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PRECEDENTIAL

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 17-1084

SPIRIDON SPIREAS,

Appellant

v.

COMMISSIONER OF INTERNAL REVENUE

On Appeal from the United States Tax Court (T.C. No. 13-10729)
Tax Court Judge: Honorable Albert G. Lauber

Argued October 10, 2017 Before: HARDIMAN, SHWARTZ, and ROTH, *Circuit Judges*.

(Opinion Filed: March 26, 2018)

Brian Killian [Argued] Robert R. Martinelli Michael E. Kenneally Morgan, Lewis & Bockius LLP 1111 Pennsylvania Ave., NW Washington, DC 20004 William F. Colgin, Jr.
Morgan, Lewis & Bockius LLP
1400 Page Mill Road
Palo Alto, CA 94304

Attorneys for Appellant

David A. Hubbert
Acting Assistant Attorney General
Bruce R. Ellisen
Clint A. Carpenter [Argued]
United States Department of Justice
Tax Division
P.O. Box 502
Washington, DC 20044
Attorneys for Appellee

OPINION OF THE COURT

HARDIMAN, Circuit Judge.

This appeal requires us to decide whether royalties paid on a technology license agreement should have been treated as ordinary income or as capital gains. The distinction is significant for taxpayers like the Appellant, Dr. Spiridon Spireas, who earned \$40 million in such royalties over just two tax years. If those earnings were ordinary income, Spireas owed a 35 percent tax; if they were capital gains he owed 15 percent.

Spireas claimed the favorable capital gains treatment pursuant to 26 U.S.C. § 1235(a), which applies to money received "in consideration of" "[a] transfer... of property

consisting of all substantial rights to a patent." The Commissioner of Internal Revenue disagreed that Spireas was entitled to § 1235(a) treatment, finding that Spireas should have treated the royalties as ordinary income. Accordingly, the Commissioner gave Spireas notice of a \$5.8 million deficiency for the 2007 and 2008 tax years. Spireas petitioned the Tax Court for a redetermination of the deficiency, but after a brief trial the Tax Court agreed with the Commissioner. Spireas appeals that final order.¹

I

Royalties paid under a license agreement are usually taxed as ordinary income. An exception to this general rule is found in section 1235 of the Internal Revenue Code, which affords special treatment to payments earned from certain technology transfers. The statute provides that "[a] transfer... of property consisting of all substantial rights to a patent... by any holder shall be considered the sale or exchange of a capital asset held for more than 1 year." 26 U.S.C. § 1235(a). Payments made "in consideration of," *id.*, transfers that meet the statutory criteria are taxed at a long-term capital gains rate that can be about half of that applicable to ordinary income. *Compare* 26 U.S.C. § 1(a), (i)(2) (2008) (providing a top marginal rate of 35 percent for married taxpayers filing jointly), *with* 26 U.S.C. § 1(h)(1)(A)–(C) (2008) (providing a

¹ Spireas filed the tax returns at issue jointly with his wife, Amalia Kassapidis-Spireas. Ms. Kassapidis-Spireas joined in the petition to the Tax Court and also joins this appeal. Since none of Ms. Kassapidis-Spireas's conduct is relevant to this case, we refer only to her husband.

top rate of 15 percent for most long-term capital gains).² Section 1235's basic requirements are straightforward. To qualify for automatic capital-gains treatment, income must be paid in exchange for a "transfer of property" that consists of "all substantial rights" to a "patent." *Id.* § 1235. As this case illustrates, not every transfer of "rights" will suffice because the statute grants capital gains treatment only to transfers of *property*.

² The cited rates apply to the 2007 and 2008 tax years at issue here, but long-term capital gains receive similarly-favorable treatment under current law. *Compare* Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, § 11001(a), 131 Stat. 2054, 2054–55 (to be codified at 26 U.S.C. § 1(j)(2)(A)) (providing a 37-percent top marginal rate for married taxpayers filing jointly), *with* 26 U.S.C. § 1(h)(1)(A)–(D) (providing a 20-percent top rate for most long-term capital gains).

³ IRS regulations provide that "[i]t is not necessary that the patent or patent application for the invention be in existence" to receive capital-gains treatment under § 1235, 26 C.F.R. § 1.1235-2(a), and courts have long held that § 1235 is satisfied "so long as the invention is patentable." *See, e.g., Burde v. Comm'r of Internal Revenue*, 352 F.2d 995, 998 n.4 (2d Cir. 1965). The Tax Court found that the drug formulations involved in this case were patentable, *Spireas v. Comm'r of Internal Revenue*, T.C. Memo 2016-163, 2016 WL 4464695, at *6 n.2 (Aug. 24, 2016), and the Commissioner does not challenge that determination.

II

Α

Spireas is a pharmaceutical scientist who, with Dr. Sanford Bolton, invented "liquisolid technology." That term describes certain drug-delivery techniques meant to facilitate the body's absorption of water-insoluble molecules taken orally. It is not, however, a one-size-fits-all solution. Rather, each application of "liquisolid technology . . . is specific to a particular drug." App. 50–51 (Stipulation ¶ 21). And creating a clinically-useful liquisolid formulation of a given drug is not a matter of rote recipe; it requires creating, through trial and error, a process specific to the substance involved.

The uniqueness of each liquisolid formulation meant that commercializing the technology was a tricky business. Before a drug could go to market in liquisolid form, a specific formulation had to "progress from... conception to... prototyp[ing] . . . , to extensive further development, to a form that c[ould] be . . . sold to the public, to actual manufacture for sale . . . , and, finally, to actual marketing to the public." See 1-6 William H. Byrnes & Marvin Petry, TAXATION OF INTELLECTUAL PROPERTY AND TECHNOLOGY § 6.02[1] (2017). Like most inventors, Spireas was unable to do all that alone, so in June 1998 he signed a licensing agreement with an established drugmaker, Mutual Pharmaceutical Co. (the 1998 Agreement).⁵ The 1998 Agreement established

⁴ Dr. Bolton is deceased, and his estate is not a party to this litigation.

⁵ We describe the parties to the 1998 Agreement in simplified terms. United Research Laboratories, Inc.—a

comprehensive framework for licensing liquisolid technology to Mutual, selecting prescription drugs to develop using the technology, developing and selling those drugs, and paying Spireas royalties out of the proceeds.

