**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Plaintiff,

v.

HOSPIRA WORLDWIDE, INC., and HOSPIRA, INC.,

Defendants.

No. 13 CV 4346

Judge Manish S. Shah

**MEMORANDUM OPINION AND ORDER**

In late 2010, GlaxoSmithKline and Hospira entered into an agreement for Hospira to manufacture GSK's flu vaccine, but the parties stopped working together within two years. GSK sued for breach of contract, promissory estoppel, quantum meruit, and unjust enrichment, and Hospira counterclaimed for breach of contract, quantum meruit, and unjust enrichment. [50]; [63].[1] Hospira now moves for summary judgment on GSK's claims. [110].

For the following reasons, summary judgment is granted on Count III (quantum meruit and unjust enrichment) and denied on Counts I and II (breach of contract and promissory estoppel).

[1] Bracketed numbers refer to entries on the district court docket. Any document previously filed under seal and referenced in this opinion shall be unsealed. The parties shall file a joint statement listing the applicable docket entries, and the Clerk's Office will then be directed to unseal those entries on the court's CM/ECF system. *See City of Greenville, Ill. v. Syngenta Crop Prot., LLC*, 764 F.3d 695, 697 (7th Cir. 2014). Subject-matter jurisdiction exists because GSK is from Belgium (GSK is a Belgian corporation with its principal place of business in Belgium), Hospira is from Delaware and Illinois (Hospira Inc. and Hospira Worldwide Inc. are Delaware corporations with their principal place of business in Illinois), [124] ¶¶ 1–3, and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332.

## I. Legal Standards

Summary judgment is appropriate if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A genuine dispute as to any material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Justifiable inferences are drawn in the nonmovant's favor, *id.* at 255, and the party seeking summary judgment has the burden of establishing that there is no genuine dispute as to any material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

## II. Background[2]

In 2006, the Food and Drug Administration licensed GSK to sell thimerosal-containing FluLaval TIV, a seasonal flu vaccine, to adults in multi-dose vials. [124] ¶ 8. ("TIV" stands for "trivalent influenza vaccine," consisting of three different virus strains; a "quadrivalent influenza vaccine" or "QIV" has four virus strains. [64] ¶¶ 10, 33.) GSK began to develop a version of FluLaval TIV without thimerosal (a mercury-containing preservative), which would be administered to patients as a

[2] [124] is GSK's response to Hospira's Local Rule 56.1 statement, and [135] is Hospira's response to GSK's statement of additional facts. Several of the parties' statements of facts are argumentative, and their responses, in many instances, are lengthy (e.g., one or two pages), overbroad, argumentative, or cite record evidence that does not properly controvert the factual statement. The purpose of Rule 56.1 is to permit the district court to identify at summary judgment which material facts are in dispute, and the parties' statements and responses are viewed with this principle in mind. Unless otherwise noted, the facts related below are undisputed or are considered undisputed because the responding party did not properly controvert the factual statement as required by local rule.

single dose in pre-filled syringes. [124] ¶¶ 9–10. On December 31, 2010, GSK and Hospira entered into a Toll Manufacturing Agreement. In the contract, GSK promised to supply Hospira with bulk vaccine and Hospira promised to "manufacture" the vaccine by filling syringes; the agreement's termination date was December 31, 2015. [124] ¶ 16; [115-14] at 6, 40. The toll agreement defined the "Vaccine Product" as "the GSK influenza vaccine product which includes the Bulk, filled and finished by Hospira." [115-14] at 11. ("Bulk" is defined as "the antigen component of the Vaccine Product." [115-14] at 7.)

Essentially, the toll agreement had two phases. [124] ¶ 24. FDA approval of Hospira's manufacturing process was required prior to commercial production, so the toll agreement required Hospira to complete validation work before it would be permitted to manufacture the vaccine for commercial use. [124] ¶¶ 23–24. In this validation or development phase, GSK agreed to transfer technical information to Hospira—as specified in the Technical Transfer Program (Schedule 4 to the toll agreement)—and Hospira agreed to perform validation work and prepare for technical regulatory filings to the FDA. [124] ¶¶ 23–24; [115-14] at 12–14. During this stage, Hospira was to be paid for nine milestones listed in Schedule 3. [124] ¶ 18; [115-14] at 51. According to the terms of the agreement, actual manufacture was conditioned on (a) GSK's approval of the first three validation batches and (b) GSK's receipt of approval from the FDA "to sell the Vaccine Product Manufactured by Hospira pursuant to this Agreement." [115-14] at 10. Hospira would then begin the commercial manufacturing process and receive payment per unit of vaccine

product; Schedule 2 provided prices for the 2013, 2014, and 2015 flu seasons. [124] ¶¶ 23–24; [115-14] at 10, 22–23, 47.

