SOTERIA BIOSCIENCES:

A Hypothetical “Case Study” in IP Do’s (and DO NOT Do’s) for AgriBio- (and other) Technology Startup to Mid-Stage Companies

Part 1: Research and Development Considerations and Ownership/Due Diligence Considerations

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I. Introduction

The following paper and a companion paper (“Part 2: Foreign Filing Considerations”) set out several early chapters in the story of Soteria Biosciences, a hypothetical agri-biotechnology company, as it progresses along a path from a startup company founded using university technology, through several phases of research and development, and into early commercialization. Along the way, Soteria encounters a number of legal issues and challenges, particularly relating to intellectual property (IP). After setting out an overview and history of the company, this paper then discusses in some detail a number of sets of IP-related legal issues that Soteria has encountered, with an eye to providing points of consideration broadly relevant to other technology companies at various stages of development. Each of these sets of legal issues is presented in the format of a hypothetical memorandum for presentation to Soteria management, having been “prepared” either by in-house or external counsel. This paper specifically addresses issues related to research and development, and ownership and due diligence.

The intention of this paper is to provide you, the reader, with a range of IP-related legal issues to be considered when working with, or as a part of, any technology-based company in the early to mid-stages of development. By basing this paper on the hypothetical “case study” of Soteria, it is the authors’ intention to provide a vivid set of examples for the reader’s consideration, and to provide a basis for lively and engaging discussion. In this regard, it should be noted that the wide-ranging IP-related issues suggested and implied by Section II below, entitled “Company Overview and History”, are more numerous than those discussed in greater detail in the following sections.

Please note that the story of Soteria is entirely a work of fiction, based on the authors’ collective imagination. All events, plant species, chemical compounds, characters and corporate entities appearing in this work are fictitious. Any resemblance to real events, corporate entities, or to any persons, living or dead, or to any real plant species or chemical compounds, is purely coincidental.

II. (Hypothetical) Company Overview and History

Soteria Biosciences Company Profile

Soteria Biosciences is an agri-biotechnology company that was initially formed to discover and develop new plant varieties of *Humurus sativa* (common name: “Humor”), a rare flowering plant within a large phylogenetic family of plants that have been generally used for fibers, seeds and seed oils, as foodstuffs, for medicinal purposes, and/or for various psychoactive effects it causes when consumed. Soteria Biosciences has been developing new varieties of Humor having modified content of humurbidiol (HBD; a chemical that has been associated with various beneficial medical effects, including anti-microbial properties, neurological, anti-inflammatory,

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5 This Section II was contributed by Lee Alan Johnson, Mark Pidkowich and Angela Dallas Sebor.
6 The Authors wish to acknowledge Suzannah Sundby, Debora Plehn-Dujovich, and Vicki Norton for their critical review of this Section II and helpful suggestions.
and anti-psychotic effects) and tetrahydrohumurbinol (THH; a chemical that has been associated with various psychoactive effects), for use in agricultural and other biotechnology commercial applications. The Company has grown from a small U.S. start-up company focused on agricultural science, to a mid-size international biotechnology company with a focus on the safe development and commercialization of a variety of products within the orphan drug, therapeutics, energy, research, industrial and agri-bio fields. This Overview will explore the early- and mid-stage development activities of Soteria Biosciences, and will set the stage for future directions for the Company.

**Early Stage Corporate History of Soteria Biosciences**

The founding research and development work that captured the interest of Soteria Biosciences (“Soteria”) was initially done at State A&M, within a large laboratory run by Dr. Metamorphosis. The research involved hybridization of various plants from the Humor family and related strains using both traditional cross-breeding and direct genetic modification, as well as the sequencing of several high and low HBD and/or THH varieties, which generated significant biomarker data. A transcription factor associated with high THH production was identified and knocked out in some strains of interest, resulting in new Humor varieties. This technology and plants formed using this technology were dubbed “NuHumor”.

Dr. Metamorphosis submitted an abstract describing the NuHumor discovery to the Annual Meeting of the American Cool Plants Society, which was accepted for a poster and oral presentation. State A&M learned of the presentation two days prior to the meeting and filed the first patent applications relating to NuHumor: both a plant and a utility provisional patent application. The applications were filed naming Dr. Metamorphosis as an inventor; no assignments were executed.

