# United States Court of Appeals for the Federal Circuit

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**VECTURA LIMITED,**
*Plaintiff-Appellee*

**v.**

**GLAXOSMITHKLINE LLC, GLAXO GROUP LIMITED,**
*Defendants-Appellants*

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2020-1054

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Appeal from the United States District Court for the District of Delaware in No. 1:16-cv-00638-RGA, Judge Richard G. Andrews.

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Decided: November 19, 2020

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CHRISTOPHER P. BORELLO, Venable LLP, New York, NY, argued for plaintiff-appellee. Also represented by DAMIEN N. DOMBROWSKI, MICHAEL S. SCERBO, JOSHUA DANIEL CALABRO, DOMINICK A. CONDE.

WILLIAM F. LEE, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for defendants-appellants. Also represented by CHRISTOPHER R. NOYES, New York, NY; THOMAS SAUNDERS, DAVID P. YIN, Washington, DC.

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Before PROST, *Chief Judge,* BRYSON and WALLACH, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Following trial, a jury in the United States District Court for the District of Delaware found that defendants GlaxoSmithKline LLC and Glaxo Group Limited (collectively, "GSK") infringed U.S. Patent No. 8,303,991 ("the '991 patent"), owned by plaintiff Vectura Limited, and that the patent was not invalid. The district court denied GSK's post-trial motions for judgment as a matter of law and a new trial. GSK now appeals from the judgment against it. We affirm.

## I

### A

Vectura filed this action in 2016, alleging that GSK had directly and vicariously infringed various claims of the '991 patent. Vectura later narrowed its infringement case to allege only direct infringement of claim 3 of the patent.

The '991 patent concerns the production of "composite active particles" for use in pulmonary administration, such as in dry-powder inhalers. The composite active particles described in the patent consist of additive material that is adhered to particles of active ingredient. '991 patent, col. 11, ll. 48–55. The active ingredient produces the desired chemical or biological effect, while the additive particles promote the dispersion and delivery of the active ingredient into the lungs when the inhaler is activated. *Id.* at col. 10, ll. 6–16.

The specification of the '991 patent first discloses a method for adhering additive material to the active ingredient. The method entails milling solid active particles in the presence of solid additive particles with sufficient energy to break down coarse particles into fine particles, resulting in the additive particles smearing over, and fusing

onto, the active particles. *Id.* at col. 2, line 4, through col. 3, line 8. The specification also discloses various composite particles that are created by the disclosed milling method. *Id.* at col. 11, ll. 44–59; cols. 13–15. The specification contains a list of additive materials that promote pulmonary dispersion and are compatible with its milling method. *Id.* at col. 8, line 62, through col. 10, line 52. Magnesium stearate is one of the additive materials discussed in the specification. *Id.* at col. 10, ll. 4–5.

The claims of the '991 patent cover the composite active particles, not the milling method. Apparatus claim 1 reads as follows:

> 1. Composite active particles for use in a pharmaceutical composition for pulmonary administration, each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material, wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm, and wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device.

Claim 2 depends from claim 1 and requires the additive material to include one or more of certain compounds, one of which is "a metal stearate or derivative thereof." Claim 3 depends from claim 2 and requires the additive material to be magnesium stearate.

B

In the district court, Vectura alleged infringement by GSK's Ellipta-brand inhalers: the Breo, Anoro, and Incruse devices. Each of the accused inhalers features one or more "blisters," which are sealed receptacles containing a single active ingredient, an excipient, and, optionally, additive material. The blisters use magnesium stearate as the additive material and lactose as the excipient. As for the

active ingredients, the blisters contain one of three drugs—vilanterol, umeclidinium, or fluticasone.

The Breo inhaler features two blisters. The first contains a mixture of vilanterol, lactose, and magnesium stearate. The second contains a mixture of fluticasone and lactose, but not magnesium stearate.

The Anoro inhaler also features two blisters. The first contains a mixture of vilanterol, lactose, and magnesium stearate. The second contains a mixture of umeclidinium, lactose, and magnesium stearate.

The Incruse inhaler features only one blister. That blister contains a mixture of umeclidinium, lactose, and magnesium stearate.

In preparing the mixtures containing magnesium stearate, GSK uses a multi-step mixing process. GSK first mixes the lactose excipient with magnesium stearate in the absence of the active ingredient. That step yields lactose particles that are discontinuously coated with magnesium stearate. After a de-lumping step, GSK then mixes the lactose particles with the active ingredient. In that step, small particles of the active ingredient are deposited onto the larger lactose particles, which are already coated with small particles of magnesium stearate.

