SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-2361-22

MEZZION PHARMA CO. LTD. and MEZZION INTERNATIONAL, LLC,

Plaintiffs-Appellants,

v.

DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,

Defendants-Respondents.

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Argued January 31, 2024 – Decided May 3, 2024

Before Judges Accurso, Vernoia and Gummer.

On appeal from an interlocutory order of the Superior Court of New Jersey, Law Division, Mercer County, Docket No. L-0098-17.

Joshua D. Curry (Lewis Brisbois Bisgaard & Smith, LLP) of the Florida and Georgia bars, admitted pro hac vice, argued the cause for appellants (Lewis Brisbois Bisgaard & Smith, LLP, and Joshua D.

Curry, attorneys; Jonathan M. Preziosi, of counsel and on the briefs).

Roger B. Kaplan argued the cause for respondents (Greenberg Traurig, LLP, attorneys; Roger B. Kaplan, on the brief).

PER CURIAM

We granted plaintiffs Mezzion Pharm. Co. LTD and Mezzion Int'l, LLC's (Mezzion) motion for leave to appeal a discovery order requiring Mezzion to turn over information Mezzion characterizes as its "competitively sensitive trade secrets" to defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (DRL), the former manufacturer of Mezzion's "flagship drug udenafil." Mezzion contends the information is irrelevant to the claims and defenses in the litigation and cannot lead to the discovery of admissible evidence but would allow DRL to compete unfairly against Mezzion "in the rare pediatric Fontan market that is valued in the billions of dollars per year." Having reviewed the extensive record presented on this interlocutory appeal and having heard oral argument, we agree with the trial court that the information is relevant and discoverable and thus affirm Judge Hurd's order compelling the discovery in accordance with the negotiated protective order entered by the court.

Although the chemistry of udenafil and the processes for manufacturing it are no doubt complicated,[1] the discovery dispute is not. According to Mezzion, "[u]denafil is an oral phosphodiesterase-5 inhibitor," approved to treat erectile dysfunction (the ED indication) in South Korea, where it was developed by Mezzion's predecessor, Dong-A Pharmaceutical Co., Ltd., and in several other countries but not in the United States. Mezzion is also developing udenafil for the treatment of congenital ventricle heart disease in adolescents post-Fontan palliative surgery (the Fontan indication). The U.S. Food & Drug Administration has designated udenafil an orphan drug for the Fontan application, meaning the number of people affected by the condition for which the drug is intended is fewer than 200,000 persons, which will permit a longer period of exclusivity to Mezzion upon approval of the drug for the Fontan indication. See 21 U.S.C. § 360cc; 21 C.F.R. 316.

Mezzion does not have its own manufacturing facility. In 2007, it partnered with DRL, a generic manufacturer based in India, to produce both the active pharmaceutical ingredient (API), that is, the udenafil, as well as the

[1] Mezzion claims the manufacturing process is complicated because it requires a separate process to manufacture a starting material critical to the manufacture of udenafil. According to Mezzion, that "procedure is highly volatile and outside of the capabilities of most manufacturers."

finished udenafil tablets for both clinical trials and commercial development in the United States. Mezzion's new drug application (NDA) for udenafil for the ED indication, filed with the FDA in December 2014, relied on DRL's drug master file to provide the detailed information about the facilities and processes DRL used in the manufacture of the drug.

A few weeks before Mezzion submitted its NDA, the FDA inspected a DRL facility in India where DRL was manufacturing udenafil. Following its inspection, the FDA issued an FDA Form 483 report to DRL, notifying it of several problems the FDA had observed at the facility regarding DRL's compliance with the agency's current Good Manufacturing Practice (cGMP) regulations through which the agency oversees the methods, facilities, and controls used in the manufacture of drugs. DRL's failure to correct the problems to the agency's satisfaction led the FDA to issue a warning letter to DRL in November 2015, and to the FDA's advice to Mezzion around the same time "that the violations at [DRL] are very serious," DRL's "responses for corrective actions were insufficient," and "the 483 observations involved udenafil."

Specifically, the FDA's Office of Compliance informed Mezzion that "the 483 observations related to lack of control on data integrity and analytical

equipment" caused "concerns for the authenticity and reliability of the analytical test results and data" generated by DRL and submitted to the FDA in support of Mezzion's NDA for udenafil. Mezzion claims it was advised by "a senior official from the Office of Manufacturing Quality at the FDA . . . that it needed to find a new commercial supplier and should not continue to rely on [DRL] in its effort to launch udenafil in the U.S." In January 2016, the FDA rejected Mezzion's NDA for udenafil based on "the serious deficiencies" identified at DRL, "currently the sole manufacturing facility" for the API. The FDA advised Mezzion its NDA could not be approved until those deficiencies were corrected.

