

PharmStar Pharmaceuticals, Inc.

Intellectual Property Valuation

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PharmStar Pharmaceuticals, Inc.

Intellectual Property Valuation

PharmStar Pharmaceuticals, Inc. (PSP) has requested a valuation of their intellectual property relating to the Aquaprin™ soluble aspirin product, including patent applications and associated know-how, and the Aquaprin trademark.

The patent applications include:

- (1) a patent application directed to the Aquaprin™ formulation; and
- (2) a patent application directed to a quick dose administration device for administering a soluble aspirin product to an individual in need of such product, e.g., as a cardioprotective intervention.

The following provides a valuation of this intellectual property.

Executive Summary

Based on the subsequent analysis in this report, the intellectual property associated with the patent, know-how and trademark positions of PSP is valued at \$32 million.

Background

The worldwide analgesic market is variously estimated at \$30 to \$75 billion dollars, with the U.S. market being in excess of \$10 billion annually.

Approximately 84% of the U.S. population regularly uses non-prescription analgesics for minor pain relief for conditions such as headache, muscle ache or backache (Simmons Market Research, 2000). Over \$2 billion worth of such analgesics are sold annually by supermarkets, drugstores and mass merchandisers.

The non-prescription analgesics market encompasses pain-relief medications having four principal active chemical ingredients, aspirin, acetaminophen, ibuprofen and naproxen sodium. Brand names are well-established in each of these segments, and include Tylenol (acetaminophen), Advil and Motrin (ibuprofen), Aleve (naproxen sodium), Bayer (aspirin or combination), Excedrin (acetaminophen), Midol and Pamprin (varied formulas for menstrual pain relief). There is a significant discrepancy between actual differentiation of near-homogeneous product formulations in this market segment, and the perceived differentiation among different brands, resulting from advertising.

The ratio of advertising to sales in the nonprescription analgesics industry among various major manufacturers can range from 20 to 50% (Getting into Your Head(ache): Advertising Content for OTC Analgesics, Simon P. Anderson, Federico Ciliberto and Jura Liukonytė, Marketing Science Institute Working Paper, February 2008, highlighting the value attributed to brand identity).

Aspirin has a number of inherent advantages. Like other pain relievers of the type discussed above, aspirin is effective for treatment of pain, fevers, arthritis, and headaches, but unlike such other analgesic products, aspirin is the only pain reliever shown to reduce the risk of heart attack. In addition, aspirin is the oldest and best established of the common pain relievers, with well over a century of use throughout the world.

In the field of aspirin pain relievers, effervescent soluble aspirin products such as Aspro or Disprin are quite popular in other countries such as Australia, Canada, Great Britain and New Zealand. In the U.S., Alka-Seltzer, an effervescent formulation including aspirin, sodium bicarbonate and citric acid. Alka-Seltzer is the world's number one cure for hangover and is currently sold in over 100 countries, generating annual sales in excess of \$100 million¹. Overall, the soluble aspirin products market worldwide exceeds \$2 billion.

The Aquaprin™ and Insta-Prin™ Products

The Aquaprin™ product being readied for commercial rollout is a third-generation soluble aspirin formulation.

The first-generation soluble aspirin products began to appear at the beginning of the last century. See, for example, U.S. Patent Number 740,703 issued in 1903. These early products were based on various soluble salts, lithium, sodium, potassium, calcium and magnesium as well as with organic amines and amino acids (lysine and ornithine), and were not stable formulations. Their instability resulted from water of crystallization contained in the salts, that resulted in degradation of aspirin into salicylic and acetic acids. Efforts to improve such products focused on removal of the water of crystallization, and formation of anhydrous salts, but the resulting compositions were difficult to handle and expensive to produce, involved unsuitably high levels of metallic elements, and were not economically competitive against aspirin.

Later developments in such first-generation products employed buffering coatings intended to neutralize gastric acidity. Clinical studies showed, however, that is not possible to coat aspirin tablets with sufficient amounts of buffering agent to totally neutralize gastric acid, and such buffering coatings are ineffective in preventing soluble aspirin particles from adhering to gastrointestinal mucosa. Enteric coatings have been alternatively utilized, but are subject to the same mucosal adhesion problems in the intestinal locus.

