

Royalty Rates for Pharmaceuticals & Biotechnology, 6th Edition

Preface, Table of Contents & Sample Reports

Preface

The 6th edition of *Royalty Rates for Pharmaceuticals & Biotechnology* continues to focus on the royalty rates associated with biotechnology and pharmaceutical intellectual property transfers. It contains over 70% more information than the prior edition. The purpose of this report is to provide a tool that can be used to optimize the pricing of biotechnology and pharmaceutical intellectual property.

This report is organized into two parts. The first part covers the theory associated with quantifying royalty rates for use in licensing technology. An overview of intellectual property value is provided along with various methods that are employed to derive royalty rates. The methods discussed are both qualitative and quantitative. Each method is also discussed relative to its strengths and weaknesses.

The second part of the report presents detailed financial information about third-party transactions that center on the transfer of biotechnology and pharmaceutical intellectual property. The parties involved in the transactions are disclosed along with a description of the technology exchanged and all of the financial details that could be discovered.

The transaction information is categorized into License Agreements and Strategic Alliances. In general, the licensing transactions involve outright transfer of the rights to practice and commercialize a patented technology. For this 5th edition we have emphasized the reporting of royalty rates and other financial compensation, associated with license agreements. We have updated and expanded information that was reported in past editions and conducted extensive research to expand the number of license agreements reported.

The transaction information presented in the second part of this report has been collected from sources believed to be reliable beginning in September 1990 through December 2001. No attempt has been made to independently verify each item of information reported. Intellectual Property Research Associates accepts no liability for any damages that may result from reliance on any information published in this report. This report includes the information presented in the first four editions of *The Royalty Rate Report for the Pharmaceutical & Biotechnology Industries* and adds over 70% more market transaction information.

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Pain Therapy	Asthma Drug - Oral Administration
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Sample Information

Cancer Treatment

Licensor: Kuslima Shogen
Licensee: Alfacell Corporation
Royalty: 5% of gross sales

Alfacell Corporation is a biopharmaceutical company organized in 1981 that went public in 1983. The company is primarily engaged in the discovery and development of a new class of anti-cancer drugs from amphibian ribonucleases. Ribonucleases degrade ribonucleic acids causing an interruption in protein synthesis resulting in the inhibition of cell growth and induction of apoptosis (programmed cell death).

Alfacell's first product under development is ONCONASE® which targets a variety of cancers, most of which are known to become resistant to other chemotherapy drugs. ONCONASE® is a novel amphibian ribonuclease that has been isolated from the eggs of the leopard frog (*Rana pipiens*). Ribonucleases mediate several important biological functions in nature, including regulation of angiogenesis (formation of new blood vessels that supply tumors), anti-viral and anti-parasitic defenses. In addition to taking advantage of the natural biological functions of ribonucleases, amphibian ribonucleases may be more therapeutically effective in humans than mammalian ribonucleases because they do not appear to be adversely affected by inhibitors found in mammals. Therefore, developing amphibian ribonucleases into therapeutics, and thereby taking advantage of the natural role of ribonucleases, may result in a new class of compounds for proliferative diseases such as cancer and AIDS. Alfacell holds a number of patents and retains all commercial rights to compounds resulting from this program.

On July 23, 1991, the Board of Directors authorized Alfacell to pay Kuslima Shogen an amount equal to 15% of any gross royalties which may be paid to Alfacell from any license(s) with respect to its principal product, ONCONASE®, or any other products derived from amphibian source extract, produced either as a natural, synthesized, and/or genetically engineered drug for which Alfacell owns or is a co-owner of the patent, or acquire such rights in the future, for a period not to exceed the life of the patents. If Alfacell manufactures and markets the drugs itself, it will pay an amount equal to **5% of gross sales** from any products sold during the life of the patents (2000 10K).

Estrogen Replacement Therapy

Licensor: Novavax, Inc.
Licensee: King Pharmaceuticals, Inc.
Royalty: 7.5% of net sales less cost of goods sold

King Pharmaceuticals, Inc. is a vertically integrated pharmaceutical company that manufactures, markets and sells primarily branded prescription pharmaceutical products. Through a national sales force of approximately 520 representatives and co-promotion arrangements, King markets its branded pharmaceutical products to general/family practitioners, internal medicine physicians, cardiologists, endocrinologists, pediatricians, obstetrician/gynecologists, and hospitals across the country and in Puerto Rico. The primary business strategy is to acquire established branded pharmaceutical products and to increase their sales through focused marketing and promotion and product life cycle management, including, securing new indications, developing

product line extensions and devising new formulations or dosages. In pursuing product acquisitions, Kings seeks to capitalize on opportunities in the pharmaceutical industry created by cost containment initiatives and consolidation among large, global pharmaceutical companies. The company also seeks attractive company acquisitions, which add products or product pipelines, technologies or sales and marketing capabilities to its key therapeutic areas. In addition to branded pharmaceuticals, King also provides contract manufacturing for a number of the world's leading pharmaceutical and biotechnology companies, including Warner-Lambert Company, predecessor to Pfizer, Inc., Centocor, Inc., Santen Incorporated and Hoffman-La Roche Inc.