C

The district court construed various claim terms in the '991 patent, two of which are relevant to this appeal. First, the court construed the phrase "promotes the dispersion of the composite active particles" (the dispersion limitation) to mean "wherein a composition that contains one or more composite active particles has increased dispersion of the active material upon activating a delivery device for inhalation into the lungs by a patient, as compared to the same composition wherein unmodified active particles are substituted for the composite active particles." *Vectura Ltd. v.*

*GlaxoSmithKline LLC*, No. 1:16-CV-00638, 2018 WL 4700222, at *9 (D. Del. Oct. 1, 2018).

Second, the court construed the term "composite active particles." GSK's proposed construction of that term included a process limitation requiring that the composite active particles be "formed by milling . . . using sufficient energy and duration to ensure sufficient break-up of agglomerates of both constituents, dispersal, and even distribution of additive over the active particles." *Id.* at *2. The district court rejected GSK's proposed construction, holding that the term "composite active particles" does not include a process limitation. *Id.* at *3–8. The court construed the term to mean "[a] single particulate entit[y/ies] made up of a particle of active material to which one or more particles of additive material are fixed such that the active and additive particles do not separate in the airstream." *Id.* at *8.

At trial, Vectura's infringement theory focused on the vilanterol and umeclidinium mixtures in the accused inhalers. Vectura presented evidence that those mixtures contain active particles coated with magnesium stearate, i.e., composite active particles, even though GSK's multi-step process does not mix the active ingredient and the magnesium stearate in isolation, but instead mixes them in the presence of lactose.

Vectura prevailed on the issues of validity, infringement, and willful infringement. The jury awarded Vectura a royalty of 3% on a royalty base of $2.99 billion in sales for the accused inhalers, which resulted in an award of $89,712,069 in damages for the period of infringement ending in December 2018.

Following the jury's verdict, GSK moved for judgment of noninfringement as a matter of law or, alternatively, a new trial on infringement. GSK argued that Vectura presented insufficient evidence to support the jury's implied finding that the accused inhalers satisfy the dispersion

limitation. GSK also moved for a new trial on damages. GSK argued that Vectura's damages theory was legally flawed and that Vectura's counsel made prejudicial comments that affected the jury's damages award. The district court denied GSK's post-trial motions, *Vectura Ltd. v. GlaxoSmithKline LLC*, 397 F. Supp. 3d 579, 596 (D. Del. 2019), and GSK appealed to this court.

II

On appeal, GSK raises four issues: First, GSK argues that it is entitled to judgment of noninfringement as a matter of law because Vectura failed to present substantial evidence that the accused inhalers use additive material that "promotes the dispersion" of the active material. In the alternative, GSK requests a new trial on infringement. Second, GSK argues that the district court's construction of the term "composite active particles" was erroneous, requiring a new trial on infringement. Third, GSK argues that it is entitled to a new trial on damages because of flaws in the calculation of the royalty proposed by Vectura's damages expert. Fourth, GSK argues that it is entitled to a new trial on damages because Vectura made prejudicial references to GSK's sales and advanced an improper "pennies on the dollar" argument in comparing Vectura's royalty request to GSK's sales.

The denial of a motion for judgment as a matter of law, an issue not unique to patent law, is governed by the regional circuit's standard of review. *Personalized User Model, LLP v. Google Inc.*, 797 F.3d 1341, 1345 (Fed. Cir. 2015). Under Third Circuit law, a district court must grant judgment as a matter of law if a jury's verdict is not supported by substantial evidence, i.e., if "the record is critically deficient of the minimum quantum of evidence from which the jury might reasonably afford relief." *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995).

This court is also bound by the Third Circuit's application of an "abuse of discretion" standard for reviewing the denial of a motion for new trial. *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1182 (Fed. Cir. 2002) (citing *Greenleaf v. Garlock, Inc.*, 174 F.3d 352, 363 (3d Cir. 1999)). Under Third Circuit law, a district court should grant a new trial only if the jury's verdict is against the great weight of evidence and either is a miscarriage of justice or cries out to be overturned. *Leonard v. Stemtech Int'l Inc.*, 834 F.3d 376, 386 (3d Cir. 2016).

A

The parties agree that, under the district court's construction of the dispersion limitation, Vectura needed to prove that the use of magnesium stearate in the accused inhalers improves the dispersion of the active ingredient compared to identical products in which only the lactose excipient is coated with magnesium stearate. GSK argues that there was no substantial evidence of infringement as to that limitation because Vectura staked its case on a defective scientific test. That test, referred to as "Study 2," was a GSK study in which GSK examined the dispersion rates of experimental blends of vilanterol, magnesium stearate, and lactose.

The principal flaw in GSK's argument is that Vectura did not rely solely on Study 2 to prove that the accused inhalers satisfy the dispersion limitation. Vectura introduced other evidence on dispersion as well. We first address GSK's criticisms of Study 2 and then turn to the other evidence introduced by Vectura.

