Intellectual property and patenting

Methods of Scientific Working (for Crop Sciences) (3502-440)

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1 Introduction

Scientific research produces different types of outcomes:

- Materials, tangible things: e.g., Varieties, pesticides
- Procedures and methods: e.g., breeding methods, methods for chemical synthesis

If the results of scientific research are of commercial importance, the results represent an **intellectual property** (IP) and can be protected by the owner.

Scientific results can also be published. There are two main forms of publication of original scientific results:

1. Peer reviewed publications
2. Patents and other forms of intellectual property

We already discussed scientific publications, and will therefore focus on the protection of intellectual property.

2 Learning goals

1. Understand the importance of patents and intellectual property for applying the outcome of scientific research.
2. Know the key regulations and conditions of IP protection and patenting.
3. Know the key regulations and conditions on plant research.
4. Know the structure or a patent application or patent description
5. Understand the importance of intellectual property protection in an international economic context. ## Introduction into patent law {#sec:intr-into-patent}

2.1 National, supranational and international laws and agreements

This part of the chapter is based on a lecture by Dr. Eva Willnegger Link

The protection of intellectual property is regulated on different organisational levels. The following laws and agreements exist and are relevant for Germany:

- *National level:* German Patent Act (PatG)
- *European level:* European Patent Convention (EPC)
- *International level:* Patent Cooperation Treaty (PCT) and Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

These laws have the following implications:

- Harmonization of Substantial Law: Making sure that essentially the same rules apply at the different levels (Nation, Europe, World)
- Essentially similar conditions and scope of protection in all Member States of the World Trade Organisation (WTO)

In the following the focus will be on the European, in particular the German situation.

2.2 Which inventions can be patented?

Patents are granted for any invention, in all fields of technology provided that they are new, involve an inventive step and are susceptible of industrial application [1].

The following subjects are exempted from patenting [2]

- plant varieties
- animal varieties
- essentially biological processes for the production of plants or animals that consist entirely of natural phenomena such as crossing or selection
- but not microbiological processes (= any process involving or performed upon or resulting in microbiological material) or the products thereof

[1] §1 I PatG, Art. 52 I EPC, Art. 27 I TRIPS
[2] §2a I, II PatG, Art. 53b EPC, Art. 27 IIIb TRIPS

However, the situation may vary between countries. In France, for example, only certain plant species that are susceptible of plant variety protection are exempted from patent protection, Art. L. 623-3 du Code de la Propriété Intellectuelle

Biotechnological inventions are patentable if they concern: [3]

- Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature
- Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety
- A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety

This raises the question why plant varieties are exempted from patent protection.

The following aspects were considered when the exemption of plant varieties from patent protection was decided: Food security, dangers of monopolies, public interest.

2.3 What is 'novelty' in IP protection?

An invention is considered to be new if it does not form part of the **state of the art** [4].

Tthe state of the art is defined as everything that was made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the patent application.

An invention is considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art [5].

2.4 Industrial Applicability

An invention is considered as susceptible of industrial application if it can be made or used in any kind of industry, *including agriculture* [6].

2.5 The terms and scope of protection

20 years from the date the application is filed. Provided that patent annuities are duly paid! [7]

A question is whether the term of patent protection may be too short for ensuring a reasonable return on investment.

The following aspects should be considered for genetically engineered plants:

- Length of research and development (10-15 years for transgenic plants)
- Patent term starts at the beginning of research (usually 15 years before marketing)
- Length of field trials for GMO approval

[3] §2a II PatG, R 27 EPC
[4] §3 I, II PatG, Art. 54 I, II EPC
[5] §4 PatG, Art. 56 EPC
[6] /§5 I PatG, Art. 57 EPC
[7] §16 I PatG, Art. 63 I EPC, Art. 33 TRIPS

For these reasons, a protection of 20 years may be considered too short for genetically engineered plants.

