IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS INC.,

Plaintiff,

v.

No. 22-cv-966-SB

LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC,

Defendants.

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MEMORANDUM OPINION

August 24, 2026

BIBAS, *Circuit Judge*, sitting by designation.

Words can be twisted, but numbers do not lie. A drug company patented a precise compound to treat cystic fibrosis. But now it says that its carefully calibrated percentages really stand for vague ranges. Just as that argument failed before the patent examiner, so too it fails as an infringement claim.

I. AFTER VERTEX PATENTS A DRUG, LUPIN MAKES A GENERIC

A. Vertex invents and patents Kalydeco

Cystic fibrosis causes mucus to build up in the lungs, leading to infection and even death. D.I. 248-1 ¶ 17. The disease is genetic. *Id.* ¶ 16. In a healthy lung cell, a gene tells the cell how to pass salts across its membrane. But in a cystic-fibrosis patient, that gene is mutated, so lung cells swell with salts and become slathered in mucus. *Id.* ¶¶ 16–17.

Though the genetic mutation is incurable, Vertex devised a treatment for cystic fibrosis. It found that it could improve the working of lung cells by using a chemical compound called ivacaftor. D.I. 276 ¶¶ 11–12. But ivacaftor is tricky to make into a useful drug: It dissolves so poorly that the bloodstream cannot readily absorb it. D.I. 272 Tr. 101:11–102:7. So Vertex took ivacaftor molecules and scattered them into other ingredients to create an amorphous solid dispersion. *Id.* Tr. 102:8–105:7. Thus dispersed, ivacaftor dissolves easily during digestion.

About twenty years ago, Vertex published its findings about ivacaftor and how to formulate it as a usable drug. It announced that "a solid dispersion comprising

amorphous [ivacaftor]" could treat cystic fibrosis. D.I. 276 ¶ 12–13. According to Vertex, an effective ivacaftor drug would comprise "about 10% by weight to about 80% by weight" ivacaftor. DTX-157 at 010 ¶ 35, 063 ¶ 25.

After going public with that discovery, Vertex tried to patent its own ivacaftor drug. But with its prior statements already public, getting a patent was an uphill battle. At first, a patent examiner rejected Vertex's claim because of the findings that it had already published. D.I. 276 ¶ 28; DTX-19 at 1162. So Vertex presented evidence that a dispersion of 80% ivacaftor (no more and no less) produced "surpris[ing] … result[s]." DTX-19 at 1275 ¶ 7. The surprise was solubility: Vertex claimed that an 80% compound was more soluble than one would expect such an ivacaftor-dense compound to be. *Id.* ¶ 8. A new examiner bought that argument and let Vertex patent a drug containing exactly 80% ivacaftor, plus some other ingredients. That 80% ratio, the examiner said, was "unexpected[ly]" effective and "should not work as well as it does." PTX-13 at 1409.

Although the examiner granted that 80% was something special, she held Vertex to it. While prosecuting a different patent, Vertex tried to claim "about 72 wt% to about 88 wt%" ivacaftor. DTX-25 at 802. But the examiner rejected that claim. Given the prior art, that wide range was "obvious." *Id.* at 1083. Even though the 80% ivacaftor formulation had proven surprisingly soluble, she reasoned that "unexpected results often do not occur over wide ranges." *Id.* at 1082. Without proof, there was no reason to think that the surprising results at 80% would recur across a wide range. So Vertex was stuck claiming "*about* 80 wt%" ivacaftor. *Id.* at 1091 (emphasis added).

The examiner allowed the "about" claim, reading that word as expanding "80%" by roughly a tenth of a percent. *See id.* at 1163 (offering "79.9%" as an example of "about 80%"). Using the 80% or about-80% specifications, Vertex got a range of patents for an ivacaftor drug. The commercial embodiment of those patents is Vertex's drug Kalydeco. D.I. 276 ¶ 1.

B. Lupin makes a generic with different parts by a different process

Lupin, another drug maker, submitted an Abbreviated New Drug Application for its own ivacaftor drug. D.I. 276 ¶ 2. Lupin's version contains an amorphous solid dispersion comprising 74.257% or 74.258% ivacaftor plus other ingredients. *Id.* ¶¶ 78–80. And some of Lupin's non-ivacaftor ingredients differ from Vertex's. DTX-154 at 017.

Lupin uses not only different ingredients and different ratios, but also a different manufacturing process. Vertex combines its ingredients in a dry form. D.I. 273 Tr. 57:8–58:1. By contrast, Lupin sprays a binder fluid onto its ingredients, making them clump into granules. *Id.* The choice of wet versus dry granulation necessitates different filler ingredients in the final product. *Id.* Tr. 60:1–14.

