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Functionally defined medical devices at the EPO – is this a thing of the past?

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From a first read, Decision T 1731/12 may have a tremendous impact on the patenting of medical devices at the European patent office. The EPO itself seems to attach quite some importance to the decision because it has provided an official headnote which serves to summarize the relevant content. In our translation, the headnote reads

> "A device which is defined by a feature that can only be obtained by means of a surgical or therapeutic step is excluded from patentability."

So where is the expected impact of this decision? Medical devices are frequently defined by resorting to so-called functional features. Functional features impart a particular clinical context to medical devices, apparatus or systems. The context is often used to argue in favor of patentability over the prior art, which may be structurally extremely similar but used in a different clinical context. The functional features are almost always expressed in method-like language. The method-like language then relates to what the medical device can do in clinical terms, i.e. how it is to be employed or what helps cure.
So what happened in T 1731/12?

European patent EP 1 613 394 had a single independent claim to a device for the desynchronization of activity of pathologically active brain areas. While the opposition was initially based on lack of novelty and inventive step (obviousness) and inadmissible extension (added matter), the opposition division of the EPO ("OD") introduced the opposition ground "exception to patentability" (patent eligibility) on its own motion. The opposition ground was introduced because the claim was thought to relate to a method for treatment of the human or animal body by surgery or therapy. After having introduced the ground, the OD dismissed it. Opponent appealed. In the appeal Opponent also argued patent eligibility. Board of Appeal 3.4.01 (a Physics board) provided a provisional opinion in which it provisionally dismissed the opposition ground raised under patent eligibility, but introduced yet another opposition ground. At such a late stage, case law from the enlarged Board of appeal makes the admissibility of this still other opposition ground be contingent on proprietor consenting. Proprietor did not consent. At the beginning of the oral proceedings, the BoA confronted the proprietor with a reversal of opinion on

eligibility. The Board said that the claimed subject matter would likely, after all, lack patentability. In support, the Board pointed to Art. 53(c) EPC and to T 775/97 (issued by another BoA). The Board ultimately revoked the patent entirely as relating to non-eligible subject matter.

The invention relates to a device for the treatment of Parkinson's disease, essential tremor, dystonia, or the like. This is a group of neurological disorders which the patent said is due to unwanted synchronization of the activities of pathologically active areas of the brain. The device for treating these conditions was claimed to be one for desynchronizing the activities of these areas. The device comprises at least two electrodes and control means. Claim 1 recites that the control means are designed such that, during operation, they control the at least two electrodes such that these stimulate at least two sub-populations of a neuron population to be desynchronized. The stimuli are further defined with reference to phase resets of the sub-populations, and the claim concludes with a functional statement that the stimuli are "such that the at least two sub-populations have different neural-activity phases after the phase resets produced by the stimuli". So in summary and at the risk of over-simplifying, claim 1 contained a requirement that there be control means which is designed such that it emits certain stimuli causing the activity of the sub-populations in the brain to change.

On the face of it, claim 1 is thus directed to a device, not a method; in a typical manner, the device is defined by means of a functional clause relating to the clinical effect. Art. 53(c) EPC, which governs exceptions to patentability or patent eligibility, conversely, is directed to methods, not devices. It says that European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. From this wording alone, one can clearly take that claims to products ought not to fall under the exception. Apparatus, device, or system claims are typically construed as product claims. Furthermore, Art. 53(c) EPC continues by clarifying in its last sub-clause that the provision recited in the first sub-clause "shall not apply to products, in particular substances or compositions, for use in any of the [non-patentable] methods".

