

## 20: Patents: Therapeutic, Surgical and Diagnostic Methods

### Article 27.3 (a) Patentable Subject Matter

Members may also exclude from patentability:  
diagnostic, therapeutic and surgical methods for the treatment of humans or animals; ...

### 1. Introduction: terminology, definition and scope

While TRIPS in Article 27.1 only requires the protection of processes and products,<sup>633</sup> some national laws have extended patentability to inventions consisting of methods of using certain products or performing certain steps.

Article 27.3(a) applies specifically to *methods* for the treatment of humans or animals. It makes clear that in this area, for the purpose of patentability, the (patentable) products or processes need to be differentiated from the methods of the treatment. In other words, *the way inventions are used* in order to heal humans or animals may be excluded from patentability. The reasons for this exception are various and depend on each country's perspective. While European countries advance ethical or moral considerations for this provision's equivalent in Article 52(4) of the European Patent Convention,<sup>634</sup> developing countries have stressed, *inter alia*, the need for local availability of treatment methods.<sup>635</sup>

Therapeutic, surgical and diagnostic methods produce effects on the human (or animal) body, and not an industrial effect. Therefore, they may be deemed not patentable because of non-compliance with the industrial applicability requirement provided for in most patent laws, even in the absence of a specific exception. However, in the United States<sup>636</sup> and other countries, such as Australia and New Zealand, patent law allows for the patenting of medical methods if they satisfy the definition of process and the other conditions of eligibility.<sup>637</sup>

<sup>633</sup> See Chapter 17.

<sup>634</sup> Set out below, Section 3 of this chapter (Possible interpretations).

<sup>635</sup> Gervais, p. 150.

<sup>636</sup> In the USA, "utility" and not industrial applicability is required, thereby allowing for a broader scope of patentability.

<sup>637</sup> A bill enacted in 1996 (amending U.S. patent law, 35 USC 287.c) determined, nevertheless, that the use of patented surgical procedures is protected from infringement suits. See, e.g., Grubb, p. 220.

### 3. Possible interpretations

## 2. History of the provision

### 2.1 Situation pre-TRIPS

Therapeutic, surgical and diagnostic methods were excluded from patent protection under European law, as well as the laws of many other countries before the adoption of TRIPS. Under Article 52(4) of the European Patent Convention, for instance, the exclusion of methods of treatment follows from the requirement of industrial applicability. This is spelled out in Article 52(4) which provides that

“Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

### 2.2 Negotiating History

Both the Anell Draft and the Brussels Draft included a provision similar to Article 27.3 (a).

#### 2.2.1 The Anell Draft

“1.4 The following [shall] [may] be excluded from patentability:

[...]

1.4.3 Methods of [medical] treatment for humans [or animals].”

#### 2.2.2 The Brussels Draft

“3. PARTIES may also exclude from patentability:

(a) [Diagnostic, therapeutic and] surgical methods for the treatment of humans and animals;”

### 3. Possible interpretations

Members may also exclude from patentability: ...

TRIPS allows Members to provide for an exclusion to patentability in the cases referred to, but does not oblige them to do so. The exclusions are facultative, or could be limited to some of the methods mentioned in Article 27.3 (a).

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; ...

The exception applies to methods of treatment; that is, to procedures designed to treat humans or animals. This possible exception does not encompass the means utilized to perform the treatment. Accordingly, while for example a novel form of surgical procedure cannot be patented, a novel form of apparatus invented to

enable that procedure to be carried out is, in principle, patentable. It can be argued that pharmaceutical products constitute a therapeutic treatment for humans and animals, and therefore might be excluded from patentability. However, it would be difficult to sustain this argument in light of the negotiating history of TRIPS, which addressed at some length issues surrounding pharmaceutical patents, as well as provisions such as the Article 70.8 “mailbox” rule that expressly cover pharmaceutical patents.

#### **4. WTO jurisprudence**

There has been no specific dispute on issues covered by this provision.

