COURT SANCTIONS ANDA FILER FOR FAILING TO DISCLOSE TESTING ERRORS

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On March 26, 2018, Judge Young in the District of Massachusetts ordered a certified copy of its opinion in the patent dispute between Shire, LLC ("Shire") and Abhai, LLC ("Abhai") to be sent to the general counsel of the Food and Drug Administration ("FDA"), stating that the FDA would be "well advised" to take notice of the defendant's litigation misconduct and that sanctions were "amply warranted here." [1] The court sanctioned Abhai for proffering incorrect test data, failing to disclose that the data was incorrect, and failing to produce corrected data obtained months before trial until four days into the trial. Abhai's actions caused a five-month delay to the proceeding.

BACKGROUND

Abhai filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Shire's Adderall XR, along with paragraph IV certifications against two Shire patents. Shire sued Abhai for infringement of those two patents, both titled "Oral Pulsed Dose Drug Delivery System." [2] Abhai asserted that its product did not infringe Shire's patent claims because Abhai's ANDA product did not meet the patent elements relating to the drug's release rate. Abhai admitted that its ANDA product met the other claim limitations.

The drug product is a capsule filled with two types of pellets or beads: Immediate Release Beads ("IR Beads") and Delayed Release Beads ("DR Beads"). The IR Beads contain a core particle, which is surrounded by a "drug layer" consisting of four active ingredients and a binder. [3] The drug layer is then covered by a sealant coating. The IR Beads contain the same ingredients for all dosage strengths. [4] The DR Beads still contain the same core particle, drug layer, and seal coating as the IR Beads. However, the DR Beads have an additional coating seal known as a delayed release coating polymer ("DR Polymer Layer"). The DR Beads are created by covering IR Beads with the DR Polymer Layer. [5]

THE LITIGATION

During discovery, Shire took the deposition of Abhai's Rule 30(b)(6) [6] witness and questioned him about the dissolution data. The deposition left Abhai's witness "confused and concerned" about the accuracy of his testimony surrounding the dissolution data. [7] Following the deposition, Abhai launched an internal investigation and discovered that the tests were incorrectly administered due to ambiguity in their test protocols. [8]

The incorrect data was related to the dissolution testing of Abhai's drug product, i.e., how long it takes the capsule to dissolve. The drug product is designed such that the IR Beads dissolve in the stomach, while the DR Beads dissolve in the small intestine, thereby extending the release. The dissolution test approximates the conditions the capsule encounters as it moves from the stomach to the small intestine. The test involves placing the drug

capsule in a vessel of dilute hydrochloric acid at a pH of 1.1 for two hours to approximate the stomach environment, adding a buffer to bring the pH up to 6.0 for the remainder of the test to approximate the small intestine environment, and sampling the drug release at 0.5, one, two, three, and four hours. The FDA accepts this two-stage test. The mistake Abhai made was miscounting the second phase. Abhai's "[t]echnicians collected samples from the dissolution medium after the ANDA Product had been in the buffer solution (pH 6.0) for three hours ([five] hours after testing began), [9] instead of one hour ([three] hours after testing began)"; three hours from the start of the second stage instead of three hours from the start of the experiment.

Abhai revised its dissolution testing protocols, citing ambiguity in its test instructions as the cause of the errors, and ordered the tests to be re-administered with the revised procedures. Abhai did not, however, notify Shire, the court, or the FDA about the error in the original testing and did not produce the corrected data, even though it later produced all of its original dissolution protocols and served errata for the Rule 30(b)(6) deposition. [10]

It was not until four days into trial, after numerous experts had testified about the original data, that Abhai finally informed Shire that the data was incorrect. Later the same day, Abhai notified the FDA that its dissolution tests were incorrectly performed. Abhai finally informed the court the next day, with two days of trial remaining. The court suspended the proceedings for 90 days and entered "an order requiring full discovery on the incorrect data and tests." [11] The new data revealed that there was a much slower release of chemicals within the first hour of exposure to pH 6.0 than had first been discovered.

The court chastised Abhai's conduct as reflecting "an appalling lack of awareness of a litigant's responsibility to our justice system," and in the case of Abhai's Rule 30(b)(6) witness, it was "conduct laced with mendacity as well." [12] The court further noted that the witness was not a "bit player," but instead was an "integral member of Abhai's litigation team." [13]

It is worth noting, however, that despite such litigation misconduct, the court declined to issue an order "holding that Abhai's ANDA Product meets the release elements of the patents-in-suit" based solely on the misconduct. [14] The court limited the sanctions to monetary penalties, commenting that "[b]asing existential reality on litigation conduct does not commend itself to this Court." [15] The court gave a monetary penalty of $30,000 for court time and indicated that it would entertain a motion for attorney's fees from Shire. The court noted that "Abhai is representing to the FDA, based on the stability testing on its ANDA Product, that a person can take its ANDA Product effectively up until 24 months," [16] even though the dissolution testing was originally performed incorrectly. [17] The court stated that the FDA would be "well advised" to take notice of the defendant's litigation misconduct and that sanctions are "amply warranted here." [18]

Ultimately, the incorrect data did not have an impact on the outcome of the case. The court was careful to outline the findings of infringement for each of the asserted patent claims and state that the finding of infringement was unrelated to Abhai's misconduct. [19] Moreover, the incorrect data actually brought Abhai's drug product closer to Shire's patent claims because it showed a much faster dissolution rate than what was actually the case. In other words, the incorrect dissolution data was actually to the disadvantage of Abhai.

CONCLUSION

This case shows the importance of prompt disclosure and the necessity of a client's communication with its outside counsel. Abhai's outside counsel was not made aware of the incorrect data until a day before Abhai informed Shire and the FDA of the errors. In that regard, this case emphasizes the importance of outside counsel

in ANDA cases communicating with the client to determine whether any aspects of the product have changed. In most instances, a client would likely be forthcoming in getting its corrected testing submitted to the FDA, but here there was no such submission or communication to outside counsel. Here, it appears that as soon as outside counsel learned of the erroneous testing, it took action to inform all involved.

In summary, ANDA applicants submitting paragraph IV certifications should communicate with outside counsel openly and quickly when there are problems or changes with the ANDA product or testing. Mistakes may arise and can often be corrected without great consequence. However, failing to correct mistakes can lead to sanctions by the court and impact a party's relationship with the FDA.

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[1] Shire LLC v. Abhai, LLC, No. CV 15-13909-WGY, slip. op. at 71 (D. Mass. Mar. 22, 2018).

[2] *Id.* at 6–7.

[3] *Id.* at 7.

[4] *Id.*

[5] *Id.*

[6] *Notice or Subpoena Directed to an Organization.* In its notice or subpoena, a party may name as the deponent a public or private corporation, a partnership, an association, a governmental agency, or other entity and must describe with reasonable particularity the matters for examination. The named organization must then designate one or more officers, directors, or managing agents or designate other persons who consent to testify on its behalf, and it may set out the matters on which each person designated will testify. Fed. R. Civ. P. 30(b)(6).

[7] Shire, No. CV 15-13909-WGY at 66.

[8] *Id.* at 67.

[9] *Id.*

[10] *Id.* at 68.

[11] *Id.* at 3.

[12] *Id.* at 70.

[13] *Id.*

[14] *Id.*

[15] *Id.* at 71.

[16] *Id.* at 14.

[17] *Id.* at 16.

[18] *Id.* at 71.

[19] *Id.*

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