The scope of the protection granted by a patent is determined as follows: [8]

- Determined by the claims (Expressed by the phrase *the name of the game is the claim*).
- Description and drawings used to interpret the claims
- *First step:* determining the literal understanding of the wording used in the claims, the description and drawings
- *Second step:* Doctrine of equivalence: equivalent means fall within the scope of a patent

All of these are defined in the patent application.

2.6 Extent of protection

A patent confers the following exclusive rights to its owner:

A **product claim** prevents third parties not having the owner's consent from making, using, offering for sale, selling, or importing for these purposes that product; [9]

A **process claim** to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2.7 Exemptions of protection

Plant varieties are exempted from protection under the following circumstances [10]

The **research exemption** exempts from the patent right research relating to the subject matter of the invention.

The **breeders' exemption** is also incorporated in the German patent law: farmers are allowed to use protected varieties for propagating purposes. But an equitable remuneration will have to be paid, which must be sensibly lower than the license fee.

2.8 The structure of a patent application

On first glance, reading a patent description is an overwhelming experience because of the amount of text written in formal language, a strange numbering system, and sometimes multiple figures.

However, patents share a similar structure, which can be easily understood with some background knowledge.

1. Field of invention
2. Background art
3. Summary of the invention
4. Claims

[8] §14 PatG, Art. 69 I EPC
[9] §9 Nr. 1, 2, 3 PatG, Art. 64 II EPC, Art. 28, 34 I TRIPS
[10] /§11 II, IIa PatG

The most important section is the Claims section, because it describes the inventions, which the inventor is claiming and owns. Usually, the most important invention of a patent is claimed first in the Claims section.

A good description of how to read a patent document is provided by Donald et al. (2018).

Each patent needs to be published and can not be kept secret. By publishing a patent documentation, the society gets to know about the invention and other inventors get to know the state of the art, which forms the basis of new inventions. In return, the holder of a patents gets exclusive rights for a limited period of time on the intellectual property described in the patent document.

3 Introduction into plant variety protection

Plant variety protection differs from the patenting system in several important was.

Similar to patents, there are national, supranational and international agreements:

- *National level:* German Plant Variety Protection Act (Sortenschutzgesetz, SortG)
- *European level:* Community Plant Variety Regulation No. 2100/94 (CPVR)
- *International level:* Union Internationale pour la Protection des Obtentions Végétales (UPOV 1991)

The laws and agreements have the following consequences:

- They harmonize substantial law in different countries of regions.
- The provide essentially similar conditions and scope of protection in all UPOV 1991 Member States

In the following presentation the focus is on European, in particular German situations.

3.1 Protectable subject matter

What can be protected as plant variety?

‘Plant variety’ means any plant grouping within a single botanical taxon of the lowest known rank which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: [11]

- Defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- Distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- Considered as a unit with regard to its suitability for being propagated unchanged.

[11] §2a III Nr. 4 PatG, §2 Nr. 1a SortG, Art. 5 Nr. 2 CPVO, Art. 1 vi UPOV 1991

3.2 Conditions of protection

A plant variety protection that includes breeder's right shall be granted where the variety is: [12]

- new
- distinct
- uniform
- stable
- designed by a denomination

These criteria are defined by specific processes developed for different crops.

The criteria are defined as in the following:

Novelty The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety. [13]

Distinctness The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application [14]

Uniformity The variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics [15]

Stability The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle [16]

The distinctness, uniformity and stability criteria are often summarized as DUS criteria.

3.3 Terms and scope of protection

A variety is protected from 25 years from grant, provided that the annuities are duly paid[17]

The following questions should be considered: What is the difference between patents and plant variety protection certificates concerning the term of protection?

