly-owned subsidiary of Merial. Merial also contends that its verbal agreement and nunc pro tunc written license from Merial SAS conferred standing upon Merial to sue in its own name without joining Merial SAS or the other two patent owners.

Neither Merial's relationship nor its agreements with Merial SAS conferred standing upon Merial to sue for patent infringement in its own name on December 15, 2005. As an initial matter, standing under the Patent Act cannot be based on the mere fact that Merial SAS is a wholly-owned subsidiary of Merial. Merial's ownership of Merial SAS alone does not make Merial the owner of the '601 Patent. See, e.g., DePuy, Inc. v. Dimmer Holdings, Inc., 384 F. Supp.2d 1237, 1239 (N.D. Ill. 2005) (dismissing case because the corporate parent of a patent owner lacked standing to sue for infringement); Beam Laser Systems, Inc. v. Cox Communications, Inc., 117 F. Supp.2d 515, (E.D. Va. 2000) ("ownership of corporate stock does not create equitable title in that corporation's property."); Lans v. Gateway 2000, Inc., 84 F. Supp.2d 112, 123

(D.D.C. 1999) (holding that the plaintiff did not have standing to bring a patent infringement action in his own name where he had assigned his rights in the patent to a company, even though he was the managing director and sole shareholder of that company); Site Microsurgical Systems, Inc. v. Cooper Co., Inc., 797 F. Supp. 333, 338 (D. Del. 1992) ("The Court is not convinced, and the plaintiff offers no authority, that a parent corporation effectively has the patent rights of owners, assignees, and licensees by virtue of its ownership of a subsidiary holding the patent."). Merial's ownership of Merial SAS, therefore, was not enough to confer standing upon Merial.

Merial and Merial SAS's verbal agreement also is not sufficient to confer standing upon Merial. To have standing to sue in its own name for patent infringement, Merial's license must be considered a virtual assignment. See Enzo APA & Son, Inc. v. Geapag A.G., 134 F.3d 1090, 1093 (Fed. Cir. 1998). While a license may be oral, if the license is going to be considered a virtual assignment, it must be in writing. Id. Accordingly, the alleged verbal agreement between Merial and Merial SAS did not confer standing upon Merial.

Perhaps in recognition of this flaw, Merial and Merial SAS entered into a written license agreement memorializing their alleged oral agreement on April 14, 2006 ("Merial License"). The

Merial License is retroactive, effective as of December 19, 2001, thus predating the filing of this suit. Nunc pro tunc assignments, like the Merial License, however, are not sufficient to confer retroactive standing upon Merial. Enzo APA, 134 F.3d at 1093 ("As a general matter, parties should possess rights before seeking to have them vindicated in court. Allowing a subsequent assignment to automatically cure a standing defect would unjustifiably expand the number of people who are statutorily authorized to sue."). Merial, therefore, did not have standing to sue Intervet on December 15, 2005.

To avoid dismissal and out of an "abundance of caution," Merial amended its complaint on April 17, 2006, to add Merial SAS as a party-plaintiff. Merial argues that the amendment relates back to the complaint. Thus, even if the court were to decide that Merial lacked standing at the time this action was filed, Merial argues that it cured the defect when it added Merial SAS because Merial SAS had standing based on the Tripartite Agreement and the amendment adding Merial SAS relates back to the time the suit was filed.

Even assuming Merial had constitutional standing such that it could amend the complaint to add Merial SAS,[4] the amendment does

[4] If Merial lacked Article III standing at the time the suit was filed, the defect could not be cured by the addition of a party

not satisfy the Patent Act's requirements for standing because the Tripartite Agreement did not confer substantial rights in the '601 Patent upon Merial SAS.[5] First and most importantly, the Tripartite Agreement does not state that Merial SAS has the exclusive right to sue for infringement. See Sicom Systems, 947 F.3d at 979 (stating that the exclusive right to sue for patent infringement is an important and often dispositive right). Although the Tripartite Agreement requires Merial SAS to bear the relevant costs of an infringement action, this requirement is not tantamount to an exclusive right to sue for infringement. At most, it suggests that Merial SAS must participate in an infringement

