

Federal Circuit Finds NuvaRing Patent Nonobvious Without Hindsight

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In a non-precedential decision issued in [*Merck Sharp & Dohme B.V., v. Warner Chilcott Co. LLC*](#), the Federal Circuit reversed the district court's obviousness ruling as being improperly grounded in hindsight. This decision provides a welcome reminder that even simple-sounding inventions can be nonobvious, but why is it non-precedential?

The Patent At Issue

The patent at issue was Merck's U.S. Patent No. 5,989,581, which is listed in the Orange Book for its NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) contraceptive product. Dependent claims 4 and 11 were at issue. Dependent claim 4 is representative.

1. A drug delivery system comprising at least one compartment which comprises a thermoplastic polymer core . . . core comprising a mixture of a steroidal progestogenic compound and a steroidal estrogenic compound in a ratio by weight that allows a direct release of both said progestogenic compound and said estrogenic compound in physiologically required amounts, said progestogenic compound being initially dissolved in said polymer core material in a degree of supersaturation of 1 to about 6 times of the amount by weight necessary for obtaining saturation concentration of said progestogenic compound in said polymer core material at 25° C, said estrogenic compound being dissolved in said polymer core material in a concentration lower than that of said progestogenic compound

4. A drug delivery system according to claim 1, wherein the amount of progestogenic compound dissolved in the thermoplastic core material is 2 to 5 times the amount necessary for obtaining saturation concentration.

Warner Chilcott asserted that the claims were invalid in view of WO 97/02015 , which relates to a two-compartment vaginal ring with etonogestrel in one compartment and ethinyl estradiol in a separate compartment. As noted in the Federal Circuit decision, the reference "criticizes one-compartment vaginal rings":

These above-mentioned one-compartment rings have the disadvantage that, when loaded with more than one active substance, release patterns of these substances cannot be adjusted independently.

Such devices usually show sub-optimum release patterns for the different substances, whereas it is generally preferred that all substances are released in a controlled rate and during a similar duration of time. As a consequence the release ratio of the active substances undergoes a change after a period of time.

Nevertheless, the district court found the Merck claims to be obvious.

The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Hughes and joined by Judges Dyk and Linn.

The Federal Circuit began its analysis with this guidance from the Supreme Court decision in *KSR* and other Federal Circuit decisions:

A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Even if all elements of the claim were known, we still must resolve whether a person of ordinary skill in the art would have found it obvious to combine these elements or modify them in a way that meets the claim. In making this inquiry, we have cautioned that “[t]he inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight.” *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012). **Thus, it is improper to combine references “like separate pieces of a simple jigsaw puzzle” without “explain[ing] what reason or motivation one of ordinary skill in the art at the time of the invention would have had to place these pieces together.”** *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1349 (Fed. Cir. 2014).

Turning to the decision on appeal, the court noted:

To arrive at the hypothetical ring that the district court relied on for obviousness, the person of ordinary skill must make the second compartment 97% of the total ring, which is outside of the usual or preferred range disclosed in PCT ’015. And the person of ordinary skill must also pick a concentration of ETO from the high end of the disclosed range, but conversely select a concentration of EE from the low end of the range. Nothing in PCT ’015 suggests picking these values out of the innumerable possible combinations of ETO concentrations, EE concentrations, and compartment length ratios. **Instead, the only way to arrive at the hypothetical ring is by using the ’581 patent as a roadmap to piece together various elements of PCT ’015. That represents an improper reliance on hindsight.**

The Federal Circuit also found error in the district court’s failure to consider “the prior art’s criticism of the one-compartment solution.” With regard to *KSR*’s guidance that a “design need or market pressure” may support a finding of obviousness, the Federal Circuit emphasized that “a person of ordinary skill in the art would pursue ‘identified, predictable solutions,’ not designs that were seemingly inoperable.” The Federal Circuit also noted that Merck “purportedly solved this problem [of sub-optimal drug release patterns] by supersaturating the ring with a progestogenic compound, a technique not taught in the prior art of record.” The Federal Circuit also questioned the expectation of success in moving from a two-compartment ring to a one-compartment ring given that “PCT ’015 warns that release rates for single compartment rings are difficult to control.”

Hindered By Hindsight

In patent prosecution, applicants often criticize obviousness rejections as being based on hindsight, but examiners rarely retreat from a rejection on that basis. The court's reminder that even if all **elements** of a claim are in the prior art it still must be shown that "a person of ordinary skill in the art would have found it obvious to combine these elements or modify them in a way that meets the claim," and that such a showing requires explanation of a "reason or motivation ... to place these pieces together" could be helpful, but would be more impactful if the decision were precedential.

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