Intellectual Property in Alternative Protein

By

Dr. Eran Noah, Patent Attorney

www.NoahIP.com, *Noah-IP@outlook.com*, *+972-54-5716112*
https://www.linkedin.com/in/eran-noah-61870261/

1. Alternative Proteins (APs) as a Technological Field.

The term "alternative protein", as defined on the Good Food Institute website (GFI), means "proteins produced from plants or animal cells, or by way of fermentation…designed to taste the same as or better than conventional animal products…".

Compared to conventionally-produced, animal-based proteins, APs benefit, at least for the coming years, from being considered "new". Certainly, the majority of APs are not new *per-se*, but new in a more profound way. For the first time, specific (albeit known) proteins are produced *ex-situ*, *i.e.* away from their natural location and milieu. More often than not, the unprecedent level purity of APs allows the APs to perform and function in ways and extents which are different than the same APs when produced *in-situ*.

Thus, many APs can be considered, to an extent, as new "compositions-of-matter", as they were not previously produced and provided as dedicated functional building blocks in human nutrition.

Obviously, APs are not produced on their own, and human initiative and ingenuity are required for their design, production and use, all under the environmental constrains of requiring fewer inputs such as land and water, and generating fewer outputs such as greenhouse gas emissions and pollution, and under the ever-deciding financial constraints of being affordable and amendable for mass production and scale up.

Therefore, the field of APs is highly technological on its own, as it spans at least the Life Sciences, engineering and food formulation.

2. Patentable Subject Matter in AP.

Innovative AP companies are often established with an original concept, usually along the lines of either non-animalic production of a known protein for its known function (the "alternative origin" approach), or non-animalic production of a known protein for a new function (the "alternative use" approach). Both concepts deviate from known methodologies and recipes, which are based on animal-made ingredients and traditional, almost-canonized, procedures and recipes.

These deviations can be defined, characterized, and experimentally reduced to practice. A non-exhaustive list of non-traditional materials and methods utilized in the AP technological fields, are:

(i) DNA manipulation and editing of target cells, e.g., for non-transient expression of APs;

(ii) RNA insertion to target cells, e.g., for transient expression of APs;

(iii) Targeting delivery of APs to specific cell compartments, e.g., into vacuoles, inclusion bodies or secretion to outside of the GMO cell;

(iv) "Upstream" protocols, e.g., for maximizing the amount of AP production;

(v) "Downstream" protocols, e.g., for minimizing loss during AP isolation and purification;

(vi) Recipes for incorporating APs into consumer products, e.g., for maximizing their desired functionality; and

(vii) Formulations of alternative, AP-containing consumer food products.

As clearly evident from reviewing the above tip-of-the-iceberg list, AP technological fields include many new methods for producing AP and/or using AP as food ingredients, as well as new food compositions and formulations which were unattainable without using AP. This finding aligns perfectly with the two categories of patentable subject matter, which are "process" and "composition-of-matter".

3. Requirements for Patentability.

For better or for worse, patents are not granted for vision and a general will to save the world. Patents are granted to protect technological and practicable inventions in all technological fields. As the AP field overlaps with several technological fields, AP-related inventions have to meet all standard requirements of the regular patent system for these fields. In general, and as will be further details in Sections 5 and 6 below, these are the minimal requirements for patentability of AP-related inventions:

(i) Define the invention;

(ii) Decide if the invention is a "process" invention requiring at least one active step performed on at least one composition-of-matter, or a "composition-of-matter" invention requiring at least one type of molecule;

(iii) Identify where the invention has utility;

(iv) Identify where the invention is beneficial;

(v) Identify where the invention is ineffective; and

(vi) Identify differences between the invention and prior solutions to the problem the invention intends to solve.

As mentioned above, the field of APs spans (at least) the Life Sciences, engineering and food formulation. Since the amount of support needed to prove an invention has in fact been made is inversely related to the predictability in the invention's field, and since Life Sciences and food

formulation are unpredictable fields, AP inventions are viewed as part of the experimental sciences. This means that it is usually not enough to generally assert that an invention has been made, and there is a need to substantiate this assertion with experimental evidence of successful reduction to practice. Thus, experimental data is regarded as an additional "(vii)" requirement for patentability of AP-related inventions, added to the list above.

