UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

PERRIGO COMPANY AND SUBSIDIARIES,

Plaintiff,

v.

UNITED STATES OF AMERICA,

Defendant.
_____/

CASE No. 1:17-CV-737

HON. ROBERT J. JONKER

OPINION AND ORDER

INTRODUCTION

This is an action for refund of federal corporate income taxes. In 2014 and 2016, the Internal Revenue Service ("IRS") issued a Notice of Deficiency to Perrigo Company and Subsidiaries ("Perrigo") assessing tax, interest, and penalties for the 2009 through 2012 tax years. The alleged deficiencies relate to sales of Perrigo's over-the-counter omeprazole product—a generic drug used to treat common gastrointestinal ailments like acid reflux. The IRS reallocated millions of dollars in omeprazole income from Perrigo's Israeli affiliate, Perrigo Israel Trading Limited Partnership and Perrigo LLC ("PITLP/LLC" or "LLC"), to Perrigo's domestic entities based on the IRS's determination that Perrigo's assignment to the affiliate of a supply and distribution agreement relating to omeprazole lacked economic substance under a number of judicial sham doctrines. Alternatively, the IRS reallocated nearly the entirety of Perrigo's omeprazole income under Section 482 of the Internal Revenue Code. All told, the IRS determined that Perrigo was subject to increased taxes here in the United States. Perrigo fully paid the

approximately $143 million in tax, penalties, and interest for the tax years at issue and then filed claims for refund, which were disallowed by the IRS. This civil action followed.

This case presents two issues for decision. The primary issue is the omeprazole issue. Here, Perrigo asks the Court to reject the Government's common-law sham doctrines and further to find that the IRS's alternative Section 482 income reallocations were arbitrary, capricious, and unreasonable. Perrigo asks the Court to conclude that its intercompany transactions surrounding the assignment were priced at arm's length under Section 482 of the Internal Revenue Code subject to its expert's determinations. The Government disagrees. It says the common-law theories do apply, but that even if Perrigo survives this threshold question, the Court should adopt its alternative Section 482 adjustments that increase Perrigo's domestic income and awards at most a small return to the affiliate.

The second issue presented at trial pertains to certain patent-related expenses that generic entities like Perrigo sometimes incur when they seek to enter the market with a new drug (Abbreviated New Drug Act "ANDA" Paragraph IV expenses). While this issue overlaps with some of the background regulatory requirements implicated in the omeprazole issue, the ANDA issue is a separate and distinct issue for decision. Perrigo contends that it is entitled to deduct its ANDA related expenses for certain tax years as ordinary and necessary business expenses. The Government again disagrees, and contends that these litigation expenses must be capitalized.

The parties presented evidence and argued the merits of their positions during a nine-day bench trial. At the close of the trial the Court took the matter under advisement. Both sides have since submitted post-trial briefing. This Opinion constitutes the Court's findings of fact and conclusions of law under Federal Rule of Civil Procedure 52. For the reasons that follow, the Court rejects the Defendant's common-law hypotheses. The Court determines the discounted cash

flow analysis of Perrigo's expert, subject to certain refinements detailed below, captures the arm's length transfer price under Section 482. The Court further determines that penalties are not appropriate here. Finally, the Court concludes that the expenses for preparation of Paragraph IV certifications are properly capitalized, not deducted, but that actual litigation expenses are property deducted. The Court will require the parties to file a proposed judgment consistent with the rulings in this Opinion.

FACTUAL BACKGROUND

OVERVIEW

At a high level, this case involves a distributor of generic pharmaceutical products and its growth from a small drug company founded one-hundred forty years ago in Allegan, Michigan into a major multinational company with billions of dollars in sales today.[1] Perrigo's growth is due, in part, to its expertise in tracking patented brand name prescription drug products that are approaching patent expiration and that are also candidates to be transitioned from prescription drug status to self-prescription, that is, over-the-counter ("OTC") purchases. The company either developed generic versions of the brand name drug or partnered with other drug companies to

[1] Tax-related judicial opinions often begin with a pithy quote or anecdote to ease the reader (and perhaps the decisionmaker too) into the complicated subject area of tax law. *See, e.g.*, *Summa Holdings, Inc. v. Comm'r*, 848 F.3d 779, 781 (6th Cir. 2017) ("Caligula posted the tax laws in such fine print and so high that his subjects could not read them."); *Comm'r v. Est. of Hubert*, 520 U.S. 93, 111 (1997) (O'Connor, J., concurring) ("Logic and taxation are not always the best of friends.") (quoting *Sonneborn Brothers v. Cureton*, 262 U.S. 506, 522 (1923) (McReynolds, J., concurring)). Eventually, however, any tax-related decision must wade into oftentimes dense facts and law. The lawyers here, well-versed attorneys in tax law, say this case is not particularly difficult and that the facts and the law are clearly on their respective sides. Yet in any case involving dozens of attorneys; thousands of pages of trial exhibits; and hundreds of pages of post-trial briefing—all relating to millions of dollars in sales, various intercompany transactions, and competing expert methods of arm's length calculations, a certain amount of wading into the weeds is required. In this section the Court distills those facts and testimony it finds most pertinent to the issues for decision.

develop and sell those products. Perrigo's business success also sprung from its decision in the late 1990s to expand from a predominantly domestic business into an international corporate player.

This case arises from the intersection of Perrigo's drug distribution business and its globalization efforts. Beginning in the 1990s Perrigo identified AstraZeneca plc's Prilosec Rx—containing the active ingredient of omeprazole (or, to be specific, omeprazole base)—as a candidate that might "switch" from prescription status to an OTC drug. Perrigo was unable to develop a generic version of the drug on a timeline that would allow it to be first out of the gate with a generic competitor, and so it eventually contracted with Dexcel Pharma, an Israeli drug company, through a domestic affiliate, L. Perrigo Company ("LPC"), to bring a generic omeprazole product to the U.S. market. And when Perrigo and its advisors went about structuring its globalization, one of the intracompany transactions was to assign Perrigo's contract with Dexcel Pharma from the domestic side of Perrigo's books (L. Perrigo Company) to the overseas Israeli affiliate: PITLP/LLC. Thereafter, LLC engaged with L. Perrigo Co.'s distribution services to actually distribute the product here in the United States. Consistent with Perrigo's obligations under the U.S. tax code, PITLP/LLC paid to L. Perrigo Co. via a demand note what Perrigo says it believed was an arm's length price for the Dexcel contract. And when Perrigo filed its U.S. taxes for the 2009, 2010, 2011, and 2012 tax years, its filings reflected omeprazole revenue and earnings consistent with the assignment of the Dexcel contract. This definitely reduced the taxes Perrigo paid here in the United States below what it would have paid absent the assignment of the Dexcel contract. When the IRS reviewed Perrigo's filings it ultimately applied three common law theories that reallocated one hundred percent of the income Perrigo reported as earned by

PITLP/LLC over to Perrigo's domestic entities. Alternatively, the IRS reallocated nearly all of the income under Section 482.

The parties agree with this rough sketch of things. But they disagree whether the IRS's reallocation (both under the common law theories and under the alternative Section 482 approach) was correct. In particular, the parties' main dispute hinges on whether Perrigo's multinational structure related to omeprazole—centering on the assignment of Perrigo's Dexcel Pharma contract to PITLP/LLC—ought to be respected as a matter of law. At the crux of the dispute is the risk and uncertainty that either was (according to Perrigo) or was not (according to the Government) present at the time the assignment was made (a date that itself is in dispute). All this is described in greater detail below.

PERRIGO'S PURSUIT OF ITS OWN OMEPRAZOLE PRODUCT

I. Perrigo's Generic Drug Business

Perrigo was founded in 1887 as a small general store marketing medicines and household provisions. (Ex. 1137). It grew over the ensuing decades into a multinational pharmaceutical company with production facilities in the United States, Israel, the United Kingdom, Germany, and Mexico. (*Id.*). And in 2013, Perrigo "went Irish" by incorporating under the laws of Ireland as the successor of the Michigan corporation. (Perrigo Co. PLC, Annual Report at 4 (Form 10-K) (Feb. 27, 2024). Perrigo is now a successful multinational company serving as the common parent of an affiliated group of corporations and subsidiaries. For the tax years at issue in this case (2009 through 2012), Perrigo's SEC filings reported $2.0 billion, $2.3 billion, $2.7 billion, and $3.21 billion in net sales. (ECF No. 235-3, PageID.3294).[2] Perrigo's more recent SEC filings reflect

[2] ECF No. 235-3 is an attachment to the parties' final pretrial order containing factual stipulations derived from the parties' admissions and responses made during the course of this litigation.

net sales of $4.65 billion and $4.375 billion for its 2023 and 2024 fiscal years, respectively. (Perrigo Co. PLC, Annual Report at 41 (Form 10-K) (Feb. 28, 2025)).

Perrigo's domestic business is primarily a consumer health care business that distributes over-the-counter products to retailers for sale under the retailer's own brand. (Trial Tr. vol. I, 153, ECF No. 379, PageID.5374).[3] In general terms, FDA-approved over-the-counter products approved can be marketed and sold either as a national brand or a generic store brand product. (ECF No. 235-3, PageID.3293). National brand OTC products include products with brand names like Advil, NyQuil, and Tylenol. (Trial Tr. vol. I, 153-154, ECF No. 379, PageID.5374-5375). Store brand products are generic equivalents to comparable national brands and sold under the retailer's own store name—stores like Meijer, Walmart, Walgreens, and CVS. (*Id.*). In this, Perrigo's business model is that of a "me too" company that sells generic alternatives to the national brands, rather than an "innovator" company that develops and sells novel patent-protected drugs. (Trial Tr. vol. IV, 54-55, ECF No. 382, PageID.5970-5971).

A. The Generic Market in General

A store brand generic equivalent is comparable in quality and efficacy to an analogous national brand. Indeed, to garner FDA approval the owner of the generic store brand OTC drug must demonstrate to the FDA that the proposed generic is "bioequivalent" to the national brand. (Trial Tr. vol. I, 159-160, ECF No. 379, PageID.5381).

Store brand generic products are usually cheaper than the national brands and can save consumers up to fifty percent in cost as compared to a higher priced national brand. Moreover, despite the lower retail price for consumers, store brands normally provide a higher profit margin

[3] More specifically, Perrigo's domestic operations primarily take place through the wholly owned subsidiary of L. Perrigo Company and other U.S. based affiliates. (Ex. 5411 at 21).

to the retailer, giving the retailer an incentive to promote store brand products. (Trial Tr. vol. I, 154-155, ECF No. 379, PageID.5375-5376; *see also* Exs. 1137 and 5130 at 40). The "magic of store brands" generally is that it permits a pharmaceutical supplier to price its store brand product at a level that enables the retailer to sell the product to consumers at a discount, yet still make more money selling the store brand than the national brand. (Trial Tr. vol. IV, 49-50, ECF No. 382, PageID.5965-5966; Exs. 1137 and 5130 at 30).

Generic manufacturers will seek to use the bioequivalent requirement to their advantage. This often takes the form of a "compare to" statement that is included on the packaging of the store brand product. FDA approval for these "compare to" statements is required. And, if approved, the statement informs retailers and consumers alike that the generic product is comparable to the national brand product. (Trial Tr. vol. I, 61-62, ECF No. 379, PageID.5282-5283). Store brand drug products with these "compare to" statements are placed in the aisles of retails stores next to the national brand products. This practice invites customers to compare the active ingredients of the national brand to the store brand and determine that the store brand product is similar to the national brand, and not some inferior substitute. (*Id.*).

B. Perrigo's Generic Drug Business

Perrigo moves generic drugs to retailers for sale as a store brand product in one of three ways. First, it can develop and sell its own products "in house." Second, it can partner with other drug companies to develop and sell the generic store brand products. Third, Perrigo can act purely in a distributor capacity where it distributes drugs on behalf of third-party manufacturers. (Trial. Tr. vol. VII, 146, ECF No. 385, PageID.6716). If it can, Perrigo prefers to develop generic drugs internally. (Trial. Tr. vol. I, 158-159, ECF No. 379, PageID.5379-5380; *see also* Ex. 203). Otherwise, Perrigo seeks to partner with an outside supplier or act as a distributor. (*Id.*). Perrigo

sometimes pursues parallel paths. It might try to develop an in-house generic product and search for potential outside suppliers at the same time. (Trial Tr. vol. IV, 71, ECF No. 382, PageID.5987).

Perrigo became a leading distributor of generic store brand over-the-counter drugs in the domestic market. During the tax years at issue in this case, its overall market share was between sixty and seventy percent. (ECF No. 235, PageID.3182). To achieve and maintain this leading share, Perrigo developed a business strategy targeted at developing positive relationships with retailers. And to help it reach a wide swath of retail customers, Perrigo developed "mass customization" capabilities over the complex and detailed operation of packaging store brand products. (Trial Tr. vol. II, 5-6, ECF No. 380, PageID.5467-5468). Taking one product as an example, Perrigo has sold 476 different ibuprofen products based on different retail customers, sizes, configurations, and case pack combinations. (Exs. 1137 and 5130 at 21). Across all its product lines, Perrigo touts product quality, a broad product line, store brand expertise, lost costs, customer service and strong customer relationships as advantages to retailers and other parties during contract negotiations. (Exs. 1137 and 5130 at 19).

All of this helps Perrigo market itself as a value-added supplier to retailers. Yet to maximize potential profits as to any one product, Perrigo (and its competitors) will seek to be "first to market" with a store brand generic product. (Trial Tr. vol. VII, 99, ECF No. 385, PageID.6669). For the generic manufacturer, the store brand "magic" is most profitable when the supplier is the first to offer an over-the-counter drug to retailers. A supplier that is successfully the first to market will be able to price the generic equivalent at a point that still maintains the "magic" for the retailer, but at a level that maximizes profits for the generic supplier. Once generic competitors enter the market for a particular over-the-counter product, retailers gain leverage in negotiating prices and terms with other suppliers. This erodes profit margins for the supplier that was first to market with

the generic product. (Trial Tr. vol. IV, 42, ECF No. 382, PageID.5958). Nevertheless, a distributor like Perrigo will seek to use its customer relationships and other assets to maintain its market share once a competitor enters the market.

To be first across the finish line with a generic drug, distributors like Perrigo track national brand drug products to identify potential candidates for a generic competitor. (Trial Tr. vol. I, 155, ECF No. 379, PageID.5376). The potential candidates include both prescription drugs and over-the-counter drugs. The possibility of moving a prescription drug to the over-the-counter market (meaning the drug would now be available to be purchased by a consumer without a doctor's authorization) presents an especially lucrative opportunity, and Perrigo became experienced in bringing store brand generic products to market against products that have recently switched from prescription only to over-the-counter status. (Trial Tr. vol. IV, 68-69, ECF No. 382, PageID.5984-5985; Ex. 5297 at pp 5-8)).

Perrigo's Business Development Department looks for these "Rx-to-OTC switch" candidate drugs. (Trial Tr. vol. I, 155, ECF No. 379, PageID.5376; *see also* Ex. 5297 at 5-8). But Perrigo cannot itself initiate this switch. Rather, the FDA must approve a switch from prescription to over-the-counter status, via an application from the innovator. (Trial Tr. vol. I, 156, ECF No. 379, PageID.5377).[4]

II. Perrigo Identifies Omeprazole as a "Switch" Target

Beginning in the 1990s, Perrigo identified AstraZeneca plc's Prilosec Rx as a potential switch candidate. (Trial Tr. vol. I, 157-158, ECF No. 379, PageID.5378-5379). Prilosec Rx is a

[4] Brand name drug companies will often seek to switch patented drugs to the over-the-counter market as the original patents expire to extend the drugs' profitability. If the drugs can be safely switched, the FDA may grant the brand name drug holder an initial period of exclusivity on the over-the-counter market.

prescription drug product used to treat heartburn, ulcers and gastroesophageal reflex disease, and AstraZeneca had been marketing and selling its patent-protected prescription product in the United States since 1989. (ECF No. 235, PageID.3182). The potential market size of a generic product largely depends on the size of the market of the target national brand product, and Prilosec Rx had done quite well as a national brand name prescription drug. (Trial Tr. vol. I, 68, ECF No. 379, PageID.5289; *see also* Ex. 5151). Accordingly, Perrigo saw Prilosec Rx as an attractive candidate for a generic competitor if it were to switch to the OTC market.

AstraZeneca eventually submitted a New Drug Application (NDA) to the FDA requesting that the FDA approve the "switch" from Prilosec Rx to Prilosec OTC. (Trial Tr. vol. I, 156-157, ECF No. 379, PageID.5377-5388). In 2003, the FDA subsequently granted AstraZeneca's NDA for Prilosec OTC, and it awarded AstraZeneca (and the marketer, Proctor & Gamble) three years of marketing exclusivity on the over-the-counter market. (Trial Tr. vol. I, 157, ECF No. 379, PageID.5378). Separately, AstraZeneca filed patents to protect Prilosec OTC. (Trial Tr. vol. VII, 32, ECF No. 385, PageID.6602-6603).

Perrigo hoped to be first to the market with a generic over-the-counter alternative once the exclusivity period elapsed (Ex. 5207 at 21), but it also understood that development risks and patent litigation could delay launch of a competing Prilosec over-the-counter generic product.

III. Perrigo Was Unable to Develop a Generic Prilosec OTC Competitor In House That Would be First to Market

Anticipating AstraZeneca would eventually seek to "switch" Prilosec to the over-the-counter market, Perrigo worked with its internal research and development group to develop an internal generic omeprazole product. (Trial Tr. vol. I, 157-158, ECF No. 379, PageID.5378-5379; *see also* ECF No. 235, PageID.3182). Perrigo spent over five years trying to develop an in-house generic alternative to Prilosec OTC. Perrigo's representatives met with the FDA on several

occasions between 2003 and 2005 to discuss Perrigo's development efforts and to better understand the requirements for submission of an NDA for Perrigo's generic alternative. (ECF No. 235, PageID.3182). Perrigo maintained an extensive R&D department to assist it in developing generic formulations of drugs. (Trial Tr. vol. III, 28, ECF No. 381, PageID.5716). Perrigo faced headwinds, however, both in its internal development and in navigating the FDA approval process.

In particular, one issue that Perrigo confronted was how to respond to the way AstraZeneca indicated it would structure its Prilosec switch. The active ingredient in Prilosec Rx is omeprazole, which is a proton pump inhibitor. (ECF No. 235-3, PageID.3293). In particular, Prilosec Rx uses a specific salt of the active ingredient (omeprazole base) that is delivered in a time-released capsule form. (*Id.*; *see also* Trial Tr. vol. I, 158, ECF No. 379, PageID.5379). When AstraZeneca sought approval from the FDA for Prilosec OTC, however, it used a different salt—omeprazole magnesium—as the active ingredient and it also formatted the over-the-counter product in a solid tablet rather than in a time-released capsule. (ECF No. 235, PageID.3182). Perrigo decided to develop a generic alternative that used omeprazole base as the active ingredient, that is, the active ingredient found in the prescription drug but not the brand name over-the-counter drug. (Ex. 203). The decision was made, in part, to avoid any issues relating to potential patent infringement of Prilosec OTC drug. (Trial Tr. vol. III, 29, ECF No. 381, PageID.5717).

Perrigo's decision to steer clear of potential patent conflicts (or at least try to) meant that Perrigo had to enter a regulatory arena with which it was relatively unfamiliar. In particular, Perrigo's decision to use a different active ingredient than Prilosec OTC affected the pathway to regulatory approval of its generic product. Under the statutory FDA approval process created in the "Hatch-Waxman" Act, "drug manufacturers seeking to market a new drug [are required] to

first obtain FDA approval via one of three different application pathways: (1) a full new Drug Application ("NDA"); (2) an Abbreviated New Drug Application ("ANDA"); or (3) an intermediate process known as a Section 505(b)(2) NDA." *Takeda Pharms., U.S.A., Inc. v. Burwell*, 78 F. Supp. 3d 65, 71 (D.D.C. 2015) (citing 21 U.S.C. § 355), *aff'd in part, vacated in part,* 691 F. App'x 634 (D.C. Cir. 2016). Neither of the first two pathways were desirable or open to Perrigo. The first pathway, contemplating a full NDA process, is generally used for "new branded drugs" that is, "pioneer" or "innovator" drugs, and requires the full panoply of detailed clinical studies, safety information, and other statutory and regulatory required information. *See id.* As a "me too" manufacturer, this was not the pathway that Perrigo wanted to pursue.

The second pathway for ANDA could be more attractive for a "me too" manufacturer. Under this approach, "[o]nce the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version" under the Hatch-Waxman Act. The amendments made by Hatch-Waxman, now codified at Section 505(j) under the federal Food, Drug, and Cosmetic Act, permit "a generic competitor to file an abbreviated new drug application (ANDA) piggybacking on the brand's NDA." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404–05 (2012). And "[r]ather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.* at 405. Perrigo had used this process before and had realized business success. (Trial Tr. vol. II, 25, ECF No. 381, PageID.5713).

But this pathway was not open to Perrigo for its generic omeprazole product. Because of the difference in active ingredients, Perrigo could not "piggy back" onto Prilosec OTC and so it had to pursue the third pathway towards FDA approval through Section 505(b)(2) of the Hatch-Waxman Act. (Trial Tr. vol. III, 24, ECF No. 381, PageID.5712). "Under § 505(b)(2) . . . a drug

manufacturer may file an NDA for a drug that is not entirely new but is not simply a generic version of a branded drug." *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 227 (3d Cir. 2013). "The § 505(b)(2) applicant must submit additional data to the FDA that demonstrates that any differences between the original drug and the § 505(b)(2) drug will not affect the § 505(b)(2) drug's safety and efficacy. *See* 21 C.F.R. § 314.54(a) (providing that § 505(b)(2) applications must provide data that supports any modification of the drug from the relied upon NDA). But, having done that, a § 505(b)(2) applicant can avoid preclinical and certain human studies necessary in full NDA applications." *Id.*

Perrigo was not as familiar with the "hybrid" Section 505(b)(2) process as it was with the ANDA process. (Trial Tr. vol. III, 25, ECF No. 381, PageID.5713). And this impacted how Perrigo went about developing its generic alternative. For one thing, during a meeting in 2003, the FDA told Perrigo that (assuming its generic was approved under the Section 505(b)(2) pathway) Perrigo would not be able to include a "compare to" statement on its packaging because it would use a different active ingredient than Prilosec OTC. (Exs. 187, 203). Perrigo had not, to that point, launched a product that did not have a "compare to" statement on its packaging. (Trial Tr. vol. VII, 81, ECF No. 385, PageID.6651). Furthermore, during an August 2004 meeting, the FDA also told Perrigo that its 505(b)(2) NDA "must include a comparative bioequivalence study (relative to the listed drug [that is, the Prilosec OTC containing the omeprazole magnesium salt], as well as a food-effect study." (Ex. 228). If the NDA could not demonstrate bioequivalence to Prilosec OTC, then Perrigo would be required to demonstrate additional clinical efficacy or other studies. (Ex. 181 at 5; *see also* Trial Tr. vol. III, 25-26, PageID.5713-5714). At trial, Brian Schuster, Perrigo's Associate Director of Regulatory Affairs during 2002 through 2015, testified that the first study would require the company to show that its generic alternative was equivalent

to Prilosec OTC in the rate and extent of availability of the drug at the site of action in the body. (Trial Tr. vol. III, 26-27, ECF No. 381, PageID.5714-5715). Mr. Schuster further testified that a "food-effect" study, as its name implies, is a study that evaluates the effect of food in the stomach when a drug is taken.[5]

Perrigo's in-house efforts led to the development of six separate omeprazole formulations. (Trial Tr. vol. III, 27, ECF No. 381, PageID.5715). Perrigo performed four pilot-scale bioequivalence studies on those formulations. (Ex. 181). These pilot studies were fasting studies (that is, studies performed where the drugs were taken without food), and were studies conducted on a smaller scale from the "pivotal" bioequivalence study that would accompany a 505(b)(2) NDA. (Trial Tr. vol. III, 27, ECF No. 381, PageID.5715). In other words, a pilot scale study was designed to predict what a pivotal study might show. (*Id.*). Perrigo's first pilot scale study took place during the summer of 2003 following "[e]xtensive preformulation work." (Ex. 181 at 8). The fourth study took place in January of 2005. (*Id.* at 14). None of the pilot studies on the various formulations indicated that Perrigo's in-house omeprazole formulations would successfully demonstrate bioequivalence if taken to a full-scale study. (Trial Tr. vol. III, 27, ECF No. 371, PageID.5715).

Ultimately Perrigo's efforts to develop its own omeprazole product up through 2006 were unsuccessful. (ECF No. 235, PageID.3182). Perrigo attributed its lack of success to two primary

[5] Mr. Shuster and other Perrigo representatives later attended a Pre-NDA meeting with FDA officials on October 6, 2005, and on November 11, 2005, the FDA gave final responses to a series of prepared questions submitted by Perrigo. In response to a question regarding bioequivalence, the FDA clarified that it did not require bioequivalence studies in the fed state relative to the reference listed product. (Ex. 5127 at 5). It appears, rather, that the FDA required the fed study to rule out "dose dumping" which takes place when a delayed-release drug (like omeprazole) releases all the drug contents into the stomach at the same time. (Trial Tr. vol. III, 35, ECF No. 381, PageID.5723).

complications. First, Perrigo sought to design around the patent-protected Prilosec OTC magnesium formulation. Second, during its testing Perrigo found that there was a high variability in the rate and extent of absorption of omeprazole within each patient. (Trial Tr. vol. I, 173, ECF No. 379, PageID.5394; vol. III, 29, ECF No. 381, PageID.5717).

Perrigo thus put its internal efforts on the back burner in April 2006.[6] Perrigo did eventually restart its internal development into producing an in-house omeprazole magnesium tablet a few years after Mr. Joseph Papa joined Perrigo as its CEO.[7] Perrigo submitted an ANDA application for the product under Section 505(j), and received approval for an omeprazole magnesium delayed-release tablet (20 mg base) on July 30, 2015. (Ex. 5363). This was after the joint-venture it entered into with Dexcel.

PERRIGO IDENTIFIES A POSSIBLE DEVELOPMENT PARTNER

I. Perrigo Identifies Dexcel Pharma as a Possible Partner to Bring Omeprazole to the U.S. Market.

While Perrigo was trying to develop its own in-house omeprazole base product, it was also pursuing the parallel path of partnering with another drug manufacturer to bring an omeprazole product to market. (Trial Tr. vol. I, 159, ECF No. 379, PageID.5380). Perrigo specifically spoke with two generic drug manufacturers: Dr. Reddy's Labs and Schwarz Pharma. (Trial Tr. vol. I, 164, ECF No. 379, PageID.5385). Neither of these prospects resulted in a successful partnership. Indeed, in 2004, Schwarz Pharma informed Perrigo that its own omeprazole product had failed a "fed pilot" study (that is, a pilot study where the omeprazole candidate was taken with food) and

[6] At this point, as discussed in further detail below, Perrigo had partnered with Dexcel Pharma on an omeprazole product, and Dexcel's product had proceeded much further along in the development and FDA approval process. (*See* Ex. 5130 at 35 (May 2006 meeting slides noting Perrigo had ended its internal omeprazole project due to the success of an "external" project).

[7] Mr. Papa became Perrigo's CEO in 2006 and the Chairman of the Board roughly a year later. (Trial Tr. vol. VII, 74-75, ECF No. 385, PageID.6644-6645). He left Perrigo in April 2016. (*Id.*).

that it had discontinued its efforts towards developing an omeprazole base alternative to Prilosec OTC. (Ex. 262 at 5).[8]

Perrigo continued to look for outside partners to bring a generic omeprazole competitor to the domestic market and in 2004 Perrigo found Dexcel Pharma. At trial, Jeffrey Needham testified that he became familiar with Dexcel Pharma while he worked in the United Kingdom to lead a separate OTC drug and personal care business that Perrigo had acquired. (Trial. Tr. vol. I, 151, ECF No. 379, PageID.5372).[9] During these years Mr. Needham had tried, unsuccessfully, to form a partnership with Dexcel to market an omeprazole product in the U.K. (Trial Tr. vol. I, 164-165, ECF No. 379, PageID.5385-5386). In the fall of 2004, Mr. Needham was preparing to return to Perrigo's domestic operations. He learned from John Hendrickson (then Perrigo's Executive Vice President and General Manager for Consumer Healthcare) that he would be taking on Perrigo's omeprazole development project. (*Id.*). During this conversation, Mr. Hendrickson told Mr. Needham that Perrigo was facing several challenges in developing an omeprazole product in-house, and Mr. Needham responded by mentioning his contact with Dexcel Pharma. (*Id.*). While Mr. Needham was familiar with Dexcel, he was not deeply knowledgeable about the company. It was a small generic company with its primary market in Europe. It was unknown in the United States. (Trial. Tr. vol. I, 166-167, ECF No. 379, PageID.5388).

[8] Perrigo was unable to successfully negotiate a joint venture with Dr. Reddy's as well. Dr. Reddy's pursued its own product, but also encountered delays and setbacks. Its generic product launched in early 2010. Unlike Perrigo's omeprazole product, Dr. Reddy's product used the same active ingredient as Prilosec OTC, meaning that Dr. Reddy's was permitted to use a "compare to" statement on its store brand labels. (Trial Tr. vol. I, 190, ECF No. 379, PageID.5411; ex. 455).

[9] Mr. Needham held a variety of other roles within Perrigo culminating with the position of Executive Vice President of Consumer Health for the Americas, a position that he held until his retirement in February 2020. (Trial Tr. vol. I, 150, ECF No. 379, PageID.5371).

