

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER AG and BAYER)
CORPORATION,)
)
Plaintiffs,)
)
v.) Civ. No. 01-148-SLR
)
HOUSEY PHARMACEUTICALS,)
INC.,)
)
Defendant.)

Rudolf E. Hutz, Esquire, Jeffrey B. Bove, Esquire, and Mary W. Bourke, Esquire, of Connolly Bove Lodge & Hutz LLP, Wilmington, Delaware, Counsel for Plaintiffs.

M. Duncan Grant, Esquire, of Pepper Hamilton LLP, Wilmington, Delaware, Counsel for Defendant. Of Counsel: R. Terrance Rader, Esquire, and James F. Kamp, Esquire, of Rader, Fishman & Grauer PLLC, Bloomfield Hills, Michigan.

MEMORANDUM OPINION

Dated: September 19, 2005
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

By opinion issued on December 4, 2003 (D.I. 305), I found U.S. Patent No. 4,980,281 ("the '281 patent")¹ to be unenforceable due to inequitable conduct. More specifically, I found that Dr. Housey, the named inventor of the patents in suit, was not credible in his testimony concerning the soft agar experiment he allegedly performed and the results thereof reflected in Table 3 of the '281 patent. By a decision issued on April 4, 2005, the United States Court of Appeals for the Federal Circuit found that I had "clearly erred in making the factual findings that support[ed my] credibility determination" concerning Dr. Housey and, consequently, vacated and remanded "to permit [me] to provide any further reason [I] may have to find Housey incredible." Bayer AG v. Housey Pharmaceuticals, Inc., 128 Fed. Appx. 767, 771 (Fed. Cir. 2005). By order dated May 24, 2005, I directed the parties to review the record again in light of the Federal Circuit's decision. (D.I. 356) The parties submitted their responsive papers in July 2005. (D.I. 361, 363)

II. THE FEDERAL CIRCUIT'S DECISION

Consistent with my December 2003 opinion, the Federal Circuit wrote that "[t]he results of the soft agar experiment were key to the issuance of the '281 patent because it was the

¹U.S. Patent Nos. 5,266,464, 5,688,655, and 5,877,007 are continuations of the '281 patent and, therefore, were found to be unenforceable as well, for the reasons stated therein.

only demonstration in the application that the process worked for inhibitors of cell activity. Dr. Housey specifically relied on the data presented in Table 3 to overcome some of the patent examiner's objections to patentability." Bayer AG v. Housey Pharmaceuticals, 128 Fed. Appx. at 768. According to the Federal Circuit, I held "that Dr. Housey fabricated the experimental results of the soft agar experiment, based on several subsidiary findings." Id.

Some of these subsidiary findings were not disturbed by the Federal Circuit in its decision. First, the "Cell Paper", written by Dr. Housey and others, "disclosed much of the framework of the claimed invention." Id. Second, the "Cell Paper" "published all of the experimental evidence reported in Dr. Housey's patent application, except for the results of the soft agar experiment." Id. Third, "some of the experimental results in the patent application were identical to experimental results credited to Dr. Housey's colleagues in the paper." Id. Fourth, "none of Dr. Housey's colleagues from the Weinstein lab remembered seeing Dr. Housey working on the soft agar experiment." Id. Fifth, there is no written record in Dr. Housey's laboratory notebooks, or otherwise, of the soft agar experiment; "on other projects, Dr. Housey kept meticulous notes." Id. at 769. Sixth, in the Weinstein laboratory, "twelve to fifteen scientists shared chemicals [and] work space." Id. at

768.

The following findings were found to be clearly erroneous by the Federal Circuit. First, because "patent law acknowledges the necessity of secretive activity before filing a patent application," I erred "in considering Dr. Housey's secretive acts as evidence of inequitable conduct." Id. at 770. I also erred "in finding that the Weinstein laboratory only had one incubator and did not use multi-well plates." Id. Specifically, the Federal Circuit declared that the record cited in support of my "one-incubator finding" was inadequate, and that the record was replete with references to multi-well plates. I also erred in "determining that Dr. Housey did not acknowledge the contributions of his colleagues" from the "Cell Paper". Id. Finally, the Federal Circuit found error in my conclusion that "Dr. Housey knowingly withheld the material prior art references referred to as Hsiao 1986 and Uehara 1985."² Id. I will address the record in light of these findings.