Vertex sued Lupin under the Hatch-Waxman Act, claiming that Lupin's application infringed its patents. D.I. 211 ¶ 3; 35 U.S.C. § 271(e)(2)(A). Four of Vertex's patents are at issue. D.I. 281 at 4. Two of them claim a drug containing exactly 80% ivacaftor. U.S. Patents Nos. 10,646,481, 11,564,916. The other two claim "about 80%" ivacaftor. U.S. Patents Nos. 12,458,635, 10,272,046. The Court has previously

construed "about" to have its plain and ordinary meaning. D.I. 106 at 1. The Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

II. LUPIN'S DRUGS DO NOT INFRINGE VERTEX'S PATENTS

To show direct patent infringement, Vertex must prove either literal infringement or infringement under the doctrine of equivalents. *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012). A drug infringes literally if it matches every element of a patented claim. *Id.* at 1167 n.11. It infringes under the doctrine of equivalents if it "contains elements identical or equivalent to each claimed element of the patented" drug. *Id.* at 1167 (cleaned up). I evaluate infringement from the perspective of a person of ordinary skill in the art, the "reasonable person" standard in patent law. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The parties agree that a person of ordinary skill in the art has a graduate degree in pharmaceutical science (or a related field) and several years of experience formulating drugs. D.I. 239-4 ¶ 6 (Vertex's proposed definition); D.I. 239-5 ¶ 9 (Lupin's proposed definition); D.I. 272 Tr. 193:11–13 (Vertex's expert concedes that any difference between the proposed definitions is immaterial); D.I. 273 Tr. 172:22–25 (same for Lupin's expert).

A. Vertex cannot show literal infringement

Literal infringement requires that "every limitation set forth in a claim must be found in an accused product, exactly." *Pozen*, 696 F.3d at 1167 n.11 (internal quotation marks omitted). It is not enough for two drugs to share the same active

ingredient; the overall composition must be identical. *See Viiv Healthcare UK Ltd. v. Lupin Ltd.*, 6 F. Supp. 3d 461, 470–71 (D. Del. 2013), *aff'd*, 594 F. App'x 686 (Fed. Cir. 2015).

Vertex wisely concedes that Lupin did not literally infringe any of its claims that specify 80% ivacaftor exactly. D.I. 281 (generally). Instead, it alleges literal infringement of its "*about* 80%" patents. *Id.* at 16 (emphasis added). So I must decide whether Lupin's roughly 74% ivacaftor drug is literally the same as Vertex's about 80% patents. The Court has already construed "about" to carry its plain and ordinary meaning to a person of ordinary skill in the art. D.I. 106 at 1. Thus, this case turns on how such a person would understand "about."

Vertex's argument for literal infringement relies on its expert, Dr. Berkland. Unfortunately for Vertex, I found him unauthoritative. As I explained at the close of trial, he was "less careful and less scrupulous and more willing to sign off on extreme statements." D.I. 274 Tr. 80. "His willingness to affirm these things undercuts his overall credibility before me." *Id.* Tr. 81. By contrast, I found Lupin's expert, Dr. Donovan, "completely credible. She was meticulous … . She was admirably careful about what she could or couldn't say." *Id.* Tr. 80. So I wholly credit Dr. Donovan's testimony over Dr. Berkland's. *Id.* Tr. 80–81. Dr. Berkland asked me to read "80% ivacaftor" as a shorthand for a "high drug load." D.I. 273 Tr. 10–11, 18. So he read the phrase "about 80% ivacaftor" to literally cover a wide range of percentages, "to at least 70 to 90 percent as a range." *Id.* at 12. Yet he gave no reason to think that is true. The phrase "high drug load" appears nowhere in the patents or their prosecution. Nor

does Dr. Berkland persuade me that drugs should be categorized as high or low load instead of by percentages. He failed to give a concrete definition of "about 80%" and offered no scientific or principled basis to conclude that Lupin's 74% ivacaftor drug is literally the same as about 80%. *Id.* Tr. 13–16. As I found at the close of trial, that opinion lacks a scientific basis. D.I. 274 Tr. 81.

By contrast, Dr. Donovan was scrupulous, defining "about" as "nearly the same as." D.I. 273 Tr. 184. Though she too did not give an exact percentage range, she limited it to less than a couple of percentage points. Her opinion was based in part on Vertex's own patent prosecution, which specified the weight of ivacaftor down to a tenth of a percentage point. *Id.* Tr. 185–86.

