Valuing the Residual Intellectual Property in Mature Pharmaceutical Products

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I. INTRODUCTION

A mature pioneer pharmaceutical product is one for which the primary exclusivity covering the product has expired. That is, sellers of generic or follow-on versions of the product are able to obtain regulatory approval to sell bioequivalent products commercially. Even at the mature stage in the life cycle of the pioneer product, various forms of residual or secondary intellectual property are embodied in the product (“residual intellectual property”).

There are various commercial reasons for valuing the residual intellectual property including licensing, litigation, and tax considerations. For this paper, I focus on valuing the residual intellectual property to comply with tax regulations governing transactions between affiliates of a multinational company located in different countries (“controlled transactions”). The company risks tax authorities assessing penalties for inaccurate values. Consider controlled transactions for a multinational research-based pharmaceutical company (“Company”) in which its US affiliate (“Affiliate”) owns the relevant intellectual property and its international affiliate (“International”), the aggregated entity consisting of all the Company’s entities involved with sales of mature products other than the Affiliate, manufactures the mature product outside of the US and sells it in countries throughout the world (“relevant controlled transactions”). To report revenues and costs accurately from the US and foreign operations in the individual countries, International

* Independent Consultant in Alexandria, Virginia, USA. This paper is based on my study of economic issues in the pharmaceutical industry for over 30 years. In general, my research has been supported by individual research-based pharmaceutical companies or organisations representing groups of such companies. Economists at NERA Economic Consulting in Washington, DC provided background support for sections of this paper. Of course, the conclusions are my own and do not necessarily reflect opinions of current or former staff at NERA Economic Consulting.

1 Primary forms of exclusivity could include composition of matter patents or other forms of exclusivity such as provided, for example, by a Cooperative Research and Development Agreement (“CRADA”) in the US CRADAs exist to encourage commercial development of technologies created through government funded research and development (“R&D”) programs. Primary forms of exclusivity effectively exclude any other company from selling a version of the product.

2 My conclusions on value apply to controlled transactions where the relevant intellectual property is owned by an Affiliate located outside the US as well. A payment for the intellectual property is made to the non-US Affiliate. The owner of the intellectual property does not have the capability to manufacture, market, or distribute the product.

3 Affiliate owns the residual intellectual property and International represents the aggregation of all other entities performing other functions.
requires a licence at an arm’s length price from Affiliate to use the residual intellectual property.

My analysis follows the *Internal Revenue Service Final Section 482 Regulations (TD 8552) for Intercompany Transfer Pricing*, issued 1 July 1994 (“Section 482 regulations”).

The governing principle for valuing both tangible and intellectual property in the Section 482 regulations is the arm’s length standard; that is, the result that would have been realised had uncontrolled entities engaged in the same transaction under the same circumstances as in the controlled transaction.

To determine the arm’s length consideration due to the Affiliate for relevant intellectual property, it is most helpful to review internal Company documents and publicly available information. Licence agreements negotiated between the Company and third parties are usually the most reliable and complete data available for determining arm’s length prices (eg, royalty rates). The Company’s agreements with third parties should be separated into three types of relevant intellectual property:

- trademarks or trade names (“trademarks”);
- intellectual property that was not a composition of matter patent (eg, process, method, or formulation patents; know-how; or technical information) (“non-composition of matter patent intellectual property”); and
- intellectual property related to generic products or embodied in products that are not covered by a valid patent claim in a given territory (“intellectual property related to generics or with no valid claim”).

Statistical tests such as Comparison-of-Means Tests should be applied to the pricing terms for the intellectual property in these various agreements.

The Company’s own behaviour in the marketplace for intellectual property generally represents the best data for measuring arm’s length prices. The comparable uncontrolled transaction (“CUT”) method as described in the Section 482 regulations is the best method for assessing the transfer of the relevant intellectual property. Applying the CUT method to determine ranges for the arm’s length transfer royalty rate yields:

- one range for trademark royalty rates; and
- another range for all other types of relevant intellectual property (ie, non-composition of matter intellectual property and intellectual property related to generics or with no valid claim).