¹ More recently, Alka-Seltzer Gold has been introduced for relief of acid indigestion, heartburn and sour stomach. Alka-Seltzer Gold contains sodium bicarbonate, potassium bicarbonate and anhydrous citric acid, but it does not contain aspirin and correspondingly is deficient in the advantages associated with aspirin as an active ingredient.

Subsequent first-generation soluble aspirin products include products based on soluble salts of aspirin, such as that disclosed in U.S. Patent No. 3,985,792, in which aspirin is reacted with sodium bicarbonate and water to form a sodium salt solution that then is treated with alcohol and cooled to crystallize sodium acetylsalicylate dihydrate. This dihydrate then is filtered, washed and dehydrated to provide the final product. Such product is, however, extremely susceptible to degradation by moisture, and additionally requires large amounts of alcohol that must be separated by distillation. Further, large amounts of sodium bicarbonate are required in these products, which carries the risk of hypertension from ingestion of sodium.

The shortcomings of the use first generation products were addressed in a second-generation formulation of soluble aspirin developed by Howard Phykitt, the inventor of the current Aquaprin™ product. The second-generation soluble aspirin product was patented by Mr. Phykitt in 1998 in U.S. Patent No. 5,723,453. This second-generation product was a stabilized, essentially sodium-free aspirin composition that was readily soluble in aqueous medium. It comprised aspirin granules of predetermined particle size and granular potassium bicarbonate with an outer surface layer of potassium carbonate on the granules, in an amount greater than that required to neutralize the aspirin granules.

The third-generation soluble aspirin product developed by Mr. Phykitt achieves marked advantages in taste, dissolution rate in water, and absence of microsolids residue. This is the new Aquaprin™ product. Mr. Phykitt has developed specially adapted manufacturing techniques for the high-volume production of such Aquaprin™ product, enabling it to be highly competitive with current non-prescription branded pain relievers, but of substantially lower manufacturing cost.

The Aquaprin™ product has numerous advantages in speed of relief, ease-of-use, levels of analgesia in relation to a corresponding amount of aspirin per se, as well as antacid behavior. The Aquaprin™ product has application to the treatment of headache, migraine, rheumatic pains, neuralgia, period pain, toothache and symptoms of colds and influenza.

Existing soluble aspirin products have major deficiencies, as sodium or calcium-based compositions that require several minutes to dissolve in water, and leave residue and undissolved particles in the liquid into which they are dispensed. In addition, soluble aspirin products commercialized outside the United States, e.g., in markets in Europe, Middle East and Asia, do not meet USP requirements for marketing in the United States. Alka-Seltzer® is the leading soluble aspirin product in the US, but has the associated disadvantage of high sodium content, and is sold as an antacid/pain reliever and not as a daily aspirin regimen pain reliever and arthritis treatment.

In addition to the Aquaprin™ product, Mr. Phykitt has developed a product called the Insta-Prin™ Applicator, which is a device in which the third generation aspirin product can be stored in dry form, and upon need for administration, the Aquaprin™ product can be immediately mixed to a liquid dose form for administration, at the onset of life-

threatening cerebrovascular or coronary events. The Insta-Prin™ Applicator can be carried by emergency medical personnel, police, firemen and other first responders, to facilitate immediate aspirin therapy intervention for prevention or amelioration of heart attack and stroke.

The Intellectual Property Assets

In considering the intellectual property of PSP, the prospective brand identity associated with the Aquaprin and Insta-Prin trademarks is a significant proprietary asset.

Although trademark rights are created by use in branding of products in the commercial marketplace, and in the absence of product branding have no associated goodwill, the value of the Aquaprin trademark is reflected by its having been approved for registration by the U.S. Patent and Trademark Office as soon as interstate commerce usage requirements are completed. Thus, there is official recognition of the distinctive character of Aquaprin as a branding name. Since the water compatibility of the product is immediately connoted by the "Aqua" portion of the trademark and since the "prin" portion of the trademark has a suggestive association to "aspirin," Aquaprin is a well-considered and communicative branding for the prospective product. It therefore provide is capable of making an instant impact, and has a highly memorable character.