The parties signed the toll agreement on December 31, 2010, but eight of the nine development milestones in Schedule 3 had been scheduled for completion prior to that date (i.e., in November and December 2010). [124] ¶¶ 16, 26; [115-14] at 51. And Hospira missed those milestones before the parties' executed the contract (Hospira's initial validation work (a "consistency campaign") was unsuccessful). [124] ¶ 25. The last milestone—preparation and review for the regulatory filing—was to be completed in 2011. [124] ¶ 19. The toll agreement stated that GSK could refuse payment for a milestone invoice "only if it is not substantially complete, requires material corrections or if the relevant milestone has not been completed according to the Technical Transfer Program [Schedule 4] criteria." [124] ¶¶ 20–21; [115-14] at 52. GSK paid all but one of Hospira's milestone invoices, but GSK points to evidence suggesting that Hospira did not invoice GSK for all of the milestones, discounted several invoices, and did not seek payment according to the milestone schedule. [124] ¶ 22. GSK temporarily suspended the project in February 2011, but did not terminate it. [124] ¶¶ 27–28. Following a series of engineering trials and some process changes, GSK elected to continue the project, and Hospira resumed its work around April or May 2011. [124] ¶ 30.

Separately, GSK attempted to obtain a pediatric indication for thimerosal-free (i.e., mercury-free) TIV. [124] ¶ 33. GSK made its FDA submission in August 2010 and expected to receive approval in June 2011. [124] ¶ 34. But in February

2011, the FDA informed GSK that it had failed to satisfy the efficacy requirement and could not obtain the desired pediatric indication for TIV without efficacy data from a QIV study; these study results were not expected until 2012 or 2013. [124] ¶¶ 35–37. During the following months, GSK attempted to seek a pediatric indication for TIV through an accelerated approval process, but was unsuccessful. [124] ¶ 38.

By the fall of 2011, GSK recognized that it was unlikely to obtain a pediatric indication for TIV in time for the 2012 or 2013 flu season. [124] ¶ 45. GSK's vaccine team reported internally that without the pediatric indication, thimerosal-free TIV would be of "no interest" because it had "no value" to the U.S. market. [124] ¶¶ 40–41.[3] Around this time, GSK also learned that the QIV study results would be available earlier than expected, allowing GSK to launch its QIV product in 2014, a year ahead of schedule. [124] ¶ 43. Hospira was not involved with GSK's pursuit of a pediatric indication, and GSK did not share information with Hospira about its pursuit of a pediatric indication or its commercial evaluation of an adult-only, thimerosal-free TIV product. [124] ¶¶ 39, 42.

In October 2011, GSK audited Hospira's plant. [124] ¶ 49. The audit found no "critical" observations but did find some "major" observations, concluding that the plant was not on track to support the submission of technical filings to the FDA and

[3] Although not disputing that this was its commercial evaluation, GSK has identified evidence in the record suggesting that it still might have submitted technical data for an adult-only TIV (which was awaiting successful validation data from Hospira) because it would have laid the groundwork for a future pediatric indication. [124] ¶¶ 40–41, 43–45. GSK also points to evidence suggesting that the launch window for TIV had been shortened by Hospira's failure to meet scheduling deadlines. [124] ¶¶ 43–45.

was not ready for an FDA pre-approval inspection; ultimately, GSK did not approve the plant for commercial manufacture. [124] ¶¶ 50–51; [135] ¶ 19. At the time, Hospira disputed GSK's observations and GSK's claim that Hospira's plant would not be read for a pre-approval inspection by the FDA. [124] ¶ 53; [135] ¶ 20. The parties dispute whether these audit findings were directed at manufacturing the TIV product specifically or were directed at the syringe-filling process more generally. *See* [124] ¶ 51.

In November 2011, GSK's Vaccine Development & Commercialization Board formally decided to delay submission of the TIV file and decided that TIV would not be launched in 2013. [124] ¶¶ 46–48.[4] The parties dispute whether this decision was the result of GSK's failure to obtain a pediatric indication for TIV, the issues and delays with Hospira's validation work, or a combination of both circumstances. *See* [124] ¶¶ 46–48; [135] ¶¶ 22, 25. GSK did not terminate the toll agreement in November 2011, and it did not provide Hospira with a notice and opportunity to cure in accordance with the contract. [124] ¶ 55.

After the board's decision, the parties' focus shifted to QIV. The parties began negotiations in November 2011 relating to QIV, and they submitted proposals, counterproposals, and price quotations, eventually meeting for discussions in

[4] GSK disputes that there was a TIV-specific FDA submission or project, arguing that the planned submission was the technical application to approve Hospira's syringe-filling process at Hospira, which would have been applicable to QIV. GSK's cited evidence indicates that GSK considered alternatives to delaying TIV prior to November 2011 and that GSK's eventual QIV technical submission was supported by some TIV data from Hospira, but GSK cites no evidence contradicting its vaccine board's repeated statements in November 2011 that submission of the TIV "file" would be delayed and that TIV would not be launched in 2013.

Belgium on December 6, 2011. [124] ¶¶ 60–61; [135] ¶ 27. Hospira asserts that GSK closed out the TIV project and was negotiating modifications to the toll agreement and its schedules for Hospira to manufacture QIV; GSK asserts that the toll agreement already covered Hospira's obligations for manufacturing QIV, and that the parties' negotiations were merely for ironing out technical details and pricing QIV validation work. [124] ¶¶ 58–70; [135] ¶¶ 26–27.

