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Case Number 25,2020

IN THE SUPREME COURT OF THE STATE OF DELAWARE

GLAXO GROUP LIMITED and HUMAN GENOME SCIENCES, INC.,	)	
Defendants Below, Appellants/Cross-Appellees,	)	No. 25, 2020
v.	)	Court below: Superior Court of the State of Delaware, C.A. No. N16C-07-218 WCC CCLD
DRIT LP,	)	
Plaintiff Below, Appellee/Cross-Appellant.	)	

APPELLANTS' OPENING BRIEF

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NATURE OF PROCEEDINGS

This case arises from the settlement of a patent dispute. Defendant-Appellants Glaxo Group Limited and Human Genome Sciences ("GSK") owned various patents protecting GSK's Lupus drug, Belimumab (later marketed as "Benlysta®"), but sought additional protection by applying for a patent covering a method of treating Lupus. Biogen, which was not developing a Lupus drug itself, held a patent covering a very similar method of treatment. GSK and Biogen disputed who had first invented that method of treating Lupus and was thus entitled to the patent rights.

In 2008, GSK and Biogen entered into a Settlement Agreement in which Biogen gave up all of its contested patent rights. In return, GSK agreed to pay Biogen an upfront payment of $3.5 million, and two Milestone Payments of $1.5 million each tied to regulatory approval of Benlysta. In addition, the Agreement required GSK to pay royalties on sales of Benlysta for so long as a "Valid Claim" arising from the previously contested patent rights existed, *i.e.*, the expiration of the last valid patent property right. The Agreement's definition of "Valid Claim" thus identified contingencies that would terminate GSK's royalty obligations. A "Valid Claim" was defined as a claim that had not, *inter alia*, been "disclaimed."

In 2011, the PTO granted GSK's patent application. GSK made the upfront and milestone payments to Biogen under the Agreement, and paid royalties to

Biogen until 2012, when Biogen sold its rights to Plaintiff-Appellee DRIT, a private investment fund. GSK paid royalties to DRIT until 2015, when GSK exercised its right under the Patent Act to "disclaim" GSK's patent and thus terminated all valid claims of the patent. *See* 35 U.S.C. § 253.

DRIT brought breach-of-contract and breach of implied covenant of good faith claims against GSK in Delaware Superior Court, contending that the 2008 Agreement implicitly limited GSK's right to disclaim its patent in order to stop royalty payments. The Superior Court dismissed DRIT's breach-of-contract claim, holding that the 2008 Agreement authorized GSK to stop paying royalties if and when GSK disclaimed the patent. Nevertheless, the court concluded that the implied covenant limited GSK's right to disclaim its patent and let this claim go to the jury.

At trial, DRIT relied heavily on its expert witness, Philip Johnson, who testified that GSK violated unwritten industry norms in disclaiming the patent. Johnson, however, explicitly declined to consider GSK's and Biogen's actual expectations in their agreement. DRIT nevertheless centered its case at trial on GSK's purported violation of Johnson's "norms," and the jury found, accordingly, that GSK had breached the implied covenant of good faith.

The Superior Court denied GSK's motion for judgment as a matter of law or new trial. The court also rejected GSK's argument that the misleading, irrelevant,

and prejudicial testimony from Johnson warranted a new trial. The Superior Court awarded DRIT $67 million in damages, plus ongoing royalties on sales of Benlysta that are likely to total the award to upwards of $100 million.

This is an appeal of the Superior Court's denial of GSK's Motion for Summary Judgment and Motion for Judgment as a Matter of Law or New Trial, and the Court's damages award.

SUMMARY OF THE ARGUMENT

1. GSK is entitled to judgment as a matter of law that GSK did not breach the implied covenant of good faith and fair dealing. DRIT wrongly invoked that doctrine below to insert an extra-textual contractual limitation on GSK's right to disclaim GSK's own patent—a right the Patent Act confers and that the Agreement expressly recognized. Namely, DRIT argued that GSK could not exercise its right to disclaim its patent in order to terminate its royalty obligations even though the royalty payments dwarfed any corresponding benefit to GSK of retaining the patent. But nobody disputes that the Patent Act gives GSK the right to disclaim its own patent. And as the Superior Court held in dismissing DRIT's breach of contract claim, the parties' agreement *expressly stopped* GSK's royalty obligations if GSK decided to exercise its patent law right to disclaim the patent.

Those principles should have foreclosed any resort to the implied-covenant doctrine, which allows courts to read in implied contractual terms only in extraordinary circumstances. For that doctrine to apply, (1) the agreement must leave a clear gap as to what would happen if GSK disclaimed its patent; (2) the parties must not have been able to anticipate a patent disclaimer at the time of contracting; and (3) it must be unambiguous that both parties would have agreed to limit GSK's right to disclaim its patent at the time of contracting, had they foreseen the possibility of a disclaimer.

None of these conditions are remotely met here. Section 1.49 of the Agreement recognizes GSK's right to disclaim its patent and thus leaves no gap whatsoever to fill. Further, section 1.49's express contemplation of patent disclaimers by GSK as a trigger for GSK to cease royalty payments eliminates any plausible argument that the original parties (GSK and Biogen) reasonably failed to anticipate the possibility of this result when they contracted. The Superior Court erred in allowing DRIT to premise its "bad faith disclaimer" assertion on GSK's motive to cease paying royalties since the Agreement expressly provided for exactly that–cessation of royalties by means of disclaimer. Finally, DRIT did nothing to carry its burden to show that *both* parties would have agreed to limit GSK's right to disclaim its patent.

The Superior Court invoked a rule that contracts affording one party discretion over a matter require that discretion to be exercised in good faith. But that doctrine applies only when the *contract itself* creates discretionary rights; here, federal law gave GSK the right to disclaim its patent. Once GSK exercised its Patent Act right to disclaim, the contract's express term eliminating further royalties followed without any exercise of GSK's "contractual discretion."

If courts can overturn agreements in the face of express terms, without finding any gap in the contractual language, the implied-covenant doctrine would cease to become the exception and would instead become the presumptive rule.

That doctrinal sea change would destabilize the predictability of contracts in Delaware and encourage endless suits by parties who want courts to grant them rights that they never secured during contract negotiations.

2. The Superior Court further erred by refusing to order a new trial in light of improper and prejudicial testimony from DRIT's star expert witness, Philip Johnson. Johnson extensively opined that GSK's conduct violated his amorphous and unwritten "industry norms," yet declined to consider the key question under the implied-covenant doctrine: whether the actual contracting parties could have reasonably expected GSK to be able to disclaim its patent and thereby cease paying royalties. Johnson did not even review the Agreement as part of his analysis. Nonetheless, DRIT repeatedly invoked Johnson's irrelevant testimony as the centerpiece of its case that GSK acted in bad faith. This was highly prejudicial because it misled the jury into ignoring the parties' expectations at the time of contracting—the relevant legal question.

