Preface

Patented technology is the coveted crown jewel of the pharmaceutical and biotechnology industry. Pharmaceutical companies are aggressively pursuing new technologies and products regardless of their source. The amounts being paid for acquisition and licensing of new technologies is rising as pharmaceutical companies, with empty research pipelines, frantically compete for new technologies.

This report is a tool that can be used to optimize the pricing of biotechnology and pharmaceutical intellectual property. The information in this resource is also useful for the valuation of patents and establishing damages for infringement litigation. The eighth edition of Royalty Rates for Pharmaceuticals & Biotechnology continues to focus on the royalty rates associated with biotechnology and pharmaceutical intellectual property transfers.

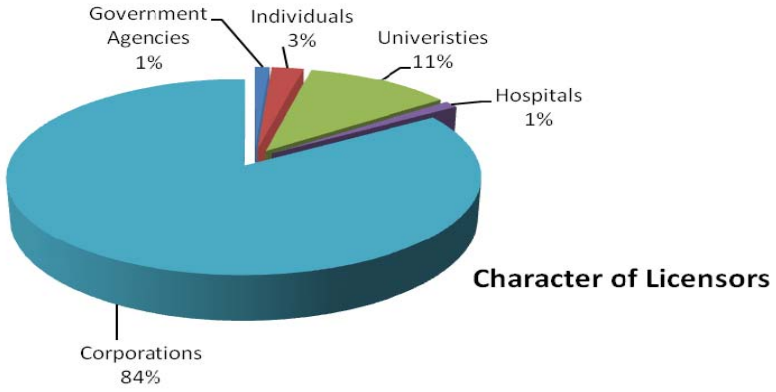
This report is organized into two parts. The first part covers the theory associated with deriving royalty rates. An overview of intellectual property value is provided along with various methods that can be employed to derive royalty rates from financial analysis. The methods discussed are both qualitative and quantitative.

The second part of this report presents detailed financial information about real world 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. For this new 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 this new edition has been collected from well-established sources believed to be reliable from September 1990 through August 2012.

The database covers a wide variety of technologies. Just some of the technology categories represented in the database address: Alzheimer's, asthma, cardiovascular, cancer, contraception, diabetes, dermatology, drug delivery, hepatitis, and pain management, personal care, sleep therapy, and vaccines. This preface provides an overview of the data.

The Parties – Licensing Between Corporations Dominates

The licensees to almost every deal in the database are corporations with plans to continue development of the licensed technology and hopefully enter in commercialization with resulting products. The licensors are predominantly corporations but also include governmental agencies, individuals, universities, and hospitals. Shown below is a pie chart depicting the character of the licensors.



Corporations are the number one source from which to license technology. Second place goes to universities. All other sources, 5%, are individuals, governmental agencies and hospitals.

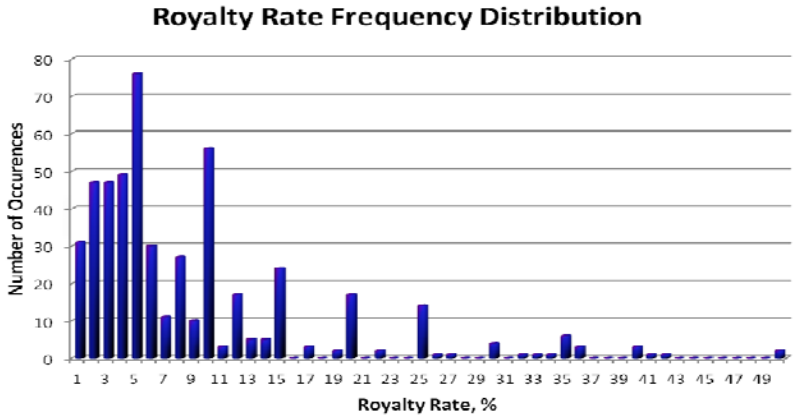
Royalty Rates

The vast majority of the deals involve the payment of running royalties as a percent of net sales once commercialization of the licensed technology is achieved. Running royalties are required in 412 of the deals studied - 92.6% of the total 445 deals in this book.

