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By Colleen Green, Howard Braithwaite and Ed Geils

taxpayers, this generally will mean a Federal income tax rate of 33.95%, 32.90% and 31.85%, respectively, for the years in question, on qualified production activities income. Importantly, the deduction applies also in calculating the alternative minimum tax. There is a limit on the amount of the deduction equal to 50 percent of W-2 wages, and the deduction will not benefit taxpayers that lose money from their production activities or that have an overall loss from all activities



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On December 21, 2005, Congress provided clarification on several technical issues relating to section 199 in the Tax Technical Corrections enacted as part of the Gulf Opportunity Zone Act of 2005 (H.R. 4440). The proposed regulations take into account many of the provisions of the Tax Technical Corrections

### Computation of the QPA Deduction

Computation of the QPA Deduction key issues for industrial manufacturing companies under section 199

#### Domestic Production Gross Receipts (“DPGR”)

Less the sum of:

- Cost of goods sold (“CGS”) allocable to such receipts
- Other deductions directly allocable to such receipts
- A ratable portion of other deductions not directly allocable to such receipts or another class of income

#### Qualified Production Activities Income (“QPAI”)

- Multiplied by 3% (or the rate effective for tax years beginning after 2006)

#### QPA Deduction

The following discussion addresses some of the key issues identified above for the Pharma industry.

### Issue 1: What activities of Pharmas will qualify as “manufactured, produced, grown, or extracted” for purposes of section 199?

#### A. In General

Section 199 defines the term “domestic production gross receipts” to include, inter alia, gross receipts “derived from” any lease, rental, license, sale, exchange or other disposition of qualifying production property which was “manufactured, produced, grown, or extracted” by the taxpayer in whole or “in significant part” within the United States.

With respect to the phrase “manufactured, produced, grown or extracted,” the proposed regulations mirror the Notice in stating that the term includes activities relating to manufacturing, producing, growing, extracting, installing, developing, improving and creating qualifying production property. Like the Notice, eligible activities under the proposed regulations include mak-

ing qualifying production property out of scrap, salvage, or junk material as well as from new or raw material by processing, manipulating, refining or changing the form of an article, or by combining or assembling two or more articles; and certain farming, fishing and mining activities. However, the proposed regulations clarify that installation and assembly activities are considered non-qualifying services unless the taxpayer

(i) has manufactured, produced, grown, or extracted the property being installed and (ii) owns the property during the period the installation or assembly activity occurs.

It should be noted that a Pharma may be considered a manufacturer through the activities of another member of its “expanded affiliated group” (“EAG”). Section 199, the Notice and the proposed regulations make clear that all members of an EAG are treated as a single corporation for purposes of section 199.

Thus, a taxpayer can be treated as performing the activities of a related party that is part of the taxpayer’s EAG, so long as the related party manufactures, produces, grows, or extracts qualifying production property in significant part within the United States. Note, however, that the proposed regulations revise the definition of an EAG set forth in the Notice, which generally is determined under section 1504(a) with certain other changes. Under the proposed regulations, a corporation eligible for the QPA deduction with respect to income of a subsidiary must own more than 50 percent, rather than 50 percent or more, of the subsidiary’s stock by vote and value. The proposed regulations also state that if all of the interests in the capital and profits of a partnership are owned by members of a single EAG at all times during the taxable year of the partnership, then the partnership and all members of that EAG are treated as a single taxpayer for purposes of section 199(c)(4) during that taxable year. As a result of these changes, the proposed regulations exclude 50/50 joint ventures from being treated as a member of an EAG.

## B. The “In Significant Part” Requirement

### i. Facts and Circumstances Test

The proposed regulations confirm that the “in whole or in significant part” requirement modifies both the “by the taxpayer” and the “within the United States” requirements, and make no changes to the operation of the “in significant part” test set forth in the Notice. A taxpayer satisfies the “in significant part” requirement if its manufacturing activities in the United States are “substantial in nature,” based on the facts and circumstances.

Consistent with the Notice, the proposed regulations explain that in determining whether a taxpayer’s manufacturing activities are “substantial in nature,” consideration should be given to several factors, including, but not limited to, the relative value

added by, and relative cost of, the taxpayer’s manufacturing activity in the United States, the nature of the property, and the nature of the manufacturing activity that the taxpayer performs in the United States. To illustrate the “substantial in nature” test, the proposed regulations retain an example in the Notice in which a taxpayer purchases and uses gemstones and precious metal to produce jewelry in the United States. The example concludes that the taxpayer is properly regarded as manufacturing or producing qualifying production property in significant part within the United States even though the value added by the taxpayer’s U.S. manufacturing may not be substantial when compared to the value of the final product because of the relatively high value of the purchased materials. Through additional examples, the proposed regulations indicate that oil refining and automobile assembly activities generally satisfy the “substantial in nature” requirement, while duplication of films onto DVDs is not substantial in nature relative to the DVD with the film.