Under the 1998 Agreement, Spireas granted Mutual two sets of exclusive rights: a circumscribed grant of rights to liquisolid technology and a much broader set of rights to specific drug formulations developed using that technology. First, the 1998 Agreement granted Mutual "[t]he exclusive rights to utilize the Technology," but "only to develop [liquisolid drug] Products that Mutual . . . and [Spireas] . . . [would] unanimously select." App. 69 (1998 Agreement § 2.1.1) (emphasis added). Second, Mutual received "[t]he exclusive right to produce, market, sell, promote and distribute . . . said Products." *Id.* (1998 Agreement § 2.1.2).

Having allocated Spireas and Mutual their respective rights to the liquisolid technology and liquisolid products, the 1998 Agreement established a multistep process for producing marketable products and paying Spireas for his work. That process began when Spireas and Mutual "select[ed] a specific Product to develop." App. 72 (1998 Agreement § 5.1). Selections had to be unanimous and made in writing. The

corporate affiliate of Mutual—was also a party to the 1998 Agreement. Since none of United's actions are relevant in this case, we refer only to Mutual. In addition, Spireas was joined on the licensor side of the equation by Dr. Bolton and Hygrosol Pharmaceutical Corp., which was an S corporation owned equally by Spireas and Bolton. Certain rights under the 1998 Agreement were granted to Hygrosol, rather than to Spireas and Bolton personally. For simplicity's sake, we refer to Spireas even when the 1998 Agreement refers to Hygrosol.

parties' practice was to memorialize their selections in letters noting the "formal engagement of [Spireas] and Mutual" for a particular product. 1 T.C. Rec. 262–75. Once the parties were so engaged with respect to a particular drug, the process continued with the development of a practical liquisolid formulation, clinical testing, FDA approval, and actual marketing. And as sales were made and funds were received, Mutual would pay Spireas a 20 percent royalty on the gross profits it earned from liquisolid products.⁶

В

In March 2000, Spireas and Mutual entered into an engagement letter (the 2000 Letter) in accordance with the 1998 Agreement. The 2000 Letter engaged Spireas to develop, using liquisolid technology, a generic version of a blood-pressure drug called felodipine.⁷ That development process succeeded after what the Tax Court found was "considerable"

⁶ The 1998 Agreement also provided for Spireas to earn payments as compensation for certain independent consulting work he performed during the product selection and development process. The tax treatment of those payments is not at issue in this appeal.

⁷ The 2000 Letter also engaged Spireas to develop liquisolid formulations for an arrhythmia drug called propafenone. A small portion of the royalty payments at issue in this appeal are attributable to propafenone sales. The Tax Court held that the analysis applicable to the two drugs was "identical in all material aspects," and did not discuss propafenone separately. *See Spireas*, 2016 WL 4464695, at *6 n.2. Neither party to this appeal challenges the Tax Court's sensible approach.

work . . . to adapt [liquisolid technology] to felodipine's idiosyncrasies." *Spireas v. Comm'r of Internal Revenue*, T.C. Memo 2016-163, 2016 WL 4464695, at *6 (Aug. 24, 2016). Spireas completed those efforts in relatively short order. "When he signed the March 2000 engagement letter, [Spireas] had completed roughly 30% of the work that ultimately resulted in" the liquisolid formulation of felodipine that he finished inventing "sometime after May 2000." *Id.* at *6, *10.

The FDA approved Mutual's Abbreviated New Drug Application for liquisolid felodipine, and Mutual marketed it to great success. During the relevant time period, Spireas's royalties on felodipine sales totaled just over \$40 million. Spireas reported all of those royalties as capital gains on his personal returns for tax years 2007 and 2008.

In 2013, the Commissioner sent Spireas a notice of deficiency for 2007–2008. "The deficiencies arose from [the Commissioner's] conclusion that the Royalties [Spireas] received under [the 1998 Agreement] are taxable as ordinary income rather than as capital gain." *Spireas*, 2016 WL 4464695, at *1. The Commissioner determined that the royalties under the 1998 Agreement should have been treated as ordinary income, and Spireas therefore owed some \$5.8 million in additional taxes.

C

After receiving the Commissioner's notice of deficiency, Spireas petitioned the United States Tax Court for a redetermination, and a brief trial was held. The main dispute in the Tax Court was whether Spireas had satisfied § 1235's requirement that he transfer "all substantial rights to a patent." *Spireas*, 2016 WL 4464695, at *8–9. IRS regulations define

"all substantial rights to a patent" to mean "all rights . . . which are of value at the time the rights to the patent . . . are transferred." 26 C.F.R. § 1.1235-2(b)(1); see also E.I. du Pont de Nemours & Co. v. United States, 432 F.2d 1052, 1055 (3d Cir. 1970).

As the Tax Court put it, the parties' differences were "encapsulated in the question: 'All substantial rights to what?'" Spireas, 2016 WL 4464695, at *9. The Commissioner argued that the dispositive point was Spireas's admitted failure to transfer all his rights to liquisolid technology generally. Mutual was not free to exploit every one of the technology's "potential application to thousands of drugs," id. at *12, and could only develop and sell those "Products that Mutual... and [Spireas]... unanimously select[ed]," App. 69 (1998 Agreement § 2.1.1). Spireas acknowledged that he had retained valuable rights in the overall technology, but emphasized that he had transferred away all of his rights to the liquisolid formulation of felodipine. Spireas, 2016 WL 4464695, at *9.

The Tax Court agreed with the Commissioner. It held that Spireas could not have transferred the rights to any particular liquisolid products in 1998 because no products existed at that time. *Id.* Thus, the only rights Spireas could have granted Mutual in 1998 were in liquisolid technology generally—"the rights to use the liquisolid technology... and to make and sell any 'Products containing the Technology." *Id.* And since Spireas had granted Mutual far less than "all substantial rights" to the overall liquisolid technology, the royalty payments he received in 2007 and 2008 did not satisfy the requirements of § 1235 and were thus taxable as ordinary income. *Id.* at *14.

After the Tax Court entered its final order, Spireas timely appealed.⁸

III

A

Spireas's argument on appeal is clear: his royalty payments qualify for capital-gains treatment under § 1235 because he received them in exchange for "all substantial rights" to liquisolid felodipine. Spireas claims the 1998 Agreement *prospectively* assigned Mutual the relevant rights long before he actually invented that particular formulation. The Commissioner responds that Spireas has waived any argument based on a prospective transfer of rights by not presenting it to the Tax Court. Spireas replies by declaring that his "position has been consistent." Reply Br. 6.

