

<b>Dompe Farmaceutici S.P.A. v Lubris, LLC</b>
2020 NY Slip Op 30934(U)
April 8, 2020
Supreme Court, New York County
Docket Number: 656142/2017
Judge: O. Peter Sherwood
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**SUPREME COURT OF THE STATE OF NEW YORK  
NEW YORK COUNTY**

**PRESENT: HON. O. PETER SHERWOOD PART IAS MOTION 49EFM**

*Justice*

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**INDEX NO. 656142/2017**

DOMPE FARMACEUTICI S.P.A.,

**MOTION DATE 6/18/2019**

Plaintiff,

**MOTION SEQ. NO. 004**

- v -

LUBRIS, LLC,

**DECISION + ORDER ON  
MOTION**

Defendant.

-----X

The following e-filed documents, listed by NYSCEF document number (Motion 005) 79-85, 89-99, 101 were read on this motion to STAY AND COMPEL RESOLUTION.

Plaintiff Dompé farmaceutici S.p.A. (Dompe) is a biopharmaceutical company based in Milan, Italy. Defendant Lubris, LLC (Lubris) is a biopharmaceutical company based in Framingham, MA. The parties entered into a series of agreements relating to the development, manufacture, and commercialization of a medical device and drug products using the substance “Lubricin” that can be used in the eye. These agreements included a Development and License Agreement dated July 14, 2014 (“License Agreement”), a First Amendment to Development and License Agreement effective December 15, 2016 (“First Amendment”), and a Commercial Supply Agreement (“Supply Agreement”, and together with the License Agreement and the First Amendment, the “Contracts”).

Under the Contracts, Lubris was to manufacture Lubricin and supply Dompe with all the product it needed to develop and sell ophthalmic products based on Lubricin (Products). Dompe was tasked to obtain the required regulatory authorizations for the Products and then market the Products in the European Union (“EU”), Norway, Switzerland, and Turkey (the Territory). Dompe received the exclusive right to develop and sell the Products in the Territory. The Products fit into two categories, medical devices and drugs, each regulated differently. The medical device path to approval is shorter, and the device products are less expensive. The parties’ plan was to bring a medical device to market first with a drug product to be developed and approval obtained later.

In the First Amendment, Lubris represented it was able to manufacture the Lubricin needed for the medical device product. However, Lubris has failed to provide Dompe with any significant amount of Lubricin. Dompe sought authorization from regulatory authorities and was prepared to sell its first Product in Europe by the end of 2017. Dompe spent about 10 million Euros in preparing and getting authorization.

In April 2016, Lubris entered into an agreement with Dompe's competitor pharmaceutical company, Novartis, giving Novartis global manufacturing rights. Lubris no longer manufactures Lubricin. Lubris has informed Dompe that Novartis intends to make and market its own products and will not make the Lubricin product for Dompe.

Lubris contends it has a contractual right to indefinitely delay supplying Lubricin to Dompe. In a footnote, the Contracts provide some circumstances by which Lubris may delay performance, but the Contracts also have provisions intended to protect Dompe's access to the product.

In this action, Dompe asserts fourteen claims, including several breaches of contract, promissory estoppel, and fraud. In this motion, defendant Lubris moves to stay this action and compel resolution by an independent expert consistent with the terms of the agreements between the parties.

According to Lubris, the License Agreement provides that this matter must be submitted to an independent expert decision as specified by section 14.5.1. The independent expert "must have experience in life sciences transactions and will be selected by a group of three independent arbitrators" (Memo, NYSCEF Doc. No. 80, quoting License Agreement, attached as Exhibit B to Dewey aff, NYSCEF Doc. No. 83, section 14.5.1). The independent expert is to review the facts and issue a written determination which will be final and binding (*id.*). Lubris argues that the agreement is clear, demonstrates the parties' intention to submit such a dispute to the independent expert, and should be enforced by the court.