Mr. Needham set up a conference call between Perrigo representatives and Dexcel leadership in October 2004 to discuss a potential collaboration to bring a generic OTC omeprazole product to the United States. During those conversations, Dexcel Pharma's President, Dan Oren, proposed a partnership whereby Dexcel and Perrigo would split any profits from a successfully launched omeprazole product on an equal basis, and that the parties further would split the product development costs. (Trial Tr. vol. I, 167, ECF No. 379, PageID.5388). Mr. Oren's proposal was "fairly typical" in Perrigo's experience of joint ventures, but it carried risks. In the main, Perrigo was still trying to familiarize itself with Dexcel and its leaders. To Perrigo, Mr. Oren seemed like "a real interesting guy." He was "kind of quirky, eccentric, extremely self confident [and] very optimistic in his ability to get things done." (Trial Tr. vol. I, 166, ECF No. 379, PageID.5387). But Perrigo also understood that Dexcel was a smaller company, focused on cosmetics, and that omeprazole was one of its first efforts towards drug development. (Trial Tr. vol. I, 57-58, ECF No. 379, PageID.5278-5279). Perrigo also understood there were geopolitical risks associated with Dexcel's location in Israel. (*Id.*).

Perrigo performed due diligence efforts before moving forward with Dexcel by assessing Dexcel's business acumen and the company's omeprazole development efforts. As part of these efforts, Perrigo spoke with representatives of Agis Industries, a company that Perrigo had recently acquired. Internal meeting notes from Perrigo dated April 18, 2005, reflect that Perrigo had learned that Agis knew of Dexcel and had seen Dexcel's facility. Agis spoke "highly of [Dexcel's] expertise and technical ability." (Ex. 5024). Dexcel also shared some information about its omeprazole product development with Perrigo. In November of 2004, for example, it shared the results of a bioequivalence study of an omeprazole product it had developed to compete against the U.K. version of Prilosec. (Ex. 5152). The next month Brian Schuster distributed Dexcel's

draft fasting pilot study protocol within Perrigo for comment. (Ex. 5154). And in January 2005, Dexcel provided Perrigo with the results of the pilot study. In a January 18, 2005, email, Mr. Schuster commented that Dexcel "did not exactly pass, but results are 'interesting.'" (Ex. 5027). Perrigo asked for and received additional information about the study, consisting of things like information on the number of study participants necessary to demonstrate bioequivalence (Ex. 5029) and dissolution data. (Exs. 5029, 5035). This was enough for Perrigo to continue negotiations over an omeprazole collaboration.

II. The Competing Proposals

At this stage of things, Perrigo and Dexcel were both trying to develop an omeprazole product in-house, and so each company viewed the other as much as a potential competitor as a potential partner. (Trial Tr. vol. I, 53, ECF No. 379, PageID.5274). Mr. Oren's original joint venture proposal on behalf of Dexcel was contingent on Perrigo abandoning its in-house efforts and fully committing to an exclusive arrangement with Dexcel to bring an omeprazole product to the domestic market. (Trial Tr. vol. I, 168, ECF No. 379, PageID.5389).

Two possible partnership options emerged from further negotiations. First, Perrigo could accept Mr. Oren's proposal and forego the right to pursue its own efforts towards developing a generic omeprazole product for the domestic market. And in return, Dexcel would agree to share certain regulatory and technical information. (Ex. 295). In other words, under this scenario, Perrigo and Dexcel would be "joined at the hip" and Perrigo would "get to see everything" Dexcel had. (Trial Tr. vol. I, 53-54, ECF No. 379, PageID.5274-5275). This was Option 1.

Option 2 was that Perrigo would "ride along" with Dexcel on its development project in return for a $100,000 payment upon signing and a further $500,000 upon the FDA's "approvable" letter. (Ex. 295). The "ride along" meant that Perrigo retained the right to terminate the agreement

and pursue an alternative path to market an omeprazole product (either by successfully developing an omeprazole product in house or by partnering with another entity). But because Perrigo would not be "joined at the hip" with Dexcel for that journey, Dexcel would restrict Perrigo's access to information about Dexcel's development efforts towards an omeprazole product for the U.S. market. (Exs. 295; 5330 at 3). For example, Dexcel would not have to share clinical information nor the status of patent-related legal proceedings. (Trial Tr. vol. I, 54, ECF No. 379, PageID.5275).

Option 2 also limited Perrigo's contributions towards Dexcel's product development and patent litigation defense costs. (Trial. Tr. vol. I, 169-170, ECF No. 379, PageID.5390-5391). For instance, the parties discussed limiting Perrigo's share of anticipated Hatch-Waxman legal costs to $500,000. (Ex. 5330 at 2). Accordingly, there was "no risk at all" to Perrigo under the terms of Option 2. (Ex. 295). If Dexcel could not bring an omeprazole product to market, Perrigo's monetary loss under the contractual terms would be as little as $100,000, and Perrigo would be able to cut its losses and pursue other pathways to bringing a product to market. Still, Perrigo was constrained from looking at all the inner workings of Dexcel's omeprazole development efforts.

III. Perrigo Contracts with Dexcel Under "Option 2"

Perrigo did not consider Option 1 to be a realistic choice for the business. Mr. Needham and Mr. Hendrickson both testified there were too many unknowns and outstanding issues for Perrigo to put its eggs entirely in one basket controlled by Dexcel. (Trial Tr. vol. I, 54, 169, ECF No. 379, PageID.5275, 5390). Beyond any outstanding reservations about Dexcel, the potential size of the generic omeprazole market meant Perrigo wanted to "have as many shots on goal" as possible, as Andrew Solomon, Perrigo's former Assistant General Counsel and Vice President, put it. (Trial Tr. vol. III, 94, 100, ECF No. 381, PageID.5782, 5788). Perrigo thus elected to proceed with Option 2.

On August 15, 2005, Perrigo's domestic affiliate L. Perrigo Company and Dexcel entered into a Supply & Distribution Agreement to bring a generic, store-brand Prilosec OTC competitor to market. (Exs. 263, 5022). The Agreement was consistent with Option 2. Under a Termination clause, for example, Perrigo could terminate the Agreement if Perrigo was able to commercialize and launch its own omeprazole product. (*See* Supply & Distribution Agreement §§ 14.3, 14.4 (Exs. 263, 5022)). But if Dexcel did successfully complete its product development and obtained FDA approval, L. Perrigo Company would be the exclusive distributor to market and sell Dexcel's omeprazole product in the United States. (ECF No. 235, PageID.3182). The agreement likewise recognized the fact that the parties were not "joined at the hip." While certain litigation exceptions were made for purposes of defending against patent-litigation (with firewalls in place), Perrigo was largely locked out from a wide swath of information concerning Dexcel's omeprazole development. (Trial Tr. vol. I, 54, ECF No. 379, PageID.5275).

Under the written Agreement, furthermore, Perrigo would provide Dexcel with information regarding the FDA approval process, and Dexcel would endeavor to provide an omeprazole product that was bioequivalent to Prilosec OTC and did not infringe on AstraZeneca's patents. Perrigo would then market that product (assuming successful development) after FDA approval. (Trial Tr. vol. III, 29-30, ECF No. 381, PageID.5717-5718). The Dexcel contract further provided that Perrigo and Dexcel would work together to defend against any patent litigation brought by AstraZeneca. Dexcel and Perrigo, for instance, would jointly select counsel and share in litigation costs subject to the litigation cap of $500,000.00 (which was later raised to $750,000). (*See* Supply & Distribution Agreement §§ 11.3, 11.4 (Exs. 263, 5022).

Assuming the product was successfully launched, the agreement provided that Dexcel would manufacture the omeprazole product and sell it to L. Perrigo Co. at cost. L. Perrigo Co.

would distribute the omeprazole product on the domestic market for a net six percent fee for sales and marketing. The remaining profit would be split 50/50 between the two companies.

Approximately three months after the agreement was reached, in October 2005, Perrigo prepared an internal summary of the Prilosec OTC project. It was reported that Dexcel's biostudy had neared completion, and Perrigo was trying to obtain a copy of the results, but because of the agreement to proceed under "Option 2," Dexcel was not obligated to share the results with Perrigo. (Ex. 5123). In a handwritten note atop the summary, Mr. Hendrickson remarked that "we hope Dexcel is successful." (*Id.*). Mr. Hendrickson testified that from this, he meant there were still "a lot of risks with Dexcel" from Perrigo's perspective. (Trial Tr. vol. I, 58, ECF No. 379, PageID.5279).

IV. Perrigo's Financial Projections Based on the Dexcel Contract

In the months and years following the execution of the Supply & Distribution Agreement with Dexcel, Perrigo kept close tabs on how valuable the omeprazole product could be for the company. In 2007, Ron Schutt—who at the time served as Perrigo's Vice President of Consumer Healthcare Marketing—took on responsibility for Perrigo's omeprazole financial projections. (Trial Tr. vol. IV, 43-46, ECF No. 382, PageiD.5959-5961). Perrigo's Pharmaceutical Business Development group often prepared projections for products in the "pipeline" like the omeprazole projection Mr. Schutt took on. These projections related to development projects that potentially would lead to company growth, and they helped Perrigo identify and prioritize these opportunities. (Trial Tr. vol. I, 186-187, ECF No. 379, PageID.5407-5408). For these reasons, it was important to Perrigo that the projections be as accurate as possible. And to this end, Perrigo's Business and Development Group gathered information from a wide array of sources to develop their projection

models. (Trial Tr. vol I, 50, ECF No. 379; PageID.5271; vol. IV, 39-40, 52-53, ECF No. 382, PageID.5955-5956; 5968-5969).

Perrigo's projections for its pipeline projects often will contain a range of scenarios of potential sales and profits based on timing. Specifically the projections will anticipate a product launch that is first to market, tied to the market with a competitor, or second to market. (Trial Tr. vol. IV, 40-41, ECF No. 382, PageID.5956-5958). These projections, however, do not adjust for any barriers or risks to a scenario actually being realized. Rather, they reflect "what would happen if the scenario came to fruition." (Trial Tr. vol. IV, 40-41, ECF No. 382, PageID.5956-5957). Perrigo separately considered the external risks to product launches. (*Id.*).

When Mr. Schutt took on the projection project for the Dexcel omeprazole product in June 2007, Dexcel's omeprazole product was entering the market planning phase with an expected launch (at the time) in Perrigo's 2009 fiscal year. (Trial Tr. vol. IV, 46, ECF No. 382, PageID.5962). As part of his modeling, Mr. Schutt reviewed Perrigo's earlier projections, including a projection completed approximately one year earlier. (*Id.* Ex. 1094). That projection estimated 25.6 million units in first year sales with a revenue of approximately $113 million. (Trial Tr. vol. IV, 53, ECF No. 382, PageID.5969; Ex. 1094). These numbers were approximately the same as those that had previously been given to Perrigo's Board of Directors. The minutes of a June 23, 2006, meeting, for example, state that the omeprazole product was expected to launch in Perrigo's 2009 fiscal year, and that the first-year sales, assuming Perrigo was first to market with an omeprazole product, would be roughly $100 million. (Ex. 5207 at Bates No. 22746). The expected launch timeframe and first year sales number (albeit "[h]igh side") stayed the same a year later during a March 2, 2007, Board meeting. (*Id.* at Bates No. 22765).

In July 2007, Mr. Schutt did a "deep dive" into the data surrounding the omeprazole development project, and his projections contemplated higher sales than previously forecasted. (Trial Tr. vol. IV, 56, ECF No. 382, PageID.5972). On July 18, 2007, Mr. Schutt emailed his updated forecast to Mr. Needham and other Perrigo employees and later that afternoon Mr. Schutt sent a revised projection forecasting $240 million in first year sales. (Exs. 1149; 1163). At trial, Mr. Schutt testified that while his revisions of omeprazole unit sales projecting first year sales of 25.8 million units were "remarkably close" to the 2006 forecast, there were several considerations that went into the higher projection in his forecast. (Trial Tr. vol. IV, 59, ECF No. 382, PageID.5975).

First, Mr. Schutt's projections added additional units and sales based on "Rx/Managed Care channel" and a term called "pipefill." The former term related to an initiative led by Mr. Schutt by which, in addition to the over-the-counter market, Perrigo would also try to sell the generic omeprazole product via a doctor's prescription. (Trial Tr. vol. IV, 54, ECF No. 382, PageID.5970). In a June 27, 2007, email to Mr. Needham, Mr. Schutt explained that it was "extremely difficult to forecast" the number of additional omeprazole units that could be sold under this initiative. (Ex. 1163). For example, the prescription and generic products were sold in different formats, and a prescription drug product would need to be sold in bulk, rather than in smaller blister packs designed for individual sale. (Trial Tr. vol. IV, 54-55, ECF No. 382, PageID.5970-5971). The 2006 projection also did not include "pipefill" which was a one-time addition of units, equivalent to approximately three months' worth of product to "fill" the "pipe" of the retail store shelves. (Trial Tr. vol. IV, 57-58, ECF No. 382, PageID.5973-5974). The 2006 projection did not account for pipefill because pipefill did not reflect actual sales or consumer demand for the product and so, relatedly, projecting pipefill too far from launch would lead to

numbers that were too dependent on uncertain events. (Trial Tr. vol. IV, 58, ECF No. 382, PageID.5974). Accounting for the RX/Managed Care initiative and pipefill led Mr. Schutt to increase the first-year revenue projections in his revised model by $89 million. (Trial Tr. 63, ECF No. 382, PageID.5979).

Mr. Schutt also made two pricing revisions to the June 2006 model based on information that had not been available to Perrigo when the June 2006 model issued. (Trial Tr. vol. IV, 60-62, ECF No. 382, PageID.5976-5978). These changes would result in additional revenue to Perrigo. (Trial Tr. vol. IV, 62-63, ECF No. 382, PageID.5978-5979). The Rx/Managed Care initiative, pipefill, and the two pricing revisions represented the vast majority of the delta between the June 2006 model and Mr. Schutt's 2006 revisions.

A few months later, in December 2007, Perrigo released a press release projecting annual sales of Dexcel's omeprazole product in the range of $150-200 million. (Ex. 416). The discrepancy between this release and Mr. Schutt's projection was due to the external risks, including potential regulatory delays and manufacturing challenges, that were not accounted for in the internal projection. (Trial Tr. vol. IV, 65-66, ECF No. 382, PageID.5981-5982).

DEXCEL'S SUCCESSFUL DEVELOPMENT OF A GENERIC PRODUCT

I. Dexcel's Early Omeprazole Development

At the time the Dexcel Supply & Distribution Agreement was executed, Dexcel was already manufacturing omeprazole products for consumers overseas. (*Id.*). And it had developed a proposed formula for a product for the U.S. market before it entered into the Supply & Distribution Agreement with L. Perrigo Company. (Ex. 5358). Dexcel's formula used omeprazole base as the active ingredient in its generic product—the active ingredient in Prilosec Rx but not Prilosec OTC. Thus, like Perrigo, Dexcel elected to pursue the Section 505(b)(2) pathway for

FDA approval because the active ingredient was different than that of Prilosec OTC (omeprazole magnesium). (Trial Tr. vol. III, 30, ECF No. 381, PageID.5718).

And like Perrigo had done before , Dexcel met with the FDA in advance of submitting its application for its proposed omeprazole product. The meeting took place on May 20, 2005. (Ex. 5017). Perrigo did not attend this meeting. (Trial Tr. vol. III, 32, ECF No. 381, PageID.5720). The Supply & Distribution Agreement with Perrigo had not yet been signed, and so Dexcel still viewed Perrigo as a potential competitor (a view that was not completely alleviated once Perrigo selected Option 2).

While Dexcel did report back to Perrigo that it had a positive meeting with the FDA (Ex. 5017) Perrigo was still left to guess as to specifics from the meeting, because Dexcel viewed those details to be a competitive advantage. (*Id.*). Perrigo did glean some information from what Dexcel had shared. For example, in a June 1, 2005, meeting, Mr. Needham remarked that Perrigo assumed "that it may likely be that FDA is not requiring Dexcel to prove bioequivalence to Prilosec OTC in a fed study." (Ex. 5330 at 3). This was something that Perrigo later confirmed in its own meeting with the FDA later that fall. (Ex. 5127 at 5).

After the favorable results of the pilot study, Dexcel performed a pivotal study and communicated those results in Perrigo in November 2005. (Ex. 316, 5157, 5158). Dexcel did not share the structure of the food effect study, since that might assist Perrigo in its own development, but Dexcel nevertheless assured Perrigo that it had "no doubt that FDA will accept the studies." (Ex. 5037). For its part, Perrigo agreed that Dexcel had passed a bioequivalence study. (Ex. 5157). There were other aspects of an application, however, that Perrigo knew Dexcel would have to fulfill to be approved by the FDA. This included things like safety and effectiveness information, other clinical studies, chemistry studies, manufacturing, controls information, labeling

information. And any outstanding legal issues would also need to be resolved. (Trial Tr. vol. III, 38, PageID.5726).

II. Dexcel's NDA Submission and the "Approvable" letter

On February 8, 2006, Dexcel filed its NDA with the FDA for approval of an omeprazole tablet, and on April 11, 2006, the FDA notified Dexcel that its NDA had been accepted for filing. (ECF No. 235, PageID.3183). Around this time, Perrigo placed its own internal omeprazole development efforts on hold. (Ex. 334 at 2).

On December 8, 2006, ten months after Dexcel filed its omeprazole NDA, the FDA sent Dexcel an "Approvable Letter." (Exs. 323 and 5026). At the time, an approvable letter was a typical occurrence in the 505(b)(2) process, and the FDA's letter to Dexcel indicated that the agency did not observe any severe deficiencies in Dexcel's application after the FDA's preliminary analysis. (Trial Tr. vol. VII, 47, ECF No. 385, PageID.6617; Trial Tr. vol. V, 140, ECF No.383, PageID.6283). To that end, the letter to Dexcel indicated that the FDA had "completed our review" of Dexcel's omeprazole NDA, and the application was "approvable" subject to several listed items. (*Id.*).

While an approvable letter is a good indication of an eventual approval, it is not a guarantee that the applicant will get final approval from the FDA. (Trial Tr. vol. VI, 27, ECF No. 383, PageID.6391). Thus, after receiving a copy of the FDA's approvable letter to Dexcel, Mr. Schuster wrote to his colleagues at Perrigo on December 11, 2006: "[n]ot to detract anything from the Dexcel effort, but I believe that all NDAs receive an approvable letter at 10 months, unless they are terminally deficient." (Ex. 324). This was based on Mr. Schuster's experience from a meeting with the FDA during Perrigo's application for a loratadine application. He learned that the FDA

had a user fee program and that it "never misses" the 10-month deadline for issuing an approvable letter. (*Id.*).

III. Issues Identified in the Approvable Letter

Accordingly, the approvable letter did not mean that Dexcel's omeprazole NDA was approved, and it did not mean that it would be approved either. Indeed, the approvable letter identified three issues that Dexcel would need to address before the application could move forward: 1) deficiencies at the clinical organization that performed the pivotal bioequivalence study for Dexcel; 2) an inspection of Dexcel's manufacturing facility that required revisions to specifications and analytical procedures; and 3) requested revisions to product labeling. (Ex. 323, 5026; *see also* Ex. 5394 at 17). While all would need to be addressed, the first issue was of chief concern to Perrigo. (Ex. 5394 at 17; Trial Tr. vol VII, 50, ECF No. 385, PageID.6620)

The bioequivalence study for Dexcel's omeprazole product was conducted by a clinical (or contract) research organization (CRO) called MDS Pharma Services ("MDS"). A CRO conducts clinical trials for NDA sponsors like Dexcel or Perrigo because drug companies usually do not have the capabilities to perform these studies in house. (Trial Tr. vol. III, 40, ECF No. 381, PageID.5278). The approvable letter to Dexcel indicated that "[d]uring a recent inspection of one [MDS] facility for this inspection, our field investigator issued a 483 Notice of Findings to the facility's representative. Satisfactory resolution of these deficiencies is required before this application may be approved." (Exs. 323, 5026).

A 483 Notice of Findings (Form 483) is a form that is issued after an inspection by the FDA (Trial Tr. vol. VI, 29, ECF No. 384, PageID.6393) that outlines the results of the inspection and any violations of the FD&C Act that were found by the inspectors. (Trial Tr. vol. III, 47, ECF No. 381, PageID.5735). Perrigo did not have the Form 483 that was referenced in Dexcel's

approvable letter. (Trial Tr. vol. III, 47, ECF No. 381, PageID.5735). And Dexcel did not give Perrigo any details about what it knew about the alleged deficiencies. (Trial Tr. vol. III, ECF No. 381, PageID.5736).[10] However, Perrigo was familiar with MDS because it had used MDS to perform studies for some of its products. (Trial Tr. vol. III, 40, ECF No. 381, PageID.5728). Specifically, Perrigo had used MDS for a bioequivalence study for its loratadine product. (*Id.*). According to Mr. Schuster, Perrigo experienced "significant problems" with MDS's studies. (*Id.*). In particular, there was contamination in some of the blood plasma samples that were taken for Perrigo's study. (*Id.* at 40-41; *See also* Ex. 348).

Regardless, when conveying the approvable letter to Perrigo on December 11, 2006, Dexcel assured Perrigo that the issue with MDS was minor, and that Dexcel had already responded to the FDA. (Ex. 324 at 2). Perrigo, naturally, wanted more than a blanket assurance. But Option 2 limited its access.

IV. The Tentative Approval

Dexcel formally responded to the FDA concerning the Form 483 issue with MDS in a December 18, 2006, communication. Thereafter, on June 14, 2007, Dexcel received a letter from the FDA stating that Dexcel's NDA was "tentatively approved" pending the outcome of ongoing patent litigation. (ECF No. 235, PageID.3183). The FDA remarked that Dexcel's December 18, 2006, response to the issues identified in the approvable letter "constituted a complete response" to those action items. (Ex. 5039). This "Tentative Approval" letter was another step in the

[10] The Government's expert, Dr. Peck, testified that the MDS issues referenced in the approvable letter related to a statistical analysis of the bioequivalence data. There were several data points that were not included in MDS's analysis, and the FDA asked MDS to reanalyze the data with the missing data points to determine whether Dexcel's omeprazole product remained bioequivalent. (Trial Tr. vol. VI, ECF No. 384, PageID.6394). The Government does not contend, however, that this was information known to Perrigo when the approvable letter issued.

statutory and regulatory process towards final approval. But as was the case with the approvable letter, the Tentative Approval letter did not guarantee approval. *See generally* 21 C.F.R. § 314.107 (describing a tentative approval in the context of determining the date of 505(b)(2) application approvals). The approval letter itself stated that the NDA was only "tentatively approved" and was contingent on the information known to the FDA at that time. It was, in other words, "subject to change on the basis of any new information that may come" up before the FDA. (*Id.*).

V. AstraZeneca Litigation

FDA approval was not the only hurdle towards a successful launch of Dexcel's omeprazole product. Patent litigation represented another, independent hurdle. (Trial Tr. vol. III, 105, ECF No. 381, PageID.5793). The patent issues referenced in the Tentative Approval letter were well known to Perrigo. Indeed, when Perrigo identified Prilosec Rx as a potential switch candidate, it also began looking into the existing patents related to omeprazole. (Ex. 182 at 4). At a minimum, Perrigo knew AstraZeneca's omeprazole patents could affect the timing of the release of a generic product that was not "at risk."

A. Opinion Letter

Early on in its own development process, Perrigo began looking into the patents protecting omeprazole. (Ex. 182). Perrigo obtained outside legal counsel—Price, Heneveld, Cooper, DeWitt & Litton, LLP—to advise the company concerning AstraZeneca's omeprazole patents. (Trial Tr. vol. III, 124-126, ECF No. 381, PageID.5812-5814). Engaging outside counsel is not out of the ordinary; generic drug companies will often seek out legal opinions help defend against a claim of willful patent infringement down the road. These opinions, however, will not lay out the entirety of the potential risks and rewards of litigation because these opinions will need to be disclosed to the adverse party during litigation. Accordingly, the opinions are tailored to refrain from

discussing litigation risks, or arguments that the adverse party might make in response to an invalidity or non-infringement argument. (Trial Tr. vol. IX, 155-156, ECF No. 387, PageID.7177-7188).

On April 9, 2004, Price Heneveld sent an opinion letter to Mr. Solomon stating that it had evaluated the U.S. Patents to identify potential infringement issues. (Ex. 5344).[11] The opinion concluded that Perrigo's planned activities would not constitute infringement. In particular, the opinion detailed that the proposed omeprazole supplier—Cipla Limited—had sold omeprazole (specifically omeprazole form A) in the United States more than one year before AstraZeneca filed one of its omeprazole patents, namely, the '380 patent. This argument, if successful, would amount to an "on-sale bar" resulting in invalidity of two claims in the patent. (*Id.*). Consistent with the purpose of such letters in general, however, the Price Heneveld letter did not evaluate the strength of the invalidity arguments or present possible rebuttal arguments that AstraZeneca might raise.

B. The Hatch-Waxman Framework and 30 Month Stay

The Hatch-Waxman Act provided the framework for litigation. The Act also effected the timeline of the FDA's approval of Dexcel's 505(b)(2) omeprazole NDA. In 2005, Perrigo viewed it as "a given" based on the Hatch-Waxman Act that AstraZeneca would sue Dexcel under these specialized procedures for infringing its patents related to Prilosec OTC once the omeprazole NDA was filed. (Trial Tr. vol. I, 58-59, ECF No. 379, PageID.5279-5280).

"In addition to streamlining the drug approval process, the Hatch-Waxman Act provides specialized procedures for brand-name and generic drug manufacturers to resolve intellectual property disputes." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132,

[11] Dexcel also elected to use Cipla's omeprazole for its 505(b)(2) NDA. Cipla's product included an active ingredient with a different polymorphic form than the ingredient used in Dexcel's UK omeprazole product. (Ex. 5358).

144 (3d Cir. 2017). Under the 505(b)(2) process described above, the Hatch-Waxman Act required that Dexcel's Section 505(b)(2) NDA include information on each patent that claimed the omeprazole drug or a method of using the drug in its application. *See* 21 C.F.R. § 314.54. The FDA includes this type of information in a publication colloquially known as the "Orange Book." The legislation further required Dexcel to transmit a Paragraph IV "notice letter" to the patent holder—AstraZeneca—to give notice of the NDA and the position of the applicant that the listed patents either are invalid, or that the application does not infringe on the patents. (21 U.S.C. § 355(b)(3); Trial Tr. vol. III, 102-103, ECF No. 381, PageID.5790-5891). The latter requirement referred to a provision in the Hatch-Waxman Act designed to protect against possible patent infringement. The act requires that every 505(b)(2) application certify to any patents "relied upon by the applicant for approval of the application." 21 U.S.C. § 355(b)(2); *see also Genus Lifesciences, Inc. v. Azar*, 486 F. Supp. 3d 450, 459 (D.D.C. 2020) (citing 21 U.S.C. § 355(b)(2) and describing the statutory process). The certification, furthermore, is required to affirmatively state one of four things about the listed patents, the fourth of which is that: the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]" 21 U.S.C. § 355(b)(2)(A)(iv). This is the "Paragraph IV" certification.

As alluded to in the Tentative Approval letter, a Paragraph IV certification and notice affects the timing of FDA approval. To help streamline things, under the Hatch-Waxman Act, "a paragraph IV certification is deemed by statute to constitute an act of infringement under patent law." *Mylan Pharms., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 200 (D.D.C. 2012). And by operation of the statute, a patent holder has 45 days to bring suit against the applicant. If the patent holder does bring such a suit, then the FDA approval process for the generic product is delayed for thirty months, or until the infringement suit is resolved. (Trial Tr. vol. I, 171, ECF No. 379,

PageID.5392; Trial Tr. vol. V, 146, ECF No. 373, PageID.6289). Thus, in an internal Perrigo slide discussing the Dexcel Supply & Distribution Agreement, Perrigo developers believed that Dexcel would file its Section 505(b)(2) NDA in early 2006. Anticipating litigation, Perrigo believed at that point that a thirty-month stay would expire in January 2009. (Ex. 262 at 2). Any product launch before that point would be "at risk," meaning that if the product launched before patent protection expired, and AstraZeneca sued to protect its patents, there could be significant penalties if the reviewing court found infringement. (Trial Tr. vol. V, 146-47, ECF No. 383, PageID.6289-6290).

C. Dexcel's Paragraph IV Notification Triggers Litigation

After Dexcel filed its Section 505(b)(2) NDA, its litigation counsel at Leydig Voit & Mayer Ltd. sent a Paragraph IV notice letter—dated April 17, 2006—to AstraZeneca. (ECF No. 235, PageID.3183; Ex. 5136). The letter referenced the certification contained in Dexcel's NDA that certain AstraZeneca patents—the '380, '810, '960, '424, '616, '265, and '338 patents—were invalid and not infringed by Dexcel's omeprazole product listed in its Section 505(b)(2) NDA. (Ex. 5136). To support its position, the letter referenced the "on-sale bar," that was referenced in the 2004 Price Heneveld opinion letter to Perrigo. (Ex. 5136 at 5).

As expected, on May 30, 2006, AstraZeneca sued Dexcel for infringement. (ECF No. 235, PageID.3183). The patents-in-suit concerned three of the patents listed in the Paragraph IV notice: the '505, '230 and '380 patents. (*Id.*).[12] By filing the suit within 45 days of receiving Leydig

[12] The parties here focus their attention on the '380 patent. The '505 and '230 patents expired on October 20, 2007. (ECF No. 235, PageID.3183). Accordingly, the '380 patent was the only one that stood in the way for any omeprazole product launch from Dexcel that took place after that date. (Trial Tr. vol. III, 128-129, ECF No. 381, PageID.5816-5817). The '380 patent covered a "Crystalline Form of Omeprazole" and was issued by the PTO on November 21, 2000. (*See* Compl. ¶ 17, *AstraZeneca AB v. Dexcel, Ltd.*, No. 1:06-cv-358 (D. Del. Filed May 30, 2006), *available at* Ex. 397 at 4). The '380 patent asserted six claims related to "omeprazole form A."

