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The Applicability of the Substantive Requirements for Patent Granting to Biotechnological Inventions: A Legal Study

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Abstract:

This study examines the applicability of the substantive requirements for patent granting to biotechnological inventions in light of the provisions of Ordinance No. 03-07 on Patents and the relevant international conventions, by examining the extent to which the requirements of novelty, inventive step, and industrial applicability are met. The examination of these requirements is particularly significant given the nature of biotechnological inventions and their association with living matter. The study concludes that the examination of such inventions requires a greater degree of precision to ensure that the requirements for protection are met and to prevent the granting of patents that are not based on genuine novelty or inventive step, which may lead to a monopoly over their exploitation, particularly in the pharmaceutical industry, with consequent effects on product prices.

Keywords: Biotechnology; Patent; Novelty; Inventive Step; Industrial Applicability.

Introduction:

Biotechnology, or “biological technology,” is considered one of the most prominent fields of scientific advancement due to its wide-ranging applications in agriculture and industry, particularly in the pharmaceutical and food industries, the treatment of genetic diseases, and the improvement of agricultural production. It refers to the use of microorganisms, plant and animal cells and their components, or any living organism or part thereof, to obtain a product of commercial value or to develop and improve existing products. Its development has resulted in inventions of significant economic value, making their legal protection, particularly through patents, an increasingly important area of concern.

In this context, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of 1994 addressed, in Article 27 thereof, the possibility of obtaining patents for inventions in all fields of technology. It allowed Member States to exclude from patentability diagnostic, therapeutic, and surgical methods for the treatment of humans or



animals, as well as plants and animals and essentially biological processes for their production, while excluding microorganisms and non-biological and microbiological processes from the scope of such exclusions. As for the Algerian legislature, Article 8 of Ordinance No. 03-07 on Patents excludes plant varieties, animal species, and purely biological processes for obtaining plants or animals from patentability. By implication, however, it does not exclude microorganisms or processes for obtaining them, nor plants and animals obtained through non-biological processes.

Biotechnological inventions, like other inventions, are subject to the substantive requirements for patentability, namely novelty, inventive step, and industrial applicability. However, the particular nature of the living matter underlying such inventions raises the question of the extent to which the application of these requirements to them is appropriate. Accordingly, the study raises the following research question: **To what extent can the traditional substantive requirements for patent granting be applied to biotechnological inventions? Or does their particular nature require specific requirements that are compatible with their characteristics?**

To address this research question, we adopted the descriptive and analytical approaches and divided the study into two sections. The first examines the requirements of novelty and industrial applicability and the extent to which they can be applied to biotechnological inventions, while the second addresses the requirement of inventive step and the extent to which it can likewise be applied to such inventions.

1- The Applicability of the Requirements of Novelty and Industrial Applicability to Biotechnological Inventions:

Novelty and industrial applicability are among the fundamental substantive requirements for patent protection, as Article 3(1) of Ordinance No. 03-07 provides: **"Inventions that are new, result from an inventive activity, and are capable of industrial application may be protected by a patent."**¹ Accordingly, this section addresses the requirement of novelty, followed by the requirement of industrial applicability.

1.1- The Novelty Requirement for Biotechnological Inventions:

The novelty requirement constitutes one of the fundamental requirements for the grant of a patent. It requires that the invention not form part of the prior art. This section addresses the meaning of novelty, followed by its particularities in relation to biotechnological inventions.

1.1.1- The Meaning of the Novelty Requirement in Patent Law:

Patent legislation requires an invention to meet the requirement of novelty. Pursuant to Article 4(1) of Ordinance No. 03-07, an invention is considered new if it is not included in the state of the art, which refers to everything that has been made available to the public before the filing date of the patent application through a written or oral description, use, or any other means.

¹Ordinance No. 03-07 of 19 July 2003 on Patents, Official Gazette No. 44, issued on 23 July 2003.

