# United States Court of Appeals for the Federal Circuit

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**BAYER HEALTHCARE PHARMACEUTICALS, INC. AND BAYER SCHERING PHARMA AG,**
*Plaintiffs-Appellees,*

**v.**

**WATSON PHARMACEUTICALS, INC. AND WATSON LABORATORIES, INC.,**
*Defendants-Appellants,*

**AND**

**SANDOZ INC.,**
*Defendant-Appellant.*

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2012-1397, -1398, -1400

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Appeal from the United States District Court for the District of Nevada in Nos. 07-CV-1472 and 08-CV-0995, Judge Kent J. Dawson.

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**BAYER SCHERING PHARMA AG AND BAYER HEALTHCARE PHARMACEUTICALS, INC.,**
*Plaintiffs-Appellees,*

**v.**

**LUPIN, LTD. AND LUPIN PHARMACEUTICALS, INC.,**
*Defendants-Appellants.*

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2012-1424

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Appeal from the United States District Court for the District of Nevada in No. 10-CV-1166, Judge Kent J. Dawson.

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Decided: April 16, 2013

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ADAM K. MORTARA, Bartlit Beck Herman Palenchar & Scott, LLP, of Chicago, Illinois, argued for plaintiffs-appellees. With him on the brief were PETER B. BENSINGER, JR. and MATTHEW R. FORD. Of counsel was PAUL J. SKIERMONT, Skiermont Puckett, LLP, of Dallas, Texas.

MARK T. JANSEN, Crowell & Moring LLP, of San Francisco, California, argued for defendants-appellants Watson Pharmaceuticals, Inc., et al. With him on the brief were CEDRIC C.Y. TAN and KRISTIN M. COOKLIN.

JOSEPH A. HYNDS, Rothwell, Figg, Ernst & Manbeck, P.C., of Washington, DC, argued for the defendant-appellant, Sandoz Inc. With him on the brief were STEVEN LIEBERMAN and LISA N. PHILLIPS.

ROBERT F. GREEN, Leydig, Voit & Mayer, Ltd. of Chicago, Illinois, argued for defendants-appellants, Lupin Ltd., et al. With him on the brief were CHRISTOPHER T.

GRIFFITH and KATE M. LESCIOTTO; JAMAICA P. SZELIGA, of Washington, DC.

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Before LOURIE, SCHALL, and PROST, *Circuit Judges*.

LOURIE, *Circuit Judge*.

In these consolidated patent infringement actions, generic pharmaceutical manufacturers Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Sandoz, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, the "Defendants") appeal from the final judgments of the United States District Court for the District of Nevada in favor of Plaintiffs-Appellees Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG (collectively, "Bayer"). In particular, the Defendants challenge the district court's entry of summary judgment that asserted claims 13 and 15 of Bayer's U.S. Patent RE37,564 (the "'564 patent") are not invalid for obviousness in view of numerous cited prior art references. *Bayer Schering Pharma AG v. Watson Pharm., Inc.*, Nos. 2:07-cv-01472, 2:08-cv-00995, 2012 WL 1079551 (D. Nev. Mar. 30, 2012) ("*Watson Summary Judgment Order*"); *Bayer Schering Pharma AG v. Lupin Ltd.*, No. 2:10-cv-01166, 2012 WL 1080296 (D. Nev. Mar. 30, 2012) ("*Lupin Summary Judgment Order*"). For the reasons that follow, we reverse.

## BACKGROUND

This case concerns pharmaceutical formulations and dosing regimens for combined oral contraceptive ("COC") products. First introduced in 1960, COCs, better known as birth control pills, deliver synthetic hormones that regulate the natural ovarian cycle and prevent pregnancy. Specifically, COCs comprise a progestin and an estrogen that together inhibit folliculogenesis—a stepwise, hormone-directed process in which an ovarian follicle containing an immature oocyte (*i.e.*, an egg cell) grows and

develops for approximately the first two weeks of an ovarian cycle, culminating in the release of a fertile oocyte at ovulation. The synthetic progestin and estrogen provided in a COC suppress production of the natural hormones that drive folliculogenesis, thus inhibiting ovulation and reducing the incidence of pregnancy in COC users. The contraceptive effects depend on the continued presence of the inhibitory synthetic hormones; folliculogenesis will commence if the synthetic progestin and estrogen are withdrawn but can be abrogated if the hormones are reintroduced before ovulation occurs.

