Patentability of Living Matter in Egypt

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I. Introduction

As a member of the World Trade Organization (WTO), Egypt is required to abide by the TRIPS agreement. This agreement requires that patents be made available for “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.” Only three exceptions are provided for in TRIPS. A member country may choose to exclude from patentability an invention that is deemed necessary to protect *ordre public* or morality, including protection of the environment, health and human, animal, or plant life. Additionally, a member country may prohibit the granting of patents for “diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.” Finally, a WTO member may opt to disallow patents for “plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological process”. This exception recognizes the dichotomy between product patents and process patents, to the effect that members may exclude product patents but requires protection for processes, except biological processes.

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3 Id. at art. 27.2
4 Id. at art 27.3(a)
5 Id. at art. 27.3
6 Product patents are patents granted for the end-result, i.e. the plant or animal; while process patents provide protection for the method of developing a product, even if that product is otherwise unable to receive patent protection. For example, while aspirin cannot be patented (as a product) because it is not a new invention, a new method of developing aspirin could be patented as a process.
Egypt, like many developing countries, has been reluctant to extend patent protection to living matter beyond the requirements of the TRIPS agreement. As allowed by TRIPS, Egypt has limited its protection to a *sui generis* system of plant variety protection and has resisted the push to allow patents for plants and animals. Despite its reluctance to do so, Egypt has offered protection for pharmaceuticals, non-biological processes, and microbiological processes for the production of plants and animals as required by TRIPS. This paper will discuss the protections for living matter offered by the Egyptian intellectual property law, Law 82-2002, as well as the conformity of Egyptian law with existing international intellectual property laws, especially TRIPS.

## II. Animals

Law 82-2002 specifically provides that a patent shall not be granted for animals, regardless of their uniqueness. Nor may a patent issue for “organs, tissues, live cells,
natural biological substances, nuclear acid or genomes”, thus effectively prohibiting the patenting of any portion of the animal. However, a patent may be granted for the non-biological and microbiological processes resulting in the production of animals. This creates a situation in which the animal, as an end-product, is not patentable but a portion, such as a cell resulting from a non-biological process, of the animal is covered by the process. For instance, if through microbiological or non-biological processes, a scientist altered a gene in a mouse, the mouse would not be patentable but the process by which the gene was altered would be, and therefore, anyone using the mouse would be required to obtain authorization from the patent holder in order to use the mouse with the altered gene. This is despite the fact that neither the mouse nor gene is patentable under Egyptian law.

Whether these provisions of Law 82-2002 conform to the requirements of TRIPS is unclear due to the ambiguous interpretations of the TRIPS Article 27. Some have suggested that the allowance of microorganism could be interpreted to include parts of an animal in the patentable classification. Others disagree. If the TRIPS agreement were to

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13 Nucleic acids, components of DNA (adenine, thymine, guanine, cytosine), cannot be patented because these are natural, inheritable material present in all cells and contain all information necessary to make protein. While altering the DNA sequences creates a different protein (protein is non-biological – a chemical), the combination in a useful way creates DNA, which is seen as biological. The distinction Egypt makes between organs, tissues & live cells is interesting in that organs and tissues are made of live cells, and is therefore repetitive.

14 Id., supra note 6, at art 2(5).

15 An example of a non-biological process for the production of a plant or animal would be the use of a chemical process that suppresses a characteristic in a gene for a plant or animal.

16 An example of a microbiological process for the production of a plant or animal would be the process through which a vector (virus, bacteria, etc.) was added to gene sequences in order to create a new plant or animal.

17 EPC, supra note 11, art 64(2). Egypt’s law in this regard is similar to that of the European Patent Office. The European Patent Convention Article 64(2) Rights Conferred by a European patent provides, “If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.”

18 Id., supra note 6, art 2(4), (5).


20 BIO Special 301 – The Biotechnology Industry Organization (BIO) argues that Egypt’s prohibition on granting patents for living cells violates Article 27.3 of TRIPS which requires countries to extend patents to microorganisms. According to BIO, Egypt’s exclusion of living cells prohibits patents on human and animal cell lines, yeast, bacteria, as well as other viable cells. Vandana Shiva, Ecologists Should Worry About the Dunkel
be interpreted to allow for the patenting of portions of an animal, Law 82-2002 Article 2 (5) would be in violation.

Furthermore, a patent is available for all animal products, so long as they meet the requirements necessary to receive a patent. Animal products include any byproduct of the animal. Thus, in order to be patented animal products must be new, involve an inventive step, and be capable of industrial application. For instance, while the milk from a cow is not patentable because it does not contain any inventive step, altering the basic milk in some way to create a new product that is capable of industrial application would allow the inventor to seek a product patent under Law 82-2002. Law 82-2002 also provides that a patent may be granted on a “modification, improvement or addition to a previously patented invention” so long as modified the product is new, involves an inventive step and is useful.