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5 Reg. Sec. 1.482-1(b)(1).

6 The internal data should include agreements negotiated by the company including negotiated by any entities the company acquired over time.

7 “Intangible property related to generics or with no valid claim” only includes royalties in which an agreement does not explicitly state the type of intellectual property covered. Any agreement which explicitly states a specific type of intellectual property that is related to generics or has no valid patent claim are categorised as non-composition of matter intellectual property.
Depending on the type(s) of relevant intellectual property embodied in a specific mature product, royalty rates in these ranges may be applied to determine an overall royalty rate to apply to International’s Net Sales\textsuperscript{8} of the mature product. If a controlled transaction includes the transfer of both a trademark and another form of relevant intellectual property the arm’s length royalty rate range is additive.\textsuperscript{9}

Tax authorities do not accept central tendencies from general industry data as a reliable basis for assessing arm’s length prices. However, it is often helpful to compare the results obtained from the Company’s own behaviour with third parties in the marketplace for intellectual property with results of studies in the licensing literature on central tendencies for similar types of transfers in the pharmaceutical and chemical industries.

The remainder of this paper is organised as follows:

— Section II provides background information on the Company in the research-based pharmaceutical industry and the importance of intellectual property in the industry;

— Section III describes the pricing methods for intellectual property in the Section 482 regulations, discusses the best data, and explains the basis for concluding that the CUT method is the best method given the available data;

— Section IV discusses the statistical analysis of the best data and the application of the CUT method to determine the value of the residual intellectual property;

— Section V addresses royalty rates in the licensing literature;

— Section VI summarises the conclusions.

II. BACKGROUND

1. Company’s worldwide activities

The Company is a research-based, global pharmaceutical company focused on discovering, developing, manufacturing, marketing, and selling large and small molecule pharmaceutical products. The Company discovers and develops innovative products through research conducted at various other locations around the world. The Company either identifies molecules at its own R&D facilities or licenses molecules for further development from third parties. During the development process, the Company evaluates the commercial or financial opportunity for a potential product and decides whether to continue development of the associated molecule.

If a molecule progresses through the development cycle, the company applies to a regulatory agency such as the US Food and Drug Administration (‘‘FDA’’) or the European Medicines Agency for approval to market the product in a country or region.

\textsuperscript{8} Net Sales represent the total amount received by International upon the sale of finished products to third parties, reduced by sales returns and allowances, including trade, quantity and cash discounts and any other adjustments, including price adjustments, billing errors, rejected goods, damaged goods, recalls, returns, rebates, chargeback rebates, fees, reimbursements or similar payments granted or given to wholesalers or other distributors, or buying groups.

\textsuperscript{9} The arm’s length royalty rate for relevant intellectual property other than trademark should be applied only once and covers all relevant intellectual property other than the trademark.
When necessary, the Company undertakes planning for associated manufacturing and marketing activities. The Company manufactures bulk material and finished pharmaceutical products at plants throughout the world.

Prior to the date of expiration of the primary composition of matter patent (or other primary form of exclusivity), the Company develops plans to compete with potential generic versions of the product from new entrants who intend to enter the market upon the pioneer product’s loss of exclusivity. These plans may involve continuing to sell the brand version of the pioneer product and/or launching an authorised generic version of the brand product, or exiting from the marketplace altogether.

2. Pharmaceutical patent process

Title 35 of the US Code, known as the Patent Act, allows innovators to obtain patents on processes, machines, manufactures, and compositions of matter that are useful, novel, and non-obvious. To receive a patent, an inventor must file a patent application including a specification about the invention that is sufficiently detailed. The patent application must also contain distinct, definite claims that set out the proprietary interest asserted by the inventor and establish no prior art. If the US Patent and Trademark Office (“PTO”) determines that the application fulfils these requirements, it will grant a patent. Granted patents give the patentee the right to exclude others from making, using, selling, offering to sell, or importing into the US the patented invention. Parties who engage in those acts without the permission of the patent holder during the term of the patent can be held liable for infringement. Although issued patents enjoy a presumption of validity, accused infringers may assert that the patent is invalid or unenforceable for a variety of reasons.