4. What should be included in your Patent Application.

Patent applications tend to have the same structure world-wide. First there is the "Background" section which reviews the problem-to-be-solved together with the deficiencies of possible previously-suggested solutions. Next is the "Description" section in which the invention is defined and described, illustrating how the invention is practiced and how it can be beneficial. Next is the "Examples" section which reviews the experimental evidence of successful reduction to practice. Last but not least is the "Claims" section which defines the metes-and-bounds of the protection sought for the invention by the applicant[1].

As a general guideline, it is advisable that each section of the patent application corresponds to all other sections in terms of concept, scope and terminology, in order to form a cohesive document. This would not only benefit any 3rd-party readers, but especially be helpful during prosecution, where the onus is on the applicant and its inventor to convince the patent examiner that an invention has indeed been made.

4.1 First Filing.

First, local or Provisional patent application filings usually serve a very specific purpose, securing a filing date for an invention as early as possible. Since time is the crucial consideration here, first filings are not meant to carry the heavy burden of delineating the entire scope of the invention they describe. Instead, they are meant to prove, in a written and documented form, that an invention has been made by a certain filing date, and not later. In view of this dedicated role, certain compromises can be made in terms of the patent application's quality and completeness.

General guidelines for the requirements of a first filing are:

(i) The invention is clear;

(ii) The different aspects of the invention are categorized as a "process" or a "composition-of-matter" invention;

[1] Inventions are made by humans ("inventors"), but patent applications are filed either in the name of the inventors or in the name of their companies (in both cases "applicants"). For convenience, the term "applicant" is more frequently used hereinafter.

(iii) The invention has demonstrated utility in at least one aspect[2];

(iv) The invention has demonstrated to be beneficial in at least one embodiment[3];

(v) Preferably, the invention has demonstrated to be ineffective in at least one embodiment;

(vi) Preferably, the differences between the invention and prior solutions to the problem the invention intends to solve are identified; and

(vii) At least one embodiment in at least one aspect is supported by experimental data (a.k.a. "proof of concept").

4.2 Further Filing.

Further patent applications, filed within a year after the first filing, usually serve to conceptually or experimentally widen or substantiate the invention described in the first filing. Since time is no longer the crucial consideration, further filings are meant to provide more aspects of the invention and/or fortify the original aspect by providing more embodiments. In view of this role, certain compromises can still be made in terms of the patent application's quality and completeness.

General guidelines for the requirements of a further filing are:

(i) The invention is clear;

(ii) The new aspects of the invention, if added, are categorized as a "process" or a "composition-of-matter" invention;

(iii) The invention has demonstrated utility in more than one aspect;

(iv) The invention has demonstrated to be beneficial in more than one embodiment;

(v) Preferably, the invention has demonstrated to be ineffective in at least one embodiment;

(vi) Preferably, the differences between the invention and prior solutions to the problem the invention intends to solve are identified; and

(vii) More than one embodiment in more than one aspect is supported by experimental data.

4.3 International Filing.

International, often Patent Cooperation Treaty (PCT) patent application filings, filed exactly one year after the very first filing, carry the heavy burden of delineating the entire and final scope of

[2] In patents, the term "aspect", when referring to an invention, refers to a way to use an invention.
[3] In patents, the term "embodiment", when referring to an invention, refers to a specific use-case within an aspect.

the invention. In view of this crucial role, no compromises should be made in terms of the patent application's quality and completeness.

General guidelines for the requirements of an international filing are:

(i) The invention is clear;

(ii) The different aspects of the invention are categorized as a "process" or a "composition-of-matter" invention;

(iii) The invention has demonstrated utility in at least one aspect;

(iv) The invention has demonstrated to be beneficial in many embodiments;

(v) The invention has demonstrated to be ineffective in several embodiments;

(vi) The differences between the invention and prior solutions to the problem the invention intends to solve are identified; and

(vii) Many embodiments in at least one aspect are supported by experimental data.

