

SPECIAL REPORT

Royalty Rate Derivation Methods for Pharmaceuticals & Biotechnology

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ROYALTY RATE DERIVATION METHODS FOR PHARMACEUTICALS & BIOTECHNOLOGY

VERY UNIQUE ASSETS

The patented technology of pharmaceuticals and biotechnology companies is very unique. It requires a huge investment in research and development, that won't generate any revenues or profits for many years, with a high probability of failure before commercialization can begin. However, when successful these products deliver extraordinarily high profit margins from billions of dollars in annual revenue. Unlike most industries, market risk is not always a significant problem. For example, if a cure for cancer is developed, the market will embrace the product.

During the past twenty years, royalty rates have been pressured upward by several conditions within the pharmaceutical industry;

1. New drug discovery has become increasingly difficult.
2. It takes more than ten years and several hundred million dollars to put a new drug on the market.
3. Pharmaceutical companies are under constant pressure to continually obtain or discover promising compounds.
4. Internal R&D pipelines are not sufficiently filled with new discoveries and products.
5. Pharmaceutical companies need to supplement their R&D deficiencies with licensing activities.
6. Pharmaceutical companies are in heated competition to acquire new molecules and technology from any source.¹

This first section of this book presents the different methods used for deriving royalty rates. It starts with a general overview of intellectual property value followed by specific derivation methods. The second section of this book reports the royalty rates and other financial terms associated with real deals.

Intellectual Property Values

Intellectual property is the central resource for creating wealth in almost all industries. The foundation of commercial power has shifted from capital resources to intellectual property. Nowhere is this truer than in biotechnology and pharmaceuticals. In fact, the definition of capital resources is shifting. No longer does the term capital resource bring to mind balance sheets of cash or pictures of sprawling manufacturing plants. The definition of capital includes intellectual property such as technological know-how, patents, copyrights and trade secrets. Corporations once dominated industries by acquiring and managing extensive holdings of natural resources and manufacturing facilities. Barriers to entry were high because enormous amounts of fixed asset investments were required to attempt displacing well-entrenched players. Today, companies that once dominated industries are finding themselves fighting for survival. Up-start companies are creating new products and services based, not on extensive resource holdings or cash hordes but on intellectual property resources.

¹ Yamasaki, M., Determining Pharmaceuticals Royalties, les Nouvelles, September 1996, page 112.

Intellectual Property Sharing Is Vital

A very quick history of healthcare potions starts with the traditional pharmaceutical companies that became multinational giants by turning chemicals into medical products benefiting millions of people. The chemical based products were easy to use and very inexpensive to mass-produce. Then came, initially from university labs, products based on genes and organisms. In many ways these new discoveries were superior to chemical based products, having fewer side effects, but biotechnology therapies were, and still are, costly to make. They are also sometimes difficult to market because they often must be injected or inhaled. Initially, big drug companies largely left biotechnology to the small companies created by scientists and venture capitalists. Eventually the big drug companies were in trouble. They were watching their research pipeline shrink while simultaneously seeing some biotech firms successfully commercialize genes and organism based products. Ernst & Young, a consulting and accounting firm, reported biotech firms were more productive than the old guard. Since 2003, biotech firms have submitted more new-drug applications to the Food and Drug Administration than have old-line firms.² In response, the old-line drug companies began shifting their focus and exploring biotechnology. Some were spending more internal research dollars on biotechnology. Some were banking on alliances, product-licensing deals, or acquisitions of small biotech firms. Some were pursuing multiple initiatives. In 2005, Glaxo spent \$5.2 billion on internal research and development but said it expected half its new products to come from outside its organization. Patricia Danson of the Wharton School, at the University of Pennsylvania said that no firm can rely exclusively on its own R&D anymore.³

How do these unique assets find into the business framework?

BUSINESS ENTERPRISE FRAMEWORK

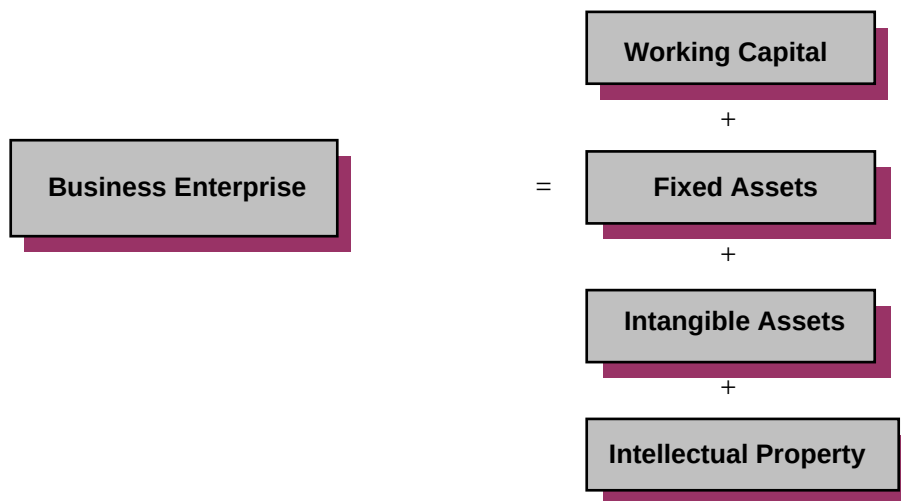
Converting intellectual property into revenues, profits and value still requires a framework of integrated complementary business assets. These assets are also needed to produce the product, package it, sell the product, distribute it, collect payments and implement the many other business functions that are required for running a business. Companies that create intellectual property and then license it to others are still not free of the fundamental need for complementary assets. While licensors may not need to acquire and use complementary assets, successful commercialization of the licensed intellectual property is still dependent on the licensee organizing such assets.

Figure 1 shows the composition of a typical business enterprise as comprised of working capital, fixed assets, intangible assets and intellectual property. It represents the collection of asset categories that all companies use to participant in an industry and generate profits.

² Thomas Ginsberg, Big Pharma faces tough competition in biotech industry, Philadelphia Inquirer, posted on the Internet June 20, 2005

³ id

Figure 1
Composition of a Business Enterprise



Working capital is the net difference between the current assets and current liabilities of a company.⁴ Current assets are primarily composed of cash, accounts receivable and inventory. Current liabilities include accounts payable, accrued salary and other obligations due for payment within twelve months. The net difference between current assets and current liabilities is the amount of working capital used in the business.

Fixed assets include: manufacturing facilities, warehouses, office equipment, office furnishings, delivery vehicles, research equipment and other tangible equipment. This asset category is sometimes referred to as hard assets. The amount of funds invested in this category can vary greatly for different companies, dependent on the industry in which they participate. As an example, huge investments in manufacturing assets are needed by companies participating in the automotive, aerospace, paper, semiconductor and telecommunications industries. In other industries the manufacturing asset investment requirement is lower. Arguably assemblers of electronic consumer goods fall into this category. Also in this category are insurance brokers, computer software publishers, manufacturers of cosmetics and many business service companies.

Intangible assets and intellectual property are the *soft* assets of a company. Generally, intellectual properties are those created by the law; such as the provision in the US Constitution that established the patent system. Trademarks, patents, copyrights and trade secrets are examples. Intangible assets are of a similar nature. They often do not possess a physical embodiment but are nonetheless still very valuable to the success of a business. Customer lists, distribution networks, regulatory approval know-how, clinical trial know-how and good manufacturing practices are examples.

All of the assets of the business enterprise contribute to the revenue and profit generating capability of the business. They are also the underlying basis for the value of the business as depicted in Figure 2. The equity and long-term debt values represent the basis by which all other assets of a company were acquired, whether by purchase or internal creation.

⁴ Current assets are defined by generally accepted accounting principles as assets, which are to be converted into cash within twelve months of the date of the balance sheet on which they appear. Current liabilities are financial obligations that are expected to be satisfied within twelve months of the same date.

Figure 2
Value of a Business Enterprise

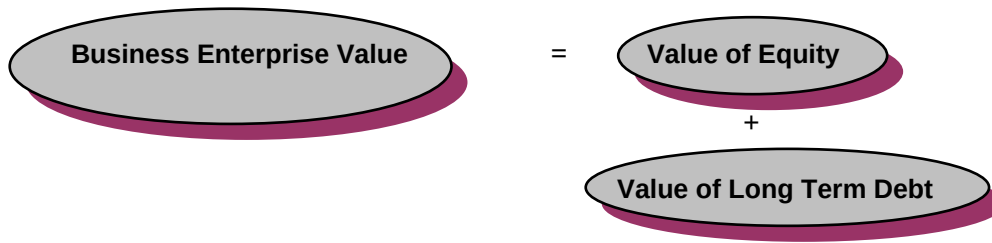


Figure 2 also shows the value of the business enterprise, as depicted in Figure 1, equals the value of the aggregate asset categories. The value of the enterprise is equal to the value of the equity and the long-term debt of the company. The sum of these two components is also referred to as the invested capital of the company. All of the assets comprising the business enterprise contribute to the commercialization of intellectual property by allowing for the creation and delivery of products or services which generate revenues and profits. The ability of a company to sustain earnings makes it a valuable investment.⁵ Estimating the portion of earnings attributed to specific intellectual property can identify the relative value of intellectual property.

Figure 3 shows that the profits of an enterprise can be allocated to the different asset categories that comprise the enterprise. The amount of profits enjoyed by an enterprise is directly related to the existence of the different asset categories. Companies lacking any one category of assets would have different profits. The earnings of a business are derived from exploiting its assets. The amount of assets in each category along with the nature of the assets and the quality of the assets determines the level of earnings the business generates. For pharmaceutical and biotechnology, companies, intellectual property is the largest contributor.

Figure 3
Distribution of Earnings

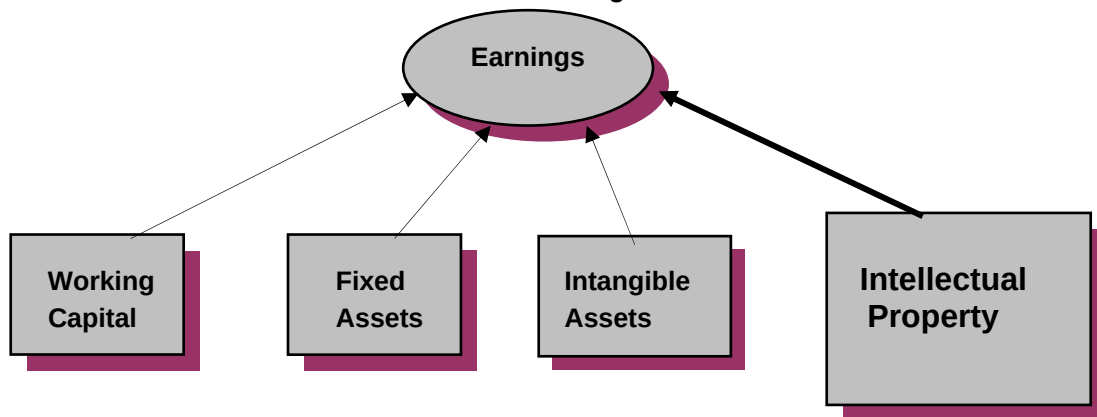


Figure 4 presents a more detailed illustration of a typical business enterprise framework.

⁵ Earnings are the basis of value. The valuation of corporate stock is most often based on the present value of the expected future earnings of a company. The amount, growth rate and risk associated with expected earnings are typically converted into a value or price of a company's stock.

