ANALYSIS OF BIOTECHNOLOGY STOCK AND WARRANT OFF-BALANCE SHEET FINANCED RESEARCH AND DEVELOPMENT (*SWORD*) CAPITAL FORMATION SPECIFIC TO THE INTELLECTUAL PROPERTY LICENSING INSTRUMENTS

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FINAL APPROVAL of RESEARCH PAPER

We the undersigned faculty/committee members after duly examining the following paper submitted in fulfillment of the writing requirement of the joint Juris Doctorate/Master of Intellectual Property (J.D./M.I.P.) degree program offered at Franklin Pierce Law Center, Concord, New Hampshire, hereby give our final approval of this paper in accordance with the Graduate Degree Program Rules promulgated pursuant to and currently in effect as of this date.

TITLE:

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To my wife, Marti, once again your patience and understanding was unwavering.

II. METHODOLOGY

This paper will address the relationship of intellectual property to biotechnology capital formation structures specific to Stock and Warrant Off-balance sheet financed Research and Development (SWORD) companies. Biotechnology companies tend to be relatively small business entities with meager profits, limited cash resources and a high cash burn rate.[1] SWORD arrangements arose as a method of dealing with the high financing pressures that face biotechnology companies in implementing research and development of new product.

As of this writing, there have only been nine SWORD companies formed since the inaugural SWORD formed in 1988. [2] Due to their relatively recent conception and degree of complexity, there have been very few scholarly treatments of biotechnology SWORDs. The first analytical approach to SWORD formation from the financial effect on the stock market perspective was completed by financial analyst Michael E. Solt.[3] Who addressed the relationship between SWORD offering and an increase in corporate investment flexibility. These SWORD financing arrangements allow a biotechnology firm to undertake research and development that it otherwise would not have been able to finance.

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[1] Solt, Michael, E., *SWORD Financing of Innovation in the Biotechnology Industry*, Financial Management. Summer 1993. pp. 173-187.

[2] These nine SWORDS include:

- ALZA/Bio-Electro Systems (1988)
- Centocor/Tocor I (1989)
- Immunex/Receptech (1990)
- Genzyme/Neozyme I (1990)
- Elan Corp./Drug Research, Inc. (1991)
- ALZA/Therapeutic Diagnostics (1991)
- Genzyme/Neozyme II (1991)
- Genetics Institute/ SciGenics (1992)
- Centocor/Tocor II (1992)

[3] College of Business, Accounting and Finance, San Jose State University, San Jose, CA 95192. The author has been in communication with Mr. Solt personally, in order to obtain his insight into the financial aspects of biotechnology SWORDs, and received his strong encouragement to attempt the as yet unaddressed analysis of the interrelationship of intellectual property licenses to SWORD structure and function.

III. HOW A *SWORD* FINANCIAL ARRANGEMENT FUNCTIONS

The financing arrangement known as a SWORD (Stock and Warrant Off-balance sheet financed Research and Development) has been used to finance new ventures in the biotechnology industry. A SWORD consists of a series of contracts that define the relationships among the parties to a SWORD and the property rights of the parties.[4] A SWORD is designed to facilitate research and development by utilizing the intellectual property of the parent company to provide flexibility to a biotechnology manager that allows the biotechnology firm to engage in research and development that might not be cost effective otherwise.[5] The intellectual property rights that are transferred to the spinoff new venture serve as the asset core of the new venture and stimulate investor risk thus providing equity financing to the new venture. Financing pressures have led biotechnology companies to explore t various financing methods to fund their research and development.[6]

Acquisition of property rights in technology should provide biotechnology companies with another way of facilitating their ultimate goal of exploiting those rights for financial gain or otherwise furthering their financial objectives in a

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[4] Solt, Michael, E., *SWORD Financing of Innovation in the Biotechnology Industry.* Financial Management, Summer 1993. pp. 173-187.

[5] *See generally,* Blackburn, Robert P., *Licensing Biotechnology,* Practicing Law Institute, 334 PLI/Pat 407 (1992). This article provides a good overview of biotechnology concerns when undertaking a licensing relationship. Specifically addressed:

- Technology from nonprofits or universities.
- Proprietary rights under patents, trademarks, trade secrets, and copyrights.
- Clinical trials.
- Marketing.
- Royalty structures.
- Joint Ventures and research and development.
- How to handle technology improvements.

[6] *See,* Glynn, Michael W., *Biotechnology Licensing and Protection,* Practicing Law Institute, 354 PLI/Pat 695 (1993). Specifically of concern in any biotechnology licensing arrangements are:

- Background property rights.
- Product patent.
- Recombinant versus Purified Product.
- Product patentability.
- Product by process.

manner that maximizes their value. [7] Additionally, there are considerable federal tax ramifications between a parent company and SWORD spinoff arrangement.[8] The conceptual model of a SWORD is based on starting a new venture as a separate organization to the parent that (1) owns the property rights to the research and development; (2) whose financial statements have no impact on those of the biotech parent; and (3) whose financing comes from a public units offering. Each unit consists of one share of the new venture common stock that can be called by the parent and one warrant to purchase one share of common stock of the parent company. Essentially, each parent biotechnology company creates its own research sponsor embodied in the SWORD spinoff, and has retained the option to takeover [9] this sponsor by calling the new venture common stock.[10]

The new venture funds <u>are not</u> commingled with the parents assets; thus the parent's existing shareholders avoid dilution of value if the new venture spinoff

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[7] Respess, William, L., *Strategies for Exploiting Property Rights in Technology*, Practicing Law Institute, 354 PLI/Pat 285, 1993. The general manner in which technology is acquired is by:

- Familiar assignment of rights -- conveys an ownership interest in the technology.
- License agreement -- right to exploit the technology without transferring any ownership interests.

[8] *See generally*, Morrow, Webb B., *Research and Development Partnerships and Pooled Funds*, Practicing Law Institute, 248 PLI/Pat 243.

Additionally, there are considerable tax consequences specific to intellectual property held by a corporation:

- IRC § 469 - limitations on deductibility of losses from passive activities.
- IRC § 461(i) - limitations on deductibility of prepaid expenses for corporate tax shelters.
- IRC § 741 - The gain or loss recognized upon the sale or exchange of joint venture interests are treated as the sale or exchange of a capital asset.
- IRC § 751 - Appreciated inventory of a joint venture is the principle asset if available to customers in the ordinary course of business or and is considered as a capital asset.

[9] 6A Fletcher Cyclopedia of the Law of Private Corporations (1992) § 2841.1 -- "The method by which one company takeover another is conceptualized as follows: One corporation makes a tender offer to acquire control of another by offering to buy all of its shares for sale at a stipulated price. Tender offers are conditional offers made to shareholders by a purchaser desiring a certain percentage of the outstanding securities of a corporation. A binding contract is created when when the shareholder tenders his/her securities in accordance with terms of the offer. When a tender offer is made by one corporation to exchange its shares for shares of another, registration is required with the Securities and Exchange Commission per the Securities Act of 1933." pp. 400-401.

[10] *See* Appendix VI; *See generally*, Freund, James C., *Through the Keyhole of the Boardroom: A Hypothetical Case Study of a Takeover*, 4 No. 3 Insights 3 "Eleventh Annual Institute on Acquisitions and Takeovers." (1990).

fails, because a failed equity financed research and development project can lead to substantial dilution of the parent company stock.[11] Because there is informational asymmetry[12] between the new investors and the new venture's management regarding the value of the research and development, new investors are unlikely to participate without a signal about the potential value of the research and development.[13] The warrants signal that the existing shareholders of the parent are willing to share the value of the parent's assets even if the new venture fails. The warrants can be costly, as they will lead to equity dilution if exercised.[14]

SWORD STRUCTURE

A SWORD consists of a series of contracts that define the rights of each entity and provide for the rights of the potential new shareholder investor. These contracts generally include (*See* Appendix II):[15]

1) Technology License Agreement -- This license generally grants to the new venture from the parent, a worldwide, exclusive, royalty-free license in perpetuity to use the parent's intellectual property and technologies in association with the development of the new venture's products. The parent has completed basic research on the technologies and then transfers this technology to the new venture. The perceived value of each new venture stems from the right to use the parent company's intellectual property rights associated with the license and the new

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[11] Solt, Michael, E., *SWORD Financing of Innovation in the Biotechnology Industry*, Financial Management. Summer 1993. pp. 173-187.

[12] Leland, H.E., and D. Pyle, *Informational Asymmetries, Financial Structure, and Financial Intermediation*. Journal of Finance (May 1977), pp. 371-387.

[13] *See* Solt at 174.

[14] *See generally*; Murtha, Emmett J., *Business Aspects of Licensing*, Practicing Law Institute, 354 PLI/Pat 273 (1993). An overview of licensing concerns is presented. Advantages and disadvantages of intellectual property licensing are also presented.

[15] *Id.*

venture maintains a perpetual claim on the future stream of operating income[16] generated by the technologies.

2) Services Agreement[17] -- The parent company agrees to provide management and administrative services to the new venture throughout the developmental process. This agreement, in effect, actually enables the new venture to function. The new venture has but little need for any technical or operating staff, because it is in essence a virtual corporation. The new venture is nothing more than a financial intermediary; the funds from the unit's offerings are invested in short-term securities and paid over time to the parent for research and development expenses, as specified in the development contract.

3) Development Contract -- The parent company performs the actual development of any new products at the parent's existing facilities. The parent company agrees to undertake any patent prosecution procedures for products or processes that may have a commercial potential. The new venture benefits from the parent's research expertise without having to obtain or train technical specialists or undergo the costs of obtaining or building duplicate laboratory facilities.[18]

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[16] *See*, Smith, Gordon V. and Russell L. Parr., Intellectual Property: Licensing and Joint Venture Profit Strategies. John Wiley & Sons, Inc. New York. 1993. The economic factors underlying a technology agreement include:

- The investment rate of return
- The total rate of investment return
- The form in which the investment will be provided
- The timing of the economic returns.
- Trend projection of the return.
- Duration of the returns.

[17] *See* Appendix II, ALZA/BES. Services agreement between the parent and the SWORD company provided for business administration.

[18] *See* Appendix III, Centocor/Tocor II. Centocor agrees to function as a contractor for the SWORD company and perform all necessary research and development work.

4) License Option Agreement[19] -- The importance of the agreement is determined by the granting clause. This type of licensing agreement contains a provision similar to the exercise provision contained in a financial option. The parent company is granted an option by the new venture to acquire a worldwide license to manufacture, use, and market any developed products in exchange for royalty payments. The new venture actually represents a bundle of real options since the parent company can exercise its right to license or sublicense any developed products or technology on an individual project basis.