Spireas's *ipse dixit* is contrary to the record. In the Tax Court, Spireas asserted a transfer of rights that took place sometime "after [the felodipine formulation] was invented," 2 T.C. Rec. 323 (Spireas T.C. Opening Br. 12 ¶ 40), which happened "sometime between the end of 2000 and spring 2001." 2 T.C. Rec. 319 (Spireas T.C. Opening Br. 8 ¶ 23). Indeed, Spireas could hardly have been more explicit that he "*did not transfer* the felodipine technology in 1998." 2 T.C. Rec. 322 (Spireas T.C. Opening Br. 11 ¶ 36) (emphasis added). In the Tax Court Spireas argued the "fundamental" view that it

⁸ The Tax Court had jurisdiction over Spireas's petition under 26 U.S.C. §§ 7442 and 6214. We have jurisdiction under 26 U.S.C. § 7482(a)(1). Venue is proper in this Court under 26 U.S.C. § 7482(b)(1)(A) because Spireas and his wife are Pennsylvania residents.

was the post-March 2000 transfer of the felodipine formulation that "constituted a transfer of 'all substantial rights" to Mutual. 2 T.C. Rec. 326–27 (Spireas T.C. Opening Br. 15–16).

Our dissenting colleague disputes our reading of the record, contending that "Spireas [has] presented a complicated but consistent argument throughout," and that further consideration of waiver is therefore "not necessary." Dissent at 8, 11. The dissent makes two arguments to that effect, neither of which we find persuasive.

First, the dissent emphasizes the many points of commonality between Spireas's position here and in the Tax Court. To be sure, Spireas has consistently "relie[d] on both the 1998 Agreement and the March 2000 Engagement letter," and argued that they "operat[ed] in conjunction" to transfer to Mutual rights to liquisolid felodipine. Dissent at 1. And the dissent rightly notes that Spireas has always maintained that those two documents are "of a piece and related," making up a "consistent course of dealing," Dissent at 2, and that the ultimate terms on which Mutual obtained "rights to drug 'Products'... depended upon the terms of the 1998 Agreement," Dissent at 3.

Notably absent, however, from that discussion of *which instruments* served to transfer rights in liquisolid felodipine is any mention of *when* Spireas claimed that transfer took place. The dissent appears to suggest that Spireas's consistency on the former point suffices to insulate him from waiver. Dissent at 5 ("Spireas's consistent emphasis on the same contractual provisions distinguishes his case from cases in which we have found waiver."). But where waiver is concerned, the question is not whether a party's position has been mostly consistent, or generally inclined toward the same subject as that raised on

appeal, but whether the same "theory" was "squarely" raised in the trial court. *Doe v. Mercy Catholic Med. Ctr.*, 850 F.3d 545, 558 (3d Cir. 2017) (citing *United States v. Joseph*, 730 F.3d 336, 338–42 (3d Cir. 2013)). So even accepting at face value the dissent's account of Spireas's consistency on some issues, that sheds no light on whether Spireas has waived his new (and contradictory) argument regarding the timing of the transfer.

The dissent's second point—that Spireas has been consistent in distinguishing between legal transfer of *rights* to felodipine in 1998, followed by a physical handover of *possession* in 2000—fares no better. Although that argument does address Spireas's timing theory head-on, its core premise is belied by the record. As we have noted, Spireas's opening brief to the Tax Court made his position clear: (1) "Spireas transferred the felodipine . . . technolog[y] . . . at some point after March 2000," and (2) "Spireas' transfer . . . *constituted a transfer of 'all substantial rights'* . . . to [Mutual]." 2 T.C. Rec. 327 (Spireas T.C. Opening Br. 16) (emphasis added).

The dissent's distinction between an earlier "legal transfer" and subsequent "physical transfer" exists only in what we find to be a strained reading of the single oral colloquy quoted in that opinion. *See* Dissent at 6. Spireas's briefing discussed only a single "transfer" that allocated "rights" (whether or not it involved a physical handover as well). 2 T.C. Rec. 327 (Spireas T.C. Opening Br. 16). We will not read an isolated extemporaneous exchange to advance a theory so at odds with the one Spireas labeled "fundamental" in his written submissions. 2 T.C. Rec. 326 (Spireas T.C. Opening Br. 15).

Citing our seminal precedent in *United States v. Joseph*, 730 F.3d 336 (3d Cir. 2013), the Commissioner contends that Spireas cannot argue on appeal that he transferred rights to felodipine in 1998 after he took the contrary position in the Tax Court. See also Gen. Refractories Co. v. First State Ins. Co., 855 F.3d 152, 162 (3d Cir. 2017) (applying *Joseph* to a civil case). Under Joseph, "merely raising an issue that encompasses the appellate argument is not enough." 730 F.3d at 337. Whether an argument remains fair game on appeal is determined by the "degree of particularity" with which it was raised in the trial court, id. at 341, and parties must do so with "exacting specificity," id. at 339. "[O]ur precedents reveal at least two characteristics that identical arguments always have. First, they depend on the same legal rule or standard. Second, the arguments depend on the same facts." Id. at 342 (citation omitted).9

⁹ The dissent faults us for "rel[ying] on *Joseph* at the exclusion of our precedent on civil waiver." Dissent at 14. In the dissent's view *Joseph* is "instructive" in the civil context, but fails to account for "our prior precedent that *civil* waiver is a prudential doctrine to be applied in a case-specific manner." *Id.* (emphasis added). We disagree that our application of *Joseph* in this case is inappropriate. At the outset, the dissent's concession that our Court has already "appl[ied] *Joseph* in the civil context" demonstrates that our reliance is hardly novel. *Id.* Nevertheless, because those prior decisions have simply cited *Joseph* without much in the way of analysis, we think that a few words clarifying its role in civil cases are in order. *Joseph* arose out of Rule 12 of the Federal Rules of Criminal Procedure, which the dissent characterizes as a very "narrow context." *Id.* We agree that Rule 12 has some unique features.

But the absence of those characteristics in the civil context clarify *Joseph*'s scope, not its applicability.