The trademark Insta-prin is also highly memorable and closely associative in relation to the character of the appertaining product. The "Insta" portion of the trademark is connotative of "instant" and the "prin" formative, as in the case of Aquaprin, has a suggestive association to "aspirin."

Since the essential value of trademarks as intellectual property resides in the goodwill and consumer brand recognition associated with them, and since trademarks are susceptible of potentially infinite duration dependent on their continued use and maintained registration in respect of the product, the true value of these trademarks as proprietary assets will not be fully realized until the respective products achieve broad penetration of the consumer analgesic market, and become associated with the products in consumers' minds.

The Aquaprin™ product is covered by the claims of the U.S. patent application entitled "ANALGESIC COMPOSITION AND METHOD OF MAKING THE SAME" in the name of Howard Phykitt ("Aquaprin™ patent application"). The claims to the Aquaprin™ product in the Aquaprin™ patent application cover the soluble aspirin product composition, the method of making such soluble aspirin analgesic composition, and the method of providing analgesia to a subject in need thereof, comprising mixing an effective amount of the dry solids analgesic composition with a solubilizing quantity of aqueous medium to produce an effervescent analgesic solution for administration to the subject.

Although the U.S. Patent and Trademark Office has not approved the patent on the Aquaprin™ patent application (typical patent pendency periods of U.S. patent applications are on the order of 2-1/2 to 3 years), the claims of this application effectively cover the Aquaprin™ product and in light of prior studies of the prior art and the clear basis of distinction of the claims over the disclosures in the prior art, there is seen to be no impediment to issuing effective claims to the Aquaprin™ product in a U.S. patent.

The Insta-Prin™ product is covered by the claims of the U.S. patent application entitled “EMERGENCY DOSE MEDICATION ADMINISTRATION DEVICE” in the name of Howard Phykitt (“Insta-Prin™ patent application”).

The Insta-Prin™ patent application contains claims to the applicator product as an emergency dose medication administration device that is structurally defined with respect to its various features. The claims of the Insta-Prin™ patent application appropriately cover the product device contemplated for commercialization.

It is acknowledged that additional efforts directed to the refinement of the current design may provide additional grounds of patentability of the above claims, but we are unaware of any prior patents, published patent applications or other prior art to the claims in the Insta-prin™ patent application that would preclude their issue in a U.S. patent based on such patent application.

Further, the claims of the Insta-prin patent application can be further augmented with more specific coverage directed to the dry solids water-soluble aspirin composition in additional claims that may be added during subsequent prosecution of the Insta-Prin™ patent application. Accordingly, the Insta-prin™ patent application provides an appropriate proprietary position to PSP on the Insta-Prin™ product.²

Detailed Analysis

Our analysis of the intellectual property rights of PSP is based on the following:

the Aquaprin™ patent application;
the Insta-Prin™ patent application;
the Aquaprin™ trademark;
the Insta-Prin™ trademark;
the know-how possessed by PSP in the accumulated knowledge, skill and experience of Howard Phykitt related to analgesic composition formulations, and appertaining manufacturing and packaging techniques; and

² It is to be acknowledged that the conclusions herein are opinions based on currently known prior art to the Aquaprin™ patent application and the Insta-prin™ patent application, and that other prior art, from medical and/or technology journals, later published patent applications or issued patents, or commercial activities of third parties may later become known that constitute prior art applicable to claims of these applications, and that the nature and impact of such currently unknown prior art may adversely affect the scope of patent rights otherwise available based on the Aquaprin™ patent application and the Insta-prin™ patent application.

various publications, statistical data and reports on patent valuation, market data and royalty rates, including sales data from various sources, including those identified in the Background section of this Intellectual Property Valuation.