Dr. Donovan's reading also accords with the examiner's views. Those views can be evidence of how a person of ordinary skill would use a term. *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005). In the context of Vertex's patents, the examiner thought that "about 80%" included 79.9%, and "about 0.5%" included 0.55%. DTX-25 at 1163. Those statements comport with reading "about" even more narrowly than Dr. Donovan's view—and a far cry from Dr. Berkland's "high drug load" approach. I find Dr. Donovan credible and adopt her reading of "about." Because Lupin's compound varies from Vertex's by more than a couple of percentage points, there is no literal infringement.

B. Vertex cannot show infringement under the doctrine of equivalents

Even if not literally identical, Vertex argues as a fallback that the drugs are functionally the same under the doctrine of equivalents. But that doctrine is an

"exceptional" path to proving patent infringement. *VLSI Tech. LLC v. Intel Corp.*, 87 F.4th 1332, 1342 (Fed. Cir. 2023). It applies only when "the nature of language makes it impossible to capture the essence" and "every nuance" of the patented invention. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). In fact, "many [claim] limitations warrant little, if any, range of equivalents" because of "the inherent narrowness of the claim language" and "prosecution history estoppel." *Moore U.S.A., Inc. v. Standard Reg. Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000). Both the claim language and prosecution history point against the doctrine of equivalents here.

Start with the claim language. Dr. Berkland's testimony would have erased the numerical limits in Vertex's patents. Instead of opining on percentages or ratios, he spoke of "high drug loads" and "very high drug loads" with no evidence that those are terms a drug maker would use. But Vertex specified its claims down to half a percentage point. The "inherent narrowness" of those specifications belies Vertex's efforts to assimilate 74.257% to about 80%. *Id.*

Next, consider the prosecution history. The doctrine of equivalents cannot "impermissibly vitiate the limitation[s]" that Vertex argued for when prosecuting its patents. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab'ys, Ltd.*, 476 F.3d 1321, 1328 (Fed. Cir. 2007). In a similar drug-patent case, a ratio of about 1:5 was "critical to the invention," so the patentee could not treat a broader range as equivalent. *Id.* So too here: To get its patent, Vertex emphasized how surprising the result at 80% was, and the examiner viewed about 80% as introducing variance of a tenth of one percent. "An

infringement analysis that stretches the bounds of [80% or about 80%] beyond those [ranges] directly conflicts with the patent's express claim." *Id.* It also risks letting Vertex patent indirectly what it had already published, thus "ensnar[ing] the prior art." *Intendis GmbH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1363 (Fed. Cir. 2016).

Even if the doctrine of equivalents did apply, Vertex could not prove it here. There are two ways to prove it: the function-way-result test and the insubstantial-differences test. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008). Neither works Vertex's way.

The function-way-result test does not fit generic drugs. That test would ask whether a new drug does the same work in the same way as a patented one. *Id.* Virtually all generic drugs do. Vertex's argument rests on the bioequivalence of Lupin's drug: Both drugs use an amorphous dispersion of ivacaftor to treat cystic fibrosis. D.I. 281 at 10–11. But bioequivalence is not enough to prove infringement. *Abbott Lab'ys v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009). If it were, selling any generic of a patented drug would be illegal. *See id.* Thus, many courts find the substantial-differences test "more suitable" for generic drugs. *Mylan Inst'l LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 869 (Fed. Cir. 2017) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)).

The substantial-differences test does not help Vertex either. Under that test, Lupin infringes if the differences between its drug and Vertex's patent claims are "insubstantial." *Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1312

(Fed. Cir. 2004). But the intrinsic evidence does not suggest that a person of ordinary skill would view 74.257% and 80% ivacaftor as equivalent drug loads. Quite the opposite: The patent examiner read "about 80%" to introduce a variance of roughly a tenth of a percentage point. Plus, Vertex and Lupin make their drugs using different processes: wet versus dry granulation. Resisting this conclusion, Vertex insists that the similar (though not identical) dissolution profiles mean that any difference is insubstantial. D.I. 281 at 5–7. But this is just another way of saying the drugs are bioequivalent. Again, Vertex may not use bioequivalence to effectively outlaw generics.

* * *

Vertex is trying to claim that its patents cover a range of ivacaftor concentrations that it failed to patent. So it runs headlong into prosecution-history estoppel, in which "statements made during prosecution" can bar later infringement claims. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1342 (Fed. Cir. 2015). Vertex is entitled to the patent claims that it prosecuted successfully, not the ones that it failed to prove. Dr. Donovan's careful testimony preserved the limits on Vertex's patents, while Dr. Berkland's reading would eviscerate them. So I hold Vertex to its word and reject all its patent-infringement claims.