For the answer, the following aspects should be considered:

- Different term (duration) of protection
- Different starting point of the protection

Plant variety protection involves a defined **scope of protection**

For protected varieties, the authorization of the breeder is required for:

1. production or reproduction (multiplication)
2. conditioning for the purpose of propagation,

[12] §1 I SortG, Art. 6 CPVO, Art. 5 I, II UPOV 1991
[13] §6 I SortG, Art. 10 CPVO, Art. 6 I UPOV 1991
[14] /§3 I SortG, Art. 7 I CPVO, Art. 7 UPOV 1991
[15] §4 SortG, Art. 8 CPVO, Art. 8 UPOV 1991
[16] §5 SortG, Art. 9 CPVO, Art. 9 UPOV 1991
[17] §13 SortG, Art. 19 No. 1 CPVO, Art. 19 II UPOV 1991

3. offering for sale,
4. selling or other marketing,
5. exporting,
6. importing,
7. stocking for any of the purposes mentioned in (1) to (6), above.

This also applies to harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material. [18]

The scope extends to varieties which are essentially derived from the protected variety ("initial variety"), where the protected variety is not itself an **essentially derived variety** (EDV). [19]

Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

A variety is an EDV, when [20]

1. it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
2. it is clearly distinguishable from the initial variety and
3. except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

The recognition of essentially derived varieties is frequently a contentious issue during the variety registration process.

3.4 Exemptions to protection

There are some important exemptions of plant variety protection: [21]

1. **Breeders' exemption** allows to use protected varieties for the purpose of breeding, or discovering and developing other plant varieties
2. **Research exemption:** allows to use protected varieties for experimental purposes
3. **The farm-saved-seed provision:** authorizes farmers to use protected varieties for propagating purposes. However, an equitable remuneration must be paid, which must be sensibly lower than the license fee

The breeder's exemptions raises the question, wheter it is an obstacle to innovation or whether it fosters innovation?

The following aspects need to be considered:

Food security By using competitor's varieties, the genetic diversity of varieties can be exchanged that contribute to food security.

Return on investment/amortisation of research costs: On the other hand a return of investment is necessary, which is guaranteed by restrictions imposed on registered varieties.

[18] §10 I SortG, Art. 13 I, II CPVO, Art. 14 Ia, II UPOV 1991
[19] §10 II SortG, Art. 13 Va CPVO, Art. 14 V UPOV 1991
[20] §10 III SortG, Art. 13 VI CPVO, Art. 14 V UPOV 1991
[21] /§10a I, No. 2, No. 3, II SortG, Art. 14 I, II CPVO, Art. 15 I ii, iii, II UPOV 1991

In order to ensure a return on investment despite the breeder's exemption, biological protection mechanisms as hybrids are used to maintain a competitive advantage.

3.5 What can be reasonably patented in plant breeding? - The 'Broccoli-patent' EP1069819

In the context of patenting versus plant variety protection the so-called broccoli patent became famous. You can find it at Google Patents.

The main claim (claim 1) of the patent refers to a process that was until then considered to be an essentially biological process. In this patent, it was crossing.

Original quote from the patent describing the main claim:

1. A method for the production of *Brassica oleracea* with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises:

- a) **crossing** wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* with broccoli double haploid breeding lines;
- b) **selecting** hybrids with levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines;
- c) **backcrossing** and **selecting** plants with the genetic combination encoding the expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both; and
- d) **selecting** a broccoli line with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes,

wherein **molecular markers** are used in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes.

The patent was challenged by two breeding companies on the grounds that it describes only an essentially biological process and therefore the invention can not be patented.

In response, the European patent office made the following decision (Decision G2/07): [22]

1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.
2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, *a step of a technical nature*, which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

[22] https://www.epo.org/law-practice/case-law-appeals/recent/g070002ex1.html

3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.
4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

3.6 Recent developments in patenting of plant-related inventions

In recent years, there was a trend towards the patenting of natural genetic characteristics as in the above broccoli patents. Plant breeding associations have a critical view of this development because it reduces the freedom to operate because patented varieties do not grant breeder's rights, which in the long term reduces genetic diversity available for plant breeding.

4 Plant-related patents in the United States

A key difference to Europe is that in the US plant varieties can be patented. This is possible because the US have an additional law, which is called Plant Patent act and allows do patent plant varieties.