Study 2 included a total of six blends of lactose and vilanterol particles. In blend 5, the lactose particles were coated with magnesium stearate, but the vilanterol particles were uncoated. In blend 6, both the lactose particles and the vilanterol particles were coated with magnesium stearate. Study 2's results showed that blend 6 produced better dispersion than blend 5, thus appearing to support

Vectura's infringement theory on dispersion, at least as to the accused inhalers containing vilanterol mixtures.

At trial, GSK sought to discount Study 2 as evidence of infringement. First, GSK introduced evidence that blend 5 was a flawed control due to its poor content uniformity. GSK pointed to a statement in the report on Study 2 that the low dispersion in blends in which magnesium stearate had been used to coat the lactose but not the active drug was likely due to poor content uniformity and that drawing conclusions regarding dispersion "is not possible for those blends." J.A. 6194. Second, GSK argued that it was improper for Vectura to extrapolate from Study 2 to the accused inhalers in light of the differences between the mixing processes used to prepare the blends in Study 2 and the processes used to prepare the blends in the accused inhalers. Finally, GSK contended that Study 2 was irrelevant to the umeclidinium mixtures in the accused inhalers because Study 2 tested only vilanterol mixtures.

While Study 2 was not a perfect model for GSK's commercial products, the authors of the report on Study 2 concluded that coating all components with magnesium stearate "produced a blend with a stable high FPF," i.e., a high degree of dispersion, and that when the active drug is coated with magnesium stearate, "better uniformity has been observed." J.A. 6193. From that evidence and the testimony of the experts at trial, the jury could conclude that despite its drawbacks, Study 2 generally supported the view that coating the active ingredient with magnesium stearate improves dispersion of the active ingredient.

As to whether Study 2 provides any support for Vectura's claim of infringement as to the blisters containing only umeclidinium, the record contained evidence that vilanterol and umeclidinium behave similarly when coated with magnesium stearate. *See, e.g.*, J.A. 1324. On this record, if the jury credited the results of Study 2 regarding

vilanterol, it could reasonably have extrapolated those results to umeclidinium.

More fundamentally, regardless of any infirmities in Study 2 as evidence for the dispersion limitation, there was ample other evidence at trial indicating that coating vilanterol with magnesium stearate and coating umeclidinium with magnesium stearate improves the dispersion of both active ingredients. That evidence included testing evidence and testimony from Vectura's infringement expert and employees of both Vectura and GSK, as well as numerous documents relating to GSK's work on dry-powder-inhaler formulations.

Vectura's witnesses testified that coating active ingredient particles with magnesium stearate helps overcome the tendency of the particles to stick together and therefore increases the dispersion of the particles in the lungs. J.A. 1151–54. Evidence of tests conducted on coated and uncoated active-ingredient particles showed that coating the active particles substantially increased the dispersion of the active-ingredient particles and thus the amount of the active ingredient that could be delivered deep into the lungs. J.A. 1154–55. Tests run on GSK's products showed that the particles of vilanterol and umeclidinium were consistently associated with magnesium stearate. J.A. 1201–04, 1208–12. And a GSK employee who was involved in testing GSK products acknowledged that the presence of magnesium stearate in the GSK products has the effect of increasing the fine particle mass of vilanterol, i.e., increasing the dispersion of the drug. J.A. 1426–27.[1]

Vectura also relied on GSK's own documents as evidence that GSK's products satisfy the dispersion

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[1] The evidence showed that "fine particle mass," "fine particle fraction," and "fine particle dose" are all indicators of dispersion. *See* J.A. 1295–96, 1426–27, 1593–94.

limitation. A 2013 GSK report documenting the "current understanding associated with the use of magnesium stearate as a stabilising excipient" in vilanterol dry-powder-inhaler formulations relied on a finding that coating the active particles with magnesium stearate "provided better drug delivery in giving higher fine particle dose [(i.e., dispersion)] than coating the matrix particles." J.A. 1259–62, 1292–95, 5008, 5013–14. Vectura's expert testified that the recited portion of the GSK report meant that "coating the drug particles give[s] better dispersion than coating the matrix particles [(i.e., in this context, the lactose particles)]." J.A. 1295. Based on the physical tests of GSK's products, GSK's documents, and his own analysis, the expert concluded that coating the active ingredients in GSK's products with magnesium stearate "would promote dispersion of the composite active particle." J.A. 1350.

Another GSK document, directed to the use of magnesium stearate as an excipient in the Ellipta inhalers, acknowledged that magnesium stearate, which acts to coat inhalation powder particles, tends to "physically stabilize the aerodynamic particle size distribution of the active ingredient." J.A. 5001. It does so, the document explained, by coating particles, thereby "reduc[ing] interparticle interactions." *Id.* Vectura's expert explained that reducing interactions between the particles improves particle dispersion. J.A. 1297–98.

