MYLAN'S OPPOSITION TO THE I.R.S. – NO SUBSTANTIAL RIGHTS

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On October 22, 2015, Mylan Inc. ("Mylan") filed its opposition to the I.R.S.'s motion for summary judgment in U.S. Tax Court arguing the transfer of its rights in a blood pressure drug, nebivolol, was a sale that was incorrectly re-characterized as a license by the I.R.S. The salient point of Mylan's opposition is that it sold and did not retain substantial rights in the drug under the 2008 agreement with Forest Laboratories Holdings Limited ("Forest"), and therefore, it properly reported the proceeds as capital gains. Mylan argues the I.R.S.'s summary judgment motion is misguided and must fail because the I.R.S.

- ignores the controlling legal standard by failing to address whether Mylan retained any "substantial rights" following its 2008 agreement with Forest;
- concedes that labels are not determinative, yet seeks to elevate form over substance by relying on labels in the 2008 agreement instead of addressing the reality of what was effectuated through that agreement; and
- focuses on irrelevant facts regarding agreements and administrative proceedings concluded with respect to tax periods that are not before the Tax Court.[1]

BACKGROUND

In the last edition of *Insights*, the article "I.R.S. Argues Mylan's Contract is a License of Drug Rights – Not a Sale"[2] discussed the *Mylan Inc. v. Commissioner* case as addressing the controversy of whether a transfer of exclusive rights to the use of a patent is a sale or a license. As explained in the last article, a sale of patent rights generally occurs for tax purposes when all substantial rights to the property have been relinquished, whereas a license occurs when the company transferring the rights retains a power or significant interest over the property. A sale receives capital gains treatment, which allows the corporation to utilize a capital loss carryback as a means of reducing taxable income. A license generates ordinary income, which cannot be reduced by a capital loss carryback.

At issue is whether Mylan retained any substantial rights in nebivolol after executing its 2008 amendment agreement with Forest. A more elaborate statement of the facts is provided in the previous article, but they may be summarized as follows. Mylan is a generic pharmaceutical company that initially entered into a license contract in 2001 with Janssen Pharmaceutica N.V. ("Janssen"), granting Mylan the exclusive right to use, make, and sell nebivolol and its products within the U.S. and

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1 *Mylan Inc. v. Commr.*, T.C., No. 16145-14, opposition to motion, Oct. 22, 2015, p.1.

2 Christine Long, Andrew Mitchel, and Stanley C. Ruchelman, "I.R.S. Argues Mylan's Contract is a License of Drug Rights – Not a Sale," *Insights* 2, no. 9 (2015).

Canada. Mylan sublicensed its rights in nebivolol to Forest under a 2006 contract in which Forest paid Mylan $75 million and agreed to royalty payments in exchange for the right to develop and commercialize nebivolol in the U.S. and Canada. Under the 2006 agreement, Mylan retained significant rights to nebivolol and reported the payments it received from Forest in 2006 and 2007 as ordinary income. In 2008, the two drug companies executed an amendment to the 2006 contract in which Mylan assigned to Forest all rights to participate in the commercialization of nebivolol. In return for the assignment, Mylan received a one-time cash payment of $370 million and about $50 million of additional royalty payments. However, Mylan retained certain limited rights and obligations in relation to the product and the supplier.

On its 2008 tax return, Mylan characterized the transfer of rights in the nebivolol patent to Forest as an installment sale and reported the payments it received from Forest as capital gains. Under a 2008 amendment, Mylan also reported the payments it received from Forest in 2009 and 2010 as capital gains. Upon examination of its returns, the I.R.S. re-characterized the 2008 contract as a license, not a sale, that generated ordinary income and issued deficiency notices totaling more than $104 million for years 2007 to 2010. Mylan filed two petitions in Tax Court, which have been consolidated into a single proceeding, for a redetermination of the amounts due, asserting that the I.R.S. improperly characterized the 2008 transfer as a license because Mylan had relinquished all substantial rights to nebivolol.[3]

In September, the I.R.S. filed a motion for summary judgment and memorandum in support of its motion arguing the transfer of Mylan's rights in nebivolol to Forest was a license because the 2008 amendment was merely an extension of the 2006 license agreement, not a relinquishment of all substantial rights. The I.R.S. asserted that as a mere amendment to a license that continues to exist, Mylan should report ordinary income. The I.R.S.'s memorandum focuses on labels used in the 2006 and 2008 agreements and contends that no genuine issue of material fact exists and that a decision in its favor should be given by the Tax Court as a matter of law distinguishing between a sale and a license.