Rule 12 provides in relevant part that certain "defenses, objections, and requests must be raised by pretrial motion" if possible. FED. R. CRIM. P. 12(b)(3) (emphasis added). And we have held that the result of failure to do so is an outright waiver of the argument in question. *United States v. Rose*, 538 F.3d 175, 176 (3d Cir. 2008). In that respect, Rule 12 sets up a different scheme than prevails under Criminal Rule 52—which provides that arguments "not brought to the [district] court's attention" are generally reviewable for plain error, FED. R. CRIM. P. 52(b)—and in the civil context—where courts retain "discretionary power to address issues that have been waived" under appropriate circumstances, *Huber v. Taylor*, 469 F.3d 67, 74 (3d Cir. 2006).

But while we have held that Rule 12 enacts a unique rule with respect to the *consequences* of not raising an argument, we have never suggested the same with respect to the distinct question of whether an argument was actually raised. Nor does anything in the text of Rule 12 itself provide any reason to do so. References to "raising" arguments are commonplace in civil cases, see, e.g., Huber, 469 F.3d at 74, and *Joseph* implicitly recognized that doctrines respecting the failure to raise arguments generally incorporate three distinct inquiries: (1) whether an argument was made, see 730 F.3d at 338, (2) the default consequences of failing to make an argument (i.e. whether an argument is waived, forfeited, or merely subject to a less-forgiving standard of review), see id. at 339 n.3, and (3) the special circumstances under which those consequences may be excused, see id. at 338 n.2 (noting that waiver under Rule 12 may be excused for "good cause"); see

But even under that strict standard, Spireas's shifting position on the *fact* of when Mutual obtained its rights in liquisolid felodipine does not necessarily mean his entire *argument* is waived. Applying *Joseph*'s particularity analysis is not a matter of comparing every stray statement or claim made in the Tax Court. Rather, *Joseph* instructs us to compare arguments, a term that we have explained is synonymous with

also Huber, 469 F.3d at 74–75 (citations omitted) (discussing examples of analogous civil doctrines).

As the dissent points out, the prudential roots of the civil waiver doctrine differentiate it from its criminal analogues with respect to the second and third questions—failure to raise an argument in a civil case is generally met with relatively softer consequences, and is more readily excused, than in a criminal case. Indeed, we have recognized our discretion to reach an argument that was not made to the district court in a number of circumstances, such as where it presents a purely legal question we think it is in the public interest to resolve. See, e.g., Covertech Fabricating, Inc. v. TVM Bldg. Prods., Inc., 855 F.3d 163, 172 n.4 (3d Cir. 2017). But Joseph addressed (and this appeal implicates) only the threshold question of whether an argument was made in the first place. See United States v. Washington, 869 F.3d 193, 208 n.53 (3d Cir. 2017) (noting that *Joseph*'s "specific framework . . . does not limit our discretion to excuse waiver or forfeiture concerns"). We see no basis for subjecting that inquiry to different standards in civil and criminal cases, and clarify today that *Joseph* provides the governing rule for both. Under that rule, Spireas failed to raise his prospective transfer argument in the Tax Court, and we decline to exercise our discretion to reach it on appeal.

"theories," "grounds," or "bases" for "granting relief." 730 F.3d at 340–42. To be sure, *Joseph* teaches that two arguments can be the same only if they "depend on the same facts," *id.* at 342, but not every fact that appears in a brief is one on which an argument "depends." Whether an argument "depends" on a given fact requires reference to the applicable legal standard. As the Supreme Court has observed in another context, "the substantive law"—in this case, § 1235 of the Internal Revenue Code—"will identify which facts are material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

 \mathbf{C}

Under § 1235's test for capital-gains treatment, changing the date on which Spireas granted Mutual rights to liquisolid felodipine changes the legal theory on which his position depends. Spireas's royalty payments are entitled to capital-gains treatment only if Mutual paid them in exchange for a transfer of "property consisting of all substantial rights" to the liquisolid formulation of felodipine. 26 U.S.C. § 1235(a) (emphasis added). Spireas cannot make that argument for the first time on appeal because it depends on a different legal standard for when that formulation became "property" than his argument to the Tax Court.

Section 1235 is explicit that in order to secure capitalgains treatment, an inventor must make a transfer of *property rights that he actually possesses* at the time of the grant. Accordingly, Spireas had to explain: (1) when he granted Mutual rights to liquisolid felodipine, and (2) how he obtained a property interest in that formulation prior to the grant. The account Spireas presented to the Tax Court was clear: he granted Mutual its rights *after* the invention of the liquisolid formulation was complete, which happened sometime after March 2000. 2 T.C. Rec. 327 (Spireas T.C. Opening Br. 16).

That timeline included a straightforward theory of when and how Spireas obtained his interest in the felodipine formulation. To possess a transferable property interest in an invention, the inventor generally must have "reduced [it] to actual practice." See Burde v. Comm'r of Internal Revenue, 352 F.2d 995, 998 n.3 (2d Cir. 1965); see generally Byrnes & Petry, supra, § 6.05[3]. That basic patent-law rule accords with the text of § 1235, which provides that a non-inventor may be a patent "holder" entitled to capital-gains treatment on the proceeds of a subsequent transfer only if he obtained his interest in exchange for consideration paid to the inventor prior to the invention's "actual reduction to practice." 26 U.S.C. § 1235(b)(2). Put another way, "actual reduction to practice" is the line between a transfer of a then-existing "property" interest (which entitles the holder-transferor to immediate capital gains treatment) and a transfer or grant of some other legal interest (which makes the transferee the new "holder" entitled to pay the capital gains rate against the proceeds of a

¹⁰ While the dissent's assertion that "transfers of future inventions are valid" is correct as a matter of contract law, Dissent at 10 (citing Byrnes & Petry, supra, § 6.05[4]), it is also a *non sequitur*. Agreements to transfer future patents are enforceable even if no property interest exists at the time of contracting. Byrnes & Petry, supra, § 6.05[3][a] ("[P]arties can agree *in advance* that *upon reduction to practice* the inventor *will* convey the property.") (emphasis added), *quoted by* Dissent at 10. For tax-law purposes, the question isn't whether the parties made a valid and enforceable contract, but whether in doing so they transferred a then-existing interest in property.

transfer that takes place after a subsequent reduction to practice).

"Actual reduction to practice" is a term of art in patent law, see generally U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 2138.05(II) (9th ed. Rev. 7, Nov. 2015), that has a slightly looser meaning in the tax context. "Generally, an invention is reduced to actual practice when it has been tested and operated successfully under operating conditions." 26 C.F.R. § 1.1235-2(e). The Tax Court decision from which the IRS borrowed that language clarifies things a bit further: "it [is] not necessary that testing... proceed[] to the point where the invention was actually ready to be put into commercial production..., but rather... that the tests should suffice to persuade... that the product will serve the purpose for which it is designed." Comput. Sci. Corp. v. Comm'r of Internal Revenue, 63 T.C. 327, 352–53 (1974) (internal quotation marks omitted).