GSK's documents also established that the active ingredient becomes coated with magnesium stearate in GSK's mixing process, and that magnesium stearate when mixed with the lactose and the drug substance in GSK's products "tends to coat drug substance and the lactose." J.A. 1309–13 (referencing documents at J.A. 5020 and 5562). The addition of the magnesium stearate, according to those documents, aids "chemical stability and/or physical (i.e., Fine Particle Dose) stability." J.A. 5025 (referring to products containing umeclidinium); J.A. 5566 (referring to products containing vilanterol). Vectura's expert

explained that fine particle dose "is how much drugs go into the lungs. So it's a measure of the dispersion." J.A. 1312; *see also* J.A. 1313–15.

In sum, substantial evidence supported the jury's implied finding that the accused inhalers satisfy claim 1's dispersion limitation.

B

GSK next challenges the district court's construction of the claim term "composite active particles." GSK contends that the court should have construed that term to require that the composite particles be produced by the "high-energy milling" process referred to in the specification.

To support its argument, GSK relies on two pieces of intrinsic evidence. First, GSK points to various passages in the '991 specification that describe high-energy milling. According to GSK, those passages indicate that the disclosed milling method is essential to the claimed composite active particles.

Second, GSK looks to the '991 patent's prosecution history and in particular an April 2012 response to an office action in which the applicants distinguished a prior art reference to Bosch et al. GSK argues that the applicants distinguished Bosch on the ground that Bosch's wet-mixing processes were different from the "aggressive milling procedure" recited in the application. For that reason, GSK argues, the applicants clearly disclaimed mixing processes other than high-energy milling, confirming that the term "composite active particles" should be construed to include a process limitation.

Because GSK challenges the district court's claim construction based only on intrinsic evidence, this court applies *de novo* review. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 332 (2015).

At the outset, Vectura argues that GSK waived its claim construction challenge by proposing a different construction in the district court. We disagree. The construction that GSK proposed to the district court required that the composite particles be crafted by "milling . . . using sufficient energy and duration to ensure sufficient break-up of agglomerates of both constituents, dispersal, and even distribution of additive." *Vectura*, 2018 WL 4700222, at *2. In support of that construction, GSK argued that the intrinsic evidence established that "'composite active particles' must be defined by how the particles are made—by a high energy milling process." J.A. 10359. GSK makes the same argument to this court. *See* Appellants' Opening Br. 53 ("Vectura disclaimed processes for making 'composite active particles' other than high-energy milling."). Also, as in its proposed construction, GSK asserts that the inherent milling process must be "capable of breaking coarse particles . . . down to fine particles" by "appl[ying] a sufficiently high degree of force or energy to the particles." *See id.* at 53–54 (quoting the '991 patent) (ellipses in original). Given the similarities between GSK's arguments here and in the district court, we find no waiver.

As to the merits of GSK's claim construction arguments, this case falls between two prior cases from this court: *Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788 (Fed. Cir. 2019), and *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361 (Fed. Cir. 2007). In *Andersen*, we construed an apparatus claim to include a process limitation. 474 F.3d at 1373–74, 1377. In *Continental Circuits*, we declined to import a process limitation into an apparatus claim. 915 F.3d at 799–800. In both cases, we recognized that "process steps can be treated as part of the product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Continental Circuits*, 915 F.3d at 799 (quoting *Andersen*, 474 F.3d at 1375). In both cases, as here, the accused infringers argued that the patent's specification made it clear that a

process was an essential part of the apparatus claim and that the patent's prosecution history confirmed that essential role. *See Continental Circuits*, 915 F.3d at 796–99; *Andersen*, 474 F.3d at 1371–75.

In *Andersen*, we emphasized that the specification used "language of requirement, not preference," when describing the apparatus-producing process. 474 F.3d at 1372. In *Continental Circuits*, however, we found that the specification "merely indicate[d] a preference for using" the apparatus-producing process. 915 F.3d at 799. We considered the specification's statements that the apparatus "can be carried out" by the disclosed process and that the process was merely "one technique for forming the [apparatus]." *Id.* at 797.