Voit's Paragraph IV notice, the 30 month stay on the FDA's approval of Dexcel's NDA was triggered. (Trial Tr. vol. III, 103, ECF No. 381, PageID.5791).

D. Option 2 of the Dexcel Contract Limits Perrigo's Access to Information About the AstraZeneca Litigation

The Supply & Distribution Agreement between Perrigo and Dexcel provided that the parties would cooperate in defending against patent litigation. (*See* Supply & Distribution Agreement §§ 11.3, 11.4 (Exs. 263, 5022)). Still, the structure of the "Option 2" arrangement did not give Perrigo unfettered access to Dexcel's information—including its litigation strategies. To ease the tension between the cooperation agreement and the decision to limit Perrigo's access to Dexcel's information, Dexcel authorized Perrigo to appoint an in-house attorney, Mr. Solomon, to represent Perrigo's interests in the litigation. (*Id.* at § 11.6). As set out in the agreement, Mr. Solomon would be given full access to information related to the AstraZeneca litigation, but with certain firewalls. Namely, Mr. Solomon would not "be allowed to share any information arising from and/or relating to the patent litigation with any other personnel within Perrigo, any of its Affiliates, or with any third party." (*Id.*).

In this role, Mr. Solomon reviewed the Paragraph IV Notice letters prepared by Leydig Voit. He did not assist in preparing them. (Trial Tr. vol. III, 103-104, ECF No. 381, PageID.5791-5792). Mr. Solomon did not independently confirm any of the facts alleged in the Notice Letter, however, because Dexcel had represented in the Supply & Distribution Agreement that its product did not infringe on AstraZeneca's patents. (Trial Tr. vol. III, 93, ECF No. 381, PageID.5781).

U.S. Patent No. 6,150,380 cols. 6-8. (filed Nov. 10, 1998). As described in the AstraZeneca Complaint, those claims related to "a novel crystalline form of omeprazole," which relate to claims 1 and 2; "pharmaceutical compositions of this novel crystalline form of omeprazole," claims 3 and 4; and "methods of using omeprazole for the treatment of gastrointestinal disorders," claims 5 and 6. (*Id.*).

After reviewing the letter, Mr. Solomon determined that it advanced a legitimate defense against the patents without any guarantee of success in court. (Trial Tr. vol. III, 104, ECF No. 381, PageID.5792).

Once litigation commenced, Mr. Solomon testified that the cooperation between Dexcel and Perrigo regarding litigation was "relatively minimal." Mr. Solomon would occasionally perform a verification check for Dexcel, but he believed that Dexcel was doing a "fine job managing the case." (Trial Tr. vol. III, 95-96, ECF No. 381, PageID.5783-5784). And while Section 11.6 of the Supply & Distribution Agreement provided that Mr. Solomon would have "full access to all documents, witnesses and proceedings relating to the patent litigation," Mr. Solomon testified that he actually had minimal access because of a protective order in the case. (Trial Tr. vol. III, 98, ECF No. 381, PageID.5786). In fact, once the litigation started, Mr. Solomon did not receive any information from Dexcel in connection with the litigation that was not already public. (Trial Tr. vol. III, 101-102, ECF No. 381, PageID.5789-5790). Thus, Mr. Solomon's role was one of "receiving after-the-fact information." (Trial Tr. vol. III, 95, ECF No. 381, PageID.5783). Mr. Solomon could, of course, confer with Dexcel's litigation counsel. (Trial Tr. vol. III, 137, ECF No. 381, PageID.5825). And he could review other publicly available information, including the prosecution history of the '380 patent. (Trial Tr. vol. III, 126, ECF No. 381, PageID.5825).

During this period, Mr. Solomon believed that absent a settlement, the earliest the litigation would resolve would be at the close of the thirty month stay sometime in October 2008. Mr. Solomon based this belief on his understanding that the presiding judicial officer in the patent litigation typically tried to issue final rulings in similar cases around the expiration of the stay. (Trial Tr. vol. III, 114, ECF No. 381, PageID.5802). And Mr. Solomon doubted that the litigation would resolve prior to that point. Indeed, Mr. Solomon believed it would be "shocking" if the

parties in the AstraZeneca litigation settled the case before the expiration of the stay. (Trial Tr. vol. III, 110-111, ECF No. 381, PageID.5798-5799). As Mr. Hendrickson explained at trial, Perrigo believed there was no reason for a brand name company to settle early and give a generic competitor a head start at launching its product. (Trial Tr. vol. I, 59, ECF No. 379, PageID.5280).

VI. An Early End to the Litigation

Dexcel, for its part, had a more optimistic take on the litigation timeline. In particular, Mr. Oren believed that an earlier conclusion to the litigation was possible. On March 8, 2007, less than a year after AstraZeneca filed its Complaint, Mr. Oren copied Mr. Solomon on an email conversation with outside legal counsel. In it, Mr. Oren summarized a meeting with counsel and reported he would potentially be speaking with an AstraZeneca representative in the near term to discuss a settlement and an early end to the litigation. (Ex. 388 and 389). Perrigo was not a part of the underlying meeting, and this was the first time that Mr. Solomon had heard about settlement discussions and the possibility of an early end to the litigation. (Trial Tr. vol. III, 107-109, ECF No. 381, PageID.5794-5797).

Mr. Solomon, and Perrigo, took Mr. Oren's representations with a grain of salt. At trial, Mr. Needham described Mr. Oren as "extremely self confident" and "very optimistic in his ability to get things done." (Trial Tr. vol. I, 166, ECF No. 379, PageID.5387). Thus, despite terming AstraZeneca's infringement claims as "baseless" in the March 8th email, (Ex. 388) Perrigo understood that nothing in litigation is certain and that Dexcel would have to carry the burden of proof of demonstrating patent invalidity by a clear and convincing standard. (Trial Tr. 109-110, ECF No. 381, PageID.5797-5798). Furthermore, some of the representations in the March 8th litigation memorandum did not make sense to Mr. Solomon. Mr. Oren wrote, for example, that he anticipated a minitrial on the formulation patents and that this minitrial would be completed

approximately within the next month. (Ex. 388). But Mr. Solomon had never heard of a minitrial in a Hatch-Waxman case, and he was not aware that the assigned judge to the AstraZeneca litigation used minitrials as part of managing the case. (Trial Tr. vol. III, 108, ECF No. 381, PageID.5796). At bottom, Mr. Solomon had no opinion on whether the settlement discussions outlined by Mr. Oren would be successful. (Trial Tr. vol. III, 109, ECF No. 381, PageID.5797).

Throughout the summer of 2007, Mr. Solomon held that uncertainty. In his mind, the case could settle; and the case could not settle. (Trial Tr. vol. III, 114, ECF No. 381, PageID.5802.) Mr. Needham, likewise, testified that he did not believe there was a way to launch Dexcel's omeprazole product before the end of the automatic stay. AstraZeneca would not, he believed, want to settle the case and give up market share space before the end of the stay. (Trial Tr. vol. I, 183, ECF No. 379, PageID.5404). And Perrigo would not launch "at risk."

Believing that Mr. Oren was perhaps overly optimistic and aware that any settlement talks could be fruitful, but also detrimental, to Perrigo's omeprazole business, Mr. Solomon sent Mr. Needham an email dated July 13, 2007, to urge that Perrigo try to obtain a copy of any settlement language. (Ex. 5332). He outlined four principal reasons why Perrigo would need the review any settlement language: 1) potential liability that Perrigo might have to Dexcel under the settlement agreement; 2) potential obligations for disclosure of a settlement under the securities laws; 3) the right Perrigo had to review such an agreement under the Supply & Distribution Agreement with Dexcel; and 4) in order to understand any provisions might have adverse consequences for Perrigo down the line. (*Id.*; Trial Tr. vol. III, 113-114, ECF No. 381, PageID.5801-5802). On August 13, 2007, Mr. Needham authored a document in which he indicated that the full terms of the proposed agreement had not been disclosed to Perrigo. What had been disclosed, however, satisfied Mr.

Needham that if a settlement agreement was reached, it would permit Dexcel to launch, pending final FDA approval, before the end of the Hatch-Waxman 30-month stay. (Ex. 5161).

Meanwhile the litigation continued. On September 4, 2007, Dexcel filed an amended answer with antitrust counterclaims. (Ex. 405). Then on September 7, 2007, Mr. Solomon sent an email to Perrigo executives that the case had been reassigned to a different judge based on publicly available information. (Ex. 392). Mr. Solomon wrote that he did not know how the change would affect the trial timeline, but at trial Mr. Solomon testified that he viewed the reassignment as being adverse to Dexcel because the new judge had a reputation for favoring brand name companies over generic drug companies. (Trial Tr. vol. III, 119, ECF No. 381, PageID.5806). Dexcel's settlement counsel at the law firm Frommer, Lawrence & Haug shared that sentiment, writing that he believed the that the new judge was "pro patent." (ECF No. 391). Settlement counsel also expressed doubt that the trial schedule could be maintained with the new judge. (*Id.*).

Mr. Oren's optimism was borne out by future events. An early conclusion was, in fact, reached later in September via a settlement of the patent infringement lawsuit between AstraZeneca and Dexcel. (ECF No. 235-3, PageID.3294). The agreement was signed on September 21, 2007, and the parties filed a stipulation of dismissal on September 27, 2007. (Ex. 329; ECF No. 235, PageID.3183). The agreement meant that as of October 21, 2007, AstraZeneca's patents no longer stood in the way of launching Dexcel's omeprazole product. Only final FDA approval was needed. (Ex. 329).

The news of a settlement, especially one before the expiration of the stay, was a surprise to Perrigo. Mr. Needham. Mr. Papa, and Mr. Hendrickson all testified that the news came as a shock and was inconsistent with their own experiences with Hatch-Waxman litigation. (Trial Tr.

vol. I, 60, ECF No. 379, PageID.5281; Trial Tr. vol. I, 184, ECF No. 379, PageID.5405; Trial Tr. Vol. III, 114-115, ECF No. 381, PageID.5802-5803; Trial Tr. vol. VII, 143, ECF No. 385, PageID.6713). This is not to say that Perrigo had not prepared for a scenario where there was an early end to the litigation and a sooner than expected launch. For example, on June 10, 2007, Ygal Seelenfreund (a Dexcel executive officer) emailed Mr. Needham about preparing launch orders for Dexcel's omeprazole product. (Ex. 5149 at 12).[13] The same month, Tom Cotter of Perrigo's business development office emailed Mr. Needham with a series of questions for Dexcel during an upcoming visit by Perrigo to Dexcel. In his message, Mr. Cotter posed a number of questions based on "a possible October 2007 launch." (Ex. No. 438). Nothing within the email indicated, however, that Perrigo expected Dexcel's omeprazole product to launch by then.

VII. The Launch

The FDA granted final approval for Dexcel's omeprazole product on December 4, 2007. (ECF No. 235, PageID.3183). Perrigo learned of the approval from Dexcel two days later on December 6, 2007. (Ex. 331). Sales of the generic omeprazole product commenced in the United States in late February of 2008. (ECF No. 235, PageID.3184).

Sales proved profitable, to put it mildly. During the tax years at issue, Perrigo's omeprazole business via the Supply & Distribution Agreement totaled $297.5 million in pre-tax operating profits. (ECF No. 235-5). There was a total of $977.4 million in net sales. (ECF No. 235-4). This was, according to Mr. Papa, the largest product launch in Perrigo's history. (Ex. 5411, 2008 Perrigo Annual Report at 6). And as Perrigo continued to experience success with omeprazole

[13] Mr. Seelenfreund further noted that Mr. Oren expected to be able to launch the omeprazole product in October. At the time, however, Mr. Needham believed that Mr. Oren was being overly optimistic.

sales, the project went on to become an example of "How to Successfully Gain Share Against an Established Brand." (Ex. 5337 at 30).

PERRIGO'S INTERCOMPANY TRANSACTIONS

The above sections explained how Perrigo, as a generic drug distributor, identified Prilosec Rx as a Rx-to-OTC "switch" candidate and ultimately launched a generic omeprazole product in the United States via the Supply & Distribution Agreement with Dexcel Pharma that generated millions of dollars in sales and profits. This section details how Perrigo restructured from a small domestic entity into a major multinational pharmaceutical company under a "tax-efficient multinational structure" also known as tax-efficient supply chain management, or "TESCM" plan developed by the accounting firm Ernst & Young. This section further describes how, as part of that restructuring, Perrigo assigned the Supply & Distribution Agreement from the domestic side of its books to an Israeli affiliate.

I. Perrigo's Initial International Plan to Supply Foreign Countries with Domestic Products

From its start as a small general store in Allegan Michigan, and over the next one hundred years, Perrigo was a domestic company that manufactured and distributed products for sale to consumers on the domestic market. (Trial Tr. 151, 160, ECF No. 379, PageID.5372, 5381). Beginning in the 1990s, Perrigo decided to expand its product lines and its international markets. These efforts launched Perrigo from a company with $100 million in sales in 1990, to a multinational company with $5 billion in sales in 2020. (Trial Tr. vol. I, 40, 160, ECF No. 379, PageID.5261, 5381).

Perrigo began its internationalization efforts in the late 1990s after determining that its domestic market in the United States had matured and that international expansion was the next logical step towards growth. (Trial Tr. vol. I, 161-162, ECF No. 379, PageID.5382-5383). As

Mr. Hendrickson put it during trial, during this time Perrigo wanted to be an international company with "more Perrigo product in the world's medicine cabinets than any other company." (Trial Tr. vol. I, 38, ECF No. 379, PageID.5259).

Perrigo's international business model, as first contemplated, was to supply the foreign markets with domestically produced products. This was a logical extension of the company's established business model. But the approach was not successful. (Trial Tr. vol. I, 162-163, ECF No.379, PageID.5383-5384). Perrigo learned that to succeed it needed to be present in the overseas marketplace for manufacturing, regulatory, and commercial finance purposes. (*Id.*). But this was all new to Perrigo. So Perrigo set about engaging outside advisors and developing a new strategy to expand its markets.

II. Perrigo Establishes an International Footprint through Mergers and Acquisitions.

Perrigo's CEO at the time, Dave Gibbons, spearheaded Perrigo's new international focus. To kick things off, he took a Perrigo executive team on a retreat to Colorado to work on Perrigo's global vision. (Trial Tr. vol. I, 37-385, ECF No. 379, PageID.5258). Perrigo subsequently hired a new tax director, Scott Rush, and an international tax specialist, Bill DeGood. From there, and continuing through subsequent leadership teams, including Joseph Papa's term as CEO and chairman of the Board, Perrigo intentionally structured an international footprint.

These efforts began with acquiring certain foreign companies. Perrigo successfully brought QUIFA (a Mexican company) and Wrafton Laboratories (a U.K. distributor of generic drugs) into its corporate folds. (Trial Tr. vol. I, 36-37, 151, 160-161, ECF No. 379, PageID.5257-5258, 5372, 5381-8382). These were a part of Perrigo's strategic vision of expansion into Europe and Asia. (Ex. 1657). Perrigo identified several other targets for mergers and acquisitions. (Ex. 1658). Perrigo saw these targets as a large part of its planned growth, and as a way to jumpstart

its broader internationalization efforts. (Trial Tr. vol. I, 44, ECF No. 379, PageID.5265). In 2005, Perrigo acquired the Israeli company Agis Industries for roughly $800 million. (*Id.*). This was a "significant" and "major" acquisition for Perrigo. (Trial Tr. vol. I, 161, ECF No. 379, PageID.5382).

By 2006, Perrigo was doing business in five countries: the U.K., Mexico, Israel, India, and China. (Trial Tr. vol. IV, 29, ECF No. 382, PageID.5945). Over the ensuing years, Perrigo continued to expand by acquiring the Irish company Elan in 2013, and Omega, a company with a foothold in over 35 European countries, in 2015. (Trial Tr. vol. I, 161, ECF No. 379, PageID.5382).

III. Perrigo Engages Ernst & Young to Structure its International Operations.

Perrigo had very little in-house experience when it began its international expansion. There were growing pains bringing the executives of acquired companies in house.[14] Separately, Perrigo needed to develop the infrastructure in its business and tax departments to handle all the added complexities of the international expansion. Perrigo had some foreign operations at that time, specifically in Mexico, but there were no cross-border transactions that would require Perrigo to determine an appropriate arm's length price for transfer of products or intellectual property between related parties. (Trial Tr. vol. II, 66-67, ECF No. 380, PageID.5528-5529; Trial Tr. vol. III, 151-152, ECF No. 381, PageID.5839-5840). That changed after Perrigo acquired Agis in 2005. The acquisition required Perrigo to perform transfer pricing studies. (Trial Tr. vol. II, 68-69, ECF No. 380, PageID.5530-5531).

[14] Mr. Hendrickson testified that after Perrigo acquired Agis Industries in 2005, Agis representatives acted like they were the ones who had acquired a company. Consequently, relations became strained. (Trial Tr. vol. I, 45, ECF No. 379, PageID.5266).

Perrigo's internal tax department was not well set up for this task. When Scott Rush joined the tax department in 2001, for example, he was the department's only employee. (Trial Tr. vol. II, 66, ECF No. 380, PageID.5528). A few years later Mr. DeGood became the department's fourth employee. But he also had no experience with transfer pricing. (Trial Tr. vol. III, 153, ECF No. 381, PageID.5841).

Accordingly, Perrigo looked outside its doors for help handling the tax department's international responsibilities. (*Id.*) Perrigo ultimately engaged the accounting firm Ernst & Young ("EY") to assist it in the company's international supply chain structure. Perrigo already had a business relationship with the firm to review the documents of the international entities Perrigo had recently acquired, and Perrigo decided to expand its relationship with EY to ask the company to assist Perrigo in building out its company infrastructure and operations to handle international growth. (Trial Tr. vol. III, 152, ECF No. 381, PageID.5840). As Perrigo told EY, its "old operating structure of developing, manufacturing, and marketing a product all in the same geographical location does not allow Perrigo to utilize its worldwide capacity and abilities." (Ex. 1 at pp 2). This "hinder[ed] Perrigo's ability to integrate its two primary businesses, Agis and Perrigo business, and impair[ed] [Perrigo's] ability to exploit and deploy its IP globally in order to achieve the full synergies of the combined operations." (*Id.*). Perrigo wanted to "utilize its worldwide cash to develop new products and to manufacture and distribute those products in the location which makes the most economic sense[.]" (*Id.*). As Mr. Rush testified, tax efficiency was important. But it was also important that Perrigo had a business structure in place to support its planned international growth. (Trial Tr. vol. II, 71, ECF No. 380, PageID.5533).

Perrigo engaged EY to assist it in two specific respects. First, the firm would perform a "straightforward transfer pricing documentation analysis" of Perrigo's existing acquisitions and

intercompany transactions across Perrigo's entities in the United States, Mexico, the UK, Israel and Germany. (Ex. 21; Trial Tr. vol. II, 123, ECF No. 380, PageID.5585). Second, Perrigo selected EY to advise the company about planning opportunities under a "tax-efficient multinational structure" also known as tax-efficient supply chain management, or "TESCM." (Ex. 21). EY & Perrigo executed a project addendum dated November 14, 2005, effective June 2005, to account for this new engagement. (Ex. 30).

Perrigo primarily worked with two EY employees—Anna Voortman and Colleen Warner—to develop a detailed "step plan" to assist Perrigo with its TESCM project. (ECF No. 234, PageID.3183). In blunt terms, Ms. Voortman testified that the goal of this project was to minimize Perrigo's global tax exposure. More tactfully, the goal of Perrigo's TESCM project was to align a company's structure with the company's business directives. Here, that meant to support Perrigo's growth and business structure, while at the same time minimizing its tax liabilities and permitting access to after-tax cash. (Trial Tr. vol. II, 132, ECF No. 380, PageID.5594). Tax reduction, in other words, was not the only purpose of this project.

IV. EY's TESCM Step Plan for Perrigo

EY went about developing its plan by speaking with Perrigo principals to gain an understanding of the company's operations and its global plans. (Trial Tr. vol. I, 46, 163, ECF No. 379, PageID.5267, 5384). Following those conversations, EY initially came up with a restructuring plan that would have Perrigo maintain a "principal structure" holding company, or hub company, in an overseas jurisdiction that had a lower tax rate. The purpose of the hub was to hold the intellectual property behind Perrigo's international cash flow in a jurisdiction with lower taxes. (Trial Tr. 70, 133, 168-169, ECF No. 380, PageID.5532, 5595, 5630-5631). Ms. Voortman described this plan as a "lift and shift" where Perrigo employees would move overseas to work for

the new hub company. Possible jurisdictions for the hub included the U.K. and Switzerland. (Trial Tr. vol. II, 133, 168, ECF No. 380, PageID.5595, 5630). EY pursued this plan to the point where it came up with models for a "Euro Principal" or "Trading Company." (Exs. 13, 14). But ultimately Perrigo decided not to restructure with an overseas hub. As Ms. Voortman testified, the issue was one of scale. Perrigo simply did not have enough people it could move offshore. (Trial Tr. vol. II, 133, ECF No. 380, PageID.5596).

So, EY went back and developed another approach throughout 2005 and into 2006 that contemplated a series of "step plans" using reverse hybrids towards a tax-efficient global supply chain structure. (ECF Nos, 2, 3, 4, 7). EY's TESCM project first called for the creation of a new holding company—U.K Finco. But rather than the "lift and shift" of the previous proposal, the U.K. partnership would act as an in-house bank to finance Perrigo's foreign subsidiaries. Following that, EY proposed that Perrigo form offshore entities to invest in its contingent contracts to free up capital for use offshore. Thus, as it panned out, EY proposed a four-step sequence. Specific to omeprazole, these steps were: (1) the formation of U.K. Finco; (2) the formation of new Israeli entities—Perrigo Israel Trading Limited Partnership and LLC ("PITLP/LLC"); (3) the subsequent assignment of the Dexcel Supply & Distribution Agreement to the LLC; and (4) the LLC's engagement with Perrigo's domestic wholly owned subsidiary L. Perrigo Company ("LPC") to distribute omeprazole on the domestic market assuming a successful launch.

A. U.K. Finco

Perrigo formed U.K. Finco in November 2005 as a partnership organized under the laws of the United Kingdom. (Exs. 56-58). The partnership was set up to act as an in-house bank for Perrigo's international subsidiaries and affiliates. It aggregated cash to be redeployed offshore towards other businesses, acquisitions, subsidiaries and co-development agreements. (Trial Tr.

vol. II, 144-145, ECF No. 380, PageID.5606-5607; Trial Tr. vol. III, 158, ECF No. 381, PageID.5846). Perrigo thus used UK Finco to perform intercompany loans. The loans would originate from a foreign subsidiary with surplus financing, and Perrigo would use those loans to provide capital to those subsidiaries in need of funds. (Trial Tr. vol. V, 57-58, ECF 383, PageID.6200-6201).

UK Finco's books reflected Perrigo's international growth and the expansion of UK Finco's role in Perrigo's corporate structure—one that eventually grew to include serving as a holding company for Perrigo's foreign subsidiaries. (Trial Tr. vol. V, 97-101, ECF No. 383, PageID.6240-6244). UK Finco's investments in Perrigo's foreign subsidiaries grew from $56,094,107 in its 2007 fiscal year, to $714,2333,298 in its 2012 fiscal year. (Trial Tr. vol. V, 15, ECF No. 383, PageID.6158).

Perrigo formalized its intercompany loan policy—using U.K. Finco as an in-house bank—in 2009. (Ex. 79). But this had been its de facto operating protocol for many years earlier, including using U.K. Finco as the in-house tool to provide capital and garner resources. (Trial Tr. vol. V, 58, ECF No. 383, PageID.6201).

B. Formation of Israeli Entities

As part of the step plan advice, EY reviewed those contracts Perrigo had with third parties related to distribution of various drug products. This was something Perrigo's CFO at the time, Douglas Schrank, asked EY to do, and it was set out in a proposed modification of the firm's agreement with Perrigo. (Ex. 5218; Trial Tr. vol. II, 136-137, ECF No. 380, PageID.5598-5599, Trial Tr. vol. III, 163, ECF No. 381, PageID.5851).

On October 15, 2005, Ms. Voortman sent an email to other EY employees about Perrigo's restructuring. (Trial Tr. vol. II, 131, ECF No. 380, PageID.5593, Ex. 20). And consistent with

Mr. Schrank's modification, Ms. Voortman's email covered Perrigo's manufacturing agreements with third parties. As Ms. Voortman testified, pharmaceutical companies often engage in agreements, sometimes referred to as co-development or co-production agreements, to bring a new drug to market. As a tax planner, these agreements were relevant to Ms. Voortman because ideally one would want the profits earned under these agreements to be in a low tax jurisdiction. (Trial Tr. vol. II, 134, ECF No. 380, PageID.5596). Ms. Voortman testified that co-development agreements operated as silent partnership agreements for tax planning purposes, whereby an individual or entity would infuse cash at the front-end, and the partner would bear the responsibility for the underlying activity in the agreement. (*Id.* at 135). Accordingly, EY agreed there was some merit to Perrigo's suggestion that the contracts be a part of Perrigo's planned international expansion. Perrigo gathered approximately thirty to forty co-development agreements for EY's analysis. (Trial Tr. vol. II, 72, 169 ECF No. 380, PageID.5534, 5631). All this led to Ms. Voortman's email October 15th email.

Ms. Voortman's email attached an analysis of several co-development projects that Perrigo asked EY to review. (Ex. 20-1). It included third-party agreements Perrigo maintained with four companies: (1) A Scopolamine patch with Aveva; (2) a Nicotine gum with Fertin Pharma; (3) Desloratine with Plantex; and (4) Omeprazole with Dexcel. (*Id.*). Ms. Voortman and Ms. Warner testified that there were a number of criteria they applied to winnow down the contracts supplied by Perrigo. First, EY identified only those contracts with activity that took place outside the United States. Agreements that contemplated activity taking place entirely in the United States were not prime candidates for foreign investment because any offshore cash that was invested would likely be subject to increased taxes here in the United States, either under a "top-up" tax or treating the investment as a distribution. (Trial Tr. vol. II, 137, ECF No. 380, PageID.5599). EY also looked

for those agreements that bore significant upfront risk, generally meaning that market risk, litigation risk, or some other contingency (like FDA approval) stood as potential headwinds towards a successful launch. (*Id.* at 143-144). The design was such that following assignment the offshore affiliate would "bear[ ] all financial risks associated" to the covered product. (Ex. 544). Of course, the affiliate would also hold the potential of success and the corresponding profits.

Ultimately three agreements, including L. Perrigo Co.'s Supply & Distribution Agreement with Dexcel were selected for potential transfer to Perrigo's offshore affiliates using the criteria developed by EY. As demonstrated in a summary of the initial step plan, EY's TESCM project always contemplated the formation of an Israeli entity and the assignment of the Dexcel omeprazole Supply & Distribution Agreement "in exchange for cash funds or a note." (Ex. 2). As things became more "granular," as Ms. Voortman put it, an adjustment was made to EY's initial TESCM step plan to account for the specific agreements that EY identified. (Trial Tr. vol. II, 149, ECF No. 380, PageID.5611). In particular, on July 20, 2006, Ms. Voortman reviewed and approved an EY memo to Perrigo that added a new step to the TESCM project to form a new Israeli LLC, a U.S. LLC, and the re-engagement with L. Perrigo Company to distribute the omeprazole product on the U.S. domestic market. The re-engagement was anticipated to take place at a future point after the FDA had approved Dexcel's application and the AstraZeneca litigation had come to a conclusion, that is, the point when Dexcel's omeprazole product could be freely distributed on the U.S. market. (Trial. Tr. vol. II, 149, ECF No. 380, PageID.5611).

Perrigo adopted Ms. Voortman's advice and went about forming the Israeli entities that would invest in and perform the obligations of the assigned contracts. This involved a series of maneuvers starting with the creation of the Perrigo Israel Trading Limited Partnership ("PITLP") on June 16, 2006, as a partnership organized under the laws of Israel. For U.S. tax purposes,

PITLP was treated as a corporate subsidiary of UK Finco. UK Finco was a limited partner of PITLP that owned ninety-nine percent of the partnership.[15] It exercised no control over the affairs of the partnership. (Exs. 5065, 5067). A few months later, on December 12, 2006, PITLP filed a form with the IRS to elect to be taxable as a corporation, effective October 1, 2006.

Next, on November 29, 2006, Perrigo formed an LLC based in Delaware with PITLP as the LLC's sole member. The next day, PITLP executed an organizing resolution for the LLC. (Ex. 69). The LLC was disregarded for U.S. tax purposes—meaning that the LLC's activities were treated as those of PITLP. (Trial Tr. vol. II, 104, ECF No. 380, PageID.5566). The LLC was not an operational entity. It had no operational employees nor assets. Instead, it used employees of other Perrigo affiliates to conduct business. (Trial Tr. vol. IV, 32, ECF No. 392, PageID.5948). This is not unusual in corporate structuring that spans international borders. (Trial Tr. vol. IV, 126, ECF No. 382, PageID.6042). And for EY's planning, the "main idea behind inserting the LLC" into the step plan was to "minimize the exposure of the Israeli partnership . . . having to file a tax return in Israel." (Ex. 5281). Perrigo's tax department also understood the implication of the LLC on the company's taxes. But as Mr. Rush testified, this was a concrete step in forming Perrigo's new international structure. The tax efficient model followed Perrigo's planned business growth. (Trial Tr. vol. II, 107, ECF No. 380, PageID.5569).

V. The Assignment of the Dexcel Supply & Distribution Agreement to the LLC & Subsequent Engagement With L. Perrigo Co. to Distribute Omeprazole on the Domestic Market.