Mezzion ended its relationship with DRL and moved the manufacture of udenafil to two new manufacturers, Polpharma in Poland for API and Halo Pharma in Canada for finished tablets, a process the parties refer to as "the tech transfer." Although Mezzion advised the FDA it might be possible to resubmit its NDA in the third quarter of 2017, it sought further extensions in 2017, 2018, 2019, and 2020, advising "the 483 observations at [DRL's] facility and the subsequent Warning Letter . . . have not been resolved causing a severe delay in resolving the CMC [chemistry, manufacturing and controls] issues that are preventing resubmission" of Mezzion's NDA. Mezzion

attributes the delay to the FDA's edict that Mezzion not use or reference any information in DRL's udenafil drug file in support of the NDA unless the information was publicly available from another source. Mezzion finally abandoned the effort to gain approval of udenafil for the ED indication sometime in 2020, claiming it missed its launch window into a "branded ED market" after the ED market opened to generics in 2017. It is continuing to pursue FDA approval of udenafil for the Fontan indication, having submitted its initial NDA for that application in June 2020.[2]

Mezzion claims the only reason the FDA denied its NDA for udenafil in 2016 was because of DRL's cGMP violations. It asserts that had Mezzion not chosen DRL as its manufacturing partner, Mezzion's NDA would have been approved in 2016. Mezzion asserts it suffered three distinct categories of damages as a result of "DRL's fraud and complete disregard for cGMP and U.S. law": the costs of the tech transfer from DRL to Polpharma and Halo, which it estimates at $20 million; its out-of-pocket costs of over $400,000 to retest tablets DRL made for Mezzion's early Fontan clinical trials, which the

[2] DRL asserted at oral argument in the trial court that the FDA had denied Mezzion's NDA for the Fontan indication in June 2020 based not on the manufacturing process for udenafil but on issues relating to the clinical trials, and that its 2021 resubmission remains pending.

FDA required Mezzion to prove were not adulterated; and the profits Mezzion lost due to its inability to obtain FDA approval to launch udenafil into a branded ED market, which Mezzion now estimates at over $900 million.

The discovery dispute is rooted in Mezzion's response to question six of DRL's third set of interrogatories, asking Mezzion to "[i]dentify and describe in detail all work performed by any manufacturer other than DRL regarding udenafil at Mezzion's request or direction after November 2015." Mezzion responded by alluding to the "laborious and time-consuming" process of transferring the technology from DRL to Polpharma and Halo from January 2016 until October 2019. And further responded that

> [d]uring the process of moving manufacturers, it became apparent that DRL's manufacturing process for udenafil contained significant flaws that were likely to present serious impediments to getting the FDA to approve of the manufacturing process that DRL was following (e.g., failed batches late in tech transfer process and discovery of unidentified and unknown impurities). This required Mezzion and its new manufacturers to spend significant amounts of time, money, and resources to attempt to remedy the problems that existed in DRL's manufacturing process.

DRL sought to compel a more specific answer to that interrogatory, arguing that any purported problems with the manufacturing process DRL developed for udenafil that Mezzion claimed had required Mezzion "and its

new manufacturers to spend significant amounts of time, money, and resources to attempt to remedy," were relevant to Mezzion's claim for its out-of-pocket costs and its lost-profit damages, as well as to DRL's defense that Mezzion had failed to mitigate its damages.

Specifically, DRL argued that invoices Mezzion produced in discovery to support its tech-transfer costs included invoices for work performed by the new manufacturers for changes to DRL's process, entitling DRL to inquire about the changes Mezzion claimed were necessary. DRL also argued information about those changes was relevant to Mezzion's claim that its commercial launch of udenafil was delayed and ultimately abandoned because of the time it took to replace DRL as the manufacturer and prepare to resubmit the NDA. DRL argued it was entitled to know why Mezzion couldn't have simply resubmitted the NDA in late 2017, as it had planned, using DRL's process with the new manufacturers' data, because had Mezzion been able to launch in 2018, it would've suffered only a year or two in lost profits instead of the damages for the permanent inability to enter the ED market it claimed.