Dr. Metamorphosis’ graduate student, who generated much of the NuHumor data, subsequently reported the data in her dissertation, a hard copy of which was filed at the State A&M library. 12 months after the filing of the provisional patent application, State A&M filed a PCT application naming State A&M as Applicant that included some additional data from Dr. Metamorphosis’ lab since the filing of the provisional application. NuHumor was developed in part with federal grant funding to Dr. Metamorphosis’ lab, and so the U.S. government has “march-in” rights.

It is at this stage that Soteria Biosciences, a newly formed start-up agri-biotechnology company, approached State A&M to evaluate the technology and negotiate an exclusive license to all of these patent applications and foreign and domestic applications claiming priority to them, as well as all State A&M “technology” related to NuHumor. Soteria is offering State A&M a significant milestone payment for “each product meeting FDA requirements for commercialization,” as well as a royalty on sales. Soteria also wants to assume control of prosecution of the State A&M patents they will license, intending to file the patent estate globally.

Memoranda from Soteria Biosciences’ in-house and external counsel in Sections III and IV of this paper will address many of the potential issues that may arise during this evaluation and negotiation, specifically related to Research and Development and Ownership and Due Diligence.
Soteria Biosciences Today, a Mid-Stage Agri-Biotechnology Company

Negotiations with State A&M were ultimately successful and, after licensing NuHumor patents, plants and technology from State A&M, Soteria Biosciences has: filed the State A&M PCT application globally, completed significant financing, formed a robust internal research and development program, and expanded to add a European division, called Soteria AG. In addition, growers who buy Soteria plants (with a license) bring the product to market as Humor for industrial uses and use as foodstuffs. Farmers pay Soteria a royalty in addition to the plant costs.

From Europe, Soteria AG and its lead researcher, a German scientist, Dr. Fettsäure, recently reported to Soteria management that the seeds of NuHumor have an unexpectedly high omega-3/omega-6 fatty acid oil profile and higher oil content overall. Soteria AG’s in-house legal department, using its European outside counsel, plans to file additional patent applications on this discovery directly in several countries and regions around the world. Soteria is planning to issue a press release announcing the oil discovery and plans to enter into discussions with several potential partners to develop and market nutraceutical products containing the oils extracted from NuHumor.

Back in the United States, the State A&M technology transfer office (TTO) has contacted Soteria regarding a memo that they claim was previously shown to Soteria people. The memo is allegedly dated prior to licensing and contains statements from a State A&M visiting scientist, Dr. Derivation, who collaborated with Dr. Metamorphosis, describing the improved oil content and profile of NuHumor. Soteria has denied having any recollection or record of such memo, and there is no written record of it being sent to Soteria or to Soteria AG. Soteria’s legal department is now conferring about this matter with Soteria AG’s legal department and with outside counsel in both the U.S. and Europe. Soteria AG’s invention disclosure names its employees as inventors, including Dr. Fettsäure and three other scientists (an American, a Canadian, and a Chinese scientist) working at Soteria Biosciences or Soteria AG, but does not name Dr. Derivation.

Prior to these developments, a third party (Mr. Cheechong), who had previously treated his gout using various well-known plants from the same phylogenetic family as Humor, grew what he thought were seeds from one of such plants that he received via mail order from a seed depository in Brazil. The resulting plant and its flower buds did not look exactly like what he expected, but he smoked the buds anyway and found that they relieved his pain without any of the psychoactive effects he had previously experienced. He extracted the plant with butter to make cookies, and they had the same effect.

Mr. Cheechong then had a private meeting with Soteria representatives where he reported his findings and provided them with the variety he found (which he has dubbed “NoPain”). Soteria paid him a $1000 up front payment, and offered a series of development milestone payments and a royalty on sales to exclusively license all his rights in the plant, products produced from the plant, and the process to produce these plants and products, which he accepted.

Soteria quickly embarked upon a research program, and discovered that “NoPain” has no THH, but a previously unreported combination of HBD and a particular isoprenoid compound.
Moreover, the phenotype seemed to be associated with the same transcription factor that was discovered in the laboratory of Dr. Metamorphosis at State A&M. Soteria then learned that NuHumor has the *same* HBD:isoprenoid profile in its flower buds.

Soteria further purified the HBD and isoprenoid fraction and discovered that the purified extract provided the same results as Cheechong reported, but additionally had no effect on appetite. Soteria named it NoPainNoGain, and the product has already shown promising results in animal studies. Soteria has recently been approached by BigPharma, who wishes to enter into discussions regarding a possible “deal” around this technology. They have sent their standard one-page, one-way nondisclosure agreement for Soteria to review.

Soteria now plans to file patent applications globally on both NoPain and NoPainNoGain. The invention disclosure completed by Soteria scientists only names Cheechong as an inventor in the NoPain invention.

Learning of Soteria’s plans to name him as an inventor only on one patent application, Mr. Cheechong has recently called Soteria, claiming that he should be named on all of the NoPainNoGain patents. He threatens: “I want my money”; his cousin is a well-known patent litigator.

Dr. Derivation has also been in touch with Soteria. He has made ownership claims to all the Soteria products and to NoPainNoGain, and says he should be named on the patents. Dr. Derivation has threatened Soteria with a derivation proceeding on the oil patents.

Finally, Soteria has just learned that another company (Copycat LLC) is developing NoPainNoGain for treating epilepsy. They have responded to Soteria’s inquiries about their program and say they will make a license request under march-in rights provisions (for the State A&M patents, as Soteria can restrict designated customers of its licensed farmers), and/or work with Cheechong in a derivation proceeding to get rights to the NoPainNoGain patents.

As mentioned above, memoranda from Soteria Biosciences’ in-house and external counsel in Sections III and IV of this paper will address many of the issues that have arisen, and are arising, for Soteria in the context of evaluation and negotiation of the State A&M license, specifically related to Research and Development and Ownership and Due Diligence.
MEMORANDUM

TO:        PRESIDENT, SOTERIA BIOSCIENCES

CC:        GENERAL COUNSEL, SOTERIA BIOSCIENCES
            JSz, VP-LEGAL, PATENTS AND INTELLECTUAL PROPERTY-
            USA, SOTERIA BIOSCIENCES
            JS, VP-LEGAL, PATENTS AND INTELLECTUAL PROPERTY-
            INTERNATIONAL, SOTERIA BIOSCIENCES

FROM:      Mark Pidkowich, International Outside Patent and IP Counsel
            Lee Alan Johnson, U.S. Outside Patent and IP Counsel

Dear President,

As requested and with reference to our discussions over the recent weeks and months, please find
below our memorandum setting out issues for consideration for, and certain recommendations
for action to, Soteria’s patent, IP, and development teams, all related to IP and other legal issues
pertaining to Soteria’s proposed ongoing and new research and development programs covering
NuHumor.

Thank you for entrusting us with this important matter.

Soteria undoubtedly has ambitious research and development goals. Nevertheless, it remains
important for Soteria to plan its research program strategically so as to efficiently deploy
resources. Soteria should be looking to determine what kind of company it is, and what products
it intends to provide. This, in turn, will inform a research program designed to cost-effectively
generate the data necessary to optimize its current intellectual property base, and to expand from
that base in a rational, directed, and resource-efficient manner.

1. The Intellectual Property Landscape

While Soteria may desire to embark on its research and development without delay, we cannot
overemphasize the value of an initial “landscape” analysis to determine where intellectual
property rights are concentrated within the general field of “hemp”. A landscape analysis seeks
to identify what intellectual property roadblocks may exist in the field, who currently owns
intellectual property rights in the field (and potential strategic partnership opportunities), areas of
research that have received and are receiving particular attention, and potential niches to be
exploited.

A crucial consideration will be “freedom to operate”, i.e. the ability to make and sell the products
of your technology without infringing the intellectual property of third parties. We presume that

7 This Section III was contributed by Lee Alan Johnson and Mark Pidkowich
Soteria will want to focus its resources toward technologies that it can commercialize in the near term. A landscape analysis may help Soteria identify and characterize crowded spaces, as well as the dominant players in such spaces, such that resources are not wasted on developing technologies for which there will not be freedom to operate. From a landscape analysis, Soteria may be able to determine its position relative to other players in the field in terms of the relative quality of its portfolio and the risk of exposure to infringement actions. Additionally, it is very likely that any potential partner from whom Soteria may seek financing assistance will require an assessment of the intellectual property landscape in order to gain comfort as to the soundness of its investment.

A landscape analysis may also help Soteria identify underdeveloped spaces that provide the greatest potential for carving out broad protection for a technology. In particular, a landscape analysis may help Soteria identify “white spaces” wherein unbridged gaps continue to exist between existing technologies.

Finally, a landscape analysis may further help Soteria identify applications for its technology that it had not previously contemplated, and who the potential customers are (i.e. farmers, handlers, manufacturers, or end consumers), and thereby understand where the real value for its technology sits in terms of both the product and the geographic market. Put another way, will it make more sense for Soteria to market plants, seeds, fiber, or value-added composite materials, or to provide breeding services? In which countries are the largest markets and/or producers likely to be found?

2. Research and Development

After identifying potential areas of focus, Soteria will face important decisions in terms of its research priorities. That is, Soteria will need to identify and prioritize further potential embodiments necessary to support broad scope for its pending application, the primary line and extent of continuing research for expanding its product and intellectual property base, and tangential lines of research that may help to keep the landscape clear in the future. We look forward to assisting Soteria in determining how resources may be best deployed in the near term to solidify the existing intellectual property base, and to focus its expansion.

a. NuHumor Technology

As you are aware, patent applications must include claims to patentable subject matter, and the claimed subject matter must be described in such clear and concise terms as to enable one of ordinary skill in the art to practice the invention without undue experimentation. While we have yet to review State A&M’s patent applications, such review may reveal information gaps in the description of the invention. These gaps may include information necessary to support claims directed to specific subject matter, information necessary to support broad claim scope, or information necessary to support additional potential patent applications.
i. Subject Matter

Soteria’s initial application relates to a technology for inhibiting the function of a regulatory protein to reduce levels of a natural product in a plant. What is considered patentable in the field of life sciences technologies varies substantially from jurisdiction to jurisdiction. This is particularly so for plant technologies. Accordingly, it will be important to identify the particular subject matter requirements for critical jurisdictions and consider claim formats to meet them.

In the United States, for example, any application relating to living matter or “natural products” should prompt a review of the claims to determine if they are actually directed to patentable subject matter in view of the Supreme Court’s decision in *Myriad*, the recently updated USPTO guidelines (the “Guidelines”), and the nature-based product examples (the “Examples”).

Depending on when State A&M’s PCT application was filed (relative to the issuance of the *Myriad* decision and the Guidelines), it may include claims directed to a nucleic acids encoding the regulatory protein, or to the regulatory protein itself. It is abundantly clear from the Guidelines and Examples that the USPTO now considers bare claims to nucleic acids and proteins as ineligible subject matter. If the application contains no other claims, then it becomes important to identify solutions for distinguishing the nucleic acids and protein from those occurring in nature.

We look forward to working closely with Soteria to identify products across the contemplated value chain that have markedly different characteristics from the nature-based products. A non-exhaustive list of products with markedly different characteristics may include:

- engineered nucleic acids useful for modulating the expression of the regulatory protein;
- isolated plants (and seeds thereof) displaying novel secondary product profiles, whether generated by traditional breeding, genetic modification, or a combination thereof;
- isolated oil;
- uses of NuHumor for treatment;
- medicaments comprising isolated NuHumor metabolites;
- bales of NuHumor;
- semi-processed textiles such as “bast” and “hurd”; and
- composite materials including NuHumor components.

ii. Support

In general, only claims for which adequate support is provided in the specification of a patent application at the time of filing will be validly issued, and no new matter may be added to the specification after the time of filing. Based on our discussions with Soteria thus far, we anticipate that a comparison of your list of contemplated products with what has been described

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9 Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ___ (2013)
in the initial application will likely uncover research gaps between what Soteria wishes to claim and what the application describes. In such case, we propose working with Soteria to collectively evaluate the most likely way that the invention will be implemented, the claims that will be required to provide adequate protection of that invention, and any additional research that will be necessary to fill any gaps in support for such claims.

In the life sciences context, patent examiners are often reluctant to allow claims having broad scope where few demonstrative examples have been disclosed, and may require the applicant to restrict the application to the exemplified embodiments. In such circumstances, post-filing data is of potentially crucial importance in convincing an examiner to allow broad claims. For example, if it is important to obtain claims that cover transgenic approaches to implementing the invention, then we would strongly advise that Soteria generate and carefully document evidence that genetic modification, e.g. an RNAi approach, can be used to successfully modulate expression of the regulatory protein.

In other circumstances, post-filing data may be of little value. For example, post-filing data is generally of little use in convincing an examiner, or a court, of the non-obviousness of a claimed invention,12 e.g. where non-obviousness rests in an unexpected result or advantage. Evidence of such advantage or unexpected results must generally be acquired prior to the claim date of the patent application. Nevertheless, if data supporting such advantages or unexpected results are subsequently obtained, then it may yet be possible to pursue such subject matter in a further application. In this regard, although we understand that you have obtained a separate memorandum addressing the issue of novelty, it is worth stressing the importance of maintaining confidentiality of all research results that have not been the subject of a filed patent application, in order to avoid jeopardizing the patentability of any inventions associated with those results through public disclosure.

If it is important to Soteria to obtain issued claims covering specific varieties that have already been generated and disclosed in the application, then it will be necessary to provide samples of each variety to a suitable depository to meet the disclosure requirements. If the varieties were not obtained through true breeding, but propagated by clones, then it may be necessary to provide cryogenically preserved samples to a depository. Assuming that deposits were made prior to the filing date of the application, it will be necessary to provide the accession numbers to the attention of the International Bureau before the PCT application is published. If deposits have not already been made with a depository recognized as an International Depository Authority for the purposes of the Budapest Treaty, then the invention Soteria wishes to claim may not be considered enabled in many jurisdictions. If so, it may be necessary to file a further application once deposits have been made.

If the provision of cryogenically preserved samples is not possible, Soteria may attempt to claim plants in terms of the process by which are bred. Since significant marker data is available, it may be possible to claim plants (and seeds) in terms of the composition of introgressed regions inherited from the parental strains. If any varieties are hybrids produced from inbred parents, then the applicant may wish to obtain claims to the inbred parents themselves (which may also

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12 *Bristol-Myers Squibb Co. v. Teva Pharm. USA Inc.*, 752 F.3d 967 (Fed. Cir. 2014), reh’g and reh’g en banc denied, No. 13-1306 (Fed. Cir. Oct. 20, 2014).
necessitate a deposit). The ability to claim plants in this manner will depend on whether or not such information has been disclosed in the application. If not, then it may be necessary to file a further application.

Once Soteria has identified these potential research gaps, it will find itself in a better position to determine what portion of its research budget it wishes to devote to filling them.

b. Further Research

With respect to future research, we advise Soteria to consult with us at all stages of the research process, including the experimental design, so that we may provide guidance as to what data may be desirable to provide strong support for subsequent patent applications. Ideally, Soteria’s applications will include claims to each product you contemplate marketing, and thus you will want sufficient data to support each. In cases where the research is directed to incremental improvements, e.g. where the experiments could be characterized as “obvious to try”, it is particularly important to have us review the experimental design to ensure that adequate controls are employed, e.g. where it may be necessary to establish an “unexpected” result or advantage.

We further advise that you pay close attention to the sources of your research materials. The sources of the plant materials used in the development of NuHumor have important implications for rights in the variety. More particularly, it is important to determine if any of the source materials have been encumbered through a material transfer agreement (“MTA”) and, if so, how far each MTA reaches through to technologies developed using these materials. Accordingly, we ask you to obtain and provide us with a complete list of the materials used in the development of NuHemp, including:

- a brief description of the material;
- the source (e.g. depository, research institution, company, etc.); and
- copies of all MTAs executed in relation to the transfer of the materials to State A&M.

With this information in hand, we shall be in a better position to advise you of any possibilities that NuHumor technology is encumbered by any third party rights.

Going forward, Soteria will want to minimize contamination of its research and development program with third party rights. It may be desirable to re-create, where feasible, research materials from non-encumbered sources to limit any further reach through from past MTAs. We further advise you to consult with us prior to obtaining any further research materials from an outside source so that we may advise you of any encumbrances flowing from the use of such materials, and thus minimize contamination of your intellectual property rights.

Once again, we thank you for entrusting us with this matter, and look forward to working closely with Soteria to assist it in aligning its research and development activities with its overall intellectual property strategy.

/LAJ
/MP
IV. Ownership and Diligence Considerations

MEMORANDUM
TO: PRESIDENT, SOTERIA BIOSCIENCES
CC: GENERAL COUNSEL, SOTERIA BIOSCIENCES
GENERAL COUNSEL, SOTERIA AG
FROM: JSz, VP-LEGAL, PATENTS AND INTELLECTUAL PROPERTY-USA, SOTERIA BIOSCIENCES

Dear President,

As requested and with reference to the specific issues you had flagged in your email correspondence over the past few days, I have prepared the memorandum below setting out issues related to IP ownership. I look forward to discussing this with you at next week’s meeting.

Ownership Diligence

With a valuable personal asset such as a house, car or jewelry, an investor or mortgagor is advised to ensure clear title to the asset before risking money on it. Why? To protect the investor against hidden financial obligations and even losing ownership of the asset. Patents have attributes of personal property, and as such, ensuring clear title is a crucial part of evaluating an acquisition of or license to a patent estate. Before analyzing whether the NuHumor and “oil” patents have clear title, let’s briefly review the general rules of IP ownership in the U.S. and abroad.

Under the U.S. Patent Act, and absent any agreement otherwise, ownership initially vests in each of the inventors, whose inventorship is determined by their contribution to the claims. The inventors must apply for the patent jointly. However, if an inventor refuses to apply, the right is given to those with a proprietary interest. Each inventor owns an undivided interest in the whole patent. This means each inventor has full rights to operate under the patent or grant nonexclusive licenses to the patent, and can exploit the patent without permission of the others or sharing any proceeds with the others. However, to enforce the patent, all owners must join suit. An inventor’s ownership interest in a patent is preserved for his or her legal representatives in the case of death or incapacity. Hence, in evaluating the title to a patent, the inventorship should be confirmed as an initial matter to identify who may have an ownership interest.

In the U.S., the ownership of the patent is freely assignable in writing, generally in the form of an agreement. For example, inventors employed by a company or university may have signed an employment agreement wherein they assign their patent rights to their employer.

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13 This Section IV was contributed by Jennifer Sieczkiewicz.
14 35 U.S.C. §§ 1 et seq.
Ownership of patents that arise from a collaboration between two companies is often governed by a collaboration agreement. For example, there may be a provision that ownership follows inventorship. Sometimes the agreement specifies that one company owns the patents regardless of inventorship. Where joint patents are contemplated, there are usually provisions governing how the owners will work to enforce any joint patent. Thus, in a diligence, it is critical to obtain and review all agreements containing IP provisions, for example, employment agreements, invention agreements, contract manufacturing agreements, service agreements, research agreements, material transfer agreements, and clinical trial agreements.

So, what are some key things to watch out for when reviewing all applicable agreements relevant to IP ownership in a diligence? Retained rights are often present in inventions emanating from a university, such as rights for internal research and development purposes, or government march-in rights under the Bayh-Dole Act\textsuperscript{15} for inventions made with federal funds. In some cases, the inventors may still be entitled to a sizable royalty from exploitation of the assigned patent. Licenses by a company to a university’s patents should ideally capture any future improvements by the company to the foundation/platform technology with limited rights back to the university to ensure those later improvements are owned and controlled by the company. The actual assignment language itself must be examined to determine if it is an active assignment rather than an agreement to assign.\textsuperscript{16} That is, rather than an inventor stating that he or she “agrees to assign” inventions made under the agreement, the inventor should state that he or she “will assign and does hereby assign my right, title and interest” in the invention.

The assignment itself must be recorded with the U.S. Patent and Trademark Office within three months its date or prior to date of any subsequent assignment in order to be valid and enforceable. Accordingly, another component of ownership diligence should comprise searching the assignment record on the U.S.P.T.O website to confirm the expected assignments were timely filed and that they are to the correct entity. Although not technically necessary, all applications in a patent family (divisionals, continuations) ideally should have an assignment recorded as it ensure confirmation of ownership more quickly by a reviewer or court. However, if new material is an a patent family member (i.e., a CIP), a new assignment should be executed and recorded, as new matter creates new property.

Timing of the transfer of the assignments, especially where a U.S. application serves as the priority document for a PCT or other foreign application, is also critical to understand. Article 4 of the Paris Convention provides that any person who has filed an application for a patent in one country of the Union or his successor in title shall enjoy the right of priority for purposes of filing in the other countries. In most countries outside of the U.S., particularly Europe, applications are filed in the name of the applicant (company, employer, university), not the individual inventors. Where there is a specific assignment of the priority application to the company, then the company clearly holds the rights as successor in title to file the later application. However, if assignments are not completed before it is time for foreign file, it is likely a priority claim cannot be made or that the priority claim will be later found invalid. This

\textsuperscript{15} University and Small Business Patent Procedures Act of 1980
\textsuperscript{16} Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al., slip.op. 563 U.S. ___(2011)
had devastating consequences in Edwards Lifesciences AG v. Cook Biotech Incorporated.\textsuperscript{17} Here, an initial U.S. filing was made in the names of three inventors, but the PCT was filed in the name of Cook Biotech, with a priority claim to the U.S. filing. Only one of the inventors was an employee of Cook at the time of invention, and the other two assigned their interests to Cook after the PCT filing. Because Cook only held one of the inventors’ interests, the court found the priority claim invalid, allowing intervening prior art to become relevant.

Abroad, inventors generally also are the default owners of the patent; however, it is generally not necessary they apply in their names for a patent. In some countries, the employer by default owns an invention made by an employee if it is related to the employer’s business, but that is not always the case. Employment agreements for foreign inventors should be scrutinized during diligence as well for the items described above, as well as remuneration provisions. In some countries such as Germany, the intellectual property rights to inventions belong in principle to the employee inventor, and the inventor has the right to a fair and reasonable remuneration or compensation for his invention if the employer takes rights to the invention. What is “fair and reasonable” varies widely among countries—for example, Japan also has remuneration laws, but the remuneration generally amounts to just a token sum.

**Ownership Diligence Considerations for Soteria in Licensing State A&M Patents**

Understanding “what really went on” leading up to filing a patent on an invention is analogous to seeing the tip of the iceberg while navigating: there could be a lot under the surface that could have devastating consequences for the expedition. How can we better focus the lens of Soteria’s counsel and/or one of their investors’ counsel telescopes while scrutinizing the State A&M and Soteria AG patent landscape? Unfortunately, no one has invented “ownership sonar” yet, but asking for and doggedly pursuing as much information about what could comprise the rest of the iceberg should be the first step. Some key first “asks” diligence counsel should make are:

- All patents and pending patent applications, domestic and foreign, that relate to the technology and copies of the supporting documentation with respect to each, including but not limited to assignments and declarations of inventorship.
- All invention disclosures or other memos relating to the technology that are not covered by patents or patent applications. Provide copies of the supporting documentation with respect to each.
- With respect to each patent or invention disclosure produced:
  - State whether it (or any element thereof) was developed internally or acquired from another source;
  - If acquired, state who it was acquired from and when and describe any right such party has currently in the intellectual property;
  - Provide copies of each agreement that transferred rights in any aspect of the technology;

\textsuperscript{17} [2009] England and Wales High Court 1304.
• Name all past and present employees, contractors, and consultants who may have participated, are participating or are expected to participate in developing any aspect of the technology (not just named inventors);
• With respect to each such person, please provide copies of his or her employment or consulting agreement with diligence entity, and any confidentiality, non-disclosure, invention assignment or non-competition agreement between such person and the entity;
• State each such person’s role with respect to the technology;
• With respect to each such person, please list where known his or her previous employers and if possible provide any relevant agreements from that employer.

In addition to the above, diligence counsel should consider a quick search engine search of the people named by the diligence entity (which may provide some light on their past) and also a prior art search of the technology (which may provide some insight as to relevant people who may have worked on the space). These efforts would also provide value for the novelty determination in evaluating the patents’ strength.

What might all this flush out with respect to the State A&M and Soteria AG patents? Some examples are:

• The graduate student should have been an inventor.
• The State A&M employment agreements do not have appropriate assignment language.
• A visiting scientist may have been an inventor on the State A&M patents and an agreement was not signed at all.
• State A&M didn’t obtain an assignment from all of the inventors at the time of filing the provisional and simply filed on their behalf, but filed the PCT as State A&M.
• It is found that Dr. Derivation should have been an inventor and has ownership rights in both the State A&M and Soteria AG patents.
• If the memo is uncovered, that Dr German is not the true inventor at all and State A&M and/or its scientists own the Soteria AG patent.
• Dr. German may have remuneration rights.

Finding any of the above could impact the deal in a number of ways depending on severity of the impact. If additional financial obligations are found to other parties, the value of deal could be reduced in view of that additional obligation. If defective assignments or additional needs to assign are found, the deal may be delayed while this is investigated and corrected. If additional owners are found and are amendable to assigning or licensing to the investing entity, time and money will be spent in negotiating with them. Of course, if the issues uncovered make the underlying financials of the deal no longer valuable, or an uncorrectable defect is found, the deal may be abandoned altogether.