Patent protection in the US lasts for 20 years from the date the application is filed. This period of exclusivity allows innovators or their assignees (including research based pharmaceutical companies) to recover the costs of investing in risky R&D. In most industries, a patent filing is delayed until the associated product is ready for commercial sale. In the pharmaceutical industry, a company will often begin the patent process for a unique, novel, and non-obvious technology while the underlying pharmaceutical product is still in development. The patent application is typically filed at the PTO before clinical trials are completed. Given the separate regulatory approval process for a

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10 Chapter 10. Patentability of Inventions, U.S. Code Browse Title 35 – Patents, GPO Access, United States Code, last updated 23 December 2008, <frwebgate.access.gpo.gov/cgi-bin/usccgi?ACTION=BROWSE&title=35us&>. Other forms of exclusivity may such as CRADAs may be available to pharmaceutical companies.


pharmaceutical product, the window of time that a pharmaceutical product may be legally distributed for commercial sale prior to patent expiration (and potential generic entry) is typically much shorter than the statutory patent term. After the composition of matter patent for a pioneer pharmaceutical product expires, other companies may obtain regulatory approval to commercialise a generic version of the product assuming they can document the bioequivalence of the generic product to the originator’s product without infringing any other patents the innovator lists in the Orange Book as covering the pioneer product that are still in effect.

3. Relevant intellectual property

Brand versions of pioneer pharmaceutical products are rarely protected by a single form of exclusivity on the underlying active ingredient (e.g., composition of matter patent), but instead are covered by multiple patents. These other secondary patents cover innovative aspects associated with a product such as coating technologies, formulation technologies, or methods of use. Although secondary patents usually do not provide the same degree of protection as the primary form of exclusivity, they are often filed after the composition of matter patents. They will have patent terms that extend beyond the patent term for the composition of matter patent. As a result, they can provide some additional protection for the brand product. In effect, a secondary patent potentially extends the commercial life of the brand product by making it more difficult for generic companies to obtain regulatory approval to commercialise a generic.

In some cases, the innovator of the brand product develops product specific know-how, trade secrets, or technical information on identifying sources of supply for active pharmaceutical ingredients used in the product, manufacturing techniques associated with scaling a manufacturing process to commercial quantities, uses of the product in certain patient populations, or other factors associated with the product that may not be available publicly. This form of intellectual property evolves from the efforts that the innovator expended in developing the pharmaceutical product. Even though an innovator does not always obtain a patent, the intellectual property in the form of a trade secret provides advantages to the innovator after the primary exclusivity has expired. The innovator should receive a consideration for developing this intellectual property.

After the primary exclusivity for a brand version of the pioneer pharmaceutical product expires and a generic pharmaceutical launches its product, the brand

18 For a complete description of the generic drug requirements in the US see “Greater Access to Generic Drugs” FDA, <www.fda.gov/drugs/resourcesforyou/consumers/ucm143545.htm>. This description applies to small molecule pharmaceutical products. US and foreign regulatory authorities are publishing standards for approving biosimilar versions of large molecule pharmaceutical products.
pharmaceutical product may still be prescribed by physicians and preferred by patients due to their familiarity with the product and the perceived reliability that comes with the first-hand knowledge of the brand pharmaceutical product and the performance over years of being prescribed, dispensed, reimbursed, and consumed. In such instances, the associated trademark provides some value because the familiarity and knowledge it conveys contribute to continued usage and sales. For these reasons, trademarks are secondary forms of intellectual property that still retain value after the primary form of exclusivity expires. The owner of the trademarks is due a consideration.\textsuperscript{21}