Accordingly, novelty is destroyed if the invention has been made available to the public prior to the filing of the patent application, whether through:

- **Written description:** through a written document containing a sufficient description of the invention.
- **Oral description:** through the disclosure of sufficient information enabling the invention to be known.
- **Use:** through the use of the invention prior to the filing of the patent application.

Pursuant to Article 24 of Ordinance No. 03-07, the Algerian legislature provides an exception for the case where the invention has been displayed at an official or officially recognized international exhibition. In such a case, the invention does not lose its novelty if the application for protection is filed within twelve months from the date on which the exhibition closes.

Accordingly, novelty means that the invention has not previously been disclosed to the public, used, or protected by a patent, since prior disclosure destroys its novelty and renders it available for exploitation without the inventor's consent ².

Following the TRIPS Agreement ³, States adopted a unified position requiring "**absolute**" novelty in an invention, both in terms of geographical scope and time, for it to qualify for patent protection ⁴. Absolute novelty means that the invention must not be identical or similar to any prior inventions anywhere in the world and must not have been made available to the public or publicly used, regardless of how much time has elapsed. Thus, an invention is not considered new regardless of the period separating its disclosure from the date of the patent application, even if that period extends for centuries. This differs from "**relative**" novelty, under which it is sufficient for the invention to be new within a specified geographical and temporal scope, as it is compared with the prior art existing during a particular period. This approach is no longer consistent with the trend of modern legislation and the principle of priority ⁵

1.1.2- The Particularity of the Novelty Requirement in Biotechnological Inventions:

The particularity of the novelty requirement in biotechnological inventions becomes apparent when determining the prevailing state of the art, as the existence of novelty is assessed by comparing the invention for which the patent application has been filed with what constitutes the prevailing or prior state of the art before the filing of the patent application⁶. Accordingly,

²Nouara Hussein, *Industrial Property in Algerian Law*, Dar Al-Amal for Printing and Publishing, Tizi Ouzou, Algeria, 2015, p. 28

³Agreement on Trade-Related Aspects of Intellectual Property Rights, abbreviated in English as (TRIPS), which stands for (Agreement on Trade Related Aspects of Intellectual Property Rights), was signed on 15 April 1994 in Marrakesh and entered into force on 1 January 1995. It is characterized by its coverage of all fields of intellectual property

⁴Jalal Wafaa Mohammadine, *Legal Protection of Industrial Property*, Dar Al-Jami'a Al-Jadida, Alexandria, 2000, p. 67.

⁵Rima Abdessamad, *The Novelty Requirement in Inventions under the TRIPS Agreement*, PhD Dissertation (LMD) in Law, Specialization in Industrial Property, Faculty of Law and Political Science, University of Batna 1 Hadj Lakhdar, 2022–2023, p. 30 et seq.

⁶Majed Walid Abu Saleh and Ramzi Ahmad Madi, *The Particularity of the Substantive Requirements for Granting Patents for Biotechnology Inventions: A Comparative Legal Study*, Dirasat: Sharia and Law Sciences, Vol. 43, Supplement 2, 2016, p. 980.

if the invention was not known to third parties before the patent application was filed, it is considered new.

Biotechnological inventions are, in part, based on elements existing in nature, such as microorganisms, which raises the distinction between **discovery and invention**. Protection does not extend to natural phenomena or natural products merely because they have been discovered, as they exist in nature and are available to all. However, human intervention in modifying living organisms or altering their characteristics may transfer them from the realm of naturally occurring matter to that of a patentable invention, as they become products of human intervention that nature could not produce spontaneously without human intervention and its effect on natural processes. This principle was upheld by the Supreme Court of the United States in 1980 in the case of *Diamond v. Chakrabarty*, in which the Court recognized the possibility of granting a patent for a bacterium (*Bacterium*) created in the laboratory by Ananda Mohan Chakrabarty, an employee of General Electric (*General Electric*). The Court held that his claim did not concern a natural phenomenon that had previously been unknown, but rather the production or creation of a non-naturally occurring composition of matter, resulting from human ingenuity, having a distinctive name, characteristics, and specific utility. The patentee had produced a bacterium that clearly possessed characteristics different from those of any other bacterium existing in nature and that had a particular useful capability; accordingly, it was eligible for patent protection⁷.