5) Financing Arrangements -- Each SWORD unit contains one share of callable common stock and one warrant to purchase one share of the parent's common stock.[20] The parent company can reacquire the property rights to the developed technologies and products by calling the new venture shares. The new venture shareholders can exercise their warrants and thus share in the parent's income stream. Even if their stock is called, the new venture shareholders can continue to receive returns from the newly developed technology by exercising their warrants. Both parent company and new venture investors maintain claims on the parent, thus their incentives appear to be aligned in a SWORD.[21] Since each company is publicly traded, there is some exposure to the parent company ownership, whereby a competitor could purchase SWORD units and then exercise the warrants to establish a position within the parent. The parent company could lessen this exposure by carefully proportioning the shares outstanding represented by the exercise of the warrants.[22]

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[19] *See* Appendix II, ALZA/BES. Provides for the parent company, ALZA, to obtain a license for any new products developed by the SWORD company. *See generally*, Morrow, Webb B., *supra.*

[20] Solt, Michael, E., *SWORD Financing of Innovation in the Biotechnology Industry*, Financial Management. Summer 1993. pp. 173-187.

[21] *See* Appendix II, ALZA/BES. The Research and Development Agreement defines the extent that rights for any technology developed will be shared between the two companies.

[22] *See* Solt, Michael, E., at 176. n.7. *supra.*

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IV. THE FIRST *SWORD*-OFFERING

BIO-ELECTRO SYSTEMS, INC.

According to Solt,[23] the first SWORD stock offering in the biotechnology industry was ALZA Corporation's spinoff, Bio-Electro Systems, Inc. (BES), formed on October 12, 1988. BES was incorporated in the State of Delaware on October 3, 1988 to further develop the proprietary Alzamer ® bioerodible polymer and electrotransport technologies of ALZA Corporation and to commercialize, through licensing or otherwise, products based on these developed technologies for the prevention treatment or cure of human illnesses, disease and other medical conditions.[24] In order to undertake its activities, BES obtained from ALZA an exclusive, worldwide, royalty-free license to use ALZA's technologies, subject to limited rights to the technologies previously granted to certain third parties. In December 1988 SWORD units were issued and began trading on the American Stock Exchange. [25]

ALZA's Parent Technology

Under this SWORD arrangement, Bioerodible polymers, including ALZA's proprietary Alzamer ® bioerodible polymer, were developed for BES by ALZA for the controlled delivery of a variety of compounds., including therapeutic drugs and polypeptides. In the presence of moisture, bioerodible polymers erode, thereby permitting a drug compound formulated with the polymer matrix to be released at a controlled rate over an extended period of time from a polymer "platform" which

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[23] Solt, Michael, E., *SWORD Financing of Innovation in the Biotechnology Industry*, Financial Management. Summer 1993. pp. 173-187. College of Business, Accounting and Finance, San Jose State University, San Jose, CA 95192.

[24] Bio-Electro Systems, Inc., Annual Report to Stockholders, 12/31/89.

[25] Bio-Electro Systems, Inc. Form 10-K, 12/31/89.

then disappears. The ALZA polymers comprise a family of polyorthoester bioerodible polymers patented by ALZA. The technology licensed from ALZA can provide a bioerodible polymer that can have a variable rate of erosion and a correspondingly variable drug delivery rate that can be controlled for optimum effect.[26]

Additionally, electrotransport systems are being developed for BES by ALZA to either deliver compounds more effectively than with traditional systems or to deliver compounds that cannot be delivered transdermally. Electrotransport technology involves the delivery of drug compounds across the skin, nails or mucosal membranes under the influence of an extremely low level of electrical current.[27] Electrotransport systems can also be used to deliver compounds in precise patterns or on an as-needed basis by the patient.[28]

SWORD Structure

Registration statement information filed with the Securities and Exchange Commission for ALZA Corp's spinoff venture Bio-Electro Systems, Inc. (BES),[29] indicates that BES was capitalized with approximately $35.7 million through a subscription offering to ALZA stockholders for the purchase of Units. Each unit consisted of one share of BES Class A Common Stock and one ALZA warrant to acquire one share of ALZA Class A Common Stock, exercisable at $30 per share beginning 13, 1990 and ending December 14, 1993. A total of 4,150,000 units were registered, with 3,246,243 Units sold in the subscription offering, at a price of $11 per unit and BES received all of the net proceeds of the offering. ALZA has an option to

[26] Bio-Electro Systems, Inc. Form 10-K, 12/31/89.

[27] ALZA Corp., Annual Report to Stockholders, 12/31/89.

[28] Bio-Electro Systems, Inc. Form 10-K, 12/31/90.

[29] Bio-Electro Systems, Inc. Form 10-K, 12/31/89; SEC Abstracted Filings, Form S-1, Registration Number 33-24909, Bio-Electro Systems, Inc., Filing Date October 12, 1988.

purchase all of the BES Class A Common Stock.[30]

Description of the Securities

Each unit consists of one BES Class A Common Share and one Warrant to purchase one ALZA Class A Common Share. Transferable rights to subscribe for the units are being distributed to holders of ALZA's Class A and Class B common stock. Eight rights are required to subscribe for one unit, with each stockholder receiving one right for each class A share held. Holders of the Class B stock may convert their stock into Class A shares, receiving two Class A shares for each Class B share. The stock and warrants were set to trade as units for two years following the closing of the subscription. The warrants expire five years after the closing of the offering and may not be exercised until the date they may be separated from the stock.[31]

Holders of BES common stock are entitled to one vote per share, to receive dividends out of funds legally available for distribution when declared by the board and to share in the assets of the company in the event of a liquidation, dissolution or winding up of the affairs of the company. The shares carry no preemptive, redemptive, or conversion rights and are not subject to sinking fund provisions. The common shares will be fully paid and non-assessable when issued.[32]

Holders of ALZA common stock are entitled to one vote per share, to receive dividends out of funds legally available for distribution when declared by the board, and to share in the assets of the company in the event of a liquidation, dissolution or winding up of the affairs of the company. The shares carry no preemptive, redemptive, or conversion rights and are not subject to sinking fund provisions. The common shares will be fully paid and non-assessable when issued.[33]

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[30] ALZA Corp., Annual Report to Stockholders, 12/31/90.

[31] Bio-Electro Systems, Inc. Form 10-K, 12/31/89.

[32] *Id.*

[33] ALZA Corp., Form 10-K, 12/31/89.

Licensing Arrangements with ALZA

As expressly stated in BES's December 31, 1989 Form 10-K, ALZA and BES entered into a series of agreements to facilitate the SWORD offering:

Development Agreement -- Specifically, BES and ALZA entered into a Development Agreement, whereby ALZA will use diligent efforts to conduct systems research and development and product development using ALZA's technologies. Payments from BES are scheduled to ALZA, and include the full amount of all development costs of the technologies incurred by ALZA beginning January 1, 1988.[34]

Development costs are charged on the same basis that ALZA generally charges other clients. BES is required to spend an amount equal to all of the net proceeds of the subscription offering plus any interest earned under the Development Agreement. Activities under the Development Agreement include systems research and development (R & D), screening evaluation and product development. The objective of the systems R & D is to develop systems utilizing the technologies that could provide multiple product opportunities. In the screening evaluation, the objective is to evaluate drug compounds for their possible inclusion into eventual product development. ALZA has the right, subject to certain dollar limitations, to designate drugs for screening, and ALZA also has the right to designate one Alzamer® Polymer product and one electrotransport product to be under development.[35]

License Option -- ALZA and BES also entered into a license option agreement, whereby BES granted ALZA an option to acquire a license to use the BES developed technologies on a product by product basis. If the License Option is exercised for any

[34] Bio-Electro Systems, Inc. Form 10-K, 12/31/89.

[35] *See* Appendix II: ALZA/BES Research and Development Agreement.

product, ALZA will then acquire a worldwide license, with the right to sublicense, make, use or sell the product. ALZA's license for any product will be exclusive for seven years after marketing approval for the product has been received from the U.S. Food and Drug Administration (FDA), and then becomes nonexclusive thereafter.[36]

ALZA's Rights under each Agreement

Under each of the above agreements, ALZA will make payments to BES based upon ALZA's and its affiliate's and sublicensee's sales of the licensed product, and limited payments based on certain amounts, if any, paid to ALZA by third parties for the development of the product.[37] The exact royalty payments will vary from product to product, based upon the proportion of the total development costs of the product paid by others. ALZA retains the right to develop products using the licensed technologies for its own account and for third parties in addition to the activities funded by BES under the Development Agreement.[38] In such instances, BES will have an exclusive license to the technology developed (other than technology relating to a third-party's proprietary compound) and any products developed will be subject to the License Option.[39] If ALZA does not exercise its Purchase Option ALZA may not acquire additional product licenses after the time for exercise of the Purchase Option has expired.[40]

Purchase Option -- ALZA retains certain rights pursuant to the Restated Certificate of Incorporation of BES to purchase all of BES Class A Common Stock (the Purchase Option). The Purchase Option will be exercisable at any time beginning on the earlier of (i) February 1, 1991 and (ii) the day BES provides ALZA with quarterly

[36] *See* Appendix II: ALZA/BES License Option Agreement.
[37] *See* Appendix II: ALZA/BES Research and Development Agreement.
[38] *See* Appendix II: ALZA/BES Research and Development Agreement.
[39] *See* Appendix II: ALZA/BES License Option Agreement.
[40] *See* Appendix II: ALZA/BES License Option Agreement.

financial statements of BES showing stockholders' equity of less than $4 million, and ending on the earlier of (i) January 31, 1995 and (ii) the 90th day after BES provides ALZA with quarterly statements of BES showing stockholders' equity of less than $4 million.[41] The purchase price may be paid in cash, ALZA Class A Common Stock or in any combination of cash and ALZA Class A Common Stock, at ALZA's sole discretion.

Under its Restated Certificate of Incorporation, BES is prohibited from taking or permitting any action inconsistent with ALZA's Purchase Option and, until the expiration of the Purchase Option, BES may not, without the consent of ALZA (holder of BES Class B Common Stock) authorize or issue additional capital stock, merge, liquidate, sell all or substantially all of its assets, or amend its Restated Certificate of Incorporation to alter the Purchase Option or the rights of the Class B Common Stock.[42]

ALZA is under no obligation to exercise the Purchase Option, and will do so only if such exercise is in the best interest of ALZA. If ALZA does not exercise the Purchase Option, its rights to make, use or sell any product utilizing the technologies will be limited to the rights ALZA obtains under the License Option[43]

Intellectual Property

Under the Development Agreement, ALZA agrees to file any patent applications with respect to the BES technologies that it believes to be of commercial importance. The commercial success of BES's acquired technology may directly

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[41] *See* Appendix II: ALZA/BES License Option Agreement. If the Purchase Option agreement is exercised, the purchase price per share will be as follows:
1) Before February 1, 1992 – $23;
2) After February 1, 1992 and before January 31, 1993 – $31;
3) After February 1, 1993 and before January 31, 1994 – $42;
4) After February 1, 1994 and before January 31, 1995 – $57.

[42] See Appendix II: ALZA/BES Restated Articles of Incorporation.