Generally, it is possible to identify several common types of secondary intellectual property from licensor agreements internal to the Company and in the public domain. These include, but are not limited to know-how, trademarks, trade names, technology, processes, systems, techniques, technical information, methods, technical assistance, formulations, designs, information, data, and intermediate patents. I refer to these types of intellectual property as residual intellectual property. Given the diverse nature of these types of intellectual property, I placed them into three general categories:

- trademarks, including trademarks, trade names, and copyrights, which are defined by the PTO as a “word, name, symbol, or device that is used in trade with goods to indicate the source of the goods and to distinguish them from the goods of others”;\textsuperscript{22}

- non-composition of matter intellectual property including know-how, technology, systems, processes, formulations, designs, information, data, technical information, technical assistance, trade secrets, and methods; and

- intellectual property associated with pharmaceutical products sold in countries without patent protection and for generic pharmaceutical products, which I refer to as intellectual property related to generics or with no valid claim.\textsuperscript{23}

Generally, the second category includes all information that represents the accumulated knowledge, skills, and experiences that could assist in the manufacture of a product and confer competitive advantages.

### III. IDENTIFYING THE BEST METHOD

In this section, I describe the methods for valuing intellectual or intangible property identified in the Section 482 regulations. I discuss the data I reviewed and explain the basis for my conclusion that the CUT method is the best method.

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\textsuperscript{22} “General Information Concerning Patents”, PTO, last modified 10 November 2011, \<www.uspto.gov/patents/resources/general_info_concerning_patents.jsp>.

\textsuperscript{23} I identified instances where arm’s length compensation is paid to the intellectual property owner although the underlying product is not protected by primary exclusivity.
1. The Section 482 regulations – intellectual property

The Section 482 regulations specify the following methods for determining the arm’s length result for the transfer of intellectual property:

— CUT method;

— comparable profits method (“CPM”); and

— comparable and residual profit split methods.

The regulations also permit the use of unspecified methods.

There is no preferred method among those specified. Rather, whether the result of a controlled transaction constitutes an arm’s length result must be evaluated using a method or methods selected under the “best method rule”. The best method is determined based on the facts and circumstances of the controlled transaction including the degree of comparability between the controlled and uncontrolled transactions, the completeness and accuracy of the underlying data, the reliability of the assumptions, the sensitivity of the results to deficiencies in the data and assumptions, and the confirmation of the results by another method.

a. Comparable uncontrolled transaction method

The CUT method “evaluates whether the amount charged for a controlled transfer of intangible property was arm’s length by reference to the amount charged in a comparable uncontrolled transaction”. To be considered comparable under the CUT method, the intellectual property involved in the controlled and uncontrolled transactions must be used in connection with similar products or processes within the same general industry and must demonstrate similar profit potential. Profit potential is most reliably measured by calculating the net present value (“NPV”) of the benefits to be realised as a result of the transfer. The circumstances of the controlled and uncontrolled transactions must be comparable.

b. Comparable profits method

The second method specified in the Section 482 regulations is the CPM, which establishes arm’s length operating profits by reference to the profitability of comparable third parties engaged in similar business activities under similar circumstances. Under this method, an appropriate profit level indicator is calculated from comparable companies’ data and applied to the tested party. The reliability of the method depends on the degree of comparability between the tested party and the uncontrolled parties.

24 Reg. Sec. 1.482-1(c).
25 Reg. Sec. 1.482-1(c)(2).
26 Reg. Sec. 1.482-4(c)(1).
30 Reg. Sec. 1.482-5(a) and Reg. Sec. 1.482-5(b)(1).
31 Reg. Sec. 1.482-5(b)(4) defines specific profit level indicators as the rate of return on capital employed, financial ratios such as the ratio of operating profits to sales or the ratio of gross profit to operating expenses, and other profit level indicators.
32 Reg. Sec. 1.482-5(b)(2)(i) defines the tested party as the participant in the controlled transaction for which the most reliable data are available and for which reliable data regarding uncontrolled comparables can be located.
c. Profit split methods

The Section 482 regulations also allow a profit split approach, which takes the form of either a comparable profit split method (“CPSM”) or a residual profit split method (“RPSM”).

