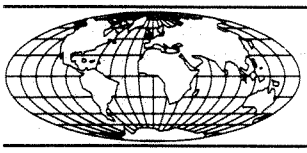

IN PRACTICE

Royalty Rates in the Pharmaceutical Industry

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Determining an arm's-length royalty rate for the transfer of intangibles between related entities can be difficult when similar transactions are not readily available. However, taxpayers are required by their governments in many instances to set their transfer prices so that the results satisfy the arm's-length principle. If a transaction does not reflect an arm's-length result, the parties may be subject to transfer pricing adjustments and double taxation—unless there is an applicable double taxation agreement.

The Organisation for Economic Co-operation and Development's revised transfer pricing guidelines state that the arm's-length standard is satisfied when related parties use consideration (prices, royalty rates, etc.) and contractual terms that unrelated parties would have used in a similar transaction under similar circumstances.[1] The OECD issued revised transfer pricing guidelines in July 1995 and April 1996 and issued Oct. 1 guidelines for cost contribution arrangements (4 *Transfer Pricing Report* 207, 8/2/95; 4 *Transfer Pricing Report* 793, 4/10/96; 6 *Transfer Pricing Report* 340, 10/1/97).

The OECD guidelines distinguish trade intangibles from marketing intangibles. Trade intangibles (such as patent and process intangibles) are the product of research and development activities, and generate a return for the developer through product sales, service contracts, or licensing agreements.[2] In contrast, marketing intangibles enhance the commercial exploitation of a product and include trademarks, trade names, customer lists, symbols, pictures, etc.[3]

In practice, it is difficult to separate trade intangibles (patents) from marketing intangibles (trade names) where both exist, and the licensing agreements reviewed in this report generally include the right to use both. See Exhibit B.

The following article outlines a procedure for finding potentially comparable transactions to determine, *ex ante*, an arm's-length royalty rate for the transfer of intangibles relating to drug products.

Search for Unrelated Agreements

To establish a range of royalty rates for the licensing of drug products in the pharmaceutical industry, a search was made for licensing agreements between uncontrolled parties with the following characteristics:

☐ The agreements contain royalty rates (as opposed to fixed-fee sales of intangible property);

☐ The agreements are between independent corporations or partnerships in the pharmaceutical industry;

☐ The agreements concern intangibles involving patented drug products, or products for which patent protection is being sought (as opposed to processes).[4]

Licensing agreements were found by searching the LiveEdgar database, which compiles information submitted by publicly traded companies to the U.S. Securities and Exchange Commission.[5] A summary of the search procedure is provided in Exhibit D.

The LiveEdgar search generated 179 agreements for the period, December 1994 through May 1997 (the period for which the LiveEdgar database had information). After reviewing each agreement, most were set aside if they did not report royalty rates or because they were not licensing agreements. The 19 remaining licensing agreements are summarized in Exhibit C. Of the agreements that reported royalty

[1] Organisation for Economic Co-operation and Development, *Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrators*, 1995 (Paris). In practice, the U.S. tax authorities follow their own §482 Regulations. The OECD guidelines are cited in this article because of their wide applicability to OECD members, including Canada and Mexico.

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[2] OECD guidelines §6.3.

[3] OECD guidelines §6.4.

[4] LiveEdgar is a database provided by Global Securities Information at www.gsionline.com. The online search occurred on June 6, 1997, involving documents containing the expressions "royalty" or "licensing" belonging to companies classified in Standard Industry Classification Code 2834 (companies primarily engaged in producing or processing drugs in pharmaceutical preparations).

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rates, another eight agreements were set aside for not satisfying the criteria set forth above.[6]

Summary of Results

The 11 selected licensing agreements pertain to the license of drug products between unrelated pharmaceutical companies or partnerships. Among other things, the agreements vary in terms of geographic scope, duration, and royalty rates. The variations are summarized below, followed by the range of royalty rates.

Geographic Scope: The selected licensing agreements generally provide the licensee the exclusive right to produce the licensed product worldwide. The exceptions include the agreements between:

☐ Eli Lilly and Co. and Jones Medical Industries Inc. (for the Brevital Sodium product), which is limited to the United States;

☐ Eli Lilly and Co. and Roberts Laboratories Inc. (for the LY315535 product), which is limited to the United States, Mexico, and Canada; and

☐ F.H. Faulding & Co. Ltd. and Purepac Pharmaceutical Corp., which is limited to the United States.