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with standing. See Schreiber Foods, Inc. v. Beatrice Cheese, Inc., 402 F.3d 1198 (Fed. Cir. 2005) ("In the area of patent infringement, this court has held that if the original plaintiff lacked Article III standing, the suit must be dismissed, and the jurisdictional defect cannot be cured by the addition of a party with standing."); Wright v. Dougherty County, Georgia, 358 F.3d 1352, 1356 (11th Cir. 2004) (affirming dismissal of the complaint and stating that "[b]y lacking standing to bring a claim the appellants also lack standing to amend the complaint to consolidate with a party who may have standing"); Lans, 84 F. Supp.2d at 115 (D.D.C. 1999) ("The Court adopts the rule that a patent plaintiff may not amend the complaint to substitute a new plaintiff in order to cure a lack of jurisdiction, because a plaintiff may not create jurisdiction by amendment where none exists."). Because the Tripartite Agreement did not confer substantial rights on Merial SAS, the court does not reach this issue.

[5] In addition, it appears to the court that one of the inventors, Mr. McNeilly, did not formally assign his rights to Merial SAS, Belfast, or Saskatchewan, until after this suit was filed.

action through the payment of costs.[6] In fact, the Tripartite Agreement appears to contemplate cooperation between all three patent owners. For example, Paragraph 7.4 states that each of the owners must notify the other owners of any apparent infringement. It also states that Belfast, Saskatchewan, and Merial SAS shall closely cooperate in any procedure and/or defense. See id. (dismissing the complaint for lack of standing, in part, because Sicom was required to consult with the patent owner and the patent owner's consent was required before settling litigation).

Second, the Tripartite Agreement does not give Merial SAS unfettered discretion to assign its rights in the '601 Patent or grant sublicenses. The Agreement, for instance, only states that Merial SAS may grant manufacturing sublicenses to its affiliates. Merial SAS's ability to assign its rights is further limited by Paragraph 8, which states that subject to Merial SAS's limited right to grant sublicenses, the rights set out in the Tripartite Agreement cannot be assigned to a third party without the express agreement of all three owners. See Sicom Systems, 947 F.3d at 979 (holding that Sicom lacked standing, in part because the license

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[6] Similarly, although Paragraph 6.2 of the Tripartite Agreement requires Merial SAS to file and keep the patents in force, Belfast and Saskatchewan retained the right to file and maintain the patents in their own name at their own expense if they do not agree with the manner in which Merial SAS was filing or keeping the patents in force.

agreement limited Sicom's right to assign its interests in the patent).

Third, the Tripartite Agreement does not grant Merial SAS the sole right to use or make the '601 Patent. Paragraph 6.1 of the Tripartite Agreement specifically states that "[t]he ownership of all and any results, inventions, and technologies . . . shall be the common equally shared property of the Parties hereto." Further, as noted above, Belfast and Saskatchewan retained the right to freely dispose of the '601 Patent to carry on any internal scientific, research, or teaching works. At most, Merial SAS received the right to use, sell, and make the '601 Patent in the industrial and commercial fields.

Although the court recognizes that Belfast and Saskatchewan have submitted affidavits stating that Merial and Merial SAS have had the exclusive right to enforce the '601 Patent since before December 15, 2005, the court must first look to the plain language of the Tripartite Agreement. The plain language of the Agreement is unambiguous, and it does not grant Merial or Merial SAS the exclusive right to enforce the '601 Patent. Furthermore, the fact that Belfast and Saskatchewan have agreed nunc pro tunc to be bound by the decision in this case does not mean that they should not be joined as party-plaintiffs. See Prima Tek II, 222 F.3d at 1381 (holding that the patentee was a necessary party to the

infringement suit, even though the patentee had expressly agreed to be bound by any judgment rendered in an action to which its licensee was a party).

Accordingly, because Belfast and Saskatchewan retained substantial rights in the '601 Patent, Merial SAS did not have standing to sue solely in its own name for infringement. See Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1468 (Fed. Cir. 1998) ("An action for infringement must join as plaintiffs all co-owners."). Intervet's motion to dismiss, therefore, is due to be granted.