The specification of the '991 patent is more like the specification in *Continental Circuits* than the specification in *Andersen*. Although the '991 patent contains a few statements suggesting that its high-energy milling is required, *see, e.g.*, col. 2, ll. 57–65, and col. 3, ll. 9–14, those statements are outweighed by the numerous statements indicating that high-energy milling is merely a preferred process. *See, e.g.*, col. 3, ll. 15–25 (describing how high-energy milling may not be required for smaller particles because the short-range Van der Waals forces may be sufficient to ensure adhesion); col. 3, ll. 59–65, and col. 5, ll. 35–37 (naming "preferred methods"); col. 4, ll. 22–25 ("Preferably, the milling step involves the compression of the mixture of active and additive particles . . . ."); col. 6, ll. 38–57. Moreover, the fact that the '991 patent criticizes other methods, *see, e.g.*, col. 2, ll. 57–65, and col. 3, ll. 52–58, is not dispositive. *See AstraZeneca LP v. Breath Ltd.*, 542 F. App'x 971, 976 (Fed. Cir. 2013) ("[M]ere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal." (quoting *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012)). We thus conclude that the specification of the '991 patent does not

make its milling method an essential part of apparatus claim 1.

We also reject GSK's argument that the prosecution history requires "composite active particles" to be construed to include a process limitation. In *Andersen*, the applicant distinguished the prior art based on the method used to produce the claimed product. 474 F.3d at 1373. We held that the applicant clearly disclaimed apparatuses produced by the prior art's methods, confirming that the apparatus claim should be construed to include a process limitation. *Id.* at 1373–74.

In this case, the applicants distinguished the Bosch reference on the ground that Bosch disclosed only "the application of surface modifier material that is in the liquid phase," while the applicants' claim recited active particles coated with "particulate additive material." J.A. 10218–19. Thus, according to the applicants, Bosch involved "wet processes that involve dissolution of the surface modifier, or use of a liquid surface modifier, and subsequently forming a film over the active particle," while "the composite particles claimed in the present application do not comprise 'coatings such as those formed by wet processes that require dissolution of one or both components.'" J.A. 10220 (quoting the patent application). The applicants added that Bosch "does not teach or suggest the milling of particulate surface modifier with drug particles. Instead, the milling operations disclosed in the Bosch reference are performed with liquid phase surface modifier, in other words, surface modifier that is a liquid or is in solution." *Id.* Because Bosch teaches "the application of a film layer of surface modifier material by adsorption, which will produce a thin, uniform, continuous coating on the drug particles," it does not "include particulate additive material on the surface of the active particles" and therefore "does not disclose the particles claimed in the present application." J.A. 10221.

Although the applicants stated that the composite particles "are fused to the active particle in a manner only possible using an aggressive milling procedure," J.A. 10218,[2] that statement did not purport to add a process limitation to the apparatus claim. Instead, that statement merely sought to demonstrate that Bosch's coated particles were necessarily different from the applicants' coated particles because Bosch used a process that could not possibly produce "particulate additive matter on the surface of [a] particle of active material," as required by the applicants' claim. Accordingly, the most reasonable interpretation of the April 2012 response is that the applicant distinguished Bosch based on the unique structure of the claimed composite particles, not the disclosed milling method. We therefore reject GSK's challenge to the district court's claim construction.

C

GSK argues that Vectura's damages theory is legally flawed, leaving the jury's award unsupported by the record. GSK requests a new trial on damages as a remedy. As explained above, we review the district court's denial of a new trial for an abuse of discretion.

The parties have a licensing history. In 2010, Vectura granted GSK a non-exclusive, worldwide license to more than 400 patents, the sum of which covered GSK's respiratory therapeutics containing vilanterol and/or umeclidinium. The centerpiece of the 2010 license was a now-expired Vectura patent with claims directed to coating lactose excipients with additive material such as magnesium stearate. The 2010 license also contained a non-assert

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[2] *See also* J.A. 10222 ("These particles can only be produced using high energy milling processes to fuse and smear the additive particles on to the surface of the active particles.").

clause for Vectura patents that covered formulations containing magnesium stearate. The non-assert clause included the application that matured into the '991 patent.

The 2010 license featured a tiered royalty structure in which GSK would pay a royalty of 3% on its first 300 million British pounds in sales, 2% on sales between 300 million and 500 million pounds, and no additional royalties on sales above 500 million pounds. The 2010 license expired on July 25, 2016.

At trial, Vectura presented a damages theory based on the 2010 license being a comparable license. Vectura's damages expert, Kimberly J. Schenk, adopted the 2010 license's first-tier royalty rate (3%) as a flat royalty rate and the 2010 license's royalty base (total sales of the licensed products) as her royalty base. Ms. Schenk declined to adopt the royalty cap from the 2010 license, citing changed circumstances by the time of the hypothetical negotiation, which would have occurred in July 2016 when the 2010 license expired. GSK presented an alternative theory, also based on the total revenue produced by the licensed products. Under GSK's theory, however, the royalty rate would have been much lower, only 0.0187%.