Accordingly, the novelty of a biotechnological invention is not established merely by discovering an organism existing in nature. Rather, novelty may be established when the inventive contribution concerns an organism or characteristics that did not previously exist as a result of human intervention, such as genetic modification by adding new characteristics, removing undesirable characteristics, or conferring specific capabilities on the organism, as in the modification of certain types of bacteria to increase their ability to produce antibiotics⁸.

1.2- The Applicability of the Industrial Applicability Requirement to Biotechnological Inventions:

Industrial applicability is one of the substantive requirements for patent protection, as it enables the inventor to move the invention from the realm of an idea to that of practical exploitation. To determine the extent to which this requirement is appropriate for biotechnological inventions, we examine its meaning in patent law, followed by its particularity in biotechnological inventions.

1.2.1- The Meaning of the Industrial Applicability Requirement in Patent Law:

National legislation and international conventions have established the requirement of industrial applicability, as provided for in Article 3 of Ordinance No. 03-07 and Article 27(1) of the TRIPS Agreement. It refers to taking an invention beyond the realm of abstract thought into that of practical implementation, thereby excluding subject matter that cannot be

⁷Case No. 303 U.S. 447, No. 136-79, dated 16 June 1980. See: World Intellectual Property Organization, Committee on Development and Intellectual Property, Patent-Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels, Part 2, Geneva, 2–6 May 2011, p. 16. Available on the website of the World Intellectual Property Organization: WIPO, accessed on 26 October 2024 at 17:30.

⁸Majed Walid Abu Saleh and Ramzi Ahmad Madi, op. cit., p. 980.

industrially applied and making its protection, where appropriate, subject to other legal means, such as copyright⁹.

Article 6 of Ordinance No. 03-07 defines an invention capable of industrial application as one whose subject matter can be manufactured or used in any kind of industry. This is a broad concept that is not limited to industry in its narrow sense, but encompasses various fields of activity, in accordance with the approach adopted by the Paris Convention for the Protection of Industrial Property¹⁰.

Accordingly, a mere abstract idea or purely theoretical scientific concept is insufficient to constitute a patentable invention. Discoveries relating to nature and its laws, as well as mathematical and arithmetical operations, are likewise excluded unless they are embodied in an industrial application, such as the manufacture of a product or the creation of a new industrial process¹¹.

In this regard, neither the manner in which the product is used nor the ultimate purpose for which it is manufactured is relevant. Nor does the ease or difficulty of implementing the invention, or the low or high costs of its production, matter. It is sufficient that the invention be capable of industrial use¹².

2.2.1- The Particularity of the Industrial Applicability Requirement in Biotechnological Inventions:

The requirement of industrial applicability assumes particular importance in the protection of biotechnological inventions, as discoveries resulting from biology and genetic engineering cannot be protected by a patent unless they are capable of industrial application. Accordingly, a biotechnological invention that remains purely theoretical or has no practical value in the real world does not satisfy this requirement. Furthermore, assessing its industrial applicability requires the patent applicant to disclose the application sufficiently, as this constitutes a fundamental criterion for assessing the industrial character of the invention¹³.

Satisfying this requirement does not merely mean that the invention might potentially be applied industrially; rather, it must be capable of definite industrial application. Accordingly, if modifying the genetic characteristics of a microorganism results in an organism possessing different and distinctive characteristics, this alone is insufficient for it to qualify for protection, even where novelty and inventive step are present, unless it has a specific and definite use in one of the industrial fields. This would be the case, for example, where the new

⁹Abdelkrim Assali, *Protection of Inventions under Algerian Law*, Master's Dissertation in Law, Business Law Specialization, Faculty of Law, Mouloud Mammeri University, Tizi Ouzou, 2004–2005, p. 44.