Figure 4

Business Enterprise = **Working Capital** + **Fixed Capital** + **Intangible Assets & Intellectual Property**

- Inventory
- Cash
- Accounts Receivable

- Offices
- Warehouses
- Manufacturing
- Research Labs

- Patents
- Trademarks
- Copyrights
- Technological Know-how
- Designs
- Formulae
- Trade Secrets

Intellectual Property

Intangible Assets

- Distribution Networks
- Supply Contracts
- Licenses
- Customer Lists
- Manufacturing Practices
- Trained Work Force
- Research Capabilities

Some of the key intellectual property and intangible assets that are specific to pharmaceutical and biotechnology companies include:

- Patented drugs and therapies on the market.
- Patented drugs and therapies in the pipeline.
- Established trademarks
- Clinical trial data and information.
- Scientific databases.
- Patent applications.
- Exclusive and non-exclusive licenses.
- Co-marketing and promotion agreements.
- Food & Drug Administration regulatory approvals.

Beyond Commodity Earnings

Working capital, fixed assets and intangible assets are arguably commodity assets that all businesses can possess and exploit. A company that possesses only these limited assets will enjoy only limited amounts of earnings because of the competitive nature of commodities. A company that generates superior or excess earnings must have something special, usually in the form of intellectual properties such as patented technology, trademarks or copyrights. The contribution of excess earnings to commercial operations generally occurs in three primary ways:

1. Price premiums can be obtained from the sale of technology-based products where the market place is willing to pay a higher price than it otherwise would for products lacking the technologically based enhancement of utility. When all, or a portion, of the premium survives manufacturing costs and operating expenses the enhanced bottom-line profit margins are considered to be directly attributed to the existence of unique technology or other intellectual property.
2. Cost savings can enhance the bottom-line profits though the marketplace may not provide a product price premium. When a technology allows for a product or service to be produced and/or delivered at a reduced cost the enhanced earnings are attributed to the technology used in the operations.
3. Expanded market share can also generate incrementally higher profit margins from economies of scale that come from high volume production. This can occur even when premium product pricing or manufacturing cost savings are not possible.

Gravel quarries are generally an excellent example of a commodity business. The products delivered by quarries lack the enhanced utility introduced by technological intellectual property. These companies possess the typical business enterprise asset categories previously discussed except for intellectual property. They may even possess extensive amounts of intangible assets in the form of customer lists, corporate procedures, and favorable union contracts. Yet the nature of their product places gravel quarries in a very competitive position where excess earnings beyond those obtainable in a commodity business are not sustainable for the long term. Overall, profit margins in the quarry business are slim. The reason is the absence of intellectual property.

Later in this report we will show the allocation of earnings among the asset categories of a business enterprise is the foundation of deriving royalty rates. The allocation is based on each asset category earning a fair rate of return on the value of the category. When the profits of the company are allocated among the investment rate of return requirements of working capital, fixed assets and intangible assets sometimes little earnings are available for allocation to intellectual property. Such would be the case for a gravel quarry business enterprise. In other industries, like healthcare, substantial amounts of earnings are still available after the rate of return requirements of non-intellectual property assets are satisfied. The excess amount of earnings is derived from the existence of intellectual property. In many cases technology is the driving force.

How do we value and price the extraordinary intellectual properties of this industry?

DRIVING FORCES BEHIND ROYALTY RATES

The primary forces driving the value of intellectual property and royalty rates are listed below⁶. It is important to remember that these forces must be considered within the framework of the business enterprise previously discussed.

1. Amount of Profits
2. Duration of Profits
3. Risk Associated with the Expected Profits

Amount of profits is the economic benefit generated by the subject intellectual property after allowing for the economic benefits derived from the investment in complementary assets used in the business enterprise.⁷ The technology that requires less investment in fixed assets to achieve its potential is more valuable than a technology requiring large complementary asset investments. A larger royalty rate is appropriate for a technology that can be commercialized while using less complementary assets.

Duration of profits refers to the future period during which the economic benefit will continue. This can be determined by patents lives or technology obsolescence.

Risk of receiving the expected economic returns captures the investment rate of return requirements to associate with an invention when calculating its value.

Listed below are some of the complex factors that should be reflected in technology pricing and valuation even if only on a qualified basis when negotiating royalty rates. Three economic factors are identified along with a subset of factors for each of the primary ones.

- ◆ Economic Benefits Derived From The Technology
 - Benefits derived from complementary assets
 - Competitor efforts impacting the economic benefits
 - Consumer reactions
 - Management competency
 - Production efficiencies
 - Commercialization expenses
 - Commercialization time frame requirements
- ◆ Duration Of The Economic Benefits
 - Rapid technological obsolescence
 - Alternate technologies
 - Validity of patent
 - Changing consumer reactions
- ◆ Risk Of Receiving The Economic Benefits
 - Technology risk
 - Economic risk
 - Regulatory risk
 - Market risk
 - Inflationary risk

⁶ An underlying assumption in this discussion is that the rights associated with the intellectual property in question are valid and enforceable.

⁷ Complementary assets are all the other business enterprise assets – working capital, fixed assets and intangible assets.

- Unexpected conditions and events

The Center for Biotechnology at the Kellogg School of Management, Northwestern University studied 105 biotechnology deals covering 1992 to 2001.⁸ The study focused on analyzing the value drivers in licensing deals and concluded:

1. Pharmaceutical companies are willing to pay more for products than are biotechnology companies. Using regression analysis, the authors found that pharmaceutical companies paid twice what biotech companies paid for acquisitions and licenses.
2. Buyers pay more for revolutionary products, which open up new markets or redesign the value chain, than evolutionary products, which improve existing products or processes.
3. Deal value is not driven by molecule size. Even though pharmaceutical companies view smaller molecules as easier to manufacture, easier to deliver and less risky, deal numbers do not vary in relation to molecule size. More important is technology serving large markets such as neurological, cardiovascular or cancer.

How do we begin to value and price intellectual property?

SIMPLISTIC RULES OF THUMB

Some of the general rules used to determine a royalty rate are discussed below along with their weaknesses.

Profit Split Rule of Thumb

Fully stated, this method calculates a royalty as 25% to 33¹/₃% of the profit, before taxes, from the enterprise operations in which the licensed intellectual property is used. In the past, profits had not been accurately defined where this rule is discussed. Gross profits, based on generally accepted accounting principle definitions, reflect the direct costs of production - manufacturing expenses. These include raw material costs, direct labor costs, utility expenses, and even the depreciation expenses of the manufacturing facilities. All of the costs and expenses associated with conversion of raw materials into a final product or service are captured in the gross profit figure. Since this is often the area of greatest contribution from intellectual property, consideration of the amount of gross profits seems reasonable. It fails however to consider the final profitability that is ultimately realized from the intellectual property. Absent from the analysis are operating expenses such as selling, administrative, and general overhead expenses. An argument for eliminating these operating expenses from the analysis might center on the idea that the value of intellectual property, such as manufacturing technology, is best measured by the enhancement of profits in the area of the business in which they have the most direct effect. A more broadened view however shows that an intellectual property royalty can be affected by selling expenses and other on-going operating expenses that are part of the commercialization.

Intellectual property that is part of a product or service which requires small amounts of marketing, advertising and selling effort is far more valuable than a product based upon intellectual property that requires huge efforts in these areas. When national advertising campaigns, highly compensated sales personnel and highly skilled technical support people are needed to provide customer support, bottom line profits are lowered. Two patented products may

⁸ Value drivers in licensing deals, by Katie Arnold, Anthony Coia, Scott Saywer, Ty Smith, Scott Minick and Alicia Loffer, *Nature Biotechnology*, November 2002, Vol. 20, page 1085.

cost the same amount to produce, each yielding a substantial gross profit. Yet, one of the products may require extensive and continuing sales and/or technical support. The added costs of extensive and continuing sales efforts make the first product less profitable to the licensee from a bottom line measure. While the two products may have the same gross profit margins it is very unlikely that they would command the same royalty given the different conditions regarding selling and support costs.

The operating profit level, after consideration of the non-manufacturing operating expenses, is a more accurate determinant of the contribution of the intellectual property. The royalty for specific intellectual property must reflect the industry and economic environment in which the property is used. Some environments are competitive and require a lot of overhead support costs that reduce net profits. Intellectual property used in this type of environment is not as valuable as intellectual property in a high profit environment where less support costs are required. A proper royalty must reflect this aspect of the economic environment. A royalty based on gross profits alone cannot reflect this reality. It is more appropriate to apply the 25% to 33¹/₃% multiplier to the operating profit margin expectations.

The 25% Rule came into fairly common usage decades ago. As times change a question is raised about whether the factual underpinnings for the rule still exist (i.e., whether the rule has much positive strength) such that it can and should continue to be used as a valid pricing tool (i.e., whether the rule has much normative strength). In Use Of The 25 Percent Rule In Valuing IP by Robert Goldscheider, John Jarosz and Carla Mulhern (published in *les Nouvelles* December 2002) the authors examined the relationship between royalty rates and company profit data. In general, they found that the rule is still a valuable tool. The authors conclude “The rule continues to have a fair degree of both ‘positive’ and ‘normative’ strength.”

There still exists some confusion as to where to apply the 25% factor. Shown below is a simple income statement for a hypothetical product. Where do you think the 25% factor should be applied? There are quite a few choices for application of the Profit Split Rule of Thumb and they include the following:

- ◆ Incremental Profit margin of 70%?
- ◆ Gross Profit margin of 55%?
- ◆ Operating Profit margin of 23%?
- ◆ Pretax Income margin of 9%?
- ◆ Net Income margin of 5%?

The appropriate profit margin to which the 25% factor should be applied is the operating profit margin of 23%.

Application of the 25% Rule in this case yields an indication of a royalty of 5.75% on net sales as the royalty base – (25% of the 23% operating profit margin). The reason has to do with the business enterprise framework and the complementary assets used to commercialize the patented invention. Remember, while patent rights are powerfully valuable they are just a piece of paper unless other assets are brought forward to commercialize them. The profits available for split between a licensor and licensee must allow for all of the operational expenses associated with making and selling the patented invention. There must also be an allowance for organizational

overhead. All of these non-manufacturing assets are directly related to commercialization and must be considered before application of a profit split. No allowance should be made for financing costs such as interest expenses. The financial structure used by a licensee has little to do with the value contributed by a patented invention. Some licensees may rely heavily on debt. After interest expenses profit margins may vaporize even after a patented invention provided enormous economic benefits.

It is the same for taxes. The tax structure and strategy of the licensee may contribute to the value of the licensee's company but it has nothing to do with the economic contribution of the patented invention. The profit split percentage should be applied before provision for income taxes. Afterward the licensee and licensor can go their separate ways and pay their respective taxes.

Typical Income Statement

Revenues	\$ 100,000	100%
Variable Manufacturing Costs	\$ 30,000	30%
Incremental Profit	\$ 70,000	70%
Fixed Manufacturing. Costs	\$ 15,000	15%
Total Cost of Goods	\$ 45,000	45%
Gross Profit	\$ 55,000	55%
Selling Expenses	\$ 10,000	10%
Marketing Expenses	\$ 10,000	10%
Administration	\$ 5,000	5%
General Overhead.	\$ 7,500	8%
Total SG&A Expenses	\$ 32,500	33%
Operating Profits	\$ 22,500	23%
Interest Expenses	\$ 3,500	4%
Extraordinary Restructuring	\$ (10,000)	-10%
Income before taxes	\$ 9,000	9%
Provision for Income Taxes	\$ 3,600	4%
Net Income	\$ 5,400	5%

Royalty Rates and Return on R&D Costs

When considering a reasonable royalty the amount spent on development of the intellectual property is a terribly attractive factor to consider. Unfortunately development costs are also terribly misleading. The analysis presented throughout this section of the report concentrates on providing a fair rate of return on the value of the intellectual property assets. The amount spent in the development is rarely equal to the value of the property. A proper royalty should provide a fair return on the value of the asset, regardless of the costs incurred in development.

