

**DRAFTING LICENSING
AGREEMENTS FOR BIOTECH
RESEARCH TOOLS:**

Key Provisions, Terms and Alternatives

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A. Introduction

Licensing agreements have been critical to the biotechnology industry since its very inception. Today, deal making, particularly in the Research Tool area, has reached dizzying heights.¹ The pharmaceutical deal tracking service “Pharmadeals” reports that it tracks over 140 new deals every month. Signals Magazine reports that, in the first half of 2001, earned alliance revenues of biotech companies were \$1.2 billion, with Research Tool companies accounting for approximately half of that total. Several trends have fueled this fire: first, in order for the pharmaceutical industry to continue to grow, more and more new “blockbuster” products are needed, intensifying the need for research; second, there has been an enormous growth in the research technology that is available to the pharmaceutical industry; thirdly, more biotechnology companies are being formed with the goal of becoming research tool companies, rather than traditional stand-alone biopharmaceutical companies.

B. What are Research Tools?

For purposes of this paper, a “Research Tool” is a technology (methods or materials) used in the discovery, research or development of biopharmaceutical products. That is, a Research Tool is not itself an FDA approved drug or diagnostic. A Research Tool can, however, be a product that is sold on the research market. Examples are Stratagene’s BacterioMatch Bacterial Two Hybrid System, Novagen’s T7 Select ® Protein/Peptide display and biopanning system for construction and screening of

¹ See “Goliath Befriends David,” *Nature*, 414:482 (November 29, 2001).

libraries, and Clontech Laboratories' Creator™ DNA Cloning Kit. Advertising for each of these products states that the product is being sold for research use only, and commercial use requires a separate license from the patent holder.

Often, patents on the Research Tool will not cover the manufacture use or sale of the final FDA approved drug or diagnostic to be sold. This creates a situation of “reach through” when the patent holder seeks to obtain royalties on products discovered through use of the Research Tool, but not covered by the patent on the Research Tool. The NIH has recently promulgated guidelines that discourage universities from seeking such royalties, on the basis that Research Tools created by public funding should be broadly shared within the research community².

Another difficulty with patents in the research tool area is the enforcement of these patents. In *Bayer AG v. Housey Pharmaceuticals*, 61 USPQ 2d 1051 (D. Del. 2001), it was held that the use of a patented research tool outside the U.S. did not give rise to liability under 35 USC §271(g) when products discovered with the research tool were imported into the U.S. Another problem with research tool patents is that their infringement may be protected by 35 USC §271(e), which permits infringement of a genetically engineered patented invention for uses “reasonably related” to an FDA submission.

² See “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Resources: Final Notice,” 64 FR 72090, December 23, 1999.

Examples of Research Tools

It is easier to exemplify research tools than to define them. A partial list follows, arranged from the smallest (small molecules) to the largest (animals). Of course, entire populations can be research tools for genomics studies. Some research tools do not involve materials at all. They are purely methodologies:

Combinatorial Libraries

DNA sequences – EST's, SNP's

DNA Sequence Databases and bioinformatics software

Protein Targets: Receptors, Enzymes, etc.

Animal Models

Methodology: assay technology, antibody humanization, directed evolution, amplification technology.

Research Tools can run the gamut from a single molecular target, useful in the development of a single class of drugs to that target, to a broadly enabling technology that can form the basis for an entire company. This makes valuation of a Research Tool difficult.

C. The Research Tool Agreement Family

The process of licensing a research tool, just like the technical nature of the research tool, can be immensely varied. Below is a list of general agreement types that are used in various licensing scenarios.

1. Secrecy Agreement

2. Materials Transfer Agreement
3. Letter of Intent
4. Term Sheet
5. Option
6. License
7. License and Collaboration Agreement
8. Other Agreements –Joint Venture, Consortium, etc.

C. 1. Secrecy Agreement

A secrecy agreement is generally fairly simple. It should specify who the disclosing party is and who the receiving party is. It may be one way or mutual. It should be remembered that potentially damaging obligations are imposed on the recipient of the confidential information. The agreement may be drafted to include oral information that is disclosed to the recipient, but require the disclosing party to reduce the disclosed information to writing within a set time after disclosure.

A secrecy agreement generally excludes information that is (i) already known to the recipient; (ii) enters the public domain through means other than an unauthorized disclosure resulting from an act or omission by the Receiving Party; or (iii) is disclosed to the Receiving Party by a Third Party having no fiduciary relationship with the Disclosing Party and owing no obligation of confidentiality or non-use. It may also include an

exception for the Recipient's independently developed technology or for information required to be disclosed by the Receiving Party by law.

The term of a typical stand-alone secrecy agreement is 3-5 years from the date of disclosure. One drafting issue to consider is the typical practice of making the term of secrecy last for the term of an agreement. In the case of a license, this term may be for twenty years or more.

Some secrecy agreements impose strict liability for disclosure of received confidential information. Other agreements require that the information be treated as the recipient treats its own confidential information. Finally, a secrecy agreement should specify what purposes received confidential information may be used for. Typically, this will be a general statement such as use "solely for purposes of carrying out this agreement."

A sample secrecy agreement from UC San Diego may be found at http://invent.ucsd.edu/site_map.html.

C. 2 Materials Transfer Agreement

Materials Transfer Agreements (MTA's) are commonly used in a "noncommercial" setting, such as between universities. The agreements are intended only to retain some control on the use and further disposition of the materials. They can be problematic when addressing the patent rights of the provider and versus those of the

recipient who makes a subsequent invention with the materials. MTA's should also be included in more complex agreements that involve the transfer of biological materials.

MTA's should have disclaimers of warranties, since, unlike license agreements, they may be regarded as contracts for the sale of goods and thus governed by the UCC.

The following are three sample agreements useful in drafting MTA's:

<http://www.nih.gov/news/stemcell/WicellMOU.pdf>

http://www.autm.net/index_n4.html - Uniform Biological material Transfer

Agreement

Lexicon agreement to supply Merck Genome Research Institute with "Mutant Mice," Lexicon Genetics S-1/A filed 3/1/2000, EX 10.11

C. 3 Letter of Intent

A letter of intent is typically used by universities and is a short agreement intended to permit the filing of a patent application in exchange for a first right of negotiation. Because it typically does not involve the payment of any option fees, it is for a short term, typically 3 to 6 months. The agreement may provide for the potential licensee to pay outside counsel costs in the filing of a patent application (e.g. \$15,000) in the case of a university letter of intent.

In a corporate agreement, a letter of intent in the form of a right of first negotiation may be used as part of a larger agreement. An example is found in the

Affymax/Maxygen agreement.³ The Affymax (Glaxo Welcome) companies were granted a first right of negotiation with Maxygen to pursue projects involving the licensed technology in certain designated areas.

One drafting issue to consider is the extent to which a letter of intent may be legally enforced if the parties are unable to reach a final agreement. That is, could the potential licensee force the licensor to grant a license? A letter of intent generally will require only that the licensor negotiate in good faith.

Generally, actual financial terms are not included in a letter of intent. Sometimes, the categories of terms to be negotiated, e.g. exclusivity/field of use, up front payments and royalty rates, etc. may be specified in the letter of intent. See a sample of this form of a letter of intent at http://www.research.uh.edu/ogc/OGC_InstFundResProg.htm.

Some parties prefer to enter into a detailed “Heads of Agreement” that is like a letter of intent in that it provides that a final agreement will be entered into at a later time, but is actually in and of itself a binding agreement. A “Heads of Agreement” will contain all of the essential terms of the final agreement. A sample “Heads of Agreement” is the Heads of Agreement: Immunogen/Genentech Collaborative Agreement, Immunogen Inc. Form: 10-K405 Filed 9/27/2000, Exhibit 10.52.