¹⁰Paris Convention for the Protection of Industrial Property, dated 20 March 1883, revised in Brussels on 14 December 1900, Washington on 2 June 1911, The Hague on 6 November 1925, London on 2 June 1934, Lisbon on 31 October 1958, Stockholm on 14 July 1967, and amended on 28 September 1979. Algeria acceded thereto pursuant to Ordinance No. 66-48 of 25 February 1966, Official Gazette No. 16, issued on 25 February 1966, and ratified its amendments pursuant to Ordinance No. 75-2 of 9 January 1975, Official Gazette No. 10, issued on 4 February 1975.

¹¹Mourtada Abdallah Khairy, *Patent Resulting from Modern Technology and Its Role in the Protection of Microorganisms: A Comparative Study*, Journal of Law and Human Sciences, published by Ziane Achour University of Djelfa, Vol. 12, No. 3, November 2019, pp. 52–53.

¹²Salah Zain El-Din, *Industrial and Commercial Property*, 1st ed., Dar Al-Thaqafa, Amman, Jordan, 2000, p. 41.

¹³Fatima Mehyawi, *Protection of Genetically Modified Products*, Master's Dissertation in Private Law, Intellectual Property Specialization, Faculty of Law, University of Algiers 1 – Benyoucef Benkhedda, 2014, p. 103.

microorganism is capable of secreting and producing certain types of amino acids or antibiotics on a large scale, thereby allowing them to be utilized in the pharmaceutical industry¹⁴.

2- The Inventive Step Requirement in Biotechnological Inventions:

For an invention to qualify for protection, it is not sufficient for it to be new; it must also involve an inventive step that goes beyond the ordinary level of development in the relevant field of industry. To clarify this requirement, we first examine the meaning of the inventive step requirement in patent law, and then its particularity when applied to biotechnological inventions.

1.2- The Meaning of the Inventive Step Requirement in Patent Law:

To determine the meaning of the inventive step requirement in patent law, we address the definition of inventive step and then the criteria for assessing it in an invention.

1.1.2- Definition of the Inventive Step Requirement:

An invention must represent genuine development that goes beyond the prior state of industrial art and ordinary and expected technological development. This is confirmed by Article 3 of Ordinance No. 03-07, which provides: **“Inventions that are new and result from an inventive activity...”** may be protected by a patent. Article 27(1) of the TRIPS Agreement likewise requires inventions to be new and to involve an inventive step.

A body of French legal scholarship defines inventive step as anything that goes beyond the prior state of industrial art, whether through the idea underlying the invention, the means by which it is achieved, or the unexpected economic results that it adds to industry¹⁵.

Article 5 of Ordinance No. 03-07 provides that an invention is considered to result from an inventive step **“if it does not follow in an obvious manner from the state of the art,”** that is, if its derivation would not be obvious to a person skilled in the relevant technological field. What may be obvious to a skilled technician in a particular field may be extraordinary to an ordinary person¹⁶.

Accordingly, it is not sufficient for an invention to constitute merely an obvious refinement or improvement; rather, it must involve an inventive step that goes beyond the existing state of industrial art¹⁷ (11). In assessing this, the majority of legal scholarship has adopted the objective theory, which considers the invention in itself without taking into account the effort made by the inventor or the extent to which the inventor deserves recognition for such effort.

¹⁴Majed Walid Abu Saleh and Ramzi Ahmad Madi, op. cit., p. 981.

¹⁵P. Roubier, cited by: J. Azéma, Brevet d'invention, in Lamy Droit Commercial, 2008 ed., Industrial Property, No. 1744, 2008, p. 5.