It is to be appreciated that the valuation of any intellectual property is based upon a number of identifiable market factors and assumptions that may vary over time. Patents provide an exclusionary right that is limited to 20 years from the filing date of the earliest U.S. application to which priority is claimed (excluding provisional applications).³ A wide variety of accepted⁴ approaches can be utilized to determine the valuation of intellectual property ("IP"), three of the most widely accepted being: (1) The Cost Approach; (2) The Market Approach; and (3) The Income Approach.⁵

The Cost Approach considers the various cost elements involved in the creation of the intellectual property and the determination of a royalty rate that will recapture the expense of its development.⁶ It therefore has limited utility since the technology is not priced competitively on "going price" principles.

The Market Approach values IP based upon comparing it to other assets that have recently exchanged under similar circumstances.⁷ Since there are no recent "comparables," i.e., completed transactions from which data can be utilized, for sales or licensing of soluble aspirin products technology, this approach has limited applicability to the present determination, except to state that Howard Phykitt's second-generation soluble aspirin patent rights were previously independently assessed for value in 1997 (the "1997 analysis").

The 1997 analysis was based on the analgesic market at that time, as having an attributed value of \$2.7 billion, with the powder segment (considered to be distinct in that analysis from the segment containing tablet formulations such as Alka-Seltzer) being assessed at \$32.7 million (1.2% of the analgesic market) based on market shares at that time of 56.3% for BC Powder, 37.9% for Goody's Powder, and 5.8% for Stanback (source: Drug Store News 11/18/96).

The 1997 analysis addressed present worth analysis, attainable market share, projected revenue and income from the patent, income analysis as based on capitalization of income as well and discounted cash flow, investor returns, cost of avoidance of the patent

³ 35 U.S.C. § 154(a)(2)

⁴ There are a number of valuation firms and organizations, including: <www.bvappraisersconference.org/>; <www.pellegrinoandassociates.com>; <<http://www.journalofaccountancy.com/Issues/2004/Nov/20StepsForPricingAPatent.htm>>; and <<http://ipmetrics.net>>; etc.

⁵ See Robert Pitkethly, *THE VALUATION OF PATENTS: A review of patent valuation methods with consideration of option based methods and the potential for further research*; The Said Business School University of Oxford

Park End Street, Oxford OX1 1HP (1997) at: http://www.cambiotec.org.mx/cyted/documentos/avaluo/doc_rpitkethly1.pdf

⁶ see, for example, http://en.wikipedia.org/wiki/Royalties#Approaches_to_royalty_rate

⁷ See David Drews, *Intellectual Property Valuation Techniques*, IP Strategies in Deals, October 2004 at: <http://www.ipmetrics.net/IPVT.pdf>

position, and license costs. In the 1997 analysis, the patent rights associated with the Phykitt second-generation soluble aspirin products technology, based on a 17-year patent life (i.e., assuming a three year pendency of the corresponding patent application) with the overall market in years 6-17 assumed to be flat, for analysis purposes, and profitability assumed to be that of year 5 with a continuous improvement of 3% per year based on the anticipated market penetration and sales revenues, and a 15% capitalization rate, the then-total present value determined for the second-generation soluble aspirin products patent rights in the 1997 analysis was \$30,926,980.

The 1997 analysis therefore incorporated the Income Approach, the third major valuation technique, in which the patent owner: (a) generates a cash-flow projection of incomes and expenses over the life-span of a license, and (b) determines the net present value (NPV) of the profit stream, based on a selected discount factor.

The Income Approach more closely realizes the true value of intellectual property patent assets when there is a reasonable projection of income and expenses (particularly with and without the intellectual property), predictable profit information, and reasonably computable market data. For these reasons, we are utilizing a modified Income Approach, factoring in an assumed scope of market share dominance⁸ along with a standard pricing scheme for the stated share of the market rates.⁹

The underlying predicate of this modified Income Approach is that the value of a patent asset should directly correlate to the value of the prospective additional profit obtainable from fully exploiting the invention claimed in the patent application and resulting patent, as compared with profits obtainable without patent protection.