Here, the Tax Court found that Spireas's "invention of the felodipine formulation occurred sometime between May 10, 2000 . . . and May 2001." *Spireas*, 2016 WL 4464695, at *7. Spireas does not challenge that finding on appeal. The Tax Court described the "invention" of the formulation rather than its "actual reduction to practice," but the relevant patent law makes clear that if Spireas invented the formulation, he necessarily reduced it to practice. "Making [an] invention requires conception and reduction to practice." *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1000 (Fed. Cir. 2014). And conception necessarily precedes actual reduction to practice, since by definition "[c]onception is [only] complete when one of ordinary skill in the art could construct the apparatus." *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994). The corollary is that actual reduction to practice always completes

the process of "inventing." So the Tax Court's finding that Spireas "invented" the felodipine formulation after May 2000 necessarily implies a finding that he reduced it to practice in the same timeframe.

Spireas's original theory hinged on a post-invention transfer of rights. On that account Spireas reduced the felodipine formulation to practice around May 2000—giving him, in theory, the property interest that the statute requires and only later passed his interest on to Mutual. But Spireas has abandoned that theory here, insisting instead that he transferred rights to Mutual in 1998. See Reply Br. 6 ("What happened in 1998 is that [Spireas] assigned Mutual his rights to future Products."). Because that was at least two years before the invention of the felodipine formulation, Spireas's current position cannot depend on the legal standard of reduction to actual practice to establish that he held a property right at the time of transfer. Nor can it depend on the same facts as did his argument to the Tax Court, the timing of felodipine's invention central among them. Spireas's sole claim on appeal is therefore waived under *Joseph*. 11

¹¹ Judge Shwartz would also conclude, even if the Court were to consider the merits of Spireas's argument based on a transfer of rights in 1998, that Spireas still transferred less than all substantial rights in the liquisolid technology that was the subject of the 1998 Agreement, and thus would not be entitled to capital-gains treatment.

For the reasons stated, and because Spireas has not offered any reason why we should excuse his waiver, we will not evaluate Spireas's new argument on appeal. The decision of the Tax Court will be affirmed.

Spireas v. Commissioner IRS

No. 17-1084

ROTH, *Circuit Judge*, dissenting.

Appellant Spiridon Spireas's entitlement to the long-term capital gains tax rate under I.R.C. § 1235 depends upon his contention that the 1998 Agreement transferred to Mutual all substantial rights to future drug formulations, agreed upon by Spireas and Mutual, including the felodipine formulation. Concluding that Spireas failed to advance this argument before the Tax Court, the Majority finds Spireas's appeal barred by the waiver doctrine. In reaching that conclusion, the Majority misconstrues Spireas's arguments before the Tax Court and misapplies our waiver precedent. Accordingly, I respectfully dissent.

I.

I turn first to the issue of consistency. The Majority sees inconsistency between Spireas's argument in the Tax Court and his argument on appeal. According to the Majority, Spireas changed the date on which he granted Mutual the rights to liquisolid felodipine. But a more careful examination of the record reveals that, both at trial and before this Court, Spireas has advanced essentially the same argument regarding the transfer of rights—an argument that relies on both the 1998 Agreement and the March 2000 Engagement Letter, operating in conjunction to convey future rights to liquisolid felodipine. On appeal, Spireas chose to

"place greater emphasis" on the 1998 Agreement. The fact that Spireas did so in order to counter what he considered to be the erroneous reasoning of the Tax Court, does not provide a basis for the Majority to contend now that Spireas has changed his position. In fact, he has merely changed the emphasis. We will demonstrate that below.

Spireas's written submissions to the Tax Court consistently reflect his argument that the 1998 Agreement and the March 2000 Engagement Letter are "of a piece [and] related parts of the contracting parties' consistent course of dealing." The purpose of the 1998 Agreement was for Spireas to grant to Mutual a license to use the liquisolid technology in connection with specific products that Spireas and Mutual would agree to develop. This was accomplished in the 1998 Agreement. Under it, Spireas did not transfer "all substantial rights" to the liquisolid technology itself but he did convey, as provided in ¶ 2.2 and 5.1, "all substantial rights" to the patentable formulation of the liquisolid version of felodipine, as provided in the March 2000 Engagement letter.

This interpretation was corroborated at the outset of the litigation when Spireas and the IRS jointly addressed the relationship between the 1998 Agreement and the March 2000 Engagement Letter in the First Stipulation of Facts (Stipulation). The Stipulation explicitly acknowledges the interdependence of the 1998 Agreement and the March 2000

¹ See Gen. Refractories Co. v. First State Ins. Co., 855 F.3d 153, 162 (3d Cir. 2017).

² Reply Br. at 3.

³ App. at 8 (T.C. Op.).

Engagement Letter, stating, "The 1998 License Agreement governed the relationship and rights of the parties but, pursuant to \P 2.2 and 5.1 of that agreement, the parties entered into specific agreements each time they agreed to develop a new liquisolid pharmaceutical product."⁴ As this language reflects, both Spireas and the IRS agreed that the 1998 Agreement governed the *rights* of the parties, including the rights transferred for each product which they subsequently agreed to develop. In addition, they explicitly acknowledged that the March 2000 Engagement Letter was entered into pursuant to the 1998 Agreement—specifically Section 2.2, which governs the conditions of Mutual's "exclusive right to Produce and Sell . . . Products," such as felodipine. Thus, from the outset, both Spireas and the IRS recognized that the transfer of rights to drug "Products," such as felodipine, depended upon the terms of the 1998 Agreement.

Spireas's post-trial briefs continue to emphasize the importance of the 1998 Agreement and the interdependence between the 1998 Agreement and the March 2000 Engagement Letter. In his opening post-trial brief, Spireas described the March 2000 Engagement Letter as a "formal agreement . . . to identify generic felodipine as a potential *product* to develop pursuant to the 1998 License Agreement . . ." He proceeded to explain, "The March 2000 [Engagement Letter] applied the terms of the 1998 License Agreement to the felodipine product. . . The parties treated the transfer of the felodipine technology after it was invented

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⁴ App. at 57.

⁵ App. at 69.

