NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

---

**MERCK SHARP & DOHME B.V.,**
*Plaintiff-Appellant*

**v.**

**WARNER CHILCOTT COMPANY, LLC,**
*Defendant-Appellee*

**WARNER CHILCOTT (US), LLC,**
*Defendant*

---

2016-2583

---

Appeal from the United States District Court for the District of Delaware in No. 1:13-cv-02088-GMS, Judge Gregory M. Sleet.

---

Decided: October 19, 2017

---

RAYMOND N. NIMROD, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for plaintiff-appellant. Also represented by GREGORY BONIFIELD, CATHERINE MATTES, MATTHEW A. TRAUPMAN; PHILIP CHARLES STERNHELL, Washington, DC.

GEORGE C. LOMBARDI, Winston & Strawn LLP, Chicago, IL, argued for defendant-appellee. Also represented by TYLER JOHANNES, KURT A. MATHAS, BRIAN J. NISBET, MICHAEL KEENAN NUTTER, ZACHARY L. SORMAN, KEVIN E. WARNER; STEFFEN NATHANAEL JOHNSON, Washington, DC.

---

Before DYK, LINN, and HUGHES, *Circuit Judges.*

HUGHES, *Circuit Judge.*

Merck Sharp & Dohme B.V. appeals from the district court's determination that claims 4 and 11 of U.S. Patent No. 5,989,581 are invalid as obvious. Because a person of ordinary skill would not have found it obvious to modify the prior art of record to arrive at the claimed invention, we reverse.

## I

The '581 patent relates to a vaginal ring used for contraception, and its commercial embodiment is sold under the brand name NuvaRing®. Warner Chilcott is seeking to introduce a generic version of NuvaRing®, and concedes that its generic product would infringe the '581 patent if the claims are found valid.

A vaginal ring is a small, flexible drug-delivery device used for contraception. The ring is inserted in the vagina for 21 days, where it releases a constant daily dose of progestin and estrogen. For this appeal, the relevant progestogenic and estrogenic compounds are etonogestrel (ETO) and ethinyl estradiol (EE), respectively.

One challenge in the design of vaginal rings is ensuring that both progestin and estrogen are released at a stable rate. Earlier prior art designs combined ETO and EE in a single compartment, but could not properly control the release rate for each compound simultaneously. The '581 patent purports to solve this problem by

providing a vaginal ring made of a polymer that is supersaturated with ETO.[1] The '581 patent explains that, under certain conditions, ETO can remain in a supersaturated state for long periods of time.

Claims 4 and 11 are at issue. Claim 4 is dependent from claim 1. Claims 1 and 4, in relevant part, state:

> 1. A drug delivery system comprising at least one compartment which comprises
>
> a thermoplastic polymer core . . . said 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.

---

[1] Supersaturation refers to a solution that contains more dissolved material than could be dissolved by the solvent under normal circumstances.

'581 patent at col. 7, l. 30–col. 8, l. 4. Claim 11 depends from claim 5. Claims 5 and 11, in relevant part, state:

> 5. A drug delivery system in a substantially ring-shaped form and suitable for vaginal administration comprising at least one compartment which comprises
>
> a thermoplastic polymer core . . . said core comprising a mixture of a progestogenic steroidal compound and an estrogenic steroidal compound in a ratio by weight of 10 parts of the progestogenic compound to 1.5–5 parts of the estrogenic compound . . . .
>
> 11. A drug delivery system according to claim 5, wherein the core material comprises 0.55 to 0.8% by weight of etonogestrel and 0.12 to 0.18% by weight of ethinyl estradiol.

*Id.* at col. 8, l. 5–col. 8, l. 49.

Importantly, claims 4 and 11 both require at least a single-compartment that includes a progestogenic steroidal compound and an estrogenic steroidal compound. Claim 4, for example, requires direct release of "physiologically required amounts" of both compounds from one compartment. *Id.* at col. 7, ll. 30–37. Claim 11 likewise requires "at least one compartment" to include a "mixture of a progestogenic steroidal compound and an estrogenic steroidal compound" in specific ratios and concentrations. *Id.* at col. 8, ll. 5–20.

In the proceedings below, Warner Chilcott argued that the asserted claims are anticipated or rendered obvious by International Patent Application WO 97/02015 (PCT '015). Like the '581 patent, PCT '015 also discloses a vaginal ring that prevents contraception by releasing ETO and EE. PCT '015, however, relies on a two-compartment design, in which a first compartment in-

cludes ETO only, and a second compartment includes ETO and EE.

PCT '015 criticizes one-compartment vaginal rings, stating that

> 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 suboptimum 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.

J.A. 3039.