### **5. Relationship with other international instruments**

#### **5.1 WTO Agreements**

#### **5.2 Other international instruments**

As noted above, there is an equivalent of this provision in Article 52(4) of the European Patent Convention. The exclusion is consistent with the object of the Paris Convention Article 1(1) which states that the countries to which it applies constitute a Union for the protection of “industrial property”. Article 1(3) provides that “industrial property” shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufacture or natural products such as wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour.<sup>638</sup> Broad as this definition is, it clearly does not cover methods of therapeutic treatment, surgery or diagnosis.

### **6. New developments**

#### **6.1 National laws**

#### **6.2 International instruments**

#### **6.3 Regional and bilateral contexts**

#### **6.4 Proposals for review**

The exclusion under Article 27.3(a) is connected to the generally accepted concept of patentable subject matter, and is unlikely to be modified without a major change in international views on this matter. Nevertheless, the view has been expressed from time to time that it might be appropriate to permit the patenting of a new surgical procedure since that would ensure its disclosure and dissemination.<sup>639</sup>

<sup>638</sup> This list should not be read as requiring the things listed to be patentable *as such*. As noted above, patents are granted for *inventions*, and the discovery of a new plant or mineral existing in nature would not be an invention. Consequently, the above listed natural products would only be patentable if they were *modified* in a way that satisfied the patentability criteria of novelty, inventive step and industrial applicability.

<sup>639</sup> Jeremy Phillips and Alison Firth, *Introduction to Intellectual Property*, 4th ed., Butterworths, Wiltshire 2000, p. 59, citing Cuthbert *Patent Law Reform in New Zealand: Should Methods*

## 7. Comments, including economic and social implications

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However, it is very unlikely that this view will find wide acceptance in the medical profession, and without such acceptance, the exclusion is likely to remain.

### 7. Comments, including economic and social implications

The exclusion authorized by Article 27.3(a) is fairly narrow, and has few implications for the way in which funding for medical research is directed. For example, new devices such as scanners and fibre optic cameras to enable surgery to be carried out without the invasive techniques that were formerly necessary, are in principle patentable. On the other hand, techniques such as keyhole surgery made possible by such devices may be excluded from patentability. Similarly, pharmaceutical products and apparatus that now render surgery unnecessary, where it was necessary previously, are patentable.

Even in countries where the patentability of such methods is allowed, patents granted are relatively rare. One possible reason for this is that enforcing such patents is very problematic. The patent owner would need to monitor the activities by a more or less large number of doctors and surgeons, who generally provide their services subject to strict privacy rules. Enforcement may be more feasible when new and complex methods are applied by a small number of easily identifiable professionals. This may be the case of gene therapies, at least until they become safer and more widely diffused.

The exclusion of therapeutic methods may have significant implications in the pharmaceutical sector, in relation to the patentability of the new use of a known pharmaceutical product.<sup>640</sup> In effect, there is no real difference between patent claims relating to the use of a substance and those relating to a therapeutic method: in both cases a new medical activity is claimed, i.e., a new way of using one or more known products.<sup>641</sup> The patenting of a new therapeutic effect of a known pharmaceutical product, therefore, is contrary to the ban on patents for therapeutic methods, where applied. Some countries have overcome this problem by admitting the patentability of a new use of an existing drug under the so called "Swiss claims", under which a method claim is drafted as a claim for the use of a product to manufacture a medicine.<sup>642</sup> There is no obligation under TRIPS, however, to adopt this approach.

*of Medical Treatment be Patentable?* Patent World, May 1997; Kell, *Expanding the Frontiers of Patentability: Methods of Medical Treatment of the Human Body*, EIPR 1995, p. 202.

<sup>640</sup> This is an issue of increasing economic importance, in part due to the decline in the discovery of new molecules with significant therapeutic value.

<sup>641</sup> Bengt Domeij, *Pharmaceutical Patents in Europe*, Kluwer Law International / Norstedts Juridik, Stockholm 2000, p. 178.

<sup>642</sup> See Chapter 17, Section 3.