³ Exhibit 10.3 to Maxygen S-1 dated 10/20/99.

C. 4 Term Sheet

As mentioned, a term sheet may accompany a letter of intent. It may also be the first step in opening negotiations in a particular deal. Generally, term sheets should be limited to business terms. A simple term sheet may be more flexibly negotiated and may involve a substantial savings of time if it becomes apparent that no deal is possible. A term sheet should include the following terms:

- (1) Properties covered (patents, trade secrets, copyright, trademark, biological materials)
- (2) Exclusivity/Field of Use
- (3) Upfront payment
- (4) Milestone Payments
- (5) Annual fees and patent costs
- (6) Earned Royalty on sales of “Licensed Products”
- (7) Diligence – commercialization efforts; commercialization rights
- (8) Equity – separate term sheet

In the case of a straightforward patent license, the above terms will cover almost the entire negotiation. In the case of a more complex technology exchange/collaboration, the above terms will have to include various sub-terms for assigning fates to different research outcomes. There may also be different commercialization options. There should also be a term sheet for the research agreement. However, the above check list is a good place to begin to lay out the frame work of the deal.

Below is a list edited from the Pharmacopeia/Bristol Myers Squibb (BMS) Collaboration and License Agreement, Exhibit 10.34 Pharmacopeia 10K, filed 4/30/98 that could be used as a check list for a collaboration involving the preparation and screening of compound libraries:

DRUG DISCOVERY COLLABORATION AGREEMENT –TERM SHEET

ARTICLE 1 DEFINITIONS

The *Italicized* words below will have to be defined to fit the circumstances.

ARTICLE 2 RESEARCH PROGRAM

STAGE I -- INITIAL SCREENING AND CHEMICAL OPTIMIZATION

Supply of *Targets, Initial Screening* and Initial Hits, *Initial Chemical Optimization*

STAGE II – PROGRAM LEAD COMPOUND IDENTIFICATION

Commencement of Stage II, Selection of Hits for Continued Optimization, Continued Optimization at BIOTECH Identification of Program Lead Compound Maximum number of total rounds Maximum number of novel compounds

STAGE III – PRE-CLINICAL LEAD COMPOUND IDENTIFICATION

Development by BIOTECH of *Pre-Clinical Lead Compounds*; PHARMA Support for *Pre-Clinical Lead Compounds*

ARTICLE 3 RESEARCH AND DEVELOPMENT EFFORTS

Research Efforts, Allocation and Support of FTEs, Disclosure of Results; Reports

ARTICLE 4 RESEARCH PROGRAM GOVERNANCE

ARTICLE 5 FINANCIAL TERMS

5.1 Technology Access Fee

5.1.1 FTE Reimbursement Fees

5.2 Extended Term Fees

5.3 Fees for Early Termination of the Research Program

5.4 Milestone Payments for *Pre-Clinical Lead Compounds* Developed by PHARMA from *Improved Hits* Discovered by BIOTECH and Further Developed by PHARMA

5.4.1 Selection of *Pre-Clinical Lead Compound*

5.4.2 Submission of IND

5.4.3 Commencement of Phase III clinical trials

5.4.4 Filing of NDA

- 5.4.5 Royalty Rate of Net Sales
- 5.5 Royalty Reduction in the Absence of Patent Protection
- 5.6 Royalty Period
- 5.6.1 One Royalty per unit of Licensed Product
- 5.7 Third Party Patent Rights

ARTICLE 6 OWNERSHIP; GRANT OF LICENSE RIGHTS

- 6.1.1 Ownership of Libraries
- 6.1.2 Availability of Library compounds to Parties for research and development
- 6.2 Ownership of *Targets*
- 6.3 Ownership of *Initial Hits*
- 6.4 Ownership of *Improved Hits*
- 6.5 Ownership of *Program Lead Compounds and Pre-Clinical Lead Compounds*
- 6.6 Development of Compounds Not Selected for Stage II or for Stage III
- 6.7 License to PHARMA under Patent Rights and Know-how
- 6.8 Rights of BIOTECH to Focused Library Compounds after Termination of the Research Program

C. 5 Option

An option agreement is straightforward in principle. It is used when a potential licensee would like time to evaluate the technology, or the technology has not yet been developed. The primary terms are an option fee and an option term specifying when the option must be exercised. The agreement should specify how the option is to be exercised and how the exercise relates to the process of finally negotiating (or, more importantly not negotiating) the license. That is, once the optionee company says, “we exercise,” what must happen next before rights under the option are extinguished?

Often the terms of the license are attached to the option. Simply granting an option without some parameters of the license to be negotiated is usually not satisfying to either party.

An interesting example of an option is found at the Geron 10-Q/A, filed 1/21/2000. This option involves the right of Geron to obtain rights to additional stem cell types in its license from the Wisconsin Alumni Foundation (WARF) and was the subject of litigation. The parties disagreed over whether Geron had exercised its option in time. The pertinent option agreement reads as follows:

2C. First Option to Negotiate.

*WARF hereby grants Geron the first option to negotiate an exclusive license for addition of cell types to the Licensed Field. Geron may exercise its option under this Section 2C by providing WARF with written notice of its desire to add a cell type to the License Field⁴ including a Development Plan detailing Geron's plan and timeline for bringing Products⁵ to market incorporating the new cell type and by paying WARF an upfront license fee to be negotiated in good faith between the parties factoring in commercially reasonable terms given the advancement of cell therapy in therapeutics and diagnostics and the value added by Geron. The terms of the exclusive license, other than the upfront license fee, shall be identical to the terms set forth in this Agreement, unless otherwise negotiated and agreed to by the parties. If the parties fail to agree on an upfront license fee for an additional cell type, WARF agrees that it will not offer such cell type to any third party on terms more favorable as a whole to such licensee than were offered to Geron hereunder for a period of [... CONFIDENTIAL ***...] ([... ***...]) months from the date Geron first exercised its option to add a cell type to the Licensed Field. In the context of this Agreement, "terms more favorable as a whole" shall mean that the combination of the commercial terms, for example the license fee, royalty rate, milestones, minimum royalties, and other fees required as consideration for the rights granted under the license are not more favorable when taken together than the package offered to Geron. The option to add cell types shall expire on [... ***...] unless extended for an additional period by written agreement on terms mutually agreeable to the parties.*

⁴ "Licensed Field" shall be limited to (i) Research Products, (ii) Therapeutic Products and (iii) Diagnostic Products developed from and/or incorporating the Materials as precursors to the following cell types as well as the following cell* types: [...***...]

⁵ "Products" shall refer to and mean Therapeutic Products and Diagnostic Products.

C. 6, 7 & 8 Licenses, Collaborations and the like

Drafting key provisions of these agreements will be the subject of the remainder of the paper. To choose whether to use a non-exclusive license, an exclusive license, or a license and collaboration or other complex agreement, the Research Tool company must evaluate both the value of the Research Tool(s) in question and the long term way in which it wishes to exploit this resource. Some Research Tools simply do not have the breadth to sustain a complex research partnership, and may simply be licensed, either exclusively or non-exclusively.

