

PUBLISHED

**UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

SUCAMPO PHARMACEUTICALS,
INCORPORATED, a Delaware
corporation,

Plaintiff-Appellant,

v.

ASTELLAS PHARMA, INCORPORATED,
formerly known as Fujisawa
Pharmaceutical Company, Limited,

Defendant-Appellee.

No. 06-1036

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.
Peter J. Messitte, District Judge.
(CA-05-687-PJM)

Argued: October 24, 2006

Decided: December 22, 2006

Before WILKINS, Chief Judge, GREGORY, Circuit Judge,
and James R. SPENCER, Chief United States District Judge for the
Eastern District of Virginia, sitting by designation.

Affirmed by published opinion. Judge Gregory wrote the opinion, in
which Chief Judge Wilkins and Judge Spencer joined.

COUNSEL

ARGUED: James D. Dasso, FOLEY & LARDNER, L.L.P., Chicago,
Illinois, for Appellant. Karen L. Hagberg, MORRISON & FOER-

STER, L.L.P., New York, New York, for Appellee. **ON BRIEF:** Derek L. Wright, FOLEY & LARDNER, L.L.P., Chicago, Illinois; Vineeta A. Bathia, FOLEY & LARDNER, L.L.P., Washington, D.C., for Appellant. Kyle W. K. Mooney, MORRISON & FOERSTER, L.L.P., New York, New York, for Appellee.

OPINION

GREGORY, Circuit Judge:

Sucampo Pharmaceuticals, Inc. ("Appellant" or "Sucampo") appeals the dismissal of its breach of contract claims against Astellas Pharma, Inc. ("Appellee" or "Astellas") on the basis of a forum-selection clause contained in the parties' licensing agreement. Because we find that the safety agreement under which Sucampo sued was at least "incidental to" the licensing agreement, and thus governed by the forum-selection clause requiring Sucampo to bring suit in Japan, we affirm the decision of the district court.

I.

The immediate relationship between the parties dates back to 1998, when a corporate predecessor to Sucampo signed an agreement ("Development Agreement") with a corporate predecessor of Astellas. The Development Agreement concerned Sucampo's development and testing of a drug based on Astellas's compound, FK506 ("FK506"). The Development Agreement was written in Japanese and executed in Japan, but did not contain a forum-selection clause. The Development Agreement contained a provision mandating that the parties agree to guidelines for the exchange of safety information relating to FK506. Later in 1998, the parties executed an agreement relating to the exchange of safety information. This agreement was "executed under" the Development Agreement (J.A. 164), contained detailed terms dictating the exchange of information relating to FK506, and was effective until the termination of the Development Agreement, unless otherwise agreed.

In 1999, the parties executed another agreement ("Basic Agree-

ment") with respect to the continued development and commercialization of FK506. Like the Development Agreement, the Basic Agreement contained a provision mandating that the parties develop guidelines for the exchange of safety information. In addition, the Basic Agreement provided that "[a]s for each item to be developed and commercialized in accordance with this Agreement, [the parties] shall separately enter into an individual agreement pursuant to the provisions hereof as a basis."¹ (J.A. 39.) The Basic Agreement contained a Japanese choice-of-law provision and a forum-selection provision governing "[t]his Agreement" and specifying the exclusive jurisdiction of the Japanese courts. (J.A. 43, 190.)

Following the execution of the Basic Agreement, the parties executed a new agreement concerning the exchange of safety information ("Safety Agreement"). The Safety Agreement provided that it was executed "[u]nder the basic agreement," and was intended to "provide a general guide for the safety information exchange on [the compound] between [the parties.]" (J.A. 24.) The term of the Safety Agreement "unless otherwise agreed upon between [the parties]" was "until the termination for whatever reason of the Basic Agreement." (J.A. 31.) The Safety Agreement did not contain either a choice-of-law or forum-selection provision.

In 2002, the parties executed a license agreement ("Basic License Agreement") and "agreed that the total legal relationship between [them] with respect to this compound shall be governed by this agreement."² (J.A. 282.) The Basic License Agreement contained a provision regarding the exchange of safety information, which provided that "[the parties] shall enter into an agreement concerning the

¹Because the Basic Agreement was executed in Japanese, the provision quoted in the text is based on the translation provided by the Appellant. Appellee's translation of the identical provision reads: "[The parties] shall conclude separate individual agreements regarding items that are to be developed and/or commercialized based on this agreement, with the provisions set forth in this agreement as the basic principles." (J.A. 178.)

