

Litigation Notes

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ASTRAZENECA'S SUMMARY JUDGMENT MOTION AGAINST TEVA AND SANDOZ IN THE SEROQUEL CASE

We read a transcript of the May 20, 2008 argument on AstraZeneca's motion for summary judgment on the inequitable conduct defense in its patent infringement case against Teva Pharmaceuticals and Sandoz involving ANDAs for generic versions of Seroquel, an antipsychotic drug. The presiding judge, Judge Joel Pisano of the U.S. District Court in Trenton effectively knocked out Teva's obviousness argument on the ground that it was bound by certain findings of fact in the Zyprexa case. However, Sandoz is not bound by the Zyprexa decision, and therefore the obviousness argument is still alive, at least for now. In the end, if Sandoz invalidates the patent because of obviousness, Teva will probably invite it to share its 180-day exclusivity, if it has not done so already.

In our thinking, however, Judge Pisano wants to make sure that AstraZeneca wins this case, and usually, once a judge decides who the winner is going to be, it is not difficult to create a pathway to that conclusion. In this case, however, the merits of the case are an unpleasant obstacle that Judge Pisano will have to overcome. Nevertheless, we think the odds are that he will grant AstraZeneca's summary judgment motion on inequitable conduct and then indicate to Sandoz in some fashion that unless potent evidence to the contrary can be found, the Zyprexa findings on obviousness adopted against Teva will be adopted against Sandoz as well. We think that the Court of Appeals will be critical of the way these proceedings were conducted; that is, unless the appeal is assigned to one or both of the pharmaceutical industry's two favorite Federal Circuit judges.

We were especially interested to read the transcript of this argument since almost all of the briefs on the motion were filed under seal, and therefore the transcript was the only source for us to ascertain what the asserted inequitable conduct arguments actually are. It turns out that although Teva and Sandoz still assert AstraZeneca's failure to disclose the death of the fifth monkey, several other inequitable conduct arguments were developed out of the factual record that we previously described, cf. *Litigation Notes*, August 10, 2007 and December 20, 2007.

In summary, what happened in the prosecution of the application leading to AstraZeneca's quetiapine (i.e., Seroquel) patent, U.S. Patent No. 4,879,288, was that the examiner rejected the application in light of two prior patents, including U.S. Patent No. 3,539,573, issued to Schmutz, and U.S. Patent No. 4,097,597, issued to Horrom. He said that the compounds in Schmutz had a "virtually identical structure" and that the side chain was taught in the Horrom patent, such that prima facie obviousness had "clearly been established." After the second rejection, the examiner provided AstraZeneca with a so-called path to allowance, which was to show unexpected results in comparison with two specific compounds, one of which was disclosed in the Schmutz patent (i.e., the "Schmutz X" compound) and the other of which was

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disclosed in the Horrom patent (i.e., the “Horrom” compound).

Responding to this rejection, AstraZeneca submitted a declaration from one of the named inventors, Dr. Bernard Migler. The declaration had data demonstrating the purportedly surprising result that quetiapine was an “atypical” antipsychotic drug, given the absence of a dyskinetic reaction by any of the four monkeys tested on it at a 40 mg dose, since dyskinetic reactions were seen in monkeys tested on both other compounds. However, instead of providing data on Schmutz X as the examiner had requested, AstraZeneca provided data on another compound disclosed in the Schmutz patent, which is called “Schmutz B.” The examiner was told that Schmutz B was used instead of Schmutz X because it would be too costly to do the testing on Schmutz X, and it also told the examiner that Schmutz B was structurally closer to quetiapine than Schmutz X. Accepting this explanation, the examiner allowed the patent to be issued.

As it happened, however, AstraZeneca’s scientists knew from prior testing that Schmutz B was a *typical* antipsychotic insofar as it did not eliminate the dyskinetic reaction, whereas Schmutz X (or at least “methyl Schmutz X”) actually did satisfy AstraZeneca’s tests for an *atypical* antipsychotic. Accordingly, AstraZeneca was able to continue making its argument to the examiner that the atypicality of quetiapine was an unexpected result compared to what it regarded as the “closest prior art.” Further, since it was providing the examiner with the comparisons that he had requested, except for Schmutz B, which Dr. Migler regarded as closer, it says that it satisfied its duty of candor to the examiner.

Focusing more deeply on the precise issue at hand, AstraZeneca’s lawyer, Fitzpatrick Cella’s Henry Renk, said that since the examiner was only asking for this limited comparison, there was no need for the AstraZeneca scientists to argue that no other compound was also an atypical antipsychotic. They never represented to the examiner, said Renk, that quetiapine was better than anything else. Since the closest prior art lacked atypicality, he argued, it is not material that other, less close compounds were atypical.