The underlying value of intellectual property is founded on the amount of future economic benefits expected to be derived from commercialization of the property. Factors that can limit these benefits include the market potential, the sensitivity of profits to production costs, the period of time over which benefits will be enjoyed and the many other economic factors that have already been discussed. Development costs do not reflect these factors in any way. Basing a royalty on development costs can completely miss the goal of obtaining a fair return on a valuable asset.

Royalty Rates and The 5% of Sales Method

For unknown reasons one of the most popular royalty rates is 5% of sales - Sales multiplied by .05 equals royalty payment. It shows up in a lot of different industries. It is associated with embryonic technology and mature trademarks. It has been found in the food, industrial equipment, electronics, construction and medical device industries. Forget profits, capital investment, earnings growth, operating expenses, investment risk and even development costs. Somehow 5% of sales prevails. Don't be fooled. It's not a magic bullet answer.

Beyond rules-of-thumb, there are general industry guidelines.

ROYALTY RATES AND INDUSTRY GUIDELINES

The Industry Guidelines method focuses on the general rates that others are charging for intellectual property licensed within the same industry. Investment risks, net profits, market size, growth potential, and complementary asset investment requirements are all absent from direct consideration. The use of Industry Guidelines places total reliance on the ability of others to correctly consider and interpret the many factors affecting royalties. Examples of general guidelines are presented below. They provide interesting information but do not help determine a specific royalty rate for a specific patent because the ranges presented are rather broad. At best, these guidelines provide an order of magnitude.

Industry	Royalty Rate
Electronics	0.5 - 5%
Machinery	0.33 - 1 0%
Chemical	2 - 5%
Pharmaceutical	2 - 10%

Source: 1998, Dr. Michael Gross, CASRIP Newsletter (V413), Actual Royalty Rates in Patent, Know-How and Computer program license agreements. This article discusses the "remuneration guidelines" of the German Law Relating to Inventions Made by Employees.

David Weiler of Royalty Source compiled 458 Pharmaceutical and Biotechnology license agreements and found the following⁹:

458 Deals	Rate
Average Royalty	7%
Median Royalty	5%
Maximum Royalty	50%
Minimum Royalty	0%

In a survey of royalty rates Degan and Horton compared royalty rates in the pharmaceutical industry with non-pharmaceutical technology transfers.¹⁰ They found the following:

⁹ www.royaltysource.com

¹⁰ A Survey of Licensing Royalties, Stephen A. Degan, and Corwin Horton, les Nouvelles, The Journal of the Licensing Executives Society, June 1997, page 91.

Category	Pharmaceutical	Non-Pharmaceutical
Revolutionary	10-15%	5-10%
Major Improvement	5-10%	3-7%
Minor Improvement	2-5%	2-3%

Information about average royalty rates by development stage is provided by Medius Associates.¹¹

Development Stage	Royalty Rate
Pre-clinical	0 - 5%
Phase I	5 - 10%
Phase II	8 - 15%
Phase III	10 - 20%
Launched Product	20%+

More focused guidance is available from Mark G. Edwards of Recombinant Capital at www.recap.com Shown below is average royalty rates for different stages of development

Average Royalty by R&D Stage	
R&D Stage	Rate
Discovery	6.4%
Lead Molecule	8.1%
Pre-Clinical	11.3%

General guidance is wonderful but something more precise is usually desired for pricing specific inventions.

¹¹ www.medius-associates.com

INFRINGEMENT DAMAGES ANALYSIS

The courts have provided some guidance for deriving royalty rates in the form of a differential profit calculation often referred to as the Analytical Approach.

The Analytical Approach

This method for deriving a reasonable royalty was first expressed in a patent infringement court decision. While a license negotiation may be independent of any legal actions, insight can be gained from considering the royalty rate models that are used in legal proceedings. The analytical approach, as dubbed by the courts, determines a reasonable royalty as the difference between profits expected from infringing sales and a normal industry profit level. The analytical approach can be summarized by the following equation:

$$\begin{array}{rcl} \text{Expected} & & \text{Normal} \\ \text{Profit Margin} & - & \text{Profit Margin} = \text{Royalty Rate} \end{array}$$

The Analytical Approach is a profit differential calculation where the profits derived from use of the technology are subtracted from the profits that would be expected without access to the technology. The difference is attributed to the technology and is considered by some as an indication of a royalty.

In *TWM Mfg. Co., Inc. v. Dura Corp.*, 789 F.2d 895, 899 (Fed. Cir. 1986) a royalty for damages was calculated based on an analysis of the business plan of the infringer prepared just prior to the onset of the infringing activity. The court discovered the profit expectations from using the infringing technology by reviewing of internal memorandums written by top executives of the company. Internal memorandums showed that company management expected to earn gross profit margins of almost 53% from the proposed infringing sales. Operating profit margins were then calculated by subtracting overhead costs to yield an expected profit margin of between 37% and 42%. To find the portion of this profit level that should be provided as a royalty to the plaintiff, the court considered the standard, *normal*, profits earned in the industry at the time of infringement. These profit levels were determined to be between 6.6% and 12.5%. These normal industry profits were considered to represent profit margins that would be acceptable to firms operating in the industry. The remaining 30% of profits were found to represent a reasonable royalty from which to calculate infringement damages. On appeal the Federal Circuit affirmed.

The Analytical Approach can work well when normal industry profits are derived from analysis of commodity products. The analysis requires that the benchmark commodity profit margin be derived from products competing in the same, or similar, industry as the infringing product, for which a reasonable royalty is being sought. The benchmark profits should also reflect similar investment requirements in complementary assets; similar to those required to exploit the enhanced product based on the infringed intellectual property.

Hypothetical Example

Presented in Figure 5 are profit margins expectations for the hypothetical Exciting Biotech, Inc. associated with commercialization of a new and patented drug therapy. The average expected profit margin is 50%. By subtracting this enhanced operating profit margin from an industry *norm*, the portion of profits that can be attributed to proprietary technology are isolated and can serve as the basis for setting a royalty.

Figure 5

New Product Revenue Forecast Exciting Biotech, Inc. (\$millions)					
	2006	2007	2008	2009	2010
Primary Market Revenues	0	25	100	300	400
Operating Profit	-25	9	50	175	225
Profit Margin	deficit	36%	50%	58%	56%
Average Profit Margin					50%

Presented in Figure 6 are the operating profit margins for a group of generic drug companies that arguably are producing commodity products. The products are competitively priced, mass produced, widely distributed and provide their makers with lower profit margins in comparison to proprietary products. The profit margins were derived from information downloaded from the Reuters.com database on public corporations. As a group, the average profit margins of these companies can be looked at as the commodity profit margin for the drugs without patent protection.

Figure 6

Generic Drug Companies Operating Profit Margins	
Company	Profit Margin
Teva Pharmaceuticals	17.0%
Mylan, Inc.	10.0%
Watson Pharmaceuticals	14.0%
Average Profit Margin	13.7%

The Analytical Approach indicates a royalty rate of approximately 36.3% as calculated by subtracting the 13.7% generic drug company profit margin from the 50% profit margin expected by Exciting Biotech, Inc. from commercialization of the new proprietary invention. It is important to note that the 36.3% advantage is the starting point for royalty rate negotiations. This is the economic benefit that should be divided, or shared, between the licensor and the licensee. In infringement litigation it can easily be argued that the entire 36.3% can be awarded as a reasonable royalty.

General Profit Margins

More data showing the profit differential between generic and patented drugs can be found in [The Risk Management Association \(RMA\) Annual Statement Studies 2003/2004](#). RMA compiles information about the balance sheets and income statements of thousands of companies. The information is classified by Standard Industry Classifications (SIC), a US government system developed by the Office of Management & Budget for classification of commercial enterprises. A comparison of the operating profit margins for different company classifications can generally provide royalty rate insight. Two SIC classifications are described below: [Pharmaceutical Preparations](#) (SIC #2834) are companies primarily engaged in manufacturing and processing drugs in pharmaceutical preparations for human or veterinary use. This broad classification likely includes companies that make and sell both patented and generic products.

Medicinal, Chemicals & Botanical Products (SIC #2833) are companies engaged in the manufacture of bulk organic and inorganic medicinal chemicals and their derivatives and processing (grading, grinding and milling) bulk botanical drugs and herbs. This broad classification likely includes companies that make and sell non-proprietary products.

The RMA Annual Statement Studies 2003/2004 indicated that pharmaceuticals companies with annual sales over \$50 million generated operating profit margins of nearly 14.4% in 2003. In comparison, companies classified as medical chemical companies earned no more than 6.6% of operating profit on sales. A general royalty rate of 7.8% is indicated by this broad comparison.¹²

More profit differential information can be found by looking at generic drug pricing.

GENERIC PRICING

Considering the price differential between proprietary drugs (under patent protection) and the same product sold as a generic drug (after patent protection expires) provides additional information that supports a royalty rate. Generic drugs are the chemical equivalent of brand name products for which patents have expired. The primary difference is the absence of patent protection. The following information indicates the enormous value of patent protection.

Eon Labs states that generic drugs sell for 20% to 80% below branded counterparts depending on the number of generic equivalents in the marketplace.¹³

The Center for Medicare & Medicaid Services recently conducted a study showing that using generic drugs in place of brand name drugs can save between 43% and 96%. Details of the study are presented below:¹⁴

Generic Drug Savings			
Generic versus (Brand Name)	Brand Price	Generic Price	Savings %
Warfarin (<i>Coumadin</i>)	19.76	11.20	43%
Metformin (<i>Glucophage</i>)	76.65	18.24	76%
Furosemide (<i>Lasix</i>)	7.44	3.84	48%
Benazepril (<i>Lotesin</i>)	31.31	7.96	75%
Glyburide (<i>Micronase</i>)	18.88	5.63	70%
Lisinopril (<i>Prinivil</i>)	28.04	6.51	77%
Fluoxetine (<i>Prozac</i>)	106.26	4.18	96%
Enalapril (<i>Vasotec</i>)	46.14	6.10	87%
Verapamil hcl SR (<i>Verelan SR</i>)	62.76	20.83	67%
Lisinopril (<i>Zestril</i>)	29.01	9.86	66%

Source: Medical Price Compare 09/27/04

A 2004 press release from Leiner Health Products reports that the company supplies nearly 30 retailers with 10 mg Loratadine tablets retailing for about

¹² It should be stressed that the operating profit margin of 14.4% is most likely weighted downward by the lower profit margins associated with generic drugs that are part of the pharmaceutical preparations classification.

¹³ Eon Labs, 12/31/2003 SEC 10K Report

¹⁴ <http://www.cms.hhs.gov/medicarerreform/drugcard/drugcardreports.asp>

\$0.37 per pill compared to the branded equivalent Claratin, priced at \$0.96 per pill. This represents a \$0.59 savings per pill or 61.5%.¹⁵

Business Week reported in 1994 that the patent protection for the ulcer drug Tagamet was about to expire and “Mylan Laboratories is planning a clone of Tagamet for half the price”.¹⁶ In the same story Business Week reported, “Gross margins for generics are 50% to 60%, vs. 90% to 95% for branded products...” A profit differential analysis indicates a royalty rate of between 30% and 45%.¹⁷ Business Week also discussed a 1994 strategy being followed by the proprietary drug companies.¹⁸ Faced with huge market share losses when a proprietary drug loses patent protection these companies introduced their own versions of generics. Business Week said “The majors often price generics at only 10% to 25% less than the brand-name product, while generics ideally should be half the full price.”