Through January and February 2012, GSK and Hospira were still discussing QIV validation work and costs. [124] ¶ 64. On March 22, 2012, Hospira informed GSK that the project needed to be stopped. [124] ¶ 71; [135] ¶¶ 29–30. By this time, Hospira had not made any QIV consistency batches (for the validation work), and GSK had not paid Hospira for any of Hospira's QIV-related prefatory work (and never did). [124] ¶ 74; [135] ¶ 31. Hospira asserts that it delayed the project to give the parties time to complete negotiations to modify the toll agreement before engaging in the QIV development and manufacturing work; GSK asserts that Hospira unilaterally terminated the toll agreement because it could not afford to devote resources to the project. [124] ¶¶ 71–72; [135] ¶¶ 28–29. GSK never brought TIV to the market, but did bring QIV to the market (without Hospira) in time for the 2014 flu season. [124] ¶¶ 75–76.

GSK then brought suit against Hospira in the Southern District of New York, asserting breach of contract (Count I), promissory estoppel (Count II), and quantum meruit and unjust enrichment (Count III). [1]; [50]. Hospira counterclaimed for breach of contract (Count I), quantum meruit (Count II), and unjust enrichment

(Count III) and successfully moved to transfer the case to this district. [23]; [63]. Hospira also moved to dismiss GSK's claims, but the motion was denied in an opinion also holding that New York law applies to the parties' breach of contract claims and Illinois law applies to their quasi-contract claims. [62] at 5–6.

## III. Analysis

### A. Breach of Contract Claim

GSK's breach of contract claim does not assert that it terminated the toll agreement pursuant to breaches by Hospira. Instead (as argued in briefing Hospira's motion to dismiss), GSK contends that New York law allows a non-breaching party to elect to continue the agreement (in lieu of termination) and sue for damages for interim breaches, if notice is given to the breaching party. Under this doctrine, GSK argues that it is entitled to damages for Hospira's failure to produce timely, acceptable TIV validation work and for Hospira's unilateral termination of the contract in 2012. Hospira seeks summary judgment on GSK's breach of contract claim, arguing that GSK relieved Hospira of its contractual obligations by stopping the TIV project before performance was due, that Hospira's conduct caused no injury because the TIV project was of no value to GSK without the pediatric indication, and that Hospira had no contractual obligations as to QIV because the parties' negotiations failed.

#### 1. *Scope of the Toll Agreement*

Hospira's arguments for summary judgment on GSK's breach of contract claim focus on whether the toll agreement encompasses both TIV and QIV. Hospira contends that QIV is not covered and that its contractual obligations ended when

GSK stopped the TIV project in November 2010, a month or two before Hospira's final development milestone was due. GSK responds that the toll agreement encompasses QIV (or at least is ambiguous) and therefore it can sue for breach relating to QIV, as well as earlier breaches regarding TIV validation work and preparedness for FDA submissions.

Under New York law, "the initial question for the court on a motion for summary judgment with respect to a contract claim is whether the contract is unambiguous with respect to the question disputed by the parties," which is a question of law. *Law Debenture Trust Co. of N.Y. v. Maverick Tube Corp.*, 595 F.3d 458, 465 (2d Cir. 2010) (marks omitted). "Where the language used is susceptible to differing interpretations, each of which may be said to be as reasonable as another, and where there is relevant extrinsic evidence of the parties' actual intent, the meaning of the words become[s] an issue of fact and summary judgment is inappropriate." *Seiden Assocs., Inc. v. ANC Holdings, Inc.*, 959 F.2d 425, 428 (2d Cir. 1992).

Language is not ambiguous simply because the parties urge different interpretations or where one party's view strains contractual language beyond its reasonable and ordinary meaning. *Seiden Assocs.*, 959 F.2d at 428. Instead, "[a]n ambiguity exists where the terms of the contract could suggest more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement and who is cognizant of the customs, practices, usages and terminology as generally understood in the

particular trade or business." *Law Debenture,* 595 F.3d at 466 (marks omitted). "Extrinsic evidence of the parties' intent may be considered only if the agreement is ambiguous," *id*. (marks omitted), and "[w]here there is such extrinsic evidence, the meaning of the ambiguous contract is a question of fact for the factfinder." *JA Apparel Corp. v. Abboud,* 568 F.3d 390, 397 (2d Cir. 2009). "If ambiguity is found, it must be resolved—as well as all inferences drawn—against the moving party, which has the burden of establishing that no facts material to the outcome of the litigation are in dispute." *Seiden Assocs.*, 959 F.2d at 429.

The toll agreement is ambiguous as to whether Hospira's manufacturing obligations encompassed QIV. The agreement defines the "Vaccine Product" as "the GSK influenza vaccine product which includes the Bulk, filled and finished by Hospira." [115-14] at 11. "Bulk" is defined as "the antigen component of the Vaccine Product." [115-14] at 7. ("Antigen" meaning the substance that stimulates an immune response. *See* Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/antigen (last visited Sept. 30, 2016).) This definition of "Vaccine Product" is quite broad and arguably encompasses any GSK influenza vaccine product, including TIV and QIV.

The definition of "Vaccine Product" must be considered in the context of the entire agreement, and the toll agreement included several schedules. The toll agreement states that (with an exception not relevant here) in the case of a conflict between the main body of the agreement and the schedules, provisions in the main body prevail. [115-14] at 12. A few of the schedules reference the vaccine product

more specifically than "GSK influenza vaccine product," but they do not resolve the ambiguity in the definition of "Vaccine Product" as provided in the main body of the toll agreement.