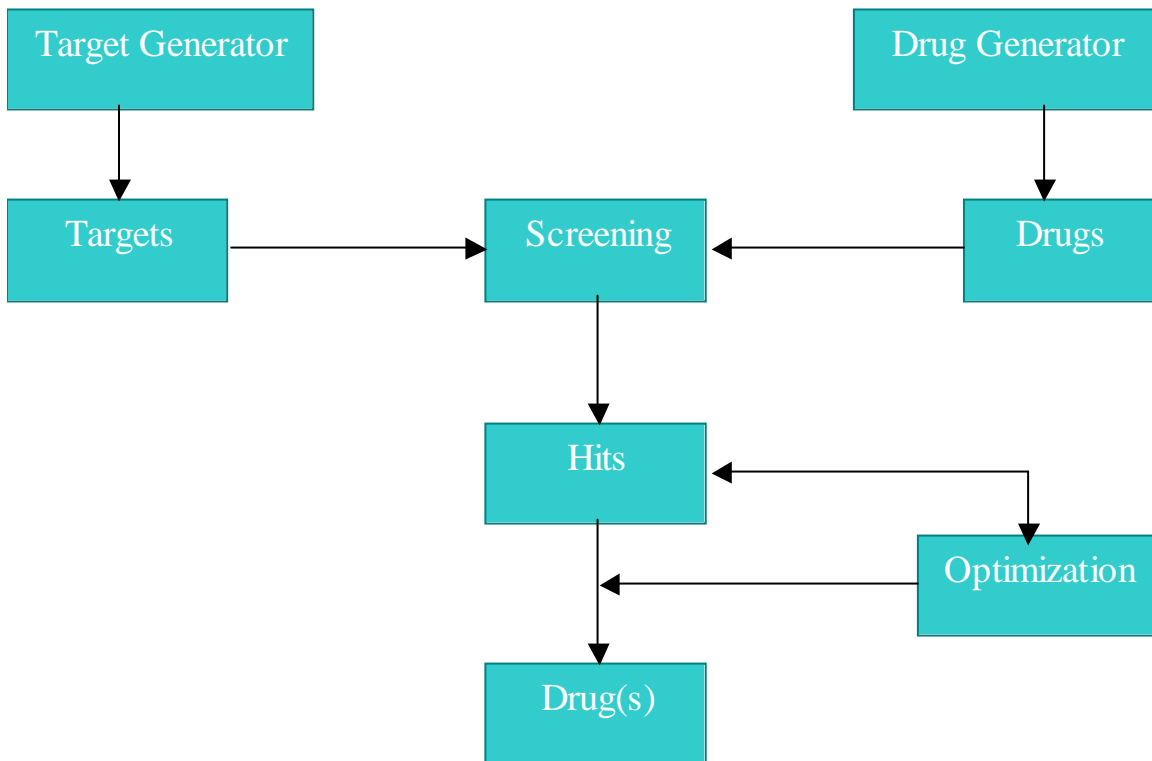
A non-exclusive license is often used in reagent licenses where various companies are given rights to sell or use research reagents. It is also used in licensing drug discovery rights and genomic databases.

An exclusive license is appropriate when the final FDA-approved product is covered in the license. Also, Research Tool companies will often license in research tools on an exclusive basis from universities when the Research Tools will be critical platform technologies for the company.

A license and collaboration agreement combines the types of agreements mentioned above. It is treated separately because it tends to be quite complex and involves a research collaboration as well as a license. Typically, such an agreement is between a pharma co. and a biotech (Research Tool Co.), where the biotech does the

research (using its various Research Tools) and the companies share promising product leads that come out of the collaboration. This is the agreement of choice for the Research Tool Co., since the Research Tool Co. often will negotiate funding and for rights to pursue its own products arising from the collaboration. The diagram below illustrates a generic structure for a License and Collaboration:

DIAGRAM



Much of the intellectual property (IP) involved in the diagrammed process has yet to be created. The presently existing IP may cover the Target Generator, or the Drug Generator, or the HTS (High Throughput Screening) system, but will not cover the final

product, the Drug(s). Furthermore, IP protection can attach to any step in this process, and the ownership and licensing of the future IP needs to be addressed in the agreement. Also, various “hits,” or potential products will be developed and may or may not be pursued. Through the optimization process(es), “hits” may include initial hits, improved hits, program lead compounds and pre-clinical lead compounds. The fate of the candidate products needs to be addressed in the agreement as well.

Generally, the Research Tool company will provide the discovery machinery and the pharma co. will provide expertise in drug development in the later stages. In some cases, however, the agreement may be between two biotech tool companies and may be more in the nature of a technology exchange agreement.

An example of a technology exchange agreement is the Genome Therapeutics/ArQule Compound Discovery Collaboration Agreement, Genome Therapeutics 10-Q Exhibit 10.1, 1/9/01. In this agreement, ArQule will provide libraries of compounds to the collaboration, which is run by a steering committee. ArQule will screen and optimize compounds against an expanded number of proprietary validated anti-infective targets which Genome Therapeutics has derived from its PathoGenome™ Database. Each party licenses the other to conduct research within the field of the collaboration. The parties will share revenues 50/50 and equally contribute internal resources to the collaboration.

Other types of Research Tool licenses are associated with joint ventures, which are legal entities established between two or more companies. Also, informal consortiums may be established among a number of companies, in which they each contribute resources to further specified research (typically at a research institution). The resultant IP is licensed non-exclusively, but only to members of the consortium.

D. Drafting Key Provisions

D. 1. Licensed Products bearing earned royalties

In the “classic” license, the Licensed Product is defined as that which is covered by the IP rights being licensed, typically patent rights. Royalties are based on sales of patented products. However, in the case of a research tool, the product sold may not be patented, or, as mentioned above, may not yet exist. This leads to differing definitions of Licensed Products.

For example, in the Tanox/Medical Research Council license of 26 June 1989 (Tanox S-1/A 2/11/2000 exhibit 10.7, there is found the following grant:

3. GRANT OF RIGHTS.

- (1) *MRC agrees to grant to the Licensee the following licenses under the Winter Patent:*
 - (i) *a non-exclusive worldwide license to exploit the Winter Patent commercially in any way whatsoever by the use of the Reshaping Process in the Fields and by the commercial exploitation in the Fields of any resulting antibodies provided always that any such exploitation does not involve the antibodies detailed in the Second Schedule hereto; and*

- (ii) a non-exclusive sublicense under the Boss Patents to the extent required to enable the licensee to use the Reshaping Process in accordance with (i) above and for no other purpose.
- (2) The Licensee shall not be entitled to grant sublicenses of the rights granted to it under this Agreement except with the prior written consent of MRC. The licensee shall use its best endeavors to ensure that any sublicensee performs its obligations under any such sublicense.
- (3) The following arrangements shall not require the prior consent of MRC:
 - (i) The appointment of any person as agent or distributor to market, sell, use or otherwise dispose of the Products in any part of the world;
 - (ii) The subcontracting of the development of new Products for the Licensee;
 - (iii) The subcontracting of manufacture for the Licensee of Products or intermediates for Products.

"FIELDS" shall mean the field of human therapy and human in vivo and in vitro diagnostics.

"THE RESHAPING PROCESS" shall mean the genetic engineering of monoclonal antibodies comprising the replacement, in whole or in part, of the complementarity determining regions of one antibody by those of another as described in the Winter Patent.

Royalties are paid as follows:

- (2) IN FURTHER consideration of the licenses granted by MRC to Licensee under this Agreement, Licensee shall pay to MRC a royalty at the rate of * of Net Receipts and VAT thereon on all sales of Products by Licensee or any Affiliate where the Products are either manufactured and/or sold in a country where the Winter Patent is granted, valid and subsisting at the date of such sale. MRC agrees to notify Licensee of any actions or oppositions contesting validity of the Winter Patent.

"THE PRODUCTS" shall mean products produced either directly or indirectly from antibodies which have been modified using the Reshaping Process and which are in a form capable of being marketed or sold upon a commercial basis (the parties intend that the Products will include in some manner such an antibody).