Indeed, Perrigo set up the LLC to invest in the Dexcel omeprazole Supply & Distribution Agreement along with a second contract (ex. 485) with Teva (an Israeli drug company) for the sale

[15] The remaining one percent was owned by the general partner Perrigo International Holdings, Inc. ("PIHI"). UK Finco and PIHI made a capital commitment commensurate with their ownership interests.

and distribution of a generic desloratadine product.[16] (Ex. 2 (steps 11, 12, 18); Ex. 51 (steps 13-15); Trial Tr. vol. II, 74-75, 107, ECF No. 380, PageID.5536-5537, 5569). As Mr. DeGood testified, when Perrigo created the LLC on November 29, 2006, it intended that its domestic affiliate— L. Perrigo Co.—would assign these two contracts to the LLC. (Trial Tr. vol. II, 73-74, 79, ECF No. 380, PageID.5535-5536, 5540; Trial Tr. vol. III, 197-198, ECF No. 381, PageID.5885-58856). Thus Perrigo treated the Dexcel omeprazole Supply & Distribution Agreement as assigned to the LLC as of the date of the LLC's formation.

Following the assignment, Dexcel remained responsible for developing the generic product; obtaining FDA approval; and proceeding through patent litigation towards launch. (Trial Tr. vol. II, 176, ECF No. 380, PageID.5638). But the assignment to LLC shifted the rights, risk and responsibilities in the Dexcel omeprazole Supply & Distribution Agreement from L. Perrigo Co. to LLC under what Ms. Voortman testified was a silent partnership model. (Trial Tr. vol. II, 138-140, ECF No. 380, PageID.5600-5602; Trial Tr. vol. VII, 175, ECF No. 380, PageID.5637). From an overarching perspective, the assignment did not impact Perrigo's global corporate business operations. (Trial Tr. vol. I, 91-92, ECF No. 379, PageID.5313). After all, LLC had no operation employees, or separate brick and mortar operations. But from another point of view, there was a very meaningful change in economic position following the transfer that reallocated risk from the domestic subsidiary to the LLC. (Trial Tr. vol. II, 180-181, ECF No. 380, PageID.5642-5643).

Following the assignment, and consistent with the EY TESCM step plans, LLC immediately engaged with L. Perrigo Co. to distribute Dexcel's generic omeprazole product here in the United States. The agreement was later memorialized under a written Sales and Distribution

[16] The brand name desloratadine product is Claritin.

Agreement (the "subcontract" in the Government's parlance). (Ex. 473, Trial Tr. vol. II, 175, ECF No. 380, PageID.5639). Thus, as contemplated, following the assignment LLC had the contractual purchase right of the omeprazole product from Dexcel under the terms of the Supply & Distribution Agreement. L. Perrigo Co. then purchased the omeprazole product from LLC under the Sales and Distribution Agreement.

VI. LLC's Payment to L. Perrigo Co. under its Arm's Length Payment Obligations

Perrigo understood that LLC would have to pay an "arm's length" price to L. Perrigo Co. both for the assignment of the Dexcel Supply & Distribution Agreement and also for L. Perrigo Co.'s performance of domestic distribution efforts following any successful launch. The transfer for an arm's length price was also contemplated in EY's step planning. (Exs. 1, 4, 51). The arm's length standard is required by statute as set out in Section 482 of the Tax Reform Act of 1986, Pub. L. No. 99-514, 100 Stat. 2085 (Tr. vol. IV, 113-114, ECF No. 382, PageID.6029-6030; Trial Tr. vol. IX, 53-54, ECF No. 387, PageID.7075-7076). In general terms, the arm's length standard requires that related parties take into account what reasonable business people knew or reasonably should have known at the time of the transaction. (Trial. Tr. vol. IV, 161, ECF No. 382, PageID.6077). This means that related parties are required to price their transaction in the same manner as unrelated parties would. (Trial Tr. vol. IX, 48, ECF No. 387, PageID.7070).

Internal Perrigo efforts to determine the arm's length price for the Dexcel omeprazole Supply & Distribution Agreement began no later than November 2005, a year before Perrigo performed the assignment. (Ex. 9; Trial Tr. vol. II, 80-81, ECF No. 380, PageID.5542-5543). At this stage, Perrigo's lack of experience in transfer pricing came to the forefront. When L. Perrigo Co. assigned the Supply & Distribution Agreement to LLC, Perrigo had no proficiency in pricing such an internal transaction. (Trial Tr. vol. III, 153, PageID.5841). So, Perrigo once again engaged

EY for assistance, and it contracted with EY to assist it in determining an appropriate arm's length transfer price. (Trial Tr. vol. II, 81, ECF No. 380, PageID.5543; Trial Tr. vol. III, 153, ECF No. 381, PageID.5841). As EY would later put it, this was to "determine a reasonable range of consideration for the sale of certain contractual rights[.]" (Ex. 545). To perform the requested function, Perrigo gave EY access to needed business information, and EY ultimately came up with a draft of its transfer-pricing model in 2006. (Trial Tr. vol. II, 95, 184, ECF No. 380, PageID.5557, 5646). Before sending its results to Perrigo, EY's models underwent an independent-partner review process (see ex. 19-2) in which the models underwent a fresh look. (Trial Tr. vol. III, 14-18, PageID.5702-5706).

On May 15, 2006, EY provided Perrigo with a transfer pricing model with two different approaches: a "cost-plus" model and a "finder's fee approach." (Exs. 10, 545; Trial Tr. vol. II, 81-82, 187, PageID.5543-5544, 5649). These were the methods that EY believed best fit the particulars of the Supply & Distribution Agreement. (Trial Tr. vol. III, 19-20, ECF No. 381, PageID.5708).[17] With respect to the cost-plus model, Mr. Warner testified that EY included this method in its transfer pricing proposal because the approach accounted for third-party costs that had already been incurred, as well as the costs that Perrigo had incurred on its own. This included things like the costs related to its work with a third party (Dexcel); searching out that party in the first place; and negotiating with that party. But it also accounted for the costs related to Perrigo's own internal, and to that point unsuccessful, efforts to develop a generic OTC omeprazole product.

[17] As both Perrigo and EY representatives testified, there are a number of models that can be used in performing the arithmetic to arrive at a price. One approach that was considered, for example, would use Perrigo's cashflow forecasts to set the price under what is known as the income method. (Trial Tr. vol. II, 84, 181-182, ECF No. 380, PageID.5546, 5643-5644). But this was considered a "best case" scenario model, specifically one that did not take into account any risk assumptions. Given the risk that Perrigo saw in the omeprazole product launch, it decided not to use the cashflow model. (Trial Tr. vol. II, 84, 181-182, ECF No. 380, PageID.5546, 5643-5644).

(Trial Tr. vol. II, 114-116, 178-179, ECF No. 380, PageID.5576-5578, 5640-5641). EY's cost-plus analysis came up with a range of arm's length values for the assignment of the Supply & Distribution agreement between $850,000 and $2 million. (Ex. 545; Trial Tr. vol. II, 184, ECF No. 380, PageID.5646).

After reviewing EY's analysis, Mr. Rush and Mr. Schrank at Perrigo selected the cost-plus method and concluded that the amount of $877,832 was an appropriate arm's length price that would account for the risk inherent in the Dexcel Supply & Distribution Agreement as of the November 2006 assignment date. (Trial Tr. vol. II, 82-83, 111-114, ECF No. 380, PageID.5544-5545, 5576). Mr. Rush testified that in Perrigo's view, there was no meaningful change in risk between 2005 and May 2006 when the selection was made. (Trial Tr. vol. II, 111, ECF No. 380, PageID.5573).[18]

EY also provided advice for the arm's length price LLC should pay to L. Perrigo co. for the latter's performance of domestic distribution efforts. (Trial Tr. vol. II, 87-88, 189, ECF No. 380, PageID.5549-5550, 5651). EY recommended—and Perrigo ultimately implemented—a "comparable profits method" or CPM to determine the markup of costs that would constitute the compensation LLC would pay to L. Perrigo Co. for distributing the generic omeprazole product on the domestic market. (Exs. 547-550; Trial Tr. vol. II, 182-183, ECF No. 380, PageID.5644-5645). Ms. Warner testified that the CPM based a transfer pricing study on "third-party comparable companies based on the profitability that they are earning for providing similar services or performing similar functions bearing similar risks." (Trial Tr. vol. II, 182, ECF No.

[18] For his part, Mr. Rush testified that he did not believe based on the information he had at the time that the Dexcel product would prove to be viable. (Trial Tr. vol. II, 83, ECF No. 380, PageID.5545). His view on this point did not change over the ensuing months. (Trial Tr. vol. II, 96, ECF No. 380, PageID.5558).

380, PageID.5644). The result was a market-based 4.31 percent markup on the distribution costs, as well as a ten percent margin, or "kicker" to give a return to Perrigo for its initial investment. (Trial Tr. vol. II, 185-186, ECF No. 380, PageID.5647-5648). Later, on January 20, 2010, following the launch of the generic omeprazole product, L. Perrigo Co. and LLC executed the written Sales and Distribution Agreement that reduced this arrangement to writing, effective as of November 29, 2006. (Ex. 473).

VII. Documenting the Transactions

The step plan that Perrigo followed treated the assignment of the Dexcel Supply & Distribution Agreement to LLC from L. Perrigo Co. as effective as of the date of the LLC's formation. (Trial Tr. vol. II, 79, ECF No. 380, PageID.5541). As the end of Perrigo's 2007 fiscal year approached, Perrigo went through its materials to execute and memorialize its intercompany transactions before the end of the year. This included booking the November 29, 2006, assignment of the Dexcel omeprazole Supply & Distribution Agreement. In particular, L. Perrigo Co. and LLC executed an agreement that provided "[t]his Assignment of Supply & Distribution Agreement between Dexcel Pharma Technologies Ltd. and L. Perrigo Company . . . is entered into effective as of the 29th day of November, 2006 . . . by and among L. Perrigo Company and Perrigo Israel LLC[.]" (Ex. 264). The written assignment agreement was signed, but it was not dated. At trial Mr. DeGood testified that the metadata for the document placed the date for the execution at some point between May 2, 2007, and June 11, 2007. (Trial Tr. vol. III, 154-155, ECF No. 381, PageID.5842-5843). And this meant that the assignment cost was included in Perrigo's federal taxable income for that year. (Trial Tr. vol. II, 80, ECF No. 381, PageID.5542).

The timing did not surprise Mr. DeGood as it corresponded with the end of Perrigo's fiscal year. Nor did it surprise Mr. DeGood that there would be a document memorializing an assignment

with an earlier effective date. It was always, he said, "a hard thing at Perrigo to get things done timely[.]" (Trial Tr. vol. III, 155, ECF No. 381, PageID.5843). Mr. Rush similarly testified that as Perrigo grew its international business, it was slow in getting its administrative process together and getting all the agreements signed and dated. (Trial Tr. vol. II, 79, ECF No. 380, PageID.5541). Ms. Voortman also was not surprised when she learned of the assignment with an earlier effective date. (Trial Tr. vol. II, 153, ECF No. 380, PageID.5615). But as a tax professional, the delay in the written assignment did not change how Perrigo had structured things; in her view a written document was not required to execute the assignment. (Trial Tr. vol. II, 154-155, ECF No. 380, PageID.5616-5617). This was something that the experts at trial generally agreed on. (Trial Tr. vol. IX, 64, ECF No. 387, PageID.7087 (DeRamus), Trial Tr. vol. IV, 139-140, PageID.6055-6056 (Frisch)).

In return for the assignment of the Dexcel Supply & Distribution Agreement, LLC tendered a demand note to L. Perrigo Co. that promised "to pay to the order of LPC by wire transfer as directed by the LPC in lawful money of the United States the principal sum of [$877,832] upon first demand of LPC together with interest at 5.80 percent per annum on the unpaid principal amount hereof outstanding, in like money and funds, for the period from the date hereof until this Demand Note is paid in full." (Ex. 122). The note was dated November 29, 2006, but Mr. DeGood testified that, like the assignment, the Demand Note could have been backdated, and he had no way of knowing when the note itself was signed. (Trial Tr. vol. III, 195-196, ECF No. 381, PageID.195-196).

Consistent with its efforts to wrap things up by the end of its 2007 fiscal year, Perrigo recorded the assignment of the Dexcel omeprazole Supply & Distribution Agreement in its accounting system. (Trial Tr. vol. V, 59-62, ECF No. 383, PageID.6202-6205). Around the same

time, LLC recorded entries relating to both the assignment, the demand note, and interest due. (Trial Tr. vol. IV, 186-187, ECF No. 382, PageID.6102-6103).

VIII. Post-Assignment Activities

Later that summer, Mr. DeGood received an email about the LLC and the shipping terms of the Dexcel Supply & Distribution Agreement. (Trial. Tr. vol. IV, 3-4, ECF No. 382, PageID.5919). This ultimately led to an amendment to the Dexcel omeprazole Supply & Distribution Agreement. (Trial Tr. vol. VII, 106-108, ECF No. 385, PageID.6696-6678). The amendment was signed on December 10, 2007, and it had an effective date of November 29, 2006—the date of assignment. (*Id.*). The same day, Mr. Papa signed a Performance Guarantee with Dexcel that was also made effective as of November 29, 2006. (Ex. 266). In the document, Perrigo promised to Dexcel that it would "guarantee[] . . . the prompt and unconditional performance of the obligations of [LLC] to [Dexcel] under" the Supply & Distribution Agreement." (*Id.*). From an accounting perspective, Ms. Voortman testified that the performance guarantee had no bearing on the risks the LLC has assumed. This was because the guarantee related to the distribution, which was already being performed by a subsidiary of L. Perrigo Co.—PITLP. (Trial. Tr. vol. II, 158-159, ECF No. 380, PageID.5620-5621).

UK Finco, in its capacity of Perrigo's in-house bank, provided LLC with needed funds for things like management fees, reimbursement of costs, and advance payment to Dexcel for the omeprazole product. These loans were set out in a Master Demand Note. (Ex. 145, Trial Tr. vol. V, 64-65, ECF No. 383, PageID.6207-6208) In February and March, 2009, UK Finco capitalized PITLP and, in turn, indirectly capitalized LLC with $3,141,796. (Trial Tr. vol. IV, 187, ECF No. 382, PageID.6103). Before this point, Mr. Rush testified, LLC did not need a capital contribution. (Trial Tr. vol. II, 91, ECF No. 380, PageID.5553). LLC used part of this infusion to pay off its

obligation for the assignment to L. Perrigo Co., including interest, and also used part of the contribution to satisfy its obligation for the separate desloratadine contract. (Trial Tr. vol. IV, 31, 187, ECF No. 382, PageID.5947, 6103).

IX. Perrigo's Tax Reporting; the IRS Audit; and Designation for Litigation

Perrigo included the $877,832 received by L. Perrigo Co. from the assignment as taxable income in its 2007 tax documents, and its subsequent filing of omeprazole sales and revenue were consistent with the assignment. (Trial Tr. vol. II, 80, ECF No. 380, PageID.5542). The IRS audited Perrigo for its 2007 year, and the following year in 2008. The IRS did not propose any adjustments regarding the assignment, and those tax years are now closed to further review. (ECF No. 235, PageID.3185, ECF No. 235-3, PageID.3290).

Perrigo also timely filed consolidated Federal income tax returns for its 2009 through 2012 tax years and made payments to the IRS in accordance with the amounts shown on those returns. (ECF No. 235-3, PageID.3290). These are the tax years currently before the Court in the instant litigation. The IRS audited these tax years too, and at the conclusion of those audits, the IRS identified income tax deficiencies with respect to Perrigo's omeprazole transactions. (ECF No. 235, PageID.3185). The IRS based its position on a number of judicial substance-over-form doctrines that reallocated the income reported as having been earned by PITLP/LLC (overseas) to Perrigo here in the United States. (See, e.g., Ex. 5371). Alternatively, the IRS reallocated nearly all of the income reported by Perrigo as earned by LLC to Perrigo under its Section 482 adjustments.[19] Accordingly, the IRS assessed tax, interest and penalties for 2009, 2010, 2011, and

[19] Under the alternative Section 482 adjustments, the IRS adjusted Perrigo's domestic income for the 2009 through 2012 years by $46,363,255; $72,920,754; $58,304,911; and $39,892,600, respectively. The amount of tax assessments in the IRS's notices of deficiency were based on the common-law doctrines, not Section 482, and Perrigo's payments were based on the assessments reached under the common-law doctrines, not Section 482. (ECF No. 235-3, PageID.3292).

2012 in the amounts of $27,817,521; $41,183,296; $40,682,094; and $33,471,975, respectively. (ECF No. 235-3, PageID.3292).

Perrigo fully paid the assessed amounts of tax, interest and penalties and thereafter timely filed claims for refund. (ECF No. 235, PageID.3185). The IRS disallowed each of the refund claims, leading to this lawsuit. Accounting for certain adjustments discussed at trial, Perrigo seeks to recover the tax, interest, and penalties that it says the IRS wrongfully collected for the four tax years.

ANDA ISSUE

The above sections discussed Perrigo's efforts to develop and distribute a generic omeprazole product in the United States; its partnership with Dexcel to accomplish this task; it's growth into a multinational corporate entity; the assignment of the Dexcel Supply & Distribution Agreement from the domestic side of Perrigo's books to a foreign subsidiary under a TESCM plan developed by EY; and the events that Perrigo says reflect the economic reality that the assignment was made at a time with very real uncertainties and risks of a successful omeprazole product launch.

Around the same time, Perrigo incurred certain legal fees to prepare Paragraph IV notifications related to its generic drug applications before the FDA, as well as fees to defend itself against patent infringement lawsuits brought against it by brand-name pharmaceutical companies. ANDA applications, along with resulting litigation, are common amongst generic drug producers. Indeed, Perrigo had business success with the ANDA process. (Trial Tr. vol. II, 25, ECF No. 381, PageID.5713). And no doubt Perrigo was familiar with the defending against patent infringement claims too.

Following its 2009 through 2012 taxable years, Perrigo deducted its legal fees as ordinary and necessary business expenses under Section 162 of the Internal Revenue Code that were incurred both to defend itself against patent infringement lawsuits brought under 35 U.S.C. § 271(e)(2), as well as those fees that it incurred for the preparation of Paragraph IV notice letters by outside counsel.[20] These are costs that are separate and distinct from Perrigo's internal omeprazole development and the AstraZeneca litigation with Dexcel. The parties have stipulated to the amounts Perrigo incurred during the four years at issue. (ECF No. 366).

The IRS subsequently denied Perrigo's deductions. The IRS determined that Perrigo must capitalize those expenses because those expenses were incurred with the goal of removing the impediment of Paragraph IV litigation, thus smoothing the road towards Perrigo's ANDA approvals. More specifically, the IRS concluded that under the applicable Treasury regulations, namely, 26 C.F.R. § 1.263(a)-4(b), these expenses qualified as costs paid "to facilitate . . . acquisition or creation" of an intangible asset as well as costs paid "to enhance" an intangible asset. Accordingly, while the IRS did not dispute the amounts of legal fees and expenses that Perrigo paid, its adjustments reflected the IRS's conclusion that the amounts should be capitalized, rather than deducted. The IRS subsequently reduced Perrigo's deductions by $2,185,376 and $7,062,889 for the 2011 and 2012 tax years respectively. (ECF No. 235-3, PageID.3296).

[20] As discussed further below, these latter costs are part of the Hatch-Waxman statutory scheme in which a generic distributor seeking approval of a generic drug must generally assert a good faith belief that the patents are either invalid or not infringed by the generic product. *See* 21 U.S.C. § 355(j)(2)(A)(vii), subcl. (IV). Perrigo initially sought refund for the legal fees it incurred to prepare these notices; but has since agreed that these costs must be capitalized and it is no longer seeking refund for those fees relating to preparing Paragraph IV notices. (ECF No. 331, PageID.4849; ECF No. 349-2, PageID.4935; ECF No. 355, PageID.4993). Perrigo continues to seek a refund for the legal fees and expenses it incurred defending patent infringement.

The parties largely agree on the legislative framework and the relevant facts here. The statutory background has also been discussed above and in greater detail in *Mylan Inc. & Subsidiaries v. Comm'r*, 76 F.4th 230 (3d Cir. 2023). For purposes of this background section, at trial Perrigo elicited testimony that sought to factually distinguish its legal expenses related to Section 271(e)(2) litigation from the two provisions of the Treasury regulations that the IRS said should lead to capitalization rather than a deduction. It did so largely through the testimony of two experts: Mr. Bradshaw, who testified regarding FDA approval; and Mr. Figg, who testified regarding patent litigation. The gravamen of the testimony was that FDA approval and patent litigation were separate and distinct hurdles that a generic drug company would have to overcome on the way to a successful commercial launch. (Trial Tr. vol. V, 175-176, ECF No. 383, PageID.6318-6319 (Bradshaw); Trial Tr. vol. VI, 6-7, ECF No. 384, PageID.6369-6370 (Figg)).

The Government did not challenge this testimony at trial. In the main, the Government simply argues that the expert testimony is not persuasive to the legal question here. It maintains that the legal expenses relate to Perrigo's efforts to obtain FDA approval of its generic products and that the litigation facilitated Perrigo's efforts to obtain that right. Accordingly, the Government maintains, the expenses cannot be deducted but rather must be capitalized.

PROCEDURAL HISTORY

After the IRS denied Perrigo's claims for refund, the matter was designated for litigation. Perrigo filed this lawsuit on August 15, 2017, under 28 U.S.C § 1346(a)(1) and Sections 6532 and 7422 of the Internal Revenue Code. (ECF No. 1). Perrigo alleges that it has overpaid its tax, interest and penalty obligations for the 2009 through 2012 tax years. The matter proceeded through pre-trial proceedings and a nine-day bench trial (ECF Nos. 367-375), and the Court has received

post-trial briefing and notices of additional authority. (ECF Nos. 389-398; 412-413; 418).[21] The matter is ready for decision following the bench trial.

ANALYSIS

Over the course of the bench trial, Perrigo presented several overarching themes to support its claims for refund of tax, penalties, and interest. These themes began with general business matters (like Perrigo's overall business as a generic manufacturer and distributor); carried through to Perrigo's international expansion and concurrent international tax planning (including E&Y's TESCM Step Plan and Section 482 pricing) and then focused further in on the Dexcel omeprazole product with testimony and evidence relating to Perrigo's own failed efforts at developing an in-house omeprazole product, the Dexcel opportunity, and the resulting assignment and reengagement before the successful launch. An added, separate, theme, was Perrigo's Paragraph IV litigation defense expenses. All of these themes relate to two separate issues for decision: the omeprazole issue, and the ANDA issue.

Perrigo and the Government are in accord that these, along with penalties, are the issues for decision. And they generally agree on what the sequence of the Court's analysis should be. As to the omeprazole issue, the parties are in agreement that the Court must first consider as a threshold matter the various common law sham theories advanced by the Government.[22] If Perrigo can persuade the Court not to disregard the targeted assignments and entities under those theories, then the Court must proceed to determine whether the IRS's alternative adjustments under Section

[21] Following the Final Pretrial Conference, Perrigo submitted a revised exhibit list (ECF No. 358) that Defendant objected to. (ECF No. 362). The matter was briefly addressed at the outset of the trial. The Court ruled on objections as they arose during the course of trial. The Court therefore dismisses as moot the pretrial objection (ECF No. 362).

[22] *See* 26 C.F.R. § 1.482-1(f)(2)(ii)(A) ("The Commissioner will evaluate the results of a transaction as actually structured by the taxpayer unless its structure lacks economic substance.").

482 of the IRC were arbitrary, capricious, or unreasonable. *See Kenco Restaurants, Inc. v. Comm'r*, 206 F.3d 588 (6th Cir. 2000). Perrigo also bears the burden on that front, and if it can make that initial showing then it secondly must also demonstrate that its own intercompany pricing satisfies the statute's arm's length standard. If not, then the Court must determine the proper result. *Eli Lilly & Co. v. Comm'r*, 856 F.2d 855 (7th Cir. 1998); *Amazon.com Inc. v. Comm'r*, 148 T.C. 108, 164 (2017). Separately, the parties also agree the Court must consider whether Perrigo's Section 271(e)(2) patent defense litigation expenses are deductible as ordinary and necessary business expenses (as Perrigo says) or must be capitalized (as the Government claims).

Of course, the parties arrive at different results throughout the sequence. With respect to the omeprazole issue, the Government believes the matter need not proceed any further than the common law theories. The Government contends that judicial common law doctrines are a useful mechanism to decide whether Perrigo's TESCM transactions related to omeprazole had practical economic substance or business purpose, and that applying its view of things there was no risk and nothing to Perrigo's transactions other a desire to escape domestic tax laws. Thus, it contends the assignment of the Dexcel Supply & Distribution Agreement as well as the Sales and Distribution Agreement should be disregarded as lacking economic substance and as sham transactions; that LLC itself should be disregarded as a sham entity; and that the assignment of income doctrine requires the Court to disregard Perrigo's intercompany transactions that shifted omeprazole income to PITLP/LLC. Perrigo disagrees; it argues the common law doctrines are an ill-fitted bludgeoning tool in cases like this, and they do not apply in any event. The issue, as Perrigo sees it, is not of substance, but rather of price. To the extent the doctrines do apply, Perrigo insists there is ample economic substance and business purpose behind the complaint of transactions; and that the corporate forms should be respected.

As for the Section 482 analysis, the Government argues that if the Court reaches the matter, its alternative reallocation under that provision properly reflects what it says is the lack of any meaningful contribution by PITLP/LLC under Dr. DeRamus's discounted cash flow ("DCF") analysis utilizing a functions, assets and risks approach. Perrigo disagrees and argues the Government's alternative reallocations are unreasonable. It presents its expert, Dr. Frisch, to argue that under his DCF analysis and adjustments, PITLP/LLC's payments to L. Perrigo Co. were proper and at arm's length.

Turning to the second issue of Perrigo's claim for refund of ANDA litigation defense expenses, Perrigo contends that long-standing principles provide that expenses incurred by private parties defending civil disputes, including patent infringement claims, are deductible as ordinary and necessary business expenses. The Hatch-Waxman Act—which underlies the Government's claim for capitalization—changes nothing, it says, and under the "origin of the claim" test, the Section 271(e)(2) cases it defends against have their origins in the patent-holders claims of infringement, not the filing of ANDA applications with Paragraph IV certifications like the Government contends. The upshot of all this, Perrigo says, is that it is entitled to recover the amounts it seeks. The Government resists all of this and argues that a Treasury regulation focused on whether the expenses were paid to facilitate the acquisition or creation of an intangible asset, or paid to enhance such an asset, is the proper analytical method. And under that lens, it believes the IRS properly determined Perrigo's patent defense litigation expenses must be capitalized, rather than deducted as ordinary and necessary business expenses. All told, the Government says its adjustments, and the applicable penalties and interest, were proper. It asks the Court to rule accordingly.

At a high level, this is what is before the Court for decision. Resolving the issues involves a certain amount of diving into the weeds of Perrigo's international growth, corresponding tax strategy, and the specifics—including timing—of the Dexcel Supply & Distribution Agreement assignment. The Court's analysis is set out below.

At bottom, in the Court's view, the common law theories are pertinent, but ultimately unavailing. They all coalesce around the same basic point—making sure that a taxpayer can't create an alternative reality simply for tax purposes. There must be some real economic substance and purpose to the transactions and structure, and there further must be some indicia that the taxpayer honored that structure. If these things are honored, then under any number of cases, it is permissible for the taxpayer to structure things with both the motive and effect of minimizing taxes. Of course, what the taxpayer can't do is generate an income stream and then construct an artificial and alternate reality to reach back and assign the income to some entity that doesn't pay taxes. But that didn't happen here. Accordingly, the Court rejects the Government's reliance on the common law judicial doctrines.

The matter then turns to price, namely the arm's length price under the Section 482 standard. Here, as Dr. DeRamus put it, "[e]conomi[sts] don't invalidate something. They just provide their opinion as to what parties are actually transacting, why are they transacting that way, and what are the effects of those transactions." (Trial Tr. vol. IX, 65, ECF No. 387, PageID.7087). Ultimately, the Government's pricing analysis under this method suffers from many of the same unpersuasive arguments underlying its common law theories. The Court holds that Perrigo has met its threshold burden of showing the Government's alternative reallocation was arbitrary, capricious or unreasonable. The Court further accepts the basic discounted cash flow analysis of Perrigo's expert, Dr. Frisch. As Perrigo now recognizes, its original arm's length computation on

a cost-plus basis was simply too low. To account for this, Dr. Frisch's method under his Scenario B produced a lump-sum net present value of LLC's expected profits of $37.4 million, which is the arm's length price Perrigo asks for here. And given the tax year of the assignment itself is closed, Dr. Frisch converted his price into a sales-based equivalent royalty rate by dividing the present value of projected cash flows by the present value of projected sales. The Court agrees with this basic approach. However, as further discussed below, the Court disagrees with two modifications that Dr. Frisch made to his analysis, and accepts the critiques of Dr. DeRamus in this respect.

The remaining matter is on the ANDA issue. Perrigo has abandoned its request for a refund of expenses it incurred preparing Paragraph IV certifications and notices. It maintains its request for refund relating to its patent defense litigation expenses. The Court determines that under either the origin of the claim test or the applicable Treasury Regulations, these expenses may be deducted as ordinary and necessary business expenses.

All told the Court largely agrees with Perrigo that it is entitled to a refund in taxes, penalties, and interest. Perrigo believes its final number is $111,072,227 together with statutory interest. Given the modifications the Court has made to Dr. Frisch's arm's length pricing, however, the Court will require the parties to submit a proposed final judgment consistent with the Court's rulings—an opportunity (as the Government puts it) to respond to "number crunching."