Schedule 4 consists of the "Technical Transfer Program,"[5] defined as the transfer from GSK to Hospira of all relevant registered processes, technology, and technical information to manufacture the "Vaccine Product" in conformity with the "Specifications" (Schedule 5). [115-14] at 5, 11, 53. The Schedule 4 attached to the toll agreement consists of a coversheet stating that the Technical Transfer Program is "included as an integral part of Schedule 5." [115-14] at 53. Versions of Transfer Plans executed April and October 2011 explain that each "describes the transfer plan associated to the transfer of the pooling, filling, and visual inspection process of FluLaval – TF to Hospira McPherson, USA." [123-2] at 132, 240.[6] These references to "FluLaval TF" are ambiguous and could refer to either the TIV or QIV version of thimerosal-free FluLaval.

Another Transfer Plan was signed in February 2012, stating that it "describes the transfer plan associated to the transfer of the pooling and filling process of FluLaval – Q-QIV to Hospira McPherson, USA." [123-2] at 284. The parties dispute, however, whether this Transfer Plan was executed pursuant to the original toll agreement or in anticipation of modifying the toll agreement for QIV. *See* [135] ¶ 8. The 2012 Transfer Plan itself is silent on the issue, although there are

[5] The parties also refer to Schedule 4 as a "Transfer Plan." *See, e.g.,* [124] ¶ 66; [135] ¶ 8.

[6] The April 2011 version includes a typo, spelling "Mac Pherson."

some indications that it may have been a new document and not a mere revision. For example, the October 2011 Transfer Plan is listed as "Version 02" and chronicles revisions from previous versions in a "History of Revision" chart. [123-2] at 238, 240. But the 2012 Transfer Plan title page and "History of Revisions" chart indicate that it was a "New Document" and "Version 01." [123-2] at 284. None of the Transfer Plans reference the toll agreement. It is not clear, on the face of these documents, whether the 2012 Transfer Plan was executed pursuant to the toll agreement or in anticipation of a new (or modified) toll agreement. Overall, the Transfer Plans do not resolve whether the toll agreement definition of "Vaccine Product" is limited to TIV.

Specific references to TIV are found in Schedule 5, the "Product Transfer Specifications" or "PTS."[7] [115-14] at 5, 10, 54. The toll agreement explains that the Product Transfer Specifications are the "preliminary specifications for the Vaccine Product" which "shall be replaced by the Specifications." [115-14] at 10. The "Specifications" are, in turn, defined as the "final specifications for the Vaccine Product to be agreed upon by the Parties in accordance with Schedule 5, replacing the Product Transfer Specifications and the additional GSK technical documents and requirements that are to be provided by GSK." [115-14] at 11. The toll agreement, therefore, contemplates that the Product Transfer Specifications may be subject to revision. The body of the agreement provides that the Specifications "may

[7] The parties also refer to Schedule 5 as "Process Transfer Specifications." *See, e.g.,* [135] ¶ 8.

only be changed by agreement in writing between the Parties, or if otherwise required by a Regulatory Authority" and that "Hospira shall not unreasonably withhold its consent to a change requested by GSK." [115-14] at 15.

The Schedule 5 attached to the toll agreement states that the Product Transfer Specification document was attached, represented "a work-in-progress and [was] not complete" as of the effective date of the toll agreement, and that the parties agreed "to consult and use reasonable efforts to prepare and complete the details of the PTS/Technical Transfer Program no later than ninety (90) days after the Effective Date." [115-14] at 54. However, the first version of the Product Transfer Specification was actually signed in December 2010, prior to execution of the toll agreement. There are four versions of the Product Transfer Specifications, executed in December 2010, February 2011, June 2011, and September 2011. [115-15]; [135-15]; [115-16]; [115-60]. Each version references TIV (not QIV) and includes the following provisions:[8]

- "This Process Transfer Specification (PTS) is applicable to the TriValent (TIV) FluLaval Thimerosal-Free Influenza vaccine, further referred to as 'FluLaval Thio-Free', 'FluLaval TF' or 'TIV TF.'" [115-15] at 5; [135-15] at 4; [115-16] at 4; [115-60] at 4.
- "Any change or modification with respect to processes or equipment needed for manufacturing will be (after written agreement from both parties) the subject of an update to this PTS." [115-15] at 5; [135-15] at 4; [115-16] at 4; [115-60] at 4.
- Under "Definition of the Product:" "This PTS describes the technical aspects and methods associated with the reception, pooling, syringe filling, stoppering and visual inspection of TIV FluLaval Thio-Free at

[8] Later versions have slight but immaterial differences in some language.

HOSPIRA McPherson." [115-15] at 7; [135-15] at 6; [115-16] at 7; [115-60] at 8.

- "Any changes or modifications to the information contained in this agreement must be authorized in writing by both parties in advance by issuing a revised PTS with a new version number" (under "PTS Changes"). [115-15] at 8; [135-15] at 7; [115-16] at 6; [115-60] at 7.
- A "TIV FluLaval Thio-Free formulation" chart listing the ingredients. [115-15] at 9; [135-15] at 8; [115-16] at 7–8; [115-60] at 8–9.