Another example in genomics is the database license where the pharmaceutical partner will pay a royalty on products developed using the licensed database. In this

case, companies may define the licensed product, for royalty purposes, as any product which arises from the collaboration between the database company and the pharmaceutical company. See, for example, the License Agreement of 15 September, 1994, between Human Genome Sciences, Inc. and SmithKline Beecham. This license may currently be viewed on the website of recap.com.

In that agreement, royalties are based on Net Sales of a Collaboration Product, which is defined as:

** “any process, product, process, method, substance, device, composition, service or compilation of information on gene sequencing which (i) incorporates or is based on or uses or is derived by use of HGS TECHNOLOGY and/or SB TECHNOLOGY and/or (ii) is covered by a HGS PATENT and/or (iii) is covered by a SB PATENT. A COLLABORATION PRODUCT shall not include a product, process, or method, substance, device, composition, service or compilation of information on gene sequencing merely because of an incidental or immaterial use of HGS TECHNOLOGY or SB TECHNOLOGY...

HGS TECHNOLOGY is defined as data, substances, processes, materials, formulae, know-how and inventions (i) with respect to GENES and or expression products thereof (including sequence and function) which are useful within the HGS FIELD or the SB FIELD and which are developed by or on behalf of HGS during or prior to the INITIAL RESEARCH TERM and which are owned by HGS or with respect to which HGS has a right to grant a license and/or (ii) developed by HGS from work funded by SB pursuant to paragraph 6.02 of the COLLABORATION AGREEMENT.

The HGS field is gene therapy and antisense; the SB field is human and animal health care, excluding the HGS field.

SB TECHNOLOGY is defined in the Collaboration agreement, and is directed to technology developed within the HGS FIELD and/or the SB FIELD, developed during the INITIAL RESEARCH TERM “which incorporate or are based on or derived by use of HGS TECHNOLOGY.” It does not include “Incidental” SB technology.

In many subsequent database licenses the pharma co. merely pays an access fee, or milestones, and there is no royalty on downstream products.

Another example of royalties payable on non-patented products may be found in the Exclusive License between The Regents of the University of California and Aurora Biosciences Corp., Aurora S-1/A, filed 6/17/97, Exhibit 10.17. There, royalties are paid on both patented products and “identified products.”

In cases where the Licensed Product is not defined by coverage by Licensed Patents, it is important to define the expiration of royalty payments. If both trade secret and patent rights are being licensed, it is advisable to provide for one royalty rate for patented products and another royalty rate and term for products covered by trade secrets. In one case, the obligation to pay royalties on unpatented products was simply read out of the agreement, due to concerns of patent misuse. *Instruments SA v. American Holographic Inc.* 57 USPQ2d 1852 (Mass. Super. Ct. 2000).

D. 2. Exclusivity/Field of Use

In March 1998, Synaptic Pharmaceutical Corp. and Glaxo entered into an Agreement pursuant to which Synaptic granted Glaxo a nonexclusive license under the company's alpha 1 adrenergic receptor patents to develop and sell alpha-1a selective compounds for therapeutic applications other than the treatment of Benign Prostate Hyperplasia (BPH). Synaptic also granted Glaxo an option to obtain a non-exclusive license to sell BPH products. This case is made fairly straightforward because Synaptic's

patents cover certain methods of treating BPH, and there is no research collaboration involved. Pertinent language from the agreement may be found at the Synaptic 10-K of 3/27/98, Exhibit 10.41. In this agreement, Glaxo is granted only an option to a non-exclusive license.

ARTICLE 2 - OPTION GRANT; OPTION AND LICENSE FEES

- 2.1 *SYNAPTIC grants to GLAXO an option (the "Option") to obtain the non-exclusive license described in Article 3.2 below upon the terms and conditions set forth in this Agreement.*
- 2.2 *As consideration for the Option and the nonexclusive licenses described in Article 3.1, GLAXO shall make to SYNAPTIC a non-refundable, noncreditable payment of \$2,000,000 (two million dollars) within 10 days of receipt of an invoice from Synaptic following execution of this Agreement.*
- 2.3 *The Option shall be exercisable by GLAXO in accordance with Article 2.4 at any time from execution of this Agreement until May 22, 1999 (the "EXPIRATION DATE") after which date it shall automatically expire.*
- 2.4 *The Option shall be exercisable by delivery of written notice from GLAXO to SYNAPTIC prior to the EXPIRATION DATE along with the payment of [**] by GLAXO to SYNAPTIC. GLAXO shall provide MERCK with a copy of the written notice to SYNAPTIC.*

ARTICLE 3 - LICENSE GRANTS

- 3.1 (a) *SYNAPTIC hereby grants to GLAXO and its AFFILIATES throughout the TERRITORY, for the sole purpose of developing, making, having made, using and selling SELECTIVE ALPHA-1a ADRENERGIC RECEPTOR PRODUCTS which are not BPH PRODUCTS, a non-exclusive license under any of the RECEPTOR PATENTS.*

The license grant in this Article 3.1(a) shall extend back in time to apply to acts by GLAXO prior to the Effective Date of this AGREEMENT.

(b) For the period beginning on the Effective Date and ending on the EXPIRATION DATE, SYNAPTIC hereby grants to GLAXO and its AFFILIATES, throughout the TERRITORY, for the sole purpose of developing, making, having made and using but not selling BPH PRODUCTS a non-exclusive license under the RECEPTOR PATENTS. The license grant in this Article 3.1(b) shall extend back in time to apply to acts by GLAXO prior to the Effective Date of this AGREEMENT.

*(c) For the period beginning on the Effective Date and ending on the EXPIRATION DATE, SYNAPTIC hereby grants to GLAXO and its AFFILIATES, throughout the TERRITORY, for the sole purpose of developing, making, having made and using but **not selling** BPH PRODUCTS a non-exclusive license under the FUNCTIONAL USE PATENTS.*

3.2 Upon exercise of the Option, SYNAPTIC grants to GLAXO and its AFFILIATES throughout the TERRITORY, for the sole purpose of developing, making, having made, using **and selling** BPH PRODUCT(S) a **non-exclusive license** under the **PATENTS**.

A complex research tool license and collaboration agreement will often have a variety of license grants, both non-exclusive and exclusive. For example, on July 17, 2001, Exelixis, Inc. announced a collaboration with Bristol-Myers Squibb Company ("BMS"). The collaboration involved three agreements: (a) a Stock Purchase Agreement; (b) a Cancer Collaboration Agreement; and (c) a License Agreement. Under the terms of the collaboration, BMS (i) purchased 600,600 shares of Exelixis Common Stock in a private placement at a purchase price of \$33.30 per share, for proceeds to Exelixis of approximately \$20 million; (ii) agreed to pay Exelixis a \$5 million license fee and provide Exelixis with \$3 million per year in research funding for a minimum of three years; and (iii) granted to Exelixis a worldwide, fully-paid, exclusive license to an

analogue to rebeccamycin developed by BMS, which is currently in Phase I and Phase II clinical studies for cancer. Exelixis has agreed to provide BMS with exclusive rights to certain potential small molecule compound drug targets in cancer identified during the term of the research collaboration.

The Cancer Collaboration Agreement, Exhibit 10.30 to the Exelixis 10-Q, 11/14/01, contains no less than ten separate exclusive, non-exclusive, and co-exclusive grants. The following is excerpted and edited from the agreement:

5.1 *LICENSES TO BMS.*

(A) *EXEL KNOW-HOW AND EXEL PATENTS.*

(I) *RESEARCH.* Exelixis hereby grants BMS a **non-exclusive**, worldwide, royalty-free license under any **EXEL Know-How** and **EXEL Patents** solely (A) to perform the research tasks assigned to it...