Here, the current market is taken as \$30 million in the powder segment, approximately the same as in 1997 for such segment, and as \$100 million for the Alka-Seltzer segment, for a total of \$130 million. In the Alka-Seltzer segment, current online prices for 36 tablet boxes, containing 18 two-tablet packets of Alka-Seltzer, are available online at prices ranging from \$5.65 to \$10.67 per box, including prices by online Canadian pharmacies. Competitive pricing, based on a packet of the Aquaprin™ product, relative to the \$5.65/box/18 packet competition, corresponding to a unit (packet) price of \$0.313 for Alka-Seltzer, suggests an Aquaprin™ product resale price of \$0.30 supported by aggressive advertising and promotional activities to be reasonable, consistent with a wholesale unit cost of \$0.20 and manufacturing unit cost of \$0.14, as an assumed structure providing a 30% margin.

A five-year time horizon is posited for achievement of market capture, following which sales would continue to grow albeit more slowly. This time horizon is selected because the basic composition patent would be issued at that point in time and additional patents

⁸ Market share would be a percentage of the whole.

⁹ As an alternative to sales of product to the market, licenses are another means to effectuate control over a greater share of the market. This analysis assumes a royalty rate from licenses would be equivalent to that profit realized from products that are regularly sold, as factoring the costs incurred by licensees.

would be pending to build out the intellectual property position, and the advantages accruing to patent-protected products early in their lifecycle would be most compelling.

A year 5 capture of 25% of the \$130 million powder + Alka-Seltzer market would provide annual sales revenue of \$32.5 million at the retail level for the Aquaprin™ product, and corresponding PSP sales for Aquaprin™ on the order of \$22 million, and pretax net profit of \$6.7 million.

The Insta-prin™ applicator product, by contrast, is sui generis, and has no established market, and its sales would be significantly smaller than the Aquaprin™ product, particularly since it is an emergency dose product, and therefore intended for emergency use. Since emergency dose products have a substantial longitudinal replacement time, with shelf-life being the primary determinant in the absence of emergency deployment, the market for the Insta-prin™ product will be created in a trailer fashion from the successful commercialization of the Aquaprin™ product, and therefore is posited to contribute only about 10% of the amount of the revenues attributable to the Aquaprin™ product. In the case of the fifth year PSP sales of Aquaprin™ product being \$22 million and pretax profit of \$6.7 million, as above calculated, the corresponding sales revenue and pretax net profit for the Insta-prin™ applicator product would be \$2.2 million and \$0.67 million, respectively, and the total revenues and pretax net profit attributable to the Aquaprin™ product and the Insta-prin™ applicator product would be \$24.2 million and \$7.37 million, respectively.

Since the 1997 analysis had posited a fifth-year pretax net profit of \$7,172,699, the current analysis fifth-year pretax net profit of \$7.37 million is remarkably close to the valuation of the profit opportunity analysis conducted in 1997. Inasmuch as the current fifth-year pretax net profit value of \$7.37 million is roughly 3% above the fifth-year pretax net profit value of the 1997 analysis, and the revenue profile of the Aquaprin™ product and the Insta-prin™ applicator product are expected to yield a conforming trajectory to that of the earlier analysis, it is reasonable to assume the total present value of \$30,926,980 obtained in the earlier analysis to the correspondingly increased by about 3%. A corresponding total present value of the prospectively patent-protected Aquaprin™ product and the prospectively patent-protected Insta-prin™ applicator product is \$31,854,789, or approximately \$32 million in rough terms.

This total present value of \$32 million is determined to be the value of the intellectual property rights associated with the Aquaprin™ product and the Insta-prin™ applicator product, since in the absence of the intellectual property applicable to these products, commercialization would not be viable, and there would be no barrier to entry to far larger competitors with correspondingly larger resources. The exclusionary rights associated with the proprietary patent position of PSP, together with the branding trademarks, and substantial know-how of Howard Phykitt, provide a reasonable basis for such valuation.

We therefore conclude that the intellectual property rights relating to the Aquaprin™ product and the Insta-prin™ applicator product are fairly valued at \$32 million.

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