Forbes reported in 1994 that patent protection for Naprosyn, a \$500 million (1992 annual sales) arthritis drug made by Syntex expired in December 1993.¹⁹ Prior to the loss of patent protection the company introduced in October 1993 a generic version of the drug to try to ease the loss of its market share. A few months after the launch of Syntex’s generic version, five other generic drug companies entered the market. Forbes said “Soon the generics were selling at one-tenth [10%] of Naprosyn and had over 80% of the market”. A royalty rate of 90% is indicated by this information.

Pharmaceutical Business News, a medical and health industry publication, reported “Generic drugs typically cost 30% to 50% less than their brand-name counterparts”.²⁰

Chemical Marketing Reporter a pharmaceutical industry publication, reported, “Industry analysts agree that brands will continue to be new drug innovators and generics will provide off-patent copies at one-fifth to one-half of the price [50%]”.²¹

Comparison of drug prices between developed and third world countries also demonstrates the generic versus patented drug differential. A comparison of prices for HIV/AIDS medicines illustrates the fact that the pharmaceutical companies sell their patented medicines at much higher prices than those charged by generic producers.

Glaxo prices 3TC (Lamivudine) in the US at \$3,271 for a year’s supply per

¹⁵ Leiner Health Products press release, June 22, 2004, www.leiner.com

¹⁶ A Big Dose of Uncertainty - An industry plagued by high costs faces health-care reform, Business Week, January 10, 1994, page 85.

¹⁷ Ibid. Also, as can be seen in the Licensing Agreements section of this report, agreements involving successfully commercialized products command this level of royalty rate.

¹⁸ The Drugmakers vs. The Trustbusters, Business Week, September 5, 1994, page 67.

¹⁹ Drug wars, Forbes, August 29, 1994, page 81.

²⁰ Market forces usher in a golden age of generic drug, Pharmaceutical Business News, November 29, 1993, published by Financial Times Business Information, Ltd., London, UK.

²¹ Into the mainstream (greater cooperation between generic drug and name-brand drug makers), Chemical Marketing Reporter, March 9, 1992, Schnell Publishing Company, Inc.

patient but in India generic manufacturers Cipla Ltd. and Hetero Drugs charge \$190 and \$98 respectively for a year's supply. The savings is 94% and 97% respectively.²²

Bristol-Myers Squibb sells Zerit (Stavudine) in the US for \$3,589 for a year's supply per patient. In India, Cipla and Hetero sell the generic version for \$70 and \$47 respectively. The savings is 98% and almost 99% respectively,²³

Beohringer Ingelheim sells Viramune (Nevirapine) in the US for US \$3,508 per patient year while Cipla and Hetero sell the generic equivalent in India for \$340 and \$202 respectively. The savings is 90% for Cipla's product and 94% for Hertero's version.²⁴

Cipla offers a year supply of the generic versions of 3TC, Zerit and Viramune for \$350 to \$600 as compared to the price of the patented medicines of between \$10,000 and \$15,000. The savings ranges between 94% and 97.7%²⁵

Another example of the price pressure provided by generic drugs can be illustrated by fluconazole. In Thailand this generic drug costs \$0.29 and in India it costs \$0.64. The patented version costs \$10.50 in Kenya, \$27.00 in Guatemala and \$8.25 in South Africa.²⁶ When the Brazilian government began producing AIDS drugs generically, the price of equivalent patented products dropped by 79%²⁷

For those not comfortable with calculations, conducting a comparable analysis can help develop royalty rates.

COMPARABLE LICENSE TRANSACTIONS

The amount at which independent parties licensed similar intellectual property can provide an indication of a reasonable royalty. Market transactions considered useful for deriving reasonable royalties are usually between unrelated parties where intellectual property is the focal point of the deal. Transactions most often cited, as useful indications for reasonable royalties are license agreements, which disclose the compensation terms for other licenses involving the intellectual property being studied. As an alternative, an analysis of licensing transactions involving *similar* intellectual property is often relied on for deriving reasonable royalties. Many aspects of market transactions should be studied closely before a specific transaction can be concluded as representing a reasonable royalty for comparison purposes. The remainder of this section considers the appropriateness of using unrelated license agreement royalty terms as a proxy for a subject case.

²² Patents vs patients: AIDS, TNCs and Drug Price Wars by Kavaljit, Public Interest Research Centere, 2001.

²³ id

²⁴ id

²⁵ id.

²⁶ Patent Injustice: How World Trade Rules Threaten the Health of Poor People, Oxfam Briefing paper, 2001.

²⁷ Prescriptions for Action, MSF Briefing for the European Parliament of Accelerated Action targeted at Major Communicable Diseases with the Context of Poverty Reduction, Medicines Sans Frontiers, 2001.

Internal Licenses Are Often Self-serving

Multinational corporations often transfer intellectual property to foreign subsidiaries. Parent companies often own keystone intellectual property and their subsidiaries hold licenses allowing them to use the property. These licenses are referred to as internal, or inter-company licenses. They had not usually been reliable market transactions for deriving reasonable royalties. Many of the royalty terms in these types of transactions were structured to shift income into jurisdictions with lower income tax burdens. Hence the royalty rate did not reflect the economic contribution of the intellectual property but reflected the differential corporate income tax rates between a multi-national corporate parent and a foreign subsidiary. Internal licenses were missing a fundamental element because the royalty terms were not established by arms-length negotiation where each party to the transaction argued their self-interests. Many other self-serving issues clouded royalties specified in internal licenses. This is beginning to change. International taxing authorities are looking at transfer pricing issues and intellectual property is getting close scrutiny. Many corporations are commissioning studies to use as the basis of their intellectual property pricing. These studies are based on market transactions and the investment rate of return analyses explored later in this book. Such studies are not common, as the IRS does not closely scrutinize many companies. As more corporations set internal transaction pricing in-line with third-party transaction pricing internal licenses will become useful indications of royalty rates.

Relevant Time Period

The price paid for a stock in the past is an interesting notation but has little to do with a current pricing analysis. The same is true when corporations engage in mergers and acquisitions. The prices at which businesses are exchanged seldom relate to amounts at which prior transactions were consummated. When considering the purchase of an investment real estate property a lot of analysis goes into determining the price to offer. Included are consideration of prevailing interest rates, inflation, rental income, operating expenses, property taxes and income taxes. All of these considerations are analyzed from the perspective of quantifying future expectations about profits and return on investment. Very little, if any, consideration is given to the price at which the property has historically changed hands. Manhattan Island was originally purchased from the original owners for \$24 worth of novelty trinkets. Historic transaction prices are interesting footnotes but not usually relevant for current transaction pricing. It's no different for intellectual property. A reasonable royalty must be based on future expectations that both the licensee and the licensor individually possess and which eventually converge as negotiations reach a conclusion. Reasonable royalties must be determined with an eye to the future.

Financial Condition of Both Licensing Parties

When one of the parties in a license transaction is desperate to complete it the amount paid for the license is clouded. A nearly bankrupt licensor may not have enough time to shop for the best offer and could leave a significant amount of money on the negotiating table. On the other hand, a manufacturing company with obsolete technology may find itself going out of business without access to new technology. A fair and reasonable royalty is best determined in an environment where both of the negotiating parties are on equal footing. Both parties should have the option to walk away from the deal. When ancillary forces are compelling one of the negotiating parties to capitulate to the demands of the other, then a fair and reasonable royalty may be not indicated.

Relevant Industry Transactions

Some licenses may involve property that is similar to a specific property under negotiation but the property is licensed for use in a different industry. To be useful for deriving a fair market royalty a proxy royalty rate must have been negotiated for similar property that is used in a similar industry. Each industry has its own set of unique economic forces. Some are highly competitive like consumer electronics. Others are oligopolies like airlines. Some industries are sensitive to interest rates - construction. Some industries are under strong pressure from foreign producers - apparel. Others are only regionally competitive - gravel quarries. All of these factors drive the profitability and growth prospects of the industry participants. These factors also impact the amount of economic benefits that intellectual property can contribute to a commercial operation that directly relates to the royalties that can be considered reasonable.

International Transactions

In developing nations where intellectual property protection is weak, the amount paid for a license would likely be far less than in developed nations where intellectual property rights are respected. A low rate in developing nations reflects that exclusive use of the property may not be realistic regardless of what the license agreement says. A low royalty in some countries might also reflect differences in governmental regulation, inflation, and general economic conditions. As such, license agreements in different countries might possess different royalty rates for the same intellectual property, none of which may be relevant for a specific case depending on the country into which the technology in question is being licensed.

Non-monetary Compensation

Compensation for the use of intellectual property can take many different forms. Sometimes cash alone is the basis of licensing compensation. The licensee makes a cash payment and no further payments are required. Lump sum payments with additional running royalties are another example of license compensation. Running royalties alone are another example. Sometimes the licensor gets a royalty and also an equity interest in the licensee's company. Sometimes the licensor gets only an equity interest. License agreements can also call for the licensee to share technological enhancements, as grant-backs, with the licensor. In return the licensee might demand a lower royalty rate because a portion of the licensor's compensation will be in the form of access to enhancements of the original property. For similar license agreements to be used as a proxy for derivation of a fair market royalty, the form of license compensation must be on a like-kind basis.

Exclusivity

What should the basis of reasonable royalties be regarding the aspect of exclusivity? Typically, higher royalty rates are associated with license agreements providing the licensee with exclusive rights to use the intellectual property. An exclusive right to use a keystone intellectual property places the licensee in a superior position. If the intellectual property provides highly desirable utility then premium prices can be demanded for the product. Competitors cannot counter with the same product, without risking infringement, and the exclusive licensee will earn superior profits. Such an arrangement is worth higher royalty payments. DuPont once negotiated a license involving worldwide and exclusive rights to a drug patent. Later the agreement was renegotiated to a non-exclusive basis. As a result the royalty dropped by 27%.

Package Licenses

Licenses don't always grant use of one specific item of intellectual property. Several patents may be granted as a group with one royalty rate specified as compensation for all of the property. Sometimes patents and trademarks are licensed together for a single royalty. Sometimes they are licensed separately. A problem of comparability arises however when licenses that are used for comparison cover not only a similar patent but also grant use for other property not pertinent to the subject analysis.

Comparative Analysis Summarized

Comparative analysis of similar technology licenses can be very useful for negotiating royalty rates but many aspects of the license agreement must be analyzed for a royalty provision to be a useful proxy. In a perfect world useful proxy licenses for establishing a fair market royalty would:

- 1) not be an internal license between a parent corporation and a subsidiary;
- 2) have been negotiated at a date that is relevant to the date of the subject analysis;
- 3) have been negotiated between two independent parties, neither of which were compelled to complete the transaction because of financial distress;
- 4) involve similar intellectual property licensed for use in the same industry in which the fair market royalty is desired;
- 5) transfer license rights for use of similar intellectual property into a country having similar economic conditions as the country in which the fair royalty is desired;
- 6) involve similar intellectual property with similar remaining life characteristics;
- 7) require similar complementary asset investment requirements for commercial exploitation;
- 8) specify royalty terms that are not clouded by non-monetary components of compensation;
- 9) include comparable aspects of exclusivity;
- 10) include royalty terms that were freely negotiated and unencumbered by governmental regulations;
- 11) specify royalty terms that are not clouded by undefined amounts that are indirectly attributed to other assets in the deal.

The next section shows a very financially oriented analysis for those comfortable with calculations.

INVESTMENT RATE OF RETURN ANALYSIS

This section presents an approach for determining a royalty rate based on investment rate of returns. This analysis requires consideration of the profits expected from exploitation of the various assets of a business including the technology that will be licensed. By allocating a fair rate of return to all of the integrated assets of a business, including the licensed technology, a fair rate of return for use of a specific patent can be derived and expressed as a royalty rate.