Duration: The selected licensing agreements generally remain operative until the patents that protect the licensed product expire, with a minimum term of 10 or fifteen years. Exhibit C contains the specific minimum term length for each agreement. Two agreements do not expire with the associated patents:

☐ Eli Lilly and Company and Jones Medical Industries, Inc. (for the brevital sodium product), which lasts indefinitely; and

☐ F.H. Faulding & Co., Ltd. and Purepac Pharmaceutical Corp., which lasts for 10 years, with 5-year terms of renewal.

Determining an Arm's-Length Range

The final set of licensing agreements contain variations in payment structures including tiered royalty payments, up-front lump sum payments, milestone payments, and other contractual terms. See Exhibit C.

To establish a range of royalty rates, the royalty rate found in each agreement was used without regard to non-royalty payments. If the agreement included tiered royalty rates, the rate at the highest tier in the range was used.[6] Exhibit A contains a summary of the royalty rates for the final set of eleven licensing agreements.

The range of royalty rates is as follows: Range (minimum to maximum): 5.0% to 10.0%; or Interquartile range: 6.5% to 8.1%.

Comparability Analysis

In general, a taxpayer will not be subject to a transfer pricing adjustment if its royalty rates fall within an arm's-length range. The OECD guidelines define an arm's-length range as a range of data that are acceptable for establishing whether the conditions of a controlled transaction are arm's length. Such data may result from the application of a transfer pricing method to multiple comparable data or from the use of different transfer pricing methods.

The determination of whether the range of royalty rates set forth above is an arm's-length range depends on the particular facts and circumstances of the drug product being transferred. If comparability can be established between the related transaction and the unrelated licensing agreements used to create the range, then the OECD guidelines provide that a royalty rate between related parties set within the range will not be subject to a transfer pricing adjustment.

To establish comparability between transactions, specific characteristics of the circumstances being compared must be sufficiently comparable.[7]

For transactions involving intangible property, relevant characteristics include the following:

☐ The form of transaction (*e.g.* licensing or sale);

☐ The nature of the patent (e.g. product or process patent);

☐ The duration and degree of protection afforded under the patent laws of the relevant countries;

☐ The length of the period during which the patent is likely to maintain economic value; and

☐ The anticipated benefits from the use of the property.[8]

Conclusion

The OECD guidelines recognize that it may be difficult to ascertain the value of intangible property at the time a controlled transaction takes place.[9] In such cases, tax authorities are expected to follow the

[5] The additional eight agreements included:

☐ Alza Corp. and Therapeutic Discovery Corp., because the licensing agreement becomes effective only upon redemption of an option agreement;

☐ Andrew Cragg and Micro Therapeutics, Inc., because the licensed products (valved-tip angiographic and infusion catheters) are devices, not drugs;

Immunex Corp. and Aastrom Biosciences Inc., because the licensing fee is provided in the form of a yearly lump sum rather than a percentage of sales;

☐ Joseph G. Cremonese and Aastrom Biosciences Inc., because the license requires payments to an individual for an unpatented product, with advances for costs associated with seeking the patent;

☐ Nastech Pharmaceutical Corp. and Consumer Health Care Group of Pfizer Inc., because the license agreement becomes effective only upon the redemption of an option agreement;

☐ Regents of the University of California and MGI Pharma, Inc., because the licensed product is a method of treatment, not a drug product;

☐ Regents of the University of Michigan and Ann Arbor Stromal, Inc., because the licensed products are inventions and know-how, not drug products; and

☐ University of Texas at Dallas and Cytoclonal Pharmaceutics, Inc., because the licensed product is a method, not a drug product.

[6] The highest tiered rate means the royalty rate applicable at the highest anticipated sales volume.

[7] OECD guidelines §1.15.

[8] OECD guidelines §§1.19, 6.21.

[9] OECD guidelines §6.29-6.35. In this regard, the U.S. §482 regulations contain the impractical requirement that comparable intangibles

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valuation arrangements that would have been made in comparable circumstances by independent parties.[10]

Because information on comparable transactions involving intangible property is often limited, the determination of an arm's-length consideration "necessarily requires exercising good judgment." [11]

After an exhaustive search and review of 179 agreements covering the period 1994 to 1997, royalty rates for the transfer of intangibles relating to drug products were found that ranged from 5% to 10% (at the highest tier of sales). For this range to be considered an arm's-length range, a taxpayer must perform the additional step of establishing comparability between the agreements used in the range and the transaction at issue. Nevertheless, the range of royalty rates above provides useful guidance on whether a specific related transaction of intangible property conforms to the agreements found in publicly available sources in the United States.

