Reversal of $200-million drug patent verdict offers hard lessons for technology collaborators

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The value of start-up companies often hinges on their intellectual property and on the commercialization of novel technology, often in partnerships with established players. But collaborative arrangements involving critical technology are fraught with risks, as was poignantly illustrated in a recent U.S. patent case. In *Gilead Sciences Inc. v. Merck & Co.* (13-cv-04057, N.D. Cal.), a jury had ordered pharmaceutical company Gilead to pay rival Merck $200 million in damages for having infringed Merck's patents to sofosbuvir, the active ingredient in Gilead's Sovaldi product. Sovaldi is a drug that cures hepatitis C, with annual sales exceeding $10 billion.

On June 6, 2016, however, a U.S. District Court judge overturned the damages verdict, holding that Merck's patents were unenforceable because it had acted inequitably. The story behind this reversal offers lessons to collaborative companies about the pitfalls that can arise when sharing sensitive technology and what steps can be taken to manage these risks.

Merck and Pharmasset's technology collaboration

Pharmasset and Merck had entered into a non-disclosure agreement (NDA) to explore opportunities in the field of hepatitis C. Pharmasset agreed to share information about its lead therapeutic agents, although not the compounds' chemical structure, and Merck agreed to use this information only to evaluate a potential collaboration.

Eventually, Merck asked that Pharmasset disclose the identity of its lead compound to conduct further testing and help frame a relationship between the companies. To address Pharmasset's confidentiality concerns, Merck offered to "firewall" a chemist to be vested with the compound's structural information to prevent any communication with Merck's own internal hepatitis C team. Pharmasset accepted the firewall approach.

As the Merck-Pharmasset collaboration evolved, a Merck patent agent involved in prosecuting Merck's own hepatitis C patent applications managed to participate in conversations with Pharmasset. In particular, the patent agent attended a telephone call with Pharmasset during which he stated he was a firewalled employee (when this was in fact not the case), and he learned the identity of Pharmasset's lead compound.

Merck's conduct leading to a finding of unclean hands

Although Merck was unaware of the Pharmasset compound, it had pending patent applications that were so broad as to encompass the compound's structure. Following the Pharmasset call, the patent agent re-crafted existing Merck patent applications to focus on

the Pharmasset compound.

Eventually, Merck's patents issued, Gilead bought Pharmasset and began selling Sovaldi, and Merck sued for patent infringement. In its defence, Gilead alleged that Merck had wrongfully appropriated sofosbuvir from Pharmasset.

The District Court held that Merck had acted inequitably and in breach of its agreement with Pharmasset. Neither Merck nor the patent agent had ever advised Pharmasset that the agent was not in fact firewalled and that he was prosecuting Merck's patent applications in the same field. In fact, the District Court concluded that the patent agent had lied under oath, violated the firewall, and that Merck knowingly misrepresented the patent agent as a firewalled employee.

Lessons to be learned

Small- to mid-size technology companies often see collaboration with large established entities as a major corporate milestone likely to increase investor interest. However, established entities are often more sophisticated at managing intellectual property and may be better positioned to seize valuable technology out from under a start-up. The Pharmasset-Merck collaboration dramatically illustrates what can go wrong in a technology collaboration, but it should also encourage collaborators to enter into robust arrangements to govern the disclosure and use of valuable new technology.

There are at least three hard lessons to be learned from the *Gilead Sciences v. Merck* case:

1. **Have clear contracts in place:** *Gilead Sciences v. Merck* illustrates the residual risk that a bad actor may appropriate valuable technology. Yet, the robust contracts between Pharmasset and Merck allowed Gilead to convince the Court that the Merck patent agent had breached the parties' understanding and trust. The Pharmasset-Merck collaboration included the following safeguards:

   a) Non-disclosure agreement: The parties executed an NDA and revisited it over time to reflect changing circumstances. **b) Clear project scope:** The parties formalized a Material Transfer Agreement, narrow in scope to permit testing of a limited number of specified compounds (including Pharmasset's lead compound), with restrictions barring Merck from determining their chemical structure. **c) Clear understanding of commercially sensitive information:** The parties showed a mutual understanding that chemical structures of tested compounds were confidential, and a firewall was put in place to prevent access by personnel who could put the compound information at risk.

2. **Don't let your guard down:** It only takes one slip-up to introduce a risk of unauthorized use of confidential information. Pharmasset clearly took steps at all times to remind Merck of its obligations, including confirming in advance that all recipients of sensitive information were within a confidential firewall. However (with the benefit of hindsight), Pharmasset could have maintained a list of firewalled Merck personnel and questioned the need and basis for a patent agent to obtain compound structure information.

3. **Take special care in crowded technology fields:** Where overlapping technology portfolios are involved, a good understanding of each party's "coming-in" position is essential to avoid the prospect of mischief before intellectual property offices or ownership disputes down the line.

For early-stage tech companies, the means used by the Merck employee to seize Pharmasset's technology may come as a shock. Unfortunately, they should not. Entrepreneurs must keep their eyes wide open to the potential risks of technology collaboration in sophisticated, competitive markets.

For any questions about the *Gilead Sciences v. Merck* case or to discuss your next technology collaboration, please contact Nathaniel Lipkus (416.862.6787, nlipkus@osler.com) or Vincent de Grandpré (416.862.6570, vdegrandpre@osler.com).