Not all of the deals requiring the payment of running royalties disclosed the actual royalty rate to be paid but royalty rates were disclosed for 345 deals. Royalty rates are either negotiated as a fixed percentage rate for all sales or a range of percentages rates as sales achieve designated levels. As such, many deals specified a range of royalty rates that can be characterized as the high-end royalty rate and the low-end royalty rate.

For all of the deals that reported royalty rates, the average of the high-end royalty rate was 9.7%. The average low-end royalty rate was 6.9%. The highest royalty rate in the data base was 50% of net sales for a recombinant form of the human enzyme. One of the lowest rates was 0.25% of net sales associated with a monoclonal antibody for cancer therapy.

Summarized below is the royalty rate data discovered in the license agreements. Only royalty rates, presented as a percent of sales, are included in the graph below. Royalty payments based on per unit sales are not included in the graph.[1] For license agreements containing more than one rate, all rates are representing with equal weight in the graph.



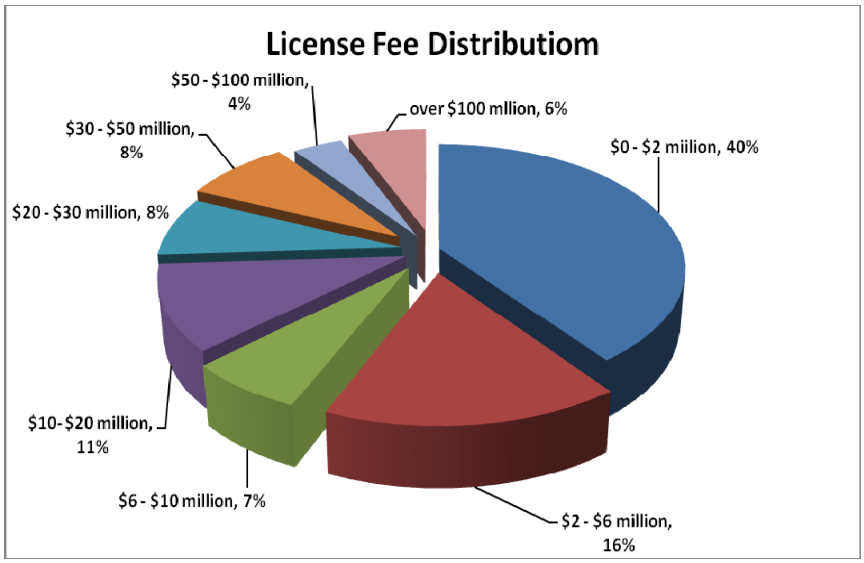
It is easy to see that the vast majority of royaty rates are at the lower end of scale. In fact, over 50% of the deals involve royalty rates of 6% of sales or less. Over 76% of the deals involve royalty rates of 10% or less. Over 90% of the deals involve royalty rates of 20% or less. Put another way, only 10% of all the deals studied involved royalty rates of 20% or more.

Royalty payments based on a portion of profits were extremely rare. This is because using profits as the basis for royalty payments is fraught with potential conflict. Often, the licensor and licensee have different definitions of profit. Arguments can easily arise about the expenses that should, and should not be included, for making the calculation of the profit base. Even a detailed definition of the profit base, as part of the license agreement can fail to fully account for all appropriate expenses. Consequently, licensing executives long ago abandoned using a profit margin base for the calculation of royalties and have focused on net sales as the royalty base to which a royalty rate (percentage) is applied.

License Fees

Quite a few of the deals included upfront license fees. In fact, 181 of the 445 deals, 41%, required the licensee to make an upfront payment to the licesnor at the onset of the deal. For these 181 deals, the average license fee is $22.2 million. This avearge however does not reflect the typical license fee that can be expected. A distribution of the license fees is presented below.

[1] Only one deal in the entire database required royalty payments based on a dollar amount per units sold.



As the chart shows, 40% of the license fees are $2 million or less, the majority, 63%, of license fees are $10 million or less. In fact, 70% of the license fees are $20 million or less. The vast majority, 90%, are $50 million or less. Occassionally, a newsworthy licensee fee is negotiated. One example is the $300 million fee that Hofman la Roche paid to Cetus for Poymerase Chain Reaction Technology.[2] Such substantial license fees are rare.