Finally, DRL argued it was entitled to "full discovery" regarding Mezzion's claim that there were problems with DRL's manufacturing process, including what the issues were, when they were discovered, why Mezzion

believed they presented impediments to the FDA's approval of a resubmitted NDA, what Mezzion and its manufacturers did to attempt to remedy the issues, whether Mezzion acted diligently to effect a remedy, and how long it took to do so, as well as full details about the allegedly new manufacturing process Mezzion and its manufacturers had developed. DRL claimed it was entitled to that information because it was relevant to its claim that Mezzion had failed to mitigate its damages by simply resubmitting the NDA using DRL's process and the new manufacturers' data.

Mezzion countered that the information DRL sought related only to Mezzion's manufacture of udenafil for the Fontan indication, and it "is not seeking any damages related to Fontan — whether out-of-pocket, lost profits, or otherwise [—] except for the out-of-pocket costs that Mezzion incurred to retest tablets DRL made for early Fontan clinical trials," which both parties agree are not part of their discovery dispute. Mezzion claimed the research and development manufacturing changes it made with Polpharma and Halo for the Fontan indication are not relevant to its claims, which are limited to the ED indication, or DRL's defenses, which are circumscribed by the claims, and would not lead to the discovery of admissible evidence under Rule 4:10-2(a).

First, Mezzion contended that because the FDA would not allow Mezzion to use any of DRL's data in resubmitting its NDA for the ED indication, the problems with DRL's manufacturing process did not become apparent until late in the tech-transfer process, leaving Mezzion no time to correct them and launch udenafil into the branded ED market. Specifically, Mezzion contended it had used its "new manufacturing details" comprised of "detailed scientific, chemistry, synthesis, research, and manufacturing data," only in connection with the Fontan indication because by the time those details were developed the ED market had already been "heavily genericized."

Second, Mezzion contended the discovery of its new manufacturing details, which would reveal to DRL exactly how to remedy the problems with its defective manufacturing process for udenafil, thus allowing it to unfairly compete in the Fontan market, which Mezzion estimates is worth more than $1 billion per year, cannot lead to the discovery of admissible evidence.[3] Mezzion argued the information DRL seeks, that is whether the FDA deemed DRL's manufacturing process deficient, whether Mezzion needed to make

[3] We note that at oral argument in the trial court, Mezzion's counsel asserted the manufacturing process for udenafil, which has been approved in other countries for the ED indication, was not developed by DRL but by Mezzion's predecessor. We do not know if that is accurate or its impact, if any, on Mezzion's damage claims.

changes to the manufacturing process, and whether the FDA would have required the changes for NDA approval, are committed to the exclusive jurisdiction of the FDA. And because whether the FDA would have approved the ED NDA on resubmission, after first rejecting it solely based on DRL's flawed process, is a question committed exclusively to the FDA, it is preempted and beyond the judge's or any jury's purview.

At argument on the motion, Judge Hurd took pains to establish that both sides agreed the manufacturing process for making udenafil would be the same whether Mezzion was producing it for the ED indication or for the Fontan indication. After carefully questioning counsel about the points made in their briefs, sharpened at oral argument, the judge agreed with DRL that the new manufacturing details were discoverable.

In a ruling from the bench, Judge Hurd concluded that "at the end of the day it's not a question of admissibility, it's a question of is it reasonably calculated to lead to the discovery of admissible evidence under [Rule] 4:10-2." He reasoned that DRL needed to have the "technical scientific R&D information" about the new manufacturing details to allow it "to test the information" Mezzion had produced. The judge acknowledged it was not clear whether the information "ultimately comes into court" but found it was

relevant to whether the ED NDA could have been resubmitted, which is "relevant ultimately to damages."

Following another hearing to settle the form of order, including the terms of the protective order under which the discovery would be produced, Judge Hurd entered an order directing Mezzion to provide an amended answer to DRL's interrogatory six, that:

> (a) sets forth a detailed narrative description sufficient to show the purported problems with the manufacturing process used by [DRL] to manufacture udenafil and any changes or remedies made to the manufacturing process by or for Mezzion (e.g., by Polpharma, Halo, or anyone else) that Mezzion considered or pursued in connection with the purported problems or that resulted in a new, different, altered, or improved manufacturing process for udenafil, including, at a minimum, sufficient details regarding technical, scientific, chemistry, research and development information to show any problems, changes, and remedies with or to the manufacturing process used by [DRL] to manufacture udenafil, including the applicable dates and timelines, how significant the problems where, the potential impact of the problems on FDA approval of the ED NDA, whether the changes or remedies needed to be made, the efficacy of the changes or remedies, the costs of the changes or remedies, and time projected and actually spent on pursuing the changes or remedies (the "New Manufacturing Details");
>
> (b) cites by bates number or makes available for inspection documents that fully provide a detailed,

> comprehensive, and complete description of the New Manufacturing Details; or
>
> (c) provides a combination of a detailed narrative description and makes available for inspection documents that fully provide a detailed, comprehensive, and complete narrative description of the New Manufacturing Detail.