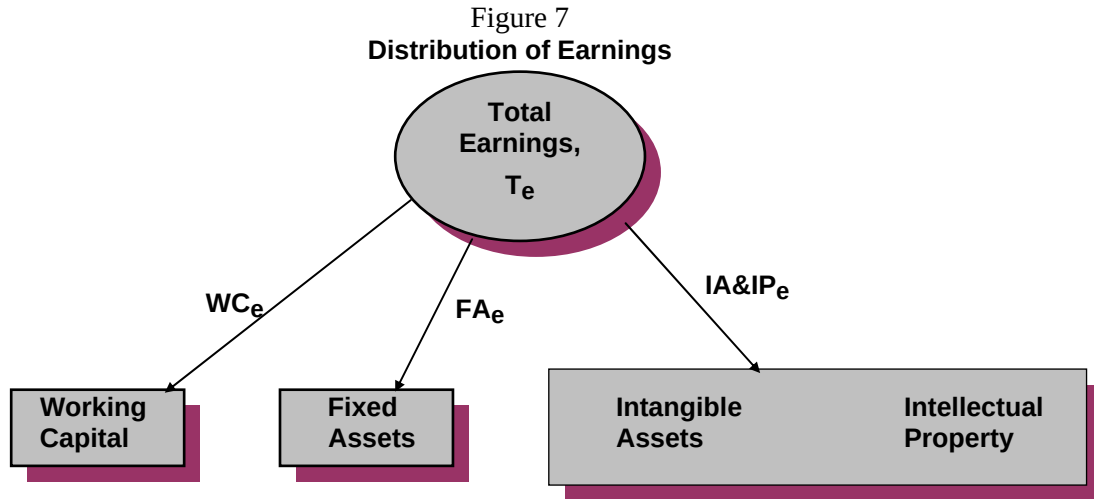
Basic Principles

The basic principles in this type of analysis involve looking at the total profits of a business and allocating the profits among the different classes of assets used in the business. When a business demonstrates an ability to earn profits above that which would be expected from operating a commodity oriented company then the presence of intellectual property, such as patented technology is identified. An allocation of the total profits derived from using all assets of the company can attribute a portion of the profits to the technology of a business. When the profits attributed to technology are expressed as a percentage of revenues, royalty rate guidance is obtained.

The investment rate of return analysis yields an indication of a royalty rate for a technology license after a fair return is earned on investment in the other assets of the business. Thus, a royalty rate conclusion that is supported by an investment rate of return analysis allows for payment of a royalty to a licensor while still allowing a licensee to earn a fair investment rate of return on its own, non-licensed assets used in the business.

Investment Rate of Return Royalty Rates

This section of the report explores the use of financial analysis techniques to derive royalty rates. The method is based on the idea of allocating the total earnings of a technologically based business among the different asset categories employed by the business. Figure 9 starts with the concepts introduced earlier and adds notations that will be used in the following paragraphs to develop the method. The earnings of a business are derived from exploiting its assets. The amount of assets in each category along with the nature of the assets, and their quality, determines the level of earnings that the business generates. Working capital, fixed assets and intangible assets are generally commodity types of assets that all businesses can possess and exploit. As previously discussed, a company that possesses only these limited assets will enjoy only limited amounts of earnings because of the competitive nature of commodity-dominated businesses.



A company that generates superior earnings must have something special - intellectual property in the form of patented technology, trademarks or copyrights. The distribution of the earnings among the assets is primarily driven by the value of the assets and the investment risk of the assets. The total earnings of the company (T_e) as expressed below, are comprised of earnings derived from use of working capital (WC_e), earnings derived from use of fixed assets (FA_e) and earnings derived from use of intangible assets and intellectual property ($IA\&IP_e$).

$$T_e = WC_e + FA_e + IA\&IP_e$$

The earnings associated with use of intangible assets and intellectual properties are represented by $IA\&IP_e$. This level of earnings can be further subdivided into earnings associated with the use of the intangible assets (IA_e) and earnings associated with the use of intellectual property (IP_e) as shown below:

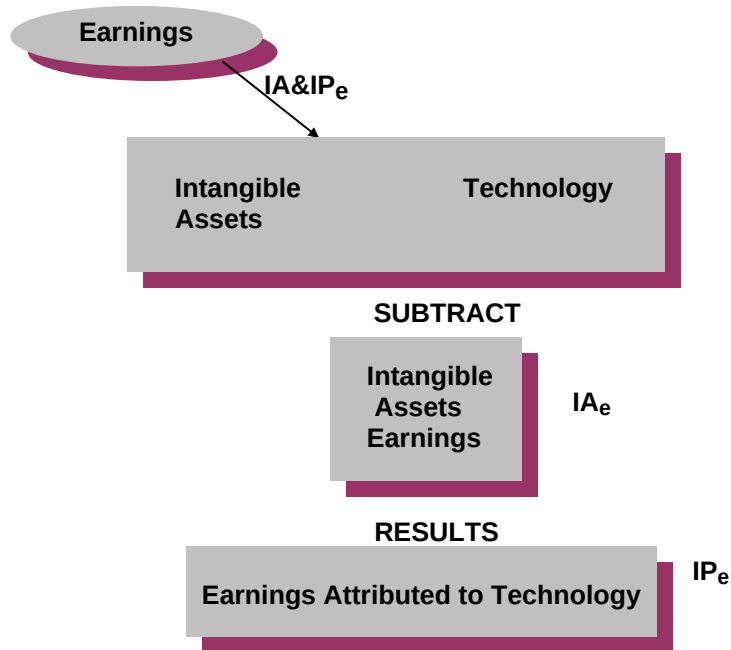
$$IA\&IP_e = IA_e + IP_e$$

Royalty Rates

An appropriate royalty rate is equal to the portion of IP_e that can be attributed to the use of the subject technology. The royalty rate to associate with a specific technology equals the earnings derived from the technology divided by the revenues derived with the technology as shown in Figure 8.

Specifically, a company lacking intangible assets and technology would be reduced to operating a commodity-oriented enterprise where competition and lack of product distinction would severely limit the potential for profits. Conversely, companies possessing proprietary assets can throw-off the limitations of commodity oriented operations and earn superior profits.

Figure 8
Excess Earnings as a Percent of Revenues



When a portion of the profit stream of a company is attributed to the proprietary assets of a company, an indication of the profits contributed by the existence of the proprietary assets is provided and a basis for a royalty is established when the attributed profits are expressed as a percentage of the corresponding revenues. The total profits can be allocated among the different asset categories based on the amount of assets in each category and the relative investment risk associated with each asset category.

Shown on Figure 9 is an allocation of the weighted average cost of capital²⁸, for an example business enterprise, allocated among the business assets used in the business enterprise. The various rates of return assigned to each of the assets reflect their relative risk.²⁹ The relative returns provided by each asset category are also indicated.

²⁸ The weighted average cost of capital is an investment rate of return required from business investments that is a weighting of the rates of return required by debt and equity investors. More information about the appropriate rate of return for this type of analysis can be found in Intellectual Property: Valuation, Exploitation & Infringement Damages, Gordon V. Smith and Russell L. Parr, John Wiley & Sons.

²⁹ The rates used in this example are for demonstration purposes only. Changing economic conditions must be considered each time this method is used.

Figure 9

Example Company Inc. Required Return on Intangible Assets & Intellectual Property (IA & IP)					
Asset Category	Amount	Percent	Required Return	Weighted Required Return	Allocated Weighted Return
Net Working Capital	10,000	10%	7.00%	0.70%	7.7%
Fixed Assets	20,000	20%	11.00%	2.20%	2.0%
IA & IP	<u>70,000</u>	<u>70%</u>	13.85%	<u>9.70%</u>	<u>90.3%</u>
Invested Capital	100,000	100%		12.60%	100.0%

Appropriate Return on Monetary Assets

The monetary assets of the business are its net working capital. This is the total of current assets minus current liabilities. Current assets are comprised of accounts receivable, inventories, cash, and short-term security investments. Offsetting this total are the current liabilities of the business such as accounts payable, accrued salaries, and accrued expenses. The value of this asset category can usually be taken directly from a company balance sheet.

Working capital is considered to be the most liquid asset of a business. Receivables are usually collected within 60 days and inventories are usually turned over in 90 days. The cash component is immediately available and security holdings can be converted to cash with a telephone call to the firm's broker. Further evidence of liquidity is the use of accounts receivable and/or inventories as collateral for loans. In addition, accounts receivable can be sold for immediate cash to factoring companies at a discount of the book value. Given the relative liquidity of working capital the amount of investment risk is inherently low. An appropriate rate of return to associate with the working capital component of the business enterprise is that which is available from investment in short term securities of low risk levels. The rate available on 90-day certificates of deposit or money market funds serves as an appropriate benchmark.

Appropriate Return on Tangible Assets

The tangible or fixed assets of the business are comprised of production machinery, warehouse equipment, transportation fleet, office buildings, office equipment, leasehold improvements, office equipment and manufacturing plants. The value of this asset category may not be accurately reflected on company balance sheets. Aggressive depreciation policies may state the net book value at an amount lower than the fair market value on which a return should be earned. Correction of this problem can be accomplished by estimating fair market value somewhere in-between original equipment costs and net book value. A midpoint between the two points is usually a reasonable compromise. Accuracy in this area is not crucial for the drug business. The amount and value of tangible assets used in the industry is usually minor relative to the value of revenues, earnings, markets and the value of the entire business enterprise.

An indication of the rate of return that is contributed by these assets can be pegged at about the interest rate at which commercial banks make loans, using the fixed assets as collateral. While these assets are not as liquid as working capital they can often be sold to other companies. This

marketability allows a partial return of the investment in fixed assets should the business fail. Another aspect of relative risk reduction relates to the strategic redeployment of fixed assets. Assets that can be redirected for use elsewhere in a corporation have a degree of versatility, which can still allow an economic contribution to be derived from their employment even if it isn't from the originally intended purpose.

While these assets are more risky than working capital investments they possess favorable characteristics that must be considered in the weighted average cost of capital allocation. Fixed assets that are very specialized in nature must reflect higher levels of risk, which of course demands a higher rate of return. Specialized assets are those, which are not easily redeployed for other commercial exploitation or liquidated to other businesses for other uses.

Appropriate Return on Intangible Assets and Intellectual Property

Intangible assets can be considered as the most risky asset components of the overall business enterprise. These assets may have little, if any, liquidity and poor versatility for redeployment elsewhere in the business.³⁰ This enhances their risk. Customized computer software for tracking the results of clinical studies may have very little liquidation value if the company fails. The investment in trained employees that know how to get government approvals may be altogether lost and the value of other elements of a going concern are directly related to the success of the business. A higher rate of return on these assets is therefore required.

An appropriate investment rate of return is then derived, and assigned to the intangible assets and intellectual property of the business, including the infringing technology, by using the weighted average cost of capital for the business, the return on fixed assets deemed appropriate and the return on working capital deemed appropriate. The earnings associated with the intellectual property and intangible assets of the company are then calculated as depicted in Figure 9. Conversion of these earnings into a royalty rate can be accomplished by dividing the earnings by the associated revenues

Figure 9 tells us that over 90% of the profits of Example Company, Inc. are derived from intangible assets and intellectual property. If Example Company shows operating profits of 20% on sales then 18% of sales should be attributed to intangible assets and intellectual property. Depending on the characteristics of the subject technology it may deserve to have the majority of the 18% attributed to its contribution to the business. The final allocation requires considering the amount, types and importance of other intellectual property used in the business. The royalty just derived may include earnings derived by the business from exploitation of intellectual property and intangible assets unrelated to specific technology.