Plaintiff Dompe opposes the motion and contends it should fail because it relies on CPLR 7601, which has been held to apply only to valuation, appraisal, and similar determinations, and not to contractual interpretation. Further, Dompe argues Lubris has waived any right to make this motion after engaging in litigation and discovery in this proceeding. Finally, the contractual

provision only applies to technical disputes, and not this issue of contractual interpretation. Section 2.4 of the First Amendment bars this procedure from being used to “seek changes to any approved Development Plan” (Opp, NYSCEF Doc. No. 89, quoting First Amendment, attached as Exhibit D to Dewey aff, NYSCEF Doc. No. 85, section 2.4). Section 14.5.1 of the License Agreement only allows the independent expert to be brought in “on any matter regarding the Development Program, the Business Plan [or] the amount of royalties” (Opp at 14). Further, the First Amendment specifies that the process cannot be used to “seek changes to any approved Development Plan or Business Plan” (*id.* quoting First Amendment section 2.4). The “Development Program” is defined as “certain research and development activities,” none of which have been conducted by Lubris to date (*id.* quoting License Agreement sections 5.2-5.21). Nor is this the kind of dispute contemplated by the License Agreement (Opp at 15-16). Dompe also claims it will suffer substantial prejudice from granting this motion, as it has used significant resources for this litigation and desires a swift resolution, since further delay in receiving Lubricin will damage it further (Opp at 11-12).

Lubris argues Dompe’s narrow reading of the License Agreement is incorrect, that the clause applies to disputes “on any matter regarding the Development Program [or] the Business Plan” (Reply, NYSCEF Doc. No. 101, at 1 quoting License Agreement section 14.5.1). Delays by Lubris may cause revision of the Development Plan and/or Business Plan, which the parties must negotiate in good faith, pursuant to section 2.7 of the First Amendment. The parties have been unable to agree on such revisions. Further, the expert is required to have experience in “life sciences transactions,” not just in the science (*id.* at 3, quoting License Agreement section 14.5.1). Section 2.7 of the First Amendment gives the expert the power to resolve disputes occurring during negotiations in the event of delays, showing the expert is not limited to technical issues (Reply at 4).

Nor does the text of CPLR 7601 limit independent expert resolution to issues of valuation or appraisal. The language of the rule allows “other issues” to be resolved by an expert. Nor do the cases prohibit such an agreement by the parties (Reply at 5). The legislative history also weighs against such a limitation (Reply at 5).

As far as Dompe argues waiver, Lubris points out it is permitted to test the sufficiency of the complaint with a motion to dismiss before deciding whether to litigate or seek an alternative process, and Lubris’ participation in this dispute is consistent with its intention to invoke the expert

dispute resolution section of the License Agreement (Reply at 6-7). Any delay occurred here because Dompe amended its complaint after the motion to dismiss was filed, which resulted in a motion to dismiss the amended complaint. The discovery stay was only lifted for a brief period, over Lubris' objections, and reinstated before the deadline to respond to demands. Lubris has been consistent and clear about its intentions here and has done nothing to show a preference for litigation (*id.* at 8). Nor has there been any prejudice to Dompe, as it was Dompe's choice to bring this suit rather than pursue the process contemplated in the License Agreement (*id.*). Further, as the only relief Dompe is currently seeking is monetary, prejudice from delay is minor, and, in fact, resolution will be faster using the contractual process, since the expert is required to resolve the dispute in 90 days (*id.* at 9).

Regarding Dompe's procedural objection, that Lubris did not file a special proceeding, the caselaw does not support Dompe's position, and the citation relied upon by Dompe is a dissent to a First Department decision in a distinguishable case (*id.* at 11-12).

CPLR provides:

"A special proceeding may be commenced to specifically enforce an agreement that a question of valuation, appraisal or other issue or controversy be determined by a person named or to be selected. The court may enforce such an agreement as if it were an arbitration agreement, in which case the proceeding shall be conducted as if brought under article seventy-five of this chapter. Where there is a defense which would require dismissal of an action for breach of the agreement, the proceeding shall be dismissed."