⁶ Appellee's Supp. App. at 7 (emphasis added).

as an exclusive transfer under Section 2.1 of the 1998 License Agreement."⁷ These statements to the Tax Court align with Spireas's argument on appeal that the 1998 Agreement effected a legal transfer of rights to the future Products and that the March 2000 Engagement Letter identified the felodipine formulation as one of the Products to which future rights had been transferred.

Spireas also explicitly relied on the 1998 Agreement when discussing the royalty payments in the Tax Court. He argued throughout his opening post-trial brief that the royalty payments were made in exchange for rights to the felodipine technology and that the payments were made pursuant to Section 4 of the 1998 Agreement. He argued, "The parties treated the transfer of the felodipine technology as subject to royalties under Section 4.1 of the 1998 License Agreement." Spireas reemphasized this point throughout the brief, later noting, "URL/Mutual paid royalties to Dr. Spireas consistent with Section 4.1 of the 1998 License Agreement."

Spireas continued to emphasize the importance of the 1998 Agreement in his answering brief. Responding to the IRS's arguments, Spireas emphasized that he "could (and did) transfer all of his significant rights in the felodipine . . . technologies to URL/Mutual under the terms of the [1998] Agreement." Spireas also contended that the IRS

⁷ Appellee's Supp. App. at 7-8.

⁸ Appellee's Supp. App. at 9.

⁹ Appellee's Supp. App. at 13.

¹⁰ Appellants' Supp. App. at 27.

misunderstood "how the terms of the 1998 Agreement applied to the actual technology transfers at issue." ¹¹

As the record demonstrates, in his written submissions to the Tax Court, Spireas focused on many of the same provisions of the 1998 Agreement that he later emphasized in his initial brief on appeal. Both his trial and appellate briefs devote particular attention to Section 2, which transfers rights to future Products; Section 4, which provides for a 20% royalty based on the sale of those Products; and Section 5. which sets forth the process by which future drug formulations will be selected as Products under the Spireas's consistent emphasis on the same Agreement. contractual provisions distinguishes his case from cases in which we have found waiver. For instance, in Frank v. Colt *Industries, Inc.*, we concluded that a finding of waiver was appropriate because appellant's new theory relied upon a separate provision of the contract that was not at issue before the trial court.¹² That is the opposite of the situation here. Spireas has relied on the same provisions of the 1998 Agreement throughout the litigation, and he has made a consistent argument about the interdependence of the 1998 Agreement and the March 2000 Engagement Letter.

The Majority's position rests upon two misunderstandings. First, the Majority confuses the legal transfer of *rights* to the felodipine formulation (and other Products) with the physical transfer (*i.e.*, the handover or disclosure) of the felodipine formulation. Second, the Majority incorrectly concludes that, as a matter of law,

¹¹ Appellants' Supp. App. at 28.

¹² 910 F.2d 90, 99-100 (3d Cir. 1990).

Spireas could not have transferred rights to the liquisolid felodipine formulation until it was reduced to practice.

The Majority's confusion on the first point is understandable, since Spireas's trial counsel did not make the distinction as clear as she could have. In fact, at the close of trial, counsel was tripped up by this distinction herself. Seeking to shift the burden of proof, counsel initially asserted, "Dr. Spireas transferred the felodipine and propafenone technologies to United and Mutual at some point after that March 7th, 2000 agreement."13 The Tax Court judge responded that the issue of transfer was not a question of fact. Recognizing the confusion her statement had caused, Spireas's trial counsel immediately clarified, "Dr. Spireas gave the formulation technologies, the specific technologies, handed those over to [,] the felodipine and propafenone technologies[,] to United and Mutual at some point after March 7th, 2000. So the completed formulas."14

This clarification actually underscored the distinction being made. The *rights* to the future drug formulations were transferred in exchange for royalty payments. That transfer of rights occurred via legal instrument—in this case, the 1998 Agreement, which granted rights to future Products in exchange for 20% royalty payments, operating in conjunction with the March 2000 Engagement Letter, which identified the felodipine formulation as a Product under the 1998 Agreement. The *actual felodipine formulation* was physically transferred or handed over to Mutual later, at least several

¹³ 2 T.C. Rec. 174.

¹⁴ 2 T.C. Rec. 175 (emphasis added).

months after March 2000, once Spireas had completed its development.¹⁵

Once this distinction is recognized, the purported inconsistency in Spireas's argument disappears. Majority finds that Spireas "could hardly have been more explicit that he 'did not transfer the felodipine technology in 1998."¹⁶ But the Majority mistakes this statement about the physical transfer of the felodipine formulation for a statement about the role of the 1998 Agreement in the legal transfer of rights to the formulation. The transfer of legal rights—not the disclosure of the formulation itself—served as consideration for Mutual's royalty payments.¹⁷ And the language immediately following Spireas's statement in his post-trial brief that he "did not transfer the felodipine technology in 1998" clarifies Spireas's position that the *rights* to that technology were transferred via the 1998 Agreement and the March 2000 Engagement Letter. 18 That is consistent with Spireas's argument on appeal.

¹⁵ See Reply Br. at 8-9.

¹⁶ Maj. Op. at 10 (quoting 2 T.C. Rec. 322).

Under any licensing agreement for a patentable product, payments are inherently made for the rights to make and sell the product, not for the product itself. Section 1235 reflects this reality, as it addresses payments made in consideration for a transfer of "all substantial *rights* to a patent." I.R.C. § 1235 (emphasis added).

¹⁸ 2 T.C. Rec. 322 ("The March 2000 Letter Agreement applied the terms of the 1998 License Agreement to the felodipine product.").

Undoubtedly, Spireas's trial counsel could have used more precise language to distinguish between the legal transfer of rights and the physical transfer of the formulation. But, under this Court's precedents, that mistake alone provides an insufficient basis to find that Spireas has waived his argument on appeal. Here, Spireas presented a complicated but consistent argument throughout his written submissions. That is not the same as failing to present an argument entirely or presenting an argument only briefly or in passing. His statements regarding the legal transfer of rights to the felodipine formulation via the 1998 Agreement and March 2000 Engagement Letter were sufficiently consistent to preserve his argument on appeal.

Responding to these arguments, the Majority contends that this dissent focuses on the question of *which* instruments transferred the rights to liquisolid felodipine, at the exclusion

Cir. 2009).