To maintain synthetic hormone concentrations sufficient for sustained follicular suppression, COCs are typically taken once daily, and since their introduction, most COCs have been provided in 28-day, 28-pill packs that align with the approximate length of a natural ovarian cycle. Early COCs relied on a 21/7 dosing regimen in which each monthly pill pack would include twenty-one active pills containing synthetic progestin and estrogen followed by seven placebo pills containing no hormones. The seven-day placebo period, also known as the pill-free interval, was originally included because it (i) triggered a "withdrawal bleed" that mimicked natural menstrual bleeding and was presumed to improve acceptance among COC users, and (ii) provided a regular break from synthetic hormone exposure that was thought to mitigate potential side effects. The 21/7 regimen persists in most COCs on the market today.

In addition to maintaining a pill-free interval, another strategy to reduce side effects has been to reduce the hormone dose provided in each pill. For example, the first COCs provided relatively high daily doses of synthetic estrogen, up to approximately 150 μg per active pill. Deleterious side effects of COC use, including thromboembolism, nausea, and bloating, have been most strongly associated with synthetic estrogen exposure, so the estrogen dose in particular has been progressively reduced

over time. The first COC containing the synthetic estrogen ethinylestradiol ("EE") at only 20 μg per pill was approved for sale in the United States in 1976.

In the early 1990s, Bayer began developing a low-dose COC containing 20 μg EE and the synthetic progestin drospirenone ("DRSP") to be administered with a reduced pill-free interval. Lowering EE dosage to 20 μg per pill limits undesirable side effects, but it also results in weaker ovarian suppression compared to higher-dose COCs. As such, some ovarian activity and follicular maturation can persist in users of low-dose COCs, and any intake errors (*i.e.*, missed pills), especially those that effectively lengthen the unregulated pill-free interval, could result in "escape" ovulation and unintended pregnancy. '564 patent col. 2 l. 38 – col. 3 l. 6. To address the risk of escape ovulation for users of low-dose COCs, Bayer implemented 23/5 and 24/4 dosing regimens, reducing the pill-free interval to five or four days, respectively, and increasing the number of active pills per cycle accordingly. Bayer demonstrated that shortening the pill-free interval to four or five days improved the contraceptive efficacy of low-dose COC formulations. Accordingly, Bayer filed its first patent application directed to such low-dose, extended-regimen COCs on December 22, 1993, and that application eventually led to the '564 patent.[1] The '564 patent includes 15 claims reciting various COC preparations; claims 13 and 15 read as follows:

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[1] The December 1993 application was a foreign priority application filed in Germany. Bayer filed its first corresponding U.S. application in June 1994 and obtained U.S. Patent 5,824,667 (the "'667 patent") as a continuation of that first U.S. application on October 20, 1998. The asserted '564 patent, issued on February 26, 2002, arose as a reissue of the '667 patent.

> 13. A combination product for oral contraception, comprising
>
> (a) 23 or 24 daily dosage units, each containing 0.020 mg of ethinylestradiol, and 2.5 to 3.0 mg of drospirenone, and
>
> (b) 5 or 4, respectively, active ingredient-free placebo pills or other indications to show that the daily administration of the 23 or 24 dosage units, respectively, is to be followed by 5 or 4, respectively, pill-free or placebo pill days,
>
> wherein each of the dosage units containing drospirenone contains the same amount of drospirenone.
>
> . . . .
>
> 15. A combination preparation of claim 13, which comprises 24 dosage units and 4 placebo pills or other indications to show that no dosage unit or placebo pill is administered during the last 4 days of the menstrual cycle.

'564 patent col. 6 l. 57 – col. 8 l. 4. Bayer markets a COC product that embodies claims 13 and 15 under the brand name YAZ®. That product includes four placebo pills and twenty-four active pills each containing 20 μg EE and 3 mg DRSP. Bayer received final approval to market YAZ® in the United States on March 16, 2006.