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have "similar profit potential." See Regs. §1.482-4(c)(2)(iii)(B) (Factors to be considered in determining comparability). Establishing a specific third party's intangible profit potential is similar to proving Pangloss' impossibility theorem.

[10] OECD guidelines §6.32.

[11] OECD guideline §1.45.

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Exhibit A

Summary of Royalty Rates and Marginal Royalty Rates for the Selected Companies

	Companies (Licensor/Licensee)	*Royalty Rate (% of Net Sales, except where noted)*	*Royalty Rate at the highest Tier (% of Net Sales, except where noted)*
1.	ALW Partnership and Panax Pharmaceutical Co., Ltd	2% to 6%	6%
2.	Boehringer Mannheim GmbH and Aronex Pharmaceuticals, Inc.	7% to 8%	8%
3.	CytRx Corp. and Vaxcel Inc.	10%	10%
4.	Dynagen Inc. and Nastech Pharmaceutical Co., Inc.	10%	10%
5.	Eli Lilly and Co. and Jones Medical Industries, Inc. (Hypertyroid product)	5%	5%
6.	Eli Lilly and Co. and Jones Medical Industries, Inc. (Brevital sodium product)	5%	5%
7.	Eli Lilly and Co. and Roberts Laboratories, Inc. (Tazofelone product)	7%	7%
8.	Eli Lilly and Co. and Roberts Laboratories, Inc. (LY246736 product)	7%	7%
9.	Eli Lilly and Co. and Roberts Laboratories, Inc. (LY 353433 product)	7%	7%
10.	Eli Lilly and Co. and Roberts Laboratories, Inc. (LY 315535 product)	8%	8%
11.	F. H. Faulding & Co. Ltd and Purepac Pharmaceutical Co.	8.2% (of gross profit)	8.2% (of gross profit)
		Range:	5% to 10%.
		Interquartile range:	6.5% to 8.1%.

Exhibit B

Rights Under Licensing Agreements

	Companies (Licensor/Licensee)	*Rights Conferred*
1.	ALW Partnership and Panax Pharmaceutical Co., Ltd	Right to manufacture, have manufactured, use, sublicense and sell products based on licensor's patents.
2.	Boehringer Mannheim GmbH and Aronex Pharmaceuticals, Inc.	Use of patent rights and know-how. Licensee granted option for participating in co-promotion activities.
3.	CytRx Corp. and Vaxcel Inc.	Use of patents and all related technical, scientific, business development and marketing data.
4.	Dynagen Inc. and Nastech Pharmaceutical Co., Inc.	Right to make, have made, sublicense, develop, use, promote, market, distribute and sell products using licensor's patents and know-how.
5.	Eli Lilly and Co. and Jones Medical Industries, Inc. (Hyperthyroid product)	Use of trademarks, marketing data, manufacturing know-how, and rights under a New Drug Application for purposes of marketing and selling the product in the U.S.
6.	Eli Lilly and Co. and Jones Medical Industries, Inc. (Brevital sodium product)	Use of trademarks, marketing data, manufacturing know-how, and rights under a New Drug Application for purposes of marketing and selling the product in the U.S.
7.	Eli Lilly and Co. and Roberts Laboratories, Inc. (Tazofelone product)	Use of all patent rights, trade secrets, and know-how to make, have made, use or sell the product Tazofelone.
8.	Eli Lilly and Co. and Roberts Laboratories, Inc. (LY246736 product)	Use of all patent rights, trade secrets, and know-how to make, have made, use or sell the product LY246736.
9.	Eli Lilly and Co. and Roberts Laboratories, Inc. (LY 353433 product)	Use of all patent rights, trade secrets, and know-how to make, have made, use or sell the product LY353433.
10.	Eli Lilly and Co. and Roberts Laboratories, Inc. (LY 315535 product)	Use of all patent rights, trade secrets, and know-how to make, have made, use or sell the product LY315535.
11.	F. H. Faulding & Co. Ltd. and Purepac Pharmaceutical Co.	Rights to use technical and industrial information to complete development of a ketoprofen product; right to manufacture and market the product in the U.S.