The quality and completeness of the international patent application is of upmost importance for several reasons. First, the application cannot be amended or expanded after filing. Second, the application will serve future patent examiners to search for prior publications in the relevant field, and thirdly, the application will serve both the patent examiners and the applicant during patent examination and prosecution. As such, all of the applicant's relevant data, rationale and arguments, to support the invention being patentable, should be included in the international patent application.

A further consideration is that the international patent application becomes public after filing. This gives the general public, including direct commercial competitors, a deep look into the technology, and possibly the commercial intentions of the applicant. Publishing a high-quality invention in a low-quality patent application can be a very regrettable step.

5. Obtaining a Patent.

Contrary to common reason, according to which an international patent application can lead to an international patent, there is no option for obtaining an international patent, only a collection of jurisdiction-specific patents. Thus, after filing an international patent application, the applicant has to choose jurisdictions in which he/she wants to obtain patent protection for its invention. Then, so-called "national-phase" patent applications are filed, which are copies of their "parent" international patent application.

Choosing jurisdictions for national-phase filing is a sensitive topic for all applicants, even more so in the young, expense-averse field of AP. There are many considerations to be made in selecting jurisdictions for filing national-phase patent applications, among which are:

(i) Jurisdiction of origin of the main ingredient or the main process;

(ii) Jurisdiction of the production of the final product; and

(iii) Jurisdiction of the present and forecasted markets of the final product.

It should be noted that choosing jurisdictions for national-phase filing should not be based solely on the up-front cost of filing, but should also take into account the considerable costs of obtaining and maintaining a patent. These tend to grow exponentially with time, and sometimes act as "poison pills" to maintaining the application, the patent, or indeed the portfolio. Thus, caution and premeditation are advised, despite the understandable desire of startups in the AP field to present investors and VCs with impressive patent portfolios.

It should further be noted that applicants cannot file additional national-phase patent applications in new jurisdictions after a certain deadline, usually 30 or 31 months after the filing date of the first filing patent application. Thus, applicants need to carefully plan and manage the cost- and strategy-sensitive step of national-phase filing.

5.1 **The Most-likely Examiner**.

Applicants within the more traditional technological sciences, such as biology, chemistry and physics, enjoy a privilege not shared with AP applicants, in that their technological fields are well versed. There are ample scientific, experimentally-control data, with many professionals either presently working in these fields or have previously been working in these fields and moved on, for example, to become patent examiners.

This is one of the major caveats, at least for the next few years, which stands before AP applicants. As AP technologies, knowledge and data are just starting to take center stage, there is a need for AP applicants to avoid assuming that their technical knowledge and terminology, considered routine within the field, are also prevalent outside the field, specifically with patent examiners.

While applicants in more traditional fields can expect facing experienced, well-versed patent examiners from the same field, often becoming patent examiners after a career in the same exact field and having first-hand experience, applicants in younger fields such as AP can expect facing less-experienced, less-versed patent examiners, often from non-AP fields.

In order to prevent, or at least alleviate, examiner-related difficulties during prosecution, at least two measures are strongly recommended:

(i) Prevention by education: To minimize the chances the examiner misunderstands the problem-to-be-solved, misunderstands the solution to the problem provided by the invention, or misunderstands how the invention is practiced or enabled, AP applicants should first assume, when drafting patent applications, that their future patent examiners do not have any technological background in the field of the invention. Then, while drafting the different patent filings, AP applicants should assume the position of teachers, and elaborate, to the best of their abilities, each and any term and nuance of the invention's technical field, including what professionals in that field would consider trivial. It is far better to prevent a misunderstanding than correcting one.

(ii) Live communication: Traditionally, and till this day, in most jurisdictions, the only way to communicate with patent examiners is in writing. This channel works well when discussing very specific and detailed nuances, but less so when the two parties are miles away in position. However, some jurisdictions allow, in special circumstances, for the applicant and the examiner to communicate directly, either by phone, or nowadays, by online video services. In special cases, the applicant and the examiner can even agree to meet face-to-face, if feasible, to discuss the issues at hand. There have been cases where AP applicants met with patent examiners and let them taste product prototypes in order to convince them of the merits of their invention. AP applicants must be aware of and take advantage of these options in order to try and avoid unnecessarily costly and lengthy prosecution procedures, when there seems to be a lot of ground to cover or when correspondence in writing reaches a dead-end.