3. At a minimum, this Court should vacate the Superior Court's damages award, which erroneously gave DRIT a windfall worth upwards of $100 million—far beyond what DRIT could reasonably have expected under the Agreement. That amount assumes GSK made no disclaimer, *i.e.* it held on to its patent rights through the entire length of the patent term through August 2022. But GSK would never have held onto its patent rights that long. Even were DRIT correct that GSK

could not *statutorily* disclaim the patent (*i.e.*, formally relinquish all claims under the patent to end its royalty obligations), DRIT's experts admitted that GSK would have acted reasonably in *terminally* disclaiming the patent. Terminal disclaimers truncate the period of a patent term, instead of relinquishing the whole term. DRIT's experts agreed that GSK could have reasonably terminally disclaimed the patent—and thus cut off royalties to DRIT—no later than October 2016. Yet the Superior Court ignored this consistent testimony and entered judgment requiring GSK to pay an additional six years of royalties.

Moreover, this Court should vacate the damages award because the Superior Court's damages calculation rested on a blatant legal error: the court believed that the patent term would have lasted 20 years from the date the patent was issued, far longer than the patent's undisputed expiration date. That error undermined the entirety of the Superior Court's analysis of the amount of damages that the parties could have foreseen when they contracted.

STATEMENT OF FACTS

GSK developed and sells the groundbreaking Lupus drug Benlysta, the first FDA-approved treatment for Lupus in 50 years. Benlysta exists only because GSK engaged in years of costly research. To safeguard that investment, GSK obtained from the U.S. Patent and Trademark Office ("PTO") a portfolio of patents covering the innovations underlying Benlysta, thereby entitling GSK to all rights that federal law confers on patentees. Those rights include the right to exclude others from practicing the invention, 35 U.S.C. § 271, as well as the right to disclaim (*i.e.*, relinquish) patent protection at any time, *id.* § 253.

1. Several patents in GSK's portfolio protect against any unauthorized use of the core antibody developed for Benlysta. Central among them was U.S. Patent No. 6,403,770 ("the '770 Patent"), which covered the core antibody. A641-44. Other patents provide narrower protection. As particularly relevant here, U.S. Patent No. 8,017,092 ("the '092 Patent") covered a method of using Benlysta to treat Lupus. GSK submitted its application for the '092 Patent in 1996. A442-43.

In 2006, while it was still pending, the '092 Patent application was involved in an "interference" proceeding at the PTO. A635-36. Under then-governing patent law, an interference occurred when two inventors attempted to obtain different patents covering the same invention. In that circumstance, one or both could initiate interference proceedings before the PTO to determine who invented

the subject matter first, and the PTO would award the first-in-time inventor all patent rights to the invention. A475-76; A721-22.[1]

Here, GSK and another biotechnology company, Biogen, disputed which company had first invented a method of treating Lupus. GSK had claimed that method of treatment in its 1996 application underlying the '092 Patent, but Biogen already held a patent for a similar method. A646-47. The PTO therefore declared an interference. The interference would either bar GSK from continuing to prosecute its patent application claiming this method, or cancel Biogen's patent. A648.

In 2008, GSK and Biogen entered into a binding Term Sheet to settle their dispute. Because GSK had already made significant strides in producing a viable Lupus treatment with Benlysta, and Biogen had no prospect of a working Lupus drug, the parties agreed that GSK would retain its patent rights to the disputed invention and that Biogen would relinquish its competing rights. In exchange, GSK agreed to compensate Biogen. A711-16; A736. That made sense: as the only party likely to market a Lupus drug, GSK had a larger incentive and was better positioned to use those patent rights to protect that drug from competitors. Biogen,

[1] In 2013, Congress switched to a "first-to-file" rather than "first-to-invent" system under the America Invents Act.

by contrast, only stood to use the patent rights as a source of revenue, which Biogen could obtain by agreeing to relinquish those rights in agreement with GSK.

Because of the interference, the parties also had to determine whether GSK would continue with its own patent application or Biogen's patent. The Term Sheet thus provided for a neutral arbitrator to decide which patent would have prevailed in the interference. The arbitrator decided that GSK had come up with the invention first, and GSK's patent application would have prevailed. So GSK continued with its patent application; Biogen's patent was cancelled. A652-54; A715-17; A721-22.

GSK and Biogen then entered into a settlement and license agreement based on the Term Sheet. The Agreement addressed uncertainties arising from the fact that the PTO had not yet granted GSK's patent application and might still deny it. Section 3.4 of the Agreement required GSK to pay Biogen royalties on sales of Benlysta until the expiration of the last "Valid Claim" of the '092 Patent, *i.e.*, the last valid property right of the patent. A085; A658-60.[2] Again, that made sense: in 2008, when the parties were in settlement negotiations, the parties had no way of knowing if the PTO would grant GSK's '092 Patent and, if so, when that patent would expire. Ordinarily, patents expire 20 years after the filing of the patent

[2] The Agreement allowed for royalties on other patents too, but the '092 Patent is the only relevant one here. A104-05; A658-60.

application—so, with an application date of October 1996, here the default expiration date was October 2016. 35 U.S.C. § 154(a)(2). But the PTO can extend that expiration date to account for processing delays. *Id.* § 154(b). Section 3.4 thus accounted for any potential PTO extensions of the '092 Patent's expiration.

Conversely, Section 1.49 addressed contingencies that could terminate the '092 Patent, and GSK's corresponding royalties to Biogen, before its expiration in the normal course. Section 1.49 defines "Valid Claim" as:

> a claim of an issued, unexpired patent within the Patent Rights that has not expired, lapsed, or been cancelled or abandoned, and that has not been dedicated to the public, disclaimed, or held unenforceable, invalid, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal can be taken or was timely taken, including through opposition, re-examination, reissue or disclaimer.

A083. Section 1.49 thus reflects that GSK, the PTO, or courts could take actions that would make the '092 Patent inoperative—cutting off GSK's royalties—before the '092 Patent term expired. A659-61. Again, that made sense given the uncertainties facing both parties. With the prospect for a commercially successful Lupus drug, GSK had the incentive to maintain and use the '092 Patent to protect that drug. But if, for instance, Benlysta competitors figured out an easy way to avoid the coverage of the patent, the patent would be near worthless. GSK thus reasonably secured language to ensure that its obligation to pay Biogen royalties would be tied to the worth of the '092 patent *to GSK*.

Other provisions of the Agreement conferred significant benefits to Biogen to compensate it for relinquishing its patent no matter whether the PTO refused to grant the '092 Patent, whether a court invalidated it, or whether GSK disclaimed it. GSK made an up-front payment of $3.5 million to Biogen upon signing the Agreement in 2008, A084; A655, and GSK paid Biogen another $3 million when FDA and foreign regulatory agencies approved marketing of Benlysta in 2011, A084; A656-57.

In 2011, the PTO granted GSK the '092 Patent, and GSK paid Biogen $2 million in royalties thereafter. A442; A671. In 2012, Biogen sold its royalty rights under the Agreement to DRIT, an investment company that purchases royalty streams and does not research or develop medicine. A419-20; A424-25; A672-73. DRIT's purchase did not alter GSK's obligations under the Agreement, and DRIT sought no warranties from GSK concerning the royalty terms. Similarly, DRIT made no attempt to amend the "Valid Claim" provisions of the Agreement. A427; A673-74. Over the next three years, GSK paid DRIT $14 million in royalties. A675-76.