(II) *BMS SELECTED TARGETS.* Exelixis hereby grants BMS an **exclusive**, worldwide, royalty-bearing (solely to the extent provided in Section 7.4) license to make and use each such **BMS Selected Target** (A) to perform research within the Research Field upon each such BMS Selected Target, including

(III) *ASSAYS.* Exelixis hereby grants BMS an **exclusive**, worldwide, royalty-bearing license to use each such **Assay** to search for, make and have made (1) Collaboration Compounds with activity against the BMS Selected Target Such license shall convert to a non-exclusive license, on an Assay-by-Assay basis, on the earlier of (x) the date that is [*] after the end of the Research Term, or (y) the BMS Selected Target relating to such Assay becomes an Abandoned Target and is selected by Exelixis as an EXEL Selected Target.

(IV) **LEAD COMPOUNDS/BACK-UP COMPOUNDS.** Exelixis hereby grants BMS a worldwide, royalty-bearing license (with the right to sublicense), under any EXEL Know-How and EXEL Patents during the term of this Agreement covering the composition, manufacture, or use of a Lead Compound delivered to BMS pursuant to Section 3.5(b) or a Back-up Compound for such Lead Compound, (A) to make derivatives of such Lead Compounds and Back-up Compounds, (B) to research, develop, and make or have made for use in the Development Field, BMS Collaboration Products comprising or incorporating such a Lead Compound or Back-up Compound or derivative thereof,

The foregoing license shall be (x) **exclusive** with respect to **Lead Compound and Back-up Compounds** delivered to BMS pursuant to Section 3.5(b) and BMS Collaboration Products containing such Lead Compounds or Back-up Compounds and (y) **non-exclusive** with respect to **derivatives of Lead Compounds and Back-up Compounds** delivered to BMS pursuant to Section 3.5(b) and **BMS Collaboration Products** containing derivatives of such Lead Compounds and Back-up Compounds. [*].

(V) **PHARMACOGENOMIC USES.** Exelixis hereby grants BMS a **non-exclusive**, worldwide, royalty-bearing license under the EXEL Know-How and EXEL Patents covering the composition, manufacture or use of an **Selected Target** of either Party,

(VI) **NEGATIVE SCREENING USING EXEL TARGETS.** Exelixis hereby grants to BMS a **non-exclusive, worldwide**, non-royalty bearing license under any EXEL Patents and EXEL Know-How covering the composition, manufacture, or use of an EXEL Selected Target, to use such EXEL **Selected Target** solely in **secondary screening assays** developed by or for BMS to identify, research and develop Collaboration Compounds and BMS Products that lack the ability to inhibit, activate or otherwise modulate the activity of such EXEL Selected Target. The foregoing license does not include the right of BMS to use any assays developed by or on behalf of Exelixis with respect to EXEL Selected Targets. [*].

(VII) **EXELIXIS VALIDATION PROTOCOLS AND REAGENTS.** Exelixis hereby grants to BMS a **non-exclusive**, worldwide, royalty-free license (without the right to sublicense except to its Affiliates) under the EXEL Know-How and EXEL Patents relating to (A) the Exelixis validation protocols and reagents listed on Exhibit 5.1(a)(vii) (as updated from time to time by the Joint steering committee)...

(VIII) **IMPROVEMENTS TO BMS VALIDATION PROTOCOLS AND REAGENTS.** Exelixis hereby grants to BMS a non-exclusive, worldwide, royalty-free license

(B) **TARGET INVENTIONS.**

(I) Exelixis hereby grants BMS an **exclusive**, worldwide, royalty-free license, under the **Target Inventions invented solely by BMS** and all Patents Controlled by Exelixis that claim such Target Inventions, to use such Target Inventions for all purposes other than those for which Exelixis has exclusive rights pursuant to Section 5.3.

(II) Exelixis hereby grants BMS a worldwide, royalty-free license (with the right to sublicense), under the **Target Inventions invented jointly by BMS and Exelixis** and all Patents Controlled by Exelixis that claim such Target Inventions, to use, without any accounting or obligation to, or consent required of, Exelixis, such Target Inventions for all purposes other than those

for which Exelixis has **exclusive** rights pursuant to Section 5.3. The foregoing license is exclusive, with respect to BMS Selected Targets, for those purposes for which BMS has exclusive rights pursuant to Section 5.1(a)(ii); such license is **co-exclusive** for all other permitted purposes.

In addition, this agreement provides for licenses from BMS to Exelixis in the areas of (A) RESEARCH, (B) EXEL SELECTED TARGETS, (C) TARGETS (sole inventions of BMS), (D) VALIDATION PROTOCOLS AND REAGENTS, (E) ASSAYS, (F) NEGATIVE SCREENING USING BMS TARGETS, and (G) PHARMACOGENOMIC INVENTIONS.

A final note on exclusivity: an exclusive license excludes even the patent owner. This however is never true in University licences; they reserve the right to conduct research using the licensed patent. These agreements usually provide that the field of use for the Research Tool license is within the Collaboration.

In general, when drafting Field of Use restrictions, the licensor should be guided by practical marketing considerations. That is, the licensor presumably would like to grant other licenses for other fields. If a field of use is based on a technical distinction, the technology may change, and future products can arise that were not contemplated at the time the license was drafted. Field of use restrictions that attempt to control disposition of products after the first sale of the product must be carefully drafted.⁶

⁶ See *Mallinckrodt, Inc. v. Medipart, Inc.* 24 USPQ 2d, 1173 (Fed. Cir. 1992), regarding placing restrictions on a product that it be “single use.”

D. 3. Milestone Payments for reaching Program Goals

Research Tool agreements are fairly consistent with regard to the events that will trigger milestone payments. These typically include events such as filing of an IND, beginning of a Phase III clinical trial, submission of an NDA or BLA to the FDA for marketing approval, and marketing approval. In some instances, earlier milestone payments may be negotiated. The sample term sheet above identifies milestone payments that could involve the identification of a potential target, the identification of a hit to the target, and entry of a selected compound into different stages of pharmaceutical development. Milestone payments are sometimes based on the pharma co.'s internal procedures – such entry of a drug candidate into a defined phase of preclinical development. A more objective milestone may be drafted according to typical FDA practices – entry of a compound into a 30 day toxicology study, for example.

Milestone payments are sometimes made creditable against earned royalties (see the GTC –BMI Agreement referenced above). Milestone payments may be viewed also as an alternative payment structure that avoid the issue of earned royalties.

D. 4. Representations, Warranties and Indemnification

These provisions are fairly consistent among Research Tool Agreements. Exclusive licenses generally involve more warranties on the part of the licensor, such as warranty of title to the patent(s) being licensed. There is generally no warranty that the patents being licensed may be practiced without infringing any third party patents.

Sometimes an “anti-stacking” provision is included to address the possibility of unforeseen royalty obligations to third parties (See the BMI-GTC Agreement, section 6.5.3).⁷ In cases where the biotech company is supplying a database or other tangible material, there may be limited warranties attached to the performance of the data or material supplied.

Often, there will be a section in the license specifying that there is no implied license in any of the licensor’s technologies other than those specifically enumerated in the license⁸. This avoids the issue of an “implied license” or a license by estoppel. It can be particularly important if the licensor is limiting the scope of the license to less than all of the applicable patents, as in the case of a geographic limitation. Universities typically include this provision because they may have dominating patents and not be aware of it!