Plant Patent Act (1930):

- Administered by US Patent and Trademark Office
- Covers asexually reproduced plants (mostly ornamentals and fruits)
- No yearly maintenance fee required
- Can exclude others from importing any part of a protected plant

Plant Variety Protection Act (PVP) (1970):

- Administered by US Department of Agriculture
- Weaker than plant or utility patents: Breeder's exemption and farmer's exemption

Utility patents (*Diamond v. Chakrabarty)* (1980):

- *Anything under the sun that is made by man* is patentable subject matter
- This includes plant varieties, parts of plants, genetically enginered organisms and gene products
- Plants covered by plant patent or PVP can additionally be covered by a utility patent
- ⇒ Dual IP protection is possible for plants in the US!

Plant varietal rights in the United States, 1930-2010

The relative importance of different types of plant varietial rights in the United states from 1930-2010 is shown in Figure ref:fig:pvpusa.

The graph shows that with the availability of utility patents for plant related inventions, the number of these patents increased.

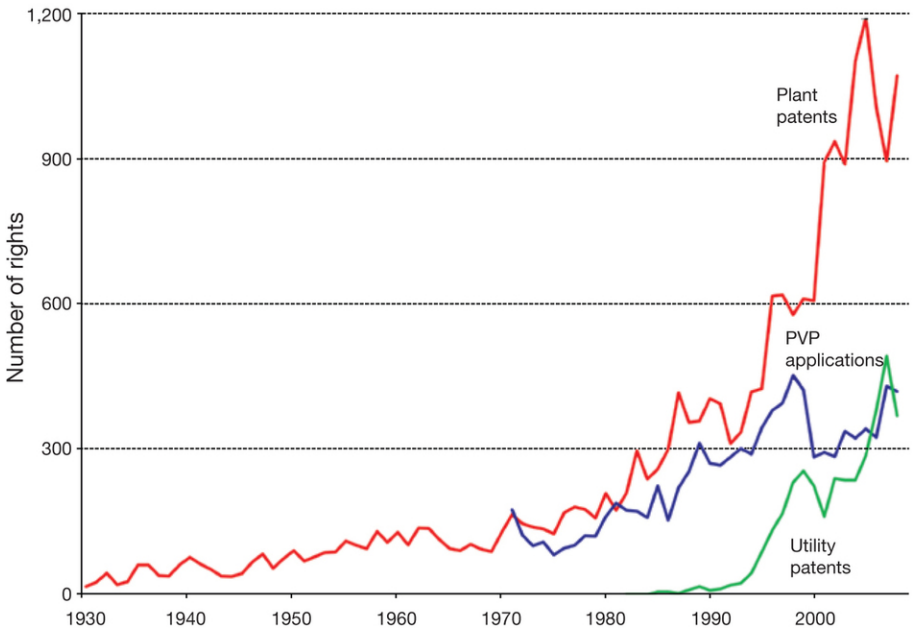

Figure 1 *– Development of plant variety protection in the United States. Source: Pardey et al. (2013)*

5 Patenting of methods like CRISPR/Cas9 based genome editing

The number of patents is an important indicator of the scientific and economic dynamics of a field, and it also allows to identify countries, which are particularly innovative in a field.

One example is the CRISPR/Cas9 genome editing technique. It was patented by their inventors and the employers, but until now it has led to multiple conflicts. Despite the ongoing struggle about the original patents, many downstream patents are being generated. A recent study surveyed the patenting landscape (Martin-Laffon et al., 2019) allows several conclusions, which are shown in Figure 2.