Royalty Rate for the Specific Patented Invention

The next step answers the question - *How much of a royalty rate should be subtracted from the derived 18% royalty rate to isolate the portion that is attributable to only the subject patents?* It must be remembered that the 18% rate is for all of the intangible assets and intellectual property possessed by Example Company, Inc. including use of the subject patented invention?

The answer to this question can be estimated by focusing on a company that operates in a similar industry and possesses most of the intangible assets possessed by a typical company. However

³⁰ The liquidity of intellectual property is starting to change. Recently, music copyrights served as the basis for investment securities when the pop-song artist David Bowie pledged a large collection of music copyrights and the royalties they generate as the foundation for bonds.

the selected company must be one that does not possess or use proprietary and patented inventions. By duplicating the same analysis presented in Figures 9 for a surrogate company we can isolate the amount of income to associate with all intangible assets and intellectual property *except* for the subject patent. When this analysis was concluded the royalty rate to associate with everything other than the subject patent was 10%. The difference is the royalty rate to associate with the subject patent – 8%:

$$\begin{array}{c}
 \textbf{Example Company, Inc.} \\
 \textbf{Royalty Rate for} \\
 \textbf{Patented Therapeutic Drug} \\
 \\
 \begin{array}{|c|} \hline \text{Investment Rate of Return Associated} \\ \text{with all Intangible Assets} \\ \text{and Intellectual Property of} \\ \text{Example Company, Inc. Including the} \\ \text{Patented Therapeutic Drug} \end{array} \\
 \\
 \textbf{Minus} \\
 \\
 \begin{array}{|c|} \hline \text{Investment Rate of Return Associated} \\ \text{with all Intangible Assets} \\ \text{and Intellectual Property of} \\ \text{Surrogate Pharmaceutical} \\ \text{Companies Excluding the} \\ \text{Patented Therapeutic Drug} \end{array} \\
 \\
 \textbf{Equals} \\
 \\
 \begin{array}{|c|} \hline \text{Royalty Rate Associated with the} \\ \text{Patented Technology} \end{array}
 \end{array}$$

When IP_e includes earnings from non-licensed intellectual property another step is needed to develop a proxy for earnings that represent the contribution from the non-infringing IP_e . Attribution of earnings for intangible assets can be accomplished by an investment rate of return analysis that derives a royalty for a company that possesses intangible assets but not technology. These earnings can serve as a proxy for the intangible assets earnings of the subject company. When they are subtracted from the earnings associated with $IA \& IP_e$ then only the earnings for IP_e are left. When these remaining earnings are converted to a royalty then a royalty rate for use of specific technology is indicated.

Benefits of Investment Rate of Return Analysis

An investment rate of return analysis enhances royalty rate determination by:

1. Considering the investment risk associated with the business and industry environment in which the licensed technology will be used.
2. Reflects specific commercialization factors associated with the licensed technology as embedded in forecasts associated with sales, production costs and operating expenses.
3. Allows for an investment return to be earned on the fixed assets used in the business

4. Allows for an investment return to be earned on the working capital assets used in the business.
5. Allows for an investment return to be earned on the other intangible assets and intellectual property used in the business *other than* the subject patent.

The next section allows for very specific analysis for very specific circumstances on the cusp of commercialization.

DISCOUNTED CASH FLOW ANALYSIS

A variation of the investment rate of return analysis can also be used for royalty rate derivation. This alternate method makes use of a discounted cash flow analysis, which converts a stream of expected cash flows into a present value. The conversion is accomplished by using a discount rate reflecting the risk of the expected cash flows. In addition to the benefits previously listed from using an investment rate of return analysis, the discounted cash flow analysis also reflects the:

- ◆ Time period during which economic benefits will be obtained.
- ◆ Timing of capital expenditure investments.
- ◆ Timing of working capital investments
- ◆ Timing and amount of other investments in intellectual property and intangible assets not associated with the subject technology.

First, the traditional discounted cash flow will be discussed along with an example. Then, another model will be presented that incorporates clinical-trial success rates. The combination of a traditional DCF model and clinical trial success rates allows for valuation and pricing of inventions at different stages of development.

The basis of all value is cash. The net amount of cash flow thrown-off by a business is central to corporate value. Net cash flow, also called free cash flow, is the amount of cash remaining after reinvestment in the business to sustain continued viability of the business. Net cash flow can be used for dividends, charity contributions or diversification investments. Net cash flow is not needed to continue fueling the business. Aggregation of all future net cash flows derived from operating the business, modified with respect to the time value of money, represents the value of a business. A basic net cash flow calculation is depicted below:

NET SALES minus
MANUFACTURING COSTS equals
 GROSS PROFITS

GROSS PROFITS minus
 MARKETING EXPENSES and
 GENERAL OVERHEAD EXPENSES and
 ADMINISTRATION EXPENSES and
SELLING EXPENSES equal
 OPERATING PROFITS

OPERATING PROFITS minus
INCOME TAXES equals
 NET INCOME

NET INCOME plus
DEPRECIATION equals
 GROSS CASH FLOW minus
 ADDITIONS TO WORKING CAPITAL and
ADDITIONS TO FIXED PLANT INVESTMENT equals
 NET CASH FLOW

Sales represent the revenue dollars collected by the company from providing products or services to customers. Net sales are the amount of revenues that remain after discounts, returns and refunds.

Manufacturing costs are the primary costs associated with making or providing the product or service. Included in this expense category are expenses associated with labor, raw materials, manufacturing plant costs and all other expenses directly related to transforming raw materials into finished goods.

Gross profit is the difference between net sales and manufacturing costs. The level of gross profits reflects manufacturing efficiencies and a general level of product profitability. It does not, however, reflect the ultimate commercial success of a product or service. Many other expenses important to commercial success are not accounted for at the gross profit level. Other expenses contributing to successful commercialization of a product include:

- Research expenses associated with creating new products and enhancing old ones.
- Marketing expenses required for motivating customers to purchase the products or service.
- General overhead expenses required for providing basic corporate support for commercialization activities.
- Selling expenses associated with salaries, commissions and other activities that keep product moving into the hands of customers.

Operating profits reflect the amount left over after non-manufacturing expenses are subtracted from gross profits.

Income taxes are expense of doing business and must be accounted for in valuing any business initiative.

Depreciation expense is calculated based on the remaining useful life of equipment that is purchased for business purposes. It is a non-cash expense that allocates the original amount invested in fixed assets to annual operations. Depreciation is calculated to account for the deterioration of fixed assets as they are used to produce, market, sell, deliver and administer the process of generating sales. Depreciation accounts for the using-up of assets. It is called a non-cash expense because the cash associated with the expense was disbursed long ago at the time that fixed assets were purchased and installed. The depreciation expense is subtracted before reaching operating profit so that income taxes will reflect depreciation as an expense of doing business.

Gross cash flow is calculated by adding the depreciation expense, previously subtracted to calculated operating income, back to the after tax income of the company. Gross cash flow represents the total amount of cash that the business generates each year. Additions to working capital and additions to fixed plant investment are investments in the business required to fuel continued production capabilities. Net cash flow is everything that remains of gross cash flow after accounting for the reinvestment in the business for fixed plant and working capital additions.

Value is derived from the net cash flows by converting the expected amounts into a present value using discount rates that reflect investment risk and time value of money as previously discussed in the investment rate of return section of this chapter.

PharmaProd Commodity Corp. Value

Consider the discounted cash flow analysis presented in Figures 10 as a simple example of using discounted cash flow analysis for royalty rate derivation. The licensed technology is on the cusp of commercialization.

Figure 10 represents the future net cash flows for PharmaProd Commodity Corp. as it currently operates. The sales, expenses and earnings for the company reflect the commodity-like nature of the current business and its products. Product prices are under pressure from strong competition translating into low profitability. Strong competition also severely limits the opportunity for the company to achieve any substantial growth in the future. The present value calculation contained in Figure 10 shows a value for the company at \$10.1 million using a discount rate of 13%. The calculation of the value of the company includes the present value of the net cash flows expected after year eleven. Constant growth, reflecting inflation and minimal volume growth into perpetuity is captured in the final year discount rate factor used in year eleven. The \$10.1 million value equals the aggregate value of all the assets of the company. This amount indicates that the company has earned its required weighted average cost of capital and an excess present value of \$10.1 million.

PharmaProd Commodity Corp. is planning to embark on a major business initiative with the introduction of a patented product using new technology and thus changing itself into New PharmaProd Corp. It will continue to offer its commodity product but also add a new proprietary product to its offerings. The technology will be licensed from another company. Figure 11 represents the present value of the company including the net cash flows from the existing operations of the company and the net cash flows from the new product initiative. Additional sales, manufacturing costs and expenses are reflected in the analysis. Also the additions to working capital and fixed assets required for the new product commercialization effort are reflected. Also reflected in the analysis are the research and development expenses needed to prove the technology and obtain FDA approvals.³¹ As a result of the initiative the present value of the company increases to \$15.6 million.³² The higher value reflects the added revenues and earnings of the new product at the higher profit margins of the new product. A comparison of Figure 10 and 11 shows that research, marketing, working capital additions and fixed asset additions are all higher and by more than just a proportional share of the higher sales forecasts. This is especially true for the early years in the discounted cash flow analysis because the new product initially does not contribute significant sales volume but definitely has expenses.

New PharmaProd Corp. Royalty Rate

What royalty rate should the company pay for use of the new product technology? The highest amount of royalty the company should be willing to pay for the licensed technology is shown on Figure 12. A royalty expense of 10.9% of the sales associated with the new product represents a royalty expense to New PharmaProd Corp. and yields a present value of \$10.1 million for the business – the initial value of the company. At this royalty the company has earned a return on the additional investment required to commercial the new product technology and not a penny more. A royalty rate of less than 10.9% would increase the value of the company.

³¹ The time span for pharmaceutical projects is greater than depicted in this example. For illustrative purposes a short time span has been used.

³² For simplicity the same discount rate of 13% has been used in Figures 10 through 12. The introduction of the new product initiative might warrant increasing the discount rate as the risk of the company is increased with the introduction of a new product.