Licenses traditionally have UCC-style disclaimers relating to warranty of merchantability and fitness of purpose. However, at least one court has held that patent licenses are not subject to the UCC.⁹

An interesting example of a warranty and representation section is found in the BMS-Exelixis agreement discussed above. In that agreement, breach of a warranty is specifically made a ground for termination by the non-breaching party. Note that each

⁷ Genome Therapeutics/Biomerieux Inc. Collaboration and License Agreement, Exhibit 10.47, Genome Therapeutics Corp. 10Q, 1/11/00 – development of DNA diagnostics using DNA database.

⁸ See paragraph 6.8 of the Pharmacopiea/BMS license for an example.

⁹ *Novamedix, Ltd. v. NDM Acquisition Corp.*, 49 USPQ 2d 1613 (Fed. Cir. 1999)

party to this agreement makes reciprocal warranties. Indemnification is also mutual.

This language is probably fairly detailed because of the extensive nature of the collaboration and the exclusive licenses being granted. In another Exelixis agreement, in the field of target identification and validation in the field of fungicides and herbicides, with Dow AgroSciences LLC, there is no warranty section at all. Excerpted language from the BMS agreement is below:

11. REPRESENTATIONS AND COVENANTS

11.1 MUTUAL AUTHORITY. *Exelixis and BMS each represents and warrants to the other that: (i) it has the authority and right to enter into and perform this Agreement, (ii) this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, subject to applicable limitations on such enforcement based on bankruptcy laws and other debtors' rights, and (iii) its execution, delivery and performance of this Agreement will not conflict in any material fashion with the terms of any other agreement or instrument to which it is or becomes a party or by which it is or becomes bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.*

11.2 RIGHTS IN TECHNOLOGY. *During [*], each Party will use commercially reasonable efforts to maintain (but without an obligation to renew) and not to breach any agreements with Third Parties that provide a grant of rights from such Third Party to a Party that are Controlled by such Party and are licensed or become subject to a license from such Party to the other Party under Article 5 or 6. Each Party agrees to provide promptly the other Party with notice of any such alleged breach. As of the Effective Date, each Party is in compliance in all material respects with any aforementioned agreements with Third Parties.*

11.3 PERFORMANCE BY AFFILIATES. *The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates, provided, however, that each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. In particular, if any Affiliate of a Party participates in research under this Agreement or with respect to Collaboration Compounds, (i) the restrictions of this Agreement which apply to the activities of a Party with respect to Selected Targets and Collaboration Compounds shall apply equally to the activities of such Affiliate, and (ii) the Party affiliated with such Affiliate shall assure, and hereby guarantees, that any intellectual property developed by such Affiliate shall be governed by the provisions of this Agreement (and*

subject to the licenses set forth in Article 5) as if such intellectual property had been developed by the Party.

11.4 THIRD PARTY RIGHTS.

(A) Except as already disclosed, each Party represents and warrants to the other Party that, to its knowledge as of the Effective Date, its performance of work under the Collaboration as contemplated by this Agreement shall not infringe the patent, trade secret or other intellectual property rights of any Third Party. Each Party represents and warrants to the other Party that, to its knowledge as of the Effective Date, it will not violate a contractual or fiduciary obligation owed to such Third Party (including without limitation misappropriation of trade secrets) to perform its work under the Collaboration as contemplated by this Agreement.

(B) Except as already disclosed, Exelixis represents and warrants to BMS that, to its knowledge as of the Effective Date, the research conducted by it to identify the Targets listed in Exhibit 1.28 did not infringe the patent, trade secret or other intellectual property rights of any Third Party. Exelixis represents and warrants to BMS that, to its knowledge as of the Effective Date, it did not violate a contractual or fiduciary obligation owed to such Third Party (including without limitation misappropriation of trade secrets) in conducting its research to identify the Targets listed in Exhibit 1.28.

11.5 NOTICE OF INFRINGEMENT OR MISAPPROPRIATION. [*] represents and warrants to [*] that, as of the Effective Date, it has received no notice of infringement or misappropriation of any alleged rights asserted by any third party in relation to any technology to be used in connection with the Collaboration.

Typically, a research collaboration provides for each party performing research to indemnify the other. In a license agreement, indemnification flows from the licensee to the licensor. The licensor does not want to be held liable for any defects in products produced by the licensee. I am unaware of any case that has actually found such liability, however. More or less typical language is found in the Pharmacopiea/BMS License. I have underlined some interesting provisions that may serve to broaden the indemnification obligations.

INDEMNIFICATION

13.1 **BMS.** BMS agrees to indemnify, defend and hold Pharmacopeia and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the "Pharmacopeia Indemnitees") harmless from and against any losses, costs, claims, damages, liabilities or expense (including reasonable attorneys' and professional fees and other expenses of litigation) (collectively, "Liabilities") arising, directly or indirectly out of or in connection with **third party claims**, suits, actions, demands or judgments, relating to (i) any Products developed, manufactured, used, sold or otherwise distributed by or on behalf of BMS, its Affiliates or Sublicensees or other designees (including, without limitation, product liability and patent infringement claims), (ii) BMS' performance of the Research Collaboration, (iii) the use of the Targets which are involved in the conduct of the Research Collaboration and the making or use of ligands to such Targets; and (iv) **any breach by BMS of the representations and warranties** made in this Agreement, except, in each case, to the extent such Liabilities result from a material breach of this Agreement by Pharmacopeia, gross negligence or intentional misconduct of Pharmacopeia.

13.2 **Pharmacopeia.** Pharmacopeia agrees to indemnify, defend and hold BMS, its Affiliates and its Sublicensees and their respective directors, officers, employees, agents and their respective heirs and assigns (the "BMS Indemnitees") harmless from and against any losses, costs, claims, damages, liabilities or expense (including reasonable attorneys' and professional fees and other expenses of litigation) (collectively, "Liabilities") arising, directly or indirectly out of or in connection with **third party claims**, suits, actions, demands or judgments, relating to (i) any product based on a Library Compound developed, manufactured, used, sold or otherwise distributed by or on behalf of Pharmacopeia, its Affiliates, licensees or other designees as permitted under this Agreement (including, without limitation, product liability and patent infringement claims), (ii) the performance of the Research Collaboration by Pharmacopeia, and (iii) any breach by Pharmacopeia of its representations and warranties made in this Agreement, except, in each case, to the extent such Liabilities result from a material breach of this Agreement by BMS, gross negligence or intentional misconduct of BMS.

13.3 **Procedure.** In the event that any Indemnatee (either a BMS Indemnatee or a Pharmacopeia Indemnatee) intends to claim indemnification under this Article 13 it shall promptly notify the other party in writing of such alleged Liability. The indemnifying party shall have the right to control the defense thereof with counsel of its choice as long as such counsel is reasonably acceptable to Indemnatee; provided, however, that any Indemnatee shall have the right to retain its own counsel at its own expense, for any reason, including if representation of any Indemnatee by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such Indemnatee and any other party reasonably represented by such counsel in such proceeding. The affected Indemnatee shall cooperate with the indemnifying party and its legal representatives in the investigation of any action, claim or liability covered by this Article 13. The Indemnatee shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim or suit without the prior written consent of the indemnifying party, which such party shall not be required to give.

D. 5. Infringement

In general, it is considered to be incumbent upon the patent owner to enforce its patents. However, the licensee may have a significant interest in stopping competitors, particularly where the licensor is not itself using the licensed patent. An exclusive licensee may have standing to sue for patent infringement in its own right, but this is not always clear, based on various court decisions.

An example of a thorough patent infringement section is found in the Pharmacopeia/BMS license. There, each party sues on its own patents, and the right to sue on joint patents is divided by technical area.