I. Common Law Doctrines

The threshold question for the Court to determine is whether the transactions and entities identified by the Government should be disregarded under various common law theories. There is no dispute that the disputed transactions and entities were set up in, and followed, literal compliance with the Internal Revenue Code (IRC) on paper. *See Stobie Creek Invs., LLC v. United States*, 82 Fed. Cl. 636, 664 (2008), *aff'd,* 608 F.3d 1366 (Fed. Cir. 2010) (citing *Coltec Industries*

Inc. v. United States, 454 F.3d 1340, 1347 (Fed. Cir. 2006)) (noting compliance with the IRC is the first step in evaluating common law doctrines). The Government argues that paper is all there is here because by the time Perrigo got everything in order, it had a proverbial sure bet in hand of the Dexcel omeprazole product's success. In such circumstances, it says, mere paperwork is insufficient to bestow substance to the Assignment of the Dexcel Supply & Distribution Agreement; the subsequent Sales and Distribution Agreement; and the LLC itself. The Court disagrees.

A. Governing Law

The primary doctrine invoked by the Government is the economic substance doctrine. The Government also points to the sham transaction and sham entity doctrines, and the assignment of income doctrines as supporting its decision to reallocate income from LLC to L. Perrigo Co. following the audits of the tax years in question. There are many decisions applying doctrines such as these, and the "presuppositions or criteria" involved in them—"tax avoidance" and "tax evasion" or "form" verses "substance"—"are so pervasive that they resemble a preamble to the Code, describing the framework within which all statutory provisions are to function. But these judicial presuppositions, like the canons of statutory construction, are more successful in establishing attitudes and moods than in supplying crisp answers to specific questions." 1 BORIS I. BITTKER & LAWRENCE LOKKEN, FEDERAL TAXATION OF INCOME, ESTATES AND GIFTS ¶ 4.3.1 (online ed. Mar. 2025). "They are, however, extremely important despite their vagueness." *Id.*

The common law doctrines, including those involved here, "vary in origin and somewhat in application, yet apply to the same analysis." *Stobie Creek Invs., LLC*, 82 Fed. Cl. at 672 n.28 (citing *King Enters., Inc. v. United States,* 418 F.2d 511, 516 n.6 (1969) ("[C]ourts have enunciated a variety of doctrines, such as step transaction, business purpose, and substance over form.

Although the various doctrines overlap and it is not always clear in a particular case which one is most appropriate, their common premise is that the substantive realities of a transaction determine its tax consequences."); *H.J. Heinz Co. & Subsidiaries v. United States,* 76 Fed. Cl. 570, 583–85 (2007) (discussing multiple formulations employed by courts to consider whether transaction has economic substance or whether it is a "sham")). In other words, the "mode of analysis implicates several related, overlapping doctrines . . . the animating principle of each is that the law looks beyond the form of a transaction to discern its substance." *Feldman v. Comm'r*, 779 F.3d 448, 454–55 (7th Cir. 2015) (citing BITTKER & LOKKEN, *supra* at ¶ 4.3).

The economic substance doctrine, for instance, has as its "general idea that a transaction has economic substance (and thus will be respected for tax purposes) if it 'changes in a meaningful way . . . the taxpayer's economic position' and the taxpayer has a valid nontax business purpose for entering into it." *Id.* at 455 (quoting I.R.C. § 7701(o)). Perrigo would end the inquiry into the doctrine there. However, the Government argues that Perrigo must meet an entirely separate subjective component of the economic substance doctrine. It points out that as set out in *Illes v. Comm'r*, 982 F.2d 163 (6th Cir. 1992), if a transaction has economic substance, "the question becomes whether the taxpayer was motivated by profit to participate in the transaction." *Id.* at 165. That is, after looking at the transaction itself, the Court must also look at the taxpayer's motivation. Some courts from outside the Sixth Circuit have questioned this aspect of *Illes*'s holding. *See Santander Holdings USA, Inc. & Subsidiaries v. United States*, 977 F. Supp. 2d 46, 54 n.5 (D. Mass. 2013) ("The Sixth Circuit's position [in *Illes*] is of dubious provenance."). Nevertheless, to the Court's knowledge, *Illes* has not been overturned or cabined, and the Court's reading of Sixth Circuit case law is generally in accord with the Government's view that an inquiry into the

subjective is part of the analysis, though notably the cases cited by the Government generally have not analyzed the subjective component in any detail.

In the Court's mind what this means is that under the economic substance doctrine a taxpayer cannot merely clothe itself in corporate jargon to point to a motivation other than tax avoidance. But the Court also believes this is not a demanding standard for the taxpayer either. Indeed, the subjective prong "does not mean a reason for a transaction that is free of tax considerations" to pass muster. *United Parcel Serv. of Am., Inc. v. Comm'r*, 254 F.3d 1014, 1019 (11th Cir. 2001); *see also Dow Chemical Co. v. United States*, 435 F.3d 594, 610 (6th Cir. 2006) (Ryan, J., dissenting) (framing the subjective business purpose prong as whether the transaction was entered into "for the sole purpose of tax avoidance"). After all, "[t]ax planning is as American as apple pie." BITTKER & LOKKEN, *supra* at ¶ 4.3.2. So, to meet the subjective prong there simply must be something more than a negative change in tax obligations. *Richardson v. Comm'r,* 509 F.3d 736, 741 (6th Cir. 2007) (after finding transaction trusts lacked economic substance, concluding the trust "also had no 'valid, non-tax business purpose.'"). And in this case the objective and subjective largely overlap; ultimately, the "essential inquiry is whether the transaction had any practicable economic effect other than the creation of economic tax losses." *Rose v. Comm'r,* 868 F.2d 851, 854 (6th Cir.1989)

Generally, the same considerations apply to the sham theories advanced by the Government. Indeed, "[t]he proper standard in determining if a transaction is a sham is whether the transaction has any practicable economic effects other than the creation of income tax losses.'" *Dow Chemical Co.*, 435 F.3d at 599 (quoting *Rose*, 868 F.2d at 853). So, the sham-transaction doctrine "look[s] at what happened in fact, not what happened on paper." *Billy F. Hawk, Jr., GST Non-Exempt Marital Tr. v. Comm'r*, 924 F.3d 821, 829 (6th Cir. 2019). Similarly, the sham entity

theory begins with the general principle that "[a] taxpayer may adopt any form he desires for the conduct of his business and that form cannot be ignored merely because it results in a tax saving." *Aldon Homes, Inc. v. Comm'r*, 33 T.C. 582, 596-97 (1959). And "so long" as the [taxpayer's] purpose is the equivalent of business activity or is followed by the carrying on of business by the corporation, the corporation remains a separate taxable entity." *Moline Properties, Inc. v. Comm'r*, 319 U.S. 436, 438-39 (1943) (footnotes omitted). Otherwise, "[t]he Government may look at actualities and upon determination that the form employed for doing business or carrying out the challenged tax event is unreal or a sham may sustain or disregard the effect of the fiction as best serves the purposes of the tax statute." *Higgins v. Smith*, 308 U.S. 473, 477 (1940).

The touchstone of the Government's alternative common law theory using the assignment of income doctrine also looks at economic reality. Here, the inquiry is whether the nominal assignor retained sufficient power and control over the income generating property such that the assignor should be treated as the recipient of the subsequent income despite the purported assignment. *See Salty Brine I, Ltd. v. United States*, 761 F.3d 484 (5th Cir. 2014). That is, "[d]etermining who earns the income depends upon which person or entity in fact controls the earning of the income, not who ultimately receives the income." *Id.* at 492.

B. Discussion

The Government's challenges to the legitimacy of Perrigo's transactions implicates several common-law judicial doctrines. The Court need not go line by line through the various doctrines. Whether the question is one of economic substance, business purpose, motivation beyond tax avoidance, or command and control of income—the Government's reliance on the doctrines fails under the facts presented at trial.

The bench trial established that Perrigo had a genuine business purpose and motivation—beyond tax planning—in diversifying and expanding its international footprint. It certainly was extremely successful in executing this overall business plan. It moved from a mainly domestic company with sales of approximately $100 million when Mr. Hendrickson joined the company in 1990 to an international generic leader with $1 billion in sales when Mr. Papa joined in 2006 and then sales of $5 billion in 2016. (Trial Tr. vol. I, 40, 160, ECF No. 379, PageID.5261, 5381; Trial Tr. vol. VII, 145, ECF No. 385, PageID.6715). This growth permitted Perrigo to insulate itself from domestic risk and align its actual supply chain assets in the international market where the work was being performed, allowing it to concentrate on its principal asset of understanding the generic distribution channels here in the United States. This was not something that Perrigo was able to do before implementing EY's TESCM plan. As Mr. Needham put it during trial, Perrigo could not simply manufacture generics in the United States and distribute those drugs abroad. Perrigo contemplated such an arrangement but quickly realized it would not be feasible. To be successful, Perrigo needed to be in the international marketplace from a manufacturing, regulatory, and commercial perspective. (Trial Tr. vol. I, 162-163, ECF No. 379, PageID.5384).

To accomplish this, Perrigo engaged EY to advise the business in pursuing its international growth; and Perrigo followed the various steps in EY's resulting TESCM sequence. The resulting planned method for expansion was fully consistent with the way Perrigo had been developing its domestic footprint up to that point: namely, it would look for drugs coming off patents that were good candidates for generic production with store brand labeling and "compare to" labeling. This was a proven method of simultaneously reducing consumer price points and maximizing store profit margins, with the natural and inevitable result that Perrigo's own sales and profits were

maximized in the process. This was the "magic of store brands" generally. (Trial Tr. vol. IV, 49-50, ECF No. 382, PageID.5965-5966; Exs. 1137 and 5130 at 30).

The added wrinkle as Perrigo expanded internationally was identifying which generic product opportunities had enough uncertainty built into development and distribution that those distribution rights could be fairly peeled off the overall opportunity and lodged in an international entity that would then assign the rights back to a domestic entity while the development opportunities were still uncertain. As part of the TESCM process Perrigo identified three such opportunities, including the Dexcel omeprazole product, as being early enough along to fairly peel off.

Separating the intangible distribution rights from the boots on the ground distribution allowed Perrigo not only to align the uncertainty in the locus with the same market as the anticipated production (here Israel), but it also allowed Perrigo to improve its tax planning by ensuring that if the bet paid off, most of the revenue stream would be attributed to the internationally based holder of the distribution rights, not the actual domestic Perrigo entity responsible for distribution. Put differently, the international holder of the distribution rights would be renting the Perrigo distribution network and know-how. In form and substance, Perrigo went about setting up the infrastructure necessary to execute its expansion plan.

It did so in ways that had meaningful activity and substance. For example, LLC engaged in business activity by borrowing money to pay for its receipt of the Dexcel Supply & Distribution Agreement. (Ex. 122). It then took over the rights and obligations of that contract, and assumed the risks that L. Perrigo Co. had under the contract in the event the Dexcel opportunity failed. It went on to purchase the actual omeprazole product from Dexcel (Trial tr. vol. IV, 190, ECF No. 382, PageID.6106). It engaged with L. Perrigo Co. to distribute omeprazole on the domestic

market. (Ex. 473). And it paid L. Perrigo Co. an operating margin on distribution activities for those sales. (Trial Tr. vol. II, 87-88, ECF No. 380, PageID.5549-5550). This is enough to constitute the business activity and carrying on of a business that generally separates the sham from the respected form. *See Moline Properties, Inc. v. Comm'r*, 319 U.S. 436, 438-39 (1943).

Certainly there are a number of cases that emphasize a taxpayer's right to structure its business in the most advantageous way possible. Perrigo identifies several in its briefing. At bottom all of the cases are grounded in the same sentiment the Supreme Court expressed ninety years ago. "The legal right of a taxpayer to decrease the amount of what otherwise would be his taxes, or altogether avoid them, by means which the law permits, cannot be doubted." *Gregory v. Helvering*, 293 U.S. 465, 469 (1935). So of course the taxpayer must structure things in a bona fide way. It can't wait until a bet pays off and then retroactively develop its international structure nunc pro tunc to reach back and reap savings retroactively. This is what the Government contends happened here, by executing paperwork retroactive to a November 2006 transfer date and delaying the LLC's capitalization via UK Finco. Its view is evocative of the film, WAKING NED DEVINE (Fox Searchlight Pictures 1998). In the film set in a small Irish village, a resident dies of shock after winning the national lottery. And in a tumultuous and humorous series of events, the remaining villagers concoct a scheme to trick the lottery inspector with an alternative reality to gain the winnings and distribute them amongst themselves.

But that's not what the credible testimony at trial reflects happened with the Dexcel omeprazole opportunity. Rather than have a winning lottery ticket in hand, Perrigo was still waiting for the numbers to be drawn. It saw significant uncertainty in Dexcel's omeprazole product. It knew from its own efforts that omeprazole was particularly difficult when it came to demonstrating bioequivalence—a necessary showing to the FDA. And at a fundamental level,

Perrigo would be partnering with an overseas company and would not have unilateral control over matters. From a business and risk-mitigation standpoint, Perrigo also wanted to continue its own efforts. But this meant riding along with Dexcel with blinders on under "Option 2." And Perrigo knew from its experience as a generic manufacturer and distributor that there were uncertainties—ranging from FDA approval to Hatch-Waxman patent litigation to manufacturing challenges—all of which could affect timing at a minimum, if not whether the product would come to market at all. (See, e.g., ex. 262; Trial Tr. vol. VII, 137-138, ECF No. 385, PageID,6707-6708). And timing was critically important. If Perrigo could not be first to market with a generic product, its revenue projections showed that sales would take a steep dive. This was consistent with its experience as a generic distributor. And success after launch was no sure thing either. To be sure, Perrigo would leverage its considerable experience in the generic market, including its labeling, packaging, and business relationships with retailers (and LLC compensated Perrigo for that expertise). But a vital piece of the technique would be missing: Perrigo could not include a "compare to" statement on the packaging, and it had not done that before. (Trial Tr. vol. VII, 138, ECF No. 385, PageID.6708).

And rather than craft an artificial retroactive narrative like the villagers in WAKING NED DEVINE, the trial testimony established that Perrigo was contemporaneously forming the infrastructure of its international expansion in a way that had meaningful business purpose with a transfer of rights and obligations that had real value. When the omeprazole opportunity moved towards launch, Perrigo was able to complete its build only because of the infrastructure that it already had in place. To be sure, the assignment paperwork was prepared with an earlier effective date. And it is also true that the LLC was not immediately capitalized. But these considerations are not indications of a sham in this case but rather reflect the reality that these were essentially

the first steps in Perrigo's international expansion plan. Those involved in Perrigo's business decision testified at trial that at the time of the assignment of the Dexcel Supply & Distribution Agreement, they fairly believed that a launch was still years away based on patent litigation and FDA approval concerns. And at the time Perrigo also wanted to preserve its own option to go to market with its own generic—something it had been trying without success to develop. At the end of the day, it was better to go with Dexcel than not go at all. But Perrigo's first choice was still to develop and use its own product. All this not only explains why the company was slow in executing the transactions on paper, but also why the company was skeptical of the optimism coming from Dexcel.

It is notable here what Perrigo actually did. It retained an outside national firm (EY) to develop an intricate step plan for going international. It then searched for the kinds of opportunities EY identified and landed on the Dexcel omeprazole product and a handful of others. It formed the entities that would be needed to hold the distribution rights, and as to the omeprazole issue relevant to these proceedings, it entered into the deal with Dexcel, and latter placed those rights in the LLC. Perrigo incorporated UK Finco too, which effectively roughed in the plumbing for later use. In short, all the structural components were in place during the fiscal year of the actual assignment.

Ultimately, during this timeframe Perrigo did not believe there was any realistic shot at FDA approval; resolution of patent litigation; and final preparations for delivery to market during that year. And these were entirely reasonably beliefs based on the decades of experience that Perrigo had in this line of work, and the perceptions of patent and administrative lawyers in general. There was no real incentive for any patent holder to cut a deal earlier than the 30-month minimum afforded as part of the Hatch Waxman process. (Trial Tr. vol. I, 57-58, ECF No. 379, PageID.5278-5279; Trial Tr. vol. V, 150, ECF No, 383, PageID.6293). And the FDA risks in this

particular case were very salient for Perrigo based on its experience. They had every reason to distrust, or at least discount, Mr. Oren's confidence as typical CEO bluster because Perrigo was still internally competing and hoping to come up with their own product that would cut out Dexcel entirely.

Once it became clear that matters were moving towards launch faster than anyone expected, Perrigo raced to get things done and booked within the critical fiscal year. It was new to all of this at the time and did not have experienced international hands. Even aside from this, every year-end for a public company is a mad rush to close books, and triage is the inevitable result. But because Perrigo already had the infrastructure in place, it could meet its deadline. The entities were on the books, and the planned transactions had been approved. It was just a matter of performing finishing touches, and then turning on the money spigot and signing the final papers.

All this reflects economic substance and a genuine business purpose behind Perrigo's transactions that defeat the Government's contention that there was no motivation behind the transactions beyond reducing tax exposure. And the planned method of execution defeats the Government's sham and assignment of income theories. The Government sees things differently, but ultimately its attempts to poke holes in the testimony of Perrigo's fact witnesses and its corresponding legal arguments all come up short.

To the Government, nothing—aside from additional paperwork—changed once Perrigo executed EY advice, at least so far as the intercompany transactions of the assignment of the Dexcel Supply & Distribution Agreement, or the Sales & Distribution subcontract, or the formation of the LLC were concerned. It draws this conclusion from Mr. Hendrickson's testimony during the first day of trial in which Mr. Hendrickson testified that following the assignment Perrigo, from an operational standpoint, continued operating the same way as it did prior to the

assignment. (Trial Tr. vol. I, 91-92, ECF No. 379, PageID.5312-5312). The Government further grounds this interpretation in Dr. Manning's testimony, in which he testified that from an economics perspective, he didn't see why it would matter if money was held in the left pocket or the right, that is, in a subsidiary or a parent. (Trial Tr. vol. VIII, 15-16, ECF No. 386, PageID.6820-6821). According to the Government, everything here was ethereal paper pushing lacking any meaningful substance or transfer of value other than facilitating a motive to escape domestic taxes. After all, the LLC had no operational equipment or employees, nor did the LLC have the financial wherewithal to carry any risk.

At a high level, the Government's paper-pushing bookkeeping analogy is an incomplete assessment. Certainly, there was nothing untoward in setting up subsidiaries, even those without brick-and-mortar office space or dedicated employees. Ms. Voortman testified that it is common for multinational employees to set up offshore finance companies; and hold intellectual property in non-operational holding companies. (Trial Tr. vol. II, 120-121, ECF No. 380, PageID.5582-5583). Nor is there any surprise in a company subcontracting its contractual rights. Dr. DeRamus testified that a contracting party may subcontract its performance obligations to another member of a related party group. (Trial Tr. vol. IX, 73, ECF No. 387, PageID.7095). Of course, just because something permissible, or even common, does not mean a transaction had business purpose or economic substance. But it did here for the reasons the Court explained above.

Nevertheless, the Government insists that everything but tax avoidance must fade as one dives into the details. All possible business rationales for the transactions save for risk avoidance, it says, are pretextual and should clearly fall away. And as for risk mitigation, it argues that at all times—before, during, and after launch—Perrigo's domestic side of things shouldered all material risks. In focusing solely on risk mitigation while brushing aside all other possible rationales as

irrelevant, at least to the omeprazole transactions, the Government ignores the fact that these transactions were a critical part in ensuring that the uncertainty was placed where the production was. This was more than redeploying costs with the possibility of using additional untaxed income down the line. Of course Perrigo's day-to-day corporate operations as a generic manufacturer and distributor remained the same. But in a meaningful and material way, there was a radical change in how Perrigo operated and was structured after the TESCM step plans were executed. And these were a necessary business component of Perrigo's expansion.

The Government disagrees because, it says, if this were the case then Perrigo's infrastructure was faulty. To bear risk, the LLC needed capital; but LLC was not capitalized until the omeprazole product was launching. Before that point, the Government believes the LLC simply could not bear or manage risk. U.K. Finco changes nothing, according to the Government. Perrigo did not assign the Supply & Distribution Agreement to U.K. Finco, it assigned the contract to LLC. U.K. Finco had no control over the entity, and the LLC had no contractual right to demand funds from U.K. Finco. Put differently, Perrigo cannot substitute what it informally intended its intercompany dealings to be from how it actually structured the piping. But Perrigo's blueprints always contemplated the formation of an in-house bank for its international subsidiaries (Ex. 2, Trial Tr. vol. II) and LLC was able to meet its financial obligations. To be sure, U.K. Finco had a limited obligation to make an initial capital contribution. But trial testimony demonstrated that Perrigo did not need a contribution until shortly before launch. (Trial Tr. vol. II, 91, ECF No. 380, PageID.5553). And the limited obligation is of no moment to how Perrigo intended U.K. Finco to relate to its subsidiaries as documented in the EY TESCM documents. Its role was to ensure that LLC was able to access sufficient funds to meet its obligations. And LLC was able to do so.

Even if LLC could carry risk, the Government's main argument is that the LLC did not carry it. At all times, it claims, Perrigo's domestic affiliates shouldered the risks (to the extent there were any risks) of the omeprazole opportunity, and thus the purported assumption of risks was merely pretext for shifting income offshore. The evidence at trial is to the contrary; there were significant risks that were transferred to the LLC in the assignment. And the Government's contention that Perrigo's domestic affiliates assumed the risks—negating any transfer of value—enjoys no support in the record. For example, while it is true that in October 2007, Perrigo reimbursed Dexcel's patent litigation costs on LLC's behalf, this was contemporaneous with Perrigo's structural set up. Nor did the performance guarantee mitigate any risk transferred to the LLC as part of the assignment. This was a guarantee made by Perrigo as a corporate parent, not L. Perrigo Co., to assuage Dexcel's own uncertainties about the relationship. And under the guarantee, LLC remained responsible for the risks and responsibilities it assumed following the assignment. (Ex. 266). Neither the Sales and Distribution Agreement nor the performance guarantee, furthermore, reflect the type of command and control such that the assignment of income doctrine properly applies. As a general matter, "[a] parent corporation may create subsidiaries and determine which among its subsidiaries will earn income." *Merck & Co. v. United States*, 24 Cl. Ct. 73, 88 (1991). And here, the contractual terms of the assignment reflect that L. Perrigo Co. did not carve out and retain matters for itself to generate the profits. LLC did.

Accordingly, the Court rejects the Government's contention that the assignment and distribution transactions should be disregarded as lacking economic substance and a non-tax purpose, that LLC was a sham entity, and that the assignment of income doctrine applies on the facts of this case.

II. Section 482 Analysis

Having rejected the application of the common-law doctrines to the Dexcel omeprazole income reported by Perrigo, both sides agree that to succeed on its claim for refund Perrigo must also show the Government's alternative Section 482 reallocations—shifting the entirety of Perrigo's omeprazole income onto the domestic side of Perrigo's books for the tax years at issue—were arbitrary, capricious, or unreasonable. *Kenco Restaurants, Inc. v. Comm'r*, 206 F.3d 588 (6th Cir. 2000). And, if it succeeds in making this showing, Perrigo must also show that its own pricing satisfies the arm's length standard. If Perrigo can meet its first burden, but not the second, then the Court must determine the arm's length price.

The arm's length standard underlies the pivotal question for decision: were LLC's payments to L. Perrigo Co. in return for the assignment of the Dexcel Supply & Distribution Agreement and L. Perrigo Co.'s distribution activities proper and at arm's length and, if not, what is the proper arm's length price? Both sides marshal experts in support of their respective positions. There is some agreement in the experts' approaches. They agree on the use of the DCF method to arrive at an arm's length transfer price, and both experts agree there must be an accounting for LLC's subsequent engagement of L. Perrigo Co. to provide distribution activities on the domestic market. And they further agree that under the contemplated arrangement, LLC acted as an investor in the omeprazole opportunity. But the experts' final numbers are much different based on a handful of core disagreements over the inputs that apply to the DCF method. Distilled down, these disagreements come down to (1) the date the assignment is deemed to have occurred; (2) the use of projections vs actual results to determine both (a) cash flow and (b) the percentage of sales used to reimburse L. Perrigo Co. for its distribution related expenses; and (3) the application of a differential discount rate to convert the lump-sum DCF value into an equivalent

royalty rate. Applying these different inputs to their analyses, Dr. DeRamus for the Government shifts the entirety of Perrigo's omeprazole income from LLC to L. Perrigo Co. Dr. Frisch's calculations—in his Scenario A—lead him to a lump sum payment of approximately $43.1 million or an equivalent royalty rate of 6.04%.

These are the central items in dispute. The experts also have additional considerations; alternative calculations; and sensitivity analyses that they apply. Dr. DeRamus favored approach, for example, examines the parties' functions, assets and risks that leads him to bundle the assignment of the Dexcel Sales & Distribution Agreement and the Supply and Distribution agreements together. In so doing, Dr. DeRamus focuses on the distribution agreement, rather than the assignment, as the transaction to be priced. And Dr. Frisch, for his part, presents different scenarios of Perrigo's operating profits that depend on whether the distribution profit that LLC agreed to pay L. Perrigo Co. reflected arm's length behavior. The above number, for instance, is found in his "Scenario A" that assumes the agreed-to profit share is not arm's length behavior. Thus, in Scenario A, Dr. Frish applies a reduced profit margin for L. Perrigo Co.'s distribution activities. But Dr. Frisch's "Scenario B"—which was the primary scenario discussed at trial—assumes the distribution agreement originally reached does reflect arm's length behavior.

For the reasons set out below, the Court largely rejects Dr. DeRamus's approach because it fails to account for and respect the real-time behavior of Perrigo, both in setting up its international structure and in its projections of the omeprazole opportunity. Accordingly, Perrigo has met its first burden of showing the Government's alternative Section 482 reallocations were arbitrary, capricious or unreasonable. When it comes to pricing the assignment, the Court concludes that Dr. Frisch's DCF method under "Scenario B" provides the correct overall approach for determining the lump-sum arm's length price. The Court further determines that Dr. Frisch's

application of his method correctly applied November 2006 as the assignment date; and further agrees with Dr. Frisch's use of Perrigo's contemporaneous financial models when calculating LLC's operating profit. But the Court disagrees with Dr. Frisch's use of L. Perrigo Co.'s actual "fully loaded" selling and distribution costs versus Perrigo's contemporaneous projections. The Court further disagrees with Dr. Frisch's decision to use different discount rates as part of his calculations for an equivalent royalty rate. The Court accepts Dr. DeRamus's critiques of these modifications.

A. Governing Law

The Treasury Regulations recognize that the arm's length standard must be applied in every case of transfer pricing among related parties. *See* Treas. Reg. § 1.482-1(a)(1), (b)(1); *see also Xilinx, Inc. v. Comm'r*, 598 F.3d 1191, 1196 (9th Cir. 2010). Under the regulations, a transaction between related parties (sometimes called a controlled-party transaction) will meet the arm's length standard "if the results of the transaction are consistent with the results that would have been realized if uncontrolled taxpayers had engaged in the same transaction under the same circumstances (arm's length result)." Treas. Reg. § 1.482-1(b)(1). To determine an arm's length price, the regulations call for the application of a transfer pricing method that provides the most reliable measure of the arm's length result. *See Veritas Software Corp. v. Comm'r*, 133 T.C. 297, 327 (2009).

Pricing intangible property, like the Dexcel omeprazole opportunity, can be difficult. Intangible property often is amongst a company's "crown jewels" with tremendous potential for profits. But, as seen at trial, actually developing that property into a sellable product is no sure thing either. At the end of the day, the arm's length standard applies just the same to transfers of intangible property. And the regulations identify several different methods for determining income

related to the transfer of intangible property between related parties (like LLC and L. Perrigo Co.). Treas. Reg. § 1.482-4-6. One such method is an unspecified method. *Id.* at § 1.482-4(d). Included here is the Discounted Cash Flow method (DCF). The DCF method values an asset based on the discounted value of the cash flow the asset is expected to generate. Both Dr. DeRamus (for the Government) and Dr. Frisch (for Perrigo) recognize the DCF as an unspecified method, and both use that method to determine their arm's length price (while disagreeing on what that price should be). (Trial Tr. vol. IV, 119, ECF No. 382, PageID.6035; Trial Tr. vol. VIII, 93, ECF No. 386, PageID.6898). The DCF method will typically result in a lump-sum arm's length price for the pertinent transaction. In this case, both sides agree the DCF method can be used to calculate an equivalent royalty rate—the amount the parties would agree to if instead of a lump-sum payment they instead opted for a perpetual royalty percentage of sales. A royalty amount is necessary here because of now-closed tax years.

The Treasury Regulations also contain certain provisions providing for periodic adjustments related to pricing intangible assets. *See* Treas. Reg. § 1.482-4(f)(2) & (f)(6). This regulation set permits the IRS to make adjustments so that the transfer price of an intangible asset shall "be commensurate with the income attributable to the intangible." The legislative history further indicates that Congress intended that ex post information can be used in making these adjustments. *See* H.R. Rep. No. 99-426, at 425-26 (1985). The Government suggests that the ex post actual omeprazole sales results should be presumptive of what Perrigo should have anticipated ex ante, if not determinative of what Perrigo should have known. But the commensurate with income requirement is designed to be consistent with the arm's length standard. The latter still controls. Put differently, the Treasury Regulations require the pricing of transfers of intangible assets both to be commensurate with income and consistent with the arm's length standard. But

in this case, the Government has not demonstrated how the actual omeprazole profits should be used as an estimate of what Perrigo should have or could have known ex ante. Notably, there is no basis for finding that Perrigo hid the ball or intentionally lowballed its original pricing based on the EY advice. Trial testimony of Mr. Rush and Mr. Schrank was to the contrary. Nor does the Government go so far as to claim that a periodic adjustment should be made any time actual profits prove higher than what was forecast. To base arm's length pricing on actuals in all instances, rather than projections, even for intangibles, would be to eviscerate the arm's length standard. At bottom, what matters here is the arm's length standard, and whether Dr. Frisch's numbers, Dr. DeRamus numbers, or some other number arrived at by the Court meets that standard, and the commensurate with income standard.