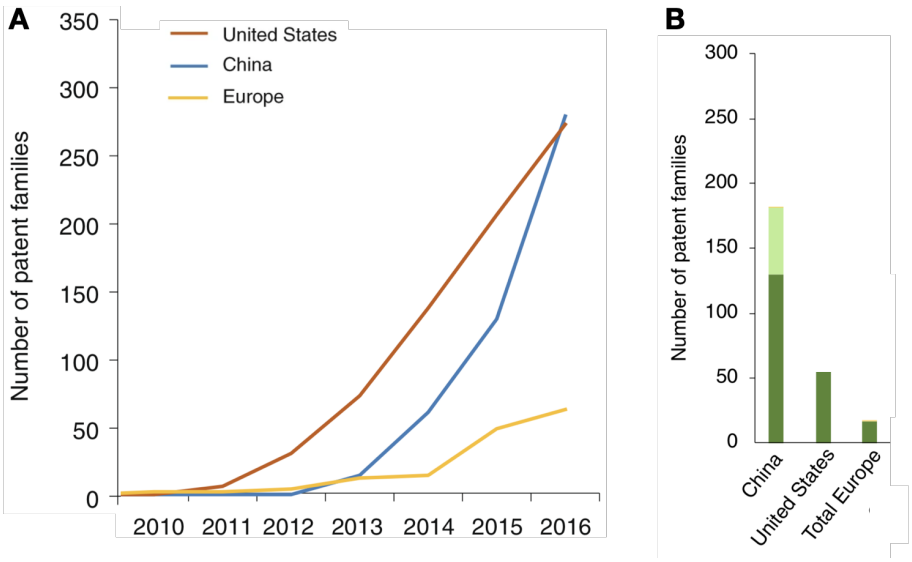

Figure 2 *– A survey of the patenting landscape of CRISPR/Cas9-related patents. A) Number of patent families over time for all CRISPR/Cas9-related patents in the USA, China and Europe. B) Numbers of plant-related patents. Modified from Martin-Laffon et al. (2019)*

First, the number of patent families[23] is growing rapidly. Many more patents are generated in the US and in China compared to Europe. China is leading in the number of genome editing patents applied to plants over the US, and Europe plays only a minor role.

It is also interesting to investigate which organisations submitted patent applications. For plant-related patents, 90% of patents in China, 50% in the US and less than 10% in Europe are generated by universities[24]

One consequence of the patenting of CRISPR/Cas9 is that any company and research organisation, which wants to use this technology needs to acquire a license (e.g., via Corteva, Link).

6 Summary

- Intellectual property (IP) is an important outcome of scientific research
- Patenting is the most important legal tool to protect IP
- Patenting is a contract between the inventor and the society: A time-limited monopoly is traded for a publication of the invention.
- Plant variety protection (PVP) is for protecting the products of plant breeding and is more liberal than patenting.
- The legal landscape for patenting in the context of biological processes and products is dynamic and complex as indicated by the broccoli patent.

7 Key concepts

- □ Intellectual property
- □ Patent
- □ Claims
- □ Plant variety protection (PVP)
- □ Essential biological process
- □ Breeder's exemption

8 Further reading

8.1 Textbooks

- Chitale et al. (2020) - An introduction into the basics of patenting for scientists.
- The article by Seeber (2007) shows how to conduct a patent research, which can accompany a literature search.
- Clancy and Moschini (2017) - A review article about the role of patenting in agricultural research.

[23] A patent family is a set of related patents
[24] These data are from the appendix of the Martin-Laffon et al. (2019) paper

9 Study questions

1. Which plant-breeding related matters are exempted from patenting?
2. What are the key requirements that a patent can be granted?
3. Which biological inventions are patentable?
4. Why are plant varieties exempted from patent protection? :::{.content-hidden .answer} Societal interest, and to prevent monopolies :::
5. How long is a patent granted? Why is this period possibly too short for biotechnological inventions?
6. What part of a patent defines the scope of protection of an invention? :::{.content-hidden .answer} The claims section :::
7. What are the key differences with respect to the patenting of plants and plant varieties in the US and in Europe? :::{.content-hidden .answer} In the US, classically bred plant varieties can be patented, in the EU, not. :::

10 In class exercises

10.1 The structure and content of a patent description

Description of the invention

The following section describes the invention.

1. What is the core of the invention?
2. Where do you recognize the inventive step?
3. How general is the patent description?