2. By 2015, the '092 Patent had become less useful to GSK in protecting GSK's investment in Benlysta. GSK had learned of a defect in the '092 Patent that would likely have rendered it invalid had GSK attempted to enforce it. A688-92. This defect did not affect other GSK patents covering Benlysta, some of which

also protected the drug far beyond the expiration date of the ’092 Patent. A452; A643-45. The ’092 Patent thus had relatively lower value to GSK in protecting Benlysta from competitors.

Moreover, GSK’s primary competition in the Lupus field, Eli Lilly, had to abandon its competitor product due to adverse safety data during development. With Eli Lilly out of the picture, the ’092 Patent’s protection of methods of treating Lupus, even if enforceable, had relatively lower value to GSK. GSK had little need to guard Benlysta with the additional ’092 patent when it would cover no likely competition anyway. A696-99.

At bottom, the benefits of maintaining the ’092 Patent no longer justified the cost of making royalty payments to DRIT. A700-02. Thus, GSK exercised its right under 35 U.S.C. § 253 to statutorily disclaim the ’092 Patent by filing paperwork with the PTO formally relinquishing any legal interest in the patent. A676-77. GSK filed such paperwork on April 27, 2015, disclaiming the entire term of the Patent from the day the PTO granted it in 2011. A469-70; A478. Because GSK’s disclaimer, by definition, cancelled any “Valid Claim” from the ’092 Patent, GSK ceased making royalty payments to DRIT. A083; A085; A659-61; A676-77.

3. DRIT sued GSK in Delaware Superior Court, asserting breach-of-contract and breach-of-implied-covenant claims.

The Superior Court dismissed DRIT's breach-of-contract claim. The court found that the Agreement required royalties only until the expiration of the last "Valid Claim" of the '092 Patent, and that the "plain and customary usage" of "disclaim" pursuant the Agreement meant that GSK owed no further royalties after it disclaimed the patent. A144-50.

The court nonetheless allowed DRIT's implied covenant claim to proceed to the jury. The court stated that "while [GSK] had unfettered discretion to use their right to disclaim, such discretion had to be exercised reasonably in light of the Agreement reached with Biogen and subsequently [DRIT]." A150-52; Ex. A (MSJ Opinion) at 20-21.

At trial, DRIT introduced no evidence that GSK, in negotiating the Agreement, would have accepted any limitations on its right under the Patent Act to disclaim its patent. Instead, DRIT introduced an opinion from its expert witness, Philip Johnson, who testified that GSK's disclaimer of the '092 Patent was "inconsistent with industry norms." A535-36. Johnson conceded that his testimony related only to "standard situations," and not the Agreement at issue (which he did not analyze), but the Superior Court denied GSK's motion *in limine* to exclude his testimony. A572-73; A407-12. The jury returned a verdict that GSK breached the implied covenant. A793.

The Superior Court denied GSK's motion for judgment as a matter of law. Ex. B (JMOL Opinion). The Court found that the disclaimer was "such an unusual event that it would not have been reasonably anticipated by the parties," but did not discuss GSK's actual expectations in light of the contract's inclusion of "disclaimer," which were the subject of undisputed testimony by GSK witnesses. *Id.* at 5-6. The Superior Court likewise denied GSK's motion for a new trial, holding, *inter alia*, that Johnson's experience in the intellectual-property field was itself a sufficient basis to admit his testimony. *Id.* at 6-8.

Finally, the Superior Court granted DRIT's motion for a determination of damages, ordering GSK to pay approximately $67 million to DRIT. *Id.* at 9-12; Ex. C (Judgment). Further, the court ordered GSK to pay DRIT ongoing royalties on sales of Benlysta as if no disclaimer occurred, which will likely bring DRIT's total award to more than $100 million.

GSK timely appealed.

ARGUMENT

I. GSK Is Entitled to Judgment on DRIT's Claim that GSK Breached the Implied Covenant of Good Faith and Fair Dealing

A. Question Presented

Whether the Superior Court erred by allowing DRIT to invoke the implied covenant of good faith and fair dealing when the Agreement expressly permitted GSK to disclaim the '092 Patent and thereby cease royalty obligations on that patent, the parties could have reasonably foreseen the possibility of disclaimer in view of the express language of the Agreement, and DRIT failed to establish that GSK would have agreed to limit its right to disclaim the '092 Patent. (Preserved A176-87; A811-24.)

B. Scope of Review

This Court reviews the denial of a motion for summary judgment de novo. *Winshall v. Viacom Int'l Inc.*, 76 A.3d 808, 815 (Del. 2013). The denial of a motion for judgment as a matter of law is reviewed de novo. *Trievel v. Sabo*, 714 A.2d 742, 744 (Del. 1998).

C. Merits of the Argument

The implied covenant of good faith and fair dealing "is a limited and extraordinary legal remedy"—and it has no place in this case. *See Nemec v. Shrader*, 991 A.2d 1120, 1128 (Del. 2010).

Delaware law strictly limits the applicability of the implied-covenant doctrine to prevent courts from rewriting contracts by implying terms that the parties never agreed to satisfy. *First*, the implied covenant applies only if "there is a gap that needs to be filled." *Allen v. El Paso Pipeline GP Co., L.L.C.*, 113 A.3d 167, 183 (Del. Ch. 2014). Unless the contract is "truly silent with respect to the matter at hand," the court should not apply the implied covenant analysis. *Allied Capital Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1032-33 (Del. Ch. 2006). *Second*, even if the contract fails to cover the matter at issue, courts cannot "fill a gap in a contract with an implied term unless it is clear from the contract that the parties would have agreed to that term had they thought to negotiate the matter." *Fisk Ventures LLC v. Segal*, 2008 WL 1961156, at *10 (Del. Ch. May 7, 2008). *Third*, the implied-covenant doctrine allows gap-filling only with respect to "developments that could not be anticipated, not developments that the parties simply failed to consider." *Nemec*, 991 A.2d at 1126. *Finally*, in a narrow category of cases, the implied-covenant doctrine can fill gaps "when a party to the contract is given discretion to act as to a certain subject"—but only if "the discretion has been used in a way that is impliedly proscribed by the contract's express terms." *Oxbow Carbon & Minerals Holdings, Inc. v. Crestview-Oxbow Acquisition, LLC*, 202 A.3d 482, 504 n.93 (Del. 2019).

This is a textbook case where the implied-covenant doctrine does not apply. There is no gap to fill; the Agreement expressly recognizes GSK's pre-existing patent-disclaimer rights. GSK never would have agreed to restrict its right to disclaim low-value patent rights and DRIT presented no evidence to suggest otherwise. Moreover, the parties *did* foresee the possibility of disclaimer as a means to eliminate a Valid Claim and the associated royalty obligations. That is why section 1.49 expressly mentions it. And GSK was not required to tell Biogen or its lawyers the obvious: that because the contract did not restrict GSK's patent law right to disclaim, GSK might exercise that right.