In recognition of Egypt’s obligations under the UN Convention on Biological Diversity, Article 13 of Law 82-2002 requires that an invention involving “biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage” be acquired through legitimate means. While the statute does not define what legitimate means are, in other portions of the intellectual property law the requirement to acquire sources in a “legitimate manner” has required parties seeking protection to give credit to local communities for their role in the traditional

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22 Law 82-2002, supra note 6, art 1.

knowledge and development of genetic material from which the new products originated.\textsuperscript{24}

While this recognition is not required under TRIPS, the 2001 Doha Declaration recognized the need to examine the relationship between TRIPS and the Convention on Biological Diversity.\textsuperscript{25}

## III. Plants

Law 82-2002 prohibits the granting of patents for plants. However, in accordance with TRIPS Article 27.3, a member country of the WTO is required to provide protection for plant varieties either through the granting of patents or an effective \textit{sui generis} system. Thus, Book 4 of Egyptian Law 82-2002 specifically provides for breeders certificates to protect against unauthorized exploitation of new plant varieties.\textsuperscript{26}

Unwilling to go beyond the basic requirements of TRIPS, Egypt has opted not to enact more stringent protections for plants. Article 2 prohibits the granting of patents for “essentially biological processes for production of plants” and disallows the patents for “tissues, living cells, and natural biological substances”.\textsuperscript{27} Thus, neither the biological production process nor parts of the plant may be patented as a method of circumventing the prohibition against plant patents. However, non-biological and microbiological processes for the production of plants may be patented. These are the same restrictions applied to the patenting of animals, which raises many of the same issues.

\textsuperscript{24} Book 4, art 200 of Law 82-2002 requires plant breeders to give recognition and, where possible, compensation to local communities in recognition of their role in developing new plant varieties as part of their heritage and livelihood.


\textsuperscript{26} Nadia Kholeif, \textit{Protection of Plant Varieties in Egypt: Law 82-2002,} \textit{OKLA. J.L. \\ & TECH.} (2005), available at \url{.}

\textsuperscript{27} Law 82-2002, \textit{supra} note 6, art 2 (4) – (5)
IV. Microorganisms

In accordance with TRIPS, Law 82-2002 allows for the patenting of microorganisms. In order to receive a patent on a microorganism, a party must submit a patent application to the Patent Office along with a patent application fee. An applicant must show that the invention is new, involves an inventive step, and is capable of industrial application. Furthermore, an applicant, in accordance with Article 6, must show that the applicant is entitled to hold the patent as the inventor first to file or as the party to commission the research. In the case where the party seeking the patent is not the inventor, Law 82-2002 requires that the name of the inventor be mentioned in the application and receive compensation.

Before a patent is approved, the Patent Office is required to send an application relating to defense, military production, security matters, or health to the relevant ministries for further approval and consultation. Article 17 provides that the ministries have ninety days from the date they are notified of the application to “oppose the publication of the application acceptance”. If, however, the application was not deemed to involve issues

28 Law 82-2002, supra note 6, art 2.
29 Id. at art 11.
30 Id. at art 3.
31 Id. at art 1. A patent may also be granted for a modification, improvement or addition to an existing patent that can be shown to create a new product capable of meeting the three requirements for patenting (new, distinct and useful).
32 Law 82-2002, supra note 6, art 6
33 Id. at art 7.
34 Law 82-2002, supra note 6, art 17, 19.
35 Id. at art 17. Law 82-2002 is unclear regarding the procedure involved here, it appears that the relevant ministries may oppose either the granting of the patent or may oppose the publication of the acceptance. Opposition by the relevant ministry to the patent itself is, according to Article 17, enough to defeat the application. Additionally the ministries may oppose the publication of the acceptance. Article 19 provides that the “grant of a patent is published one year from the date of filing the application and remains confidential during this period”. Thus, it appears that the ministries have the authority to require a patent relating to national security remain confidential throughout the term of the patent. Thus, defeating one of the goals of patent systems, namely to provide the public with the knowledge in order to foster further innovation.
relevant to the ministries and the application is accepted and made public through publication in the Patent Gazette, the Ministries of Defense, Military Production, Interior and Health may still object to the granting of the patent if it appears that it “relates to defense, military production, security or is of military, security or health significance.” The Ministries may oppose either the publication of the patent or may oppose the granting of the patent, in which case the application shall be denied.

In the case of microorganisms, an applicant is required to “disclose the identity of the organism and deposit a live culture” with the authorities in accordance with the Regulations to Law 82-2002. Once a patent application is approved, the holder of the patent shall be entitled to protection for 20 years against any unauthorized exploitation of the invention. Law 82-2002 provides limited exceptions to the patent protection.

V. Pharmaceuticals

As an extension on the patenting of microorganisms and non-biological processes, Law 82-2002 permits the patenting of pharmaceuticals. This is one of the most highly contested aspects of Law 82-2002 and TRIPS. Many developing countries, including Egypt, regard the patenting of pharmaceuticals to be a violation of public interest. However,
developed countries have granted a number of concessions to encourage developing countries to sign on to the TRIPS agreement.

To assuage Egypt’s fear that allowing patents on drugs would lead to prohibitively high priced drugs, Law 82-2002 creates the Drug Price Stability Fund.\textsuperscript{42} Donor countries, inter-governmental and non-governmental organizations have agreed to provide contributions to the Fund in order to maintain price stability in the drug market.

Additionally, under TRIPS, developing countries had a grace period during which pharmaceutical patents were not granted, but rather protected against subsequent claims through the mailbox system of first priority.\textsuperscript{43} Under the mailbox system, prospective patent applicants were able to file their applications with the Patent Office after January 1, 1995. The applications for pharmaceuticals filed between January 1, 1995 and December 31, 2004 were held by the Patent Office in the order they were received.\textsuperscript{44} Starting January 1, 2005 the Patent Office began examining the applications for compliance with Law 82-2002. If the Patent Office granted a patent, the patent was deemed to have become effective on the date the original application was submitted to the Patent Office and continues in effect for twenty years from the original application date.\textsuperscript{45}

Under Article 17, all pharmaceutical patents must be reviewed by the Ministry of Health.\textsuperscript{46} When the application is sent to the Ministry, the Patent Office must notify the applicant of the review. The Ministry then has ninety days to oppose the publication of the application acceptance or oppose the granting of a patent.\textsuperscript{47}

\textsuperscript{42} Law 82-2002, \textit{supra} note 6, art 18.
\textsuperscript{44} \textit{Id.} at art. 43.
\textsuperscript{45} \textit{Id.} at art. 9.
\textsuperscript{46} Law 82-2002, \textit{supra} note 6, art. 17.
\textsuperscript{47} \textit{See} discussion above under \textit{Microorganisms} and note 33.
Once a patent has been granted, the Ministry of Health, upon approval of a ministerial committee, may grant non-voluntary licenses for the exploitation of patented pharmaceuticals if the patent will benefit a non-commercial public interest, including protection of health or food safety and other emergencies. A non-voluntary license may also be granted if the Ministry of Health finds that the quantity of medicine produced under the patent is insufficient to meet the national needs. \(^{48}\) The Ministry also reserves the right to issue non-voluntary licenses if the holder of the patent produces drugs of unacceptable quality, offers the medicines at prohibitive prices, or if the “patent is related to medicines addressing critical cases, incurable or endemic diseases or products used in the prevention of these diseases” and products that are used in the production of those medicines. \(^{49}\) These exceptions for drug related patents are in addition to the other exceptions, such as failure to exploit the invention in Egypt, where the patent owner unreasonably refuses to grant licenses to other parties, or if the patent holder abuses the rights conferred by the patent. \(^{50}\) In all cases of non-voluntary licenses, the patent holder shall receive compensation for the exploitation of the invention, although the compensation due “shall take into account the prejudice caused by arbitrary or unfair competition practices”. \(^{51}\) The patent holder has the right to appeal all decisions to grant non-voluntary licenses before the committee established in Article 36 to deal with patent appeals. \(^{52}\)

In the testing phase of pharmaceuticals, an inventor may obtain the protections of Law 82-2002 for undisclosed information involving new chemical compounds, which have

\(^{48}\) Id. at art. 23.
\(^{49}\) Id.
\(^{50}\) Id.
\(^{51}\) Id.
\(^{52}\) Id. at art 24 (3), 36.
not yet been the subject of a patent. The applicant must submit a request to the authorities responsible for regulating new drugs to obtain such protection. In order to qualify for protection under Law 82-2002 as undisclosed information, the information must be confidential, has commercial value because of its confidential nature, and has been protected against disclosure through reasonable means.

The authorities that receive the confidential information in the process of testing new pharmaceuticals shall protect against “disclosure and unfair commercial use from the date of its submission to the competent authorities until it is no longer confidential, or for a period not exceeding five years, whichever comes first”. Thus, developers of new drugs have five years from the date they submit drugs for testing to obtain patent protection. Failure to take advantage of the patent protections offered will result in the information becoming public and no longer capable of obtaining patent protection. However, if disclosure of the information is deemed to be necessary for protection of the public, the authorities shall not be in violation of the inventor’s rights and may release the information as necessary to protect the public.

VI. Conclusion

Despite its reluctance to do so, Egypt has complied with the requirements of TRIPS by offering patent protection for non-biological and microbiological processes. While declining to offer patent protection to plants and animals, future decisions relating to the

54 Id. at art 55. Information is confidential when “it is not, as a body or in the precise configuration or assembly of its components, generally known or common among those involved in the industrial art within the scope of which the information falls”.
55 Id. at art 56.
56 Id.
interpretation of TRIPS with regard to the protection of cells placed in plants and animals will test the limits of the Egyptian patent law as currently written.