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Protecting Proprietary Compound Structures: Key Lessons from Merck's Unclean Hands

Companies disclosing proprietary compound information must take steps to protect their interest in such information. Equally important, but often overlooked, companies receiving another party's proprietary information also need to take steps to avoid being contaminated by such information. Merck learned that lesson the hard way in its patent litigation with Gilead.

Merck was awarded a \$200 million patent win against Gilead when a California federal jury found in March 2016 that two Merck patents covering the active compound in Gilead's hepatitis C drugs were valid. But Merck's victory was short-lived. On June 6, 2016, a California federal judge ruled that Merck is barred from asserting its two patents against Gilead after finding "a pervasive pattern of misconduct by Merck and its agents," including its patent attorney. The case is *Gilead Sciences Inc. v. Merck & Co. Inc. et al.*, case number 5:13-cv-04057 in the U.S. District Court for the Northern District of California.

The pattern of Merck's misconduct dates back to 2004, when Pharmasset (Gilead's predecessor-in-interest) disclosed the structure of its proprietary hepatitis C compound during a teleconference with Merck in furtherance of exploring possible collaboration opportunities relating to antiviral agents against hepatitis C virus. Before the teleconference, Pharmasset had taken usual steps to protect its proprietary

compound information. A material transfer agreement (MTA) was executed to permit Merck to test certain compounds, but prohibited Merck from determining the chemical structure of the compounds. A non-disclosure agreement (NDA) was in place that restricted Merck's use and disclosure of Pharmasset's information, and included a requirement to impose a firewall to limit disclosures to only individuals not involved in Merck's own hepatitis C drug development program. Pharmasset was assured that each participant in the teleconference was firewalled when, in fact, a Merck patent attorney responsible for prosecuting Merck's hepatitis C patents, was participating on the call, thus triggering the cascade of misconduct that lasted for over a decade, resulting in two unenforceable patents and an overturned damages verdict for Merck.

NDAS AND MTAS

The first step generally taken to protect proprietary compound information is execution of appropriate agreements, such as NDAs and MTAs, that include restrictions on the use and disclosure of compound structures. Use of compound information should be restricted to a specific narrow purpose. The parties may expressly agree that no compound structures will be disclosed during initial discussions. If compound structures need to be disclosed to a recipient that has or had a competing compound development program, the

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agreement should require use of a "firewall" whereby compound information is disclosed only to those individuals not involved with such development programs.

When proprietary compounds are provided under an MTA, compounds should be supplied in an anonymized format and the MTA should include provisions prohibiting the recipient from reverse engineering the compounds or otherwise attempting to determine the chemical structure of the compounds.

In any agreement under which proprietary compound information is disclosed, the term of the confidentiality and non-use provisions, and any other appropriate restrictions, should be of sufficient duration to adequately protect the information.

FIREWALLS

A firewall should cover not just scientists and technical personnel, but any individuals involved in past or current competing development projects, including consultants, legal personnel and other advisors.

A company should diligently manage its firewall obligations. If a firewalled individual is exposed to restricted information, the disclosing party should be notified immediately of the firewall breach and measures should be taken to control any further unauthorized use of such information. After learning the structure of Pharmasset's compounds, Merck's patent

attorney not only continued prosecuting Merck's hepatitis C patents but amended the claims of one patent to cover the structure of Pharmasset's compounds, continuing the pattern of misconduct.

INDEPENDENT CHEMISTS

Disclosure of proprietary compound information can be facilitated using an independent medicinal chemist as a screen between a holder of proprietary structure information and a recipient. An independent chemist should execute a separate agreement that expressly states the chemist's role and contains appropriate confidentiality obligations. An independent chemist may evaluate the compound structures and provide the recipient with a general summary of certain characteristics of the structures without disclosing the identity of the compound or the structure itself. Or an independent chemist may first approve any structural information before such information is disclosed to a recipient to ensure that the recipient is not receiving any information that it does not wish to receive, for example, if such information could contaminate the recipient's own competing development program.

Putting appropriate protective measures in place is a critical step when disclosing or receiving information relating to proprietary compound structures. Equally as important is ensuring that such measures are complied with and any breach is promptly and properly managed.

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