[43] *See* Appendix II: ALZA/BES License Option Agreement.

depend on its parent's ALZA, ability to obtain patent protection.[44] Early in 1990, ALZA, BES, and Medtronic, Inc. (A Minnesota Corporation), entered into a collaborative arrangement under which BES and Medtronic would share technology related to electrotransport drug deliver, and managed thereby by ALZA.[45] According to their 1990 annual report,[46] ALZA's patents and patent applications, or patents obtained or licensed under the arrangements with Medtronic, and any patents obtained in the future covering the technologies may be of vital importance to future operations. ALZA and Medtronic have filed patent applications covering various aspects of their electrotransport technology; patents have been issued to both ALZA and Medtronic, but there is no assurance that any others will issue or that there will be any significant commercial value. The Alzamer ® polymer technology has been patented, with the primary patent set to expire in 1996. ALZA will, where appropriate, apply for patents covering improvements to the Alzamer ® polymers and specific products incorporating the technologies.[47]

V. Analysis of the BES Licensing Agreements

As part of its filing requirements under the SEC, BES included a number of instruments pertaining to their first SWORD filing those instruments are as follows:[48]

A) Exhibit 3.2 -- Restated Certificate of Incorporation

The certificate of incorporation recitals state that BES was incorporated in the

[44] *See* Appendix II: ALZA/BES Research and Development Agreement.

[45] ALZA Corp., Annual Report to Stockholders, 12/31/90.

[46] ALZA Corp., Annual Report to Stockholders, 12/31/90.

[47] *Id.*

[48] *See*, Marver, James D., *Planning the Business for a Future Initial Public Offering*. Start-Up Companies: Planning, Financing, and Operating the Successful Business. Vol. 2,§§ 21.1-21.07. (1993).

State of Delaware under the General Corporation Laws.[49] Of particular note is the inclusion of the requisite Purchase Option Agreement in the certificate itself.[50] This repurchase option pertains to one of the essential legally operative rights needed to effectuate a SWORD offering, as the parent company eventually needs to regain full rights over its intellectual property after the spinoff obtains the exclusive right to use all of the parent's intellectual property in order to conduct research and development.[51] This purchase option grants to ALZA:

> an exclusive irrevocable purchase option to purchase all issued and outstanding shares of Class A Common Stock of this corporation. The Purchase Option, if exercised, must be exercised as to all issued and outstanding shares of Class A Common Stock only. At any time during a period beginning on the earlier of (i) February 1, 1991 and (ii) the day this corporation provides ALZA with quarterly financial statements of this corporation showing stockholders equity of less than $4 million, and ending on the earlier of (i) January 31, 1995 and (ii) the 90th day after this corporation provides ALZA with quarterly financial statements...showing stockholders equity of less than $4 million (the expiration date)...the purchase option may at ALZA's option, be transferred to this corporation.[52]

This unique Purchase Option as set forth in the certificate of incorporation grants to BES's parent, ALZA, a fundamental right to buy-out and foreclose all of BES's outstanding stock and thus close-out BES as a business entity no later than January 1, 1995. This characteristic is important in two ways: (1) it allows shareholders to obtain a maximized return on their investment; (2) its legal effect operates to "pull-back" ALZA's intellectual property which had been exclusively licensed to BES. It is important to note that this provision will happen

[49] *See* Appendix II: ALZA/BES Restated Articles of Incorporation.

[50] *Id.*

[51] *See* Appendix II: ALZA/BES Restated Articles of Incorporation; ¶ 5.

[52] *See* Appendix II: ALZA/BES Restated Articles of Incorporation; ¶ 5(a).

automatically, without any further actions by BES or ALZA. The certificate expressly states that ALZA shall pay an increasing rate for each outstanding share of Class A Common stock repurchased on a sliding scale ranging from $23 to $57 dollars over a time period of five years, with all shares of BES Class A Common slated to have been repurchased by January 31, 1995.[53]

BES further provides in yet another provision for title to the shares to revert back to ALZA by allowing ALZA to repurchase all outstanding shares of Class A Common stock. Specifically:

> [t]ransfer of title to all of the issued and outstanding shares of Class A Common Stock *shall be deemed to occur automatically* on the Closing Date and thereafter the corporation shall be entitled to treat ALZA as the sole holder of all of the issued and outstanding shares of its Class A Common Stock, notwithstanding the failure of any holder of Class A Common Stock to tender the certificates representing such shares to the Payment Agent (emphasis added).[54]

B) Exhibit 10.1 -- Technology License Agreement

The main enabling agreement in any SWORD arrangement is the Technology Licensing Agreement that allows the internal spinoff company to obtain exclusive rights to the parent company's proprietary technology.[55] The technology license agreement between ALZA and BES created a unique cross-licensing arrangement; BES obtained from its parent, ALZA, the necessary technology needed to conduct research and development and ALZA obtained all rights to any new technologies developed by BES under the technology licensing arrangement. The recitals of the agreement state that ALZA has certain proprietary rights to the Licensed Technology

[53] *See* Appendix II: ALZA/BES Restated Articles of Incorporation; ¶ 5(c)).

[54] *See* Appendix II: ALZA/BES Restated Articles of Incorporation; ¶ 5(h)).

[55] *See* Appendix II: ALZA/BES Technology License Agreement (¶ 2.1):
"ALZA hereby grants to BESI, on the terms and conditions of this agreement and subject to the Preexisting Right, a worldwide, royalty-free, exclusive license, in perpetuity, to practice the Licensed Technology in the Field, but for no other purpose whatever."

and that BES proposes to undertake further research and development of the Licensed Technology to develop products and acquire its own certain technology in connection therewith.[56] BES and ALZA are entering into both a licensing option and research and development agreement. In consideration of the foregoing agreements, ALZA is willing to grant to BES a license to practice the Licensed Technology in the field under certain circumstances.[57] Of particular note, the specific definitions of the agreement grant a license to BES for all of ALZA's technology.[58]

These definitions expressly state that any and all proprietary technology,

[56] *See* Appendix II: ALZA/BES Technology License Agreement (¶ 2.1(c)).

[57] *See* Appendix II: ALZA/BES Technology License Agreement (¶ 2.1(D)).

[58] 1.1 "ALZA Proprietary Rights" shall mean all Proprietary Rights of ALZA to the extent now or hereafter owned and controlled by ALZA and which ALZA has or will have the right to license.

1.2 "ALZAMER® Bioerodible Polymers" shall mean the family of polyester bioerodible polymers disclosed and patented by ALZA in U.S. Patent No. 4,189,646, when used to deliver a compound.

1.3 "BESI Technology" shall mean technology necessary or useful in the field developed by or on behalf of BESI or acquired or licensed by BESI from third parties, in each case on or before January 31, 1995 (or such earlier date on which the Development Contract is terminated).

1.7 "Field" shall mean all applications of ALZAMER® Bioerodible Polymers or Electrotransport Systems for use in the prevention, treatment or cure of illness, disease or other medical condition in humans, but not the diagnosis thereof.

1.9 "Licensed Technology" shall mean ALZA Proprietary Rights developed on or before January 31, 1995 (or such earlier date on which the Development Contract is terminated as provided therein) which are necessary or useful for research in the Field or the development, manufacture or sale of Products.

1.10 "Preexisting Rights" shall mean the rights of the entities listed on Exhibit A hereto to use the Licensed Technology in the field.

1.11 "Products" shall mean all products in the Field developed by ALZA and Affiliates utilizing or based upon or arising out of the Licensed Technology or BESI Technology.

whether patented or not, inclusive of all know-how and show-how shall be included and available to BES in the defined subject matter under this license. This allows BES to *stand in the shoes* of ALZA regarding access to ALZA's technology; a necessity, because BES as a virtual corporation has no facilities or research employees of its own, thus it contractually retains ALZA to conduct all research and development and administration on its behalf.

The Granting Clause

The most important provision in defining the licensing rights between the parties is the granting clause.[59] "The terms of the grant which describe the legal character of the license being extended and the provisions which define the subject matter included in the license are clearly the essence of any patent licensing agreement."[60] The granting clause of ALZA to BES is as follows:

> 2.1 Grant of License. ALZA hereby grants to BESI, on the terms and conditions of this agreement and subject to the Preexisting Rights, a worldwide, royalty-free, exclusive license, in perpetuity, to practice the Licensed Technology in the Field, but for no other purpose whatsoever. Except as provided in other agreements between the parties, BESI shall not sublicense the Licensed Technology to, or enter into other arrangements with respect to the Licensed Technology with, any third party for any purpose before January 31, 1995 (or such earlier date on which the Purchase Option terminates) without the prior written consent of ALZA.[61]

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[59] *See generally,* Coolley, Ronald B., *Drafting a Granting Clause,* Les Nouvelles, December 1992, pp 212-14. The essential components of a granting clause address:

- The precise subject matter granted.
- The rights that are to be granted.
- Conditions in the license.
- Nonassertion clauses.
- Restrictions on use, territory, quantity, style.
- Restrictions on the Transfer of technology.

[60] Mayers, Harry R., and Brian G. Brunsvold, Drafting Patent License Agreements. Bureau of National Affairs. Washington, D.C., 1992. p. 51.

[61] *See* Appendix II: ALZA/BES Technology License Agreement (¶ 2.1).

Analysis of the Granting Clause

Of particular note, ALZA has granted an "exclusive license" of all of its Licensed Technology, on a "worldwide" basis, "royalty-free" and "in perpetuity" to practice the Licensed Technology in the Field, but for no other purposes. The following points of the license are noted:[62]

ALZA has granted all of its licensed technology to BES under an exclusive license with no rights vesting in BES to sublicense. Mayers and Brunsvold[63] citing to a line of cases starting with Waterman *v. MacKensie,*[64] suggest that any exclusive license so "absolute in its terms may constitute a *pro tanto* " 'assignment' " of patent rights that would imply a right in the licensee to further assign the license or subdivide it by granting nonexclusive licenses under it.[65] Mayers and Brunsvold also suggest that for commercial reasons, a parent company licensing its technology to another, such as ALZA and BES, may wish to grant the right to enter into additional licenses of commercially important technology with third parties during the time period in question. However, under this licensing agreement, there was no legal right to sublicense granted to BES for any of the ALZA technology.

Additionally, ALZA did not reserve to itself a license to make, use or sell any of the proprietary technology described in the Licensed Technology. ALZA has granted to BES an exclusive license to all of ALZA's proprietary technology, without anticipating that it would wish to continue to use its technology within the scope of its own ongoing business. Apparently, ALZA presumably continued(es) to use the Licensed Technology granted to BES in breach of the express license terms.[66]

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[62] *See* Appendix II: ALZA/BES Technology License Agreement. (¶ 2.1).

[63] Mayers, Harry R., and Brian G. Brunsvold, Drafting Patent License Agreements. Bureau of National Affairs. Washington, D.C., 1992. p. 51.

[64] 138 U.S. 252 (1891).

[65] *Id.* at 38, § 6.01.

[66] *See* Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 2.1 - 2.5).