i. Comparable Profit Split Method. The CPSM may be applied when reliable income and cost data exist for uncontrolled companies comparable to the controlled party in the relevant business activity. Factors that could affect prices or profits must be evaluated in establishing the comparability of transactions under the CPSM. These factors are: functions performed, contractual terms, risks assumed, economic conditions, and property or services transferred. Once comparable uncontrolled transactions are identified, an arm’s length result is determined by applying the relevant profit split for the uncontrolled transactions to the combined operating profits of the controlled transaction.

ii. Residual Profit Split Method. The RPSM uses a two-step approach to determine an arm’s length allocation of operating profits or losses for both routine contributions and non-routine intellectual property. First, RPSM requires an allocation of “operating income to each party to the controlled transactions to provide a market return for its routine contributions to the relevant business activity”. Second, the RPSM requires that the resulting residual profits attributable to non-routine intellectual property be allocated among the controlled parties based upon the relative value of contributions of non-routine intellectual property to the overall enterprise.

d. Unspecified methods

If an unspecified method provides a more reliable arm’s length result under the best method rule than any of the three specified methods, it should be applied to determine the true taxable income of a controlled party. The unspecified method must meet the same comparability and quality of data standards discussed with regard to the specified methods.

33 Reg. Sec. 1.482-6(a) and Reg. Sec. 1.482-6(c)(1).
34 According to Reg. Sec. 1.482-6(a), a controlled party’s operating profits should be derived from the most narrowly identifiable business activity for which data are available that includes the controlled transaction.
35 Reg. Sec. 1.482-6(b).
36 Reg. Sec. 1.482-6(c)(2).
37 Reg. Sec. 1.482-1(d)(1).
38 Reg. Sec. 1.482-6(c)(3)(ii)(A).
39 Reg. Sec. 1.482-6(c)(3)(ii)(B).
40 Reg. Sec. 1.482-4(d)(1).
2. Data available

Selecting among the methods described above to determine the best method to apply to a controlled transaction depends on the data available. To identify comparable uncontrolled transactions that transferred relevant intellectual property in the pharmaceutical industry, I suggest searching the following sources:

— internal company files;
— Windhover’s *Pharmaceutical Strategic Alliances®*;
— *RoyaltySource®*;
— *RoyaltyStat®*;
— *Compact Disclosure*; and
— *Edgar® Online*.

In searching these sources, focus on identifying arm’s length licence agreements or uncontrolled transactions with royalty rates expressed as a percentage of sales paid to the innovator or patent owner for exclusive rights to relevant intellectual property; that is, trademarks, non-composition of matter patent intellectual property, and/or intellectual property related to generics or with no valid claim. These data are the best data for the transfer pricing analysis of the relevant controlled transactions.

3. The best method

The CUT method is the best method for determining the arm’s length consideration due Affiliate given the available data. The comparability factors for the CUT include: functions performed, contractual terms, risks assumed, economic conditions, and property or services transferred.41

a. CUT method

To apply the CUT method, the Section 482 regulations require that I identify uncontrolled transactions that are comparable to the controlled transaction based on the nature of the intellectual property, profit potential, and circumstances.42 The uncontrolled transactions I identified involve the transfer of intellectual property for pharmaceutical products, specifying the consideration due to the licensor during the late stages of the products’ lifecycles. The potential profits for pharmaceutical products are often similar once the primary patents covering the products have expired and generic versions of these products have been approved.43 The Company’s agreements for the transfer of intellectual property embodied in mature pharmaceutical products are the

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41 Reg. Sec. 1.482-1(d)(1).
42 “In order for the intangible property involved in an uncontrolled transaction to be considered comparable to the intangible property involved in the controlled transaction, both intangibles must – (i) be used in connection with similar products or processes within the same general industry or market; and (ii) have similar profit potential.” Reg. Sec. 1.482-4(c)(2)(iii)(B)(1).
most complete and accurate data available for determining the arm’s length royalty rates for the intellectual property embodied in a product at a mature stage. Given these data, the CUT method is the best method under the Section 482 regulations. In cases where the profit potential of a mature product is extraordinarily high or low or the circumstances surrounding the product are unique, a subset of the best data may be most appropriate. The data I identified and the CUT method are the best data and best method, respectively.