Certain costs are excluded from the determination of whether the facts and circumstances test is met. For a discussion, see section B.iii., below.

### ii. Safe Harbor Rule

The proposed regulations maintain the safe harbor rule set forth in the Notice under which a taxpayer is considered to satisfy the “in significant part” requirement if the taxpayer’s conversion costs for the property (direct labor and related factory burden) for manufacturing activities in the United States are at least 20% of the total COGS. EAG corporate members and EAG partnerships are subject to special rules in the application of these tests. The proposed regulations do not define the term “related factory burden for purposes of the safe-harbor.

In applying the safe harbor rule, certain costs are excluded. For a discussion, see section B.iii., below.

### iii. Excluded Costs

Similar to the Notice, the proposed regulations disregard research and experimental (“R&E”) activities and costs in determining whether the taxpayer meets the “in significant part” requirement for any tangible personal property. However, the proposed regulations substitute section 174 R&E expenditures in place of “design and development costs” referred to in the Notice. According to the Notice, such activities give rise to the creation of an intangible asset and are not section 199 manufacturing activities. Thus, under the proposed regulations, R&E expenditures under section 174 and the costs of creating intangibles do not qualify as conversion costs for any qualifying production property other than computer software and sound recordings, and such costs are excluded from the numerator or denominator for purposes of computing the safe harbor rule.

Consistent with the Notice, the proposed regulations exclude packaging, repackaging, labeling, and minor assembly activities in determining whether the taxpayer has met the “in significant part” requirement.

#### iv. Shrink Back Requirement

One of the most significant changes made by the proposed regulations relates to the new definition of “item.” Under the proposed regulations, a taxpayer must treat as the “item” any portion of the property offered for sale that meets the requirements of Prop. Reg. §§ 1.199-1 and 1.199-3 if the property offered for sale to customers otherwise does not meet all of the applicable qualifying requirements under section 199. In other words, a taxpayer still has the opportunity to benefit from the QPA deduction if, for example, the taxpayer fails to meet the “in significant part” requirement with respect to the property offered for sale. In such case, if the overall final product does not qualify, but one or more component parts of the product do qualify, the qualifying component(s) must be treated as qualifying property.

An example in the proposed regulations illustrates the application of the shrink back rule with respect to Pharmas. In this example, the taxpayer bulk produces the active ingredient for a pharmaceutical product in the U.S. and sells the active ingredient in bulk form to a foreign corporation, presumably an unrelated party. The foreign corporation uses the active ingredient to produce the drug in finished dosage form and sells the drug in finished dosage back to the taxpayer, which then sells the drug to customers. The proposed regulations conclude that the taxpayer realizes domestic production gross receipts from the first, bulk sale of the active ingredient to the foreign corporation, assuming all the other requirements of Prop. Reg. §§ 1.199-1 and 1.199-3 are met. Furthermore, the taxpayer must treat proceeds from the second sale of the finished dosage form of the drug as domestic production gross receipts, unless the requirements of proposed regulations §1.199-1 and §1.199-3 are not met, in which case the taxpayer must treat the active ingredient portion of the finished dosage form of the drug as the item if the ingredient meets the requirements.

At first glance, this example appears quite favorable to Pharmas. Not only is the taxpayer eligible to receive the section 199 benefit with respect to the first bulk sale of the active ingredient, but the proposed regulations appear to require the taxpayer to recognize additional domestic production gross receipts with respect to the second sale of the finished dosage form of the drug. Indeed, this example confirms that where the entire product does not qualify under section 199, a taxpayer must treat as the item any underlying component manufactured by the taxpayer that does meet the requirements under the proposed regulations. With respect to the second sale, the example in-

dicates that the taxpayer must apply the shrink back rule if it does not meet the in significant part requirement for the finished dosage. In this regard, taxpayers should be aware that to the extent the second sale results in a net loss, the shrink back rule may actually reduce the taxpayer’s QPA deduction. Furthermore, this example demonstrates the detailed level of recordkeeping required in order to comply with the “item-by-item” requirement set forth in the proposed regulations.

#### PwC Observations – General

Because many Pharmas conduct much of their manufacturing outside the United States, they may have difficulty satisfying some of the threshold requirements, in particular, the “in significant part” requirement. However, the shrink-back rule may permit Pharmas to recognize a benefit with respect to any manufacturing operations that do take place in the United States.