Cited in: Khayra Mosaddaq, The State of the Art in Algerian and French Patent Law – Assessment of the Novelty Requirement and the Inventive Step Requirement, International Review of Law, published by the College of Law, Qatar University, Vol. 9, No. 2, 2020, p. 293.

¹⁶Farhat Hamou, Protection of Inventions under Algerian Law, Academic Journal of Legal Research, published by the Faculty of Law and Political Science, University of Bejaia, Vol. 3, No. 1, 2012, p. 250.

¹⁷Mohammed Hossam Mahmoud Lotfi, Intellectual Property Laws in Arab Countries, paper presented at a WIPO seminar, 19 November 1996, pp. 8–9

The inventive step differs from novelty. Novelty requires that the invention not have been known to others prior to the filing of the patent application, whereas the inventive step requires that the invention not constitute merely an obvious improvement to a person skilled in the relevant field. Accordingly, an invention may be new because it was not previously known to others, yet fail to satisfy the inventive step requirement if it does not go beyond obvious improvements¹⁸ (22). The requirements of novelty and inventive step are both linked to the state of the art, which has led some legal scholars to consider non-obviousness, i.e., the inventive character of the invention, as a limitation on novelty, although the legislature has devoted a separate provision to it in order to avoid complicating the provision governing novelty.

In this context, the question arises as to the reference person against whom obviousness is to be assessed under Algerian law. While the French legislature specified in Article L611-14 of the Intellectual Property Code the criterion of **"a person skilled in the art"**¹⁹ (33), the Algerian legislature did not specify in Article 5 of Ordinance No. 03-07 the person whose level of obviousness should be relied upon in assessing the inventive step. However, Article 22(3) of the same Ordinance requires the description of the invention to be clear and complete enough to enable a skilled person to carry it out. This raises the question as to why the Algerian legislature did not adopt the same reference person when assessing the obviousness of the invention, which supports the call for expressly identifying the reference person in the aforementioned Article 5.

Given the difficulty of determining the existence of an inventive step, a number of indicators may be used to establish its presence, the most important of which include:

- Achieving significant technical progress or an unprecedented technological breakthrough.
- Achieving a surprising or unexpected result.
- Going beyond what was prevailing in the relevant technological field and providing a solution that could not have been envisaged, even by a person skilled in the art.
- Overcoming technical difficulties to meet needs that have existed for a considerable period, and the resulting economic and commercial success of the invention.

2.1.2- Criteria for Assessing the Inventive Character of an Invention:

The inventive step, or non-obviousness, is assessed by comparing the invention with the state of the art, with the assistance of a person skilled in the art. Accordingly, the assessment of the inventive character is based on two fundamental criteria: the state of the art and the person skilled in the art.

- The State of the Art:

¹⁸Majed Walid Abu Saleh and Ramzi Ahmad Madi, op. cit., p. 981.

¹⁹Article L611-14 of the French Intellectual Property Code (CPIF): "An invention shall be considered to involve an inventive step if, for a person skilled in the art, it does not follow in an obvious manner from the state of the art." Law No. 92-597 of 1 July 1992 relating to the Intellectual Property Code (Legislative Part), JORF No. 0153 of 3 July 1992

The state of the art consists of all information made available to the public and everything published before the filing date of the patent application or the claimed priority date. The inventive step is assessed in light of the technical and industrial level existing prior to the invention and the level that ordinary technological development in the industry could have reached, while excluding conventional and commonly known techniques that are almost necessarily known to a person skilled in the art²⁰.

- The Person Skilled in the Art:

A person skilled in the art refers to an individual possessing the ordinary knowledge relating to the technology associated with the field of the invention for which protection is sought. Such person is not presumed to possess a high degree of knowledge or inventive ability, nor to be familiar with every technical detail; rather, it is sufficient that they possess general knowledge of the technical elements falling within their field of expertise²¹.