²The Basic License Agreement was executed in Japanese. Quotations in the text are from the Appellee's translation, provided in the record. The Appellant did not provide the Basic License Agreement, either in its original or a translated version.

exchange of such safety information through separate discussion." (J.A. 289.) Following the execution of the Basic License Agreement, the parties continued to exchange safety information under the protocols specified by the Safety Agreement. The Basic License Agreement contained a choice-of-law provision specifying Japanese law and a forum-selection clause specifying that "[a]ny dispute in relation to this agreement or any agreement incidental hereto" be brought in Osaka, Japan. (J.A. 314.)

In 2004, wishing to make certain changes with respect to the manufacture of any codeveloped drugs, the parties executed a successor agreement to the Basic License Agreement ("Amended Basic License Agreement"), which was identical in all relevant respects, but was drafted in English and changed the exclusive forum for suit to Tokyo, Japan.

On February 14, 2005, the United States Food and Drug Administration ("FDA") issued two alerts regarding a link between cancer and the use of Protopic, a drug marketed by Astellas, and containing FK506. The following day, the FDA Pediatric Advisory Committee ("Advisory Committee") recommended that Protopic carry a so-called "black box warning" about the potential cancer risk. Prior to the February 15 meeting of the Advisory Committee, Astellas sent a background document regarding Protopic to the Committee. There is no indication in the record that Astellas informed Sucampo about the document sent to the Advisory Committee. On March 10, the FDA adopted the Advisory Committee's recommendation and required that Protopic carry a black box warning. The FDA also issued a public health advisory concerning Protopic's potential cancer link. Sucampo subsequently suspended development of its ophthalmologic product containing FK506.

On March 11, Sucampo brought a breach of contract action against Astellas, alleging that Astellas had breached the Safety Agreement by failing to disclose the FDA's concerns over Protopic and, as a result of such failure, Sucampo suffered serious damages relating to the development of products based on FK506. Astellas filed a motion to dismiss on the basis of Federal Rule of Civil Procedure 12(b)(1),(2), and (3). Astellas based its 12(b)(1) and (3) objections on the forum-selection clause contained in the Amended Basic License Agreement.

Astellas argued that the Safety Agreement was at the very least considered incidental to the Amended Basic License Agreement, therefore Sucampo's claims were subject to the exclusive jurisdiction of the courts of Tokyo, Japan, and the district court either lacked subject matter jurisdiction or was an improper venue. In addition, Astellas argued that the district court lacked personal jurisdiction over Astellas.

On November 28, 2005, without ruling on the personal jurisdiction objection, the district court held that the Safety Agreement was incidental to the Amended Basic License Agreement and granted Astellas's motion to dismiss on the basis of the forum-selection clause in the Amended Basic License Agreement. This appeal followed.

II.

This Circuit has not decided the appropriate treatment of a motion to dismiss based on a forum-selection clause. *See, e.g., In re Milenium Studios, Inc.*, 286 B.R. 300, 306 (D. Md. 2002) ("There is currently no procedural mechanism specifically tailored to handle a motion to dismiss based on a forum-selection clause. The Fourth Circuit has not decided the issue of what approach to take and which subsection of Rule 12(b) is most appropriate for the situation."). Other circuits have characterized such motions as motions under Fed. R. Civ. P. 12(b)(1), (3), or (6). *See, e.g., Silva v. Encyclopedia Britannica Inc.*, 239 F.3d 385 (1st Cir. 2001) (treating motion to dismiss based on forum-selection clause as a Rule 12(b)(6) motion to dismiss); *Lipcon v. Underwriters at Llyod's, London*, 148 F.3d 1285 (11th Cir. 1998) (holding that motions to dismiss based on forum-selection clause should be analyzed under Rule 12(b)(3)); *AVC Nederland B.V. v. Atrium Inv. P'ship* 740 F.2d 148 (2d Cir. 1984) (affirming dismissal of action under Rule 12(b)(1) on basis of forum-selection clause).