III. DISCUSSION

I start, as did the Federal Circuit, with the undisputed proposition that the results of the soft agar experiment, as reflected in Table 3 of the '281 patent, were critical to the issuance of the '281 patent. If these results were fabricated by

²I do not further address the Hsiao 1986 or Uehara 1985 prior art references.

Dr. Housey, he committed inequitable conduct before the PTO and the '281 patent would not be enforceable. Because there is absolutely no objective record that the soft agar experiment was ever conducted by Dr. Housey, the determination of inequitable conduct rests solely on Dr. Housey's credibility.

As the finder of fact who sat through the bench trial, I was required to, and did, make subjective credibility determinations about the witnesses who testified, including Dr. Housey. Unlike a jury, who has the luxury of incorporating its credibility determinations into its verdict without specifically articulating them, a trial judge writing a bench opinion has the obligation to be more forthcoming. I did not believe Dr. Housey's testimony at trial, and a further review of the record has not convinced me otherwise, for the following reasons.

The Federal Circuit has instructed that the lack of any documentation concerning the underlying data for the soft agar experiment is not, in and of itself, evidence of inequitable conduct, as secretive activity is permitted under the patent law. Nevertheless, and aside from the fact that written records can be secreted and that Dr. Housey was in the habit of keeping meticulous records of his other experiments, it is clear from the record in the case that Dr. Housey was not forthcoming in this regard. The criticality of the soft agar experiment, the only original experiment in his patent application, is undisputed.

Dr. Housey testified in multiple pretrial depositions that "the underlying data for the experiments in Table 3" were "[p]resumably, somewhere in the boxes, or the photos, films, whatever" produced during discovery. (D.I. 281 at 333-35) After I issued an order directing defendant to produce the underlying data (D.I. 179), Dr. Housey reported that he could not find any such data in handwritten form, as referenced in his prior deposition testimony. (D.I. 281 at 336) He ultimately testified, however, that there was no documentation of the underlying data because he performed the soft agar experiment using a hand-held computer and intentionally did not create any records thereof (e.g., by printing out the results of the computer-generated calculations). (Id. at 336-37) The reason given by Dr. Housey for not creating any records was the importance of not "leaving things lying around on [his] desktop or whatever that would be potential disclosures of [his] inventions." (Id. at 339)

With respect to how Dr. Housey allegedly conducted the soft agar experiment, he clearly recollects using "two, 24-well tissue culture plates where each compound, either H-7 or tamoxifen, as the case may be, is treated, is performed in duplicate." (Id. at 332) The cells on the plates were incubated for "[p]robably 28" days, during which time Dr. Housey had to feed the cells to keep them alive. (Id. at 345) When asked, "And during the course of

incubating those cells, you had to use **the incubator** in Dr. Weinstein's laboratory, correct?", Dr. Housey responded, "Yes." (Id.)³ At the end of the incubation period, Dr. Housey put the cells under a microscope, counted the colonies in each well, and entered

them in that - a hand-held calculator that immediately computes how many colonies with the, what we call, the cleaning efficiency, which is the number of colonies that grew in soft agar as a percentage of total number of cells that were put in. And it's expressed as a percentage in Table 3 in my patent.

And I would use a hand-held calculator to just crank - to just input those numbers and have it output the results immediately.

And those results I would, in turn, enter into the report that I would give to Mr. Cooper.^[4]

(Id. at 358-359) Dr. Housey further testified at trial that, "the way in which I compiled the data was to take them home, write them up, put them into reports and provide them directly to Mr. Cooper." (Id. at 340) Dr. Housey told Mr. Cooper, however, that "all of the findings and discoveries of [his] invention were documented in [his] laboratory notebooks." (Id. at 341)

With respect to the 24-well plates allegedly used by Dr. Housey, there is evidence of record to support the finding that,

³See also D.I. 283 at 829-30 ("24-well plates wasn't [sic] even available in the labs, so if I spot any 24-well plates around **in the incubator**, it would stick into my mind . . .") (emphasis added).