¹⁹ For example, in *Keenan v. City of Philadelphia*, a case in which we stated that "the crucial question regarding waiver is whether [a party] presented the argument with sufficient specificity to alert the district court," we nonetheless based our finding of waiver on the fact that the argument presented by the defendants on appeal appeared "[n]owhere in their submissions to the district court (or to this court before oral argument)." 983 F.2d 459, 471 (3d Cir. 1992). In a similar vein, in *In re Insurance Brokerage Antitrust Litigation*, we noted that arguments "properly preserved for appeal are limited to those . . . presented with at least a minimum level of thoroughness to the District Court," even if they were presented in a "conclusory fashion." 579 F.3d 241, 262 (3d

of considering *when* the transfer took place.²⁰ This is a false distinction. All parties to this appeal agree that there are, at most, two possible "instruments of transfer"²¹—the 1998 Agreement and the March 2000 Engagement Letter—and the Tax Court record reflects a consistent focus on these documents. There were no other instruments governing the transfer of rights. If, as the Majority contends, Spireas's argument below depended solely upon a post-March 2000 transfer of *rights*, then the extensive discussion of the 1998 Agreement and March 2000 Engagement Letter in Spireas's briefs²² and trial testimony²³ would be incongruous.

The Majority opinion also incorrectly concludes that an inventor cannot avail himself of § 1235 if he has not reduced an invention to practice before transferring the rights to that invention.²⁴ As a result, the Majority's approach forecloses reliance on the 1998 Agreement. But the law is not as absolute as the Majority opinion would lead us to believe. Although it may be the "general rule" that "an invention must have been actually reduced to practice at the

²⁰ Maj. Op. at 11-12.

²¹ Cf. 26 C.F.R. § 1.1235-2(b).

²² See supra notes 8-11 and accompanying text.

²³ See e.g., 2 T.C. Rec. 77 (trial testimony of Spiridon Spireas) (describing the March 2000 Engagement Letter as "the agreement . . . to transfer to Mutual those specific three products at the time to be worked and developed based on some technologies that were available at the time.").

²⁴ See Maj. Op. at 16.

time of the sale,"²⁵ in order for the seller to receive favorable tax treatment under § 1235, it is equally true that transfers of future inventions are valid²⁶ and that "parties can agree in advance that upon reduction to practice the inventor will convey the property to the purchaser."²⁷ In these situations, a seller may be entitled to the benefit of § 1235, particularly where, as here, the future inventions are improvements on an existing invention.²⁸

Moreover, the Majority's position not only precludes reliance on the 1998 Agreement, it would also seem to have us throw out the March 2000 Engagement Letter, as that agreement similarly predates the felodipine formulation's reduction to practice. By the Majority's own account, the felodipine formulation was not reduced to practice until May 2000 at the earliest.²⁹ The Majority erroneously concluded that "Spireas's original theory hinged on a post-invention transfer of rights" that occurred at some point after May

²⁵ William H. Byrnes & Marvin Petry, TAXATION OF INTELLECTUAL PROPERTY AND TECHNOLOGY § 6.05[3][b] (2017).

²⁶ *Id.* § 6.05[4] (citing *Dreymann v. Comm'r*, 11 T.C. 153 (1948)).

²⁷ *Id.* § 6.05[3][a]. *See also New Britain Mach. Co. v. Yeo*, 358 F.2d 397, 405 (6th Cir. 1966) (discussing construction of contracts assigning future inventions and improvements).

²⁸ *Id.* § 6.05[4]. For purposes of patent law, the liquisolid felodipine formulation was an "improvement" of the general liquisolid technique. *See* 35 U.S.C. § 101. All parties acknowledge that Spireas conveyed limited rights to the general liquisolid technique via the 1998 Agreement.

²⁹ Maj. Op. at 18.

2000.³⁰ This conclusion reinforces the Majority's misunderstanding of the distinction between the physical transfer of the completed formulation and the transfer of rights. Moreover, it is difficult to reconcile with the extensive discussion of both the 1998 Agreement and the March 2000 Engagement Letter in Spireas's Tax Court briefs.

It is clear that Spireas's position before the Tax Court was consistent with his position here. When looked at closely, Spireas has waived nothing because he presented the full facts and legal argument to the Tax Court. The Tax Court erred in its interpretation of what was presented. Spireas has brought the same facts and the same legal argument before us. In view of his consistent position, I would reverse the opinion of the Tax Court and remand this case with instructions to grant Spireas long-term capital gains treatment of the royalty payments in question.

II.

In light of the above, I submit that consideration of the issue of waiver is not necessary. However, the Majority depends on waiver, and I believe it is helpful to review the errors of the Majority's position on waiver.

"[T]he crucial question regarding waiver is whether [the party] presented the argument with sufficient specificity to alert the [trial] court."³¹ Although the case law does not prescribe a specific list of factors to consider in evaluating waiver, an assessment of waiver must be grounded in the

 $^{^{30}}$ *Id*.

³¹ Keenan, 983 F.2d at 471.

prudential origins of the doctrine. The guiding principle is that parties should have a chance to present all relevant evidence at trial and should "not be surprised on appeal by . . issues upon which they have had no opportunity to introduce evidence." The waiver doctrine is most strictly applied where a party's failure to timely raise the issue below has resulted in an incomplete factual record on appeal. In contrast, "we are less inclined to find a waiver when the parties have had the opportunity to offer all the relevant evidence and when they are not surprised by issues on appeal," and we are "reluctant to apply the waiver doctrine when only an issue of law is raised."

Courts of appeals may exercise discretion in considering issues or arguments not directly raised below.³⁶ Ordinarily, "[f]or an issue to be preserved for appeal, a party 'must unequivocally put its position before the trial court at a point and in a manner that permits the court to consider its

³² Hormel v. Helvering, 312 U.S. 552, 556 (1941).

³³ Shell Petroleum, Inc. v. United States, 182 F.3d 212, 219 (3d Cir. 1999) ("This general rule applies with added force where the timely raising of the issue would have permitted the parties to develop a factual record,' because we cannot know on appeal what evidence the adverse party would have presented or brought out through cross-examination." (quoting Harris v. City of Phila., 35 F.3d 840, 845 (3d Cir. 1994))).

³⁴ *Huber v. Taylor*, 469 F.3d 67, 75 (3d Cir. 2006).

³⁵ *Id*. at 74.