The Defendants filed Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of YAZ®. Those ANDA filings included Paragraph IV certifications asserting that the '564 patent is invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006). Bayer responded by bringing patent infringement actions alleg-

ing that the Defendants' ANDA filings infringed claims 13 and 15 of the '564 patent under 35 U.S.C. § 271(e)(2).[2]

Before the district court, the Defendants conceded that their ANDAs infringed the '564 patent under § 271(e)(2). *Bayer Schering Pharma AG v. Watson Pharm., Inc.*, No. 2:07-cv-01472, 2011 WL 1235154, at *1 (D. Nev. Mar. 31, 2011); *Bayer Schering Pharma AG v. Lupin Ltd.*, No. 2:10-cv-01166, slip op. at 2 (D. Nev. July 22, 2011), ECF No. 86. The Defendants responded and counterclaimed, however, that the asserted claims of the '564 patent were invalid for obviousness in view of numerous prior art references. Each side moved for summary judgment on the obviousness issue, and the district court granted Bayer's motions, holding that the asserted claims of the '564 patent were not invalid in view of the cited prior art. *Watson Summary Judgment Order*, 2012 WL 1079551, at *16–23; *Lupin Summary Judgment Order*, 2012 WL 1080296, at *14–21. The district court thereafter entered final judgment against the Defendants, *Bayer Schering Pharma AG v. Watson Pharm., Inc.*, No. 2:07-cv-01472 (D. Nev. May 29, 2012), ECF No. 354 (Partial Final Judgment); *Bayer Schering Pharma AG v. Lupin Ltd.*, No. 2:10-cv-01166, (D. Nev. Apr. 11, 2012), ECF No. 107 (Judgment in a Civil Case), and issued orders pursuant to 35 U.S.C. § 271(e)(4)(A) prohibiting the FDA from approving the Defendants' ANDAs before the '564 patent expires on June 30, 2014, *Bayer Schering Pharma AG v. Watson Pharm., Inc.*, Nos. 2:07-cv-01472,

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[2] Bayer filed suit against Watson on November 5, 2007, and against Sandoz on August 1, 2008. The district court consolidated those actions on November 4, 2008. *Bayer Schering Pharma AG v. Watson Pharm., Inc.*, Nos. 2:07-cv-01472, 2:08-cv-00995 (D. Nev. Nov. 4, 2008), ECF No. 43 (Order to Consolidate Related Cases). Bayer initiated parallel infringement proceedings against Lupin on July 15, 2010.

2:08-cv-00995, 2013 WL 592890 (D. Nev. Feb. 11, 2013); *Bayer Schering Pharma AG v. Lupin Ltd.*, No. 2:10-cv-01166, 2013 WL 592017 (D. Nev. Feb. 11, 2013).

The Defendants now appeal. We have jurisdiction under 28 U.S.C. § 1295(a)(1).[3]

## DISCUSSION

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). We apply regional circuit law, in this case the law of the Ninth Circuit, when reviewing a district court's grant or denial of a motion for summary judgment. *Teva Pharm. Indus. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1381 (Fed. Cir. 2011). The Ninth

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[3] Bayer has suggested that we lack jurisdiction to entertain this appeal. Appellees' Br. 3–4. Specifically, Bayer contends that it has unresolved claims for damages relating to alleged at-risk launches of infringing generic products by Watson and/or Sandoz that preclude appellate jurisdiction under 28 U.S.C. § 1292(c)(2). We need not address that argument, however, because our jurisdiction over this appeal does not depend on § 1292(c)(2). The district court granted summary judgment against the Defendants on their invalidity counterclaims and, pursuant to Federal Rule of Civil Procedure 54(b), entered partial final judgment that the '564 patent was not invalid for obviousness. *Bayer Schering Pharma AG v. Watson Pharm., Inc.*, No. 2:07-cv-01472 (D. Nev. May 29, 2012), ECF No. 354 (Partial Final Judgment). The district court did not abuse its discretion in applying Rule 54(b), and its judgment in that part of the case is final. *See Sun Pharm. Indus. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010). We therefore have jurisdiction to review the district court's partial final judgment under 28 U.S.C. § 1295(a)(1).