After a four-day bench trial, the district court found that PCT '015 renders obvious the '581 patent claims. Specifically, the court reasoned that "a person of ordinary skill would have been motivated to optimize PCT '015 such that the second compartment released physiologically required amounts of ETO and EE." J.A. 19–20. The district court also found that PCT '015 discloses target release rates for ETO and EE, and that "it would have been obvious for a person of skill to derive the claimed ratios of progestin and estrogen" from the target release rates. J.A. 21. Accordingly, the district court held that claims 4 and 11 are invalid as obvious.

Merck appeals the district court's judgment of invalidity. We have jurisdiction under 28 U.S.C. § 1295(a).

## II

Obviousness is a question of law that we review de novo, and any underlying factual questions are reviewed for clear error. *Honeywell Int'l v. United States*, 609 F.3d

1292, 1297 (Fed. Cir. 2010) (citations omitted). The underlying factual issues include the scope and content of the prior art, the difference between the prior art and claims at issue, level of ordinary skill in the art, and any secondary considerations of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"[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).

We start with Claim 4 of the '581 patent, which requires a physiologically effective amount of progestogenic and estrogenic steroid compounds to be released from one compartment. PCT '015 discloses a two-compartment ring where the first compartment is loaded with ETO only, and the second chamber is loaded with ETO and EE. The purpose of this design is to better control the release profile by delivering the two compounds through separate compartments. PCT '015 explains that "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 . . . ." J.A. 3039.

The district court concluded that it would have been obvious to modify the two-compartment ring so that pharmaceutically required amounts of both ETO and EE are delivered from one compartment. In doing so, the district court found that "PCT '015 discloses a two-compartment ring in which the second compartment: (1) is loaded with both ETO and EE; (2) has a higher concentration of ETO than EE; and (3) comprises 97% of the ring." J.A. 19. The district court reasoned that a person of ordinary skill in the art would have optimized the second compartment to release physiologically required amounts of ETO and EE. Thus, there would be "little reason to keep the first compartment in place." J.A. 20.

The problem, however, is that PCT '015 does not actually disclose a ring with a second compartment that comprises 97% of the ring, and includes a higher concentration of ETO than EE in the second compartment. Instead, PCT '015 provides a broad range of values for the relative size of each compartment as well as concentrations of each compound. For example, PCT '015 states that the "[r]atios of the lengths of the first and second compartment are contemplated to be between 30:1 and 1:30, but usually are between 15:1 and 1:1, and preferably are about 2:1." J.A. 3041. Thus, the second compartment can occupy anywhere from 3% to 97% of the ring. Elsewhere, PCT '015 explains that "the second compartment is loaded with 0.05-3% w/w" of ETO and "0.05-5% w/w" of EE. J.A. 3042.

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 district court's reliance on hindsight is further underscored by the prior art's criticism of the one-compartment solution. PCT '015 expressly states that one compartment rings are undesirable because it is difficult to control the release rates for both compounds. Yet the district court found that a person of ordinary skill would be motivated to use a single compartment to reduce manufacturing costs. J.A. 20. In some instances, a person of ordinary skill may have "good reason to pursue the known options" based on "design need or market pressure." *KSR*, 550 U.S. at 421. But a person of ordinary skill in the art would pursue "identified, predictable solutions," not designs that were seemingly inoperable. *See id.* Here, PCT '015 expressly warns that a one-compartment ring has sub-optimal release patterns. The '581 patent purportedly solved this problem by supersaturating the ring with a progestogenic compound, a technique not taught in the prior art of record. Because PCT '015 criticizes the use of one compartment to deliver both compounds, the person of ordinary skill would not be motivated to modify PCT '015 to make a one-compartment ring.

Claim 11, unlike claim 4, does not require a physiologically required amount of progestogenic and estrogenic steroid compounds to be delivered from one compartment. Claim 11, however, requires one compartment to have specific concentrations for each compound. To show that

PCT '015 discloses such concentrations, Warner Chilcott relies on the target drug release rates disclosed in PCT '015, and argues that it would have been obvious to calculate the relative concentrations for each compound based on those release rates.

The dosage rates disclosed in PCT '015, however, apply to a two-compartment ring. Thus, an ordinary artisan would need to calculate the relative concentrations for a two-compartment ring, and apply those concentrations to a single compartment. But again, PCT '015 warns that release rates for single compartment rings are difficult to control. Indeed, PCT '015 explains that its design can achieve consistent release rates *because* there are two compartments. *See, e.g.*, J.A. 3040 at ll. 7–23 (describing how a ring-shaped device containing two separate compartments fulfills the requirement of a good release pattern). Therefore, an ordinary artisan would not discard the two-compartment design but still expect the ring to deliver a controlled dose of both compounds.

Because it was not obvious to load the claimed concentrations of progestogenic compounds and estrogenic compounds in one compartment, we reverse the district court's finding of invalidity.

**REVERSED AND REMANDED**