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Exhibit C

Licensing Agreements with Reported Royalty Rates

Licensor	*Licensee*	*Product*	*Royalty Rate*	*Duration*	*Territory*
Eli Lilly and Company (USA)	Roberts Laboratories, Inc. (USA)	Tazofelone	$10 million plus 7% of net sales	15 years or expiration of patents	Worldwide
Eli Lilly and Company (USA)	Roberts Laboratories, Inc. (USA)	LY246736 for use in treating gastrointenstinal disorders	$1 million plus 7% of net sales	15 years or expiration of patents	Worldwide
Eli Lilly and Company (USA)	Roberts Laboratories, Inc. (USA)	LY353433 for use in treating gastrointestinal disorders	$1 million plus 7% of net sales	15 years or expiration of patents	Worldwide
Eli Lilly and Company (USA)	Roberts Laboratories, Inc. (USA)	LY315535 for use in treating gastrointestinal disorders	$5 million plus 8% of net sales	15 years or expiration of patents	USA, Canada, Mexico
Alza Corp. (USA)	Therapeutic Discovery Corp. (USA)	Not provided	5% maximum of net sales, determined as: 1% net sales; 0.1% net sales for each $1 million in development costs paid by Therapeutic Discovery	Indefinite	Not provided

Licensor	*Licensee*	*Product*	*Royalty Rate*	*Duration*	*Territory*
ALW Partnership (USA)	Panax Pharmaceutical Co., Ltd. (USA)	Solid dosage sodium phosphate salts	2% of net sales for first $5 million; 4% for sales between $5 million and $10 million; 5% on sales over $10 million. To keep exclusivity after six years, $100,000 per year.	Expiration of patents	Worldwide
Immunex Corp. (USA)	Aastrom Biosciences, Inc. (USA)	Cytokines and enzyme-linked immunoassay reagents and cell culture technology	$1.5 million up-front; $1 million per year to maintain license; no royalty.	5 years	United States and Canada
Regents of the University of Michigan (USA)	Ann Arbor Stromal, Inc. (USA)	Inventions and know-how for producing blood cells	2% of net sales	Expiration of patents	Worldwide
Joseph G. Cremonese (USA Individual)	Aastrom Biosciences, Inc. (USA)	Automated culture systems or bioreactors	3% of net sales; advance to cover cost of acquiring patents	Expiration of patents	Worldwide
Dynagen Inc. (USA)	Nastech Pharmaceutical Co.,Inc. (USA)	NicErase smoking cessation agent	10% of net sales; 50% of gross payments if sub-licensed	Expiration of patents	Worldwide

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Licensor	*Licensee*	*Product*	*Royalty Rate*	*Duration*	*Territory*
Nastech Pharmaceutical Corp. (USA)	Consumer Health Care Group of Pfizer Inc. (USA)	Method and dosage form for inducing sleep	$425,000 plus incentives; 9% of net sales if sold under prescriptions; 5% of net sales if over-the-counter.	Expiration of patents	Worldwide
CytRx Corporation (USA)	Vaxcel Inc. (USA)	Copolymer used as vaccine adjuvant	10% of net sales	Expiration of patents or ten years	Worldwide
Andrew Gragg, M.D. (USA)	Micro Therapeutics, Inc. (USA)	Valved tip angiographic and infusino catheters	1% of net sales for 12 years	No expiration	Worldwide
University of Texas at Dallas (USA)	Cytoclonal Pharmaceutics, Inc. (USA)	Method for selecting target sequence zones of nucleic acids	4% of net sales	Expiration of patents or 20 years if no patent is obtained	Worldwide
Eli Lilly and Company (USA)	Jones Medical Industries, Inc. (USA)	Hyperthyroid pharmaceutical products	$26,010,000 plus royalty of 5% of net sales for 10 years	Expiration of patents	Worldwide
Regents of the University of California (USA)	MGI Phara, Inc. (USA)	Method of treating tumors using illudin analogs	Up-front lump payment and annual fees; varied royalty rates from 5% to 11%	Expiration of patents or ten years	Worldwide

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Licensor	*Licensee*	*Product*	*Royalty Rate*	*Duration*	*Territory*
F.H. Faulding & Co. Ltd (Australia)	Purepac Pharmaceutical Co. (USA)	Daily ketoprofen product substitutable for Oruvail 200	8.2% of gross profit	10 years with automatic 5-yr terms of renewal	USA
Eli Lilly and Company (USA)	Jones Medical Industries, Inc. (USA)	Brevital Sodium	$7 million plus 5% royalty on net sales	Perpetual	USA

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