Key Technologies

The database covers a wide variety of pharmaceutical and biotechnology inventions. But, over 40% of the deals focused on seven specific indications: alzheimer's, cancer, cardiovascular, diabetes, hepatitis, pain management and personal care (see pie chart on next page). It is not surprising that these indications are the focus of technology development and licensing because they present the largest markets for commercializtion. As an example consider heart disease.

In the U.S., all cardiovascular disease costs $273 billion each year, including heart conditions, stroke, peripheral artery disease, and high blood pressure. In fact, of all the money spent in the U.S. on health care, 17% goes toward treating cardiovascular disease, says Paul A. Heidenreich, MD, a cardiologist at the VA Palo Alto Health Care System in California and associate professor of medicine at Stanford University. Heart conditions such as heart failure, heart attack, bypasses, etc., account for nearly $96 billion of that total.[3]

Another example invovles pain. America spends upwards of $635 billion every year on the treatment of chronic pain, according to MedPage Today. A recent Institute of Medicine report, mandated by the Affordable Care Act, found that pain afflicts at least 116 million U.S. adults annually.[4]

How about the cost of cancer treatment? From 1990 to 2008, annual spending on cancer care soared to more than $90 billion from $27 billion. The increase was driven by the rising costs of sophisticated new drugs, robotic surgeries and radiation techniques, as well as the growing number of patients who are eligible to take them, says Peter Bach of New York's Memorial Sloan-Kettering Cancer Center, co-author of an analysis in today's Journal of the American Medical Association.[5]

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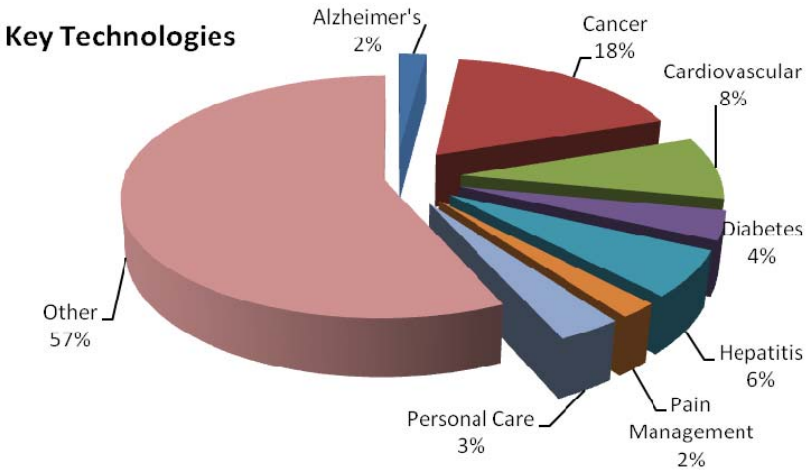
[2] This particular deal involves a $300 million payment for outright ownership of the subject technology.

[3] WebMD, http://www.webmd.com/healthy-aging/features/heart-disease-medical-costs

[4] MedBen News, http://blog.medben.com/index.php/2011/07/19/over-600-billion-spent-on-pain-managemen?blog=2

[5] "Patients bear brunt as cancer care spending hits $90 billion", March 18, 2010, by Liz Szabo, USA Today, http://www.usatoday.com/news/health/2010-03-17-cancer17_ST_N.htm



Shown below is some summary information for key technologies. Pain mangement technology commands the highest avearge license fee and the higest average royalty rate. Cardiovascular technology commanded the third largest average license fee and the second highest royalty rate. The average licesne fee for cancer technology was only slightly less than cardiovascular technology and had the next higest royalty rate. Clearly royalty rates are linked to the size of the commerical market for different indications.

Key Technologies	No. of Deals	Average License Fee	High Rate	Low Rate
Alzheimer's	9	$1,000,000	4.8%	3.9%
Cancer	79	$10,142,439	9.9%	7.4%
Cardiovascular	37	$11,141,182	11.6%	8.4%
Diabetes	17	$1,988,750	7.4%	5.1%
Hepatitis	27	$22,231,389	8.8%	8.3%
Pain Management	9	$37,608,333	14.1%	8.3%

Developmental Stages of Technology

Technologies that is closer to commercialization is more valuable than technologies requiring more development funding and time. This proposition is supported by the database.