Circuit reviews summary judgment rulings without deference, "asking 'whether there are any genuine issues of material fact' while '[v]iewing the evidence in the light most favorable to the nonmoving party.'" *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1320 (Fed. Cir. 2012) (quoting *Burke v. Cnty. of Alameda*, 586 F.3d 725, 730–31 (9th Cir. 2009)). Obviousness is a question of law premised on underlying issues of fact. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007).

The sole issue before us is whether the district court erred in granting summary judgment in favor of Bayer and holding that asserted claims 13 and 15 of the '564 patent are not invalid for obviousness in light of the presented prior art.

The Defendants rely on six prior art references: Australian Patent Application 55094/90, published November 22, 1990 ("AU'094"); European Patent Application Publication 0 253 607, published April 29, 1992 ("EP'607"); B.G. Molloy et al., *"Missed Pill" conception: fact or fiction?*, 290 Brit. Med. J. 1474 (1985) ("Molloy"); John Guillebaud, *The forgotten pill—and the paramount importance of the pill-free week*, 12 Brit. J. Fam. Plan. 35 (1987) ("Guillebaud"); B-M. Landgren & E. Diczfalusy, *Hormonal Consequences of Missing the Pill During the First Two Days of Three Consecutive Artificial Cycles*, 29 Contraception 437 (1984) ("Landgren"); and N.D. Goldstuck et al., *Use and misuse of oral contraceptives by adolescents attending a free-standing clinic*, 3 Advances in Contraception 335 (1987) ("Goldstuck"). According to the Defendants, the combination of AU'094 with any of EP'607, Molloy, Guillebaud, Landgren, or Goldstuck would have rendered the asserted claims of the '564 patent obvious at the time of invention. In particular, the Defendants argue that AU'094 discloses a COC combining 20–40 μg EE and 1–10 mg DRSP per active pill—dosage ranges that encompass those recited in claims 13 and 15 of the '564 patent. The Defendants further contend that

EP'607, Molloy, Guillebaud, Landgren, and Goldstuck each disclose 23/5 and/or 24/4 dosing regimens and that those references provided motivation to combine such regimens with the low-dose COCs disclosed in AU'094 by identifying the problem of missed-pill conceptions and suggesting a shortened pill-free interval as a solution. Finally, the Defendants contend that the district court erred by misapplying and misinterpreting the cited references and by crediting legally insufficient evidence as secondary indicia of nonobviousness.

In response, Bayer argues that AU'094 and EP'607 were directed to narrow subpopulations of patients primarily in need of hormone-replacement therapy, so those references would not have been combined by a person of ordinary skill seeking to develop a COC in 1993. Furthermore, according to Bayer, the prior art as a whole taught away from the claimed COC preparations at that time in view of the entrenched use of traditional 21/7 dosing and the perceived risks from increasing total synthetic hormone administration by shortening the pill-free interval. Finally, Bayer defends the district court's reliance on its evidence of unexpected results, expert skepticism, industry praise, and copying as secondary indicia of nonobviousness.

We agree with the Defendants that the district court erred in holding the claims not invalid. A claim is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2006). In this case, the cited prior art references set forth every limitation required by the asserted claims and provide express motivation to combine those teachings to derive the claimed COC products. Accordingly, the asserted claims are invalid under § 103.