[illegible]

Figure 11
New PharmaProd Corp.
Business Enterprise Value
with Licensed Technology

Y E A R	1	2	3	4	5	6	7	8	9	10
Sales	25,000	25,750	26,523	27,318	28,138	28,982	29,851	30,747	31,669	32,619
Cost of Sales	12,500	12,875	13,261	13,659	14,069	14,491	14,926	15,373	15,835	16,310
New Product Sales	100	1000	4000	8000	10000	11000	12100	13310	14641	15080
New Product Cost of Sales	<u>35</u>	<u>350</u>	<u>1400</u>	<u>2800</u>	<u>3500</u>	<u>3850</u>	<u>4235</u>	<u>4658.5</u>	<u>5124</u>	<u>5278</u>
Gross Profit	12,565	13,525	15,861	18,859	20,569	21,641	22,791	24,025	25,351	26,112
Gross Profit Margin	50.1%	50.6%	52.0%	53.4%	53.9%	54.1%	54.3%	54.5%	54.7%	54.7%
<u>Operating Expenses:</u>										
General & Administrative	3,012	3,210	3,663	4,238	4,577	4,798	5,034	5,287	5,557	5,724
Research & Development	5,000	1,500	0	0	0	0	0	0	0	0
Marketing	2,510	2,675	3,052	3,532	3,814	3,998	4,195	4,406	4,631	4,770
Selling	<u>5,020</u>	<u>5,350</u>	<u>6,105</u>	<u>7,064</u>	<u>7,628</u>	<u>7,996</u>	<u>8,390</u>	<u>8,811</u>	<u>9,262</u>	<u>9,540</u>
Operating Profit	(2,977)	790	3,042	4,025	4,551	4,849	5,171	5,521	5,901	6,078
Operating Profit Margin	-11.9%	3.1%	11.5%	14.7%	16.2%	16.7%	17.3%	18.0%	18.6%	18.6%
Income Taxes	<u>(1,131)</u>	<u>300</u>	<u>1,156</u>	<u>1,530</u>	<u>1,729</u>	<u>1,842</u>	<u>1,965</u>	<u>2,098</u>	<u>2,242</u>	<u>2,310</u>
Net Income	(1,846)	490	1,886	2,496	2,822	3,006	3,206	3,423	3,659	3,768
Net Profit Margin	-7.4%	1.9%	7.1%	9.1%	10.0%	10.4%	10.7%	11.1%	11.6%	11.6%
<u>Cash Flow Calculation:</u>										
+ Depreciation	368	387	408	428	450	472	495	518	542	567
- Working Capital Additions	160	330	755	959	564	369	394	421	451	278
- Capital Expenditures	<u>3,665</u>	<u>188</u>	<u>193</u>	<u>199</u>	<u>205</u>	<u>211</u>	<u>217</u>	<u>224</u>	<u>231</u>	<u>238</u>
Net Cash Flow	(5,303)	360	1,346	1,766	2,503	2,898	3,090	3,296	3,520	3,820
Discount Factor	13%	<u>0.9413</u>	<u>0.8330</u>	<u>0.7372</u>	<u>0.6524</u>	<u>0.5773</u>	<u>0.5109</u>	<u>0.4521</u>	<u>0.4001</u>	<u>0.3541</u>
Present Value	(4,992)	300	992	1,152	1,445	1,481	1,397	1,319	1,246	1,125
Net Present Value	15,593									

Y E A R		1	2	3	4	5	6	7	8	9	10
Sales		25,000	25,750	26,523	27,318	28,138	28,982	29,851	30,747	31,669	32,619
Cost of Sales		12,500	12,875	13,261	13,659	14,069	14,491	14,926	15,373	15,835	16,310
New Product Sales		100	1000	4000	8000	10000	11000	12100	13310	14641	15080
New Product Cost of Sales		<u>35</u>	<u>350</u>	<u>1400</u>	<u>2800</u>	<u>3500</u>	<u>3850</u>	<u>4235</u>	<u>4658.5</u>	<u>5124</u>	<u>5278</u>
Gross Profit		12,565	13,525	15,861	18,859	20,569	21,641	22,791	24,025	25,351	26,112
Gross Profit Margin		50.1%	50.6%	52.0%	53.4%	53.9%	54.1%	54.3%	54.5%	54.7%	54.7%
<u>Operating Expenses:</u>											
Royalty	10.9%	11	109	437	873	1,092	1,201	1,321	1,453	1,598	1,646
General & Administrative		3,012	3,210	3,663	4,238	4,577	4,798	5,034	5,287	5,557	5,724
Research & Development		5,000	1,500	0	0	0	0	0	0	0	0
Marketing		2,510	2,675	3,052	3,532	3,814	3,998	4,195	4,406	4,631	4,770
Selling		<u>5,020</u>	<u>5,350</u>	<u>6,105</u>	<u>7,064</u>	<u>7,628</u>	<u>7,996</u>	<u>8,390</u>	<u>8,811</u>	<u>9,262</u>	<u>9,540</u>
Operating Profit		(2,988)	681	2,605	3,152	3,460	3,648	3,850	4,068	4,303	4,432
Operating Profit Margin		-12.0%	2.6%	9.8%	11.5%	12.3%	12.6%	12.9%	13.2%	13.6%	13.6%
Income Taxes		<u>(1,135)</u>	<u>259</u>	<u>990</u>	<u>1,198</u>	<u>1,315</u>	<u>1,386</u>	<u>1,463</u>	<u>1,546</u>	<u>1,635</u>	<u>1,684</u>
Net Income		(1,853)	422	1,615	1,954	2,145	2,262	2,387	2,522	2,668	2,748
Net Profit Margin		-7.4%	1.6%	6.1%	7.2%	7.6%	7.8%	8.0%	8.2%	8.4%	8.4%
<u>Cash Flow Calculation:</u>											
+ Depreciation		368	387	408	428	450	472	495	518	542	567
- Working Capital Additions		160	330	755	959	564	369	394	421	451	278
- Capital Expenditures		<u>3,665</u>	<u>188</u>	<u>193</u>	<u>199</u>	<u>205</u>	<u>211</u>	<u>217</u>	<u>224</u>	<u>231</u>	<u>238</u>
Net Cash Flow		(5,310)	292	1,075	1,225	1,826	2,154	2,271	2,396	2,529	2,799
Discount Factor	13%	<u>0.9413</u>	<u>0.8330</u>	<u>0.7372</u>	<u>0.6524</u>	<u>0.5773</u>	<u>0.5109</u>	<u>0.4521</u>	<u>0.4001</u>	<u>0.3541</u>	<u>2.9459</u>
Present Value		(4,998)	243	793	799	1,054	1,100	1,027	958	895	8,247
Net Present Value		10,118									

RISK ADJUSTED NET PRESENT VALUE

Incorporation of clinical trial success rates is the next step for creating a model that can provide valuation and pricing conclusions specific to different stages of development.

Drug development is expensive, time-consuming, complex and risky. The drug research process is categorized by development stages: Preclinical Testing, Phase I, II and III clinical trials, and Regulatory Review by the Food and Drug Administration (FDA). Sometimes the FDA asks for Phase IV clinical trials to gain more information about side effects or how the new compound interacts with other medicines. Before any new medical product can hit the market the FDA must approve it. New products start out as new molecular (biological-based) entities (NME) or new chemical entities (NCEs). Typically to gain FDA approval for commercialization clinical trials are performed on humans and animals in three phases.

Phase I – Healthy volunteers are given a new compound to determine toxicity and to determine a proper dosage. Information about absorption, distribution, metabolism and excretion is obtained. A small number of volunteers are used for this first phase, between 20 and 80 humans. This phase typically takes 1 year. Costs are between \$8,000 and \$15,000 per test subject plus \$500,000 for supplemental animal studies.³³

Phase II – If the phase I trial shows promising results then 100 to 300 patients are given the new compound. More information is obtained about efficacy, optimal dosage, side effects and regimen. This phase typically takes 2 years. Costs are again between \$8,000 and \$15,000 per test subject plus \$1 million for supplemental animal studies.³⁴

Phase III – If the new compound passes Phase II it is then given to many thousand patients to confirm efficacy, monitor long-term side effects, and confirm safety. Costs per test subject are between \$4,000 and \$7,500. Supplemental animal studies are approximately \$1.5 million.³⁵ This phase takes 3 years.³⁶

FDA Approval – Once all the clinical trials are completed, approval for commercialization must be obtained from the FDA. This final hurdle can take between 1 and 2 years. Costs are between \$800,000 and \$1.8 million plus a \$300,000 fee for the Prescription Drug User Fee Act II.

Success Rates

A large amount of data exists about clinical trial success rates. The Tufts University Center for the Study of Drug Delivery periodically publishes summaries of this data. Success rates for NCEs vary by therapeutic class. On average, for NCEs entering into Phase I clinical trials the success rate of ultimately becoming a commercialized product is 22.6%. For NCEs in Phase II the success rate is 32.7% and for NCEs in Phase III trials the success rate is 78.5%. After Phase III is completed there is still a chance the FDA might not approve the NCE. The data shows the FDA approves 80% of all NCEs submitted. The FDA typically takes 2.5 years to review data and process an approval.

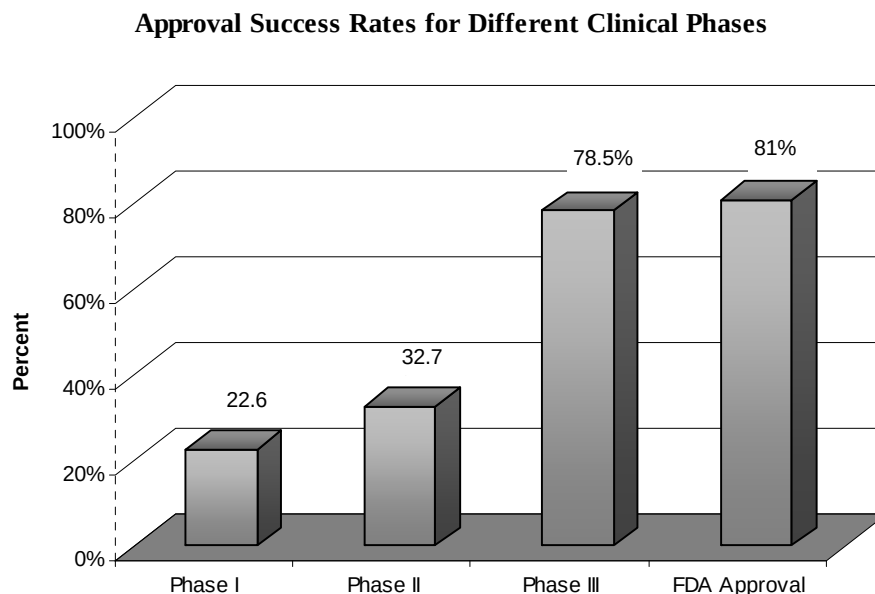
³³ Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, GPO 1998, GPO stock #052-003-01315-1.

³⁴ Id.

³⁵ Id.

³⁶ Phases of Product Development by Dale E. Wierenga, PhD and C. Robert Eaton, Office of Research and Development, Pharmaceutical Manufacturers Association.

Figure 13



Source: DiMasi J. A. Risk in new drug development: Approval success rates for investigational drugs. Clinical Pharmacology & Therapeutics, Fig.8, May 2001, Vo. 69, No. 5.

The chances of success for a preclinical NCE are more difficult to estimate. Obviously, these NCEs are less likely to be successful than Phase I NCEs. But the data on preclinical is not exact. Drug companies investigating a NCE, never reaching Phase I, might not ever publicize the failure. As such, preclinical data is difficult to accurately find. Nonetheless, the Pharmaceutical Research and Manufacturers of America (PhRMA) cites the success rate of preclinical NCEs at 10%.

Figure 16 shows data available regarding success rates for specific categories of therapeutic classes.

Figure 14

Current and Maximum possible success rates by therapeutic class for self-originated NCEs with INDs first filed from 1981 to 1992					
Therapeutic Class	NCEs	Approved NCEs	Open NCEs	Current Success Rate	Maximum Success Rate
Analgesic/anesthetic	49	10	4	20.4%	28.6%
Anti-infective	57	16	3	28.1%	33.3%
Antineoplastic	38	6	6	15.8%	31.6%
Cardiovascular	120	21	6	17.5%	22.5%
Central Nervous System	110	16	14	14.5%	27.3%
Endocrine	33	6	4	18.2%	30.3%
Gastrointestinal	15	3	2	20.0%	33.3%
Immunologic	13	2	0	15.4%	15.4%
Respiratory	25	3	0	12.0%	12.0%
Miscellaneous	43	3	4	7.0%	16.3%

Source: DiMasi J. A. Risk in new drug development: Approval success rates for investigational drugs, Clinica Pharmacology & Therapeutics, table 1, May 2001, Vol.69, No. 5.

Success Rate Adjusted DCF Example

Incorporating success rates into a discounted cash flow can be accomplished as illustrated in the following example. At different stages of development there is strong interest in knowing the value of the project. The first step is to start at the end.