Technology licenses from university licensees are typically for technologies at early developmental stages. Such technologies require extensive funding and often a decade of research before commercialization may become possible. Such technologies are typcailly licensed for low-single digit royalty rates. Examples include:

- An antiviral and anti-infective therapy was licensed by Gilead Sciences, Inc. from the University of Colorado at Boulder for a royalty of 2.0% of sales.

- A blood cell and bone marrow production technoogy was licensed by Aastrom BioSciences, Inc. from the University of Michigan for a royalty of 2.0% of sales.

- A cancer treatment technology was licensed by Omnimmune Corp. from Columbia University for a royalty of 2.0% of sales.

In contrast, consider the following deal terms for a technology license involving more advanced development showing success in Phase II clinical trails:

- Abbott Laboratories, Inc. agreed to license an ovarian cancer treatment from UK based Antisoma. Theragyn is an antibody to which radioactivity has been attached. The antibody binds to a target protein on the tumour cell and the radioactivity is then

supposed to kill off or retard the growth of the cancer cells. In a small Phase II trial, some 80 per cent of ovarian cancer patients treated with Theragyn, which is applied after surgery, were still alive five years later, compared to rates of 55 percent in a group of women Antisoma studied using historical data. Antisoma has agreed to a deal with Abbott Laboratories, involving royalties at 20% to 30% of sales.

- Also consider that Rhone-Poulenc Rore, Inc. obtained the licensing right to Dilacor™ XL (Diltiazem). Dilacor™ XL is an AgeNet preferred form of treatment for hypertension and/or angina. It is a benzothiazepine calcium channel blocker that works by relaxing the blood vessels that lead to the heart, thereby improving blood flow to the heart. The licensor received a 20% royalty on the sales of the already commercilized Dilacor™ XR.

This new edition provides a wealth of financial deal terms that can provide those in the middle of technology negotiations with real-world pricing guidance.

Licensing Deals Contents

License Agreements and Strategic Alliances

This section of the report presents detailed financial information about third-party license agreements that centered on the transfer of biotechnology and pharmaceutical technology. The parties involved in the transactions are disclosed along with a brief description of the technology exchanged and all of the financial details disclosed. The transaction information has been collected from sources believed to be reliable from September 1990 through August 2012. Some of the information has been obtained from Licensing Economics Review and other information has come from recent company 10K Filings with the Security and Exchange Commission. The information obtained from Licensing Economics Review is presented as it was at the time of the announcement of the transaction. Some of the companies involved have merged or ceased to exist and some of the research and development efforts have been abandoned but the deal parameters are presented in light of the conditions and circumstances that existed at the time the transaction was negotiated.

1,2-diphenylethanes, 1,3-diphenylpropanes and benzyl tetralins

Licensor: **University College Cardiff Consultants Limited**

Licensee: **Bioenvision, Inc.**

Royalty: **5% of net sales**

Bioenvision Inc. and the University College Cardiff Consultants Limited entered into a license agreement dated June 21, 1999 regarding patent applications on each of the subjects of i) 1,2-diphenylethanes and 1,3-diphenylpropanes and derivatives and ii) benzyl tetralins and derivatives. Part of the consideration for the license and rights granted to Bioenvision is payment to the University of a royalty of 5% of net sales of each licensed product produced by Bioenvision and 35% of net receipts from sub-licenses granted by Bioenvision.

Actimmune - interferon gamma-1b

Licensor: **Connetics Corporation**

Licensee: **InterMune, Inc.**

Royalty: **$ 5.7 million plus 0.25% to 4% of sales**

Intermune, Inc. is a biotech company focused on developing and commercializing innovative therapies in pulmonology and hepatology. Pulmonology is the field of medicine concerned with the diagnosis and treatment of lung conditions. Hepatology is the field of medicine concerned with the diagnosis and treatment of disorders of the liver.