Obligations Relating to "Patents"

Under the terms of the "Patents" provision of the Technology License, BES must both notify ALZA and cooperate with ALZA to prevent or terminate any patent infringement. The license specifically provides that:

> BESI shall notify ALZA of any infringement or alleged infringement known to BESI of any patent rights included in the Licensed Technology or of any unauthorized or alleged unauthorized use known to BESI of the license Technology by the manufacture, use or sale by a third party of any product in the Field. In the event of such alleged infringement or unauthorized use, ALZA shall have the right, at its own expense and with the right to all recoveries, to take appropriate action to restrain such alleged infringement or unauthorized use....[67]

Of particular note is the drafted provision that is to be used to determine when BES shall have the assumable right to undertake patent litigation on its own behalf. Specifically:

> [i]f within six months after written notice from BESI, ALZA *has not commenced* any action to restrain such alleged infringement or unauthorized use, and if at such time, the annualized unit sales volume of *such infringing product equals or exceeds ten percent of the unit sales volume of the related Product*, BESI shall have the right, at its own expense and with the right to all recoveries, to take such action as it deems appropriate to restrain such alleged infringement or unauthorized use.... (emphasis added).[68]

Close inspection of the first above cited "Patents" provision reveals that ALZA "shall have the right, at its own expense and with right to all recoveries, to take appropriate action to restrain such alleged [patent] infringement or unauthorized use." However, the language of this 'patents' clause may have exposed ALZA to legal challenge for lack of "standing to sue," if it ever tried to

[67] *See* Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 4).

[68] *Id.*

enforce the proprietary technology or patented technology that was 'granted' by an 'exclusive license' to BES, with no reservation of rights to ALZA to continue to make, use or sell intellectual property rights granted to BES under the Technology License Agreement. Under the granting clause, "all" proprietary rights of ALZA were exclusively granted to BES, which when strictly read removes ALZA from enforcing any of "its" proprietary rights. Therefore, it is apparent that BES is the only entity that can have legal standing to enforce or recover on any of the proprietary rights which were exclusively licensed to it by ALZA.

The last sentence of the "patents" provision states that "BESI shall not settle any such action relating to any alleged infringement or unauthorized use without the prior written consent of ALZA."[69] As ALZA granted its legal rights to its proprietary technology in an exclusive license to BES, it is apparent that this clause would also be legally inoperative if ALZA is deemed not to have legal standing. BES would be the named party in a patent infringement lawsuit and would thus be the party that would have to give consent to any subsequent settlement agreement.

Confidentiality

The Technology License Agreement also provides for an extensive confidentiality agreement between ALZA and BES relating to the class of technology transferred or disclosed to BES in the Technology Licensing Agreement. Specifically, the license definition of confidential information provides:

> 1.4 "Confidential Information" shall mean, without limitation, the originals or copies of all information, data documents, inventions, laboratory notebooks, drawings, specifications, bills of materials, devices, equipment, prototype models and tangible manifestations relating to or embodying any Licensed Technology disclosed hereunder except any of the foregoing which: (1) is known to or used by BESI prior to the time of disclosure hereunder as evidenced by its written records; (b) lawfully is disclosed to BESI

[69] *See* Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 5).

by a third party having the right to disclose them to BESI; or (c) either before or after the time of disclosure to BESI becomes known to the public other than by an unauthorized act or omission of BESI or any of its employees or agents.[70]

The confidentiality agreement provision specifically provides:

> [s]ubject to the other provisions of this Agreement, during the term of this Agreement and for a *period of five [5] years* following its termination, BESI shall maintain in confidence all Confidential Information; provided, however, that nothing contained herein shall prevent BESI from disclosing any Confidential Information to the extent that such Confidential Information is required to be disclosed... (i) in connection with securing... governmental approvals for the marketing of products, (ii) for the purpose of complying with governmental regulations, (iii) for the purpose of any sublicense to ALZA under the Development Contract or (iv) for the purpose of any other sublicense permitted hereunder after ALZA's rights under the License Option Agreement have terminated. *The obligations pursuant to this Section 5 shall survive the termination of this Agreement for any reason.* (emphasis added).[71]

The drafters of the confidentiality agreement expressly provided that BES must maintain the confidential relationship for a calender period of five (5) years, and they have presciently included a clause that this confidential obligation shall survive the termination of this Agreement for "any reason."[72] However, the drafters did not expressly provide for what "shall maintain in confidence" means. The level of confidentiality, or who "needs to know" has not been defined. The agreement is silent as to what measures (legal/physical) must be undertaken by BES in order to comply with maintaining the confidentiality level.

Termination Provision

Under the termination clause, "[e]ither party may terminate this Agreement

[70] *See* Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 1.4).

[71] *See* Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 5).

[72] *Id.*

effective upon the giving of written notice of such termination to the other party in the event such other party:"

> (a) breaches any of its material obligations hereunder and such breach continues for a period of 60 days after written notice thereof by the other party; or (b) enters into any proceeding, whether voluntary or otherwise, in bankruptcy, reorganization, arrangement for the appointment of a receiver or trustee to take possession of such other party's assets or any other proceeding under any law for the relief of creditors, or makes an assignment for the benefit of such party's creditors. This agreement shall automatically terminate upon the termination by BESI of the Development Contract or any other agreement between the parties without the consent of ALZA, other than due to a breach thereof by ALZA.[73]

Thus the drafters have provided that the Technology License Agreement terminates if BES should come under any form of legal control for the satisfaction of creditors. This provision attempts to preserve the intellectual property assets that were granted in an exclusive license to BES. The Technology License Agreement will also terminate if BES materially breaches any other agreement between ALZA and BES.

C) Exhibit 10.2 -- The Research and Development (Services) Agreement

The third SWORD facilitating agreement between ALZA and BES is the Research and Development Agreement.[74] This extensive agreement contractually obligates ALZA, as the parent company (Contractor), to conduct the research and development (R & D) work on behalf of BES (Client), which embodied as a SWORD company does not employ anyone for research and development nor does it maintain any research facilities of its own.[75]

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[73] *See* Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 7).

[74] See Appendix II: ALZA/BES Research and Development Agreement.

[75] *Id.*

In the recitals, the parties are designated as to their function, as well as defining what the obligations of the parties are. Specifically:[76]

> A. Client [BES] is a corporation organized for the purpose of developing and commercializing products in the Field utilizing the Licensed Technology.
>
> B. Contractor [ALZA] is engaged in the business of research and development of pharmaceutical products.
>
> C. Client desires to have Contractor perform, on behalf of Client, further research and development activities using the Licensed Technology."

In keeping with the scope of this paper, emphasis will be placed on the Research and Development Agreement provisions relating to the intellectual property of both companies. Intangible property rights encompassing the sum total of the intellectual property of both companies is contractually at stake in this Research and Development Agreement. It is critical that this Agreement define and transfer the legally operative rights of either party to enable the SWORD (BES) to function, as well as providing for adequate legal protection to both entities to ensure that their intellectual property does not become infringed, invalid or rendered known to the public. In particular, this Agreement provides for several "precising"[77] definitions: [78]

> 1.2 "ALZA Proprietary Rights" shall mean Proprietary Rights of Contractor to extent now or hereinafter owned or controlled by Contractor and existing during the term of this Agreement other than the Developed Technology, and which Contractor has or will have the right to license.
>
> 1.5 "Developed Technology" shall mean Proprietary Rights in the Field that (i) are generated, developed, conceived or first reduced to practice, as the case may be, by Contractor under this

[76] *See* Appendix II: ALZA/BES Research and Development Agreement. ¶ A, B, and C.

[77] Mayers, Harry R., and Brian G. Brunsvold, Drafting Patent License Agreements. Bureau of National Affairs. Washington, D.C., 1992. p. 19.

[78] *See* Appendix II: ALZA/BES Research and Development Agreement ¶ 1.2 - 1.19.

Agreement; (ii) are acquired by or on behalf of Client from persons other than Contractor; or (iii) are (a) generated, developed, conceived or first reduced to practice, as the case may be by Contractor during the term of this agreement pursuant to an agreement providing for the development or commercialization of a product in the Field with an unrelated third party, (b) are not related to a proprietary drug compound owned by or licensed to such third party, and (c) which contractor has or will have the right to license to Client hereunder.

1.14 "Licensed Technology" shall mean ALZA Proprietary Rights existing during the term of this Agreement which are necessary or useful for the research and development, manufacture or sale of products in the Field.

1.19 "Proprietary Rights" shall mean data, inventions, information, processes, know how and trade secrets, and patents or patent applications for any of the foregoing, owned or licensed to a party and which such party has the right to license hereunder.

Intellectual Property Provisions

The "Hiring Provision" provides *inter alia* that the "[c]ontractor [ALZA] shall have discretion to attempt to obtain, on behalf of and at the expense of Client, any *patent or technology license* from any third party that Contractor reasonably determines to be necessary or useful to enable Client to conduct Systems Research and Development and Product Development Programs under this Agreement." (emphasis added). [79]

The importance of this clause is clear, as the Contractor [ALZA] shifts the decision-making control to itself, and places the financial burden [cost] on the Client [BES] for any patent or technology deemed necessary by ALZA. This clause in particular reveals the underlying basis of the SWORD arrangement, i.e., getting capital back to the parent. In doing so, it may be necessary for the Contractor (ALZA) to obtain technology from third-party companies to facilitate the SWORD company's

[79] *See* Appendix II: ALZA/BES Research and Development Agreement ¶ 3.1.

continued research and development of new p[roducts for the parent. The commercial risk of this licensing arrangement is placed back on the parent, however the clause states that the "expense" of obtaining this technology or patent will be borne by BES. Thereby ALZA's financial balance sheets do not reflect the economic liability for obtaining the additional technology.[80]

There is an additional provision that further places the economic burden ion the SWORD company. The financial benefit to ALZA is apparent in the "Payment for Services" provision whereby BES is obligated to reimburse ALZA for all of ALZA's Developmental Costs, to expend all of its Available Funds, including paying for ALZA's licensing fees to several third-party research entities.[81]

License Granting Clause

The licensing provisions provide that the Client [BES] grants to "Contractor [ALZA] a sublicense to practice the Licensed Technology and the Development Technology *solely* for purposes of performing its duties hereunder and the activities contemplated hereby...."[82] Of interest, this provision limits ALZA to use of "its" Licensed and Developed Technology *solely* for the purpose of performing its obligations to BES under this agreement. ALZA is restricted in that it cannot use this sublicensed technology for its own purposes, somewhat of a handicap for such a large parent corporation with its own product line in development.