10.6 Enforcement and Defense.

10.6.1 Notice. *Each party shall promptly notify the other of any knowledge it acquires of any potential infringement of the Licensed Technology or the BMS Technology by a third party.*

10.6.2 Joint Inventions. *In the event Pharmacopeia or BMS becomes aware of any actual or threatened infringement of any patent filed pursuant to Section 10.2.1(b) (Joint Inventions), that party shall promptly notify the other and the parties shall promptly discuss how to proceed in connection with such actual or threatened infringement. Unless otherwise agreed by the parties, the terms of Sections 10.6.3 and 10.6.4 shall apply; provided, the parties may decide to jointly defend against any patent infringement by third parties, in which case the parties shall also agree on allocation of costs and damages.*

10.6.3 BMS. *BMS shall have the initial right, but not the obligation, to take reasonable legal action to enforce against infringements by third parties or defend any declaratory judgment action relating to any patent filed pursuant to Section 10.2.1(b)(i)¹⁰, at its sole*

¹⁰ BMS shall be responsible for: (A) preparing, filing, prosecuting and maintaining in the Core Countries, and any additional countries agreed by BMS and Pharmacopeia, patent applications and patents directed to **Joint Inventions** that claim one or more compositions of matter relating to an Active Compound, Other Compound or a Derivative Compound thereof, or a method of use of any of the foregoing, and conducting any interferences, re-examinations, reissues and oppositions relating thereto, and....

cost and expense. If, within six (6) months following receipt of such notice from Pharmacopeia, BMS fails to take such action to halt a commercially significant infringement, Pharmacopeia shall, in its sole discretion, have the right, at its sole expense, to take such action. BMS shall have the right to enforce patents filed pursuant to Section 10.2.1(c),¹¹ in its sole discretion, unless Pharmacopeia has acquired a license to BMS' interest in such patents pursuant to Section 9.3.

10.6.4 Pharmacopeia. Pharmacopeia shall have the initial right, but not the obligation, to take reasonable legal action to enforce against patent infringement by third parties or defend any declaratory judgment action relating to any patent filed pursuant to Section 10.2.1(a) (**Pharmacopeias Inventions**) or 10.2.1(b)(ii) (**Joint Inventions not in (b)(i)**), at its sole cost and expense. If, within six (6) months following receipt of such notice from BMS, Pharmacopeia fails to take such action to halt a commercially significant infringement, BMS shall, in its sole discretion, have the right, at its expense, to take such action.

10.6.5 Cooperation; Costs and Recoveries. Each party agrees to render such reasonable assistance as the prosecuting party may request. Costs of maintaining any such action and amounts recovered therefrom shall be paid by and belong to [***]; provided, any such recovery [***] shall be considered [***] of the relevant Product.

10.7 Infringement Claims. If the manufacture, sale or use of any Product pursuant to this Agreement because of the practice of the Licensed Technology or the BMS Technology results in any claim, suit or proceeding alleging patent infringement against Pharmacopeia or BMS (or its Affiliates or Sublicensees), such party shall promptly notify the other party hereto in writing setting forth the facts of such claim in reasonable detail. The defendant shall have the exclusive right and obligation to defend and control the defense of any such claim, suit or proceeding, at its own expense, using counsel of its own choice; provided, however, it shall not enter into any settlement which admits or concedes that any aspect of the BMS Technology (in the case of Pharmacopeia) or the Licensed Technology (in the case of BMS) is invalid or unenforceable, without the prior written consent of such other party. The defendant shall keep the other party hereto reasonably informed of all material developments in connection with any such claim, suit or proceeding.

The Pharmacopeia/BMS agreement involved an exclusive grant to BMS to make active compounds. In some agreements, the exclusive licensee is granted the right to sue for patent infringement. See, e.g., the AHP (Wyeth Ayerst) – Genome Therapeutics agreement, Exhibit 10.1, GTC 8-K filed 3/8/2000, for development of genes involved in bone disorders.

¹¹ BMS Inventions

D. 6. Assignability

Generally, Research Tool license agreements may not be assigned by either party without the written consent of the other party, except in cases of the sale of the entire business, or that portion of the business to which the license pertains. Sometimes the issue of affiliates will arise. Affiliates may be included in the definition of the licensed party and are often dealt with in definitions of net sales. In the absence of language to the contrary, patent licenses are not assignable. The following language, from the Biomerieux/Genome Therapeutics License, is typical:

12.2 ASSIGNMENT. This Agreement may not be assigned or otherwise transferred by either party without the consent of the other party; PROVIDED, HOWEVER, that either GTC or BMI may, without such consent, assign any or all of its rights and obligations under this Agreement (i) to any Affiliate, or (ii) in connection with a merger, consolidation or sale of substantially all of such party's assets to an unrelated Third Party; PROVIDED, HOWEVER, that such party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction and shall not be transferred separate from all or substantially all of its other business assets, including those business assets that are the subject of this Agreement. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. For the sake of clarity, the rights and obligations described in the present Agreement, taken separately or as a whole, may be exercised or performed by either party and/or, as the case may be, their respective Affiliates.

In some cases, a party may be worried about the assignment of an agreement to a competitor. Some licenses simply prohibit assignment. (The Merck/Lexicon Agreement is an example).

D. 7. Term and Termination

When royalties are tied to something other than licensed patents, they will not automatically expire on the expiration of the licensed patents. A specific time for the expiration of royalty obligations must be set. There are significant patent issues (i.e. patent misuse) involved in collecting royalties beyond the expiration of the patent term.

It is a good idea to specify that the licensee has a paid up license upon termination. Whatever rights or obligations are intended to extend beyond the term of the agreement should also be spelled out, such as confidentiality, books and records, indemnification, etc. There is some dispute as to whether or not license agreements can be terminated for bankruptcy under U.S. law, but in other countries this is permitted.¹² Note that the sample agreement below permits termination in the event of acquisition of the biotech company by a competitor of the pharma company.

Research Agreements often have a provision for continued research payments for a time after the sponsor (pharma co.) terminates. A license agreement may provide for a “re-licensing fee” or liquidated damages if the licensee terminates prior to product development. This is not typical, however, since the licensor will get the technology back on termination. The licensor may ask also for improvements to be transferred back to the licensor upon early termination.

¹² A non-exclusive licensee who goes bankrupt may not transfer or keep its licensee as part of its reorganization. *In re Catapult Entertainment, Inc.*, 165 F. 2d 747, LEXIS 1072, (9th Cir. 1999).

In general, the licensee is given the permission to terminate a license at will, since it may determine that it is simply not going to pursue development of the licensed technology. An issue that is not commonly addressed in biopharm licenses is the right of the licensee to challenge a licensed patent and pay royalties into escrow, while keeping the license. This may become a significant issue in the future, when earned royalties become more common as Research Tool-derived drugs hit the market.