To the extent design costs fail to qualify as deductible section 174 costs and must be capitalized under section 263A (obviously not a desired result), such costs arguably should qualify for the “in significant part” test under the proposed regulations.

#### PwC Observations – Pharma Activities

A variety of activities of a Pharma (either directly or indirectly) may constitute qualified production activities.

In general, the production of Pharma products first requires the manufacture of bulk “active Pharma ingredients” (APIs), followed by secondary manufacturing activities such as bulk formulation and “form, fill and finish” operations. The primary manufacturing process of APIs is a capital intensive process requiring extensive research and development. Secondary manufacturing activities typically are more labor intensive and entail full scale re-production of the API and mass production of the drug at high volumes. Form, fill, and finish activities include compressing blended materials to attain certain physical properties; conducting a stability assessment of the final formula; “tableting” the drug into a useable form; and packaging, labeling and storing the final product in accordance with FDA guidelines.

- Regarding the primary manufacturing process, a significant portion, if not all, of the process consists of R&E activities. Because R&E costs are typically the highest costs of a Pharma, they arguably should be allowed to include such costs for purposes of meeting the “substantial in nature” test or the safe harbor rule. Accordingly, Pharmas should consider requesting that the IRS include in the final regulations that R&E activities should be taken into account for purposes of determining whether a Pharma is engaged in qualified production activities.

Regarding the secondary manufacturing activities, the “form, fill, and finish” activities necessary to convert bulk chemicals into an administrable drug seem akin to the gemstone example in the Notice and proposed regulations where a taxpayer that purchases and uses gemstones and precious metals to produce jewelry in the United States, and is considered to satisfy the “substantial in nature” test. Pharmas should request that the IRS include an additional example illustrating the “substantial in nature” test in the final regulations that specifically illustrates its application to pharmaceutical drugs.

Under the Notice and proposed regulations, packaging, repackaging, labeling, and minor assembly operations are not taken into account for purposes of the “in significant part” requirement. In this regard, the IRS could take the position that much of the “form, fill and finish” activities of a Pharma constitute ineligible packaging costs and are excluded in determining whether the taxpayer meets the “in significant part” requirement. Although the transformation of the API into an administrable form such as a tablet would appear to constitute a manufacturing activity, the treatment of packaging and labeling costs of Pharma products is less clear. It might be argued though that the stringent and numerous FDA requirements with respect to the receipt, preparation, identification, storage, handling, sampling, and examination of Pharma products cause such activities to surpass the mere packaging and labeling activities contemplated in the Notice and proposed regulations.

Pharmas should request clarification regarding packaging, repackaging, labeling, and minor assembly operations as it relates to pharmaceutical drugs, and provide examples in which such activities should not be disregarded for purposes of the “substantial in nature” test and safe harbor rule

Even assuming the primary and/or secondary manufacturing activities of a Pharma are qualified production activities, other requirements of the section must be satisfied (i.e., “by the taxpayer,” “within the U.S.”).

## Issue 2. How should contract manufacturing arrangements be treated?

The proposed regulations continue to provide that the “by the taxpayer” language in section 199(c)(4)(A) means that only one taxpayer may claim the QPA deduction with respect to a qualified production activity. Under this rule, if one party manufactures or produces qualifying production property for another party under a contract manufacturing arrangement, only the party that has the benefits and burdens of ownership of the property during the qualified production activity is considered to have “manufactured, produced, grown, or extracted” the prop-

erty for purposes of section 199. If a contractor does not have the benefits and burdens of ownership during the production activity, it is a mere service provider. Conversely, if a contractor does have the benefits and burdens of ownership, it is a manufacturer or producer.

With respect to the benefits and burdens of ownership, the proposed regulations do not supply a list of factors that the IRS believes should be considered in applying the benefits and burdens test. Rather, the proposed regulations simply state that it is a facts and circumstances determination (and title alone is not determinative). Factors to consider may include the right to possession, title, risk of loss or damage, responsibility of economic loss or gain upon sale, direct supervision, and control over the details of the manufacturing process. In addition, the type of contract entered into by the parties (e.g., fixed-price or cost-reimbursable) should be considered. The proposed regulations have specific examples involving different types of contract arrangements.

### PwC Observations

The contract manufacturing position taken in the proposed regulations may hurt certain industries, such as Pharmas, where taxpayers often outsource segments of their manufacturing process to third parties. Unless the taxpayer maintains the benefits and burdens of ownership, it will not satisfy the “by the taxpayer” requirement. The question of what constitutes the benefits and burdens of ownership is subject to dispute and may turn on one of many factors courts have used in making such determinations. Moreover, it may be difficult to apply in practice.