GSK argues that Vectura's evidence was insufficient to support the jury's damages award. GSK first attacks Ms. Schenk's use of the total sales of the accused inhalers as her royalty base. GSK argues that, under this court's precedents, Ms. Schenk needed to show that the patented vilanterol and umeclidinium mixtures drove consumer demand for the accused inhalers before presenting a damages theory based on the entire market value of the accused inhalers. GSK contends that Ms. Schenk did not make such a showing and, as a result, she needed to apportion her royalty base to account for the non-infringing components in the accused inhalers, such as the fluticasone blister in the Breo inhaler. Appellants' Opening Br. 61 (citing

*Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201 (Fed. Cir. 2014)).

The damages theories tried in this case present a rather unusual circumstance. Ordinarily, an entire-market-value royalty base is appropriate only when the patented feature creates the basis for customer demand or substantially creates the value of the component parts, and apportionment is required when an entire-market-value royalty base is inappropriate. *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014). However, this court has explained that when a sufficiently comparable license is used as the basis for determining the appropriate royalty, further apportionment may not necessarily be required. *See, e.g.*, *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353 (Fed. Cir. 2020); *Elbit Sys. Land & C4I Ltd. v. Hughes Network Sys., LLC*, 927 F.3d 1292 (Fed. Cir. 2019); *Commonwealth Sci. & Indus. Rsch. Organisation v. Cisco Sys., Inc.*, 809 F.3d 1295 (Fed. Cir. 2015). That is because a damages theory that is dependent on a comparable license (or a comparable negotiation) may in some cases have "built-in apportionment." *See, e.g.*, *Commonwealth*, 809 F.3d at 1303.

This is one such case. Although GSK refers to the 2010 license as being "purportedly comparable," the evidence clearly supports Vectura's contention that the 2010 license was sufficiently comparable for use in its damages calculation. Indeed, GSK's own damages expert, Dr. William Kerr, testified that the 2010 license was "a very close comparable, much closer than you ever find in a patent case." J.A. 1857–60.

Built-in apportionment effectively assumes that the negotiators of a comparable license settled on a royalty rate and royalty base combination embodying the value of the asserted patent. *Id.* As the district court noted, a party relying on a sufficiently comparable license can adopt the comparable license's royalty rate and royalty base without

further apportionment and without proving that the infringing feature was responsible for the entire market value of the accused product. *Vectura*, 397 F. Supp. 3d at 593 (citing *Commonwealth*, 809 F.3d at 1301–04).

That is what Ms. Schenk did when she adopted the royalty rate and royalty base that was used in the 2010 license. To support Ms. Schenk's damages theory, Vectura offered evidence that the circumstances of the 2010 license and the hypothetical negotiation in 2016 were highly comparable and that principles of apportionment were effectively baked into the 2010 license. J.A. 1447–48; *see Bio-Rad*, 967 F.3d at 1373.

We have cautioned that "district courts performing reasonable royalty calculations [must] exercise vigilance when considering past licenses to technologies other than the patent in suit" and "must account for differences in the technologies and economic circumstances of the contracting parties." *Virnetx*, 767 F.3d at 1330. Here, GSK argues that even if the 2010 license is superficially comparable, Ms. Schenk failed to account for the technical and economic differences between the 2010 license and the hypothetical negotiation that would have occurred when the 2010 license expired in 2016. GSK notes that the 2010 license encompassed rights to more than 400 patents and that the royalty established in that license was subject to a cap for sales above a certain amount.

Vectura introduced evidence, however, that the key component of the 2010 license was permitting GSK to use Vectura's invention of coating lactose particles with magnesium stearate. The 2010 license and the hypothetical negotiation thus cover "roughly very similar technologies," as Ms. Schenk testified. J.A. 1448. Similarity of scope is confirmed by the fact that the mixtures Vectura points to as infringing the '991 patent would have been the very same mixtures covered by the 2010 license. On appeal, GSK has offered nothing to undermine that conclusion. Accordingly,

the fact that other patents were included in the 2010 license does not fatally undermine Ms. Schenk's theory of comparability.

Ms. Schenk also considered and rejected the argument that there were meaningful economic differences between the benefits of coating the lactose particles and coating the active ingredients. J.A. 1481–82. She also considered and rejected the suggestion that there were other technical or economic distinctions between the 2010 license and the 2016 hypothetical negotiation that rendered them not comparable. J.A. 1465–85. GSK cross-examined Ms. Schenk on those matters, and the disputes over that evidence were properly left for the jury to resolve. *See Bio-Rad*, 967 F.3d at 1374.

GSK's second line of attack focuses on the absence of a royalty cap in Vectura's damages theory. GSK argues that if the 2010 license is truly a comparable license, it was improper for Ms. Schenk to discard the royalty cap while simultaneously retaining the royalty rate and royalty base used in the 2010 license. For support, GSK asserts that the royalty cap was an integral part of the 2010 negotiations and that in 2016 Vectura had proposed an extension of the 2010 license that would have retained the royalty cap.

