IP Alert: Confidentiality Agreements Get Teeth

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By Sarah A. Kagan

Do you consider Non-Disclosure Agreements (NDAs) and Material Transfer Agreements (MTAs) mere hoops to jump through before you can get what you really want? Do you think you can sign them and then forget about them, without a program to monitor and enforce compliance? If so, you may want to rethink your assumptions and actions. A recent admitted patent infringer used a patentee's failure to comply with an NDA as the basis to jettison infringement damages.

On February 5, 2018, a three-judge panel of the U.S. Court of Appeals for the Federal Circuit entertained a marathon of oral argument in an appeal seeking to overturn a district court's holding of unenforceability of two patents, U.S. Patent 7,105,499 ('499) and 8,481,712 ('712), due to unclean hands. Gilead Sciences, Inc. v. Merck & Co., Inc. (16-2302, 16-2615). A jury held the two patents were infringed and not invalid, and awarded Merck $200 million in damages for sales of hepatitis C virus (HCV) therapeutics Solvadi ® and Harvoni®. In a subsequent bench trial on equitable defenses, the district court judge found egregious misconduct, including lying, misusing confidential information, breaching confidentiality and firewall agreements, and lying under oath at deposition and trial. The fact

that the main purveyor of lies was an attorney exacerbated the unconscionableness of the misconduct, according to the district court.

One source of misconduct found by the district court was a due-diligence telephone conference in which Gilead[1] disclosed the structure of its lead compound to Merck. The court found that, during the telephone conference, Merck falsely stated and confirmed that its two participants were firewalled from its own ongoing HCV program. In fact, one of the two, Dr. Durette, was the prosecuting attorney on Merck's application that matured into the '499 patent.[2] In addition, an NDA controlled the parties' exchange of information. Merck did not disclose to Gilead Dr. Durette's role. Dr. Durette did not thereafter recuse himself from his role in the Merck HCV program, nor did Merck remove him. Rather, Dr. Durette continued to work on the Merck HCV program for another six years, until his retirement. The district court found the participation in the telephone conference to be a breach of the NDA and firewall agreements, which infected both the '499 and the '712 patents.

Another source of misconduct found by the district court was Dr. Durette's submission of an amendment in Merck's '499 application, narrowing a very broad genus of recited HCV inhibitor compounds to a subgenus that included Gilead's disclosed lead compound. The district court found that this was a misuse of confidential information. Merck argued on appeal that Merck was free to make the amendment because it occurred after Gilead's lead compound was published in its patent application. That argument was deflated, however, by Dr. Durette's testimony that he would not have been able to identify the lead compound from the published Gilead application without his foreknowledge gained in the telephone conference. The filing of the subsequent '712 application by Dr. Durette on behalf of Merck was also deemed misconduct by the district court, because Dr. Durette should have recused himself.

The district court also called out Merck's trial behavior with disapprobation. The district court faulted Merck's failure to warn the court or Gilead prior to trial that Dr. Durette would significantly change his trial testimony from his deposition testimony. A number of facts that Dr. Durette

testified to at trial were found to conflict with his deposition testimony and with other evidence that the district court found more credible.

One interesting legal theory that Merck pursued during the bench trial was that the failure of the jury to find derivation of the claimed invention from Gilead's confidential disclosure precluded a finding of unclean hands. The jury had found no derivation under 35 U.S.C. §102(f) because it found adequate written support for the claims as of the priority date, which preceded Gilead's disclosure to Merck. The district court rejected that preclusion theory, however, because the acts alleged to constitute unclean hands were not limited to the acts constituting derivation.

At oral argument before the Federal Circuit, the panel was not satisfied by discussion of the overarching legal issues, but dug into the facts. For example, when Merck asserted that the unclean hands holding rested on acts that were not linked to a disadvantage to Gilead, the panel asked Merck to walk it through the specific acts at each of the relevant time periods where egregious acts had been found by the district court.

The panel pushed Merck to point to evidence that Dr. Durette would have made the amendment focusing a large genus down to a subgenus encompassing Gilead's lead compound, even had he not received Gilead's confidential information. Merck replied that such an amendment was inevitable. When pressed for a yes-or-no answer by the panel on the existence of evidence to support inevitability, Merck admitted that the record contained no evidence of inevitability of the amendment. Merck tried to point to a similar amendment made five years later by a different Merck patent attorney in the '712 application as evidence of inevitability. The panel seemed to reject that later act as relevant evidence of what would have happened five years earlier in the absence of the misconduct.

During Gilead's time before the panel, the judges again pressed the question of inevitability. Was it inevitable that Merck would have seen the Gilead published disclosure, recognized the lead compound among a plethora of disclosed compounds, and amended the Merck claims from genus to subgenus claims? Gilead relied on Dr.

Durette's testimony that he, a Ph.D. chemist, would not have been able to recognize the lead compound among a plethora of disclosed compounds. Gilead also pointed out that at trial Dr. Durette gave three reasons for making the amendment, and none of them was the published disclosure of Gilead.

Gilead addressed the issue of nexus between the misconduct and each patent. Merck's failure to remove Dr. Durette from prosecuting the '499 and '712 applications was an unacceptable business practice, Gilead indicated, citing the district court opinion. Therefore, the misconduct was linked to both patents.

The appellate panel asked Gilead if the publication of its application rendering public the Gilead lead compound removed the taint of the misconduct from Merck. Gilead responded that recusal may have removed the taint, but the failure to recuse led to a compounding of the errors and lies.

The panel explored the balancing of equities in assessing unclean hands. What public harm was caused, it asked Gilead. Gilead responded that attorney lies and litigation misconduct harm the judicial system and that business misconduct would stifle business collaborations. Gilead pointed to the district court's opinion stating that such conduct would "bring the marketplace to a halt as companies would be weary (sic) to engage in due diligence lest a competitor uses that information to obtain patents."

Merck tried to assign the misconduct to the '499 patent and isolate it from the '712 patent. The two patents, however, share a common specification, were filed by the same Merck patent attorney, and were asserted in the same infringement suit. Moreover, the claim sets are very similar. The '499 patent is directed to a method of treating HCV using a set of compounds of formula III, and the '712 patent is directed to an overlapping set of compounds per se. Merck tried to break the chain linking the misconduct to the '712 patent by pointing out the independence of the second Merck patent attorney who prosecuted the '712 patent after Dr. Durette retired. The panel expressed skepticism that the chain of causation

based on the misconduct was broken simply by Dr. Durette's retirement and replacement in the normal course of events.

Throughout the oral argument, there was an undercurrent of disagreement of the appellate panel with the conclusion of the jury that the priority application of the two patents provided an adequate written description of the claimed subgenus. Although the jury's verdict was only conditionally challenged on appeal (i.e., if the unclean hands ruling were reversed), the underlying issue came up in the panel's questions about Dr. Durette's motivation for making the narrowing amendment. "Where were the blaze marks?" the panel asked. This language seemed to question both the motivation to make the amendment as well as the written description support for the amendment.

This dispute should caution parties who regularly use NDAs and MTAs to grease the skids of their research and development that the agreements can have real consequences. Their restrictions need to be communicated within organizations, monitored, and obeyed. Gone are the days when such agreements can be signed and shoved into a file cabinet. Accused infringers are on notice that violations of these agreements can be a powerful defense.

Click here to hear the oral arguments in Gilead Sciences, Inc. v. Merck & Co., Inc.

[1] "Gilead" is used here to represent itself and its predecessor-in-interest, Pharmasset.

[2] The applications maturing into these patents are also referred to here by those same numbers.

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