5.2 The Most-likely Rejections.

While the patent system is jurisdiction-dependent, creating a variety of examination procedures, certain criteria must be met in all jurisdictions for patent applications to be granted a patent. Formalities aside, each invention is examined to fulfill several minimal requirements, to which applicants must be aware when conceiving their invention, reducing it to practice, and ultimately drafting their patent application. Unable to cover all types of these requirements in all jurisdictions, we will now focus on the four most common ones. The first two relate to the essence of what makes an invention, and the last two relate to technical sides of patent application drafting.

5.2.1 The invention is not novel.

An invention must be new. This seems redundant as obviously it has just been created by its inventor, but the bar is different and much higher – has the invention ever (at any time) been made

public (at any place)? Generally speaking, a single written publication or commercial product can deprive novelty from an invention.

5.2.2 The invention is obvious.

An invention must be inventive. This also seems redundant as obviously its inventor was surprised it works, but the bar is again different and much higher – would others, of average skill in the field, be surprised it worked as well, or would they assume, based on their knowledge and experience, that it should work? Generally speaking, if one can be certain in advance that an invention would work, this deprives inventiveness from an invention.

5.2.3 The patent application lacks clarity.

In an ideal world, there would not be a need to draft patent applications. Applicants would just meet and explain their inventions to the interested listener until they are fully satisfied he or she understands their invention to a tee.

Unfortunately, this is clearly not a feasible arrangement, and the only way to file a patent application is in writing. While certainly accommodating applicants, examiners, and the general public, the written format is severely limited in conveying information. As patent applications are not made of prose, which can and sometimes should be interpreted differently by different readers, but of highly technical language and data, which should be interpreted uniformly by all readers, the problem only aggravates.

5.2.4 The patent application lacks enablement.

In the known “Rumpelstiltskin” tale, a miller (an applicant) claims his daughter (an inventor) can spin straw into gold (an invention). However, it later turns out that the inventor cannot reduce the invention to practice, with a grave effect. The moral is that applicants must be careful in not only asserting that they have made an invention, but further describe in great detail how the invention can be performed, and reduced to practice, using available technologies. It is further highly advisable not to hyperbole from a limited set of data to pursuing an infinitely large scope of protection, as each invention has its technical limitations.

6. Future of IP in AP.

The AP field is no different from any other technological field, and as such, must adopt the lessons learned throughout history regarding what makes companies successful in free commercial markets. Being business-savvy is surely critical to any company’s management, but so is being IP-

savvy. Specifically, innovative AP companies should strive to not only compete in the commercial sense, but also have advantages over their equally-adapt competitors.

These advantages are at least twofold. First, having a high-quality portfolio of patents to protect all patentable aspects of a company's core technologies ensures that the company's competitors cannot legally copy their technologies. If these technologies lead to better products or services then this exclusivity is directly translated to profits. Second, having a high-quality understanding of patents, as well as their weaknesses and limitations, can assist in depriving the company's competitors from protection of lucrative technologies. If these technologies lead to better products or services then the lack of exclusivity allows an even playing field.

A word of warning may be prudent. While innovative AP-related methods can be, at least in theory, kept as a trade secret, AP-related products, such as alternative meats, eggs and dairy, will ultimately be provided, on larger and larger scales, to the public. These alternative products can be very susceptible to reverse-engineering, and if proven to be commercially-successful, would indeed be reverse-engineered by competitors. The only way to deter competitors from exploiting an innovative reverse-engineerable innovation is by the patent system. As AP companies are here to change the world, they must first make sure they survive enough time to make a difference.

7. Summary.

The above is a brief summary of my personal thoughts and ideas regarding how IP, specifically patents, should be perceived and managed by innovative AP companies. While it is not the make-or-break factor in a company's life cycle, management should plan ahead, and be prepared, for the odd chance of success.

***

Dr. Eran Noah for NOAH IP