A.

The district court dismissed Sucampo's complaint on the basis of the forum-selection clause contained in the Amended Basic License Agreement before resolving Appellee's motion to dismiss for lack of personal jurisdiction. Accordingly, we must resolve whether a dis-

missal based on a forum-selection agreement is under Rule 12(b)(6), because the dismissal of a case on an issue relating to the merits of the dispute, such as failure to state a claim, is improper without resolving threshold issues of jurisdiction, including personal jurisdiction. *See Ruhrgas AG v. Marathon Oil, Inc.*, 526 U.S. 574, 583 (1999) ("Personal jurisdiction . . . is 'an essential element of the jurisdiction of a district . . . court,' without which the court is 'powerless to proceed to an adjudication.'" (quoting *Employers Reinsurance Corp. v. Bryant*, 299 U.S. 374, 382 (1937))); *Constantine v. Rectors & Visitors of George Mason Univ.*, 411 F.3d 474, 480 (4th Cir. 2005) ("The validity of an order of a federal court depends upon that court's having jurisdiction over *both* the subject matter *and* the parties." (internal quotation marks omitted)).

B.

To analyze a motion to dismiss based on a forum-selection clause under Rule 12(b)(1), a court must engage the legal fiction that the clause affects the power of the court to adjudicate the dispute. *See M/S Bremen v. Zapata Off-Shore Co.*, 407 U.S. 1, 13 (1972) ("The argument that [forum-selection] clauses are improper because they tend to 'oust' a court of jurisdiction is hardly more than a vestigial legal fiction."); *Lipcon*, 148 F.3d at 1289-90 ("[T]he basis upon which the defendants seek dismissal—namely, that the agreement of the parties prohibits the plaintiff from bringing suit in the particular forum—is unrelated to the actual basis of federal subject matter jurisdiction—namely, federal question jurisdiction or diversity of citizenship, as the case may be.").

In addition to this theoretical incongruence, treating a motion to dismiss on the basis of a forum-selection clause under Rule 12(b)(1) presents practical difficulties that undercut the benefits gained from enforcement of the clauses. For example, the court must raise the issue of subject-matter jurisdiction *sua sponte*, if necessary. *See* Fed. R. Civ. P. 12(h)(3). Thus, in cases involving forum-selection clauses, both district and circuit courts would be under an obligation to confirm that the clause was not applicable before reaching the merits of the action. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 101-02 (1998) (disapproving of hypothetical-jurisdiction doctrine); *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 379

(1981) ("A court lacks discretion to consider the merits of a case over which it is without jurisdiction.").

More importantly, a motion to dismiss under Rule 12(b)(1) is non-waivable and may be brought at any time—even on appeal—regardless of whether a litigant raised the issue in an initial pleading. *See* Fed. R. Civ. P. 12(h)(3); *Kontrick v. Ryan*, 540 U.S. 443, 355 (2004) ("A litigant generally may raise a court's lack of subject-matter jurisdiction at any time in the same civil action, even initially at the highest appellate instance."). Litigants, therefore, could hold back forum-selection clause objections, until after discovery—or even an adverse verdict. *See, e.g., Grupo Dataflux v. Atlas Global Group L.P.*, 541 U.S. 567 (2004) (dismissing an action for lack of subject-matter jurisdiction where jurisdictional defect, which had been cured prior to a jury verdict, was raised for first time on appeal). Allowing this strategy could result in a waste of judicial resources and allow defendants to "test the waters" of the plaintiff's chosen forum, before invoking their rights under the forum-selection clause. The use of such a strategy undermines the efficiency and convenience that we believe is gained from enforcement of forum-selection agreements. *See M/S Bremen*, 407 U.S. at 13-14.