Claims made in the patent application

1. Are the first claims (of a long list not shown) general claims or specific claims?
2. Do you understand the claims?
3. Do you recognize a strategy to make the claims as broad as possible, or are the claims very specific?

The complete patent application is at this link.

WO 2017/192117 PCT/US2016/030392

Highly Effective and Multifunctional Microbial Compositions and Uses

TECHNICAL FIELD OF THE INVENTION

[0001] The present technology relates generally to compositions and methods of a highly effective and multifunctional strain of *Trichoderma gamsii* (formerly *T. viride*).

BACKGROUND OF THE INVENTION

[0002] The following description is provided to assist the understanding of the reader. None of the information provided or references cited is admitted to be prior art to the present invention. Microbial agents applied as seed treatments or other methods of application have been shown to increase plant growth and development. The most effective of these organisms colonize plant roots internally and induce beneficial changes in gene expression and that therefore give rise to changes in plant physiology. These alternations in plant physiology include coordinated up-regulation of entire biochemical pathways in plants. Nevertheless, the need remains for highly functional seed treatments and applications that improve upon the prior art, where efficient and efficacious changes in this respect include (i) reliable and consistent plant growth and yield promotion, (ii) enhanced root growth and development resulting in larger and deeper root systems, (iii) improved resistance to such abiotic stress including too little or too much water, salt and soil contamination, (iv) increased fertilizer use efficiency and especially nitrogen fertilizer use efficiency, enhanced antioxidant levels in produce, where all of the effects noted above require energy, and can only occur if photosynthesis is enhanced. These microbial agents efficiently improve photosynthesis.

SUMMARY OF THE INVENTION

[0003] The present technology relates generally to compositions, methods and systems entailing one or more microbial agents possessing multifunctional capabilities selected from the group consisting of an increase in one or more beneficial plant attributes comprising plant growth, yield, root development, resistance to abiotic stresses, photosynthetic efficiency, reduction of foliar disease, controlling nematodes, inducing systemic changes in plant gene expression, remaining localized in the plant root system, protecting planted seeds from soil-borne pathogens, and controlling populations of insect pests, wherein the increase in the one or more beneficial plant attributes is compared to a plant or plant system without the one or more microbial agents; and an agronomic carrier.

Figure 3 *– First page of a patent application of using Trichoderma in plant cultivation*

CLAIMS

What is claimed is:

1. A composition comprising:

   a. one or more microbial agents possessing multifunctional capabilities selected from the group consisting of an increase in one or more beneficial plant attributes comprising plant growth, yield, root development, resistance to abiotic stresses, photosynthetic efficiency, reduction of foliar disease, controlling nematodes, inducing systemic changes in plant gene expression, remaining localized in the plant root system, protecting planted seeds from soil-borne pathogens, and controlling populations of insect pests, wherein the increase in the one or more beneficial plant attributes is compared to a plant or plant system without the one or more microbial agents; and

   b. an agronomic mediator selected from the group consisting of an adjuvant, a carrier, a planting medium, and/or one or more nutrients, wherein at least one component of the agronomic mediators does not naturally occur in combination with one or more of the other agronomic mediators.

2. The composition of claim 1, wherein the agronomic mediator is selected from the group consisting of humic acid, fulvic acid, nitrogen containing proteins, urea, ammonium nitrate, sodium, phosphorous, potassium, calcium, magnesium, sulfur, iron, manganese, magnesium, copper, boron, granule, and/or composite compositions for stimulating the formulation of granules, dust, powders, slurries, films, liquid suspensions, coating, pelleting and/or combinations thereof.

3. The composition of claim 1, wherein the one or more microbial agents is a single microbial agent possessing all of the one or more beneficial plant attributes.

4. The composition of claim 3, wherein the single microbial agent is *Trichoderma gamsii* (NRRL B-50520).

5. The composition of claim 1, wherein the agronomic carrier is selected from the group consisting of composite compositions for stimulating the formulation of granules, dust, powders, slurries, films, liquid suspensions, coating, pelleting and/or combinations thereof.

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Figure 4 *– The claim section of the patent*

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