B. Discussion

1. Whether Perrigo Must Show its Original Transfer Price of $877,832 Satisfies the Arm's Length Standard.

In May 2006, Perrigo priced the assignment at $877,832. (Trial Tr. vol. II, 100-101, ECF No. 380, PageID.5562-5563). This was within the range EY provided under its cost-plus approach in the May 15, 2006, analysis. (Ex. 545). As things developed at trial, both sides agree (or at least are not presently contesting) that the May 2006 pricing that Perrigo pursued through administrative proceedings was too low. For its part Perrigo, based on Dr. Frisch's Scenario B, values the assignment at $37.4 million (or what it says is an equivalent sales-based royalty rate of 5.24 percent of omeprazole sales). This is much less than Dr. DeRamus' final numbers (that reached a lump-sum of over $400 million and a royalty rate exceeding twenty percent), but still much more than the May 2006, $877,832 pricing that Perrigo reported to the IRS. Perrigo's trial position raises a threshold question of whether a taxpayer can argue for a different, here higher, arm's length price, than what it pursued through administrative proceedings. The Government believes Perrigo cannot

do so and that its claim for refund through the above described framework must rise or fall based on whether its original calculations satisfy the arm's length standard. At trial, defense counsel indicated that using a new number, rather than defending its May 2006 pricing, would be "problematic." Counsel furth described Dr. Frisch's pricing as a "hypothetical" because it was not the transaction that Perrigo actually pursued. In this, the Government sees improper lowballing that seeks to manage risk after the fact. Put differently, the Government contends that to prove the Government's alternative Section 482 reallocation adjustments were arbitrary, capricious, or unreasonable, Perrigo must demonstrate its original pricing satisfies the arm's length standard. (ECF No. 389, PageID.7378-7379). The Court finds no merit in this contention.

Perrigo is not required to demonstrate that its original transfer pricing satisfies the arm's length standard. This is one way that Perrigo may meet its burden, but not the only way. The Government's position is at odds with the regulations that provide an adjustment that results in an increase of taxable income may be made "at any time." Revenue Procedure 99-32, 1999-2 C.B. 296. It is also inconsistent with the two separate burdens a taxpayer bears here. If the taxpayer had to first demonstrate its original pricing satisfied the arm's length standard, then above framework would be unnecessary. At a minimum, it would render irrelevant Sixth Circuit case law providing that if a taxpayer urges a different arm's length price at trial, the court is tasked with establishing the arm's length price, which may be the new number proffered by the taxpayer, or some other number. *See Sundstrand Corp. & Subsidiaries v. Comm'r,* 96 T.C. 226, 375 (1991) (determining arm's length price after neither the IRS nor the taxpayer made a convincing showing).

Relatedly, the Government claims that Perrigo cannot substitute a different valuation methodology (the discounted cash flow method employed by Dr. Frisch) for the original cost-plus markup method (presented by EY as part of the TESCM plan and used by Perrigo in its

administrative refund claims) without violating the variance doctrine, meaning, according to the Government, the Court lacks subject matter jurisdiction over this entire matter, or is at least stuck with Perrigo's original calculation method. And because all sides now agree Perrigo's original math under the cost-plus method did not result in a true arm's length price for the assignment, and the DCF provides the best method, the Government contends as an *ipso facto* matter that Perrigo cannot meet its burden and this Court must accept the Government's alternative Section 482 reallocation, if it does not find the common law judicial doctrines apply, or dismiss this case outright for lack of subject matter jurisdiction. (ECF No. 389, PageID.7387-7390).

It is somewhat surprising to see the argument raised for the first time deep into the post-trial briefing beyond the passing statement in opening that the Frisch pricing was "problematic." To be sure, the Government asserted variance as one of its defenses in its Answer. (ECF No. 115, PageID.975). And it is well established a litigant may raise a court's lack of subject matter jurisdiction at any time. *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004). Still, there was ample opportunity where the Government could have, and should have, raised and developed this type of argument including, at a minimum, as a pretrial motion in limine.

Ultimately, the Court is satisfied the Government's variance-based argument fails to make out a successful challenge. For one thing, the Court sees no subject matter jurisdiction problem. The purpose of the 'variance rule' is to prevent surprise, and to give the IRS adequate notice of the claim and its underlying facts so that it can make an administrative investigation and determination regarding the claim." *McDonnell v. United States*, 180 F.3d 721, 722 (6th Cir. 1999). This expressed purpose more closely aligns with claims processing—that can be waived or forfeited—than it does in jurisdictional grounds. *See generally Wilkins v. United States*, 598 U.S. 152 (2023) ("[C]ourts will not lightly apply [the jurisdictional label] to procedures Congress

enacted to keep things running smoothly and efficiently."). Thus, the Court concludes the jurisdictional wrapping on the Government's challenge misses it mark and by failing to muster any meaningful challenge based on the variance doctrine until well after trial, the Court further finds the Government has waived or forfeited a variance doctrine-based argument.

But on the merits, there was no litigation surprise and no variance problem in Perrigo's selection of the DCF method at trial. During its administrative claims for refund, Perrigo plainly challenged the Government's primary theory—that the transactions lacked economic substance—and the alternative Section 482 reallocation as arbitrary and capricious. To be sure, it maintained that its CPM method pricing was within an acceptable range. (See, e.g., Ex. 5364). The Court is still eminently satisfied there is no variance problem when, during trial, the taxpayer attempts to satisfy its burden by presenting a different arm's length pricing model under the same statutory provision—Section 482—underlying its claim for refund. This is especially true where, as here, it would lead to an increased tax obligation. If it were otherwise, it would undermine the well-established framework set out above, and simply leave the Court to determine whether it agreed, or not, with the IRS's administrative determination under an arbitrary or capricious standard of review. Accordingly, there is no variance problem where Perrigo asks for a different arm's length price at trial.

2. Summary of Expert Opinions

Returning to the framework, and the arm's length pricing of the assignment, the matter comes down to a battle of the experts. As the Government puts it, if the Court credits the methodology of Dr. DeRamus, then Perrigo's claim for refund must fail. The flip side of this is that if the Court credits Dr. Frisch's opinion over Dr. DeRamus's opinions, then Perrigo has met both its burdens of showing the Government alternative Section 482 reallocation was arbitrary,

capricious, or unreasonable and that its pricing (as presented at trial) satisfies the arm's length standard. The third possible result (the one the Court reaches) is that neither expert's calculations properly reach the arm's length result.

At a high level, both sides agree that the discounted cash flow (DCF) method is a proper transfer pricing method for pricing the assignment of the Dexcel Supply & Distribution Agreement. But while the method is the same, the resulting numbers are different. Drastically so. The difference is primarily based on the expert's application of several variables. This includes different focuses (for example, Dr. DeRamus takes a bundled approach that primarily looks at the distribution agreement, rather than the assignment) and the experts' diverging views on certain inputs, including the date the assignment is deemed to have occurred and the sales data (ex-ante forecasts or ex-post actuals) used to determine the cash flows; along with the original $877,832 payment from LLC to L. Perrigo Co. The experts also disagree about whether L. Perrigo Co.'s reimbursable distribution costs should be five percent, as Dr. DeRamus says they should be based on Perrigo's 2006 projections, or should be adjusted for the ex-post fully loaded distribution costs for sales, general, and administrative expenses, as Dr. Frisch says (and pegs at 9.27 percent based on Mr. Broadhurst's calculations). Furthermore, to arrive at a royalty rate, the experts' methods also differ on the discount rate to convert the lump-sum DCF value into an equivalent royalty rate. Dr. Frish says an accounting should be made for the difference in the risk profiles between lump-sum payments and royalty-rate payments based on a percentage of sales. Accordingly, his math uses different discount rates for the numerator and denominator, applying a ten percent discount rate for cash flow, and an eight percent discount rate for Perrigo's omeprazole sales. Dr. DeRamus says the discount rate for cash flows and sales should remain the same at ten percent.

In the below subsections the Court provides greater detail of the experts' testimony. Then in the next section, the Court explains its ultimate arm's length decision.

a. Dr. DeRamus

The Government requested that Dr. DeRamus consider "two big buckets" of information related to Perrigo's omeprazole income reporting. In the first bucket, the Government asked Dr. DeRamus to evaluate the economic or business opportunities and risks associated with Perrigo's omeprazole development efforts, specifically as it related to the Supply & Distribution Agreement; the assignment of that agreement from L. Perrigo Co. to LLC; and three other inter-company transactions. The second bucket concerned the actual pricing of the assignment, and Dr. DeRamus's responses to Dr. Frisch's DCF calculations. (Trial Tr. vol. VIII, ECF No. 386, PageID.6879-6880). He reviewed a broad range of documents, including internal analyses, board presentations, the agreements at issue, depositions, and sales data, to reach conclusions for each of the specific assignments in the two general buckets. Dr. DeRamus's analytical framework began with the arm's length standard, which he testified was the general approach used in transfer pricing analyses. Applying that standard to the Government's requests, Dr. DeRamus used a functions, assets and risks approach to evaluate the transactions.

Dr. DeRamus's overall view of the economic effect of the transactions was consistent with the Government's sham theories. Indeed, Dr. DeRamus was reluctant to agree that the assignment should be respected at all. But to the extent it should be respected, Dr. DeRamus concluded that there should be at most a minimal return to LLC. As the Government put it, Dr. DeRamus's analysis focused on what L. Perrigo Co. and LLC brought to the proverbial table. Looking at three points in time—the November 2006 date used by Perrigo; the Spring 2007 timeframe when Perrigo formalized the paperwork; and the May 2008 date when LLC was capitalized—Dr. DeRamus

concluded that at no point in time did LLC perform any function, assume risk, or add value. (Trial Tr. vol. VIII, 90, ECF No. 386, PageID.6895). Accordingly, he believed that LPC should receive the entirety of Perrigo's omeprazole income. (*Id.*).

This was consistent, in Dr. DeRamus's mind, with a second core question he evaluated—whether the conduct of the parties was inconsistent with the agreed to terms. (Trial Tr. vol. VIII, 77, ECF No. 386, PageID.6882). Dr. DeRamus identified the performance guarantee, a quality assurance agreement, and Perrigo's retention of new omeprazole product development—while transferring the crown jewels of opportunity—as conduct that was inconsistent with the purported transfer and mitigation of risk. (Trial Tr. vol. VIII, 83, ECF No. 386, PageID.6888). It was also important for Dr. DeRamus to consider the Assignment and subsequent Distribution Agreement together as a bundle, as one would razors and blades for example. In Dr. DeRamus's opinion, at arm's length the pricing terms for the distribution agreement would have been determined after taking into account the pricing L. Perrigo Co. received under the assignment. These were, in other words, two unknown variables in a single equation. Dr. DeRamus found it appropriate to take the assignment price as a given, and to price the distribution agreement because the former price was a known number. (Trial Tr. vol. VIII, 90, ECF No. 386, PageID.6895). And based on his functions, assets, and risk approach, Dr. DeRamus concluded that at arm's length, all of Perrigo's omeprazole income should accrue to the domestic side of Perrigo's books (*Id.*; ex. 5434) or at most a small financing return (Table 18 in Dr. DeRamus's report).

Alternatively, and concluding that the $877,832 assignment price was not arm's length behavior, Dr. DeRamus took the distribution pricing as a given and solved for an arm's length price of the Assignment using the DCF method with an assignment date of March 1, 2008. (Trial Tr. vol. VIII, 137-140, ECF No. 386, PageID.6942-6945; ex. 5509). The starting point here was

determining cash flow, and then accounting for certain costs (such as L. Perrigo Co.'s distribution profit of 4.31 percent and ten percent kicker as called for in the distribution agreement). Critically, Dr. DeRamus's analysis used Perrigo's actual sales data from FY2008 through 2012 based on his determination that, having failed to contemporaneously make an arm's length payment at the time of assignment, Perrigo should not receive the benefit of a bargain it did not make. (Trial Tr. vol. VIII, 93-95; 108-109; 138; 140, ECF No. 386, PageID.6898-6900; 6913-6914; 6943; 6945). For the FY2013 to FY2017 years, Dr. DeRamus applied sales estimates from Dr. Frisch (for Perrigo's report). (Trial Tr. vol. VIII, 138, ECF No. 386, PageID.6943)). Similarly, Dr. DeRamus applied Perrigo's projected sales, general, and administrative (SG&A) costs at five percent as L. Perrigo Co.'s reimbursable distribution costs. Because Dr. DeRamus found it appropriate to use ex post data, he applied a negative growth rate to apply a terminal value (that is estimates going forward in perpetuity) for cash flow based on Perrigo's actual profit experience. (Trial Tr. vol. VIII, 138-139, ECF No. 386, PageID.6943-6944). Dr. DeRamus then applied a ten percent discount rate based on Perrigo's cost of capital. All this led Dr. DeRamus to arrive at a lump-sum amount of $474 million to value the assignment.

Dr. DeRamus also converted this lump sum amount into a royalty rate using the same discount rate. He testified that an equivalent royalty rate at arm's length would be 21.5 percent for the Assignment of the Dexcel Supply & Distribution Agreement.

Dr. DeRamus proceeded to testify on several other points that included his critiques of Dr. Frisch's DCF application. He also testified about certain calculations he made at the request of the Government (see Exs. 5312, 5313) that an included a comparison of LLC's expected profits with its reported profits. But his overall determination set out above regarding the Assignment and Distribution Agreements is ultimately what the Government uses here to argue that a proper

application of the arm's length standard would shift the entirety of the omeprazole income to L. Perrigo Co.

b. Dr. Frisch

Perrigo engaged Dr. Frish to determine the arm's length price of the assignment of the Dexcel Supply & Distribution Agreement. Unlike Dr. DeRamus's more sweeping charge, Dr. Frish's task was more closely tailored to L. Perrigo Co.'s assignment of the Dexcel Supply & Distribution Agreement to LLC. Dr. Frisch, like Dr. DeRamus, reviewed myriad documents and case materials, including Perrigo's business forecasts and deposition testimony. His testimony summarized his report, and began with a description of Perrigo's business as a market leader in manufacturing and distributing generic products, a discussion of Perrigo's multinational expansion under the step plan developed by EY; and a summary of Perrigo's pursuit of the omeprazole opportunity. With this background information, Dr. Frisch was able to place the assignment in context with the risk and functions in bringing the Dexcel omeprazole product to market here in the United States and compute an arm's length price for the assignment. Like Dr. DeRamus, Dr. Frisch agreed that the cost-plus method used by Perrigo to reach its $877,832 pricing did not result in an arm's length price. And Like Dr. DeRamus, Dr. Frisch believed that the DCF method would best determine the arm's length price for the assignment of the Dexcel Supply & Distribution Agreement to LLC.

To that end, Dr. Frisch described the Discounted Cash Flow method and how he reached his ultimate lump sum payment amount and equivalent royalty rate. Applying the arm's length standard, Dr. Frisch specified the inquiry as what would an investor have been willing to pay, and the owner of the rights willing to receive, for Perrigo's share of the omeprazole business represented by the Dexcel Agreement. To answer that question using the DCF method, Dr.

Frisch's testimony went through the various inputs in his calculations. These inputs are the types of information an investor and owner would have had access to at the time the deal was made, that is, ex ante information.

First up was the threshold determination of when the deal was made. Dr. Frisch determined the valuation date for the assignment was November 29, 2006. Fixing the assignment date at this point in time, Dr. Frisch concluded, was consistent with Perrigo's real-time execution of the EY step plan. (Trial Tr. vol. IV, ECF No. 382, PageID.6040-6041). Another "crucial" input was the sales information tied to the omeprazole opportunity. Determining LLC's operating profit was the beginning of Dr. Frisch's DCF analysis, and the first step of this determination was a projection of sales and cost of sales. Dr. Frisch inputted Perrigo's contemporaneous financial information to make this calculation and in particular he applied two models that were dated in the months preceding and following the November 2006 transfer date. The two models that bracketed the date of assignment both projected first year sales of $113 million under the first-to-market scenario. (*See, e.g.*, Ex. 1094, last saved by "tmcotter" June 15, 2006 (cell E57 of first to market tab); ex. 1108, last saved by "dxliu" Jan. 18, 2007 (cell E57 of first to market tab); Trial Tr. vol. IV, 132, PageID.6048).

Perrigo's business models made up the first of the two "drivers" in Dr. Frisch's calculations of operating profit. The second driver were those ongoing costs incurred by LLC that were covered in lines three through ten of his Table 1B. This too depended on Perrigo's modeling, but Dr. Frisch made various adjustments to the modeling that he testified were necessary to achieve an arm's length price. First, he accounted for the terms of the Supply & Distribution Agreement that provided for a sales and marketing fee of six percent of sales, rather than five percent (line 5). Second, Dr. Frisch increased the projected sales, general, and administrative (SG&A) costs from

the five percent used in the above models, to 9.27 percent of sales. Dr. Frisch made this change because the modeling's estimate represented only those incremental distribution costs, rather than the fully-loaded distribution costs (that were based on actual cost calculations provided by Mr. Broadhurst). Dr. Frisch believed that arm's length behavior would look to fully-loaded costs over incremental distribution costs. (Trial Tr. vol. IV, 144-145, ECF No. 382, PageID.6060-6061).

Dr. Frisch's analysis then split into two alternative scenarios based on the compensation LLC would pay to L. Perrigo Co. for distribution services. "Scenario A" gave L. Perrigo Co. a distribution profit of 2.6 percent to LPC. This was less than what was specified in the Sales and Distribution Agreement but Dr. Frisch opined that the terms of the Supply & Distribution Agreement provided LPC with too much compensation for its distribution activities, and that the lesser amount used in his calculations more properly reflected arm's length behavior. However, because LPC and LLC's performance followed the terms of the distribution agreement, Dr. Frisch determined an alternative "Scenario B" that retained the two agreed to profit elements in the assignment: 4.31 percent of sales and an additional ten percent "kicker" to be paid to L. Perrigo Co..

Dr. Frisch proceeded to calculate the amount of residual profit given to LLC and Dexcel under the terms of the Supply & Distribution Agreement. Thereafter, in both scenarios (and after accounting for development costs and the original $877,832 payment made) Dr. Frisch was able to calculate the operating profit for Perrigo's FY2009 through FY2016 years by deducting those costs LLC would incur from the total projected sales in Perrigo's models. (Trial Tr. vol. IV, 141-144, ECF No. 382, PageID.6057-6060).

Having determined LLC's operating profits for its investment in the omeprazole opportunity, Dr. Frisch next converted that number to expected cash flows in his Table 2. This

was a relatively "minor conversion" beginning with his operating profit calculations. (Trial Tr. vol. IV, 148, ECF No. 382, PageID.6064). Using, where he could, the parameters of Perrigo's modeling for discounting, as well as information from the Congressional Budget Office, Dr. Frisch adjusted from operating profit to cash flow. Among other things, Perrigo's modeling called for a ten percent discount rate of cash flows year over year, which reflected its estimate of the weighted average cost of capital. These adjustments further accounted for things like the loan LLC was obligated to repay to UK Finco, to determine a cash flow, and resulting discounted cash flow. (Trial Tr. vol. IV, 149-150, ECF No. 382, PageID.6065-6066). That resulted in a net present value of $43.1 million in Scenario A, or $37.4 million dollars in Scenario B, that reflects the cash flows if L. Perrigo Co. received an arm's length amount of profit for its distribution functions. Accordingly, he concluded in Scenario A that LLC would have made a payment to L. Perrigo Co. on November 29, 2006, of $43.1 million. In Scenario B, Perrigo's payment would be $37.4 million.

Dr. Frisch went on determine an alternative way that LLC could compensate L. Perrigo Co. for the value of the Dexcel Supply & Distribution Agreement at arm's length price by making an equivalent periodic payment through ongoing royalties. Royalty payments are permitted under the Treasury Regulations, and are preferred by Perrigo here given certain tax years are now closed. A royalty rate is based on income over sales. Dr. Frisch's calculations then placed the 43.1 million amount (or 37.4 million in Scenario B) in the numerator of the equation using the ten percent discount rate of Perrigo's modeling. The denominator was the expected net present value of omeprazole sales. Here, rather than use Perrigo's ten percent discount rate, Dr. Frisch applied an eight percent discount rate to account for the difference in risk profiles between a lump-sum payment versus royalty payments. Dr. Frisch explained that he applied this reduced discount rate

because sales are less risky than income. (Trial Tr. vol. IV, 152, ECF No. 382, PageID.6068). Thus, he arrives at a net present value of sales of $713.4 million using that rate. Dividing $43.1 million net present value of cash flow by $713.4 million leads him to a royalty rate of 6.04 percent. Using a net present value of $37.4 (under Scenario B) results in a royalty rate of 5.24 percent. This is what Perrigo contends the final result here should be. (See ECF No. 391, PageID.7748 ("Dr. Frisch's 5.24 percent equivalent royalty rate is the arm's length royalty rate and, when applied against actual revenues, correctly determines the arm's length royalty in FYs 2009-2012).

3. The Court's Decision of Arm's Length Pricing for the Assignment

The arm's length standard guides the Court's analysis of the experts' opinions. Applying that standard, the Court is satisfied that neither expert's analysis arrives at a full arm's length price, and so the Court must determine the price for itself, consistent with its obligation under the above governing law. *See Eli Lilly & Co. v. Comm'r*, 856 F.2d 855 (7th Cir. 1998). It is emblematic that the arm's length standard contemplates pricing what was known on the ground at the time the transaction took place. This doesn't mean that a party can hide the ball; parties must take into account what was known or reasonably should have been known when the transaction took place, as Dr. Frisch testified. (Trial Tr. vol. IV, 161-162, ECF No. 382, PageID.6077-6078). So where, as here, there are projections that are contemporaneous to the transactions to be priced, those forecasts should guide the application of the arm's length standard unless other real-time information that is a part of the mix provides a basis for rejecting them. To reiterate, what is vital to the standard is clinging where possible to an ex-ante perspective. This is something that IRS rulemaking itself recognizes. *See* Section 482: Methods To Determine Taxable Income in Connection With a Cost Sharing Arrangement, 70 Fed. Reg. 51,116, 51,117 (Aug. 29, 2005) ("The ex-ante perspective is fundamental to achieving arm's length results."). Yet years later, after the

transactions were completed and the results known, it can be tempting in hindsight to conclude that what has come to pass should be used to determine an arm's length price either by shoehorning the actual results in the "should have known" box or through some other means. But to do so would be to place the ex-ante foundation of the arm's length standard on shaky ground. And ultimately the Court concludes that both experts succumb to the temptation to use ex-post information in their calculations without persuasively justifying their departure. Dr. DeRamus primarily does so in his use of Perrigo's actual omeprazole sales data to determine cash flows—concluding that Perrigo should not be able to reap a reward from failing to pay an arm's length price in its original reporting. But Dr. Frisch does so too in the changing Perrigo's contemporaneous projections for the cost of distributing the omeprazole product to include fully-loaded sales, general and administrative costs.

Both experts provide justifications and explanations for their use of ex-post information. At the end of the day, the Court is persuaded that neither of the experts' inclusion of post-hoc information is proper, and that Perrigo's projections provide a reliable pathway to determining an arm's length price. This means that the Court largely adopts Dr. Frisch's DCF approach using his Scenario B. The Court also agrees with Dr. Frisch's use of November 29, 2006, as the date of the assignment of the Supply & Distribution Agreement to LLC and the date on which LLC's obligation to pay an arm's length price to L. Perrigo Co. arose. But the Court agrees with the Government's critiques of Dr. Frisch's decision to deviate from Perrigo's projections of SG&A expenses in his Table 1 as well as Dr. Frisch's decision to use a different discount rate in calculating an equivalent royalty rate. It appears the Government, based on Dr. DeRamus' table E-5, believes that accepting these two critiques would result in a lump-sum payment of $58.39 million and an equivalent royalty rate of 11.12 percent. It is not clear whether Perrigo agrees. The

Court will direct the parties to submit a proposed final judgment that either provides an agreed upon number to account for these two changes to Dr. Frisch's calculations or provides their arguments for using a different number.

All this is by way of overview. Below the Court provides further explanation, beginning with a discussion of the assignment date (and Dr. DeRamus's "Bucket A" opinions regarding risk). Next the Court discusses Dr. DeRamus's use of Perrigo's actual omeprazole sales data in his DCF analysis, and Dr. Frisch's use of Perrigo's projections. The Court proceeds to discuss SG&A expenses, and then concludes by considering Dr. Frisch's use of a different discount rate in pricing an equivalent royalty rate.

a. Assignment Date and Dr. DeRamus's Functions, Assets and Risks Approach.

The first step is determining when the assignment took place. The parties' arguments here, including the expert reports, largely overlap with their positions on the government's sham theory. Perrigo fixes the date of assignment at November 29, 2006, consistent with the testimony of its fact witnesses. Dr. Frisch agreed this was the appropriate date to price the transaction. The Government asked Dr. DeRamus to evaluate several different dates, though Dr. DeRamus (and the Government) ultimately arrives at March 1, 2008, as the date on which to value the assignment.[23] This is, according to Dr. DeRamus and the Government, the earliest that LLC could bear risk. And by that point, Dr. DeRamus (building on the opinions of Dr. Manning) concludes that any risks related to the omeprazole product were materially dissipated, if not entirely resolved. Even using the earlier dates, however, the Government and Dr. DeRamus maintain that a functions, assets,

[23] That is, to the extent such transaction should be respected for purpose of analysis. The Government maintains, through its sham theories, that the assignment should not be respected.

and risks approach should lead to assigning the entirety of Perrigo's omeprazole income to L. Perrigo Co. The Court concludes that Perrigo has the better argument.

The Court need not rehash the analysis related to the Government's sham theories. The Court is satisfied that Dr. Frisch and Perrigo properly value the Assignment of the Dexcel Supply & Distribution Agreement as occurring on November 29, 2006, based on the persuasive testimony of Perrigo's fact witnesses. At this point in time, LLC assumed the risks of the Dexcel omeprazole product and the potential upsides. This date was consistent with Perrigo's intentions that were reflected in EY's step planning. To be sure, Perrigo did not cross the "t's" and dot the "i's" on the final paperwork until later in the same fiscal year, but as Dr. DeRamus agreed, transactions between related parties are sometimes documented after the fact (Trial Tr. vol. IX, 66, ECF No. 387, PageID.7088) and as a general matter the Treasury regulations do not require transfer agreements to be in writing to be effective (Trial Tr. vol. IX, 64, ECF No. 387, PageID.7086). Thus, there is no reason to depart from the general approach in the Treasury Regulations providing that the allocation of risk between related parties in written agreements should be respected to the extent such terms are consistent with the economic substance of the underlying transactions.

In arguing for the latter date of March 1, 2008, as the date on which to evaluate the transfer (the date when LLC made a cash payment to L. Perrigo Co. consistent with the demand note) Dr. DeRamus and the Government seek to impose too high a burden on LLC. The date on which cash flowed is not dispositive when it comes to when risk transferred. The Government simply repeats its sham theories that ignore how U.K. Finco was designed to act as the in-house bank. Ultimately, Dr. DeRamus's preferred valuation dates, and his Bucket A economic conclusions all falter against the testimony of Perrigo's fact witnesses who credibly testified about EY's step planning; Perrigo's international expansion; Perrigo's difficulty in developing an in-house omeprazole product; and

its reasonable skepticism that Dexcel would be able to do any better in bringing an omeprazole product through the morass towards a successful launch. Accordingly, the Court adopts this part of Dr. Frisch's analysis.

b. Actual Sales vs. Sales Projections

After fixing the valuation date, the next step is determining cash flows. This primarily entails a look at sales and costs of sales. Here, Dr. Frisch uses two of Perrigo's business group's projections for omeprazole sales that bracket the November 29, 2006, transfer date. Dr. DeRamus critiques the reliability of these projections, and argues that instead Perrigo's actual sales data must be used to determine cash flow. Dr. DeRamus's critique is unconvincing, and his decision to use ex post actuals is an unsupportable application of the arm's length standard.

i. Dr. DeRamus's Preferred Approach and Dr. Frisch's Scenario A.

Both experts provide a preferred approach that they believe properly accounts for the distribution agreement. Dr. DeRamus's preferred approach is to price the Distribution Agreement (the subcontract) rather than the Assignment itself. Dr. Frisch's Scenario A calculates Perrigo's operating profit based on his determination that the agreed-to profit share in the distribution agreement is not arm's length behavior and that LLC paid too much for the distribution. His Scenario B assumes that the agreement is reflective of arm's length behavior. The Court is not persuaded by either of the expert's preferred approach.

The Government sees several advantages if the Distribution Agreement, rather than the Assignment, is the transaction that is priced. (ECF No. 389, PageID.7363-7365; ECF No. 395, PageID.7903-7906). There is no dispute that both the Assignment and the Distribution Agreement must be considered in the DCF analysis, but the Court is not persuaded with the Government's argument. The Government and Dr. DeRamus believe that pricing the Distribution Agreement is

the best approach because of the two unknown variables in the equation they see, the pricing of the Assignment--$877,832—was a known variable. Indeed, at the time of Perrigo's valuation date of November 29, 2006, the Government maintains, this was the *only* known variable. (ECF No. 389, PageID.7364). Noting the result of the equation should equal the overall expected value of the Dexcel omeprazole opportunity, Dr. DeRamus preferred approach here awards at most a nominal sum of omeprazole profits to LLC. As Perrigo persuasively points out, however, while L. Perrigo Co. should receive the expected value of the omeprazole opportunity following the two transactions, the result advanced here by the Government based on ex post sales data is not reflective of arm's length behavior. Nor does the Government and Dr. DeRamus explain why the Distribution Agreement should be priced over the Assignment and fix Perrigo's original pricing as a given, when it agrees that the $877,832 was not reflective of arm's length behavior.