b. CPM

The CPM “evaluates whether the amount charged in a controlled transaction is arm’s length based on objective measures of profitability (profit level indicators) derived from uncontrolled taxpayers that engage in similar business activities under similar circumstances”.\(^\text{44}\) Whereas the CUT method relies on the results from comparable transactions between unrelated parties, the CPM is based on the profitability of uncontrolled companies that engage in similar business activities under similar circumstances.\(^\text{45}\) Given that applying the CPM involves using profitability measures based on the operating profits of uncontrolled companies, the reliability of CPM as an arm’s length measure may be reduced by factors such as varying cost structures, differences in business experience, or differences in management efficiency.\(^\text{46}\) The data underlying a CPM analysis are not as reliable as the data used in a CUT analysis.

In addition, the Section 482 regulations require adjustments to the uncontrolled companies’ operating profits for any such differences.\(^\text{47}\) In general, the tested party for a CPM analysis is “the least complex of the controlled taxpayers and will not own valuable intangible property or unique assets that distinguish it from potential uncontrolled comparables”.\(^\text{48}\) The complex nature of the parties involved in the Company’s intercompany transactions and the other third party uncontrolled transactions I identified would likely require that adjustments be made to the operating profits of the uncontrolled companies. Since the reliability of any method is reduced as the number of adjustments increases,\(^\text{49}\) the CPM analysis would not be as reliable as the CUT method in this case.

c. Profit split methods

i. CPSM. The CPSM may be applied when there exist reliable income and cost data for uncontrolled companies with similar transactions, activities, and operating profits to those exhibited by the controlled taxpayer in the relevant business activity.\(^\text{50}\) Factors that could affect prices or profits must be evaluated in establishing the comparability of transactions under the CPSM. These factors are: functions performed, contractual terms, risks assumed, economic conditions, and property or services transferred.\(^\text{51}\)

\(^{44}\) Reg. Sec. 1.482-5(a).
\(^{45}\) Reg. Sec. 1.482-5(a).
\(^{46}\) Reg. Sec. 1.482-5(c)(2)(iii).
\(^{47}\) Reg. Sec. 1.482-5(c)(2)(iv).
\(^{48}\) Reg. Sec. 1.482-5(b)(2)(i).
\(^{49}\) Reg. Sec. 1.482-1(c)(2)(i).
\(^{50}\) Reg. Sec. 1.482-6(c)(2).
\(^{51}\) Reg. Sec. 1.482-1(d)(1).
Once comparable uncontrolled transactions are identified, an arm’s length result is determined by applying the relevant profit split for the uncontrolled transactions to the combined operating profits of the controlled transaction. Given that revenue and expense data related to the uncontrolled transactions were not available, the CPSM is not the best method in this case.

**ii. RPSM.** The first step in an RPSM analysis is to determine the appropriate market returns for routine contributions to relevant business functions by comparing the returns to an uncontrolled company.\(^{52}\) This step is subject to the same data and comparability considerations as those involved in a CPM analysis. These data and comparability considerations make CPM less reliable than the CUT method. Since the same difficulty exists for the RPSM, it is also less reliable than the CUT method. The second step in the RPSM is to determine the amount of residual profits attributable to each of the controlled parties based on the relative value of non-routine intellectual property contributed by each party to the overall enterprise.\(^ {53}\) This step does not rely on uncontrolled benchmarks. Under the best method rule, “data based on the results of transactions between unrelated parties provides the most objective basis for determining whether the results of a controlled transaction are arm’s length”.\(^ {54}\) Given that I have identified reliable uncontrolled transactions, the RPSM is not the best method available for determining the arm’s length result in this case.\(^ {55}\)

d. Unspecified methods

Even though an unspecified method may be applied, the CUT method provides reliable and accurate results in this case given the available data. It is unnecessary to employ an unspecified method in this case.

