Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

Medical Methods, Risks to Public Health and Exclusion from Patentability

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On 15 February 2010 the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) released an important decision regarding the exclusion from patentability of certain surgical methods (in the case G1/07).[1] Under the European Patent Convention (EPC), methods of treatment by surgery are not patentable. Yet the exact scope of this exclusion has never been clear, as to date the EPO Technical Boards of Appeal seems to have reached different decisions on this matter.

The patent application examined by the referring board in G1/07 concerned magnetic resonance methods for imaging pulmonary and cardiac vasculature and assessing blood flow using dissolved polarised 129Xe. In the context of these methods an embodiment relies on directly delivering such polarised 129Xe to an area of the heart through injection, and these methods may be applied before either surgery or a drug therapy for the treatment of pulmonary and cardiac problems. During surgery they may provide useful real-time feedback in order to confirm success (e.g., surgically induced variations in blood perfusion).[2] In the context of therapy they may permit the effect of the drug to be determined.

The EBA was then asked *inter alia* whether the above methods should be excluded from patent protection as a "*method for treatment of the human or animal body by surgery*" pursuant to the previous version of Article 52(4) of the European Patent Convention (EPC), even if the above-described step – i.e. the injection of a contrast agent into the heart – does not *per se* aim at maintaining life and health.

In the latest version of EPC (EPC 2000) this exclusion from patentability has been moved to Article 53(c). The aim of this exception – which also covers therapeutic and diagnostic methods – is to eliminate obstacles to the freedom of practitioners to choose the best medical treatment to be applied to a patient, and to prevent any delay in the provision of such medical treatment. Indeed, this exclusion pursues a public interest, by aiming to prevent medical practice from being hindered by patent protection.

The EBA verified whether the injection in question can be considered as a "*method for treatment of the human or animal body by surgery*". It did so even though in the context of the above methods the physical intervention on the body does not *per se* aim at maintaining life and health, but just serves the purpose of collecting data during an examination phase of a medical diagnosis. In other words, the question referred to the EBA was whether imaging methods comprising the described invasive step would fall under the surgery-related exception to patentability (now) contained in Article 53(c) EPC, even though such methods do not have curative purposes or cause curative effects.

The *ratio decidendi* and conclusion of the EBA has been straightforward.

The EBA initially noted that the claimed methods involve physical interventions on the body which require professional medical skills to be carried out and involve substantial health risks, even when executed with the required medical professional care and expertise. The EBA held that the presence of such risk-related factors – e.g., harmful side effects or health risks for the subject – is material when verifying whether invasive surgical methods (as the one in G1/07) should be excluded from patentability, regardless of whether they have no curative purposes or effects.

The EBA concluded that methods having purely or mainly non-therapeutic aims which include a substantial intervention on the body and do involve

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1 G 0001/07 Medi-Physics/Methods for imaging pulmonary and cardiac vasculature and evaluating blood flow using dissolved polarized 129Xe. The decision can be downloaded at <http://documents.epo.org/projects/babylon/eponet.nsf/0/cdd5fb0c3153e9c3c12576cb00563d2d/$FILE/G1_07_en.pdf>.

2 The description of the application makes specific references to the usefulness of the claimed methods during surgeries. For example, the methods in question may generate images which directly allow surgeons to decide on the course of action to be taken.

health risks should be excluded from patentability under the surgery-related exception now contained in Article 53(c) EPC. The EBA also clarified that with reference to such risky inventions the rationale for the exception – i.e. to free doctors from being potentially prevented by patents from applying the best possible treatment on their patients – clearly applies and justifies their exclusion from protection. In the decision the EBA took pains to give some examples of the above methods: i.e., (i) sex change operations, (ii) elimination of wrinkles, (iii) breast enhancement, (iv) embryo transfer, (v) organ transplantation, (vi) cosmetic surgery, (vii) sterilization and (viii) castration.

On the other hand, uncritical methods involving only a minor intervention and no substantial health risks (when carried out with the required care and skill) are to be considered patentable. Indeed, the EBA stressed that the progress and advance in safety and "*the now routine character of certain, albeit invasive techniques, at least when performed on uncritical parts of the body, have entailed that many such techniques are nowadays generally carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours and it appears, hence, hardly still justified to exclude such methods from patentability*".[3] Examples of such uncritical methods could be (i) hair removal by optical radiation, (ii) micro abrasion of the skin, (iii) piercing, (iv) tattooing, etc.

The lesson we can draw from this decision is that risk-related factors are paramount when it comes to deciding whether or not medical methods are to be excluded from patentability. These factors are amongst the socio-ethical and public health related considerations which must be taken into account when dealing with the inventions in question. This is therefore a relevant decision from EBA, which is the most important body in EPO. Indeed, it is competent to take decisions only when the case law of lower boards – i.e., the Technical Boards of Appeal (TBA) – becomes inconsistent or when an important point of law arises, thus ensuring uniform application of patent law across Europe.

In the past, the EPO has released decisions regarding the patentability of medical methods in which it mentioned risk-related factors; such decisions, however, came from TBA.