A discounted cash flow calculation, as previously demonstrated in this book, might be used to find the fair market value of a new compound at the date of commercialization. Assume for example, at the start of commercialization – end of the development process – a highly profitable therapy is expected to be in the market place. Commercialization is expected to run for twelve years before expiration of the underlying patents. All research, clinical trials and regulatory hurdles have been successfully completed. Consequently, no technical or regulatory risk exists at the commercialization date. Market acceptance is strongly anticipated and the DCF analysis indicates the huge amount of \$1 billion as the value of the new therapy at the future date when commercialization begins. This is the starting point for determining the value at different development stages. Finding the value at the different stages of development can be graphically displayed as shown in Figure 15. Success rates for this example are based on the data developed and published by DiMasi.³⁷

³⁷ DiMasi J. A., Risk in new drug development: Approval success rates for investigational drugs. Clinical Pharmacology & Therapeutics, Fig. 8, May 2001, Vol. 69, No. 5.

Figure 15

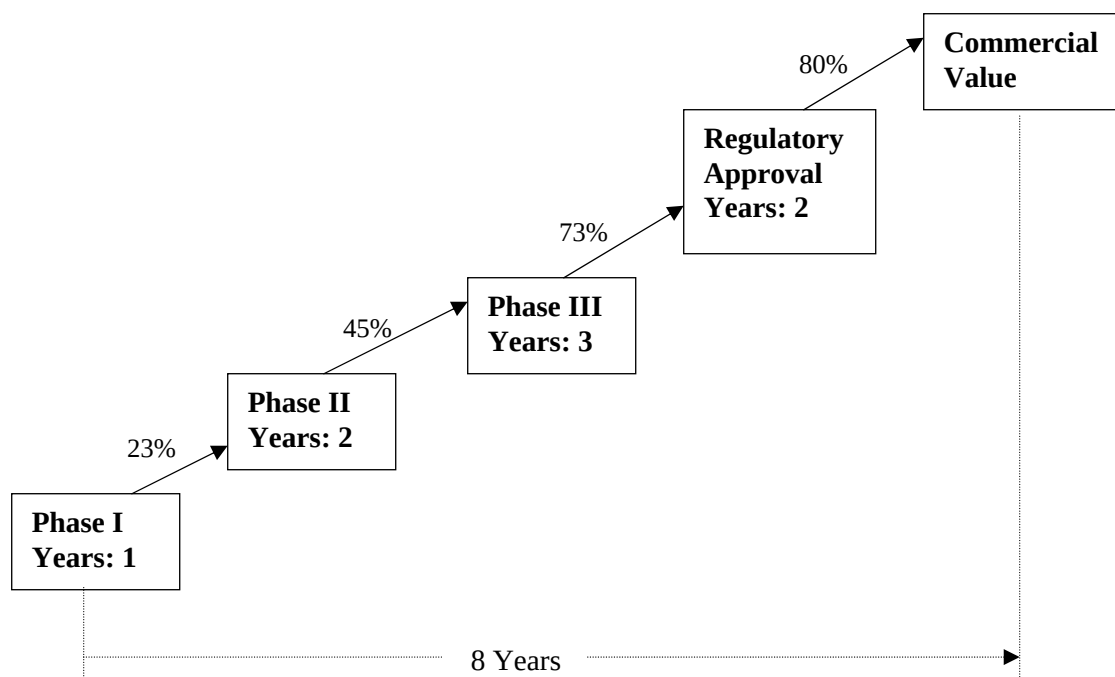


Figure 16 shows a calculation incorporating success rates into a value determination. Also reflected in the calculation is a discount rate for the years of clinical trials and regulatory approvals as well as the cost to fund the different development stages. As this illustrative new venture enters Phase I its end-stage \$1 billion value is worth \$20 million. The discount rate of 12% is estimated as a typical industry rate of return and does not need to account for technical risks because the success probabilities incorporate those specific elements of risk directly into the calculation.

Figure 16

Valuation of New Compound Using Success Rate Adjusted Present Value Calculations (dollars in millions)						
Stage	Success Rate	Years	Discount Factor	Success Rate & Discounted Value	Research Cost	FMV
Commercial Value	100%	0	1.000	\$1,000	\$0	\$1,000
FDA Approval	80%	1	0.893	\$714	\$2	\$712
Phase III	73%	2	0.797	\$415	\$25	\$390
Phase II	45%	3	0.712	\$125	\$6	\$119
Phase I	23%	2	0.797	\$22	\$2	\$20
Discount rate	12%					

A somewhat simple valuation model is next.

VALUATION USING THE RELIEF-FROM-ROYALTY METHOD

A popular method for valuing patented technology is called the Relief From Royalty Method. This method is popular because it is relatively easy to implement and can provide a very credible indication of value. The ease of implementation derives from the limited number of inputs needed to fuel the model. However, each of the inputs must be appropriate and precise if the model is to yield a worthwhile result.³⁸

The Relief From Royalty Valuation Method can be used to value a patented invention. Alternately it can be used to determine the combined value of a patented invention and the underlying technological know-how used to commercialize the invention. The valuation of a patent is more accurately characterized as valuing the rights associated with ownership of a patent or patent portfolio. Remember, a patent provides its owner with rights to exclude others from making, using, offering for sale, or selling an invention in the United States or importing the invention into the United States. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention.

The underlying theory of the Relief From Royalty Method is based on the present value of forecasted income. The forecasted income takes the form of savings. The savings come from owning a patent. Ownership of a patent relieves the owner from having to license it from another party, which typically requires payment for use of patent rights. Most often payment is made in the form of running royalties. The royalty amount a licensee must pay is calculated based on a percentage of company revenues – the royalty rate. Sometimes the royalty is based on a fixed amount per unit but mostly the royalty is prescribed as a percentage of future sales. Examples of the royalty rates associated with licensed pharmaceutical biotechnology patents can be found throughout the remainder of this book.

Inputs for the Relief From Royalty Method

This method calculates the present value of the money saved by owning a patent and not having to pay royalties to a third party for a license to the patent. It can also be looked at as the present value of future savings.

Five inputs must be determined to implement the Relief From Royalty Method. The key inputs of this method include the following:

- ◆ Remaining Life of the Patent Protection
- ◆ Forecast Revenues
- ◆ Royalty Rate
- ◆ Tax Rate
- ◆ Discount Rate

³⁸ Please note the examples presented in this section, as with the other examples already presented, are for illustrative purposes only. Inputs used for the examples may not be appropriate for every application of the Relief From Royalty Method. Each case is specific and will require development of appropriate inputs.

Remaining Life of the Patent Protection

This input determines the period over which the forecasted savings will be enjoyed from owning the patent. Make sure the remaining life reflects not only the remaining life of the patent protection but also the remaining life of the underlying invention. Forecasting beyond the remaining life of the invention captures value that does not exist. A patent lasts for 20 years but in some industries a new technological invention may become obsolete far sooner than the expiration of the patent. So, the forecast period must reflect not only the remaining life of the patent but may be subordinate to the remaining life of a technology life cycle.

A key question becomes, will the patented invention being valued provide useful utility for as long as the patent lasts? One way to answer this question is to look into the history of the subject technology. By studying the historic changes in technology for the relevant industry insight can be gained for answering this key question. Investigation of current research and development efforts can also indicate when a new technology will obsolete a current technology.

Forecast Revenues

This input is a powerful component of the future savings enjoyed by owning a patent. It must be based on the forecasted revenues expected from the products or services that commercialize the patented invention. Revenue forecasts must be limited to only those products or services benefiting from the patent protection. They do not have to be based solely on the revenues of the owner and can include other applications that are reasonable to anticipate.

Licensing trends continue to develop. In many industries corporations are licensing their inventions to others, including direct competitors, as a new source of income. Texas Instruments earns billions of dollars licensing its patent portfolio. Sometimes TI earns more from licensing than it does from its operations. Alternately, Procter & Gamble rarely licenses its patents. It prefers to exclusively internalize its own patents.

Usually the value of the patent to the owner is dominated by the protection it enjoys from its own exclusive exploitation. An assumption may be required that the exclusive use of the patent rights is the best use of the patent or possibly the only use. Otherwise, in order to capture the full economic value of a patent, applications beyond those of the owner must be considered.

Royalty Rate

This input is the third component required to calculate the future savings enjoyed by owning the patent. It is estimated as the rate at which the owner would have had to pay to license the patent rights had it not owned them. Most often a royalty for the specific patented invention being valued is not available because the patent at issue has not been licensed. As a result a proxy royalty rate must be developed. A proxy is often obtained from market data reporting the royalty rate at which similar patent rights have been licensed between independent third parties. Alternately a proxy royalty rate for use in the Relief From Royalty Method can be estimated using The Profit Split Rule of Thumb, Profit Differential Calculation or a Discounted Cash Flow analysis. All of these royalty estimation methods have already been discussed in this book.

Tax Rate

This input converts the royalty savings into an after tax cash flow, which is converted into a patent value. Use an effective tax rate but not one that is impacted by unique events not associated with normal business operations. A company for example may enjoy unusually low tax rates from Loss Carry-forwards. Use of such tax rates distort the benefits associated with the patents by capturing value associated with tax strategies and not the technology.

Discount Rate

This input reflects the risk associated with obtaining the forecasted income. This rate should reflect more than the weighted average cost of capital (WACOC) of the firm using the patented invention. When considering the WACOC of a firm you must remember that the firm is comprised of a portfolio of assets including net working capital, fixed assets, intangible assets and intellectual property. Each of these asset classes carries different levels of risk. Some have very definite liquidation values such as cash, accounts receivable and fixed assets. Others have no liquidations value such as the intangible asset of a trained and assembled work force. All together the collection of assets that comprise a firm contribute to a firm's WACOC. When valuing a distinct element of the overall firm, such as a patent, the appropriate discount rate is not always the firm's overall WACOC. That said, if the forecasts are subjected to discounts for success probabilities, then a typical WACOC is appropriate.

Present Value Calculation

Presented below is an example of the Relief From Royalty Method.

Figure 17

Relief-From-Royalty Method of Valuation					
Year	Revenues	Saved Royalties	Aftertax Savings	Discount Factor	Present Value
1	20,000,000	600,000	360,000	0.8696	313,043
2	21,000,000	630,000	378,000	0.7561	285,822
3	22,050,000	661,500	396,900	0.6575	260,968
4	23,152,500	694,575	416,745	0.5718	238,275
5	24,310,125	729,304	437,582	0.4972	217,556
6	25,525,631	765,769	459,461	0.4323	198,638
7	26,801,913	804,057	482,434	0.3759	181,365
8	28,142,008	844,260	506,556	0.3269	165,594
9	29,549,109	886,473	531,884	0.2843	151,195
10	31,026,564	930,797	558,478	0.2472	138,047
				Total	2,150,504
5% Revenue growth rate					
3% Royalty rate					
40% Tax Rate					
15% Discount rate					

In this example the inputs are as follows:

- ◆ The current year revenues are expected to grow at an annual rate of 5%.
- ◆ The royalties saved on future sales of the product or service protected by the underlying patent rights are calculated using a proxy royalty rate of 3% of net revenues.
- ◆ Income taxes have been calculated at 40% of income.
- ◆ The remaining life of the patented invention is ten years from the date of the valuation.
- ◆ The after tax income saved has been discounted to present value using a required investment rate of return of 15%.

The value indicated for the patented protection is \$2.1 million. It is important to note at this moment the difference between patent rights and the technological know how. The royalty rate of 3% was determined based on third party licenses at which similar naked patent rights have been exchanged on an exclusive basis. Consequently this value does not capture any proprietary technological know how that the company using the patent rights created for commercializing the protected invention. The value expressed in this example is solely for the patent rights.