The decision below would rewrite the parties' carefully negotiated Agreement by reading in an implied limitation on GSK's undisputed Patent Act right to disclaim. Letting a jury decide that disclaimer is unusual under industry practice is entirely irrelevant when disclaimer is a patent right, *and* the Agreement expressly contemplated the exercise of that right would result in the cessation of GSK's royalty obligation. If left undisturbed, that ruling would explode the doctrine of the implied covenant. Why enter into a contract if the contract can be undone by a jury?

1. The Agreement Leaves No Gap

DRIT's implied-covenant claim fails at the threshold: the Agreement contains no gap to fill. Sections 1.49 and 3.4 of the Agreement expressly authorize

GSK to stop paying royalties upon disclaimer of the '092 Patent. That authorization was the reason the Superior Court rejected DRIT's breach-of-contract claim. A149-50. Under settled Delaware law, that holding should have ended DRIT's breach-of-implied-covenant claim, too.

a. The Patent Act confers a host of rights upon patentees—including the right to disclaim the patent at any time, for any reason. First, "[a] patentee . . . may, on payment of the fee required by law, make disclaimer of any complete claim." 35 U.S.C. § 253(a). That right is often called a "statutory disclaimer" and allows a patentee to give up some or all of the *claims* of a patent (*i.e.*, the individual property rights conveyed by the patent). Second, a "patentee . . . may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted." *Id.* § 253(b). That right is commonly called a "terminal disclaimer," and allows the patentee to give up some or all of the remaining *term* of the patent (*i.e.*, the patentee may cause the patent to expire earlier).

Had the Agreement sought to limit GSK's patent rights, particularly if it meant forcing GSK to keep paying royalties on a disclaimed patent, the Agreement could and would have said so expressly. Instead, the Agreement acknowledges GSK's pre-existing disclaimer rights by expressly *eliminating* disclaimed patents from GSK's royalty obligations. Section 3.4 obligates GSK to pay royalties only

"until expiration of the last Valid Claim" of the '092 Patent. A085 (§ 3.4). Section 1.49 defines "Valid Claim" as:

> a claim of an issued, unexpired patent within the Patent Rights that has not expired, lapsed, or been cancelled or abandoned, and that has not been dedicated to the public, *disclaimed*, or held unenforceable, invalid, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal can be taken or was timely taken, including through opposition, re-examination, reissue or *disclaimer*.

A083 (emphases added).

Unquestionably, the terms "disclaimed" and "disclaimer" in section 1.49 acknowledge GSK's pre-existing right to disclaim the '092 Patent. By contemplating that "a claim" may be "disclaimed," the Agreement recognizes GSK's right under the Patent Act to "make disclaimer of any complete claim," 35 U.S.C. § 253, as well as the related right to terminally (*i.e.*, partially) disclaim the patent, *id.* § 253(b). Nor does the Agreement limit GSK's rights under the Patent Act. Thus, the Superior Court dismissed DRIT's breach of contract claim because there is no "express contractual restriction or limitation on [GSK's] ability to disclaim [its] rights to patents," and "once [GSK] disclaimed the patent rights covering Benlysta, [GSK was] no longer required under the Settlement Agreement to pay royalties." A149-50.

Section 1.49's language is particularly illuminating because the parties could have easily drafted language restricting GSK's patent-disclaimer rights. A court

"should be most chary about implying a contractual protection when the contract could easily have been drafted to expressly provide for it." *Nationwide Emerging Managers, LLC v. Northpointe Holdings, LLC*, 112 A.3d 878, 897 (Del. 2015) (quotations omitted). Both Biogen and GSK were sophisticated parties that were well aware of a patent owner's rights under the Patent Act, and they could have limited GSK's exercise of its right to disclaim its patent. Instead, the Agreement treats disclaimer in the same way that it treats contingencies like the patent's invalidation by a court—as a potential future event that would end GSK's royalty obligations.

b. DRIT contended below that the Agreement implicitly prohibited GSK from disclaiming its patent for the purpose of terminating royalty payments because the Agreement does not state something like, GSK may "disclaim royalty bearing patents to cut off royalty payments." A253. That is silly. Elimination of a Valid Claim ended royalties on that claim, by the Agreement's express terms. GSK was not required to tell Biogen or its lawyers the scope of GSK's patent rights, let alone that the Agreement expressly stated the consequences of GSK exercising those rights.

2. No Evidence Suggests That GSK Would Have Agreed to Limit Its Patent Disclaimer Rights

The implied covenant independently is inapplicable as a matter of law because DRIT adduced *no* evidence suggesting that GSK would have agreed to

limit its right to disclaim its patent. Courts imply terms only if it is clear that *both* parties would have agreed to the term at the time of contracting. *See Fisk*, 2008 WL 1961156, at *10; *Nationwide*, 112 A.3d at 897. Evidence that Biogen would have insisted on a limit to GSK's disclaimer rights is insufficient unless DRIT also established that GSK would have agreed to such a limitation. DRIT failed to carry that burden.

a. No evidence, let alone a preponderance of evidence, suggests that GSK would have agreed to limit its right to disclaim the '092 Patent if its royalty payouts to DRIT exceeded the patent's value to GSK. The most significant evidence showed the opposite—section 1.49 of the Agreement itself makes clear that GSK wanted to retain its patent disclaimer rights without limiting those rights in any way. And it makes no sense that GSK implicitly agreed to limit its right to disclaim in order to end royalty payments in a provision that was all about contingencies that would end GSK's royalty obligation. Further, GSK patent attorney Dr. Michelle Wales, who participated in negotiating the Agreement for GSK, testified that the parties drafted the Valid Claim provision of section 1.49 specifically to "cover every possible way [GSK] could envision a patent could be abandoned." A730; *see also* A668 (GSK sought to preserve the "ability to terminate the patent at any stage").

Those expectations make sense in light of GSK's and Biogen's incentives during the negotiations. At that time, Biogen had a patent, but did not know whether that patent would survive the interference proceeding, and had no prospect of its own Lupus treatment. On the other hand, GSK had a high prospect of a valuable Lupus drug—Benlysta—but was uncertain whether the PTO would grant the '092 Patent application, whether the PTO would extend the patent's term, whether a court might invalidate the patent, or whether GSK would even need the patent if no other competitors were on the horizon.

Both parties therefore agreed to a mutually beneficial payment structure. In exchange for relinquishing its patent rights, Biogen received upfront multimillion dollar payouts from GSK and the potential for additional royalties contingent on Benlysta sales for as long as the '092 Patent's claims remained in effect. In turn, GSK obtained assurance that it could launch Benlysta unhindered by Biogen's Patent, while protecting itself against liability for royalties in the event the '092 Patent turned out to be unenforceable or of limited value.