During 2005, Intermune divested the Amphotec® (amphotericin B cholesteryl sulfate complex for injection) product as well as the oritavancin compound. Until December 2005, Intermune's revenue base was provided primarily from the sales of two products, Actimmune® (interferon gamma-1b) and Infergen® (consensus interferon alfacon-1). As part of the company's efforts to refocus its corporate strategy, it completed the sale of the Infergen product, including related intellectual property rights and inventory, to a wholly-owned subsidiary of Valeant Pharmaceuticals International in December 2005. Concurrent with the above transaction, Intermune made the decision to significantly reduce investment in field-based idiopathic pulmonary fibrosis (IPF) disease awareness activities, which, when combined with the sale of the Infergen assets, led to a significant headcount reduction of approximately 160 full time equivalent employees.

In October 2006, Intermune entered into an exclusive license and collaboration agreement with Hoffmann-LaRoche Inc. and F. Hoffmann-LaRoche Ltd. (collectively, Roche) to develop and commercialize products from Intermune's chronic hepatitis C virus (HCV) protease inhibitor program, including Intermune's lead candidate compound ITMN-191.

In October 2006, Intermune also reached a comprehensive settlement with the government concerning promotional activities for Actimmune by former employees during a period that ended in June 2003. The settlement resolved all outstanding government investigations of InterMune without criminal sanctions. As part of the settlement, the company also entered into corporate integrity and deferred prosecution agreements with the government.

Effective March 2007, as a result of disappointing clinical trial results and based upon the recommendation of the study's independent data monitoring committee (DMC), Intermune discontinued further development of Actimmune for IPF.

Through an assignment and option agreement with Connetics Corporation (acquired by Stifel Laboratoties, Inc.), Intermune paid Connetics $5.7 million to acquire rights to Actimmune and is obligated to pay to Connetics a royalty of 0.25% of net United States sales for Actimmune until net United States sales cumulatively surpass $1.0 billion. Above $1.0 billion, Intermune is obligated to pay a royalty of 0.5% of net United States sales of Actimmune. Through a separate purchase agreement, Intermune paid Connetics $0.4 million to acquire rights related to scleroderma and are obligated to pay Connetics a royalty of 4.0% on net revenue from sales of Actimmune for the treatment of scleroderma. Source: Intermune, Inc. 2009 10K.

Agriculture – Animal Health/Trilostane

Licensor: **Bioenvision, Inc.**

Licensee: **Dechra Pharmaceuticals, PLC**

Royalty: **$1.25 million plus 1% to 4% of net sales**

Bioenvision, Inc. and Dechra Pharmaceuticals, PLC entered into a license and sublicense agreement as of May 13, 2003 whereby Dechra obtained from Bioenvision a license of all of Bioenvision's rights and entitlements (including without limitation the marketing and development rights), within the territory of the United States and Canada, in and to the chemical compound known as trilostane and methods of using trilostane solely with respect to animal health applications.

The term "Licensed Technology" in the agreement means patented and unpatented, patentable and unpatentable, proprietary technology related to a dehydrogenase inhibitor and receptor blocker developed by or on behalf of either or both of Bioenvision and Stegram useable with respect to animal health applications. Previously, Bioenvision entered into a Co-Development Agreement with Stegram Pharmaceuticals Limited, dated July 15, 1998, pursuant to which Stegram granted to Bioenvision certain rights and entitlements (including the marketing and development rights) in and to the chemical compound known as trilostane, an inhibitor of 3a-hydroxysteroid dehydrogenase, and methods of using trilostane. Pursuant to the terms set forth in the Co-Development Agreement, Bioenvision gained right to grant sublicenses.

At the execution of the agreement, Dechra paid Bioenvision US$1.25 million. If Dechra receives approval of a New Animal Drug application from the FDA for trilostane prior to the issuance of a licensed patent by the United States Patent and Trademark Office to either Stegram or Bioenvision, then (a) Dechra will pay to Bioenvision US$1,500,000 and (b) Dechra shall deposit US $1,500,000 in an escrow account which will be released upon the issuance of a licensed patent by the USPTO. If Dechra receives a NADA Approval from the FDA for trilostane simultaneously with or after the issuance of any licensed patent by the USPTO to either Stegram or Bioenvision, then upon Dechras receipt of the NADA Approval, Dechra shall pay to Bioenvision US$3,000,000.