2.2- The Particularity of the Inventive Step Requirement in Biotechnological Inventions:

The inventive step requires the invention to represent an extraordinary advancement that goes beyond the ordinary development of the existing state of industrial art. In the field of biotechnology, the question arises as to the extent to which this requirement is satisfied by biotechnological inventions and how they can be distinguished from mere discoveries. To address this issue, we examine the particularity of assessing the inventive step, followed by the particularity of the criteria used for its assessment.

2.2.1- The Particularity of Assessing the Inventive Step in Biotechnological Inventions:

Biotechnological inventions may consist of a new product, a new process, or a combination of a product and the process for producing it. Their inventive step is assessed after verifying compliance with the novelty requirement. Where the invention concerns new products, such as microorganisms including bacteria, yeasts, fungi, and viruses, or non-biological or microbiological processes for producing animals and plants, it must first be established that they are not purely natural products, but rather resulted from human intervention that has limited or altered the natural process.

However, merely producing a microorganism with new characteristics and properties is not sufficient to establish an inventive step unless such result is the product of human intervention that has altered the natural course and produced an unexpected result going beyond mere improvement or modification. Accordingly, when assessing the inventive step, it is necessary to determine the degree of human intervention, based on the criterion of a person skilled in the art who is familiar with the prevailing state of the art.

Accordingly, establishing the inventive step in a microorganism requires its examination from several aspects, particularly its genetic composition, its products, and the processes used to produce it. Demonstrating the inventive step in biotechnological inventions becomes more difficult in view of the nature of living matter and its characteristics of change and rapid

²⁰Naeem Mughbghab, *Patent: Industrial and Commercial Property, A Comparative Law Study*, 1st ed., Al-Halabi Legal Publications, Beirut, 2003, p. 58

²¹Nouri Hamad Khater, *Explanation of Intellectual Property Rules (Industrial Property): A Comparative Study of Jordanian, Emirati and French Laws*, 2nd ed., Dar Wael Publishing, Amman, 2010, p. 37.

development, in addition to the difficulties associated with researching, discovering, isolating, and producing microorganisms.

2.2.2- The Particularity of Applying the Inventive Step Criteria to Biotechnological Inventions:

It is difficult to determine the inventive step in biotechnological inventions in the abstract. Therefore, it is first necessary to determine the prevailing state of the art and then to establish who is meant by a person skilled in the art in this field.

- Determining the Prevailing State of the Art in a Biotechnological Invention:

Article 5 of Ordinance No. 03-07 provides that: **“An invention shall be considered to result from an inventive step if it does not follow in an obvious manner from the state of the art.”** Accordingly, the inventive step requires that the invention not be obvious in light of the state of the art.

For example, a biotechnological invention that merely consists of combining known elements or making a routine modification to an existing technology does not involve an inventive step and, therefore, does not qualify for patent protection ²².

However, assessing the non-obviousness requirement in a biotechnological invention is characterized by difficulty and complexity, given that such inventions rely on objects and elements that already exist in nature. Accordingly, the assessment begins by determining the state of the art and what has previously been disclosed to the public concerning the subject matter of the invention, and then considering the level that ordinary and customary development would have been expected to reach in this field. This determination becomes particularly important in view of the existence of highly knowledgeable and technically qualified scientists and experts who continuously work in biotechnology laboratories, whose research forms part of the development of the state of industrial art in this field.

Accordingly, the question arises as to which person should be referred to in assessing the obviousness of the invention: is it sufficient for that person to possess ordinary knowledge and average experience in his or her field of specialization, as a person skilled in the art, or does the particular nature of biotechnological inventions require such person to have a high level of expertise, skill, and knowledge in specialized fields, such as molecular biology or genetic engineering?

- The Meaning of a Person Skilled in the Art in the Field of Biotechnological Inventions:

A person skilled in the art refers to a person with average experience and skill in the relevant technical field. According to some legal scholarship, such person should possess four elements: experience in the field of the invention, the ability to distinguish between original and imitative work, qualifications in his or her field of specialization, and the ability to distinguish between ordinary industrial matters and those that are not ²³.