As far as Dompe relies on *873 Third Ave. Corp. v Madison Assoc.* (56 AD2d 748 [1st Dept 1977]) ["In view of this mandate contained in CPLR 7601, the lessee should have sought relief in a special proceeding rather than in a plenary action for declaratory judgment"], that case then treated the action as a special proceeding and considered it, rather than rejecting it, as Dompe seeks the court to do here. As far as Dompe relies on *Rad v IAC/InterActiveCorp* (64 Misc 3d 1201(A) [Sup Ct, NY Country, 2019], *affd*, 176 AD3d 635 [1st Dept 2019]), for the premise that "because [plaintiffs] do not seek to confirm an appraisal award or seek an order that the parties must submit to an appraisal, this action falls outside of the purview of CPLR 7601," that court also noted that "here, the Agreements do not expressly refer to arbitration or an arbitration-like procedure." That court's determination does not apply here. Nor does *Penn Cent. Corp. v Consol. Rail Corp.* (82 AD2d 208, 216 [1st Dept 1981], *affd*, 56 NY2d 120 [1982]) preclude application of CPLR 7601 here. To

the contrary, the request to enforce an agreement requiring this matter to be sent to a person to be selected pursuant to an agreement by the parties falls squarely under CPLR 7601 (*see City of Buffalo v Buffalo Police Benevolent Ass'n, Inc.*, 280 AD2d 895, 896 [4th Dept 2001]).

The License Agreement states:

“In case of dispute (by the JSC or the CEOs, as the case may be) on any matter regarding the Development Program, the Business Plan, the calculation of the amount of royalties to be paid by Dompe and/or Lubris under this Agreement, including but not limited to results of royalties reports, which cannot be amicably resolved according to Section 14.4.1 above, then the Parties hereby agree to submit the relevant determination to an independent expert decision (the "Independent Expert Decision"). The independent expert responsible for making Independent Expert Decisions (the "Expert") must have experience in life sciences transactions, and will be selected by a group of three independent arbitrators.”

(License Agreement, section 14.5.1). The License Agreement continues, providing the process for selecting the arbitrators and for the expert to make a determination. As far as Dompe relies on section 2.4 of the First Amendment, that section bars certain disputes from being submitted to an expert, but provides an exception for certain delays, including “delays by Lubris under the plan for the Manufacture and supply of Lubricin provided by Lubris and approved by Dompe . . . [and] delays or failure or shortage in the supply of Lubricin . . . .” (First Amendment section 5.4). This is such a dispute.

Nor has Lubris waived its right to enforce that provision of the License Agreement. Lubris is entitled to move to dismiss the complaint before seeking this relief (*see Flynn v Labor Ready, Inc.*, 6 AD3d 492, 493 [2d Dept 2004] [“a defendant is entitled to have the sufficiency of a complaint tested before a duty to seek arbitration arises”] citing *Matter of Haupt v Rose*, 265 NY 108, 111 [1934]; *Singer v Jefferies & Co.*, 78 NY2d 76 [1991]; *Matter of Terminal Auxiliari Maritima, S.A. [Winkler Credit Corp.]*, 6 NY2d 294 [1959]). “In the absence of unreasonable delay, so long as the defendant's actions are consistent with an assertion of the right to arbitrate, there is no waiver” (*De Sapio v Kohlmeyer*, 35 NY2d 402, 405 [1974]). Here, there has been no unreasonable delay, and Lubris’ actions in moving to dismiss the complaint and amended complaint, and the very limited discovery, are consistent with Lubris’ motion here. There is no waiver.

Therefore, this motion is granted. Accordingly, it is hereby

ORDERED that the parties shall submit plaintiff's claims to an independent expert consistent with the terms of the agreements between the parties; and it is further

ORDERED that this action is hereby STAYED pending the issuance of a decision of the independent expert pursuant to the terms of those agreements. This case may be reopened by motion from either party seeking to confirm or reject the decision of that expert.

4/8/2020  
DATE

*O.P. Sherwood*  
O. PETER SHERWOOD, J.S.C.

CHECK ONE:

CASE DISPOSED

GRANTED

SETTLE ORDER

INCLUDES TRANSFER/REASSIGN

DENIED

NON-FINAL DISPOSITION

GRANTED IN PART

SUBMIT ORDER

FIDUCIARY APPOINTMENT

OTHER

REFERENCE

APPLICATION:

CHECK IF APPROPRIATE: