BIOTECH LAW OF IRAN, THE NEED FOR A COMPREHENSIVE LAW

Introduction

Let us start this News & Analysis with the following paragraph taken from Céline Lafontaine's book titled 'Le Corps-Marché' published by Édition du Seuil in April 2014 (at page 246):

"Un article du Monde intitule «Médicament: épidémie de pénuries», paru en novembre 2013, tirait la sonnette d'alarme sur le fait que la course aux profits qui gouverne l'industrie biopharmaceutique a maintenant des répercussions directes sur l'accès aux traitements pour certains patients au sein même des pays développés."

What is the situation in Iran? How the biotech industry is developed? Are the existing biosafety laws, policies, and practical measures sufficient and satisfactory? And finally, is there a comprehensive legal system that can help manage different aspects of biotechnology activities in Iran?

It is not easy to give clear and satisfying responses to the above questions because the biotech law of Iran is in its infancy phase. It is true that few initiatives to draft and devise a comprehensive law and strategy are undertaken by different public entities but at the end of the day, a deep gap exists between the current biotech law of Iran and similar laws in the legal systems of the EU, the US, and Canada. This News & Analysis is the summary of a paper prepared to raise and analyse the above questions.

IP law and biotechnology

Articles 3(b) and 3(c) of the *Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the Legal Protection of Biotechnological Invention* ("the *Directive*") state that further to general conditions of patentability, the following inventions are patentable:

b. Inventions that concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used shall be patentable; and
c. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Articles 1 and 2 of the *Patents, Industrial Designs and Trademarks Registration Act of Iran* ("the *Act*") and Articles 10 and 13 of the *Executive Regulations of Patent, Industrial Designs and Trademarks Registration Act* ("the *Regulations*") provide detailed rules about patentability but both the *Act* and the *Regulations* are completely silent about biotech inventions.

Further, under Articles 4 to 6 of the *Directive*, the following subjects are excluded from patentability:

a) Plant and animal varieties;
b) Essentially biological processes for the production of plants or animals with the exception of the inventions which concern a microbiological or other technical process or a product obtained by means of such a process;
c) Inventions which concern plants or animals if the technical feasibility of the invention is confined to a particular plant or animal variety;
d) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;
e) Elements isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene;
f) Inventions whose commercial exploitation would be contrary to *ordre public* or morality;
g) Processes for cloning human beings;
h) Processes for modifying the germ line genetic identity of human beings;
i) Uses of human embryos for industrial or commercial purposes; and
j) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Again, apart from paragraphs a), b), d) and f) of the *Directive*, the other paragraphs of the *Directive* can neither be found in the *Act* nor in the *Regulations*.

Finally, according to Articles 8 and 9 of the *Directive*, the subjects of protection are:

a. biological material possessing specific characteristics as a result of the invention;
b. a process that enables a biological material to be produced possessing specific characteristics as a result of the invention; and
c. a product containing or consisting of genetic information.

The *Act* and the *Regulations* are completely silent about the above distinctions between three different subjects of IP protection.

By comparing corresponding parts of the *Act* and the *Regulations* with those of the *Directive* it can be observed that the general concepts and rules that are included in the laws and regulations of Iran are not sufficient to respond to the complex questions raised in the field of biotechnology-related IP rights. There is an urgent need to pass new laws and regulations based on similar texts that exist in the legal system of the developed countries in order to regulate and facilitate development of biotech activities in Iran.

1. International framework of biotech law

The biotech law and bioethics are too complicated and too global to be left to domestic legal systems. International treaties and conventions, as well as multilateral and bilateral agreements regulate and control biotech activities all around the world. Has Iran adhered or acceded to these international conventions or agreements?

Paris Convention - Iran is a member of Paris Convention. It acceded to the Convention on September 1, 1959 and the Convention is in force in Iran since December 16 of the

same year. Iran has ratified the Stockholm Act (1967) on December 12, 1998 and this Act is in force since March 12, 1999.

It must also be noted that the *Paris Convention* does not have specific provisions to protect biotechnological creations. In other words, to apply the Paris Convention to these creations, the only solution is to apply the general provisions of the Convention and to interpret them extensively.

The practical result of this observation is that membership of Iran in *Paris Convention* does not fill the existing gaps in the domestic biotechnology law of Iran. Joining the *TRIPS Agreement*, on the contrary, may help the biotechnology law of Iran to adapt itself to the international standards set by this Agreement.

Patent Cooperation Treaty - Iran became a member of the *Patent Cooperation Treaty* on October 4, 2013. The PCT Newsletter No. 07/2013 (July 2013) reported that:

On 4 July 2013, the Islamic Republic of Iran deposited its instrument of ratification to the PCT, thus becoming the 148th Contracting State of the PCT, and on 4 October 2013, will become bound by the PCT. Consequently, any international application filed on or after 4 October 2013 will automatically include the designation of the Islamic Republic of Iran.

Also, because the Islamic Republic of Iran will be bound by Chapter II of the PCT, it will automatically be elected in any demand for international preliminary examination filed in respect of an international application filed on or after 4 October 2013. Furthermore, nationals and residents of the Islamic Republic of Iran will be entitled, as from 4 October 2013, to file international applications under the PCT.