Among other things, accepting this approach means that while Dr. DeRamus's calculations assume that LLC owned the Supply & Distribution Agreement, his pricing awards no value to LLC for its ownership. Instead, all profits are moved to L. Perrigo Co. (ECF No. 397, PagID.7986). Little more needs to be said to state that this clearly is not reflective of arm's length behavior. Furthermore, while Perrigo agrees that the price to be paid to L. Perrigo Co. under the distribution agreement should be incorporated into the DCF analysis, the Court credits Perrigo's argument that it is unnecessary to fix the price of the assignment to determine an arm's length price for L. Perrigo Co. distribution services. The Government's only response here is a policy-based argument: that Dr. DeRamus took an aggregate approach, and to provide a higher value for the assignment would be to award Perrigo a windfall by crediting LLC for an assignment it never made. (ECF No. 389, PageID.7363). This overlaps with the rationale that the Government and Dr. DeRamus use to apply Perrigo's actual sales data into the DCF analysis. The Court addresses

that dispute in the next section, but for present purposes it is enough to say that this is not a persuasive argument for departing from the typical rule.

Considering the Distribution Agreement also raises the two scenarios used by Dr. Frisch with respect to the profit split in the agreement. His Scenario A assumes that the Distribution Agreement was not arm's length behavior. His Scenario B takes the position that the Distribution Agreement was arm's length, and leaves that pricing intact. The Court believes that Scenario B provides the correct roadmap. The agreed to profit split compensation that LLC agreed to give L. Perrigo Co. for its distribution activities may be on the higher side, but as several Perrigo witnesses testified, Perrigo was tremendously experienced in distribution activities, and the company leveraged its institutional know-how to garner a large swath of the generic drug market. Accessing these potentially lucrative channels comes at a price, and the Court concludes that the profit-split in the distribution agreement reflects arm's length behavior. For this reason, the Court adopts Scenario B of Dr. Frisch's DCF analysis to this extent.

To conclude, the Court rejects Dr. DeRamus's preferred approach to price the Distribution Agreement, rather than the Assignment, and uses the framework of Dr. Frisch's Scenario B.

ii. Applying the Arm's Length Standard Requires the Use of Sales Projections at the time of the Assignment, not After-the-Fact Sales Data

Dr. Frisch and Dr. DeRamus's DCF analyses both look at sales to arrive at an arm's length price. But they look at different sales data. Dr. Frisch uses Perrigo's business group's projections bracketing the November 29, 2006, Assignment date. Dr. DeRamus and the Government believe those projections are unreliable. So, the Government contends that "actual profit experience is a viable substitute for the anticipated profit experience" in the arm's length calculation. (ECF No. 389, PageID.7373). Dr. DeRamus's similarly includes actual sales data in his alternative DCF

analysis that priced the Assignment. In other words, the Government contends Perrigo's actual omeprazole sales data can and should be used to determine sales and costs of sales as part of the DCF method for an arm's length price. And the Government further contends there is no hindsight problem using this data because Congress provided the IRS with broad enforcement powers to make periodic adjustments when adjudicating mispriced intangible transactions. (ECF No. 389, PageID;.7372-7373; ECF No. 395, PageID. 7906-7913). Moreover to use anything but actual sales data, the Government believes, would be to award LLC with a windfall of the benefit of a bargain it did not make.

The Court is not persuaded by Dr. DeRamus and the Government's justifications for using Perrigo' actual sales data. It cannot be the case that anytime a party fails to pay an arm's length price for a transaction involving intangible assets, the only avenue towards correction is to use actual sales. If it were otherwise, the analysis under the line of cases including *Kenco Restaurants, Inc.*; *Eli Lilly & Co. v. Comm'r*, 856 F.2d 855 (7th Cir. 1998); and *Amazon.com Inc.* would be simple: the IRS could make Section 482 reallocations using actual sales data anytime profits proved higher than expected, and the taxpayer would have no recourse. The Government makes a fair point that taxpayers could sometimes intentionally lowball their pricing, and run the risk that of slipping through the cracks of an IRS audit. There must be a stick, in other words, to disincentivize taxpayers from dodging the arm's length standard. But this is ultimately an argument that is either best handled by penalties or by Congress. For example, the negligence penalty applies whenever there has been a "failure to make a reasonable attempt to comply with the provisions of the internal revenue laws or to exercise ordinary and reasonable care in the preparation of a tax return." 26 C.F.R. § 1.6662-3(b)(1). And on these facts the Court fails to see

how a contrary outcome would provide Perrigo with some unwarranted benefit. The whole point of this aspect of trial was to determine an appropriate arm's length price for the Assignment.

To be sure, Perrigo agrees there may be cases without any reliable contemporaneous information where actual profits could be a useful estimate of what would have been anticipated to determine an arm's length price. But this isn't one of those cases because Dr. DeRamus and the Government's critiques of Perrigo's projections are unpersuasive. The Government contends there is reason to believe the projections used by Dr. Frisch were rough drafts that did not include all the data that was known or knowable to Perrigo at the time the metadata in the files would suggest. The Government sees other flaws too, primarily related to risk adjustments in the projections. The Court sees no basis on which to discard all of this in favor of ex post actual sales data that would contravene the arm's length standard. Mr. Schutt testified extensively about the projections at trial, and trial testimony established that Perrigo's business group routinely prepared projections like those used by Dr. Frisch in the normal course of its business. The business group's projections were provided to Perrigo's Board of Directors. Here the data provided to the Board of Directors in June 2006 expected first year sales at first to market of $100 million. (Ex. 5207). This is consistent with the projections used by Dr. Frisch. To be sure, these projections were not made as part of contemplating the specific transactions to be priced, but there is no requirement that they would be.

The Government also asserts that Dr. Frisch should have included subsequent projections made by Mr. Schutt. These projections were dated months after the November 29, 2006, Assignment. Ultimately, however, Dr. DeRamus could not explain how this information was known or knowable at the time of the Assignment. (Trial Tr. vol. IX, 108-110, ECF No. 387,

PageID.7130-7132). The Government doesn't either, other than to surmise that drilling into the details, Perrigo could have anticipated Mr. Schutt's projections.

At bottom, the Court rejects the Government's critiques of Perrigo's contemporaneous projections in an effort to use ex-post sales data. The Court believes that Dr. Frisch's DCF method that uses Perrigo's projections is a proper application of the arm's length standard.

c. SG&A Expenses

In the above section the Court found that the two profit elements—4.31% of sales and an addition element of 10% of net residual profit—that LLC agreed to pay to L. Perrigo Co. in the Distribution Agreement for its distribution services reflected arm's length behavior. In addition, LLC also needed to reimburse L. Perrigo Co. for its distribution-related expenses. As of November 29, 2006, Perrigo projected these expenses at five percent. In his DCF analysis, Dr. Frisch replaced this estimate with 9.27 percent of sales because the projections represented only Perrigo's incremental distribution costs, and did not include the fully loaded distribution activities, referred to as SG&A costs.[24] Dr. Frisch testified that unrelated parties acting at arm's length would include fully-loaded costs in their pricing. In essence, at this stage of the analysis Perrigo takes the opposite side of its argument with respect to sales data: without any reliable contemporaneous information, ex post actual distribution expenses can be used in place of Perrigo's projections.

Ultimately, what is good for the sales goose is good for the distribution-expenses gander. Perrigo fails to provide a convincing reason for departing from Perrigo's projections. Perrigo sees a meaningful distinction between SG&A costs and the sales data in the 2006 projections because

[24] Dr. Frisch also departed from Perrigo's projections by increasing Perrigo's Sales & Marketing fee from 5% to the contractually stipulated 6% in the Dexcel contract. This adjustment is not challenged by the Government, and like the contractually agreed to profit-split, the Court finds that this adjustment properly reflects ex ante arm's length behavior.

unlike sales, Perrigo's projections simply did not provide *any* forecasts for fully loaded distribution costs. Perrigo proceeds to argue that because LLC lacked any of its own overhead costs, all these costs would fall on L. Perrigo Co. and Perrigo contends, LLC would need to compensate L. Perrigo Co. for the expected benefit of the corporate executive activities it would receive. The Court is not convinced. The point of using projections versus real numbers is to identify uncertainty and, in the case of transfer pricing, put the risk as well as the potential payoff somewhere else. That the projections are less refined than later ones simply reflect that point. Thus the Court seeks no basis to depart from Perrigo's projections, including those of SG&A costs. five percent may have been too low, but this was mostly based on Dr. Frisch's own belief. Perrigo consistently used five percent in its own contemporaneous projections, and this is what should be used in computing an arm's length price. Accordingly, the Court adheres to Perrigo's projection of five percent, and makes this change to Dr. Frisch's Scenario B.

d. Different Discount Rate for Computing Royalty

Both sides agree that an arm's length price can be reflected in either a lump-sum valuation or an equivalent royalty rate. Here, the latter method is preferable given the closure of certain tax years. To convert his lump-sum valuation of the Assignment to an equivalent royalty rate, Dr. Frisch divided the present value of projected cash flows by the present value of projected sales. The latter was determined using an eight percent discount rate, as opposed to the ten percent rate used to calculate cash flows.

Dr. Frisch's modification is due to the perceived difference in risk profiles between sales and cost flows. Dr. Frish testified that sales are less risky than cash flows due to fixed costs. *See also* RICHARD BREALEY, STEWART MYERS & FRANKLIN ALLEN, PRINCIPLES OF CORPORATE FINANCE, 249-50 (9th ed. 2008) ("A production facility with high fixed costs, relative to variable

costs, is said to have high *operating leverage*. High operating leverage means high risk."). The Court does not disagree as a general matter than there may be a difference in sales and cash flows, but Perrigo fails to convince the Court that to calculate an *equivalent* royalty a *different* discount rate should be used. The Court credits Dr. DeRamus's critiques of the different rates used by Dr. Dr. Frisch, specifically that a risk-adverse company would prefer to receive an upfront lump sum payment over a portion of future sales. (Trial Tr. vol. VIII, 176-179, ECF No. 386, PageID.6981-6984).

Accordingly, the Court rejects this part of Dr. Frisch's Scenario B, and applies a 10% discount rate to the equivalent royalty rate determination.

e. Conclusion

For all the above reasons, the Court is convinced that Dr. Frisch's DCF analysis using his Scenario B provides the best approach for determining an arm's length price for the assignment. The Court modifies Dr. Frisch's calculations in two respects: First, the Court adheres to Perrigo's projection of five percent for SG&A expenses. Second, the Court applies a ten percent discount rate for determining an equivalent royalty rate.

III. ANDA Issue

Having resolved the omeprazole issue, the outstanding matter is on Perrigo's standalone claim related the ANDA issue. Perrigo argues that it is entitled to deduct its Section 271(e)(2) patent litigation expenses as ordinary and necessary business expenses. The parties have stipulated to the total amount of legal fees and expenses that Perrigo incurred during its 2009 through 2012 taxable years. (ECF No. 366). In total, accounting for its previous concessions, Perrigo seeks a refund in the amount of $8,455,674 together with statutory interest. (ECF No. 398,

PageID.8031).[25] Perrigo seeks a refund of these legal expenses for three primary reasons. First, it says long standing case law supports its position. *See Mylan Inc.*, 76 F.4th at 239 ("When an infringer is required to pay damages to a design patentee, the amount so paid is deductible from his income tax.") (quoting *Schnadig Corp. v. Gaines Mfg. Co., Inc.*, 620 F.2d 1166, 1169 (6th Cir. 1980)). Second, it says, a contrary application here would run afoul of the intent of the Hatch-Waxman Act. It maintains that FDA and patent litigation processes run on separate tracks, and that because Perrigo's patent defense litigation costs arise out of and seek to protect its generic drug business, they are costs that Perrigo may deduct as ordinary and necessary business expenses. Finally, Perrigo contends that under the case law's "origin of the claim" approach, its litigation expenses are deductible.

First in the summary judgment briefing, and now here following a bench trial, the Government claims these legal expenses must be capitalized, rather than deducted. The Government primarily grounds its position in a Treasury regulation issued in 2004, but it also claims a deduction is inappropriate because defending Section 271(e)(2) litigation does not result in any current benefit to the taxpayer. It further has an alternate take on the application of the "origin of the claim" test. Here, it says, the origin of Perrigo's Paragraph IV litigation expenses is part of the ANDA approval process under the Hatch-Waxman Act through which Perrigo seeks to gain a capital asset meaning, it says, a deduction is improper.

The parties' dispute relates to two provisions of tax law. Section 162 of the Internal Revenue Code permits a taxpayer to deduct "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business." *Mylan Inc.*, 76 F.4th at 238

[25] As stated, *supra*, Perrigo is no longer seeking refund for those legal expenses incurred to prepare Paragraph IV certifications and notices.

(quoting 26 U.S.C. § 162(a)). Section 263 of the Code, however, "allows no deduction for a capital expenditure[.]" *Id.* (quoting *INDOPCO, Inc. v. Comm'r*, 503 U.S. 79, 83 (1992)). Pertinent here, Treasury regulations provide further guidance on how to apply Section 263 to intangible assets. *Id. See* 26 C.F.R. § 1.263(a)-4. For the reasons set out below, the Court concludes that Perrigo's position has merit.

A. Statutory Background

1. ANDA Filings

Before digging into the parties' arguments, some contextual discussion is necessary. The parties largely agree with the statutory framework, which in turn mainly aligns with the background discussion in two recent decisions from the Federal and Third Circuits: *Actavis Laboratories FL. Inc. v. United States*, 131 F.4th 1345 (Fed. Cir. Mar. 21, 2025); *Mylan Inc. v. Commissioner of Internal Revenue*, 76 F.4th 230 (3d Cir. 2023). These cases provide a thorough examination of the regulatory framework related to FDA approval of pharmaceutical products in the United States, and the rules governing tax deductions and capitalizations. Some of this has already been discussed in the above sections relating to the arm's length price for the assignment of the Dexcel Supply & Distribution Agreement; this section provides additional detail that is pertinent to the deductions and capitalization.

"Drug manufacturers must obtain FDA approval to market any new pharmaceutical in the United States." *Mylan Inc,* 76 F.4th at 233 (citing 21 U.S.C. § 355(a)). The ordinary process is "formidable." *Id.* at 234. "Typically, a manufacturer submits a New Drug Application ("NDA") to the agency, and so begins 'a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA.'" *Id.* at 233-34 (quoting *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013)). Up until approximately forty years

ago, "generic drug manufacturers needed to comply with [the NDA process] fully, even though they were marketing essentially identical versions of preexisting, FDA-approved drugs." *Id.* at 234 (citing *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230-31 (4th Cir. 2002)). In addition to going through this costly exercise, generic manufacturers also faced expenses associated with legal liability "since the development and testing of a proposed generic drug was deemed to be an act of patent infringement[.]" *Id.*

In 1984, "[i]n an effort to change the risk-reward ratio and entice the development and marketing of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act." *Id.* In relevant part, "the Hatch-Waxman Act established an expedited process for obtaining FDA approval to sell generic drugs." *Id.* Today, following the enactment of the Hatch-Waxman Act, "generic manufacturers [may] now file an Abbreviated New Drug Application ('ANDA')." *Id.* (citing 21 U.S.C. § 355(j)). "ANDA requires [a] 'simpler showing that a generic drug has 'the same active ingredients as, and is biologically equivalent to, [the already approved] brand-name drug.'" *Id.* (quoting *Actavis, Inc.*, 570 U.S. at 142) (brackets in *Mylan Inc.*).

Hatch-Waxman also changed the rubric with respect to legal liability and patent challenges. It "provid[ed] a legal safe harbor for the development of generic drugs prior to the expiration of a branded drug manufacturer's patents." *Id.* (citing 35 U.S.C. § 271(e)(1)). This is part of the Act's efforts "'to facilitate the resolution of patent-related disputes over pharmaceutical drugs' through a 'streamlined mechanism for identifying and resolving patent issues related to the proposed generic products.'" *Id.* at 235 (quoting *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). Under this expedited process, "brand-name manufacturers list[] the patents that cover their drugs in a FDA publication known as the Orange Book, and generic drug manufacturers will in

turn certify[] in their ANDA filings that they 'will not infringe' any relevant patents, or that the patents are invalid." *Id.* (citing *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012); 21 U.S.C. § 355(b)) (internal footnote omitted). The ANDA applicant "can provide that assurance in one of four ways: by certifying (1) that no patent information on the branded drug has been submitted to the FDA (a Paragraph I certification); (2) that any relevant patents have expired (a Paragraph II certification); (3) that any relevant patents will expire on a stated date, implying that they will have expired by the time the generic drug goes to market with FDA approval (a Paragraph III certification);[26] or (4) that any relevant patents are 'invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug for which the [ANDA] is submitted' (a Paragraph IV certification)." *Id.* (citing and quoting from 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV)) (brackets in *Mylan Inc.*).

The last type of certification, a Paragraph IV certification, is most frequently used by ANDA applicants. *Id.* "By filing a Paragraph IV certification, it is possible that the ANDA filer will obtain effective FDA approval, allowing immediate sale of its proposed generic drug product, before the expiration of the NDA holder's patents." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1349. "Making a Paragraph IV certification, thus, has several consequences." *Id.* "First, submitting a Paragraph IV certification to the FDA triggers a requirement that the ANDA filer send a notification letter ("Paragraph IV Notice") to the patent owner[.]" *Id.* (citing 21 U.S.C. § 355(b)(2)(B)). "Second, filing an ANDA with a Paragraph IV certification is, under the Hatch-Waxman Act, an act of patent infringement." *Id.* This reflects the balance that the Act created

[26] Alternatively, the Paragraph III certification may request the FDA make any approval effective only upon the expiration of the listed patent. "Filing a Paragraph III certification allows the ANDA filer to avoid the risk of infringing the NDA holder's patents, but at the cost of having to delay launching its generic drug product until those patents expire." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1349 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(III)).

when it formed the safe harbor for generic drug development. The Paragraph IV certification and notice requirement is "designed to give patentholders a chance to start the dispute-resolution process without waiting for the creation of a case or controversy by an ordinary act of infringement[.]" *Mylan Inc.*, 76 F.4th at 235. "At that point, the branded drug maker can choose to respond to the technical act of infringement by filing suit, by negotiating, or by walking away from the fight." *Id.* at 236 (internal footnote omitted).

If the branded drug patent holder chooses to litigate, the Paragraph IV process gives the patent holder "the ability to prevent the FDA from giving final, effective approval to the ANDA for up to 30 months." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1350. It does so by filing a lawsuit under 35 U.S.C. § 271(e)(2) that provides:

> It shall be an act of infringement to submit . . . an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Mylan Inc., 76 F.4th at 236 (quoting 35 U.S.C. § 271(e)(2)) (brackets and omissions in *Mylan Inc.*).

While the stay is in effect during litigation under Section 271(e)(2), the FDA's review process continues, "but the generic manufacturer cannot bring its drug to market while the litigation is ongoing, even if the FDA completes its review favorably." *Mylan Inc.* 76 F.4th at 237. Rather, "any FDA approval of the ANDA will be 'tentative,' meaning that it will not be effective (and, therefore, will not permit sale of the generic drug) until the last of the infringed, valid patents covering the NDA product expires." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1350, "If, however, (i) the litigation concludes in favor of the ANDA filer before the end of the 30-month period; (ii) the 30-month period expires while the litigation is still pending; or (iii) the patentee fails to file suit

within 45 days of receipt of the Paragraph IV Notice, then the FDA may grant final, effective approval without delay and the generic drug can enter the market." *Id.* (citing 35 U.S.C. § 355(j)(5)(B)(iii)). "These scenarios incentivize generic drug manufacturers to file ANDAs with Paragraph IV certifications." *Id.* As a further incentive, the Hatch-Waxman Act "grants certain successful ANDA filers a 180-day period of exclusivity to market the first approved generic version of a brand-name drug." *Mylan, Inc,* 76 F.4th at 235 (citing 35 U.S.C. § 355(j)(5)(B)(iv)(I)).

2. Patent Litigation and FDA's ANDA Review

Based on the above framework, both the decisions in *Mylan Inc.* and *Actavis Laboratories* concluded that Section 271(e)(2) litigation and the FDA's ANDA review were independent from each other. "A brand-name drug manufacturer's decision to engage in or abstain from patent infringement litigation plays no role in the FDA's review of an ANDA." *Mylan Inc.*, 76 F.4th at 237. Or, as *Actavis Laboratories* put it, "while Hatch-Waxman litigation very frequently follows the filing of an ANDA accompanied by a Paragraph IV certification, and will often affect the timing of effective FDA approval of an ANDA, it does not affect the FDA's review of the ANDA on the merits." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1350. Perrigo's experts, Sheldon Bradshaw and Tony Figg, agreed during the bench trial in this matter that there is a factual separation between the FDA approval process and the patent litigation process. Indeed, as the Third Circuit Court of Appeals observed in *Mylan Inc.*, the separation is found in the language of the statute and the regulations. *Mylan Inc.*, 76 F.4th at 237 (noting that whether an application is approved or rejected turns on scientific and technical issues, none of which concern patents).

3. Tax Treatment

While the dispute invokes the FDA's regulatory review process and the Hatch Waxman Act's provisions for resolving patent disputes under Paragraph IV, the parties' disagreement comes

down to various provisions of the Internal Revenue Code. As a general matter, Section 162 of the Code permits taxpayers to deduct "ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1350. Section 263(a) of the Code goes on to prohibit deductions for "capital expenditures" which are "'costs incurred in the acquisition or disposition of a capital asset;' generally, a capital asset is 'property having a useful life substantially beyond the taxable year.'" *Id.* (quoting *Woodward v. Comm'r*, 397 U.S. 572, 575 (1970)); *see also INDOPCO, Inc. v. Comm'r*, 503 U.S. 79, 93 (1992) (discussing Section 263(a)(1)). "Capital assets may be tangible . . . or may be intangible." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1351. "[C]ertain Treasury Regulations lay out the rules for applying § 263 to intangible assets[.]" *Mylan Inc.*, 76 F.4th at 238 (citing 26 C.F.R. § 1.263(a)-4; Final Regulations, 69 Fed. Reg. 436 (Jan. 5, 2004)). Relevant here, the regulations require capitalization for "an amount paid to facilitate . . . an acquisition or creation of an intangible." 26 C.F.R. § 1.263(a)-4(b)(1)(v). Also required to be capitalized are amounts "paid to . . . enhance a[n] . . . intangible asset." *Id.* at § 1.263(a)-(4)(b)(1)(iii). The term "facilitate" is additionally defined as "the process of investigating or otherwise pursuing the transaction." *Id.* at § 1.263(a)-4(e)(1)(i). Further clarifying things as only the Treasury regulations can do, the term "transaction" is then defined as "all of the factual elements comprising an acquisition or creation of an intangible." *Id.* at § 1.263(a)(4)-(3).

B. Discussion

1. Treasury Regulations

The Government sees a fairly straightforward path in the regulatory text to support its position. While the relevant statutory and regulatory provisions may be buried under paragraphs and subparagraphs, the Government says a simple dictionary definition of "facilitate" and

"enhance" is sufficient to direct a conclusion that Perrigo's Paragraph IV litigation expenses must be capitalized under the regulation. Defending Paragraph IV litigation "facilitates" obtaining ANDA approval, it contends, because the litigation removes an impediment to obtaining that approval. Put differently the Government argues litigation makes it easier, or less difficult, to obtain ANDA approval. (ECF No. 389, PageID.7408-7409) (quoting Webster's Third New International Dictionary (1986) as found in *United States v. Scheiblich*, 788 F. App'x 305, 309 (6th Cir. 2019)). In a similar way, the Government contends that defending Paragraph IV litigation "enhances" the value of an ANDA approval because an actively defended lawsuit (as opposed to default) carries the potential to bring a product to market earlier. Under what it says is a proper broad reading of these two terms, the Government argues Perrigo's litigation expenses must be capitalized. It resists a narrower "but for" reading of the term that would cut off any connection between ANDA approval and Paragraph IV litigation. To the contrary, it says Paragraph IV litigation is one of the series of steps that is carried out as a single plan to obtain FDA approval. (ECF No. 194, PageID.2131-2132).

The Government's read, however, is inconsistent with the way the Hatch-Waxman Act was designed to reduce pharmaceutical costs, and the lack of any tether between patent litigation and FDA approval. Indeed, as the decisions in *Myland* and *Actavis Laboratories* make clear, the Government's position is at odds with the way the Hatch-Waxman litigation and FDA ANDA approval are entirely independent from each other. For example, if the FDA is ready to approve an ANDA, ongoing Hatch-Waxman litigation does not prevent the FDA from issuing its approval. *Mylan Inc.*, 76 F.4th at 243 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). And if the generic manufacturer loses the lawsuit, then the intervening ANDA approval is simply effective after the expiration of the patents. *Id.* Moreover, the generic manufacturer can always launch "at risk." *Id.* At bottom,

the "generic drug company is not obligated to demonstrate patent invalidity or noninfringement to the FDA to obtain ANDA approval, nor is it obligated to show the technical acceptability of its ANDA application to the court during Hatch-Waxman litigation." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1354 (quoting district court's decision).

The Government believes all this is not relevant to what it says is the ultimate question: why would a generic manufacturer or distributor, like Perrigo, choose to defend, rather than default, once Paragraph IV litigation is initiated. The only reason a manufacturer does so, it says, is to overcome a hurdle to ANDA approval. This should be enough, it believes, to require capitalization under the regulation. (ECF No. 396, PageID.7929). The Court disagrees. In presenting this argument, the Government confuses "facilitate" with "motivate." In fact, the Government made a similar contention in *Actavis Laboratories* in which the Government claimed that "[t]he *only* reason a paragraph IV applicant defends against a Hatch-Waxman suit [rather than default] is to obtain FDA approval that is effective prior to the patent-expiration date." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1359. The Federal Circuit Court of Appeals rejected this argument in a persuasive analysis:

> [J]ust because this is the ANDA filer's motivation, and the impact of the litigation might be to end delay of effective ANDA approval, it does not follow that the expenses incurred by the generic filer in the Hatch-Waxman suit "facilitate" that approval. The ANDA filer would prefer *not* to be sued and then to obtain final FDA approval that becomes effective upon the FDA's completion of its regulatory review, without a 30-month stay and risk of losing the litigation and needing to wait until the expiration of all pertinent patents. Hence, the reality that an ANDA filer making a Paragraph IV certification has the option, upon being named a defendant . . . of converting to a Paragraph III certification and choosing not to defend the lawsuit, does not render the lawsuit—which cannot result in the district court granting effective FDA approval—a *facilitating* step in the FDA regulatory approval process.

Id. at 1359-1360.

The same reasoning applies to the Government's contention that the Paragraph IV notification "enhances" ANDA approval. The Government's contention that Paragraph IV litigation speeds up ANDA approval is simply incorrect. Indeed, under the legislative scheme, "'Hatch-Waxman litigation can only *delay*, never accelerate, final ANDA approval.'" *Mylan Inc.*, 76 F.4th at 243 (quoting *Actavis Labs., FL Inc. v. United States*, 161 Fed. Cl. 334, 370 (2022)). That is, the litigation can only delay the point when the FDA's approval may be effective. It has no bearing on the timing of the FDA's ANDA approval. Indeed, it is not considered at all by the FDA. "Obtaining regulatory approval from the FDA requires the ANDA filer to show that its proposed generic drug product is safe, effective, and bioequivalent to the reference drug of the NDA holder. Prevailing in Hatch-Waxman litigation requires the ANDA filer to defeat the NDA holder's patent infringement claim or prove the patent claims are invalid. There is no necessary link between these two showings: whether the NDA holder succeeds or fails before the FDA, it may also succeed or fail in the district court." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1358. "The district court presiding over the related Hatch-Waxman lawsuit has no power to grant approval of an ANDA; its only ability to impact FDA approval is to delay its effectiveness, first through the automatic 30-month stay and, after entering a final judgment in favor of the patentee, until expiration of the last of the pertinent patents." *Id.* That the generic manufacturer may choose to pursue a course that might end a delay of effectiveness of the FDA's ANDA approval does not "enhance" the value of the approval.

Accordingly, under Section 1.263, Perrigo's Paragraph IV litigation expenses do not "facilitate" a pursuing of the intangible asset of effective FDA approval of its ANDAs, nor does it enhance the value of such. Therefore, under the regulation these expenses are not capital expenses that cannot be deducted.

2. Judicial Doctrines

The Government believes that the Treasury regulation is dispositive; but in the alternative, the Government has argued that the expenses must be capitalized under the "original of the claim" and "future benefits" tests set out in previous Supreme Court decisions. *See Woodward v. Comm'r*, 397 U.S. 572, 577 (1970) (setting out the origin of the claim test as "involve[ing] the simpl[e] inquiry whether the origin of the claim litigated is in the process of acquisition itself."); *INDOPCO, Inc. v. Comm'r*, 503 U.S. 79 (1992) (costs associated with creation or acquisition of intangible assets that "produce[ ] significant benefits . . . that extend[ ] beyond the tax year" should be capitalized). However it is unclear whether *INDOPCO, Inc.'s* future benefit test has independent legs. As the Court in *Actavis Laboratories* pointed out, the Treasury Regulation at § 1.263 was designed to implement the *INDOPCO* decision. *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1358-59; *see also Guidance Regarding Deduction and Capitalization of Expenditures*, 67 FR 77701-01 ("Consequently, the IRS and Treasury Department believe that simply restating [*INDOPCO, Inc.'s*] significant future benefit test, without more, would lead to continued uncertainty on the part of taxpayers and continued controversy between taxpayers and the IRS. Accordingly, the IRS and Treasury Department have initially defined the exclusive scope of the significant future benefit test through the specific categories of intangible assets for which capitalization is required in the proposed regulations."). Regardless, as both *Actavis Laboratories* and *Mylan, Inc.*, make clear, the Government's reliance on these doctrines suffers from the same faulty premise underlying its principal regulatory argument. *See Mylan Inc,* 76 F.4th at 246 n.24 ("Once peeled back, the Commissioner's arguments rely on the same faulty premise we have already rejected—that the litigation costs facilitate the acquisition of an effective FDA approval.").