Therefore, each version of the Product Transfer Specifications references TIV and that modifications are subject to the parties' written agreement. GSK acknowledges that no agreed version of the Product Transfer Specifications references QIV. [124] ¶ 66. Despite the broad definition of "Vaccine Product" in the body of the agreement, the Product Transfer Specifications could suggest that Hospira's manufacturing obligations were limited to the TIV version of the vaccine. However, the toll agreement states that the provisions in the main body of the agreement prevail in the event of a conflict with the schedules, [115-14] at 12, and Hospira does not dispute that the parties anticipated that the Product Transfer Specifications (in addition to the Transfer Plan) could and did change several times. [135] ¶ 8. So there is a reasonable argument that the broad definition of "Vaccine Product" was not intended to be limited by the non-final specifications in the Product Transfer Specifications.

Schedule 7 consists of the "Quality Agreement," which sets out the parties' respective responsibilities "for technical and quality matters." [115-14] at 5, 11, 56. The Quality Agreement, executed in December 2010, defines the product as "seasonal FluLaval TF." [123-2] at 104. While this term is not necessarily

inconsistent with a TIV-only formulation—as the Product Transfer Specification included "FluLaval TF" as an alternative definition for the TIV formulation—it does not clearly resolve the ambiguous definition of "Vaccine Product" in the toll agreement; Schedule 7 provides one piece of evidence in Hospira's favor, but is inconclusive for purposes of summary judgment. Based on all the toll agreement schedules, the parties' flexible approach to the project, and the breadth of the definition in the controlling agreement, there are reasonable arguments that "GSK's influenza vaccine product" includes both TIV and QIV forms. Conversely, the contract may be limited to only TIV by virtue of the parties' intent expressed in the Product Transfer Specifications and Quality Agreement. The ambiguity must be resolved at trial.

Hospira also argues that there are no material terms in the toll agreement relating to QIV and material terms left up to future negotiations cannot form the basis for an enforceable contract relating to QIV. While it is true that "[a] mere agreement to agree, in which a material term is left for future negotiations, is unenforceable," a contract is not unenforceable "merely because it expresses the idea that something is left to future agreement," and "not all terms of a contract need be fixed with absolute certainty." *Tractebel Energy Mktg., Inc. v. AEP Power Mktg., Inc.*, 487 F.3d 89, 95 (2d Cir. 2007). Hospira does not argue that the toll agreement was not legally binding (at least for TIV), yet the executed version left several key schedules relating to the development phase and technical issues as coversheets or a work in progress. *See, e.g.,* [115-14] at 53–54, 56. The toll

agreement provided prices for commercial manufacture of the "Vaccine Product," and a maximum cap on development phase payments in Schedule 3. [115-14] at 47–48, 51. While Schedule 3 also provides a milestone schedule (purportedly for TIV—GSK does not argue that it was applicable to QIV), all but one of the milestone dates had already passed by the time the parties executed the toll agreement. It is not clear that the parties treated details in the schedules as material terms necessary to a binding agreement for manufacturing services. "The law of New York is clear that a contract will not fail for indefiniteness unless the matters left open are material." *Tractebel Energy*, 487 F.3d at 96. Given the evidence of the parties' flexible approach, Hospira has not established as a matter of law that, even if the toll agreement definition of "Vaccine Product" covered QIV, the agreement omitted material terms related to QIV. *See, e.g., id.* (contract was binding where details left to be worked out in operations protocol were not material). Perhaps one should expect sophisticated entities to be specific about goals, obligations, and pricing in an agreement over a manufacturing process, but the evidence in this record does suggest that the parties did not consider such formality to be material to their bargain.

While there is extrinsic evidence bearing on the parties' intentions for the scope of the toll agreement, it cuts both ways and therefore is to be considered by the factfinder, not at summary judgment. *See Seiden Assocs.*, 959 F.2d at 428 (Where language is ambiguous and "where there is relevant extrinsic evidence of the parties' actual intent, the meaning of the words become[s] an issue of fact and

summary judgment is inappropriate."). For example, GSK cites evidence that Hospira knew that GSK was developing FluLaval QIV, that the syringe-filling process would have been essentially the same regardless of whether Hospira manufactured TIV or QIV, and that the parties contemplated that regardless of the number of strains, the particular strains for inclusion would change seasonally as dictated by world health organizations. [123] ¶¶ 8–12. On the other hand, there is also extrinsic evidence suggesting that the parties may have intended the toll agreement to cover only TIV. Before the QIV study results came in earlier than expected, QIV was scheduled for a 2015 launch. [124] ¶ 43. But the toll agreement had a December 31, 2015 termination date and only covered flu seasons during 2013 to 2015, and it can be argued that because the timeframe covered by the toll agreement largely preceded the expected QIV launch date, the parties did not intend the toll agreement to cover manufacture of QIV.