For example, in 1994 the TBA clarified that a therapeutic method in which a laser was used in order to modify a synthetic lenticule implanted on the cornea was deemed as not patentable, partly because it would be performed by or under the supervision of a medical practitioner due to the health risks concerned. In particular, it was held that "*the intention underlying [Article 52(4)] is to ensure that nobody who wants to use the methods specified in this Article as part of the medical treatment of humans or animals, should be prevented from this by patents. Such medical treatments need not necessarily be carried out by physicians* [...]. *However, where, in view of the health risks connected with such a treatment, a claimed method of treatment has to be performed by a physician or under his supervision, it will normally fall within the exclusion*".[4]

In 1997, a further decision was released concerning a diagnostic method of Nuclear Magnetic Resonance (NMR) imaging including a step of injecting contrast agents into the body. These agents were not devoid of any risk of side effects (e.g. headache, malaise, fever, generalised lymphadenopathy, arthralgias, urticaria and even fatal anaphylactic shock), and so the method required the involvement of medical and technical staff. The Board therefore said that the above was a diagnostic method excluded from patentability pursuant to Article 52(4) EPC (now Article 53(c)).[5]

Furthermore, in 1999 it was held that those physical interventions on the human or animal body which – whatever their aim – are specifically designed to maintain the life or health of the body on which they are performed are to be considered methods for treatment by surgery within the meaning of Article 52(4) EPC (now Article 51(a)). The Board clarified that this applies both to healing and to cosmetic surgery, and generally to all physical interventions whose application is riskier and more complex, i.e., those interventions aimed at altering functions of the living body (e.g. castration to bring about changes in body functions linked to sex), as well as the removal of body parts (e.g., for transplantation).[6]

3 G1/07 Medi-Physics/Methods for imaging pulmonary and cardiac vasculature and evaluating blood flow using dissolved polarized 129Xe, p. 59.

4 T 24/91 Thompson/Cornea, OJ EPO 1995.

5 T 655/92 Nycomed/Contrast agent for imaging, OJ EPO 1998.

6 T 35/99 Georgetown University/Pericardial access, OJ EPO 2000.

The above decisions from TBA clearly took into consideration risk-related factors.

However, it seems that in G1/07 the position taken by EBA is more straightforward, and attaches more importance to the risks stemming from the application of the examined surgical method than ever before. Indeed, in this decision risk-related factors have been deliberately taken into account several times by the EBA, even in the final order. This did not happen in the previous TBA rulings.

Moreover, the risks which are relevant in G1/07 seem to be more *objectively* related to and stemming from the claimed method, and particularly its physical intervention on the body (without linking the risk factor with the involvement of practitioners). On the other hand, the previous cases heard by TBA linked the medical risk exclusively to the further issue of whether a medical or technical staff should be responsible for carrying out said processes: i.e., a *subjective* requirement. In other terms, by stressing that an invasive method involving a substantial health risk should be excluded from patentability without requiring the presence of medical staff[7], the EBA made such a risk requirement more "objective" (as opposed to the previous TBA decisions).

Such a change in EPO case law is probably also due to a previous opinion released by EBA itself in G1/04 (concerning *inter alia* the proper interpretation of the terms "diagnostic methods")[8]. In this opinion it was held *inter alia* that whether or not a diagnostic method should be excluded from patentability may not depend on the participation of a medical or veterinary practitioner. This is because (i) it is difficult (if not impossible) to provide a definition of medical or veterinary practitioner in Europe within the framework of EPC and (ii) therefore for reasons of legal certainty the European patent grant procedure may not be rendered dependent on the involvement of such practitioners. This appears to be correct, as the exclusion at issue refers to the method, and not to the individual carrying out such method. Likewise, risk factors are related to medical methods as such, not to the further issue of whether medical or technical staff should participate and be responsible for carrying out these processes.

7 Yet the EBA decision added that surgical methods such as the one described in the patent application is excluded from patentability if it also requires professional medical expertise to be carried out.

8 G1/04, OJ EPO 2006 (Reason No 6.1).

Pharmaceuticals

This section updates readers on the latest developments in pharmaceutical law, giving information on legislation and case law on various matters (such as clinical and pre-clinical trials, drug approval and marketing authorisation, the role of regulatory agencies) and providing analysis on how and to what extent they might affect health and security of the individual as well as in industry.

End of the Transitional Period for Traditional Herbal Medicinal Products Coming Soon*

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The transitional period for the application of the rules on traditional herbal medicinal products (THMP) is expiring on 30 April 2011. The approaching end of the transitional period presents a timely opportunity to present some reflections on the regulatory experience and the future perspectives of THMP.

A significant number of medicinal products, despite their long tradition, do not fulfil the requirements of a well-established medicinal use with recognised efficacy and an acceptable level of safety, nor are they eligible for a marketing authorisation. To maintain these products on the market, the Member States have enacted differing procedures and provisions. The differences that currently exist between the provisions laid down in the Member States may hinder trade in traditional medicinal products within European Union and lead to discrimination and distortion of competition between manufacturers of these products. They may also have an impact on the protection of public health, since the necessary guarantees of quality, safety and efficacy could be impaired by the lack of consistent provisions[1]. Moreover, taking into account that THMP are in most cases classified as non-prescription medicinal products (OTC) and that there is a risk associated with possible interactions of herbal substances with other medicinal products, it is important to harmonise EU legislation on THMP.

* All views expressed in this paper are strictly personal and should not be understood or quoted as being made on behalf of the European Medicines Agency.

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1 Please see recital 3 of the Directive 2004/24/EC.