**IV. APPLYING THE BEST DATA AND BEST METHOD**

1. **Statistical analysis of the best data**

   **a. Descriptive statistics**

   Descriptive statistics based on the midpoint royalty rate for each of the observations of the Company’s agreements with third parties are usually helpful.\(^ {56}\) The range of royalty rates from the observations and the interquartile range of royalty rates are relevant. Prepare a histogram with the distribution of royalty rates in the database, which illustrates royalty rates for the relevant intellectual property. Change in the value of the relevant intellectual property over time is sometimes raised by tax authorities. To anticipate this question, construct a plot of the data by the year of the agreement with the

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\(^{52}\text{Reg. Sec. 1.482-6(c)(3)(i)(A).}\)

\(^{53}\text{Reg. Sec. 1.482-6(c)(3)(i)(B).}\)

\(^{54}\text{Reg. Sec. 1.482-1(c)(2).}\)

\(^{55}\text{See Example 8 (iii) in Reg. Sec. 1.482-8.}\)

\(^{56}\text{Midpoint royalty rates were calculated as the average of the upper and lower bounds when a range of royalty rates was given in a particular agreement.}\)
associated trend line. In my experience, there does not appear to be a trend between royalty rates and time.

There are three main types of intellectual property embodied in mature pharmaceutical products:

— trademarks;
— non-composition of matter patent intellectual property; and
— intellectual property related to generics or with no valid claim.

Separate the observations of royalty rates applied to sales for exclusive rights to these categories of relevant intellectual property and provide the descriptive statistics for each category.

b. Comparison-of-means

Investigate whether the differences in the mean royalty rates for certain subsets of relevant intellectual property are statistically different from each other. The variables to investigate included licensor and licensee type (e.g., company, university, individual), source of the data, type of intellectual property, territory, as well as whether the agreement contained supply provisions,\(^57\) separate compensation terms for a composition of matter patent(s),\(^58\) or additional forms of compensation (e.g., upfront payment or milestone payments).\(^59\) Apply the Comparison-of-Means test to determine whether the royalty rates\(^60\) for the rights to relevant intellectual property were significantly impacted by these variables.\(^61\) Based on the results of these analyses, determine whether the variables I considered were statistically insignificant.

Given that patents are distinct from trademarks from both legal and economic perspectives, it may be possible to test whether royalty rates for non-composition of matter patents and royalty rates for intellectual property related to generics or with no valid claim differ from the royalty rates in the database for trademarks. The null hypothesis is that there is no difference in the means of the royalty rates for residual patents and royalty rates for trademarks. Construct a regression model with two dummy variables, one for intellectual property in the residual patent agreements and one for trademarks. For the first dummy variable, assign a “1” to each observation containing royalties for rights to intellectual property for non-composition of matter patent intellectual property or royalty rates for intellectual property related to generics or with

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57 This category includes agreements stating that the licensor is responsible for functions related to manufacturing or supply, but the compensation is detailed in a separate arm’s length agreement(s). Agreements that outline compensation for relevant intellectual property as well as manufacturing or supply were not included in my sample given that the compensation could not be reliably segmented by function.

58 This category includes agreements that segment the intellectual property licensed and specific separate royalty rates for relevant intellectual property and the composition of matter patent(s). Agreements that do not segment compensation for relevant and non-relevant intellectual property were not included in my sample given that compensation could not be reliably segmented by type relevant and non-relevant intellectual property.

59 Agreements that are royalty-free, but include other forms of compensation were excluded from my sample given that I did not have sufficient information to calculate effective royalty rates.