The origin of the claim test asks "whether the origin of the claim litigated is in the process of acquisition" of a capital asset. *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1353 (quoting *Woodward*, 397 U.S. at 577). Here, the Government argues the origin of the claim litigated is the "artificial" patent infringement under the Hatch-Waxman Act that Perrigo committed when it filed its Paragraph IV notification. (ECF No. 194, PageID.2134). The Government contends this—the filing of the Paragraph IV notice—is one of the steps Perrigo took to obtain FDA approval to market its drugs and thus the litigation expenses are properly capitalized. Perrigo counters that the true origin of the claim is the patent holder's assertion that the patents are valid, and the subsequent commencement of litigation containing Section 271(e) claims. (ECF No. 392, PageID.7819-7822). Thus, like in any other infringement suit, it claims its legal expenses may be deducted. As Perrigo sees it, all Section 271(e)(2) does to accelerate the point in which a patent-holder has standing to bring, but it does not change the nature of the patent-holder's claim.

The Court agrees with Perrigo that the origin of the claim is not the acquisition of FDA approval of an ANDA. That the Paragraph IV notice may precede the filing of a complaint does not fundamentally transform the litigation. *See Boagni v. Commissioner*, 59 T.C. 708, 713 (1973) ("[T]he 'origin-of-the-claim' rule does not contemplate a mechanical search for the first in the chain of events which led to the litigation."). And at the other end, is "the fact that infringement litigation cannot provide the ANDA filer what it wants—only the FDA can." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1355. Put differently, "[w]hen generic manufacturers . . . defend themselves in patent infringement suits resulting from a Paragraph IV certification, they obtain no rights from a successful outcome. They acquire neither the intangible asset of a patent nor an FDA approval." *Mylan, Inc.*, 76 F.4th at 246 n.24. The Government points to a number of considerations as to why Perrigo might choose to actively defend its lawsuit, or what could possibly (but not necessarily)

follow from the litigation. But as *Woodward* made clear, the origin of the claim test does not "consider the taxpayer's motives or purposes in undertaking defense of the litigation[.]" *Woodward*, 397 U.S. at 578. So too are the consequences of the litigation on the generic manufacturer. *Id.* And none of these demonstrates the patent litigation "is actually *part of* the FDA process." *Actavis Lab'ys FL, Inc.*, 131 F.4th at 1356 (emphasis in *Actavis Lab'ys FL, Inc.*). For these reasons, the Court agrees with Perrigo that the origin of the claim is the patent-holder's assertions of the validity of their patent rights, and that applying the origin of the claim test leads to a conclusion that Perrigo's litigation expenses are ordinary and necessary business expenses that may be deducted.

The same holds true under *INDOPCO's* future benefits test, to the extent it has any independent force beyond the Treasury regulation. Here the Government attempts to distinguish Section 271(e) litigation from other patent litigation by arguing that in Section 271(e), the generic defendant seeks to launch a new product, not protect an existing one. (ECF No. 396, PageID.7932). The Court does not agree. As the Third Circuit Court of Appeals concluded, "[w]hen businesses succeed in defending themselves against ordinary patent infringement suits, they may obtain several years worth of revenue that would have been unavailable if the patent had stood in the way." *Mylan Inc,* 76 F.4th at 246 n.24 (citation and quotation marks omitted).

Accordingly, the Court concludes that Perrigo's Section 271(e)(2) litigation defense expenses are deductible. The parties have stipulated to the legal fees and expenses that Perrigo incurred during its 2009 through 2012 taxable years in defending patent infringement cases under Section 271(e)(2). (ECF No. 366). As calculated by Perrigo, and accounting for previous concessions, the Court's conclusion that Perrigo's litigation expenses are deductible entitles it to $$8,455,674.00, together with statutory interest. The Court is requiring the parties to submit a

proposed final judgment that accounts for the Court's rulings on the omeprazole issue. The parties' proposed final judgment should account for the refund due to Perrigo on the ANDA issue as well with a short statement of the parties' positions to the extent there is any disagreement on the final number.

IV. Penalties

The omeprazole issue and, to a lesser extent the ANDA litigation fee issue, constitute the bulk of this case. The remaining issue for decision relates to the penalties the Government says are owed for what all sides now agree was Perrigo's underreporting of omeprazole income. Both sides spend a considerable time in the post-trial briefing addressing penalties. (*See* ECF No. 389, PageID.7391-7407; ECF No. 391, PageID.7748-7761; ECF No. 395, PageID.7913-7920; ECF No. 397, PageID.8003-8015). The Government, largely speaking, contends penalties are plainly warranted for what it sees as a pure tax avoidance scheme lacking economic substance. Perrigo, by and large, argues the Government is regurgitating its meritless economic sham theories and that—because it acted in good faith and in reliance on EY's advice--none of the four theories advanced by the Government should succeed. Perrigo's position has merit.

"A taxpayer is not required to be perfect for this would be an unrealistic expectation. Even tax specialists cannot be perfect. The Code is complex. Reasonable minds can differ over tax reporting and sometimes the IRS disallows certain transactions. Every time a transaction is challenged or disallowed, the taxpayer is not liable for penalties. Only those taxpayers who fail to meet the applicable standard of care—to do what a reasonable taxpayer would do under the circumstances—can be slapped with . . . penalties and interest." *Mortensen v. Comm'r*, 440 F.3d 375, 385 (6th Cir. 2006). This general rule is gleaned from the text of the Internal Revenue Code. *See BASR P'ship v. United States,* 795 F.3d 1338, 1360-61 (Fed. Cir. 2015) (Prost, C.J., dissenting)

("Given that the taxpayer must pay any tax penalty, Congress may reasonably only intend to penalize the taxpayer when the taxpayer is culpable."). In particular, Section 6662(a) of the IRC "imposes an accuracy-related penalty on any portion of an underpayment of tax required to be shown on a return if such portion is attributable to one or more of the following types of misconduct: (1) Negligence or disregard of rules or regulations; (2) Any substantial understatement of income tax; or (3) Any substantial (or gross) valuation misstatement [as further defined]." 26 C.F.R. § 1.6662-2(a) (internal parentheses and citations omitted). The IRS will impose a penalty equivalent to twenty percent of the underpayment, but in egregious cases with a gross valuation misstatement (as set out in Section 6662(h)(2) of the IRC and further defined in Section 1.662-5(e)(2) of the regulations), the IRS may impose an accuracy-related penalty of forty percent of the underpayment. *See* 26 C.F.R. § 1.6662-2(b)(1)-(2).

The IRS imposed multiple penalties for the 2009 through 2012 tax years under four alternative bases. (ECF No. 235-3, PageID.3292). The IRS's primary position was based on its common-law sham theories. Here, the IRS imposed a twenty percent accuracy related penalty for substantial understatement of tax or, in the alternative, for negligence of rules and regulations. (*Id.* at 3292-3293). These are first two bases. Next, under its alternative transfer-pricing theory, the IRS imposed a forty percent gross valuation misstatement penalty. (ECF No. 235-3, PageID.3293). Finally, in the alternative, it assessed a twenty percent accuracy-related penalty for a substantial valuation misstatement. (*Id.*). The individual penalty components do not stack, that is, they are not cumulative. So, if an underpayment is attributable both to negligence and a substantial underpayment of income, the twenty percent ceiling is the same. 26 C.F.R. § 1.6662-2(c).

The alternative forty percent gross valuation misstatement penalty appears to be the Government's preferred approach if the Court (as it has) rejects the sham theories. That said, a great deal of the Government's briefing on penalties is spent defending its original assessments based on the sham theories. (*See* ECF No. 389, PageID.7392-7405). While the Court has rejected those theories, the parties' briefing here is particularly dense and contains arguments that pertain to several different theories at the same time. So, it is not precisely clear how the two sides see the remaining issues. Still, the parties' briefing largely addresses the same general topics, albeit with disparate organization. Given that Perrigo has the burden of proof here, the Court's discussion largely tracks the three primary arguments made by Perrigo as set out in its principal brief. (*See* ECF No. 391, PageID.7751). These are: 1) Accuracy-Related Penalty for Substantial Understatement of Tax; 2) Accuracy- Related Penalty for Negligence / Disregard of Rules or Regulations; and 3) the Gross / Substantial Valuation Misstatement Penalty.[27] The reasonable taxpayer standard underlies all of this. With respect to negligence, for example, the regulations provide that "[n]egligence is strongly indicated where . . . [a] taxpayer fails to make a reasonable attempt to ascertain the correctness of a deduction, credit or exclusion on a return which would seem to a reasonable and prudent person to be 'too good to be true' under the circumstances." 26 C.F.R. § 1.6662-3(b).

A. Substantial Understatement of Income Tax Penalty

The IRS will apply a twenty percent substantial understatement of income tax penalty if the amount of the understatement for a taxable year exceeds the lesser of (i) ten percent of the tax

[27] One of the main differences in the parties' framing is whether the penalties that it applied under the sham-transaction and transfer-pricing theories are "mutually exclusive" as Perrigo says they are, and the Government says they are not. The Court believes the issues it addresses above broadly encompass all the issues it needs to decide.

requirement to be shown on the taxpayer's return for the taxable year (or, if greater, $10,000) or (ii) $10,000,000. 26 U.S.C. § 6662(d)(1)(B). But "[a] taxpayer may reduce or eliminate this penalty by establishing that 'substantial authority' supported" the taxpayer's treatment of the item in the original reporting. *See Est. of Kluener v. Comm'r,* 154 F.3d 630, 637 (6th Cir. 1998). Moreover, the accuracy penalty does not apply to that portion of an underpayment of tax where the taxpayer demonstrates the underpayment was made in good faith and based on reasonable cause. *Id.* at 640 n.3. *See* 26 U.S.C. § 6664. Perrigo contends that the substantial understatement of income tax penalty does not apply here, both because substantial authority supported its position and because its underpayment was made in good faith and based on reasonable cause for its position based on EY's tax advice. The Court agrees with Perrigo.

The substantial authority standard is an objective analysis of the law and its application to the facts. 26 C.F.R. § 1.6662-4(d)(2). This is "less stringent than the more likely than not standard . . . but more stringent than the reasonable basis standard" set out elsewhere in the regulations. *Id.* The term "authority" as set out in the regulations, "includes several sources of law, such as statutes, court cases, legislative history, and regulations, although none of these is particularly relevant if 'materially distinguishable' on its facts. *Kluener*, 154 F.3d at 637. "Authority" can also include factual evidence. *See id.* at 638-39. Substantial authority supported Perrigo's original tax reporting.

The parties' positions here largely track their sham positions. The Government maintains that Perrigo "cannot produce legal authorities that would constitute substantial authority, and Perrigo's conduct during the years at issue precludes its use of factual evidence as sufficient authority." (ECF No. 389, PageID.7404). The Government explains "Perrigo knew full well that the Assignment did not occur in November 29, 2006, but it doubled down on its unsupported

position as reflected in its tax returns." (ECF No. 389, PageID.7404). It goes on to argue there is no reduction under the Code for tax shelters; and that trial testimony established that tax avoidance was a "significant purpose" for the Assignment of the Dexcel Supply & Distribution Agreement from L. Perrigo Co. to LLC, and the subsequent Sales and Distribution Agreement between LLC and L. Perrigo Co. (*Id.*). The cases cited by Perrigo, it claims, "in no way provide authority for the round-trip Assignment and Subcontract transactions involving a reverse hybrid empty box." (ECF No. 395, PageID.7918).

The Court has rejected this basic sham position advanced by the Government, and the Court need not repeat things here. Perrigo's fact witnesses demonstrated that it had a real business purpose in structuring its international expansion in a tax efficient manner, and as part of this expansion placed the risk of Dexcel's omeprazole product overseas. This was part of its core business operations, and the partnership with Dexcel was typical of the way that Perrigo had operated domestically. Numerous cases support Perrgo's position that tax planning is, as a general matter, permissible and the facts demonstrated that Perrigo acted consistent with this general rule. The facts presented at trial demonstrated that Perrigo did not structure things purely for tax avoidance in a manner unrelated to its business operations, as the Treasury Regulations generally contemplate for tax shelter. *See* 26 C.F.R. § 1.6662-4(g)(2)(i)(C). The method that Perrigo selected for pricing the Assignment was the cost-plus approach. This was provided to Perrigo by EY. (Trial Tr. vol. II, 187, ECF No. 380, PageID.5649). And the particular price that Perrigo ultimately selected for the Assignment was within the range of values provided by EY under this method. (Trial Tr. vol. II, 100-101, 184, ECF No. 380, PageID.5562-5563, 5646). Dr. Frisch credibly testified that while the DCF method was the best method for calculating the arm's length

price of the Assignment, the cost-plus method was an appropriate method for valuing the transfer of intellectual property. (Trial Tr. vol. IV, 128-129, ECF No. 382, PageID.6044-6045).

In a similar vein, Perrigo asked EY to determine the arm's length pricing for the Distribution Agreement. (Trial Tr. Vol. II, 87-88, 189, ECF No. 380, PageID.5549-5550, 5651). EY used the comparable profits method to determine the pricing. (Trial Tr. vol. II, 182-183, ECF No. 380, PageID.5644-5645). This too is a recognized method in the regulations. Treas. Reg. § 1.482-5; and it requires a comparison of L. Perrigo Co. profits from its distribution activities to the profits of comparable companies and comparable activities. The Government complains that L. Perrigo Co. was no mere distributor. But as Mr. Papa testified, while Perrigo strove to be better, these were not unique activities in the industry. (Trial Tr. vol. VII, 148, ECF No. 385, PageID.6718). In sum, substantial authority supported Perrigo's position.

Trial testimony also established that Perrigo acted in good faith and had reasonable cause for the underpayment. *See* 26 C.F.R. § 6664(c)(1); 26 C.F.R. § 1.6664-4(b). The focus here is on EY's advice. In particular, the Government contends that Perrigo could not rely on EY's advice because EY had an inherent conflict of interest. Since EY had an active role in structuring the transactions leading to the underreporting of income, the Government believes that EY was not an independent advisor, but rather the designer of what it sees as a botched execution of a faulty TESCM scheme. The Sixth Circuit Court of Appeals has determined that reliance on promoters, or their agents, of an investment will not support a good faith defense. *Mortensen v. Comm'r*, 440 F.3d 375, 387 (6th Cir. 2006) (colleting cases and stating "[i]n order for reliance on professional tax advice to be reasonable . . . the advice must generally be from a competent and independent advisor unburdened with a conflict of interest and not from promoters of the investment.").

The Government points to *Mortensen* to support its position, but that case is distinguishable. In *Mortensen*, the taxpayer made deductions based on his investment in a cattle breeding partnership established by Hoyt, who was later convicted of several crimes. Promotional materials for the investment were titled "The 1,000 lb. Tax Shelter." Hoyt operated a tax return preparation company that prepared the investors' tax returns that included deductions for the partnerships' losses. The IRS later audited the returns and questions, found an underpayment, and awarded penalties. The Sixth Circuit Court of Appeals later determined that the good faith defense based on the taxpayers' reliance on Hoyt was not available because Hoyt "and his organization created and promoted the partnership, they completed petitioner's tax return, and they received the bulk of the tax benefits from doing so. For petitioner to trust Mr. Hoyt or members of his organization for tax advice . . . was inherently unreasonable." *Id.* The other cases cited by the Government contain similar confirmed fraud or tax shelters. *See Pasternak v. Comm'r*, 990 F.2d 893 (6th Cir. 1993) (investors could not claim good faith defense where they relied on promoters of investment scheme lacking economic substance); *New Phoenix Sunrise Corp. v. Comm'r*, 408 F. App'x 908 (6th Cir. 2010) (penalty based on tax deficiency stemming from tax shelter upheld against good faith defense where taxpayer relied on promoter of transactions related to currency speculation that lacked economic substance); *Kerman v. Comm'r*, 713 F.3d 849 (6th Cir. 2013) (defense unavailable where taxpayer knew, or should have known, that financial opinion related to sham transaction was not independent advice.").

This case is factually distinguishable from the four cases cited by the Government. All the cases cited by the Government involve tax shelters or sham transactions lacking economic substance. This Court has found that these theories do not apply to the Assignment and Distribution agreements that are integral to the omeprazole issue. This alone distinguishes the

cases cited by the Government. There are other distinguishing considerations as well. For example, in *Mortensen*, the taxpayer granted Hoyt authority to sign promissory notes and control investments without confirmation or consultation; despite initial promotional materials including warnings that the taxpayer seek outside consultation. *Mortensen*, 440 F.3d at 386. The taxpayer also proceeded despite the receipt of multiple communications from the IRS alerting him to problems with Hoyt's operations. *Id.* Thus *Mortensen* and the other cases cited by the Government, illustrate the dividing line between "advisers [who] not only participated in structuring the transaction, but arranged the entire deal." *106 Ltd. v. Comm'r*, 136 T.C. 67, 80 (2011). EY did not arrange the entire deal here. It provided the advice that Perrigo engaged it to provide. That a tax advisor receives compensation for this advice does not render the advisor, or its agents, a promoter or give the advisor a conflict of interest. *See id.* (citing *Countryside Ltd. P'ship v.* Comm'r, 132 T.C. 347, 352-55 (2009) (a tax advisor is not a promoter where, *inter alia*, the advisor "has no stake in the transaction besides what he bills at his regular hourly rate."); *see also Am. Boat Co., LLC v. United States,* 583 F.3d 471, 483 (7th Cir. 2009) (rejecting per se rule that a taxpayer "may never rely upon the legal advice of the same adviser who counsels the individual on restructuring."). The Court concludes, therefore, that EY did not have a conflict of interest that would preclude the reasonable cause defense here.

Moving on, Perrigo has established that it acted with reasonable cause and in good faith. "Generally, the most important factor is the extent of the taxpayer's effort to assess the taxpayer's proper tax liability." 26 C.F.R. § 1.6664-4(b)(1). Certainly EY was competent to render advice in the area of international business expansion and the related field including the TESCM step plan. As Mr. Rush testified, when he joined the company in the early 2000s, Perrigo had limited international operations and had not engaged in cross-border transactions that contemplated

transfer pricing. (Trial Tr. vol. II, 66-67, ECF No. 380, PageID.5527-5528). As the company expanded, Perrigo selected EY to provide advice on its corporate structure and intercompany transactions across the world. (Trial Tr. vol. II, 166, ECF No. 380, PageID.5628). Mr. Rush testified that the company did not select BDO, its outside financial advisor at the time, because BDO did not have the worldwide breadth and experience that Perrigo was looking for. (Trial Tr. vol. II, 69-70, ECF No. 380, PageID.5531-5532). EY provided that sought after expertise.

Perrigo worked closely with Ms. Voortman at EY, who had extensive experience in the pharmaceutical and life sciences industries. (Trial Tr. vol. II, 118-119, ECF No. 380, PageID.5580-5581). She primarily worked with domestic based multinational companies advising the companies on their corporate restructuring—to align the tax function with the business objectives of the company. (Trial Tr. vol. II, 119-20, ECF No. 380, PageID.5581-5582). Also involved with the project at EY was Ms. Warner, who had decades of experience in transfer pricing spanning across various sectors including life sciences. (Trial Tr. vol. II, 163-64, ECF No. 380, PageID.5625-5626). Mr. Rush communicated with Ms. Voortman and Ms. Warner, and Perrigo gave EY the materials it needed to render advice on Perrigo's restructuring. (Trial Tr. vol. II, 71-72, 95, ECF No. 380, PageID.5533-5534, 5557). Based on these facts, the Court concludes that Perrigo acted in good faith and had reasonable cause for its reporting that included underpayment of tax.

In arguing for a different result, the Government primarily contends that based on all facts and circumstances, including Mr. Rush and Mr. DeGood's education and experience, Perrigo must have been aware that there were flaws in EY's advice. (ECF No. 389, PageID.7400-7401). The primary flaw it sees is building off of a November 29, 2006, Assignment date. (*Id.* at PageID.7394). But this was no flaw; to the contrary it accurately reflected the sequence of events

in executing the advice EY gave to Perrigo, as Perrigo's fact witnesses credibly testified. The Government seeks to poke holes in other aspects of an April 2008 memorandum, but ultimately they fail to convince the Court that the reasonable cause defense does not apply here. "When an accountant or attorney advises a taxpayer on a matter of tax law, such as whether a liability exists, it is reasonable for the taxpayer to rely on that advice. Most taxpayers are not competent to discern error in the substantive advice of an accountant or attorney. To require the taxpayer to challenge the attorney, to seek a "second opinion," or to try to monitor counsel on the provisions of the Code himself would nullify the very purpose of seeking the advice of a presumed expert in the first place." *United States v. Boyle,* 469 U.S. 241, 251 (1985). Because Perrigo has shown it acted with reasonable cause and good faith based on the advice of EY, the Court concludes that the substantial understatement of income tax penalty does not apply here.

B. Negligence / Disregard of Rules or Regulations

The negligence penalty will apply where there has been a "failure to make a reasonable attempt to comply with the provisions of the internal revenue laws or to exercise ordinary and reasonable care in the preparation of a tax return" 26 C.F.R. 1.6662-3(b)(1). The regulations further define a disregard of rules or regulations as including "any careless, reckless or intentional disregard of rules or regulations." 26 C.F.R. § 1.6662-3(b)(2). More colloquially, a reasonable and prudent taxpayer cannot ignore "warning signals" (*Hansen v. Comm'r*, 471 F.3d 1021, 1030 (9th Cir. 2006)); play "ostrich" (*Mortensen*, 440 F.3d at 385 ("[W]hen the predators are circling, no reasonable ostrich sticks its head in the sand."); or move forward with a return that would appear "too good to be true" under the circumstances. 26 C.F.R. § 1.6662-3(b). Negligence is a "lack of due care or failure to do what a reasonable and ordinarily prudent person would do under the circumstances" and includes "any failure to make a reasonable attempt to comply with the

provisions of the Internal Revenue Code." *Mortensen*, 440 F.3d at 385. Courts will look both at the underlying transaction and the taxpayer's position on the events in question. *Hansen*, 471 F.3d at 1029.

Like with the penalty for a substantial understatement of income tax penalty, there are defenses to a negligence penalty. In particular, "[a] return position that has a reasonable basis . . . is not attributable to negligence." 26 C.F.R. § 1.6662-3(b)(1). "Reasonable basis" in turn is a "relatively high standard. . . . If a return position is reasonably basis on one or more of the authorities set forth in § 1.6662-4(d)(3)(iii) . . .the return position will generally satisfy the reasonable basis standard. " *Id.* at § 1.6662-3(b)(3). Thus this is less stringent than the substantial authority position that the Court has found Perrigo has already met. *See* 26 C.F.R. § 1.6662-4(d)(2). Here, however, the Government claims that Perrigo must have actually relied on these authorities. (ECF No. 389, PageID.7393). The Government's position is taken from the Eighth Circuit's decision in *Wells Fargo & Co. v. United States*, 957 F.3d 840, 852 (8th Cir 2020) and the plain language of the term "base" in the regulation. But the Court finds persuasive the position of the dissent in that case, which noted an actual reliance requirement is not found in the text of the regulation, and that reading Sections 1.6662-3(b)(3) and 1.6662-4(d)(3)(iii) together simply leads to the conclusion that the IRS and the courts—not the taxpayer—must decide whether there was a reasonable basis for the taxpayer's return position based on the authorities set out in the regulation. *Wells Fargo & Co. v. United States*, 957 F.3d 840, 857 (8th Cir. 2020) (Grasz, J., dissenting). This is consistent with the objective look set out in *Mortensen* that uses the reasonable and ordinarily prudent person standard. Finally, in addition to reasonable basis, both sides agree that the reasonable cause defense is also available to the negligence penalty. (See ECF No. 389, PageID.7393; ECF No. 391, PageID.7754).

The Government contends that Perrigo was negligent because it knew or should have known that the pricing of the Distribution agreement between L. Perrigo Co. and LLC was unreasonable; did not reflect economic reality; and was not based in fact. But ultimately none of the nits the Government has with EY's memo reflects the type of head in the sand behavior or pursuit of a return that is too good to be true for the same reasons Perrigo established the substantial understatement of income tax penalty. Indeed, because Perrigo had substantial authority supporting its positions, it also had a reasonable basis for its position. The reasonable cause exception, furthermore, applies for the same reasons the Court stated above.

C. Valuation Misstatement Penalties

The final penalties raised in the briefing relate to the valuation misstatements that arise from the Section 482 adjustments. Assuming, without deciding, that the Government can pursue penalties under Section 482 adjustments even where, as here, the tax-deficiency determinations were made on the common law theories, the Court determines the penalties do not apply in any event.

Section 6662(e) of the Internal Revenue Code imposes a twenty percent accuracy related penalty to underpayments of taxes due to substantial valuation misstatements. A forty percent penalty, the one sought by the Government here, applies where the price adjustment exceeds the lesser of $20 million or 20% of the taxpayer's gross receipts. A substantial valuation misstatement arises if "the net section 482 transfer price adjustment for the taxable year exceeds the lesser of $5,000,000 or 10 percent of the taxpayer's gross receipts." 26 U.S.C. § 6662(e)(1)(B)(ii). The term "net section 482 transfer price adjustment" means:

> The net increase in taxable income for the taxable year (determined without regard to any amount carried to such taxable year from another taxable year) resulting from adjustments under Section 482 in the price for any property or services (or for the use of property).

26 U.S.C. § 6662(e)(3)(A).

In a manner similar to the substantial understatement penalty, the regulations exclude those portions of the net increase in taxable income if each of the following three conditions are met:

> (I) it is established that the taxpayer determined such price in accordance with a specific pricing method set forth in the regulations prescribed under section 482 and that the taxpayer's use of such method was reasonable,
>
> (II) the taxpayer has documentation (which was in existence as of the time of filing the return) which sets forth the determination of such price in accordance with such a method and which establishes that the use of such method was reasonable, and
>
> (III) the taxpayer provides such documentation to the Secretary within 30 days of a request for such documentation.

26 U.S.C. § 6662(e)(3)(B)(i).

Of these three, the Government only contests the first. The Government contends that it was unreasonable for Perrigo to depend on EY's advice for the reasons it has advanced above and those the Court has rejected. It argues that EY's analysis resulted in undercompensating Perrigo for its distribution activities. That argument, standing alone, carries little weight because this whole inquiry will only arise if there has been some type of failure to adequately compensate. Next, the Government's contends that EY's advice regarding the Distribution Agreement was a failed effort to patch over an unreasonable Assignment price. (ECF No. 389, PageID.7406). This is argument, to be sure, but the Government fails to support this argument with any factual basis. Finally, the Government argues it was unreasonable to use the CPM method because EY failed to account for the one-year nature of the Distribution Agreement. The Court fails to see how this undercuts the condition.

For this reason, the Court concludes that Perrigo has established that these penalties, along with those discussed above, are inappropriate in this case.

CONCLUSION

Perrigo's partnership with Dexcel on bringing a generic omeprazole product to launch in the domestic market proved tremendously successful. It became a paradigm example of "How to Successfully Gain Share Against an Established Brand." (Ex. 5337). In the ensuing years, sales ballooned into the hundreds of millions of dollars. But none of this was known at the time when Perrigo went about its international expansion in the early 2000s and, as part of that build-out, assigned the rights (and the risks) of its partnership with Dexcel to LLC in November 2006. Risks of success were real. Perrigo had tried, and failed, to develop their own product in house, on a timeline that would allow it to be first to market with a generic alternative to Prilosec. So, it partnered with Dexcel and its optimistic CEO. Perrigo hoped for success and its projections reflected that a generic omeprazole product would prove profitable to the company if it could be first to market. But Perrigo had doubts too, and rather than put all its eggs in one basket with Dexcel, it continued to pursue development of an in-house product.

All this was in the mix when Perrigo assigned the Dexcel Supply & Distribution Agreement from L. Perrigo Co. to LLC in November 2006. Because the assignment had economic substance, the Court rejects the Government's common-law theories that it used to move the entirety of Perrigo's omeprazole income onshore. The Court further determines that Dr. Frisch's DCF method, particularly his "Scenario B" provides the best framework for determining an arm's length price of that assignment. The Court makes two modifications to his calculations, however. First, the Court concludes that L. Perrigo Co.'s reimbursable distribution costs should be five percent, rather than the 9.27 percent used by Dr. Frisch. Second, when it comes to determining an

equivalent royalty rate, the Court determines that the discount rate should be ten percent both for the numerator and the denominator. For the reasons fully explained above, the Court further concludes that penalties are inappropriate in this case. Finally, the Court determines that expenses for preparation of Paragraph IV certifications are properly capitalized, not deducted, but the actual litigation expenses may be deducted.

These are the rulings and decisions of the Court. Because the Court's decisions do not grant, in full, the relief requested by either side, the Court requires the parties to submit a joint proposed final judgment that is consistent with this Opinion no later than **thirty days** from the date of this decision. If the parties cannot agree on that number, they may each submit briefs no greater than 25 pages setting out the basis for the disagreement by the same date, with responsive briefs due **fourteen days** after service of the opening brief. Of course neither side will waive or forfeit any post-judgment or appellate rights by providing a proposed final judgment based on the Court's rulings.

IT IS SO ORDERED.

Dated: September 25, 2025

/s/ Robert J. Jonker
ROBERT J. JONKER
UNITED STATES DISTRICT JUDGE