MYLAN'S OPPOSITION

Mylan's opposition to the I.R.S.'s summary judgment motion contends that Mylan sold its rights in nebivolol to Forest and properly reported the payments received pursuant to the 2008 agreement as capital gains. Mylan's opposition lays out its arguments as follows:

1. Genuine issues of material fact exist that must be resolved to determine whether the 2008 agreement was a sale or a license.
2. Substance, not labels, controls whether the 2008 agreement resulted in a sale.
3. The all substantial rights doctrine controls whether the transfer of patent interest constitutes a sale or a license for Federal income tax purposes.
4. The parties intended the 2008 agreement to be a sale.[4]

[3] *Mylan Inc. v. Commr.*, T.C., No. 16145-14, petition, Jul. 11, 2014.

[4] *Mylan*, opposition to motion, Table of Contents.

Genuine Issues of Material Fact

Mylan's opposition asserts that the I.R.S.'s motion for summary judgment should be dismissed because there are genuine issues of material fact as to whether the 2008 agreement was a sale or license. Mylan argues the I.R.S.'s motion "paints an incomplete picture," only focuses on labels, fails to address the substance of the transaction, and merely denies that the 2008 agreement was effectively a sale without addressing the controlling legal issues of whether Mylan transferred all substantial rights in nebivolol.[5] Mylan points out that the I.R.S. has not satisfied its burden of proof that no material dispute of fact exists and does not present indisputable evidence of a sale or demonstrate that a decision may be rendered as a matter of law. Mylan also asserts that the I.R.S.'s contentions, at the very least, present genuine issues that should be determined at trial.

Substance Controls, Not Labels

In its opposition, Mylan argues that the I.R.S.'s motion solely relies on the label of the 2008 agreement as a "license" and ignores the controlling legal standard of whether Mylan retained any substantial rights. Although the I.R.S. does acknowledge that labels are not conclusive, it still wrongfully focuses on the agreements' labels in spite of the fact that the Third Circuit and other courts have clearly established that labels are not determinative and "in the patent context, are essentially irrelevant."[6] The case law of the Third Circuit is significant because it would be the venue for an appeal to this case.[7]

Mylan cites numerous cases that support its contention that the substance of a transaction is determinative, not the labels or terminology used.[8] Mylan equates its transfer of rights in nebivolol to other cases where the courts held that the transfer of patent rights was a sale. Mylan points out that the pharmaceutical industry does not rely on the terms "license" and "sale" to determine whether a sale occurred and the industry uses the term "exclusive license" to refer to a sale, which the Third Circuit also recognizes.

The I.R.S.'s motion also asserted that the "Danielson Rule" is applicable to Mylan's case as a matter of contract law because the form of Mylan's agreement is as a license it is not designed as a sale. In *Commr. v. Danielson*,[9] the Third Circuit held that a taxpayer may challenge the tax consequences of its own contract only by introducing evidence that would invalidate the contract itself. However, Mylan's opposition argues that the Danielson Rule is irrelevant because Mylan is not trying to change the terms of the agreement, unlike the sellers in Danielson. Mylan is instead arguing that all substantial rights of value were transferred pursuant to the 2008 agreement and, "to the extent the taxpayer is not arguing to change the terms of the applicable agreement, *Danielson* does not apply."[10]

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5 *Id.*, p. 19.

6 *Id.*

7 *Id.*, p. 2.

8 *Id.*, p. 21.

9 *Commr. v. Danielson*, 378 F.2d 771 (3d Cir. 1967).

10 *Mylan*, opposition to motion, p. 29.

Ultimately, Mylan's opposition emphasizes that patent cases support its argument that the labels and terminology of the 2008 agreement do not control whether it was a sale or license for Federal income tax purposes and the I.R.S.'s motion failed to focus on the substance of the agreement being a relinquishment of all substantial rights in nebivolol.

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All Substantial Rights

The main argument of Mylan's opposition is that, in its 2008 agreement with Forest, Mylan transferred all remaining substantial rights that it originally obtained from Janssen in 2001.[11] The I.R.S.'s motion ignores this fact and ignores the standards of the all substantial rights doctrine, which controls whether the transfer of patent interest constitutes a sale or license for Federal income tax purposes.[12] Mylan's opposition states that the express language of the 2008 agreement directly refutes the I.R.S.'s claim that Mylan retained certain rights. The I.R.S. merely lists various "rights" Mylan retained after the 2008 agreement and does not explain why those rights are significant. Mylan's opposition explains that any rights that were retained were "(i) eliminated by the 2008 Agreement, (ii) made irrelevant during the interim period between the two agreements, or (iii) solely to protect Mylan's role as guarantor to Janssen, and thus, did not constitute substantial rights."[13]

In order to demonstrate that Mylan transferred all substantial rights in nebivolol to Forest, Mylan's opposition includes a chart of the "purported 'right[s]'" and the "status after the 2008 agreement," indicating that Mylan did not have significant rights in nebivolol after the 2008 agreement:

- *The Right to "Supply Compound to Forest"*: After the 2008 agreement, this became a "burden, not a right, as Mylan was required to act as a middle man between Janssen and Forest."
- *The Right to "Review Development and Marketing Materials"*: After the 2008 agreement, "Mylan had no right to vote on or assert any control over any of Forest's decisions with respect to nebivolol."
- *The Right to "'Use' of Nebivolol and Mylan Know-How"*: "Mylan's ability to 'use' nebivolol was transferred to Forest in 2008; [after the 2008 agreement] Mylan had no rights to know-how and Mylan developed no know-how in connection with nebivolol [that was] of any value to Mylan."
- *The Right in "Discounting Restrictions on Forest"*: After the 2008 agreement, the "discounting restrictions did not interfere with Forest's full and exclusive use of the patent rights, and only served to protect Mylan's contingent consideration for the three years following the 2008 Agreement."
- *The "Right to Negotiate with Forest to Be Distributor of Authorized Generic*": After the 2008 agreement, "Mylan's first right to distribute an authorized generic was eliminated, and all that remained was that Forest would offer to negotiate with Mylan if Forest chose not to use its own in-house generic division."

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[11] *Id.*, p. 20.

[12] *Id.*, p. 35.

[13] *Id.*, p. 36.

- *The “Right to Approve Sublicenses to Non-affiliates”*: After the 2008 agreement, “Forest could simply assign rather than sublicense any of its rights to nebivolol if Mylan tried to unreasonably block or delay its consent to a ‘sublicense.’”

- *The “Right to Exploit the Migraine Indication”*: After the 2008 agreement, the “migraine indication was co-exclusive (*i.e.*, Forest had the same option) and placed dosage restrictions on just Mylan that made it economically worthless to Mylan.”

- *The Right to “Commercialization”*: After the 2008 agreement, “Forest had the ‘sole authority and responsibility…for all Commercialization activities’ [as per] 2008 Agreement § 3.1 (Caron Ex. A).”

- *The Rights to “First Option to Launch Authorized Generic,” “Development Decision-making Authority,” “Marketing Decision-making Authority,” “Primary Contact with FDA and Regulatory Strategy Participation,” “Option to Co-promote,” “Participation and Approval Re: Publication Plans and Announcements,” and “Prosecute and Defend Patent Infringement Suits”*: All have all been eliminated in the 2008 agreement.[14]

The Parties Intended a Sale

Mylan’s final argument in its opposition is that the parties intended for the 2008 agreement to be a sale, which is evidenced by the companies’ actions. The opposition points out that both Mylan and Forest made the sale public knowledge, as each party issued press releases indicating Mylan sold its rights to Forest and the parties’ federal securities filings also demonstrate a sale; and Mylan’s intention to sell is further evidenced by the fact that the 2008 agreement included a “large up-front nonrefundable payment and elimination or significant reduction in Mylan’s continued involvement with nebivolol.”[15]

Furthermore, Mylan’s opposition argues that its prior closing agreement with the I.R.S. is irrelevant in determining whether the 2008 agreement constitutes a sale or license. The I.R.S.’s motion contends that Mylan “admitted that the 2006 Contract is a License” and, therefore, the 2008 agreement must be a license as well. However, Mylan argues that the characterization of the 2008 agreement does not depend on the 2006 characterization and that it actually eliminated most of the rights Mylan had in the 2006 agreement.[16] Mylan refers to the Internal Revenue Code and quotes the Commissioner in supporting its argument that closing agreements must have explicitly covered the tax years at issue. Since the closing agreement the I.R.S. refers to in its motion only covers years under the 2006 agreement, it does not apply to the 2008 agreement.[17]

Mylan’s opposition concludes by emphasizing that “in the patent context where the governing precedent is clear – labels do not control and the determinative question is whether a party transfers all of the substantial rights it holds in the patent.”

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[14] *Id.*, p. 53-55.

[15] *Id.*, p. 55.

[16] *Id.*, p. 59.

[17] *Id.*, p. 61.

CONCLUSION

The I.R.S.'s motion for summary judgment will probably be denied. Mylan's opposition thoroughly addresses and counters the I.R.S.'s unsubstantiated arguments, and the I.R.S. has barely addressed whether the rights Mylan retained after the 2008 agreement were substantial. Nonetheless, genuine issues of material fact still remain as to whether the 2008 agreement is a sale or license.

Mylan appears to have met the controlling legal standards of the all substantial rights doctrine and sale versus license determinations in the patent context. Mylan's opposition demonstrates how Mylan transferred all substantial rights in nebivolol to Forest, which should be treated as a sale generating capital gains.

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