Despite numerous comments suggesting elimination or modification of the benefits and burdens test as well as suggestions for safe harbors to allow the contracting parties to choose who is entitled to the deduction, the Treasury and the IRS have not wavered in its use or provided practical guidance.

## Issue 3. Will royalty income earned from third parties constitute eligible gross receipts?

Pharmas generally realize substantial revenue from royalties on the license of patents and know-how. Under section 199, the definition of domestic production gross receipts includes gross receipts of the taxpayer derived from any lease, rental, license, sale, exchange, or other disposition of “qualifying production property” which was manufactured, produced, grown, or extracted by the taxpayer in whole or in significant part within the United States. (Royalty income from the licensing of qualifying production property to “related persons” is not qualifying gross receipts.) Under section 199(a)(5), the term “qualifying production property” includes tangible personal property, computer software, and sound recordings.

## PwC Observation

- Under well established case law, patent rights are intangible property, not tangible property. See *E. I. du Pont de Nemours & Co. v. U. S.*, 432 F.2d 1052 (3rd Cir. 1970). Accordingly, a traditional royalty for the use of a patent, e.g., for a drug compound, even if developed by the royalty recipient, would not be qualifying domestic production gross receipts because the patent is not qualifying production property (i.e., it is not tangible personal property).

## Issue 4. How should Puerto Rican business operations be treated?

To be eligible for a deduction under section 199, the qualifying production property must be manufactured in whole or in significant part within the “United States” Section 199 does not define the term “United States” Section 7701(a)(9), however, provides that the term “United States” when used in a geographical sense includes only the States and the District of Columbia. Consistent with section 7701(a)(9), the proposed regulations adopt without change the definition of United States set forth in the Notice, which provides that the term “United States” for purposes of section 199 includes only the fifty States and the District of Columbia along with the territorial waters of the United States and the continental shelf adjacent to those waters, but specifically excludes possessions and the territories of the United States or airspace over the United States.<sup>1</sup>

## PwC Observations

It is interesting to note that the production activities of a possessions corporation (section 936) that is a member of a Pharma company’s EAG may be attributed to the Pharma for determining whether the company is engaged in a qualified production activity (under the EAG rules), but not for determining whether the manufacturing activities are considered to be within the United States. As sections 936 and section 30A phase out by the end of 2005, this point has limited duration.

In response to the phase out of section 936 and section 30A, Pharmas have changed, or will change, their classification or structure in Puerto Rico, either by continuing such activities as domestic corporations, liquidating into domestic parent corporations, converting to disregarded entities, or becoming controlled foreign corporations. Under current guidance, however, none of these restructuring alternatives will cause the manufacturing activity of the new entity to be considered to be within the United States for purposes of section 199.

- Pending legislation (S. 1816, S. 1818, and H.R. 4388) would extend the application of section 199 to activities conducted in Puerto Rico or to possessions of the United States including

Puerto Rico. At this time, it is uncertain whether any such legislation ultimately will be enacted.

## Issue 5. Will some Pharmas have difficulty meeting the “actual conduct of a trade or business” requirement?

Section 199 applies by only taking into account items which are attributable to the “actual conduct of a trade or business.” (Emphasis added). Neither section 199 nor its legislative history defines the phrase “actual conduct of a trade or business.” Further, no other section of the Code defines the phrase. The proposed regulations simply state that Prop. Reg. § 1.199-3, which provides rules regarding domestic production gross receipts, is applied by taking into account only items that are attributable to the actual conduct of a trade or business. Thus, the Treasury and the IRS appear to view the “actual conduct of a trade or business” requirement as relevant only in the identification of domestic production gross receipts. Thus, for example, the computation of the wage limitation under Prop. Reg. § 1.199-2 potentially could include wages not attributable to the actual conduct of business.

With regard to the phrase “trade or business” for purposes of section 162(a), the Supreme Court observed:

The phrase “trade or business” has been in § 162(a) and in that section’s predecessors for many years. Indeed, the phrase is common in the Code, for it appears in over 50 sections and 800 subsections and in hundreds of places in proposed and final income tax regulations. The slightly longer phrases, “carrying on a trade or business” and “engaging in a trade or business,” themselves are used no less than 60 times in the Code. The concept thus has a well-known and almost constant presence on our tax-law terrain. Despite this, the Code has never contained a definition of the words “trade or business” for general application, and no regulation has been issued expounding its meaning for all purposes. Neither has a broadly applicable authoritative judicial definition emerged. Our task in this case is to ascertain the meaning of the phrase as it appears in the sections of the Code with which we are here concerned.