The Superior Court turned this carefully-constructed bargain on its head by re-writing the Agreement: the terms expressly eliminating royalties by disclaimer of an otherwise Valid Claim became, in effect, "disclaimer does *not* eliminate royalties on a Valid Claim (but all other contingencies in Section 1.49 still do)." No evidence supports insertion of this contra-textual proposition.

b. Below, DRIT contended that Biogen never would have signed an Agreement that did not implicitly limit GSK's patent disclaimer rights. A274-75. And the Superior Court agreed, explaining that "if Biogen knew the Defendants had even contemplated using a statutory disclaimer as a means to end royalty payments, Biogen" would have considered "not entering into the Settlement Agreement." Ex. A (MSJ Opinion) at 20. But DRIT, as the party seeking to invoke the implied covenant, must prove a *meeting of the minds* on that implied term—not that only one party would not have signed the agreement as written. *See Allen*, 113 A.3d at 184; *Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 146 (Del. Ch. 2009); *Fisk*, 2008 WL 1961156, at *10. Otherwise, one party could always claim that the implied term was necessary to its agreement, no matter how overwhelming the evidence that the other party never would have agreed to the implied term.

The closest DRIT came below to suggesting that GSK would have agreed to limit its disclaimer rights was to contend that Biogen had leverage over GSK during negotiations because the PTO designated GSK the party having the burden of proof (*i.e.*, the "junior party") in the interference proceeding. A853-54. But DRIT failed to link that fact with evidence that *GSK believed* that Biogen was likely to prevail in the interference and thus deferred to Biogen's wishes by limiting its Patent Act disclaimer rights. Rather, the only evidence presented at

trial on who was likely to win the interference corroborated GSK's belief that it held a stronger position: a neutral arbitrator had concluded that GSK would have won. A647-48; A653-54. DRIT quibbled with the form of this arbitration but never entered any evidence to undermine GSK's beliefs. Anyway, the competing leverage points resulted in an Agreement that "priced in" GSK's Patent Act disclaimer rights *without* any limitation.

DRIT similarly contended that Biogen had leverage to insist on limits to GSK's patent disclaimer rights because, if the PTO deemed *Biogen*'s patent valid and not GSK's, Biogen could have blocked GSK's launch of Benlysta. A853-54. But DRIT is wrong that Biogen could have blocked Benlysta's launch even had Biogen prevailed in the interference. Because there was no other viable Lupus drug, Biogen was unlikely to obtain an injunction blocking patient access to Benlysta. *See High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556-57 (Fed. Cir. 1995). Again, on its face, the Agreement's upfront payments and conditional royalty provisions "priced in" whatever actual leverage Biogen had in the negotiations.

Finally, DRIT contended below that sections 7.2 and 7.5 of the Agreement show that Biogen would not have accepted GSK's unqualified patent-disclaimer rights. A274-75. Sections 7.2 and 7.5 provide that in the event of a material breach of the Agreement, royalties would continue for any product "covered by a

Valid Claim" of the '092 Patent. A093-94. These sections do not undercut the parties' agreement in section 1.49 that royalty payments would stop if certain events, including disclaimer, came to pass—rather, they affirm it by using the express term "Valid Claim."

3. The Parties' Reasonable Expectations Included the Possibility of GSK's Disclaimer

DRIT's implied-covenant claim falters for an additional, independent reason: it was entirely foreseeable that GSK would statutorily disclaim the '092 Patent. And the "implied covenant only applies to developments that could not be anticipated, not developments that the parties simply failed to consider." *Nemec*, 991 A.2d at 1126. That inquiry looks to whether it was *objectively* reasonable for the parties to anticipate the development, not whether they actually did so. *See id*.

a. Section 1.49 of the Agreement listed a host of developments that could terminate the '092 Patent and GSK's royalty obligations. Just as the parties foresaw that GSK might "disclaim" the patent, DRIT does not dispute that the parties foresaw other ways that the Agreement called for royalties to cease. Section 1.49 contemplates that the '092 Patent might be "abandoned." The section also envisions that the patent could be "held unenforceable, invalid, or cancelled by a court or administrative agency." Indeed, the section even calls for royalties to cease if GSK had "dedicated [the patent] to the public." Clearly, the parties foresaw many ways by which GSK, the PTO, or courts could terminate the '092

Patent, and understood each equally to end royalty obligations. It would have been objectively unreasonable for Biogen to write off the possibility of a disclaimer, because the Agreement expressly lists that contingency as one of many events that would unambiguously end GSK's royalty obligations.

Trial testimony from DRIT's experts underscores the point. DRIT's experts conceded that section 1.49 put Biogen on notice that GSK could terminally disclaim the '092 Patent (*i.e.*, disclaim the patent's remaining term) when GSK learned that the '092 Patent would be defective as of October 2016. *Infra* pp. 44-45. But if Biogen could have foreseen that GSK might relinquish the tail end of the patent term, section 1.49 should equally have alerted Biogen to the possibility that GSK would *statutorily* disclaim the patent (*i.e.*, formally relinquish all rights to the patent). Nothing in section 1.49 makes one form of disclaimer more legitimate than the other. The Patent Act recognizes both types of disclaimers as part of a patent-holder's bundle of rights and describes both in similarly unqualified terms. *See* 35 U.S.C. § 253. Both disclaimer rights effectively make patents expire early, so for DRIT to characterize terminal disclaimer as foreseeable but statutory disclaimer as "unheard of" strains credulity. *Infra* p. 37, 44-45.

b. Below, DRIT contended that section 1.49's reference to "disclaimer" did not do enough to put Biogen on notice that GSK might disclaim its patent *to avoid royalty payments*. A268-69. But that makes no sense. The whole point of section

1.49 was to allow GSK to terminate its royalty payments if certain events, like disclaimer, came to pass. As a sophisticated entity with an extensive portfolio of patents and access to patent lawyers, Biogen obviously knew of the rights that patent law vests in patent-holders and could not have been surprised by GSK's exercise of those rights consistent with patent law. At the very least, Biogen knew what the Agreement said.

DRIT nonetheless argued that Biogen and GSK could not have foreseen that GSK would file a statutory disclaimer (*i.e.*, full relinquishment of all patent rights), because those disclaimers are unusual in the industry. A284. And the Superior Court agreed, finding "that the statutory disclaimer was such an unusual event that it would not have been reasonably anticipated by the parties." Ex. B (JMOL Opinion) at 5. But evidence that statutory disclaimer is unusual in "standard situations" (as DRIT's expert Johnson testified) does not shed light on the key question here: whether *these parties* could reasonably have foreseen, in the context of this Agreement, that GSK could statutorily disclaim the '092 Patent if GSK's royalty payments exceeded the patent's utility to GSK. *Infra* p. 37-38.

4. Cases Limiting a Party's Exercise of Discretionary Contractual Rights Are Inapplicable

The Superior Court's implied-covenant analysis rested on the theory that, while the Agreement expressly recognized GSK's right to disclaim its patent, that right was discretionary and thus subject to an implicit requirement that GSK

exercise the right "reasonably" and in good faith. Ex. A (MSJ Opinion) at 12, 18-20. That holding seriously misapplies the implied-covenant doctrine.

a. The rule that contracts affording one party discretion over a particular matter require that discretion to be exercised in good faith applies only when the *contract itself* creates discretionary rights. *See Airborne Health*, 984 A.2d at 147 & n. 1 (Del. Ch. 2009); *Amirsaleh v. Bd. of Trade of City of N.Y., Inc.*, 2008 WL 4182998, at *8 (Del. Ch. Sept. 11, 2008). That rule does not apply here, where the Agreement merely recognized GSK's pre-existing right under the Patent Act to disclaim its patent.