The ownership of any Developed Technology is provided for in this agreement.[83] ALZA as parent company and designated Contractor for its Client (BES) under this agreement is granted as follows:

> [c]ontractor shall own all Developed Technology; provided, however, that Contractor hereby grants to Client, subject to

[80] *See* Appendix II: ALZA/BES Research and Development Agreement. (¶ 3.1).
[81] *See* Appendix II: ALZA/BES Research and Development Agreement. (¶ 4.1-4.2).
[82] *See* Appendix II: ALZA/BES Research and Development Agreement. (¶ 6.1).
[83] *Id.*

Preexisting Rights, a worldwide, exclusive, royalty-free license (*with the right to sublicense*), in perpetuity, to the Developed Technology. There shall, however, be excluded from the license granted above and specifically retained by Contractor all of the right, title and interest in and to all proprietary Rights and all physical manifestations or embodiments thereof, generated, developed, conceived or first reduced to practice during the term of this Agreement and are not included within the Developed Technology.[84]

Analysis of the License Granting Clause

The above provision grants ownership (title) to ALZA for all newly developed technology to the Contractor [ALZA], with the additional grant of an exclusive license to BES with right to sublicense. However, there are no additional clarifications or restrictions on BES's right to sublicense, such as whether BES may grant a royalty-bearing sublicense or more specifically, whether BES may grant a royalty-free sublicense to a competitor of ALZA.

Patents Provision

The research and development agreement addresses the subject of who has responsibility for patent prosecution and payment of patent maintenance fees.

7.2 Patents. Contractor [ALZA] shall cause appropriate United States patent applications to be prepared and prosecuted with respect to inventions included in Developed Technology and licensed to Client pursuant to Section 7.1 above and which Contractor believes to be patentable and commercially and technically significant, and to cause such patents to be maintained, as Client shall request in writing, all at Client's expense; provided, however, that to the extent and with respect to inventions which have substantial application beyond Developed Technology or outside the Field, the expenses of preparing , prosecuting and maintaining such patents shall be shared equally by the parties, unless agreed otherwise.... [c]ontractor further agrees to use its diligent efforts to cause each of its employees and agents to do all such acts and to execute, acknowledge and deliver all instruments or writings reasonably requested and necessary for the perfection of

[84] *See* Appendix II: ALZA/BES Research and Development Agreement (¶ 7.1).

patent rights to Developed Technology in the Field for License to Client.[85]

This provision provides that the responsibility of obtaining patent protection will rest with ALZA; however, the *cost* of ALZA's obtaining patent protection and maintaining that protection shall be borne by BES. Again this provision is to the benefit of the SWORD parent, ALZA, who as Contractor to its Client BES, receives that benefit of patent or invention ownership and patent prosecution/maintenance costs are derived directly from BES, as the Client.[86] This provision also reveals the purpose of a SWORD arrangement; getting funding from the SWORD entity to the parent [ALZA] with risk of loss shifted to the SWORD [BES] company.

Confidentiality Provision

A confidentiality clause is also included in the Research and Development Agreement. Similar in scope to the Technology License Agreement,[87] this provision provides for a five [5] year period for confidentiality, and provides for the legal effect to survive beyond the termination of this agreement.[88]

D) Exhibit 10.3 – License Option Agreement

This license agreement grants to ALZA from BES, a license option for ALZA to acquire Products produced under the Development Agreement.[89] The subject matter under consideration pertains to an option to ALZA to obtain a license from BES:

> 1.6 "License Option" shall mean the option granted to ALZA, pursuant to Section 2 of this Agreement, too use the BESI Technology to develop, make, have made, use or sell the Licensed Product.

[85] *See* Appendix II: ALZA/BES Research and Development Agreement (¶ 7.2).
[86] *Id.*
[87] Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 2.1).
[88] *See* Appendix II: ALZA/BES Research and Development Agreement (¶ 8.1).
[89] Appendix II: ALZA/BES Technology Licensing Agreement. (¶ 2.1).

> 1.8 "Product" shall mean (i) any product for which a Screening Evaluation is performed under the Development Contract, or (ii) any product in the Field using or incorporating BESI Technology or Licensed Technology which is the subject of research and/or development work by ALZA performed for a third party or for its own account or (iii) any product useful in the Field acquired by BESI.

ALZA may exercise the option when the following occurs:

> 2.2 Time for exercise. ALZA may exercise the License Option with respect to each product, on a Product by Product basis, at any time during the period beginning upon the completion of the Screening Evaluation therefore under the Development Contract... and ending 90 days after FDA approval to market the Product. With respect to any Product acquired by BESI after FDA approval to market the Product has already been obtained, the License Option shall be exercisable for 90 days after BESI has notified ALZA in writing that the product has been acquired, which notice shall provide a detailed description of the Product and the underlying technology. Notwithstanding the foregoing, in no event shall the License Option be exercisable after the earlier of (i) January 31, 1995 and (ii) the date that is 60 days after the termination of the Development Contract. The License Option will automatically expire if not exercised within the foregoing time period....[90]

Analysis of the License Option Granting Provision

This provision sets forth the option to ALZA to obtain a license from BES for Products that have obtained the requisite FDA approval to market such pharmaceutical products. However, the License Option is silent as to what form of license agreement (exclusive/nonexclusive) or assignment to ALZA will be offered. Also, as BES is obligated to cease its existence on January 31, 1995 per its Restated Certificate of Incorporation,[91] there is an outer finite time period of 60 days after the Development Contract expires, which gives at the most, 60 days beyond January 31,

[90] *See* Appendix II: ALZA/BES License Option Agreement (¶ 2.2).

[91] *See* Appendix II: ALZA/BES Restated Certificate of Incorporation.

1995 for ALZA to exercise its option or else the option will expire.[92]

Financial Results

During the first year of operation in 1989, BES reported a net loss of $8.2 million, consisting primarily of research and development expenses of $10.6 million for the year, reduced by cash income. BES had approximately $22.5 million in cash,cash equivalents and short term investments at the end of 1989.[93]

The first-year historical stock price trend of ALZA and BES shows both ALZA and BES with a steady parallel growth in share price.[94] This growth is especially apparent in the latter half of 1991, whereby both the parent and the SWORD show parallel upward growth in there share price. This growth in the parent/SWORD share price may be attributed to the FDA's marketing approval of Procardia XL which are based on ALZA technology and marketed by Pfizer Corp. This pharmaceutical reached over $1 billion in annual sales. Procardia is now the largest selling cardiovascular product in the United States. ALZA's (BES) time-release bioerodible technology was used to create a once a-day time-release oral tablet for relief of angina pectoris. In November 1991, ALZA exercised its purchase option to acquire all outstanding shares of BES Class A Common stock for approximately $75 million. Relating to the original BES offering, ALZA has 6.4 million warrants outstanding, exercisable at $15 per share through December 14, 1993.[95] On February 7, 1992 Bio-Electro Systems, Inc. was merged into ALZA Corp. and each BES share exchanged for 0.5772 of an ALZA share. Previously, ALZA exercised its option to acquire all Class A Common shares of BES for $23 per BES share, payable in ALZA Class A Common shares.[96]

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[92] *See* Appendix II: ALZA/BES License Option Agreement.

[93] Bio-Electro Systems, Inc., Annual Report to Stockholders, 12/31/89.

[94] *See* Appendix V: Graph of Parent/SWORD Stock Trends.

[95] Standard & Poor's Daily News, January 21, 1993.

[96] Standard & Poor's Daily News, January 21, 1993.

VI. SWORD Profile

COMPARISON WITH A RECENT SWORD OFFERING STUDY

TOCOR II

The recent January 12, 1992 SWORD offering of Tocor II, Inc. (Malvern, PA), is a spinoff of its parent company, Centocor, Inc. (Malvern, PA). This SWORD company is profiled to show the increasing level of sophistication in the biotechnology- related legal field regarding the use of intellectual property in the structuring of a SWORD offering since the first SWORD offering in 1988.[97]

Background

Tocor II was incorporated on November 6, 1991 in the British Virgin Islands; the company commenced operations on January 12, 1992. As a SWORD company, virtually all of the company's activities are conducted pursuant to contracts with Centocor, Inc. The company does not maintain staff or occupy any facilities other than office facilities, thus, it is heavily dependent upon Centocor. Tocor II was formed by its parent Centocor, Inc. to engage in the research, development and preliminary clinical studies in the field of peptide-based pharmaceutical products for the treatment of human diseases.[98] Tocor II conducts research for product development in the treatment of rheumatoid arthritis and other autoimmune diseases; also, adult respiratory distress syndrome, other inflammatory conditions and certain cardiovascular disorders related to blood-clot formation.[99]

Initial Public Offering

Tocor II and Centocor, Inc. completed a public sale of 2,250,000 Units in

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[97] *See generally*, Ziemer, Marilyn, *A Primer for Genetic Engineering*, Les Nouvelles, June 1992, pp. 95-101. This article provides a good overview of the biotechnology that is the subject matter of the Centocor/Tocor II SWORD offerings.

[98] Annual Report to Stockholders, 12/31/92, Tocor II, Inc., 200 Great Valley Parkway, Malvern, PA.

[99] *Id.*

January 1992.[100] Each unit consisted of one share of callable common stock of Tocor II, one series T warrant, and one callable warrant. Each warrant entitles the holder to purchase one share of Centocor (parent company) common stock. The series T warrant is exercisable from January 1, 1994 through December 31, 1996 at an exercise price of $64.50 per share. The callable warrant will be exercisable from the earliest of January 1, 1996. The termination power unexercised of the purchase option or the sale of substantially all of Centocor's assets will continue through December 31, 1997.[101]

Centocor had the option to acquire the callable common stock of Tocor II between January 1, 1993 and December 31, 1995. The purchase option exercise price is $58 per share during 1993, $76 per share during 1994, and $107 per share during 1995. The exercise price may be paid in cash, shares of Centocor common stock, or a combination thereof, at Centocor's discretion. If the purchase option is exercised by Centocor, the callable warrants will terminate.[102]

Present and Projected Sources of Funding

Tocor II's principle cash source in 1992 was the approximate $83,925,000 net proceeds from the initial public offering (IPO) of its callable common stock. From the initial offering period of January 21, 1992 through December 31, 1992, cash flows from the company's operations were negative, resulting primarily from the payment of $18, 318, 000 back to Centocor, Inc. under the Development Agreement,[103] and from the payment of a non-refundable fee of $2,500,000 to Centocor under the License Agreement.[104] These outflows were partially offset by cash inflows from the interest earned on Tocor II's investments.[105]

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[100] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.
[101] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.
[102] *Id.*
[103] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.
[104] *Id.*
[105] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

The company is obligated to pay substantially all of its available cash, cash equivalents, investments and interest earned on these funds back to Centocor for conducting the initial phases of research and development with respect to small peptide molecule-based pharmaceutical products for the treatments of diseases. The proceeds from Tocor II's initial public offering are expected to provide sufficient funding to undertake the initial phase of product research and development. If the IPO funding proves inadequate for the completion of the initial pharmaceutical product developmental stages, then the parent, Centocor, may decide not to exercise its Purchase Agreement option[106] and may forego its option to purchase all of the callable common stock of Tocor II. If the aforementioned circumstance occurs, then Tocor II will have to obtain additional funding in order to continue as a functioning entity.[107]

Centocor has sole discretion as to how to allocate its resources that are available to Tocor II for its research and development. Under the Development Agreement,[108] Centocor must use reasonable efforts in deciding how it will allocate its resources. Centocor thus retains the right to limit resources that are currently available to Tocor II, thereby delaying the development of Tocor II products. The research and development activities conducted by Centocor for Tocor II's small peptide molecule program are heavily integrated with activities conducted in Centocor's ongoing monoclonal antibody program. Additionally, under the terms of the Development Agreement,[109] certain costs of Centocor's research, development, and clinical activities are allocated to Tocor II. These costs are related to activities that have the potential to be of benefit to Tocor II, as well as Centocor.[110]

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[106] *See* Appendix III: Centocor/Tocor II International Memorandum of Association.