Again, language from the Pharmacopeia/BMS license is used for purposes of illustration:

PAYMENTS

7.4.2 Trade Secret Royalties. *The parties acknowledge and agree that the principal value contributed by Pharmacopeia is accelerated time to market, enhanced probability of success and the potential for multiple Target leads and that Pharmacopeia may not own or control patents that cover the manufacture, sale or use of a particular Product. BMS acknowledges and agrees that the value BMS receives hereunder is in the access to the Library Compounds and enablement in the solid-phase synthesis and high throughput screening thereof, and accordingly BMS shall pay the royalties at the rates specified in this Section 7.4, regardless of whether the applicable Collaboration Compound or Product is covered by a patent application or patent within the Licensed Technology or BMS Technology.*

7.4.3 Single Royalty; Non-Royalty Sales. *No royalty shall be payable under this Section 7.4 with respect to sales of Products among BMS, its Affiliates and Sublicensees for resale; and in no event shall more than one royalty be due hereunder with respect to any Product unit even if covered by more than one patent included in the Licensed Technology.*

7.4.4 Royalty Term. *BMS' obligation to pay royalties to Pharmacopeia shall continue for each Product, on a country-by-country basis, until the later of (i) ten (10) years after the first commercial sale of such Product in such country, or (ii) the expiration of the last to expire issued patent within the Licensed Technology or BMS Technology which contains a composition-of-matter or method of use claim covering any formulation of such Product in such country.*

TERM AND TERMINATION

14.1 Term. *The term of this Agreement shall commence on the Effective Date, and shall continue in full force and effect on a country-by-country and Product- by-Product basis until BMS and its Sublicensees have no remaining royalty payment obligations in a country, unless terminated earlier as provided in this Article 14.*

14.2 Termination for Breach. *Either party to this Agreement may terminate the Research Collaboration and/or this Agreement in the event the other party hereto shall have materially breached or defaulted in the performance of any of its material obligations hereunder, and such default shall have continued for sixty (60) days after written notice thereof was provided to the breaching party by the non-breaching party. Any termination shall become effective at the end of such sixty (60) day period unless the breaching party (or any other party on its behalf) has cured any such breach or default prior to the expiration of the sixty (60) day period; provided, however, in the case of a failure to pay any amount due hereunder, such default may be the basis of termination ten (10) business days following the date that notice of such default was provided to the breaching party.*

14.3 Termination for Insolvency. *If voluntary or involuntary proceedings by or against a party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such party, or proceedings are instituted by or against such party for corporate reorganization, dissolution, liquidation or winding-up of such party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or if such party makes an assignment for the benefit of creditors, or substantially all of the assets of such party are seized or attached and not released within sixty (60) days thereafter, the other party may immediately terminate the Research Collaboration and/or this Agreement, effective upon notice of such termination.*

14.4 Termination Due to Acquisition. *During the Research Term, if any major pharmaceutical company which, in the good faith determination of BMS, is a competitor of BMS acquires Pharmacopeia (whether through merger, consolidation or acquisition, directly or indirectly, of stock representing 50% or more of the outstanding voting stock or other equity securities of Pharmacopeia, sale of all or substantially all the assets of Pharmacopeia or otherwise), BMS may terminate the Research Collaboration and/or this Agreement effective ninety (90) days after written notice is transmitted to Pharmacopeia, its parent, successor, or the surviving or new entity, as the case may be.*

14.5 Permissive Termination. *If BMS terminates the Research Collaboration pursuant to Section 2.4.3(d) prior to the end of the Initial Term, the Agreement shall terminate in its entirety concurrently.*

14.6 Effect of Breach or Termination.

14.6.1 Accrued Rights and Obligations. *Termination of this Agreement for any reason shall not release either party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period*

prior to such termination nor preclude either party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

14.6.2 Return of Materials. Upon any termination of the licenses granted to either party pursuant to this Agreement, BMS and/or Pharmacoepia, as the case may be, shall promptly return to the other all Confidential Information (including, without limitation, all Know-How) received from the other party, except one copy of which may be retained for archival purposes.

14.6.3 Post-Termination Product Sales. In the event of the cancellation or termination of any license rights with respect to a Product prior to the expiration of this Agreement, inventory of such Product may be sold for up to one year after date of termination or such longer period as the parties may agree, provided earned royalties are paid thereon.

14.6.4 Licenses.

(a) Following expiration of the term of this Agreement with respect to a Product in a country pursuant to Section 14.1, BMS shall have the royalty-free, perpetual right to make, have made, use and sell such Product in such country. Following expiration of the term of this Agreement with respect to every Product in every country pursuant to Section 14.1, BMS shall have the royalty-free, perpetual right to continue to make, have made, use and sell all Products worldwide.

(b) The licenses granted to BMS herein shall terminate in the event of any termination of the Research Collaboration by BMS prior to the end of the Initial Term pursuant to Section 2.4.3(d) or any termination of the Agreement by Pharmacoepia pursuant to Section 14.2 or 14.3.

(c) Subject to Section 9.3.1, if more than one Product is being commercially developed or exploited by BMS or its Affiliates or Sublicensees hereunder, and Pharmacoepia terminates this Agreement pursuant to Section 14.2 due to a breach relating only to a single Product, then Pharmacoepia shall be entitled to terminate this Agreement only with respect to the applicable Product.

(d) Except as expressly provided in this Section 14.6.4, in the event of any termination of this Agreement, the licenses granted under this Agreement to either party prior to the effective date of such termination shall remain in effect, subject to the terms and conditions of this Agreement applicable thereto. In such event, the applicable provisions of Articles 6, 7, 9 and 14 shall survive and be applicable to such licenses in addition to the provisions which survive pursuant to Section 14.7.

14.7 Survival Sections. Sections 2.4.4(effect of termination on research collaboration), 2.6 (exclusivity in providing compounds), 2.7 (records, inspection rights), 4.3 (ownership of libraries), 5.1 (screening of libraries by BMS), 5.3.4 (designation of compounds), 6.4 (licenses to compounds and research licenses), 6.8 (no implied license), 6.9 (no commercialization of compounds outside license), 7.4 (royalties), 9.3.2 (grant back), 9.3.3 (regulatory filings), 14.6 (effect of breach or termination – accrued rights) and 14.7 (this very section!) of this Agreement, and Articles 8 (payments, books and records), 10 (intellectual property – ownership), 11(confidentiality) , 12 (representations and

warranties), 13(indemnification) and 15 (miscellaneous) shall survive the expiration or termination of this Agreement for any reason.

Closing Remarks

Drafting Biopharm licensing agreements for research tools must be preceded by an analysis of the transaction in question. The strategic goals of the parties will dictate the general type of agreement to be drafted. At that point, the drafter should carefully consider the issues that should be covered without attempting to “over-lawyer” the process.

Once drafting begins, it is important to draft for clarity. Avoid definitions within definitions and other overly circular internal references. Try to use terms in their ordinarily understood meanings. Counter-intuitive definitions will be continually confusing to the reader. The individuals initially responsible for negotiating the agreement should be considerate of those who will later, perhaps many years later, inherit the agreement.

Finally, as time goes by, there will inevitably be questions raised about the agreement. Hopefully, these can be resolved by amendment. If disputes arise and litigation ensues, remember that basic contract law will apply, as well as basic intellectual property law.

Courts will generally interpret patent licenses under state law. They will give effect to the clear language of the contract, and, failing that will try to discern the intent of the parties.¹³ In one recent case, a licensor was able to set aside a license and collect punitive damages based on a jury finding that it fraudulently induced the granting of a license by not revealing positive test results of its genetically engineered corn.¹⁴ All of the general rules regarding contract interpretation will apply¹⁵, including the basic obligation of good faith and fair dealing, which, aside from being a legal requirement is the key to successful licensing as a business matter as well.

¹³ See *Institut Pasteur v. Cambridge Biotech Corp.*, 51 USPQ2d 1321 (Fed. Cir. 1999).

¹⁴ *Rhone-Poulenc Agro SA v. DeKalb Genetics Corp.*, 60 USPQ 2d. 1769 (Fed. Cir. 2001)

¹⁵ e.g. “specific terms control over general,” see *Air-Sea Forwarders, Inc. v. United States*, 166 Fed. 3rd 1170, LEXIS 867 (Fed. Cir. 1999).