The Superior Court's cited authorities, Ex. A (MSJ Opinion) at 12-13, 18-19, underscore this point. For example, the implied-covenant doctrine applied to the agreement in *Amirsaleh* because the contract gave the defendants complete discretion over when to set a particular deadline required under their contract. *See* 2008 WL 4182998, at *1-*3, *8. The court treated this term as an instance where the agreement "explicitly defer[ed] key decisions" and "endow[ed] one side or the other with the discretion and authority to make those decisions during the course of performance." *Id*. Because the contract was the source of this discretion, the court presumed that "parties never accept the risk that their counterparties will exercise their *contractual* discretion in bad faith." *Id*. (emphasis added). Likewise, in *Charlotte Broad., LLC v. Davis Broad. of Atlanta, L.L.C*, 2015 WL 3863245 (Del.

Sup. Ct. June 10, 2015), the court applied the implied covenant because the relevant agreement authorized either party, "in its sole discretion," to terminate the agreement. WL 2015 3863245, at *7. Thus, where the contract itself creates a discretionary right, courts have incorporated the implied covenant as a background constraint to ensure the exercise of that discretion consistently with the contract's other terms.

Those cases do not apply to pre-existing rights that a contract recognizes but does not create, like GSK's patent disclaimer rights. Patent law defines the scope of those incorporated rights, and imposes no limitations on their exercise. Indeed, such limitations would be antithetical to the nature of patent rights; patents are limited in duration but allow for absolute monopoly rights while in effect. By enshrining GSK's right to disclaim in the Agreement, section 1.49 neither gave GSK a discretionary right that it did not already possess nor limited GSK's pre-existing patent rights.

b. Further, this Court "ha[s] declined in other cases to imply new contract terms merely because a contract grants discretion to" one party. *Oxbow*, 202 A.3d at 503. First, courts can imply good-faith requirements only if "the discretion has been used in a way that is impliedly proscribed by the contract's express terms." *Id.* at 504 n. 93. Second, "[a] party does not act in bad faith by relying on contract

provisions for which that party bargained where doing so simply limits advantages to another party." *Nemec*, 991 A.2d at 1127 n.23, 1128.

Here again, the Agreement expressly recognizes GSK's right to disclaim its patent. And nothing in the "express terms" of the Agreement implicitly limits that right; to the contrary, section 1.49's reference to the royalty term provides clarity that GSK could exercise its disclaimer right to eliminate the royalty obligation. Moreover, that GSK's disclaimer of the '092 Patent "limit[ed] advantages to [DRIT]" does not mean GSK acted in bad faith. *Id.* Contracts often contain provisions that terminate royalties or otherwise allocate benefits to the parties to the agreement. Those provisions must be enforced to preserve "the value that flows from interpreting clear contracts as written." *Allied Capital Corp.*, 910 A.2d at 1025.

II. The Improper Admission of Johnson's Prejudicial Testimony Warrants a New Trial

A. Question Presented

Whether the Superior Court abused its discretion in refusing to order a new trial in light of Johnson's irrelevant and highly prejudicial expert testimony. (Preserved A334-42; A824-30.)

B. Scope of Review

This Court reviews the Superior Court's denial of a motion for a new trial for an abuse of discretion. *Dunn v. Riley*, 864 A.2d 905, 906 (Del. 2004). A new trial must be ordered if the trial court improperly admitted evidence and the "mistakes constituted significant prejudice so as to have denied the appellant a fair trial." *Barriocanal v. Gibbs*, 697 A.2d 1169, 1171 (Del. 1997) (quotations omitted).

C. Merits of the Argument

Johnson provided extensive expert testimony at trial that GSK's statutory disclaimer of the '092 Patent was contrary to amorphous, unwritten industry "norms." DRIT offered this testimony to support what it described as a "central issue in this case—whether GSK exercised its discretion to disclaim the '092 Patent in bad faith." A389. Johnson's testimony was, in particular, critical to the Superior Court's conclusion that that "the statutory disclaimer was such an unusual

event that it would not have been reasonably anticipated by the parties." Ex. B (JMOL Opinion) at 5.

Johnson's testimony had nothing to do with GSK's and Biogen's expectations *in this case*, the only relevant legal inquiry. Relying on his unwritten "industry norms"—especially given his concession that the Agreement here involved an atypical situation—was irrelevant, confusing, and highly prejudicial, warranting a new trial.

1. Johnson's testimony was inadmissible under Delaware Rule of Evidence 702. Under Rule 702, expert testimony "requires a valid . . . connection to the pertinent inquiry as a precondition to admissibility." *M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 523 (Del. 1999) (internal quotations omitted). Absent this "special nexus" to the facts of the case, expert testimony confuses or misleads the jury and unduly prejudices the opposing party. *Wheat v. State*, 527 A.2d 269, 274 (Del. 1987).

Invoking Rule 702, this Court has repeatedly rejected generalized expert testimony that fails to take into account the facts of a particular case. In *Eskin v. Carden*, for example, this Court rejected expert testimony that an automobile accident did not injure the plaintiff because, in general, such accidents were unlikely to cause the extent of injuries the plaintiff suffered. 842 A.2d 1222, 1226-32 (Del. 2004). The Court reasoned that the proffered testimony failed to connect

general conditions to the "particular 'abnormal' human body" at issue. *Id.* at 1231. Admitting expert testimony about "the norm," this Court explained, "would have unfairly prejudiced [the plaintiff] who . . . did not have a normal, average human body, at the time of the accident." *Id.* at 1232; *see also Mason v. Rizzi*, 89 A.3d 32, 37-38 (Del. 2004) (failure to tie expert testimony to plaintiff's unique medical history); *Crowhorn v. Boyle*, 793 A.2d 422, 433 (Del. Super. Ct. 2002) (similar).

Here, Johnson's testimony fits precisely that improper mold. Johnson testified extensively to his opinion that GSK's statutory disclaimer of the '092 Patent was "inconsistent with industry norms." A535-36. According to Johnson, even if GSK believed the '092 Patent was defective, the "industry norm" would have been for GSK to either maintain the '092 Patent until its natural expiration, or "terminally" disclaim the patent, *i.e.*, disclaim part of the end of the patent term. A609-10.

But Johnson declined to tie his testimony to the parties' expectations *in this case*, confining his analysis to so-called "standard situations." A572-73. Johnson acknowledged that he did not "undertake to try to analyze the license agreement" and that his "testimony was not intended to be expert testimony as to the specific license agreement terms of this case." A573.