Conclusion

For the reasons discussed above, the court GRANTS IN PART and DENIES IN PART Intervet's motion to dismiss [Doc. No. 16]. Intervet's motion [Doc. No. 16] is DENIED to the extent it seeks transfer of this case to the District Court for the District of Columbia and to the extent that it seeks dismissal with prejudice. Intervet's motion [Doc. No. 16] is GRANTED, however, to the extent that it seeks dismissal of this action without prejudice. This case is DISMISSED WITHOUT PREJUDICE and the clerk is DIRECTED to close the file.

Because the court concludes that Merial lacked standing to bring this lawsuit and, thus, dismissal is proper, Merial's motion for a temporary restraining order [Doc. No. 14] and Merial's motion

for a preliminary injunction [Doc. No. 13] are also DISMISSED as moot.

SO ORDERED, this 27th day of April, 2006.

/s/ Charles A. Pannell, Jr.
CHARLES A. PANNELL, JR.
United States District Judge

EXHIBIT B

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March 28, 2007

VIA E-Mail

Michael Loughnane
Kenyon & Kenyon LLP
One Broadway
New York, NY 10004.

Re: *Intervet v. Merial et al*

Dear Mike:

For the sake of good order, I want to confirm our recent discussions with respect to the following matters:

1. **Intervet's declaratory judgment action with respect to the '594 patent:** The summons and complaint have yet to be served on the Merial entities named in Intervet's action filed in the United States District Court for the District of Columbia on March 20, 2007, and when we spoke yesterday, you were unable to tell me what Intervet's intentions with respect to service are. However, as I indicated to you, I have been authorized to accept service of process of the summons and complaint on behalf of Merial Limited and Merial SAS. If Intervet decides to serve the summons and complaint, please arrange to have the original of the summons and complaint sent to me.

2. **The protective order in the declaratory judgment action with respect to the '601 patent:** Merial believes that the "fine" provisions of the order should be modified to apply only to counsel for the parties who receive access to attorneys' eyes only documents and information. Accordingly, Merial cannot agree to Intervet's suggestion that the "fine" provisions apply only to specified in-house attorneys and to counsel that prosecute patents for the parties and who have access to attorneys' eyes only documents and information. Drafts of a motion, brief, and protective order that are intended to reflect Merial's position are attached for Intervet's consideration. Merial believes that the motion to amend should be brought to the attention of Magistrate Judge

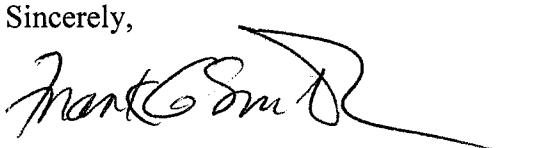
Facciola promptly and therefore asks that Intervet let me know by noon, EDT this Friday, March 30, 2007, if Intervet will, or will not, agree to join in the motion.

3. **Call with Judge Kennedy 11:00 a.m. April 9, 2007:** Merial will arrange to set up the call. Please provide me with the names of the attorneys representing Intervet who you want to be on the call, and we will set up a dial-in number.

4. **Production of Intervet's documents:** Although I understand that Intervet has not at this time decided whether it will appeal Magistrate Judge Facciola's ruling on Merial's motion for a protective order or whether it will join in Merial's motion to amend (item 2 above), there is no reason for Intervet not to have gathered and have ready for production the documents which Merial has requested Intervet to produce. Accordingly, once the protective order issues are resolved, Merial expects Intervet to produce immediately all of the remaining documents Merial has requested.

5. **Experts on claim construction issues:** In response to your suggestion that we exchange the names of expert witnesses who will provide testimony in connection with claim construction, I suggest that we agree to exchange the names of any such witnesses two weeks prior to the submittal of the initial claim construction briefs, *i.e.*, by April 18, 2007 and that the depositions of such experts take place following service of the initial claim construction briefs but prior to service of the second claim construction briefs, with the understanding that the expert(s) agree to make themselves available at reasonable times and places during that time-frame. Merial has considered Intervet's suggestion that the parties will not be required to retain or produce drafts of expert(s)' reports and cannot agree to it. In particular, Merial expects that all drafts of expert reports associated with the Georgia action will be retained and produced at the appropriate time.

Sincerely,



Frank G. Smith, III

FGS,III/jrh
cc: All Counsel of Record

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