GSK has raised a factual dispute as to whether Hospira's contract obligations were limited to the TIV formulation because the term "Vaccine Product"—defined broadly and ambiguously in the toll agreement—arguably could cover other flu vaccine products in addition to TIV. This, in turn, raises a factual dispute as to whether Hospira's performance was not yet due under the toll agreement. And regardless of whether Hospira's contract obligations had been limited to the TIV formulation, there is evidence that GSK still wanted the benefits of Hospira's TIV-related work, even without a full TIV product launch. Therefore, GSK did not, as a

matter of law on this record, prevent Hospira's performance by ending the TIV project.[9]

2. *Notice of Breach*

New York law does not treat as inconsistent the right to continue performance under a contract (on the one hand) and the right to sue for damages based on a breach (on the other). *Luitpold Pharms., Inc. v. Ed. Geistlich Söhne A.G. Für Chemische Industrie*, 784 F.3d 78, 97 (2d Cir. 2015). Instead, "'[a] party to an agreement [that] believes [the agreement] has been breached may elect to continue to perform the agreement' and later sue for the alleged breach, so long as that party does not waive its right to sue by, *inter alia*, failing timely to notify its counterparty of the breach." *Id*. (quoting in part *Capital Med. Sys. Inc. v. Fuji Med. Sys., U.S.A. Inc.*, 658 N.Y.S.2d 475, 478 (3d Dep't 1997)). As addressed in the opinion denying Hospira's motion to dismiss, GSK is not precluded from bringing a claim for breach even though it continued under the toll agreement in lieu of termination. [62] at 6–8. Hospira now argues that GSK waived its right to sue for breaches related to TIV by failing to satisfy the "notice and cure" provision in the toll agreement.

The notice and cure provision in the toll agreement refers to the parties' rights to *terminate* the contract for material breaches and therefore is not applicable to continuing performance while preserving the right to sue for breach. Hospira cites *USI Ins. Services LLC v. Miner*, 801 F.Supp.2d 175 (S.D.N.Y. 2011), for the

[9] Hospira also argues that by stopping the TIV project, GSK's conduct waived the "no waiver" provision in the toll agreement, barring GSK from bringing a claim for breach relating to TIV. This argument, however, is dependent on finding that Hospira's obligations under the toll agreement were limited to TIV, an issue that is disputed.

proposition that without notice and the opportunity to cure, there can be no action for breach. However, *USI* involved a contract requiring notice and cure for *any* breach, not just for the right to terminate based on material breach. *See id.* at 181. The notice and cure provision in *In re 4Kids Entertainment, Inc.*, 463 B.R. 610 (Bankr. S.D.N.Y. 2011)—cited by Hospira for the proposition that adequate notice must put the breaching party on notice of the repercussions of its failure to cure—was also broader than the parties' agreement here. *Id.* at 664. There is no clause in the toll agreement addressing notice and cure for *any* material breach, only for the non-breaching party's right to terminate the contract for a material breach.

The termination clause provides that if either party commits "any material breach of this Agreement" and fails to remedy the breach within two weeks' notice (if the breach was capable of remedy), the non-breaching party may terminate the agreement. [115-14] at 40. Although Hospira argues that this provision also applies to GSK's right to elect to continue performing but to sue later, the contract does not say that. And New York law permits more flexible notice on this election. *See, e.g., Luitpold Pharms.,* 784 F.3d at 97 (communications between the parties "raising concerns" created factual dispute as to whether notice was given); *Richard A. Hutchens CC, L.L.C. v. New York*, 872 N.Y.S.2d 734, 738 (3d Dep't 2009) (non-breaching party did not waive breach by continuing performance while making requests for more information which "convey[ed] concern rather than consent"); *Capital Med.*, 658 N.Y.S.2d at 478 (plaintiff did not waive breach of contract claim where it "timely complained" to defendant that it did not receive the commission to

which it was entitled). Hospira has not established as a matter of law that the notice and cure provision in the termination clause applies to the notice required to continue performance and later sue for breach. Hospira also cites no authority for the proposition that the non-breaching party needs to give the breaching party an opportunity to cure. For example, *Hallinan v. Republic Bank & Trust Co.*, merely holds that if a party chooses to continue to perform and sue for damages, it must give notice—the case says nothing about requiring an opportunity to cure. 519 F.Supp.2d 340, 351 (S.D.N.Y. 2001).[10]

Instead, communications raising concerns about the other party's contractual obligations suffice, at least at the summary judgment stage, to raise a genuine factual dispute precluding summary judgment. For example, in *Luitpold Pharmaceuticals, Inc. v. Ed. Geistlich Söhne A.G. Für Chemische Industrie*, 784 F.3d 78 (2d Cir. 2015), a counter-defendant was not barred from suing for breach when it did not terminate the agreement, and evidence of communications between the parties—raising concerns about counter-plaintiff's marketing and sale of a certain product—created a genuine factual dispute as to whether the counter-

[10] Hospira also argues *any* notice of breach under the toll agreement required written notice to Hospira's corporate vice president and legal department, and that GSK has not shown that it complied with this provision. The toll agreement contains a notice clause, separate from the notice and cure termination provision, stating that "[a]ny notice given in accordance with this Agreement shall be in writing and shall be properly served" upon Hospira's corporate vice president and legal department. [115-14] at 42. While this clause was briefly referenced in a footnote in Hospira's opening brief and in its LR 56.1 statement in the context of the notice and cure provision for termination ([114] at 8 n.2; [124] ¶ 29), the particular argument that the notice clause applied to any notice pursuant to the toll agreement was not developed until Hospira's reply brief. [134] at 8. Arguments raised for the first time in the reply brief are waived. *Mendez v. Perla Dental*, 646 F.3d 420, 423–24 (7th Cir. 2011).