The PCT Notification No. 204, however, indicated that:

“The said instrument of ratification contains the declaration that, pursuant to Article 64(5) of the said Treaty, the Islamic Republic of Iran does not consider itself bound by Article 59 of the said Treaty.”

Article 59 of the PCT states that:

"Subject to Article 64(5), any dispute between two or more Contracting States concerning the interpretation or application of this Treaty or the Regulations, not settled by negotiation, may, by any one of the States concerned, be brought before the International Court of Justice by application in conformity with the Statute of the Court, unless the States concerned agree on some other method of settlement. The Contracting State bringing the dispute before the Court shall inform the International Bureau; the International Bureau shall bring the matter to the attention of the other Contracting States".

International Union for the Protection of New Varieties of Plants (UPOV) - Iran is not a member of the *International Union for the Protection of New Varieties of Plants (UPOV)*. However, Iran is one of the States which has been in contact with the Office of the Union for assistance in the development of laws based on the *UPOV Convention*. Iran also has observers in the Council of the UPOV. The next step taken by Iran in this

direction is passing the *National Seed Act* in 2003 whose provisions are influenced by but not fully compatible with the UPOV provisions.

Becoming a member of the World Trade Organization – Iran's application for accession to the WTO was received by the WTO on July 19, 1996. Iran's request for accession entered the General Council of the WTO but the US representative stopped the process of considering the application of Iran by stating that: "[h]er government was currently reviewing this matter internally and was not in a position to discuss Iran's accession request at this time."

On 26 May 2005, the General Council finally established a working party to examine the accession request of Iran. Under the comprehensive long-term agreement, the P5+1 offered Iran its support for membership of Iran in the WTO but later due to Iran's disagreement with the P5+1 on its nuclear activities, this offer was retracted. Finally Iran submitted its Memorandum on the Foreign Trade Regime in November 2009. The next phases are multilateral and bilateral negotiations that normally result in the final accession package. Iran's proper interaction with influential members of the WTO becomes primordial in passing successfully through the negotiation phases.

To understand the current standing of Iran in the international scene, we need to look at the negotiations currently going on between Iran and the 5+1. The Joint Plan of Action signed by Iran and the 5+1 in Geneva on November 24, 2013 is silent about the WTO membership of Iran. This issue may be included in the agenda of the talks later.

As far as the IP law of medical biotechnology is concerned, the practical result of becoming a member of the WTO for Iran is the flexibility provided by the TRIPS Agreement as explained on the website of the WTO:

> The TRIPS Agreement is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

Biosafety law of Iran

I. The domestic framework of biosafety law of Iran includes the following elements:

a. The National Biosafety Act of Iran (the NBAI): It came into force on August 27, 2009. Scope of the *NBAI* is determined by its Article 2:

> All of the issues related to the production, release, transport, export, import, sale, purchase, application and use of living modified organisms are permitted with the observance of the provisions of this Act. The government should provide necessary arrangements for performing the provision of this Act.

Article 10 of the *NBAI*, on the other hand, excludes from the scope of the *NBAI* the laboratory and green house researches of living modified organisms and the issues related to pharmaceuticals and their derivatives that have human consumption.

b. Article 3 of the *NBAI* establishes the National Biosafety Council:

"The National Biosafety Council (NBC) is established consisting of following members: First Deputy of President; The Minister of Science, Research and Technology; The Minister of Health and Medical Education; The Minister of Agriculture; The Director General of the Environmental Protection Organization; one specialist from scientific societies (NGOs) holding a PhD degree with the recommendation of these societies and approval of the Minister of Science, Research and Technology and order of the president; one person form the scientific members related to biosafety in universities with the recommendation of the Minister of Health and order of the president; one person from the members of the Agriculture, Water and Natural Resources Commission; and one person from the Health and Medical Commission of the Islamic Consultative Assembly with the opinion of mentioned commissions and the vote of the parliament that will act as supervisors.

II. The international law framework of biosafety law of Iran is comprised of the following texts:

a. *Convention on Biological Diversity*: Iran joined this convention in August 1996. Paragraph 8 of this *Convention* provides that Iran commits itself to the creation and maintenance of tools necessary for supervising, managing and controlling risks in the use or release of living modified organisms resulting from modern biotechnology with regards to human health and the environment.

b. *Cartagena Protocol on Biosafety*: Iran signed this protocol on April 23, 2001. The Parliament of the country ratified it on November 2003 and it came into force on February 18, 2004.

CONCLUSION

The legal system of Iran is in dire need of a comprehensive law to cover different aspects of biotechnology activities in Iran including the IP law, biosafety rules and regulations, environmental laws, bioethical rules, etc. Our experience resulting from involvement in a project in the years 2002-2003 concerning preparation of a comprehensive biotechnology law has proved to us that the EU law comprises detailed rules, directives, and regulations that can be used as the starting point for drafting a comprehensive legal and bioethical text for Iran. Sporadic measures taken by different public entities involved in this field normally result in counter-productive consequences that postpone establishing a solid system to an unknown future. This must be avoided by any means necessary.