Comparison between the EPO and the CNIPA with respect to non-patentable subject-matter in the Pharmaceutical/Biotechnological field

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Both the European Patent Convention (EPC) and the Patent Law of the People's Republic of China (Chinese Patent Law) have stipulated exceptions to patentability.

Article 52 (1) of the EPC stipulates that: European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

Paragraph (2) reads:

The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

Additionally, Article 53 of the EPC stipulates three kinds of exceptions to patentability. European patents shall not be granted in respect of: “(a) inventions the commercial exploitation of which would be contrary to ’ordre public’ or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

Article 25 of the Chinese Patent Law stipulates that for “any of the following, no patent right shall be granted: (1) scientific discoveries; (2) rules and methods for mental activities; (3) methods for the diagnosis or for the treatment of diseases; (4) animal and plant varieties; (5) substances obtained by means of nuclear transformation; (6) two dimensional designs of images, colours or combinations of the two that mainly serve as indicators. For processes used in producing products referred to in item (4) of the preceding paragraph, patent right may be

granted in accordance with the provisions of this Law." In addition, Article 5 of the Chinese patent law stipulates that "No patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to public interest."

In the field of pharmaceutical and biotechnological inventions, there are literally some similarities between the EPC and the Chinese Patent Law concerning exceptions to patentability. However, in recent years, the European Patent Office (EPO) has narrowly interpreted Article 53 and thus gradually confined the scope of non-patentable subject-matter. Differences exist between the practice in the EPO and the National Intellectual Property Administration of the P. R. China (CNIPA). The practice in the EPO appears to be more user friendly than that in China. Some technical solutions that seem to be literally speaking, non-patentable subject-matter, actually can be patented under special circumstances. In addition, even in China, suitable patent drafting can help converting some technical solutions that are related to non-patentable provisions, into patentable subject-matter. A thorough understanding of the practice and the standards in the EPO and the CNIPA, can help applicants to build stable patent portfolio and gain strong protection in these areas.

1.Transgenic plants and transgenic animals

1.1 Practice in the EPO

Although Article 53 (b) of the EPC provides two bars to the patentability of plant or animal varieties, after a series of decisions, exceptions to patentability have been narrowed.

It has been concluded by the Enlarged Board of Appeal with its Decision G 1/98 (OJ EPO 2000, 111) that, “A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties”. The decision loosened the restrictions on technological solutions related to transgenic plants.

For transgenic animals, considering that unlike plant varieties which can be protected by other industrial property rights, the EPO provides also narrowed interpretation of exceptions to patentability. In the decision T 19/90 (OJ EPO 1990,476), it is stated that “It is now the task of the European Patent Office to find a solution to the problem of the interpretation of Article 53(b) EPC with regard to the concept of ‘animal varieties’, providing a proper balance between the interest of inventors in this field in obtaining reasonable protection for their efforts and society's

interest in excluding certain categories of animals from patent protection. In this context it should, inter alia, be borne in mind that for animals - unlike plant varieties - no other industrial property right is available for the time being", and it is concluded that "As indicated above, Article 53(b), 1st half-sentence, EPC is an exception to the general principle of patentability contained in Article 52(1) EPC. The second half-sentence is an exception to this exception, ensuring that the patentability bar does not cover microbiological processes or the products thereof. In other words, the general principle of patentability under Article 52(1) EPC is restored for inventions involving microbiological processes and the products of such processes. Consequently, patents are grantable for animals produced by a microbiological process." Following this decision, transgenic non-human animals, which can be seen as a product of microbiological processes, are patentable in the EPO.

1.2 Practice in China

According to Article 25(4) of the Chinese Patent Law, animals and plant varieties cannot be patented. New plant varieties may be protected by another "Regulations for the Protection of New Plant Varieties." Microorganisms and microbiological methods, similar to the rules set by the EPO, are patentable in China. However, unlike the EPO, China does

not regard animals produced by microbiological methods as products that are obtained by microbiological methods, and consequently does not consider them as exceptions to non-patentable subject-matter. In other words, plants or animals, even if produced by microbiological methods, are considered non patentable subject-matter in China.

Concerning "plant cells" and "animal cells", if they are able to regenerate individuals, they also belong to the categories of "plant varieties" or "animal cultivars", and are therefore not patentable. Section 9.1.2.3 of Chapter 10 of the Patent Examination Guidelines 2010 stipulates that: “An embryonic stem cell of an animal, an animal at the various stages of its formation and development, such as a germ cell, an oosperm, an embryo and so on, belong to the category of the ’animal variety’.” “A single plant and its reproductive material (such as seed, etc.), which maintains its life by synthesizing carbohydrate and protein from the inorganic substances, such as water, carbon dioxide and mineral salt and so on through photosynthesis, belongs to the category of the ’plant variety’.”

Compared with the EPO, the CNIPA does not narrow the interpretation of exceptions to patentability with respect to “plant varieties” and “animal varieties”, but on the contrary broadens the interpretation of these

exceptions. In other words, it is more difficult to patent “plant varieties” and “animal varieties” under Chinese practice.

This is the first instalment of a serialised article.