

MERCK v. HEALTHCARE PHARMACEUTICALS INC., Appeal Nos. 2015-2063, -2064 (Fed. Cir. May 13, 2016). Before Dyk, Mayer, Hughes. Appealed from D. Del. (Judge Andrews).

Background:

Merck and Weider were exploring a partnership to market Merck's patented crystalline calcium salt as a dietary supplement. At the beginning of the relationship, the two entities signed an agreement providing that "unless and until [a] definitive agreement regarding a transaction...has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such transaction."

Weider later notified Merck that it was interested in purchasing two kilograms of the salt, and requested pricing information "in order to complete the transaction." Merck's initial response included price, delivery, and payment terms and indicated that Merck could arrange for immediate delivery. Weider confirmed that it would order the two kilograms, and Weider and Merck continued to exchange additional information until the "order" was eventually canceled three months later.

During litigation between two of Merck's subsidiaries and a filer of an Abbreviated New Drug Application (ANDA), the district court upheld the validity of the patent, holding that there had been no invalidating offer for sale because Merck's initial response did not include safety and liability terms that were conventionally included in purchase orders, and the response was not signed by both parties. The ANDA filer appealed.

Issue/Holding:

Did the district court err in holding that Merck's communication failed to trigger the on-sale bar? Yes, reversed.

Discussion:

In determining whether Merck's initial response constituted an offer for sale, the Federal Circuit applied traditional contract law principles. Under these principles, an offer for sale exists when the other party could make the offer into a binding contract by simple acceptance. The court noted that Merck's communication was sent as a direct response to Weider's request to purchase the salt, and was not an unsolicited price quote. Additionally, the response included essential price, delivery, and payment terms. Such terms are sufficient to constitute an offer.

The Federal Circuit rejected the district court's determination that the response failed to constitute an offer for sale because the communication was not signed by both parties. The Federal Circuit concluded that the requirement that the agreement be signed by both parties was essential only to create a binding contract, but not an offer for sale.

The Federal Circuit also rejected the district court's position that the response would not be understood to be an offer for sale because it lacked safety and liability terms, explaining that these terms were not typically included in *offers* (as opposed to the finalized contracts). Furthermore, the response indicated that everything would be arranged for immediate delivery, indicating that Merck intended the communication to be an offer that could be made into a binding contract by simple acceptance. The Federal Circuit therefore held that Merck's initial response constituted an offer for sale, triggering the on-sale bar.