In their briefs on this interlocutory appeal, the parties reprise the arguments they made to the trial court, with Mezzion emphasizing that the court erred in ordering it to produce its proprietary, trade-secret manufacturing information even pursuant to the protective order, the terms of which Mezzion does not challenge. Mezzion asserts the information DRL seeks will not be admissible at trial because its only use would be to second guess the FDA in deciding whether to approve a new drug for manufacture and sale.

Our review of a discovery order is decidedly deferential. Brugaletta v. Garcia, 234 N.J. 225, 240 (2018). "We will not ordinarily reverse a trial court's disposition of a discovery dispute 'absent an abuse of discretion or a judge's misunderstanding or misapplication of the law.'" Ibid. (quoting Capital Health Sys. Inc. v. Horizon Healthcare Servs. Inc., 230 N.J. 73, 79-80 (2017)). We approach our review mindful of "the well-established principle that requests for discovery are to be liberally construed and accorded the broadest possible latitude to ensure that the ultimate outcome of litigation will depend

on the merits in light of the available facts." Piniero v. Div. of State Police, 404 N.J. Super. 194, 204 (App. Div. 2008).

Rule 4:10-2(a) provides "[p]arties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action whether it relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party." The Rule further makes clear "[i]t is not ground for objection that the information sought will be inadmissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence." The burden of overcoming the presumption of discoverability is on the party resisting the discovery. R. 4:10-3; Kerr v. Able Sanitary and Env't Servs., Inc., 295 N.J. Super. 147, 155 (App. Div. 1996).

The touchstone for discovery in our State is relevancy, that is "evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401; Payton v. N.J. Tpk. Auth., 148 N.J. 524, 535 (1997). "The relevance standard does not refer only to matters which would necessarily be admissible into evidence, but includes information reasonably calculated to lead to admissible evidence respecting the cause of action or its defense." R.L. v. Voytac, 402 N.J. Super. 392, 408 (App. Div.

2008) rev'd on other grounds, 199 N.J. 285 (2009); Serrano v. Underground Utils. Corp., 407 N.J. Super. 253 (2009) (same).

Mezzion claims it was permanently locked out of the ED market for udenafil, suffering hundreds of millions of dollars in damages, based solely on the FDA's denial of its NDA in 2016 because of DRL's "multiple failures . . . to comply with cGMP." When DRL propounded interrogatories to understand why Mezzion elected to abandon the ED market in 2020, instead of simply resubmitting the NDA in late 2017 using data from its new manufacturers as it planned, Mezzion revealed it had discovered "significant flaws" in DRL's process for manufacturing udenafil. Mezzion claimed those problems, including "failed batches late in [the] tech transfer process and discovery of unidentified and unknown impurities," "were likely to present serious impediments to getting the FDA to approve of the manufacturing process that DRL was following," requiring Mezzion "and its new manufacturers to spend significant amounts of time, money, and resources to attempt to remedy the problems that existed in DRL's manufacturing process."

We agree with Judge Hurd that DRL is entitled to know the "significant flaws" Mezzion alleges it discovered in DRL's manufacturing process for udenafil, when Mezzion discovered them, what it did to remedy them, how

long it took and how much it cost to do so, as the information is central to Mezzion's ability to establish its claims and the extent of its damages.

Although Mezzion asserts in its complaint that DRL's "multiple failures . . . to comply with cGMP were the sole cause of the denial" of its NDA in 2016, it's Mezzion that's cast doubt on that claim by averring that DRL's process for manufacturing udenafil, separate from its cGMP problems, contained "significant flaws that were likely to present serious impediments to getting the FDA to approve of the manufacturing process that DRL was following." If Mezzion is aware of flaws in the manufacturing process DRL was using that Mezzion believes would have prevented or put in doubt the FDA's approval of udenafil in 2016, DRL is obviously entitled to the information as it would bear on whether Mezzion can prove DRL's regulatory violations were the sole reason that prevented approval of the NDA.