³⁶ See, e.g., Singleton v. Wulff, 428 U.S. 106, 121 (1976); Bagot v. Ashcroft, 398 F.3d 252, 256 (3d Cir. 2005).

merits."³⁷ Waiver is not an absolute bar, however, and must be considered on a case-by-case basis. Even when an issue or argument is otherwise waived, exceptions may apply.³⁸

Our decisions in this area³⁹ reflect the sliding scale that we have applied to questions of waiver. They reinforce the discretion that has always been a part of our waiver analysis in civil cases. Each of our waiver decisions is grounded in the prudential considerations underlying the doctrine: that parties have an opportunity to present all relevant evidence at

³⁷ In re Ins. Brokerage Antitrust Litig., 579 F.3d at 262 (quoting Shell Petroleum, Inc., 182 F.3d at 218).

Hormel, 312 U.S. at 557 ("There may always be exceptional cases or particular circumstances which will prompt a reviewing or appellate court, where injustice might otherwise result, to consider questions of law which were neither pressed nor passed upon by the court or administrative agency below."); *Huber*, 469 F.3d at 74 ("[E]ven if an issue was not raised, '[t]his Court has discretionary power to address issues that have been waived." (quoting *Bagot*, 398 F.3d at 256)).

³⁹ See e.g., Huber 469 F.3d at 75-76 (emphasizing the "prophylactic and prudential origins of the [waiver] doctrine" and holding that a purely legal argument could and should be considered on appeal, even if it had been waived); In re Insurance Brokerage Antitrust Litig., 579 F.3d at 262 (holding the waiver doctrine did not bar consideration on appeal of arguments presented to the District Court in a "conclusory fashion"); Frank, 910 F.2d at 99 (holding an argument to have been waived where its presentation on appeal would "raise important issues of first impression . . . as well as difficult questions of fact").

trial and develop a complete factual record, and that the parties not be surprised by new issues on appeal.

The Majority, much like the Commissioner, rests its analysis almost entirely on *United States v. Joseph*, 40 a case it characterizes as "our seminal precedent" on waiver. 41 Joseph was a *criminal* case, and the question of waiver arose in the narrow context of a motion to suppress evidence, pursuant to Federal Rule of Criminal Procedure 12.42 As such, the Joseph majority expressly noted that it "d[id] not have occasion to consider whether the framework explained here applies in other waiver contexts, such as . . . waiver in civil cases."43 Thus, although *Joseph* remains instructive, particularly with regard to the distinction between issues and arguments, it does not and cannot undermine our prior precedent that civil waiver is a prudential doctrine to be applied in a case-specific manner. Both the majority opinion in *Joseph* itself⁴⁴ and subsequent decisions applying *Joseph* in the civil context reflect this reality. 45 Yet the Majority relies on *Joseph* at the exclusion of our precedent on civil waiver.

⁴⁰ 730 F.3d 336 (3d Cir. 2013).

⁴¹ Maj. Op. at 13.

⁴² See Joseph, 730 F.3d at 338.

⁴³ *Id.* at 339 n.3

⁴⁴ *Id.* (citing *Huber*, 469 F.3d at 74-75).

⁴⁵ See, e.g., Gen. Refractories Co., 855 F.3d at 162 (discussing the waiver standard in *Joseph* and concluding that "even if [Appellant's] argument had not been placed before the District Court, we would nevertheless consider it in reaching our conclusion"). The Majority opinion relies on *In re J&S Properties*, LLC, 872 F.3d 138, 146 (3d Cir. 2017), for the proposition that *Joseph* applies to civil cases. *J&S*

As noted, waiver is a prudential doctrine, not an absolute rule. Its purpose is to provide parties "an opportunity to offer all evidence they believe relevant to the issues" and ensure "that litigants may not be surprised on appeal by final decision there of issues upon which they have had no opportunity to introduce evidence." These justifications inform our approach to the waiver doctrine and explain the flexible approach we have taken across various decisions. In cases that do not present the particular problems the waiver doctrine protects against, we are less likely find that an issue has been waived. This is such a case.

The evidentiary record in this case is fully developed. The relevant documents—primarily the 1998 Agreement and the March 2000 Engagement Letter—have been available to all parties from the outset of this litigation. On appeal, neither Spireas, nor the IRS in response, rely on any evidence not presented to the Tax Court. The substantive question of whether the 1998 Agreement effected a transfer of future rights to Products can be resolved fully based on the current record.

Properties includes only a brief discussion of waiver and a single citation to Joseph, with no substantive analysis of the case or its applicability in the civil context. Other recent cases, such as General Refractories, make clear that Joseph may be instructive in the civil context but does not alter the prudential and fact-specific nature of the civil waiver doctrine.

⁴⁶ *Hormel*, 312 U.S. at 556.

⁴⁷ See Huber, 469 F.3d at 74-75.

⁴⁸ *Id*. at 75.

In addition, the IRS cannot credibly claim to be "surprised" by any of the issues presented on appeal. As Section I demonstrates, Spireas's position regarding the 1998 Agreement was apparent throughout his written submissions to the Tax Court. Furthermore, the Tax Court actually decided the question of what agreement served as the instrument of transfer.⁴⁹ The Tax Court's ruling certainly gave the IRS sufficient notice that the issue might be raised on appeal.

This case presents none of the core problems that the waiver doctrine is designed to protect against. The relevant issues can be decided based on the available record without prejudice to either party. Thus, Spireas has preserved his current argument, and the circumstances of this case weigh against applying the waiver doctrine strictly and in favor of deciding this appeal on the merits.

III.

⁴⁹ See App. at 25-34 (T.C. Op.). The Tax Court, unfortunately, misstated Spireas's position on this issue by relying almost exclusively on the testimony of George Gould. See Id. at 29-30 & n.6 (treating Gould's testimony as Spireas's position regarding the 1998 Agreement and March 2000 Engagement Letter). Spireas's post-trial briefs, however, include no mention of the alternative theory Gould concocted at trial and cite almost exclusively to Gould's expert report rather than his trial testimony. See 2 T.C. 307-44 (Spireas's Post-trial Opening Brief); 2 T.C. 366-422 (Spireas's Post-trial Answering Brief).

For the above reasons, I conclude that the Majority has misinterpreted the facts of record and has erred in concluding that Spireas waived his argument on appeal. I therefore respectfully dissent. The Majority, having found Spireas's argument waived, does not reach the merits of this appeal. Were we to reach the merits, I would conclude that Spireas is entitled to long-term capital gains rate under I.R.C. § 1235 because he received the royalty payments in exchange for all substantial rights to the liquisolid felodipine formulation.