Critically, Johnson conceded that the circumstances of this Agreement materially departed from the "standard situations" he outlined to the jury. Johnson

agreed that the Agreement was "a different situation than the normal patent license," explaining that it "stemmed from the settlement of an interference, whereas most license agreements don't involve interferences." A570. That is no slight difference. Johnson explained that "in most license agreements, the patent owner is the one who . . . receives the royalty"; here, however, the patent owner "is also the party paying, not receiving." A570-71. While it might be unusual for a patent owner to disclaim a patent on which the owner is *receiving* royalties, the incentives flip when the patent owner is *paying* the royalties on the patent. Instead of serving as a source of revenue that the patentee would desire to maintain as in most license agreements, the '092 Patent was a *cost* that GSK had a rational—and foreseeable—incentive under the Agreement to limit via disclaimer.

Johnson's failure to tie his testimony to the Agreement rendered his opinion irrelevant and misleading to the jury. Whether it is unusual generally to statutorily disclaim a patent is irrelevant to whether, in the unusual circumstances of this Agreement, GSK and Biogen could have anticipated that GSK could disclaim the '092 Patent. *See Eskin*, 842 A.2d at 1232 ("[The expert's] testimony, focused on the norm, would have unfairly prejudiced [the plaintiff] who . . . did not have a normal, average human body . . . ."); *Mason*, 89 A.3d at 37-38 (similar). The Superior Court should have excluded Johnson's "one-size-fits-all" theory of statutory disclaimer.

The Superior Court nonetheless deemed Johnson's testimony admissible solely because of his "45 years of practice in the intellectual property area." Ex. B (JMOL Opinion) at 7. But "to conclude that the trial judge's role as the gatekeeper for scientific or technical expert opinion testimony is fulfilled by concluding, without more, that an individual who is properly credentialed in a recognized field of expertise will present a reliable expert opinion, is entirely too facile." *Mason*, 89 A.3d at 37; *see Eskin*, 842 A.2d at 1228. Johnson's qualifications do not grant him free reign to offer irrelevant and misleading expert opinions, and the Superior Court erred in holding otherwise.

2. Johnson's expert testimony severely prejudiced GSK and warrants a new trial. The implied covenant of good faith requires "assess[ing] *the parties'* reasonable expectations at the time of contracting." *Nemec*, 991 A.2d at 1126 (emphasis added). But Johnson "confuse[d] the issue by shifting the fact finders' attention from the particular to the universal." *Mason*, 89 A.3d at 37. By extensively testifying to unwritten industry "norms" in a vacuum divorced from the Agreement at issue, Johnson blurred the distinction between the expectations of the parties to *this* Agreement and the expectations of those involved in the field of intellectual property generally. That the Superior Court eventually instructed the jury to consider the expectations of the parties, A782, means nothing when DRIT spent the entire trial confusing the jury as to how to evaluate those expectations.

Worse, Johnson's testimony introduced confusion into the central issue of whether GSK's statutory disclaimer constituted bad faith. *See R.T. Vanderbilt Co. Inc. v. Galliher*, 98 A.3d 122, 129 (Del. 2014) ("[T]he erroneous admission of the statements by [plaintiff's expert] was especially problematic because the statements went to the core of [defendant's] case."); *Cooney-Koss v. Barlow*, 87 A.3d 1211, 1217 (Del. 2014) (similar). DRIT presented no evidence that GSK's statutory disclaimer was unforeseeable to the parties at the time of contracting. DRIT instead relied exclusively on Johnson's testimony about "industry norms" to fill that void. Aggravating the problem, DRIT's counsel repeated Johnson's testimony that GSK acted contrary to industry norms *seven* times during his closing argument in statements like, "Mr. Johnson, an incredible industry expert, told you how unusual this was. His testimony was unrebutted." A750, A752, A756-57, A758, A764, A766, A770. The Superior Court therefore relied on that evidence alone when evaluating the parties' expectations in its denial of GSK's motion for judgment as a matter of law. Ex. B (JMOL Opinion) at 5. The admission of Johnson's testimony was a clear abuse of discretion that warrants a new trial.

III. This Court Should Vacate The Superior Court's Damages Determination

A. Question Presented

Whether the Superior Court erred (1) by assessing millions of dollars in expectation damages by declining to consider actions GSK would have taken had it not statutorily disclaimed the '092 Patent and (2) independently by making a clear legal error in identifying the patent's expiration date. (Preserved A888-97.)

B. Scope of Review

This Court reviews the Superior Court's factual findings for clear error and its damages award for abuse of discretion. *Bhole, Inc. v. Shore Invs., Inc.*, 67 A.3d 444, 449 (Del. 2013).

C. Merits of the Argument

The Superior Court handed DRIT a massive and unjustifiable windfall by compelling GSK to pay some $100 million in royalties through August 2022. *First*, undisputed trial evidence showed that, had a statutory disclaimer been unavailable, GSK could and would have "terminally" disclaimed the '092 Patent in October 2016 based on defects in the patent and ended royalty payments at that time. No matter what, DRIT would not have received tens of millions of additional dollars in royalties through August 2022, when the patent term would otherwise have expired. *Second*, the Superior Court's damages award independently warrants vacatur because the court completely bypassed the critical

question for expectation damages: how long the parties at the time of the Agreement would have expected the patent term to extend, at a time when the PTO had yet to grant any patent. The court assumed that patent terms run from the date the patent application is *granted*, but, by statute, patent terms actually run from the *filing* date and can be extended by the PTO to account for processing delays.

1. GSK Would Have Terminated DRIT's Royalties Even If Statutory Disclaimer Were Unavailable

The damages award never should have extended beyond October 2016; the most DRIT could receive would be damages for the period from April 2015 to October 2016. Damages for breach of contract "give the nonbreaching party the benefit of its bargain by putting that party in the position it would have been but for the breach." *Genencor Int'l, Inc. v. Novo Nordisk A/S*, 766 A.2d 8, 11 (Del. 2000). Courts thus look to the "'but-for' world—*i.e.*, the hypothetical world that would exist if the Agreement had been fully performed." *eCommerce Indus., Inc. v. MWA Intelligence, Inc.*, 2013 WL 5621678, at *43-44 (Del. Ch. Sep. 30, 2013); *Umbach v. Carrington Inv. Partners (US), LP*, 851 F.3d 147, 165 (2d Cir. 2017) (Delaware law prescribes assessment of but-for conditions). Otherwise, the promisee could claim windfall damages far beyond what it could reasonably have expected by ignoring the actions the promisor would have taken—consistent with the agreement—to optimize its position.

In *Paul v. Deloitte & Touche, LLP*, for instance, this Court rejected the notion that an improperly terminated employee was entitled to expectation damages for his salary up to his mandatory retirement age. 974 A.2d 140, 144 (Del. 2009). Because the employer could and would have properly terminated the employee well before his retirement date during his probationary period, the employee could only have reasonably expected damages through the end of that period. *Id.* at 147.