Mezzion's assertion that it developed its new manufacturing details only after it ended its relationship with DRL and only in connection with developing "a new and improved manufacturing process for udenafil" for the Fontan application, making them irrelevant to the claims and defenses in this case, which relate solely to the manufacture of udenafil for the ED indication, ignores its concession that the API of the drug is the same regardless of the

application. The issue is not whether Mezzion's manufacturing process changes were made in connection with the ED or the Fontan indication; it's whether the changes were necessary to secure the FDA's approval of the API, the udenafil, for either indication.

The evidence is also important to Mezzion's claim for damages. Although Mezzion asserts in a footnote in its reply brief that it "is not seeking damages based upon the costs to develop the New Manufacturing Details," that assertion is not clear from its complaint or its answers to interrogatories. Mezzion alleges in its complaint that it "has been forced to incur out-of-pocket costs that are likely to total well over $10 million to secure the new manufacturers, conduct the required new interactions with the FDA, undertake the new studies, prepare the revised NDA, and move ahead with the Fontan clinical trials." In its interrogatory answers, Mezzion claims the tech-transfer "required Mezzion and its new manufacturers to spend significant amounts of time, money, and resources to attempt to remedy the problems that existed in DRL's manufacturing process."

Further, in its opening brief to this court, Mezzion asserts it has incurred over $20 million in out-of-pocket costs to move udenafil manufacturing to Polpharma and Halo, and that it "is seeking its costs to transfer the udenafil

manufacturing (i.e., tech-transfer costs) and to cure the defects in DRL's manufacturing process."[4] (Emphasis added). Obviously, DRL is entitled to know the details of Mezzion's efforts to cure any purported defects in DRL's manufacturing process for which Mezzion is seeking reimbursement. And there is no basis of which we are aware that would preclude the admissibility of that evidence at trial.

The new manufacturing details, as well as when Mezzion discovered the defects in DRL's process, when it acted to remedy them and how long it took to do so are also critical to assessing the validity of Mezzion's claim that discovery of the flaws came too late in the tech-transfer process to allow it to correct them and launch udenafil into the branded ED market, not simply delaying its entry into the ED market but locking it out forever. And the information is likewise important to DRL's claim that Mezzion failed to mitigate its damages by resubmitting the NDA with its new manufacturers' data without changes to the manufacturing process.

We are unpersuaded by Mezzion's claim that its new manufacturing details are immune from discovery because the information will be

[4] Asked about this at oral argument, Mezzion's counsel asserted the emphasized wording was not correct and was mistakenly included in the brief.

inadmissible at trial as DRL could use it only "to second-guess the FDA's decision on whether the FDA would or would not have required the manufacturing changes if Mezzion's . . . NDA for the ED indication had been resubmitted after the FDA rejected it because of DRL."

Leaving aside that at this juncture it appears it's Mezzion that is speculating "that DRL's manufacturing process for udenafil contained significant flaws that were likely to present serious impediments to getting the FDA to approve" it and DRL that's maintaining Mezzion could have timely cured the only stated basis for the FDA's denial by resubmitting the NDA with data from a cGMP-compliant manufacturer, Mezzion has not established that any of the discovery ordered, none of which has yet been produced, would be inadmissible at trial.

We agree with Judge Hurd it is not possible to divine from this record the admissibility of the information Mezzion has been ordered to produce, which is plainly relevant to whether Mezzion could have resubmitted its ED NDA, which is, in turn, relevant to damages. Without knowing what the evidence will reveal, it is premature to rule on its admissibility. See Marrero v. Feintuch, 418 N.J. Super. 48, 62 (App. Div. 2011) (noting it premature to

assess whether information gleaned from a deposition would be admissible in a malpractice action without knowing the content of the testimony).

We are not insensitive to Mezzion's claim that discovery will disclose its trade secrets to a would-be competitor; it is the reason we permitted it an interlocutory appeal.[5] Having considered its arguments, however, in light of both the record and our Supreme Court's admonition that "discovery rules are to be construed liberally in favor of broad pretrial discovery," Payton, 148 N.J. at 535, we are satisfied the trial court did not err in compelling the discovery subject to the heavily-negotiated protective order entered by the court. Although we cannot at this juncture say whether the evidence would be admissible at trial, we can say there is no reason on this record to question its discoverability. See Isetts v. Borough of Roseland, 364 N.J. Super. 247, 262 (App. Div. 2003).

Affirmed.

[5] Neither party, however, has submitted the certification of an expert explaining why these processes are proprietary.