Analyzing forum-selection clauses under Rule 12(b)(6) does not present the problems that analysis under 12(b)(1) would present. *See Lipcon*, 148 F.3d at 1290 (holding that consideration of forum-selection clauses under Rule 12(b)(6) does not present "significant doctrinal error"). Nevertheless, Supreme Court precedent suggests that 12(b)(6) is not the appropriate motion for enforcing a forum-selection clause. In *Argueta v. Banco Mexicano*, 87 F.3d 320, 324 (9th Cir. 1996), the Ninth Circuit noted that "[u]nder the Supreme Court's standard for resolving motions to dismiss based on a forum-selection clause, the pleadings are not accepted as true, as would be required under a Rule 12(b)(6) analysis." (citing *Carnival Cruise Lines v. Shute*, 499 U.S. 585 (1991); *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614 (1985); *Scherk v. Alberto-Culver Co.*, 417 U.S. 506 (1974); *M/S Bremen*, 407 U.S. 1). In addition, because a 12(b)(6) motion may be brought at any time prior to adjudication on the merits, analyzing forum-selection clauses under Rule 12(b)(6) would present some of the same timing concerns as in the 12(b)(1) context. *See* Fed. R. Civ. P. 12(h)(2); *Silva*, 239 F.3d at

388 ("Accordingly, a motion to dismiss based on a forum-selection clause may be raised at any time in the proceedings before disposition on the merits.").

Analyzing forum-selection agreements under Rule 12(b)(3) would avoid the doctrinal and timing disadvantages of utilizing Rule 12(b)(1) or (6) and be consistent with Supreme Court precedent. In *Lipcon*, the Eleventh Circuit discussed the Supreme Court's decision in *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22 (1988), noting that "[a]lthough the Supreme Court did not decide the precise question . . . , the Court's conclusion that the federal transfer-of-venue statute governs district court decisions in enforcing forum-selection clauses provides support for our view that motions to dismiss based upon forum-selection clauses are cognizable as motions to dismiss for improper venue." 148 F.3d at 1290.

In addition to being consistent with *Stewart*, because a motion under Rule 12(b)(3) is a disfavored 12(b) motion, a defendant will have to raise the forum selection issue in her first responsive pleading, or waive the clause. *See* Fed. R. Civ. P. 12(h)(1). This will result in an efficient disposition of cases involving forum-selection clauses and not waste judicial resources on a case that ultimately will have to be dismissed and relitigated in another forum. Treating a motion to dismiss based on a forum-selection clause under Rule 12(b)(3) avoids the logistic and theoretical intricacies of utilizing 12(b)(1), allows the court to freely consider evidence outside the pleadings, unlike under a 12(b)(6) motion, *Argueta*, 87 F.3d at 324, and is more consistent with the Supreme Court's treatment of such clauses, *Lipcon*, 148 F.3d at 1290. Accordingly, a motion to dismiss based on a forum-selection clause should be properly treated under Rule 12(b)(3) as a motion to dismiss on the basis of improper venue.³

³Because a district court has the discretion to dismiss on the basis of improper venue before reaching the issue of personal jurisdiction, the district court did not err in dismissing Sucampo's complaint on the basis of the forum-selection clause without addressing Astellas's personal jurisdiction objections. *See Ruhrgas*, 526 U.S. at 584-85; *Leroy v. Great W. United Corp.*, 443 U.S. 173, 180 (1979).

III.

We review a district court's grant of a motion to dismiss under Rule 12(b)(1), (3), or (6) de novo. *See, e.g., Suter v. United States*, 441 F.3d 306, 310 (4th Cir. 2006) (reviewing dismissal under 12(b)(1)); *Mitrano v. Hawes*, 377 F.3d 402, 405 (4th Cir. 2004) (reviewing dismissal under 12(b)(3)); *Partington v. Am. Int'l Specialty Lines Ins. Co.*, 443 F.3d 334, 338 (4th Cir. 2006) (reviewing dismissal under 12(b)(6)).