defendant provided timely notice of any breach. *Id.* at 97.[11] While GSK has not pointed to any communications specifically telling Hospira that GSK was giving notice of a material breach but electing to continue under the contract, there is evidence in the record that GSK informed Hospira of perceived deficiencies relating to its TIV validation work and plant preparedness. *See, e.g.,* [124] ¶ 51; [135] ¶¶ 19–21. Whether these communications constituted timely notice of Hospira's alleged breaches raises a factual dispute precluding summary judgment.[12] Hospira's other arguments that any alleged breaches were not material if GSK chose not to invoke the notice and cure provision or not to threaten termination are arguments about the weight of the evidence, and are best left to the factfinder.

3. *Damages*

Hospira also argues that GSK cannot establish damages for any TIV-related breaches because TIV was of no commercial value to GSK without the pediatric indication. However, as GSK explains, it is not seeking damages for lost sales, but instead seeks damages for the money it spent on trying to obtain useful validation work from Hospira. GSK has pointed to evidence in the record suggesting that even if the project no longer had commercial value to GSK, it had value to GSK for

[11] *BMC Industries, Inc. v. Barth Industries Inc.*, 160 F.3d 1322, 1327 (11th Cir. 1998), also cited by Hospira, applied Florida UCC law on waiver, not New York law on election of remedies.

[12] Hospira also argues that the UCC requires an express reservation of rights, but that argument was first made in its reply brief, [134] at 11, and is deemed waived. Moreover, Hospira has not explained how the UCC applies to the toll agreement and whether it is a contract for goods or for services. *See* [115-14] at 6 ("WHEREAS, GSK wishes to engage the services of a Hospira [sic] to Manufacture the Vaccine Product (as herein defined).").

regulatory reasons because a technical application for an adult-only TIV would have paved the way for a later TIV pediatric indication (if it could be obtained) or a QIV formulation. *See* [124] ¶ 40. GSK has raised a factual dispute regarding its damages for breach of contract, so summary judgment is not appropriate on these grounds.

Hospira is not entitled to summary judgment on GSK's breach of contract claim.

### B. Quasi-Contract Claims

#### 1. *Existence of Toll Agreement*

Hospira also seeks summary judgment on GSK's claims for promissory estoppel, quantum meruit, and unjust enrichment, arguing that the existence of the toll agreement precludes GSK's quasi-contract claims. For the unjust enrichment and quantum meruit claim, Hospira also asserts that there is no evidence that Hospira unjustly retained a benefit as a result of work on QIV. GSK responds to these arguments in a single paragraph, acknowledging that the quasi-contract claims are triable only if the toll agreement does not cover QIV work but contending that GSK has a viable theory for recovering the benefit of millions of dollars' worth of QIV bulk and components supplied to Hospira for QIV validation work. As GSK acknowledges, GKS's quasi-contract claims based on TIV work are precluded by the existence of the toll agreement. *See Cromeens, Holloman, Sibert, Inc. v. AB Volvo*, 349 F.3d 376, 397 (7th Cir. 2003) ("Once a valid contract is found to exist, quasi-contractual relief is no longer available."). However, because there is a factual dispute as to whether the toll agreement encompassed QIV, GSK is not precluded from trying its quasi-contract claims related to QIV.

2. *Promissory Estoppel*

Hospira also argues that even if QIV is outside the scope of the parties' written contract, summary judgment is warranted on GSK's promissory estoppel claim because there is no evidence that Hospira promised to work on QIV and, in any event, GSK could not show detrimental reliance because it was able to get QIV on the market under an accelerated timetable. GSK responds (very briefly) that its damages would be the money it wasted on QIV materials given to Hospira for validation work.

To establish claim for promissory estoppel, a plaintiff must prove that (1) defendant made an unambiguous promise, (2) plaintiff relied on such promise, (3) plaintiff's reliance was expected and foreseeable by defendants, and (4) plaintiff relied on the promise to its detriment. *Newton Tractor Sales, Inc. v. Kubota Tractor Corp.*, 233 Ill.2d 46, 51 (2009). Here, GSK has shown a factual dispute over whether Hospira promised to work on QIV. In addition to the parties negotiations and proposals, they signed a QIV-related Transfer Plan in February 2012, which described GSK's transfer of the syringe-filling process for "FluLaval – Q-QIV" to Hospira. [123-2] at 284. If the QIV-related Transfer Plan was not part of the toll agreement but instead was signed in anticipation of the parties reaching a modified agreement for manufacturing QIV, it could be evidence that Hospira made promises regarding QIV validation work. There is also evidence in the record suggesting that GSK provided QIV materials to Hospira, who engaged in QIV-related prefatory work. [124] ¶ 74; [135] ¶ 31. Therefore, there is some evidence permitting a reasonable inference that Hospira promised to perform QIV validation work. If

Hospira promised to perform QIV validation work, was given materials from GSK to do so, and then did not perform the validation work, then damages for those QIV materials would restore GSK to the position it had been prior to relying on the promise. *See, e.g., Newton Tractor*, 233 Ill.2d at 59 ("Where there has not been mutual assent, and the terms are not sufficient to constitute a contract, damages may appropriately be limited to restoring plaintiff to the position he was in prior to relying, to his detriment, on the promise.").