Renk then addressed the independent element of intent, which must also be shown in an inequitable conduct case. Mere knowledge of internal data by some individuals who had a duty to disclose “is not deceitful intent unless the individuals withheld it knowing of its importance or knowing of its materiality.” Renk’s argument, as it appears to us, is that since the examiner was only interested in the comparison of quetiapine to the closest prior art, which was provided to him, the individuals with a duty to disclose were justified in believing that no other prior art known to them was material.

To us, this argument is so flawed that it does not even present a close question, but given Judge Pisano’s previously demonstrated tendencies in this case, we think the odds are that he will buy it. As explained by Goodwin Proctor’s Ira Levy on behalf of Teva, materiality is determined by what would be important to a reasonable examiner, not what was important to this one examiner in this case. It is pretty easy to see that a reasonable examiner would have found it important that other prior art antipsychotics (other than clozapine, which suffered from an unrelated side effect) were atypical. In fact, given the examiner’s request for a showing of unexpected results, we doubt he would have allowed the patent at all if he had been informed that various other atypical antipsychotics were already in the prior art, since atypicality is not unexpected if other prior art antipsychotic drugs have the same characteristic.

It is on this point that we expect Judge Pisano to go wrong. We think he will probably conclude that since this one examiner wanted to see only the closest prior art, all the other art became immaterial, and we think he will obscure the difference between this examiner and a reasonable examiner. We think he is also likely to conclude that since obviousness is out of the case (at least with respect to Teva), the prior art is immaterial since it does not invalidate the patent.

One of Judge Pisano's first questions to Levy was the following: "So, if there's no defense of invalidity and if there's no defense of obviousness, how do you make the argument that anything relating to these other four [prior art] compounds have material value?" Levy responded by saying that inequitable conduct has never been a "but-for" argument, to which Judge Pisano said: "I never said it was." In fact, the only reason obviousness is out of the case is Judge Pisano's flawed collateral estoppel ruling adopting the Zyprexa findings against Teva on the so-called objective indicia of nonobviousness. Levy said that this collateral estoppel ruling has nothing to do with whether the examiner was misled by intentional and material misrepresentations about the scope and content of the prior art.

The crux of Levy's argument is that there was a number of other compounds that satisfied AstraZeneca's tests for an atypical antipsychotic, but the examiner's attention was intentionally directed away from these other compounds in favor of the two compounds that were *structurally* closest but lacked the atypicality that the inventors had been seeking. This manipulation, it was said, permitted the examiner to believe that no other compounds possessed the combination of antipsychotic and reduced dyskinesia features of quetiapine. Levy cited a prior Syntex case in which the Court of Appeals held that the closest prior art does not necessarily mean that it is the *best* prior art, or that the best prior art is not material. Again, Levy said, the critical question is what a reasonable examiner would want to know in order to assess the merits of the patent application.

At about this time, Judge Pisano demonstrated his enthusiasm for Teva's argument by stating: "Let me say this to you. I turn into a pumpkin at 5:00 o'clock." Levy apologized that the record was fairly detailed, to which Judge Pisano replied: "I'm not being disrespectful to you. I'm stating a fact of life."

Then Levy threw a hardball. Schmutz X was material per se, he said, because the examiner asked for it, and therefore the misrepresentation that it would be too expensive to get data on Schmutz X, disavowed by the inventors themselves in their depositions, was also material. To us, saying that Schmutz X was too expensive when it was not, thereby knowingly concealing the fact that Schmutz X would reinforce the examiner's obviousness rejection and probably doom the application once and for all, is conduct that the law is designed to discourage.

Levy addressed intent in his final remarks, but we thought that the lawyer for Sandoz, Douglass Hochstetler of Schiff Hardin in Chicago, was more articulate in describing the evidence that the people involved with prosecution of the application intended to deceive the patent examiner. These people, he said, are presumed to know the materiality of the various prior art compounds exhibiting the same characteristics as those claimed for the subject compound. Additionally, he said that there was a pattern of volunteering information that was helpful to patentability while concealing information that was unhelpful, and he said that intent can be inferred from a pattern of conduct. Third, the "too expensive" representation was unsupported in the depositions, suggesting (at least to us) that it was an intentional falsehood. Fourth, he said that there was an implied representation that the data provided was the best prior art, which is an independent indication of an intent to deceive.

Judge Pisano scheduled a trial in this case on August 11, 2008, and he also has a motion hearing scheduled for August 4, 2008 on any pretrial motions that may be filed between now and then. The due date for such motions is July 7, 2008. However, if Judge Pisano rules as we expect on the inequitable conduct claims in the case, then we question whether the trial would go forward at all. The only issue left if the inequitable conduct claims are eliminated would be the Sandoz obviousness defense, and we think that Judge Pisano would probably require Sandoz to make an offer of proof on the specific factual issues on which Teva is collaterally estopped. We think that Judge Pisano's collateral estoppel ruling against Teva was flawed in just about every respect, as discussed in our December 20, 2007 report, but we think he would be happy to adopt it against Sandoz, cancel the trial and then let the Federal Circuit decide whether it wants to affirm.