[107] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.

[108] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

[109] *Id.*

[110] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

Until the termination of the Purchase Option Agreement,[111] Tocor II is not permitted to issue additional capital stock, borrow more than $1,000,000 in the aggregate, declare or pay dividends out of funds required to be paid to Centocor under the Development Agreement,[112] merge, liquidate, or sell substantially all of its assets without the approval of its parent, Centocor.

Licenses and Contractual Agreements with Centocor

The 1992 Annual Report[113] indicates that Centocor (Parent Company) entered into a Technology License Agreement whereby Centocor granted to Tocor II (SWORD) a worldwide, exclusive, royalty-free, perpetual, fully-paid license to the proprietary rights owned or controlled by Centocor during the terms of the Development Agreement[114] which are necessary or useful for the research, development, manufacture, or sale of the commercial products developed. Under the Technology License Agreement,[115] Tocor II granted back to Centocor, a worldwide, fully-paid, exclusive, royalty-free right and license in perpetuity to any of Tocor II's technology, either owned, acquired, or developed during the term of the Development Agreement for any uses of such technology outside of Tocor II's field of activity. Under the terms of the Technology License Agreement,[116] Tocor II paid a non-refundable fee of $2,500,000 to Centocor during the first quarter of 1992.

In January 1992, Tocor II entered into a Development Agreement[117] with Centocor, under which Centocor agreed to conduct research and development with respect to new commercial products. Under this agreement, Tocor II is obligated to

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[111] *See* Appendix III: Centocor/Tocor II International Memorandum of Association.

[112] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

[113] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.

[114] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

[115] *See* Appendix III: Centocor/Tocor II Technology License Agreement.

[116] *Id.*

[117] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

pay to its parent, Centocor, an amount consisting of: (1) substantially all of the net proceeds of the public offering (less $1 million to be retained by Tocor II as working capital, the non-refundable fee of $2,500,000 paid under the License Agreement, and an amount retained for Tocor II's general and administrative expenses); (2) any interest and other income earned through temporary investment of Tocor II's funds is also payable to Centocor under this agreement. Under this Development Agreement,[118] Centocor was reimbursed for the research and development costs incurred on behalf of Tocor II, plus a management fee equal to 10 percent of such costs. Tocor II incurred expenses under the Development Agreement of $16, 548,000 for the period January 21, 1992 through December 31, 1992.[119]

Centocor's Obligation and Discretion Under this Agreement

Under the Development Agreement,[120] Centocor is obligated to use reasonable efforts to utilize its resources for the research and development needs of Tocor II. Centocor retains the right to determine the allocation of Centocor resources that will be available to Tocor II to conduct research and development under the Development Agreement. Centocor also retained the right to limit the available resources to Tocor II, thereby delaying development of products. Of note, certain costs of Centocor's research, development, and clinical trial activities are allocated to Tocor II pursuant to the Development Agreement, as such activities have the potential to benefit Tocor II, as well as Centocor. As a result, funding provided by Tocor II benefits Centocor in its activities outside of Tocor II's field of activity.

Termination of the License and Development Agreement

Either Tocor II or Centocor may terminate the Development Agreement (1) if the other party breaches any material obligation under the Development

[118] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

[119] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.

[120] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

Agreement[121] or the Technology License Agreement,[122] subject to a 60-day cure period or (2) if the other party enters into any voluntary proceeding in bankruptcy, reorganization, or an arrangement for the benefit of its creditors, or 60 days (exclusive of any stay in effect) after any involuntary proceeding if not dismissed during such 60-day period. The Development Agreement will terminate automatically upon the termination of the Purchase Option Agreement[123] or the Technology License Agreement.[124]

Tocor II has also entered into a services agreement (Services Agreement) with Centocor and a wholly owned subsidiary of Centocor, whereby Centocor or its subsidiary provides certain management and administrative services to Tocor II on a fully burdened cost reimbursement basis. Centocor is also paid a management fee by Tocor II equal to 110 percent of any service costs incurred.[125]

VII. Analysis of the Tocor II Licensing Agreements.

A) Memorandum of Association Tocor II -- International Form (Articles of Incorporation)

Tocor II, Inc., (a spinoff from its parent corporation, Centocor, Inc. (Malvern, PA) was incorporated on November 6, 1991 in Tortola, British Virgin Islands. The Articles state that the object of Tocor II "is to engage in any act or activity that is not prohibited under any law for the time being in force in the British Virgin Islands.[126] As stated in the agreement, under the general business laws of the British Virgin Islands, Tocor II may NOT: "(1) carry on business with persons resident in the British Virgin Islands; (2) own an interest in real property situated in the British

[121] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.
[122] *See* Appendix III: Centocor/Tocor II Technology License Agreement.
[123] *See* Appendix III: Centocor/Tocor II International Memorandum of Association.
[124] *See* Appendix III: Centocor/Tocor II Technology License Agreement.
[125] *See* Appendix II: Centocor/Tocor II Services Agreement.
[126] *See* Appendix III: Centocor/Tocor II International Memorandum of Association. (¶ 2,3).

Virgin Islands... (3) carry on banking or a trust business... insurance business... company management... or carry on the business of providing an office of registered agent." [127]

Additionally, Tocor II shall not be treated as carrying on business with persons resident in the British Virgin Islands if: "(1) makes or maintains deposits with a person carrying on banking business within British Virgin Islands; (2) it makes or maintains professional contact with solicitors, barristers, accountants, bookkeepers, trust companies, or other similar persons carrying on business within the British Virgin Islands; (4) it maintains books and records; (5) it holds a lease of property for use as an office to communicate with members and where the books and records of [Tocor II] are prepared or maintained; (6) it holds debt or securities in a company incorporated in the British Virgin Islands; (7) shares, debt obligations or other securities are owned by any person or corporation resident in the British Virgin Islands." (emphasis added).[128]

Analysis of Article of Incorporation Recitals

The Articles of Incorporation under the laws of the British Virgin Islands state the purpose of Tocor II, and clearly state the general business laws of incorporation that prevent this international company from "carrying on business" with persons resident in the British Virgin Islands; however, the company still must maintain all "ongoing business" indicia within the British Virgin Islands in order to maintain this incorporation status.

Purchase Option of Centocor

Tocor II embeds the Purchase Option Agreement between itself and its parent Centocor in its articles of association (incorporation). Specifically:

> Centocor, Inc., a Pennsylvania corporation ("Centocor"), holds an exclusive, irrevocable purchase option (the

[127] *See* Appendix III: Centocor/Tocor II International Memorandum of Association. (¶ 4(b) 1-6).
[128] *Id.*

"Purchase Option") as described in the Purchase Option Agreement (the "Purchase Option Agreement")... by and among Centocor and the other parties thereto to purchase all of the then issued and outstanding shares of Callable Common Stock issued by or on behalf of the Company in connection with the unit offering of by the Company and Centocor, each unit consisting of one share of Callable Common Stock, one series T Warrant to purchase one share of common stock, par value $ 0.01 per share of Centocor ("Centocor Common Stock") and one Callable Warrant to purchase one share of Centocor Common Stock... The Purchase Option if exercised, may be exercised only as to all of the then issued and outstanding shares of Callable Common Stock, at any time during the period beginning on January 1, 1993 and ending on December 31, 1995... if the Research and Development Agreement is terminated prior to January 1, 1993, Centocor may exercise the Purchase Option for a period of 30 days after such termination. Upon exercise of the Purchase Option, Centocor is required to make a payment for each share of the callable Common Stock (the "Purchase Option Exercise Price"), in accordance with the following schedule.[129]

Analysis

The drafters of the Tocor II articles of incorporation included the parent corporation's (Centocor, Inc.) Purchase Option Agreement in the body of the document. This characteristic was initially used in the articles of incorporation of the ALZA/BES SWORD offering. The operative legal effect of embedding the Purchase Option into the Articles of Incorporation places the directors of Tocor II on notice that one of their fiducial duties to Tocor II is to recognize the right of Centocor, Inc. to buy all outstanding shares of Tocor II offered in the Unit for a set price depending upon the date the option is exercised. Accordingly, the importance to the parent company (Centocor) of ensuring that the directors of Tocor II will not

[129] *See* Appendix III: Centocor/Tocor II International Memorandum of Association. (¶ 8(a),(b)).
1) January 1, 1993 through December 31, 1993 — U.S. $58.00;
2) From January 1, 1994 through December 31, 1994 — U.S. $76.00;
3) From January 1, 1995 through December 31, 1995 — U.S. $107.00.

act contrary to this purchase option provision can be discerned from the express language of the following provision also included in Tocor II's articles:

> The Company [Tocor II] and its shareholders *shall not take*, or permit any other person or entity within its control to take, *any action inconsistent with Centocor's rights under the Purchase Option Agreement.* The Company shall not enter into any arrangement, agreement or understanding, either oral or written, that is inconsistent with the rights of Centocor and the obligations of the Company [Tocor II] hereunder. (emphasis added).[130]

B) Technology License Agreement

This license enables Tocor II, Inc. to function as a research and development spinoff from its parent Centocor, which has certain technology and intellectual property needed by Tocor II.

Grant of Technology License to Tocor II

This provision grants Centocor's technology to Tocor II as follows:

> Centocor hereby grants to Tocor, on the terms and conditions of this Agreement, a worldwide, exclusive (even as to Centocor and its affiliates), royalty-free, fully-paid up right and license, in perpetuity, to the Licensed Technology in order to engage in any and all uses of the Licensed Technology: provided, however, that the foregoing license grant with respect to Centocor Proprietary Rights controlled by Centocor pursuant to any applicable Field License Agreement shall be subject to the execution and terms, which terms shall include the assumption by Tocor of any obligations, including royalty payments, due by Centocor under any such Field License Agreement relating to the Licensed Technology, of a sublicense with respect to the Licensed Technology, of a sublicense with respect to such Field License Agreement as it relates to the Field on mutually acceptable terms between Centocor and Tocor and the receipt of any consent from any third party required under the applicable Field License Agreement. Except as provided in other agreements between the parties, Tocor, *without the prior written consent of Centocor shall not sublicense the Licensed*

[130] *See* Appendix III: Centocor/Tocor II International Memorandum of Association. (¶ 12).