⁴Mr. Cooper was Dr. Housey's patent counsel.

during the relevant time period, "single well tissue culture plates were the standard format for conducting cellular work in the Weinstein laboratory," because multi-well plates could produce inaccurate results when using a microscope to count cell colonies in soft agar experiments. (D.I. 281 at 434-35; D.I. 283 at 853) Although "multi-well plates" were used in the Weinstein laboratory, defendant was unable to identify a single item of evidence,⁵ aside from Dr. Housey's trial testimony and the numbers in Table 3, that demonstrated the use of **24-well** plates in the Weinstein laboratory. (D.I. 361 at 2-11) Moreover, regardless of the number of incubators in the Weinstein laboratory or what kinds of dishes or plates were used, it is undisputed that the scientists conducting experiments in the laboratory "shared incubator space" and, consequently, "everybody [had] to clearly mark their dishes with their initials and dates and what type of cell on the dish." (D.I. 283 at 793-94) None of Dr. Housey's former colleagues remember his working on any

⁵I note in this regard that defendant, in its response to the May 24, 2005 order, has asked me to take judicial notice of laboratory notebooks produced in discovery but not admitted into evidence at trial, of portions of deposition transcripts not read into the record at trial, of articles referred to in Dr. Weinstein's curriculum vitae but not admitted as exhibits at trial, and of facts disclosed in patents assigned to Columbia University for experiments conducted in laboratories other than the Weinstein laboratory. (D.I. 361 at 2-11) I decline to do so, as the Federal Circuit specifically stated that "[t]he purpose of the remand is not to open the record for further evidence or to allow further argument by the parties." Bayer AG v. Housey, 128 Fed. Appx. at 771.

experiment that matches Dr. Housey's description of the soft agar experiment.

With respect to the "Cell Paper," I acknowledge that none of Dr. Housey's former colleagues claim inventorship over the invention as Dr. Housey understood it; indeed, Dr. Weinstein testified that he did not believe the data in Table 3, the only data that arguably proves that Dr. Housey invented what he claims. (D.I. 282 at 742-46) In my December 2003 opinion, I did not mean to infer that Dr. Housey should have acknowledged the contributions of his colleagues for the invention allegedly disclosed in Table 3. What I attempted to communicate was the fact that Dr. Housey's failure to acknowledge the contributions of his colleagues for "all of the experimental evidence reported in [his] patent application, except for the results of the soft agar experiment," Bayer AG v. Housey Pharmaceuticals, 128 Fed. Appx. at 768, is some evidence that Dr. Housey acted with less than total candor. (See, e.g., '281 patent, col. 7, ll. 47-68; col. 8, ll. 1-30; cols. 19-20, Tables 1(a), 1(b), 1(c), and 2)

In summary, when I review the record at bar, I find no objective evidence that Dr. Housey actually conducted the soft agar experiment. I find his story of invention inconsistent with the credible testimony of his former colleagues in the Weinstein laboratory and, at least with respect to his recollection of how the experiment was documented, internally inconsistent. Mindful

of the Federal Circuit's admonition that secrecy cannot be evidence of inequitable conduct, I do not know how else to judge Dr. Housey's credibility other than to test it against the credibility of others who testified and against whatever objective evidence of record there is. Based on the record presented to me at trial,⁶ I find Dr. Housey's credibility wanting in the comparison.

IV. CONCLUSION

I have reviewed the record consistent with the Federal Circuit's mandate, and have attempted to provide further support for my finding that Dr. Housey is not credible. For the reasons stated, I continue to believe that the clear and convincing evidence of record supports my conclusion that Dr. Housey is not credible and that he committed inequitable conduct before the PTO by presenting fabricated experimental results that were material to the issuance of the patents in suit.

An order shall issue.

⁶I do not presume to know what my decision might have been had defendant introduced at trial the materials submitted in connection with this remand.

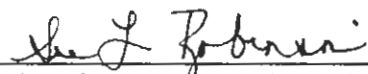
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O R D E R

At Wilmington this 19th day of September, 2005, having been given the opportunity to review the record in light of the Federal Circuit's April 4, 2005 decision and, consistent with the memorandum opinion issued this same date, having found clear and convincing evidence of record that the results of the soft agar experiment reflected in Table 3 of the '281 patent were fabricated;

IT IS ORDERED that the clerk shall enter judgment in favor of plaintiffs and against defendant.



United States District Judge