King acquired an exclusive license from Novavax on January 8, 2001 to promote, market, distribute and sell Estrasorb™, Novavax's topical, transdermal estrogen replacement therapy, worldwide except in the United States, Canada, Italy, the Netherlands, Greece, Switzerland and Spain. King will pay Novavax during the term of the license a royalty based on **7.5% of net sales** of Estrasorb™ in any exclusive territory. Novavax and King will co-market Estrasorb™ in the United States and Puerto Rico. Under the co-promotion agreement, Novavax will pay us an amount equal to 50% of net sales, less cost of goods, of Estrasorb™. Novavax has indicated that it expects to file a New Drug Application for Estrasorb™ in 2001.

The gross profit from licensed products increased \$3.3 million or 14.6% to \$26.0 million in 1999 from \$22.7 million in 1998. The increase is primarily due to the continued year-over-year increases in unit sales of Adenoscan®, a drug for which the company pays a royalty of **3% of net sales** to a third party and Adenocard®, a drug for which the company pays a royalty of **12.5% of net sales** to the University of Virginia Alumni Patents Foundation.

On January 8, 2001, the company entered into a license agreement with Novavax, Inc. to promote, market, distribute and sell Estrasorb™ worldwide, except in the United States, Canada, Italy, Netherlands, Greece, Switzerland and Spain. The company will pay a royalty to Novavax based on **7.5% of net sales** of Estrasorb™ within the territory. The company and Novavax will co-market Estrasorb™ in the United States and Puerto Rico. Under the co-promotion agreement, Novavax will pay King an amount equal to 50% of Estrasorb™ margins. Marketing expenses for Estrasorb™, approved pursuant to the co-promotion agreement, will be shared equally by the parties (2001 10K).

Nuclear Matrix Protein Technology

Licensor: Hybritech, Inc.

Licensee: Matritech, Inc.

Royalty: 3% to 6% of net sales

Matritech, Inc. develops, manufactures and markets innovative cancer diagnostic products based on its proprietary nuclear matrix protein technology. The nuclear matrix, a three dimensional protein framework within the nucleus of cells, plays a fundamental role in determining cell type by physically organizing the contents of the nucleus, including DNA. The company has demonstrated that there are differences in the types and amounts of NMPs found in cancerous and normal tissue and believes the detection of such differences in NMPs provides important diagnostic information about cellular abnormalities, including cancer. Using its proprietary NMP technology and expertise, the company has developed non-invasive or minimally invasive cancer diagnostic tests for bladder and cervical cancer and is developing additional tests for breast, colon and prostate cancer. The company's objective is to develop tests that will be more accurate than existing non-NMP tests and will result in lower treatment costs and a higher standard of patient care than currently available tests.

In August 1994, the company entered into a non-exclusive license agreement with Hybritech, Inc. for the manufacture and sale of certain patented technology for immunometric assays using monoclonal antibodies. The company is required to pay a royalty equal to the greater of **8% of net sales** of licensed products or \$25,000 per year until the expiration of patent rights on a country-by-country basis beginning in 2000 through 2008. The company paid \$25,000, \$42,540 and \$25,000 in royalties in the years ending December 31, 1998, 1999 and 2000, respectively.

Pain Therapy

Licensor: Unidentified University
Licensee: Endo Pharmaceuticals Inc.
Royalty: 4% of net sales

Endo Pharmaceuticals Inc. and Endo Inc. are engaged in the research, development, sales and marketing of branded and generic prescription pharmaceuticals used primarily for the treatment and management of pain. Branded products comprised approximately 68% and 76% of net sales for fiscal years 1999 and 2000, respectively.

Through a national dedicated contract sales force of approximately 230 full-time sales representatives, Endo markets branded pharmaceutical products to doctors, drug wholesalers and other healthcare professionals. Endo markets its generics through sales and marketing activities as well as customer service activities directly with wholesale drug distributors and chain and independent retail pharmacists. Endo's portfolio of branded products includes recognized brand names such as Percocet®, Percodan®, Zydone® and Lidoderm®. Endo's portfolio of generic products includes products for various indications, most of which are focused on pain management. Endo seeks to continually expand its product portfolio through on-going investment in research and development and product acquisitions.

All of Endo's products are manufactured by third parties. Currently, Endo's primary suppliers of contract manufacturing services are DuPont Pharmaceuticals, Merck & Co. and Teikoku Seiyaku Pharmaceuticals.

The Company has licensed from a university certain patents and pending patent applications in the field of pain management. The company is required to pay royalties equal to **4% of sales** of licensed products. In addition, the company will pay the university 50% of royalty payments received from any sublicensees until such payments total \$500,000 for a given year, 33% until the payments total an additional \$500,000 for such year and 25% thereafter (*2001 10K*).