Technology to, or enter into other arrangements with respect to the Licensed Technology with any third party... for any purpose before the termination of the Purchase Option Agreement. During the term of this Agreement and thereafter, Tocor shall maintain in confidence Developed Technology outside the Field. (emphasis added).[131]

Analysis of the Grant Clause

Proprietary information and technology is granted to Tocor II under an exclusive license agreement. However, it is of note that this granting clause, unlike the granting clause of BES, does *not* grant all of Centocor's technology or proprietary information to Tocor II. Specifically, the definitions [132] provide that this grant pertains to only "necessary or useful" proprietary rights for the manufacture or development or sale of products in the Field.[133] Centocor is expressly withholding from Tocor II any transferal of rights to use their proprietary monoclonal antibody technology. This limitation on the development of products[134] by Tocor II specifically reserves to Centocor all rights to Centocor's monoclonal antibody technology, with no interpretation of a negative implied right to Tocor II to use this technology. However, Centocor has not provided for a reservation of the right to use the licensed technology to itself for any of its current applications of subject matter of the licensed technology.

This license provision is more sophisticated than the first SWORD grant clause (*See* BES, *supra*), in that Centocor grants to Tocor II the right to sublicense

[131] *See* Appendix III: Centocor/Tocor II Technology License Agreements (¶ 2.1).

[132] "Licensed Technology" shall mean Centocor Proprietary Rights which are necessary or useful for the research and development, manufacture or sale of products in the Field and, if not otherwise excluded, shall specifically exclude Monoclonal Antibody Technology. (See "Glossary Attached as Schedule I.").

[133] "Field" shall mean Products for the treatment of any human disease and , if not otherwise excluded, shall specifically exclude the use of Monoclonal Antibodies and Monoclonal Antibody Technology.

[134] "Products" shall mean all pharmaceutical products based on Small Molecules in the Field developed by Centocor and its Affiliates utilizing, based upon or arising out of, the Licensed Technology and/or Developed Technology in the Field.

after securing the written permission of Centocor. This allows a broader granting of rights to the SWORD, and still allows Centocor complete discretion over any sublicensing to third parties. Additionally, Tocor II assumes the obligation to pay any outstanding royalties due and owing by Centocor prior to entering into this license agreement. Thus, the significant purpose of a SWORD, i.e., getting cash or equivalent to the parent company is ensured.

Reciprocal Grant to Centocor

Also, this license provides for a sophisticated provision by including a grant-back clause, whereby:

> Tocor hereby irrevocably grants to Centocor a worldwide, exclusive (even as to Tocor and its Affiliates), royalty-free, fully-paid up right and license (with the right to sublicense), in perpetuity, to engage in any and all uses of the Developed Technology outside of the Field.[135]

The importance of this provision is apparent in that the parent company, Centocor, receives the right to use any new developed technology that arises out of the SWORD arrangement. This license provision provides for a completely exclusive licensing arrangement whereby only Centocor can use the developed technology, for any reason, with no obligation to make any future royalty payments to Tocor II.

Patents

Tocor II is under an obligation to notify Centocor of any patent infringement or alleged infringement which is or becomes known to Tocor. Specifically:

> Tocor shall promptly notify Centocor of any infringement or alleged infringement which is or becomes known to Tocor of any patent rights included in the Licensed Technology... by the manufacture, use or sale by a third party of any product in the Field. In the event of any such alleged infringement or

[135] *See* Appendix III: Centocor/Tocor II Technology License Agreement (¶ 2.2).

> unauthorized use, Centocor shall have the right, but not not the obligation, at its own expense, to take appropriate action to restrain such alleged infringement or unauthorized use and/or seek damage for such alleged infringement... in such event twenty-five (25) percent of any amount recovered, whether by judgment or settlement, after repayment of all reasonable expenses of Centocor incurred with such action, shall be paid to Tocor, and ... seventy-five percent retained by Centocor... (b) each party agrees not to settle any action it may bring hereunder in a manner that is prejudicial to any patent owned or licensed by the other party without such other party's written approval.[136]

Of interest is the reservation by Centocor of the right to "restrain" any infringement or alleged infringement of the Licensed Technology which includes any of the patented technology licensed to Tocor II. However, Centocor may be exposed to legal challenge for *lack of standing*, as the granting clause grants an exclusive license to Tocor II. No provisions were included that granted or allowed Centocor to retain the right to use its own technology that was licensed to Tocor II.

Confidentiality

Under the terms of this provision (substantially similar to the wording of the first SWORD, BES), Tocor II agrees to maintain in confidence all Centocor confidential information; but allowing for disclosure for *inter alia*; (i) in connection with securing necessary governmental approvals for the marketing of Products, (ii) purpose of complying with applicable laws and regulations, (iii) in connection with any sublicense to Centocor under this agreement. [137]

Surprisingly, Tocor II is under an obligation to maintain the confidentiality of Centocor's confidential information only up to and not beyond the termination of Centocor's Purchase Option, also there is an indefinitely stated period provided for Tocor to maintain in confidence Centocor's information after termination of the

[136] *See* Appendix III: Centocor/Tocor II Technology License Agreement (¶ 4(a), (b)).

[137] *See* Appendix III: Centocor/Tocor II Technology License Agreement (¶ 6(a)).

Developmental Agreement.[138]

Payments to Centocor

The financial aspect of this SWORD arrangement in generating or providing cash to Centocor is expressly provided for in this Technology License Agreement:

> [w]ithin two (2) days following the first purchase and sale of the securities comprising the units... Tocor shall make a nonrefundable payment to Centocor in the amount of $2,500,000 in consideration of Centocor's entering into this Agreement and in recognition of Centocor's expertise which it has developed over a period of years through its research and development expenditures directly or indirectly related to activities in the Field or otherwise. The parties understand and agree that no future performance is required by Centocor during the term of this Agreement or otherwise in order to earn the fee paid pursuant to this section 2.4.[139]

C) The Research and Development Agreement

This agreement pertains to Tocor II's grant back of the necessary technology to Centocor in order for Centocor to perform the necessary research and development of products for Tocor II. Unlike the first SWORD research and development agreement of BES (*supra*), the research and development grant provision of Tocor II is drafted to allow Centocor to contract and collaborate with third parties, including any research institutions performing research and development work. This agreement also addresses Tocor II's intellectual property rights that may be necessary for Centocor to continue in the research and development of commercial products. Tocor II granted to Centocor:

> Tocor hereby grants to Centocor a worldwide, royalty-free sublicense to engage in any and all uses of Licensed Technology and a worldwide, royalty-free license to engage in any and all

[138] *See* Appendix III: Centocor/Tocor II Technology License Agreement (¶ 6(a)).

[139] *See* Appendix III: Centocor/Tocor II Technology License Agreement (¶ 2.4).

> uses of Developed Technology solely for purposes of performing its duties hereunder and the activities contemplated hereby....[140]

The provision that addresses patent procurement reveals once again the underlying purpose a SWORD arrangement, i.e., getting cash from the spinoff to the parent company. Specifically:

> [C]entocor, at Tocor's expense, shall cause appropriate United States and foreign patent applications to be prepared and prosecuted with respect to inventions included in the Developed Technology and which Centocor believes to be patentable and commercially and technically significant, and to cause such patents to be maintained, as Tocor shall request in writing, provided, however, that to the extent and with respect to inventions which have substantial application beyond developed technology or outside the Field, the allocation between Centocor and Tocor of the expenses of preparing, prosecuting and maintaining such patents shall be based upon an allocation between Centocor and Tocor of the expenses of preparing, prosecuting and maintaining such patents shall be based upon an allocation negotiated on a case by case basis between Centocor and the Tocor II Board of Directors.[141]

Third Party Claims

Another provision that reveals the underlying purpose of a SWORD arrangement, i.e., to get cash from Tocor II to Centocor, is by the structuring of the channeling of cash through a conduit in the license agreement provision dealing with third party claims. Specifically:

> Each party shall promptly notify the other party of any claim, suit, action or proceeding against it, and to the extent known by it, arising from the Research and Development conducted by Centocor, its Affiliates, agents or subcontractors under this Agreement. Centocor *shall have the right to assume sole control of the defense*, on behalf of the parties, of any such claim, suit, action or proceeding, but shall consult with Tocor with respect to such defense. Centocor shall pay any damages

[140] *See* Appendix III: Centocor/Tocor II Research and Development Agreement (¶ 6).

[141] *See* Appendix III: Centocor/Tocor II Technology License Agreement (¶ 7.1).

> and costs finally awarded in connection with, and any amounts paid in settlement of... and be liable hereunder... only from Research and Development conducted by Centocor.... Tocor *shall not settle any such claim, suit, action or proceeding without the prior written consent of Centocor.* (emphasis added).[142]

Centocor reserves the right to assume sole control of any defense to a patent infringement claim, even though Centocor's technology was exclusively licensed to Tocor II in the Technology License Agreement. This clause may subject Centocor to challenge for lack of standing to sue, as the technology was exclusively licensed to Tocor II. Additionally, the clause whereby "Tocor shall not settle any such claim... without the prior written consent of Centocor," raises a question of <u>just how independent</u> a legal entity is Tocor II, if it must obtain written consent from Centocor in order to settle a claim arising under the licensed technology.

<u>D) The Services Agreement</u>

The Services Agreement delineates the obligations of Centocor, B.V. (CBV) (A Dutch Corporation), the corporation that is to perform the following services for the spinoff Tocor II:

> Advice and services on accounting and financial matters, marketing, government and public relations, procurement, purchasing, inventory control, planning and investigation, management information systems, legal, tax, insurance and administrative matters, including without limitation, maintenance of books and records, bank accounts, and preparation of budgets, forecasts and financial statements..... Treasury services....recordkeeping... [h]andling of regulatory and related matters as required.[143]

This provision pertains to the business administration requirements of Tocor II. Of special note is the use of a foreign corporation (CBV) to perform these

[142] *See* Appendix III: Centocor/Tocor II Research and Development Agreement (¶ 7.3).

[143] *See* Appendix III: Centocor/Tocor II Services Agreement (Schedule A).

business administration services, as well as having a foreign corporation, CBV, as the recipient of compensation for any services rendered. The underlying objective of this SWORD arrangement, i.e., to get cash away from Tocor II to the parent, Centocor, or in this instance, to a foreign subsidiary of Centocor (CBV), is revealed in the provision dealing with compensation, in part: "Tocor shall pay to CBV one hundred ten percent (110%) of CBV Costs (with exception of any out-of-pocket expenses as to which Tocor shall pay one hundred percent (100%) of CBV's Costs)."[144]

Financial Results

Cash and cash equivalents and short-term investments were approximately $64,267,000 as of December 31, 1992, representing the net proceeds of the IPO of Tocor II's callable common stock less amounts paid under agreements with Centocor. Prepaid research and development expenses resulted from a prepayment made to Centocor pursuant to the terms of the Development Agreement.[145]

Tocor II had a loss of $19, 594, 083 ($8.71 per share) of callable common stock for the period January 21, 1992 through December 31, 1992. This loss stems from the expenses incurred under the IPO agreements with Centocor. These expenses were partially offset by net investment income of approximately $2,913,000. Future results are expected to reflect lower interest income as available cash is used to fund operations. The company expects that its activities will be limited to conducting research and development for the next several years, and therefore does not expect to generate any income other than interest income, thus expecting to continually show losses for this period. Tocor II anticipates that the net proceeds of the January 1992 IPO will be available to fund research under the Development Agreement[146]

[144] *See* Appendix III: Centocor/Tocor II Services Agreement (¶ 3).