Ms. Schenk testified that the assumption of validity and infringement in a hypothetical negotiation, among other changed circumstances, supported not including a cap on her proposed royalty. J.A. 1458, 1484. The jury was entitled to credit that testimony and to note that by 2016 the accused inhalers had already become hugely successful, which would have increased Vectura's leverage in the hypothetical negotiation. It was therefore permissible for the jury to credit Ms. Schenk's testimony and to award damages without applying a royalty cap. In sum, the district court did not abuse its discretion in denying GSK's motion for a new trial on damages.

D

Finally, GSK contends that the district court should have ordered a new trial on damages because Vectura made improper references during the trial to GSK's $3.8 billion in U.S. sales for the accused inhalers. In particular, GSK complains that Vectura overemphasized GSK's U.S. sales and made an improper "pennies on the dollar" argument by framing its requested damages as small compared to those sales. Under Third Circuit law, a new trial is proper with respect to such claims if the appellee made prejudicial remarks and it is "reasonably probable" those prejudicial remarks influenced the jury's verdict. *Draper v. Airco, Inc.*, 580 F.2d 91, 97 (3d Cir. 1978).

At the outset, Vectura argues that GSK waived its prejudice arguments by not moving to bar Vectura from referring to GSK's total inhaler sales and by not making timely objections to those references during trial.

The waiver issue is complicated by the unusual way that the evidentiary record developed at trial. In a motion in limine directed to the issue of sales, GSK requested that Vectura be prohibited from introducing evidence of GSK's foreign sales, and the motion was granted. Notably, however, GSK did not request that evidence of the volume of U.S. sales be prohibited. In fact, GSK admitted at trial that "under the agreement of the [motion in limine], the sales of the accused products come in. But global sales for GSK, global sales for the respiratory division, anything else are out." J.A. 1464.

Vectura referred to GSK's U.S. sales of the accused inhalers twice during its opening statement and once during the direct testimony of Vectura's corporate witness, all without objection from GSK. Not until Vectura elicited the amount of GSK's sales during Ms. Schenk's testimony on damages did GSK's counsel object. Counsel claimed that it was improper for Ms. Schenk "to give an opinion on the entire market value of the product" without apportioning

damages to the infringing features; that it was improper for her to rely on the 2010 license between Vectura and GSK "without apportioning between the value of the patent-in-suit, and that license, and all other intellectual property rights that were obtained in that license"; and that she should not be allowed to "rely on the entire market value rule without addressing non-infringing alternatives." J.A. 1429. Counsel also stated that it was "inflammatory to put billion dollar numbers in front of juries, and that should be avoided if at all possible." J.A. 1430–31. Counsel added that it was inflammatory "to put up billion dollars on the screen, and then do the math from that, or worse to do what we heard a little bit in the opening of, and I expect to hear in closing, all we want is three percent of the billions of dollars that GSK made." J.A. 1435–36.

The district court noted that GSK had not filed a pretrial *Daubert* motion. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). For that reason, the court determined that GSK had waived its general objections to Ms. Schenk's built-in apportionment testimony and would be required to object to any particular question asked of her. However, the court made clear that it did not regard GSK as having waived its objection to the argument that "it's just pennies on the dollar, so what's the big deal?" The court added, "I don't think the sales should be in any way emphasized beyond what is strictly required by the law. So if I hear that happening, I will make my own objection and I will sustain it because that should not be an argument." J.A. 1437–40.

Subsequently, Ms. Schenk provided testimony on damages, in which she referred several times to GSK's U.S. sales. GSK did not object to those references or to the demonstrative exhibits that included the dollar amount of those sales.

During GSK's case, its damages expert, Dr. Kerr, testified that he thought Vectura's three percent royalty rate

was "holding GSK over a barrel." J.A. 1886. On cross-examination, Vectura's counsel challenged that statement, saying, "so it's your testimony that a three-percent royalty would be putting GSK over a barrel when they had $3 billion worth of infringing product at stake?" J.A. 1887. At that point, the trial judge interceded, noting that he had said that he would police excessive references to the sales amounts. He added: "Let's not talk any more about [the] 3 billion figure." J.A. 1888.

There was no further reference at trial to the amount of GSK's sales. Following the close of the evidence, the court instructed the parties not to refer to the overall sales figure during closing arguments. In his closing argument, Vectura's counsel referred to GSK's profits, but not the amount of its sales. GSK did not object to counsel's closing argument.