In the field of biotechnology, if, for example, the invention concerns the genetic modification of a bacterium for the purpose of obtaining a particular product or a new type with

Biotechnology: How to Innovate and Register Your Biotechnology Patent as Intellectual Property. Available on the website: ²² <https://fastercapital.com/arabpreneur>, accessed on 27/10/2024 at 11:23
Nouri Hamad Khater, op. cit., p. 37²³

distinctive characteristics, the person skilled in the art need not be specifically specialized in microbiology. Rather, it is sufficient for that person to be specialized in genetic engineering, as a general field whose techniques are applied to various living organisms, including microorganisms, thereby enabling such person to understand the novel and inventive elements of the invention²⁴.

However, the complexity of biotechnological inventions may make the assessment of the inventive step require a team of specialists possessing ordinary knowledge and creative ability. For example, if the invention concerns a new antibiotic obtained through a microbiological process, such as the use of genetic modification to modify a particular fungus and stimulate it to produce the antibiotic, the person skilled in the art in this case may comprise experts in genetic engineering, microbiology, or molecular biology, together with a pharmacology expert, in order to determine the extent to which arriving at the invention was obvious in light of the state of the art²⁵.

Conclusion:

The study concluded that biotechnological inventions have particular characteristics arising primarily from their reliance on living matter and the knowledge associated with it, which has given rise to differing views as to whether they should be characterized as mere discoveries or as inventions deserving legal protection. The TRIPS Agreement has provided protection for such inventions within the patent system, and this has been reflected in comparative legislation, particularly European Directive No. 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, which established provisions adapted to their particular nature.

Although biotechnological inventions, like all other inventions, are subject to the general substantive requirements for patent granting, namely novelty, inventive step, and industrial applicability, the application of these requirements to such inventions raises difficulties and particularities imposed by the nature of living matter and the continuous development of this field.

Accordingly, the following main findings and recommendations can be drawn:

- Biotechnological inventions are subject to the criterion of absolute novelty. The particularity of this requirement lies in the difficulty of determining the prior state of the art in relation to inventions that are partly based on elements existing in nature, such as microorganisms.
- The mere discovery of a natural element is not sufficient to obtain patent protection. Rather, human intervention plays a decisive role in transforming the invention from the realm of a natural phenomenon or product into an invention eligible for protection.
- A biotechnological invention must be capable of industrial applicability; a theoretical or merely potential possibility of use is not sufficient.

²⁴Majed Walid Abu Saleh and Ramzi Ahmed Madi, *op. cit.*, p. 983

²⁵*Ibid.*, same reference and location

- Establishing the inventive step in biotechnological inventions is particularly difficult because of the nature of living matter and its rapid change and development, which requires the invention to be examined from multiple perspectives, such as its genetic composition and the processes used to produce it.
- Assessing the inventive step requires determining the prevailing state of the art and then referring to a person skilled in the art. The nature of certain biotechnological inventions may require the assistance of a team of specialists from different scientific fields.

In light of these findings, we propose the following:

- Clarifying the position of the Algerian legislator regarding the protection of biotechnological inventions and establishing rules better suited to the development of biotechnology and the sciences associated with it.
- Enhancing the efficiency of patent examination bodies and providing specialized training for their personnel, while strengthening cooperation between these bodies, universities, and research centers in order to verify the scientific and technical aspects of biotechnological inventions.
- Strengthening the examination of the substantive requirements, particularly novelty and inventive step, in order to prevent the granting of patents that are not based on a genuine invention and the resulting potential monopolization, especially in the pharmaceutical industry.
- Strengthening legal frameworks in developing countries to protect their biological resources and ensure their exploitation in a manner that prevents their loss or exploitation without adequate legal protection.

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