Sucampo does not dispute the validity of the forum-selection agreement, but argues that the instant case is not governed by the clause because the dispute arises under the Safety Agreement, which is not incidental to the Amended Basic License Agreement. Under general principles of contract interpretation, this argument must fail.⁴

To begin, the definitions of "incidental" cited by Appellant include "subordinate." The Safety Agreement explicitly notes that it was executed "under the Basic Agreement," with a term concurrent with the Basic Agreement. There is no dispute that the Amended Basic

⁴We note that rejection of Sucampo's argument accords with the substantive law of Japan. Appellee cites two decisions of the Tokyo District Court, *Vulcan Int'l Servs. Ltd. v. Makashi-Ya, Inc.*, 1077 Hanrei Taimuzu 282 (Tokyo D. Ct., Nov. 24, 2000), and *Riken v. Mabuchi*, 1244 Hanrei Jihō 97 (Tokyo D. Ct., Oct. 11, 1987). Both *Vulcan* and *Riken* held a forum-selection clause contained in one agreement applicable to a dispute between the parties under a different agreement. Based on these cases, Astellas's expert concluded that a Japanese court would find that the Safety Agreement is incidental to the Amended Basic License Agreement and, thus, the forum-selection clause in the Amended Basic License Agreement encompasses the instant dispute regarding the Safety Agreement. The cited cases and the affidavit of an expert are sufficient to establish Japanese law on the issue of whether the Safety Agreement is incidental to the Amended Basic License Agreement. *See United States v. Mitchell*, 985 F.2d 1275, 1280 (4th Cir. 1993) ("In determining questions of foreign law, courts have turned to a wide variety of sources including affidavits and expert testimony from . . . a South African attorney; foreign case law . . . ; and the court's own independent research and analysis of a Yugoslavian law." (citations and internal quotations omitted)).

License Agreement is a successor agreement to the Basic Agreement. The Safety Agreement, then, had no independent validity apart from the continued validity of the Basic Agreement. When that agreement was succeeded by the Basic License Agreement, the Safety Agreement either became null or was extended by the force of the Basic License Agreement. As the parties continued to exchange information under the Safety Agreement after the effectiveness of the Basic License Agreement (and, later, the Amended Basic License Agreement), the latter must have occurred. Given this, it is hard to conceive of the Safety Agreement as anything but subordinate to the Amended Basic License Agreement, when the Safety Agreement would have no continued validity without the Amended Basic License Agreement.

In addition, the Safety Agreement lists as its purpose the facilitation of exchange of safety information. It does not contain any independent obligations of the parties beyond that exchange, nor does it list the contemplated reliance of the parties on the information. There is no governing law, confidentiality terms, or the like. Rather than having the attributes of an independent agreement, the Safety Agreement reads as a specific explication of procedures for sharing safety information as contemplated by the Basic Agreement (and, later, the Basic License Agreement and Amended Basic License Agreement). Again, these attributes are the very definition of incidental. *Cf. Kvaerner ASA v. Bank of Tokyo-Mitsubishi, Ltd., N.Y. Branch*, 210 F.3d 262, 265 (4th Cir. 2000) (holding that agreement referencing "rights and remedies" of another agreement was subject to the referenced agreement's arbitration clause).

Finally, Sucampo cannot avoid the fact that the Safety Agreement is incidental to the Amended Basic License Agreement by artful pleading. Sucampo included a copy of the Amended Basic License Agreement with its complaint and referenced the agreement in its damage calculation. The Safety Agreement was executed under the Basic Agreement and contains none of the terms that one would expect from an independent agreement. In sum, even if we assume that the breach was confined to the terms of the Safety Agreement, because that agreement has no existence apart from the Amended Basic License Agreement, we would need to consult the Amended Basic License Agreement to fully adjudicate Sucampo's claims. *Cf. Drews Distributing, Inc. v. Silicon Gaming, Inc.*, 245 F.3d 347, 350

(4th Cir. 2001) ("Although the complaint carefully alleges only fraud in inducing Drews to enter into the Letter Agreement . . . , it expressly acknowledges . . . that the Letter Agreement 'contemplated' that the parties would enter into the Distributor Agreement, which 'would control the rights of the parties as to the sale of these Odyssey machines.'")

There is no reasonable reading of the word "incidental" in the forum-selection clause that would exclude the Safety Agreement from its coverage. Given this, Sucampo's suit could only be filed in the Tokyo District Court, not the District Court of Maryland.

IV.

Because the Safety Agreement is incidental to the Amended Basic License Agreement, the forum-selection clause contained in the Amended Basic License Agreement governs Sucampo's complaint. The District Court of Maryland was thus an improper venue and the ruling of the district court dismissing the suit is hereby affirmed.

AFFIRMED