Here, even had GSK breached the implied covenant through its statutory disclaimer (it did not), GSK undisputedly retained the right to lawfully disclaim the '092 Patent via a *terminal* disclaimer (*i.e.*, cause the patent to expire earlier), which GSK would have done by October 2016 in light of a defect in the patent. The terminal disclaimer, once effective, would have terminated GSK's royalty obligations to Biogen under section 1.49. A083; A085. In the "but-for" world that would exist absent GSK's purported breach of the Agreement, DRIT would never have received royalties past October 2016. *Umbach*, 851 F.3d at 165; *eCommerce Indus.*, 2013 WL 5621678, at *43-44. DRIT's reasonable expectation of royalties thus ended by that date.

The undisputed trial evidence shows why. GSK's '092 Patent had a defect that had become apparent by April 2015: GSK owned an earlier patent called the '770 Patent, which had claims similar to those of the '092 Patent. That created an

"obviousness-type double patenting" defect in the '092 Patent, *i.e.*, the claims of the '092 patent were obvious based on what was shown in GSK's '770 Patent and thus unjustifiably extended the monopoly the '770 Patent granted. At trial, DRIT never disputed that the '092 Patent had this defect or that GSK was aware of it. A462-63; A503; A511; A545.

DRIT further conceded below that GSK could have reasonably addressed that defect by filing a terminal disclaimer, *i.e.*, disclaiming only the tail end of the patent term. Had GSK filed a terminal disclaimer, GSK could make the '092 Patent expire at the same time as the earlier, '770 Patent, thereby extinguishing the improper extension of the earlier patent's monopoly. *See generally Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1346-50 (Fed. Cir. 2010). The '770 Patent expired in October 2016, so GSK could have filed a terminal disclaimer of the '092 Patent by October 2016 to resolve the defect. A463-65; A552-53; A643.

Undisputed trial evidence shows that, were statutory disclaimer unavailable, GSK could have terminally disclaimed the '092 Patent without breaching any implied covenant. DRIT's patent procedure expert recognized that filing a terminal disclaimer was "a common way" or even "[t]he accepted practice" to resolve the defect in the patent. A468-69; A472; A501. Likewise, DRIT's expert Johnson repeatedly confirmed that "one of the options" that would have "been

within industry norms" was for GSK to file a terminal disclaimer in response to the defect. A606; A609-10. Even if doing nothing would have been the "preferred" option, DRIT's experts' testimony that filing a terminal disclaimer was an "accepted" option "within industry norms" forecloses any argument that the parties could not have expected such a disclaimer.

The undisputed record is equally clear that GSK would have filed a terminal disclaimer of the '092 Patent by the time the '770 Patent expired in October 2016 if GSK could not simply disclaim the whole patent term through a statutory disclaimer. GSK chose to file a statutory disclaimer over a terminal disclaimer only because the former allowed it to terminate royalties sooner. Facing a choice between (a) filing a terminal disclaimer and terminating royalties or (b) doing nothing and paying millions of dollars in further royalties, GSK—like any rational actor—would have picked the former. A700-02.

Thus, whatever the propriety of GSK filing a *statutory* disclaimer of the '092 Patent, filing a *terminal* disclaimer by October 2016 remained an industry-accepted option (even according to DRIT) that GSK could and would have pursued. The Superior Court clearly erred in assessing damages for royalties far beyond October 2016 and holding GSK liable for royalties until the '092 Patent would have expired in August 2022. Ex. B (JMOL Opinion) at 8-12; Ex. C (Judgment) at 3; A525.

2. The Superior Court's Damages Award Rests on an Undisputedly Flawed Legal Premise

At a minimum, this Court should vacate the Superior Court's damages determination and remand for further proceedings because the court's award of damages rested on a basic error of patent law.

a. By statute, the standard term for a patent is 20 years from the filing date of the application. 35 U.S.C. § 154(a)(2). Thus, absent later correction, PTO delays in examining a patent application shorten the patent term for the ultimately issued patent—*i.e.*, if the PTO takes three years to examine an application, the patentee loses three years of patent exclusivity. *See Pfizer, Inc. v. Lee,* 811 F.3d 466, 468 (Fed. Cir. 2016). To account for any undue delays in patent examination caused by the PTO, the PTO extends the standard 20-year term of a patent in the event of examination delays. *See* 35 U.S.C. § 154(b). The PTO's extensions vary based on the facts underlying various delays; the PTO calculates the patent-term adjustment when "patent is ready to issue." *Pfizer*, 811 F.3d at 469.

Here, GSK's effective filing date for the '092 Patent was October 1996, so the '092 Patent's standard expiration date was October 2016, or 20 years later. But the PTO did not issue the '092 Patent until December 2011. A441-43; A449. The PTO accounted for its delay by granting a modified expiration date for the '092 Patent of August 2022. A452. Critically, however, the PTO did not make this modification until February 2015. A120; A127.

Thus, when the parties executed the Agreement in 2008, it was unclear whether the PTO would grant the ’092 Patent, let alone when it would expire. The duration of GSK’s royalty obligations under the Agreement remained unfixed, because the Agreement required GSK to pay royalties until the last “Valid Claim” of the ’092 Patent expired (or other contingencies pretermitted those royalty obligations). In other words, obligating GSK to pay royalties until the expiration of the last Valid Claim did not specify how much royalties GSK would owe.

To calculate damages for a breach of that license agreement, therefore, the critical question was the parties’ expectations *in 2008* as to how long the PTO would likely extend the ’092 Patent term, assuming it granted GSK’s patent application. *See Duncan v. Theratx*, 775 A.2d 1019, 1022 (Del. 2001) (“[T]he standard remedy for breach of contract is based on the reasonable expectations of the parties *ex ante*.”). If the PTO did not modify the patent term, the ’092 Patent would have expired in October 2016.

b. The Superior Court’s analysis profoundly misunderstood this inquiry. The court concluded that the “expectation of the parties to the initial contract was that, in the absence of certain identified events, [DRIT] would continue to receive royalties until the patent expired, which would normally have been twenty years after the date it *took effect*.” Ex. B (JMOL Opinion) at 10-11 (emphasis added). But, by law, the standard patent term of 20 years commences on the date the patent

application is *filed*, not when the patent takes effect. 35 U.S.C. § 154(a)(2); *Pfizer*, 811 F.3d at 468.

This mistake short-circuited the Superior Court's entire damages inquiry. Because the Superior Court believed that patent rights extend for 20 years from the *grant* of a patent, it assumed that the parties expected 20 years of royalties, no matter when the patent was granted or how much of an adjustment the PTO made to the patent term. Ex. B (JMOL Opinion) at 11 ("The fact that there was a delay in the issuance of the patent by the patent office simply delayed when the royalties would begin."). Thus, the court never considered the parties' expectations in 2008 as to how the PTO might adjust the patent-term period.

Because the Superior Court's damages calculations rested on a clearly erroneous legal premise, this Court should at a minimum vacate the award and remand for further proceedings.

CONCLUSION

This Court should reverse the Superior Court's denials of GSK's Motion for Summary Judgment and Motion for Judgment as a Matter of Law or New Trial, or at least vacate the Superior Court's damages award.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 7, 2020, a copy of the foregoing was served by LexisNexis File & Serve on the following attorneys of record:

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