GSK has raised factual disputes precluding summary judgment for Hospira on GSK's promissory estoppel claim.

3. *Quantum Meruit and Unjust Enrichment*

Hospira is entitled, however, to summary judgment on GSK's claim for unjust enrichment and quantum meruit. GSK pleaded quantum meruit and unjust enrichment theories in the same claim, but they are distinct, albeit similar, quasi-contract causes of action.[13] Both theories permit recovery of a benefit unjustly

[13] Quantum meruit concerns situations in which services are rendered non-gratuitously, but no payment is forthcoming. *Bernstein & Grazian, P.C. v. Grazian & Volpe, P.C.*, 402 Ill.App.3d 961, 979 (1st Dist. 2010). A plaintiff must prove that it performed a non-gratuitous service to benefit the defendant, that the defendant accepted this service in the absence of a contract to prescribe payment, and that its services were "of some measureable benefit to the defendant"—the measure of recovery is the "reasonable value of [the] work" performed by the plaintiff. *Id*. To prove unjust enrichment, a plaintiff must show that the defendant unjustly retained a benefit, to the plaintiff's detriment, and that the defendant's retention of the benefit "violates the fundamental principles of justice, equity, and good conscience." *Cleary v. Philip Morris Inc.*, 656 F.3d 511, 516 (7th Cir. 2011) (quoting *HPI Health Care Servs., Inc. v. Mt. Vernon Hosp., Inc.*, 131 Ill.2d 145, 160 (1989)). "[U]njust enrichment does not seek to compensate a plaintiff for loss or damages suffered but seeks to disgorge a benefit that the defendant unjustly retains." *Id.* at 518. While earlier Illinois courts recognized unjust enrichment as an independent cause of action, more recent courts do not. *See C. Szabo Contracting, Inc. v. Lorig Constr. Co.*, 2014 IL App (2d) 131328, ¶ 24 (unjust enrichment is remedy, not an independent cause of action); *Gagnon v. Schickel*,

retained by the defendant and both require a plaintiff to show that "valuable services or materials were furnished by the plaintiff, received by the defendant, under circumstances which would make it unjust for the defendant to retain the benefit without paying." *Hayes Mech., Inc. v. First Indus., L.P.*, 351 Ill.App.3d 1, 9 (1st Dist. 2004). "In a quantum meruit action, the measure of recovery is the reasonable value of work and material provided, whereas in an unjust enrichment action, the inquiry focuses on the benefit received and retained." *Id*. "Notably, even when a person has received a benefit from another, he is liable for payment only if the circumstances of its receipt or retention are such that, as between the two persons, it is unjust for him to retain it. The mere fact that a person benefits another is not of itself sufficient to require the other to make restitution therefor." *Id*. (marks omitted).

GSK briefly asserts that Hospira received the benefit of millions of dollars' worth of QIV bulk vaccine material and components, for which GSK received no value. But even if GSK considered the QIV materials to be a loss after the project did not pan out, GSK fails to explain how Hospira "unjustly retained" the QIV materials or how they were of any benefit to Hospira. For example, GSK does not argue or cite evidence that Hospira could have reused or resold QIV materials, or

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2012 IL App (1st) 120645, ¶ 25 (same); *compare HPI Health*, 131 Ill.2d at 160 (listing elements for "a cause of action based on a theory of unjust enrichment"); *Peddinghaus v. Peddinghaus*, 295 Ill.App.3d 943, 949 (1st Dist. 1998) (Illinois recognizes an independent cause of action for unjust enrichment) (citing *HPI Health*, 131 Ill.2d at 160). The Seventh Circuit has not yet addressed whether unjust enrichment provides an independent cause of action under Illinois law. *See, e.g., Enger v. Chicago Carriage Cab Corp.*, 812 F.3d 565, 571 (7th Cir. 2016); *Cleary*, 656 F.3d at 516–18. Neither party has briefed that issue, however, so it need not be addressed in this opinion.

that they resulted in some sort of pecuniary gain to Hospira. Without such evidence, GSK's quantum meruit and unjust enrichment claim fails. *See, e.g., Prod. Process Consultants, Inc. v. Wm. R. Hubbell Steel Corp.*, 988 F.2d 794, 797 (7th Cir. 1993) (quantum meruit claim failed where the defendant failed to receive any direct pecuniary gain from plaintiff's improvements to a joint-venture production line). At this point, any such arguments are undeveloped and waived.

GSK has not shown a triable issue of fact regarding whether Hospira "unjustly retained" a benefit from GSK. Hospira is granted summary judgment on GSK's claim for quantum meruit and unjust enrichment.

## IV. Conclusion

Hospira's motion for summary judgment, [110], is granted on GlaxoSmithKline's Count III and denied as to Counts I and II. A status hearing is set for October 14, 2016 at 9:30 a.m.

ENTER:

Manish S. Shah
United States District Judge

Date: 9/30/2016