In its opinion on the motion for judgment as a matter of law and for a new trial, the district court found that Vectura had "repeatedly emphasized the amount of revenues made by Defendants and the relative smallness of the damages award they were requesting," and that its conduct in that regard was improper. *Vectura*, 397 F. Supp. 3d at 594. However, the court agreed with Vectura that, unlike in most cases in which there was no legitimate reason for the jury to hear large total revenue figures, in this case "there was no smallest salable patent-practicing unit, and the total revenue was an appropriate base that the jury needed to hear to understand Plaintiff's damages expert's analysis." *Id.* at 596. For that reason, the court concluded, "I do not find the introduction of the total revenue figure to be so prejudicial that the damages verdict 'cries out to be overturned.'" *Id.*

With respect to the issue of waiver, the district court concluded that GSK had not waived its objections to the "pennies on the dollar" argument or to statements "emphasizing [GSK's sales] beyond what's strictly required by the

law" in proving damages. J.A. 1439–40, 1888. We agree with the district court that although GSK may have waived its more general objections to Ms. Schenk's damages testimony, it did not waive its objections to the "pennies on the dollar" argument or to statements unnecessarily emphasizing GSK's billion-dollar sales. The district court's finding of no waiver is particularly well-founded in light of the court's statement during trial that it would enter its own objection if it heard such arguments being made.

We also agree with the district court that where Vectura made such arguments, they were improper. The district court pointed to three places in the trial record that Vectura made what the court considered to be the improper "pennies on the dollar" argument: during opening statement; during the cross-examination of Dr. Kerr; and in closing argument, where counsel referred to Vectura's three percent royalty as "a small portion of GSK's profits, which are in excess of 75 percent of its sales." J.A. 2023.[3]

The district court was correct in not condemning the remaining references to GSK's total U.S. sales because those remaining references were neither objected to nor objectionable. They were not objectionable because it was necessary for Vectura to reference GSK's total sales, either directly or indirectly, considering that Vectura's damages theory asked the jury to multiply the three-percent royalty rate by the royalty base, i.e., GSK's total sales. In particular, it was legitimate for Ms. Schenk to reference GSK's total sales when calculating her proposed damages award because her royalty base was the total sales of the accused

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[3] Notably, however, the remarks made by Vectura's counsel in his opening statement, which were not objected to, occurred prior to the time the district judge announced that he would make his own objections to any references to GSK's sales that were directed to the "pennies on the dollar" argument.

inhalers. As the district court noted, GSK did not attempt to prevent her from doing so with a motion in limine or a *Daubert* motion.

It was also proper for Ms. Schenk to refer to the sales figures when analyzing the comparability of the 2010 license and the 2016 hypothetical negotiation—an analysis critical to any built-in apportionment theory. She explained that the 2016 negotiation, unlike the 2010 negotiation, featured certainty as to commercial success and profitability, considerations that bear on the eighth *Georgia Pacific* factor, "the commercial success and profitability of the accused products." *See Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). Her references to GSK's sales in that connection were therefore proper. *See Bio-Rad*, 967 F.3d at 1373–74; *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1210 (Fed. Cir. 2010) (rejecting defendant's argument that its financial numbers from the years after the hypothetical negotiation were irrelevant for purposes of the eighth *Georgia Pacific* factor).[4] The same is true of the brief reference to GSK's sales by Vectura's corporate representative, in the context of addressing the uncertainties surrounding the 2010 negotiation relative to 2016. *See* J.A. 1108–09.

After carefully surveying the remarks GSK identified as prejudicial, the district court found that the effect of the

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[4] Ms. Schenk's references to GSK's sales do not suffer from the flaw found in the references to the defendant's total sales in *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011), relied on by GSK. In *Uniloc*, we held that the patentees' using the defendant's $19 billion in sales as a "check" on its proposed damages was "irrelevant and tainted the jury's damages award." 632 F.3d at 1318–21. Unlike in this case, the patentee's damages theory in *Uniloc* did not depend on the use of the total amount of sales of the accused products. *See id.* at 1312.

remarks that it found improper was not so prejudicial as to require a new trial. On the issue of the impact of improper conduct at trial, the views of the judge who supervised the trial proceedings are entitled to considerable weight. *See Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 207 (3d Cir. 1992) ("Because the trial judge was present and able to judge the impact of counsel's remarks, we defer to his assessment of the prejudicial impact."). We find no basis to second-guess the judgment of the experienced trial judge in this regard. We therefore decline to conclude that the district court abused its discretion, and we uphold the court's decision denying a new trial on this ground.

## III

For the foregoing reasons, we affirm the district court's post-trial order denying GSK's motion for judgment of non-infringement as a matter of law, GSK's motion for a new trial on infringement, and GSK's motion for a new trial on damages. We also uphold the district court's claim construction with respect to the "composite active particles" limitation in claim 3 of the '991 patent.

**AFFIRMED**