60 When a range of royalty rates was given, I relied upon the midpoint royalty rate.

no valid claim and a “0” for each of the remaining observations. For the second dummy variable, assign a “1” to each observation containing royalties for exclusive rights to a trademark and a “0” for each of the remaining observations. Perform Ordinary Least Squares ("OLS") regression analysis using a multivariate linear regression model where the dependent variable is the royalty rate and the independent variables are the dummy variables.\textsuperscript{62} The equation is:

\[ Y = \beta + \alpha_i x_i + \alpha_{ii} x_{ii} + \epsilon \]

where

- \( Y \) equals Royalty Rate;
- \( \beta \) equals the constant term;
- \( \alpha \) equals the slope parameter for the associated \( x \) variable;
- \( x_i \) equals the dummy variable related to intellectual property for non-composition of matter patent intellectual property or royalty rates for intellectual property related to generics or with no valid claim;
- \( x_{ii} \) equals the dummy variable for a trademark; and
- \( \epsilon \) equals the error term.\textsuperscript{63}

Depending on the P-value for the Trademark dummy variable, accept or reject the null hypothesis at a standard confidence level. Based on my experience, the type of relevant intellectual property is a statistically significant explanatory variable for determining the royalty rate in this type of model and that the difference between the means of the samples of royalty rates is statistically different than zero. The mean royalty rate for trademarks is likely statistically different from the mean royalty rate for the combined data on non-composition of matter patents and intellectual property related to generics or with no valid claim. That is, the mean royalty rate for intellectual property related to a trademark is typically lower than the mean royalty rate for non-composition of matter intellectual property or the royalty rate for intellectual property related to generics or with no valid claim. Trademarks are less valuable forms of protection in arm’s length negotiations. In fact, a survey of pharmaceutical R&D managers reported that trademarks are less important than process patents for protecting the results of R&D.\textsuperscript{64}

2. \textbf{Determining the arm’s length price based on the CUT method}

Assume for the remainder of this analysis that the royalty rates for intellectual property for trademarks are statistically different from the royalty rates for non-composition of matter patent intellectual property and intellectual property related to generics or with no valid claim. Applying the CUT method to determine an arm’s length transfer price (royalty rate) for an exclusive licence to two types of intellectual property embodied in mature pharmaceutical products requires constructing two arm’s length ranges: one

\textsuperscript{62} ibid.

\textsuperscript{63} It represents all other factors that affect \( y \) besides \( x_i \) and \( x_{ii} \). Wooldridge, supra, note 61, p 25.

\textsuperscript{64} Levin, Klevorick, Nelson and Winter, supra, note 21, p 810.
range for trademarks, and another range for non-composition of matter patent intellectual property and for generics or with no valid claim.

V. COMPARING THE RESULTS TO LITERATURE ON LICENSING

To put the results using the CUT method in perspective, it is helpful to search licensing literature for information on royalty rates in the pharmaceutical and chemical industries for limited intellectual property protection. Sources such as les Nouvelles, a journal published by the Licensing Executives Society are relevant for this task. Although not generally accepted by tax authorities as the primary analysis, such studies provide benchmarks for assessing the results using accepted methods.

VI. CONCLUSIONS

To determine a general transfer pricing methodology for intellectual property embodied in mature pharmaceuticals, review internal Company documents and publicly available data. Focus on licence agreements with distinct royalty terms for the relevant types of intellectual property embodied in mature pharmaceutical products. The observations identified from the Company’s agreements with third parties generally provide the most reliable and complete data available for determining an arm’s length range. The CUT method emerges as the best method for determining an arm’s length transfer price (ie, royalty rate) for the relevant intellectual property under the Section 482 regulations. Apply the CUT method to determine an arm’s length transfer prices (range of royalty rates) due Affiliate from International for exclusive licence separately for trademarks, and for non-composition of matter patent intellectual property and for generics or with no valid claim.

In some cases, the Affiliate may own a trademark and another form of relevant intellectual property associated with the mature pharmaceutical product. In such a controlled transaction, the rates identified above should be aggregated.

Tax authorities have generally been reluctant to accept transfer prices based on industry benchmarks as the primary data. However, it is helpful to compare the results obtained by the approach described in this paper with studies in the licensing literature on central tendencies for similar types of transfers in the pharmaceutical and chemical industries.