### **Commissioner v. Groetzinger, 480 U.S. 23, 26 (1987).**

Not only is the phrase “trade or business” used throughout the Code, but varying standards of the phrase apply depending on the section of the Code under consideration. Compare, for example, section 162, “carrying on a trade or business,” with section 174, “in connection with his trade or business.” See *Snow v. Commissioner*, 416 U.S. 500, 503 (1974). With regard to section 174, and the phrase “in connection with his trade or business,” the Tax Court stated:

Although the Supreme Court established in *Snow* that the taxpayer need not currently be producing or selling any product in order to obtain a deduction for research expenses, it did not eliminate the ‘trade or business’ requirement of section 174 altogether. For section 174 to apply, the taxpayer must still be engaged in a trade or business AT SOME TIME, and we must still determine, through an examination of the facts of each case, whether the taxpayer’s activities in connection with a product are sufficiently substantial and regular to constitute a trade or business for purposes of such section.

**Green v. Commissioner, 83 T.C. 667, 686-687 (1984).**

Similarly, in a key decision under section 936, a court concluded after much analysis of the phrase that a taxpayer “actively conducts a trade or business” if it participates regularly, continually, extensively, and actively in the management and operation of its profit-motivated activity. *Medchem (P.R.), Inc. v. Commissioner*, 116 T.C. 308, 336 (2001), *aff’d* 295 F.3d 118 (2002).

Given the lack of statutory definition regarding the phrase “actual conduct of a trade or business” for purposes of section 199, the scope of this limitation is unclear. The term “actual” as used in section 199 is not the same as the term “active” used elsewhere. Thus, it cannot be determined with any degree of certainty whether the two terms will be interpreted similarly by the IRS.

The proposed regulations do not provide any guidance explaining how taxpayers might meet or violate this statutory requirement.

**PwC Observation**

- Venture based Pharmas organized as partnerships and Pharmas engaged in early stage research arguably may have difficulty meeting the “actual conduct of a trade or business” requirement.

**Issue 6. As a practical matter, to what extent will a non-diversified large Pharma benefit from section 199?**

Under section 199, a taxpayer’s qualified production activity income cannot exceed its taxable income. Taxable income for this purpose is defined by section 63, i.e., after a net operating loss carryovers and carrybacks. Accordingly, taxable income effectively limits the extent to which a taxpayer may benefit from a deduction under section 199.

**PwC Observation**

- Transfer pricing strategies may limit the extent to which a Pharma may benefit from a deduction under section 199 due

to the taxable income limitation.” A Pharma is not likely to modify its transfer pricing strategies simply to maximize the benefit under section 199 because to do so would require that taxable income be increased at a tax cost of upwards of 32% — 34%. The tax cost obviously exceeds the benefits under section 199 (effective reduction in the tax rate of 1% — 3%). Thus, it likely will not make sense to engage in strategies that will result in an overall higher U.S. tax. With that said, to the extent a Pharma has taxable income taking into account its transfer pricing strategy, it should work within that strategy to maximize its qualified production activities income.

**Pharmas need to participate in guidance process**

With final regulations expected in the near future, the Pharmas should consider marshalling their forces to argue for fair and appropriate treatment. For example, Pharmas should request clarification on the following key issues:

- R&E activities should be included in determining whether a Pharma company has engaged in qualified production activities.
- Packaging, repackaging, labeling, and minor assembly operations that are subject to stringent FDA requirements should not be disregarded for purposes of the “substantial in nature” test and safe harbor rule.
- Guidance should be requested to address the meaning of the phrase “actual conduct of a trade or business.”

**Reference**

1 The legislative history to section 199 would appear to support the position taken in the Notice. In the Senate report, “domestic production gross receipts” included gross receipts “derived in the actual conduct of a trade or business from any sale, exchange or other disposition, or any lease, rental or license, of qualifying production property that was manufactured, produced, grown or extracted (in whole or in significant part) by the taxpayer within the United States or any possession of the United States” (emphasis added). The Conference Committee Report which did not per se adopt the Senate Report did not include the “any possession of the United States” language.

2 For 2005, a Pharma may have taxable income as a result of repatriation of income under the Homeland Investment Act. However, tax planners should be aware that the creation of taxable income in that manner will not create qualified production activities income.

For more information about this whitepaper, or the proposed regulations under section 199, please contact one of the following principal authors:

- Colleen Green (202-414-1382)
- Howard Braithwaite (202-414-4443)
- Ed Geils (202-414-1326)

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