[145] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

[146] *See* Appendix III: Centocor/Tocor II Research and Development Agreement.

through December 31, 1995.[147]

The current financial status of Centocor reflects a series of corporate events that have led to a substantial loss in market price for Centocor.[148] A series of events took place with a 40-day period (Week 11 through 13) during the Spring of 1992 and the Spring of 1993 (Week 39) that has led to over a 35 (55%) point drop in market price. In 1992, a patent infringement suit was initiated against Centocor by Xoma Corp. and Pfizer Inc., and was filed on 02/18/92.[149] There was the FDA's refusal to grant Phase III clinical approval for Centocor's "HA-1A" therapeutic products on 04/15/92.[150] A notice of reexamination issued on 04/14/92 from the USPTO that there would be a reexamination of all claims to Centocor's patent U.S. Patent No. 4,918,163.[151] Centocor was sued in a series of stockholder derivative suits that were all filed within a three-day period, each suit claiming negligent misrepresentation and breach of fiducial duty.[152] On 04/28/92, Centocor's president and CEO resigned.[153] Notably, the resignation of the executive vice president and division president also occurred on 04/28/92.[154]

In 1993, there was an additional setback for Centocor, as Centocor suspended

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[147] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.

[148] Compuserve "Prices" Database Library.
(High of 50 on 01/31/92, Low of 5 3/4 on 4/23/93, Currently 11 1/2 as of 05/01/94).

[149] Tocor II, Inc., Annual Report to Stockholders, 12/31/92. 200 Great Valley Parkway, Malvern, PA.

[150] *Id.*

[151] U.S. Patent No.. 4,918,163. *Monoclonal Antibodies Specific for Lipid-A Determinants of Gram-Negative Bacteria.*This patent discloses novel hybridoma cell lines which produce monoclonal antibodies that bind epitopes found on lipopolysaccharides most commonly associated with the endotoxin core of gram negative bacteria. The monoclonal antibodies are useful in the detection of bacterial infections, therapy and prophylaxis of bacterial endotoxemia and infection caused by gram negative bacteria.

[152] Centocor, Disclosure Incorporated, (1994):
- Aronberg et al. v. Schoemaker, et al. (Chairman).
- Denenberg v. Schoemaker, et al. (Chairman).
- Zarowitz v. Schoemaker, et al. (Chairman).
- Lubell v. Tocor II.

[153] James E. Wavle, Jr.

[154] Elizabeth E. Tallett.

clinical trials of its "HA-1A" Centoxin anti-sepsis pharmaceutical due to the FDA's refusal to grant Phase II approval (Week 39).[155] This decision was reflected, as the share price average for Centocor also significantly dropped during the first quarter of 1993 (Week 39) due to the Centocor's withdrawal of its anti-sepsis drug from clinical trials.[156]

VIII. CONCLUSION

The intent of this paper has been to address the interworkings of the various contractual arrangements that are essential to a SWORD arrangement. The two most remarkable aspects of the two SWORD arrangements analyzed herein are (1) the formulations of the licensing agreements used to define the rights of the parties specific to the parent company's intellectual property, and; (2) the steady manner in which the SWORD company's price per share tends to parallel its parent's share price values, but without the frequent fluctuations in value reflected in the parent company's share prices. The general structuring of a SWORD is based upon the intellectual property rights granted to the SWORD, which help form, in effect, a virtual corporation having the intellectual property of the parent corporation as its only asset. As in all corporate organizations, a SWORD is but a nexus of contractual rights, set up as a holding company for the parent company's assets.

The main focus of this paper has been on the licensing agreements used for capital formation in the SWORD structures. The parent companies initiate these arrangements by exclusively licensing their intellectual property and other proprietary rights to the SWORD company. The parent company then enters into a series of contractual relationships whereby the parent company provides research and development services to the SWORD company, receives a stream of capital back

[155] Centocor, Disclosure Incorporated, (1994).

[156] *Id.*

from the SWORD company and retains a license option to purchase or license back any commercially successful products developed by the SWORD company.

The study of these SWORD licensing agreements and associated documents indicates some degree of asymmetry between the SWORD companies' 10-K's, annual reports, and what was found to actually appear in the provisions of the licensing agreements.[157] This asymmetry appears to originate from a less than trumpeted account of just how little operative independence is contractually granted to a SWORD company either in its articles of incorporation, licensing agreements, or to the great extent that the SWORD company's own levels of capitalization are destined to flow back to the parent company through artfully-drafted contractual capital conduits. The underlying cash flow direction of the SWORD structures is revealed in the services agreements,[158] wherein the parent corporation invariably charges a high fee for its research and administrative services, showing that these service agreements function as a conduit for the transfer of SWORD company capital to the parent corporation.

A comparison between the first ALZA/BES SWORD licensing arrangements and the latter offered Centocor/Tocor II SWORD shows a marked increase in the level of license drafting sophistication. In particular, Centocor reserves some rights to its own intellectual property rights while licensing to Tocor II only that which would be necessary for general product development. The initial parent/SWORD offering between ALZA and BES shows a more brute force approach to SWORD formation. ALZA exclusively licensed *all* of its intellectual property rights to its SWORD company (BES) and elected not to reserve the right to continue to use its technology for its own product development, but presumably continued to do so. This licensing provision might create some exposure to ALZA to a legal challenge

[157] *See* Appendices II, III.

[158] *Id.*

for lack of standing to sue in the event of litigation, or when ALZA otherwise acts as though it retained the rights it exclusively licensed to its spinoff (BES). However, the recent SWORD offering between Centocor and Tocor II is characterized by Centocor having only licensed *some* of its technology to Tocor II.[159] This provision skillfully preserves the intellectual property rights associated with Centocor's primary product line of monoclonal antibody pharmaceutical products.

An unexpected result became apparent after constructing a graph of share price[160] trends for each parent and SWORD company.[161] The price per share of each parent and SWORD company was projected for one year (52 weeks) from the date of the SWORD company's initial public offering. Each company's weekly average closing share price was used to compile a graph of normalized[162] share price data. The data reflects that the SWORD companies have a much lower volatility (*beta*) than their parent companies and generally trend with the parent's share price. This trend is readily apparent in the Centocor/Tocor II projection.[163] Interestingly, both Centocor and Tocor II expressed a precipitous decline in share price during the 11th through the 13th week after Tocor II's initial public offering.[164] A series of events occurred[165] affecting the parent company, Centocor, during this time period (patent reexamination of an essential Centocor patent, a series of shareholder derivative suits and the FDA's failure to grant marketing approval) which appears to have sparked a decline for both Centocor and its SWORD, Tocor II. Notably, in both parent/SWORD companies studied, there was an apparent insulation of volatility of

[159] *See* Appendix II: Centocor/Tocor II Technology Licensing Agreement.

[160] Compuserve - Historical stockmarket values retrieved from the "Prices" database service.

[161] *See* Appendix V.

[162] "Normalization of values" -- was achieved by assigning a value of "100%" to the initial public offering price of each company; subsequent values were computed as a percentage of that initial public offering price.

[163] *See* Appendix V.

[164] *See* Appendix V.

[165] Annual Report to Stockholders, 12/31/92, Tocor II, Inc., 200 Great Valley Parkway, Malvern, PA.

the overall SWORD company price per share from their associated parent company's higher volatility in share price. In both SWORD studies, the SWORD share price projections are much flatter in relation to the parent company's share prices.[166] When an event occurred effecting the parent companies' share price not stemming from the parent company's intellectual property assets, the SWORD companies did not correspondingly express the same share price volatility. The market may be perceiving these SWORD companies as having much more independence from events effecting the parent companies. This suggests there may be a somewhat high degree of informational asymmetry between the biotechnology management and the pool of potential investors. In the alternative, there may in fact be a symmetrical distribution of information regarding events that are affecting the parent companies, thus the market is correctly perceiving and distinguishing events that are separate from the intellectual property assets of the parent company. One aspect in support of this hypothesis was the simultaneous drop in share price expressed by both Centocor and Tocor II after the announcement of both a patent infringement suit and a patent reexamination of the same patent during the 11th week.[167] Notably, there was not corresponding volatility in Tocor II price when a shareholder derivative suit involving Centocor occurred in January 1993.

This study indicates that the most remarkable aspect of a SWORD company is the creation of a spinoff company having as its only asset the intellectual property of its parent company. The analysis of the two parent/SWORD companies in this paper suggests that SWORD companies may provide a future opportunity to develop a method of valuation of a company's intellectual property or its other difficult to quantify intangible assets by use of some form of the SWORD method.

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[166] *See* Appendix V.

[167] *See* Appendix V; *see also*, Annual Report to Stockholders, 12/31/92, Centocor, Inc. and Tocor II.

private placement., or PIPES.[169] PIPES facilitate investors to purchase large blocks of stock at a price discounted to the current market price per share with immediate liquidity when the stock is available for resale. This technique allows money to be raised without the underwriting expenses incurred in a public offering. However, current shareholders are at a disadvantage, since their stock holdings are diluted, and some purchasers of PIPES have entered into agreements where the PIPES can be "flipped," in that their stock can be immediately sold in the open market to lock in a quick profit. To provide a market perspective, biotech analyst John F. Wong reported that in January 1994, Alliance Pharmaceutical (San Diego, CA) and Seragen, Inc. (Hopkinton, MA) each used a PIPE to raise cash in the amounts of $16.4 and $6.6 million, respectively, to finance their research and development efforts.

Private Placements -- Public companies allow private investment holdings pursuant to the 1933 Act in Regulation D, for institutional investors who receive a certain number of shares at a discounted price.

SIRRS -- (Stock Index Reset Rights) -- These initial public offerings allow downside protection to the investor through a conversion feature that kicks in if the stock does not meet a targeted price within a specified period. This conversion feature allows the investor to automatically receive additional shares to close the gap in valuation and bring the overall value up to the targeted rate of return.

SPARC -- (Special Purpose Accelerated Research & Development Company) These companies are very similar in structure to the SWORD structure (*infra*).

[169] Wong, John, F., *Biotechnology Stocks Can Expect a Receptive Market Over the Short Term*, Genetic Engineering News, February 1, 1994, Vol. 14, No. 3. p. 27.

Spinouts -- Parent company forms an independent spinout entity with its own developing technology, which then seeks its own financial security.

SWORD -- (Stock and Warrant Off-balance sheet Research and Development company) A new company is formed, whereby the parent company's technology is licensed to the new venture, which is obligated to attempt to develop new products which are then licensed back to the parent company. Shares in the new company are packaged with warrants which are exercisable in the parent company.