There is no dispute that claims 13 and 15 of the '564 patent require a COC product defined by the following limitations: (1) 20 μg EE per active pill, (2) 2.5–3.0 mg DRSP per active pill, and (3) a 23/5 or 24/4 dosing regimen. '564 patent col. 6 l. 57 – col. 8 l. 4. Nor is it disputed that the cited prior art references disclose each of those limitations. For example, EP'607 discloses a combination dosage form that can provide hormonal replacement therapy and contraceptive protection, using a "preferred administration cycle [of] 24 days of the combination dosage form and 4 days of no dosage form." EP'607 col. 1 ll. 3–18; *see also id.* col. 3 ll. 46–57 (describing 24/4 and 23/5 dosage regimens as "preferred"). In addition, the disclosed active dosage form includes an estrogen and a progestin; EP'607 lists EE (8–30 μg per dose) among three estrogen choices and describes several suitable progestins, but DRSP is not disclosed. *Id.* col. 2 l. 35 – col. 3 l. 25. AU'094, however, discloses DRSP as an additional progestin suitable for use "alone or in combination with estrogens in contraceptive preparations." AU'094 at 1. Furthermore, AU'094 indicates that EE is a preferred estrogen complement to DRSP for COC use and suggests using daily doses of 20–40 μg EE with 1–10 mg DRSP. *Id.* at 4–5. AU'094 even refers expressly to EP'607, stating that the disclosed EE/DRSP preparations can be used "analogously" to the EP'607 combinations and expressly incorporating the disclosure of EP'607 by reference. *Id.* at 5–6. In sum, EP'607 and AU'094 disclose all three limitations required by the asserted claims. AU'094 discloses COC preparations that encompass the claimed doses of EE and DRSP, and EP'607 discloses similar COCs, also comprising the claimed dose of EE, administered via the claimed 24/4 and 23/5 regimens.

With every limitation of the asserted claims thus disclosed in the cited references, the question, as the district court recognized, becomes whether a person of ordinary skill in the art would have been motivated to combine

those teachings to derive the claimed subject matter with a reasonable expectation of success. *See, e.g.*, *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) ("Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination. Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements . . . .") (citing *KSR*, 550 U.S. at 418, 421); *see also Watson Summary Judgment Order*, 2012 WL 1079551, at *18 ("What was not known based on the prior art was the desirability of using the claimed drospirenone and EE doses together with the claimed monthly regimen.").

The prior art before us provides that motivation. In addition to AU'094's express reference to EP'607, several of the cited references highlight evidence that the unregulated ovarian activity that occurs during a seven-day pill-free interval can achieve significant follicular development, and those references also express concern that inadvertently extending the traditional pill-free interval via one or more missed pills could lead to escape ovulation and unintended pregnancy. *See, e.g.*, Molloy at 1475 ("The demonstration of ovarian folliculogenesis . . . on the seventh pill free day, means that during the early days of the subsequent pill cycle, some women harbour significantly developed follicles, ready to [ovulate] if oestrogen suppression were to fail because of a missed pill."); Guillebaud at 35 (stating "that it is precisely because of this seven day break that most pregnancies occur, and that the pill omissions of greatest concern are those that lead to a lengthening of the pill-free interval") (quotation omitted); Landgren at 444 ("These data seem to suggest that ovulation is more likely to occur when the pill is omitted during the first days of the artificial cycle. Hence, the prolongation of the pill-free week by two or more days is likely to increase the risk of 'escape' ovulation."). In

addition, Bayer's expert acknowledged that one of skill in the art at the time of the invention would have expected an even greater risk of such "missed pill" ovulation for users of low-dose COCs (*i.e.*, those containing 20 μg EE per active pill). J.A. 2032–35.

The evidence thus demonstrates that missed-pill ovulation was a recognized concern with traditional 21/7 COCs, particularly for those on the market by 1993 that—like the claimed COC preparations—relied on low-dose EE. As the Supreme Court has stated, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR*, 550 U.S. at 420. Furthermore, the references in this case go beyond just illuminating a known problem; they also expressly propose the claimed solution: "To reduce the risk of missed pill conception a 28 day pack containing 23 pills and 5 blanks could be substituted for the current 21 day pack. This would still permit a withdrawal bleed without the risk of significant follicular development." Molloy at 1475; *see also* Goldstuck at 338 ("The suggestion [for 24/4 dosing] is of considerable merit. This would both maintain a 28-day regimen and help reduce the pill-free interval in those women who inadvertently miss a pill."); Guillebaud at 43 ("[I]t is preferable to shorten the pill-free interval, usually to four days, in women where there is a suspicion of an increased risk of breakthrough ovulation."). Accordingly, the prior art's direct recommendations to use 24/4 and 23/5 dosing regimens to minimize the risks of escape ovulation would have motivated one of ordinary skill in the art to implement such a shortened pill-free interval for use with known low-dose COCs, as recited in the asserted claims.

Bayer's arguments do not support a contrary conclusion. Bayer contends that EP'607 and AU'094 "are primarily directed to older women who have reached premenopause and are in need of hormone replacement

therapy," and that therefore a "skilled person setting out to design an oral contraceptive using EE and DRSP would not have used the 24/4 regimen intended to achieve effective [hormone-replacement therapy]." Appellees' Br. 39–40. But those references plainly disclose preparations with hormone replacement *and* contraceptive applications, and the product claims at issue do not distinguish between target patient populations, whether by age or otherwise.

In addition, Bayer argues that the prior art taught away from the claimed COC preparations, focusing on statements in Guillebaud as indicating that the "conventional wisdom" in the field favored 21/7 dosing for most patients and as suggesting that a reduced pill-free interval should be used together with higher-dose COCs for patients perceived to be at risk of escape ovulation.[4] Those statements, however, do not overcome the express teachings of multiple references, including Guillebaud, that a shorter pill-free interval would improve COC efficacy. Furthermore, Guillebaud may have suggested condensing the pill-free interval while concurrently increasing the hormone dose for at-risk patients, but those two measures are never described as mutually dependent, and each could be expected to reduce missed-pill ovulation

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[4] Bayer also contends that Goldstuck "endorsed" Guillebaud's suggestion to use a higher-dose formulation with a 24/4 or 23/5 regimen and therefore teaches away on the same basis. Appellees' Br. 47–48. In citing Guillebaud, however, Goldstuck makes no mention of hormone dose: "The suggestion that manufacturers make 28-day packages consisting of 24 active tablets and 4 bran [placebo] tablets is of considerable merit [Guillebaud]. This would both maintain a 28-day regimen and help reduce the pill-free interval in those women who inadvertently miss a pill." Goldstuck at 338. Goldstuck thus offers little support for Bayer's position.

risks with or without the other. "[A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed . . . is the preferred, or most desirable, combination." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). Just because one of several references indicated a preference for using 24/4 or 23/5 dosing regimens in tandem with higher-dose COCs does not mean the same missed-pill rationale could not also motivate applying the shorter pill-free interval to similarly improve other COC preparations.

Finally, Bayer's evidence of secondary indicia of non-obviousness, including alleged unexpected results, expert skepticism, industry praise, and copying by others, is legally insufficient. To demonstrate unexpected results, Bayer relies on data showing that 23/5 administration results in reduced follicular activity compared to 21/7 dosing of the same COC formulation. But those data merely confirm that administering additional active pills results in additional follicular suppression, which would have been a matter of "common sense," as even Bayer's expert agreed.

As evidence of expert skepticism, Bayer cites an FDA request for clinical safety data and data demonstrating efficacy benefits sufficient to justify the added synthetic hormone exposure required for the proposed 24/4 dosing regimen. That request in no way indicates that FDA experts would have been surprised to receive such data. *See Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1352 (Fed. Cir. 2010) (rejecting proffered evidence of expert skepticism that "d[id] not directly address whether there was actual skepticism concerning the invention"). Rather, the cited request reflects attention to the FDA's normal duties ensuring the safety and efficacy of new drugs by requiring actual data to corroborate statements in a new drug application.

Next, Bayer claims that its invention "was widely praised by experts in the COC field." Appellees' Br. 61. In making that claim, Bayer relies on journal citations that reference the findings stated in Bayer's published efficacy studies or discuss possible non-contraceptive indications for 24/4 COC regimens. Another article describing Bayer's 24/4 COC regimen as an "innovative strategy" was authored by the first-named inventor of the '564 patent. Such bare journal citations and self-referential commendation fall well short of demonstrating true industry praise. Furthermore, industry praise of what was clearly rendered obvious by published references is not a persuasive secondary consideration.

Lastly, we reject Bayer's contention that copying of its COC preparations by the Defendants and other generic manufacturers supports its validity position. Such evidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval. *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 377 F. App'x 978, 983 (Fed. Cir. 2010).

## CONCLUSION

We have considered Bayer's remaining arguments and find them unpersuasive. Accordingly, nothing Bayer has presented overcomes the plain disclosures and express motivation to combine those disclosures in the prior art. We therefore conclude that claims 13 and 15 of the '564 patent are invalid for obviousness in view of the cited references, and we reverse the judgment of the district court.

**REVERSED**