There is a sizeable body of case law discussing Art. 53(c) EPC as an opposition ground with respect to apparatus, device, or system claims. The overwhelming majority of cases handled by the EPO found the opposition ground not to apply to these claims. There seems to be one exception, and this exception is also mentioned as authority in T 1731/12. That one exception is T 775/97. After analyzing the function of Art. 53(c) EPC, the prior decision cited as authority, some commentaries on the EPC, further case law, and some of the national statutes on possibly infringing acts, the Board of Appeal in T 1731/12 then came to the conclusion that the device of claim 1 of the opposed patent is non-patentable subject matter. The primary reason for this finding was that the last functional feature of claim 1 (control means which is designed such that it emits certain stimuli causing the activity of the sub-populations in the brain to change) can only be met once the electrodes emitting the stimuli have been implanted. Making devices meeting the functional limitation would therefore require carrying out a step of implantation which, in turn, is a surgical step and which has the consequence that the device itself is not patentable.
On the facts, the board relied on the description of the opposed patent teaching that the control means is to be adapted to the conditions found post-implantation so that the phase reset of sub-populations can be carried out. Adapting the control means, in turn, would be necessary for the proper functioning because the parameter of the stimuli are determined by positioning the electrodes. The specification would distinguish between cases in which the electrodes are placed directly in the neural tissue to be stimulated, and cases in which at least one of the electrodes does not lie in the neuron population to be desynchronized. In the latter cases, the latency of the stimuli

from the electrodes to the neuron population would have to be taken into account and, to this end, be measured. The board could not see how such a measurement can take place prior to implanting the electrodes. Moreover, the specification would mention advantages, and that the position of the implanted electrodes would have to be taken into account so as to achieve these advantages. Again the Board concluded from the specification that the position can only be determined post-implantation so that the control means cannot be configured pre-implantation such that the functional feature is fulfilled.

On the basis of these facts the Board concluded that the claimed device is defined by at least one feature which can only be obtained by way of implantation, i.e. by means of a surgical step.

On the law, the Board recognized the function of Art. 53(c) EPC, namely, that the exceptions to patentability of methods is to protect the medical and veterinary practitioners' freedom to use the best available treatments to the benefit of their patients is uninhibited by any worry that some treatment might be covered by a patent, by excluding these activities from patentability. The board went on to stipulate that decision T 775/97 would have transferred this approach to certain products. T 775/97 would have treated a patent claim reciting a new product which was made by means of a surgical step in the human body. T 775/97 would have decided that a European patent must not be granted to products that are defined by means of a design that can only be made by means of a surgical step in a human or animal body. Further, the Board in T 1731/12 agreed with the consideration it saw in T 775/97, that a product which is defined by means of a surgical step cannot exist without this step so that the surgical step is part of the claimed product.

If one disregards what we think are clear errors in understanding the decision T 775/97 cited as authority, for instance that T 775/97 dealt with a use claim and construed the use to be an activity and the activity to contain a surgical step, that T 775/97 only found the activity non-patentable but found the corresponding product claim patentable, and that the statement that a European patent must not be granted to products that are defined by means of a design that can only be made by means of a surgical step in a human or animal body was only an obiter dictum in the midst of the discussion of an activity, the approach of T 1731/12 to the law is still interesting with respect to how the Board reasoned that excluding products from patentability is not in contradiction to the last sub-clause of Art. 53(c) EPC.

As previously stated, the last sub-clause reads that the exclusion of surgical and therapeutic activities under the EPC shall not apply to products for use in any of the exempted methods. The board took a particular approach in identifying the term "use" as recited in Art. 53(c) EPC. The Board reasoned that this "use" relates to possibly infringing acts. The board then distinguished between "use" as a possibly infringing act versus "making" or "manufacturing" as a different possibly infringing act. For patented products both these acts would be reserved to the patent proprietor.

The decisive difference between these acts would, however, be that using a patented product would generally be allowed once the product has been legally acquired. The proprietor of the patent would then have received the reward he deserves for the invention and the party having acquired the product can freely use it. The Board interpreted the last sub-clause of Art. 53(c) EPC as permitting the patenting of products which can, after acquisition in proper form, be used in a surgical or therapeutic method. The only constraint imposed on medical personnel would then be the obligation to acquire the patented product in conformity with the law.

Manufacturing a patented product, conversely, would necessitate that the medical personnel obtain a license to the method of manufacturing. If there were a surgical or therapeutic step in the method of manufacturing, the medical and veterinary practitioners' freedom to use, which is to be safeguarded by Art. 53(c) EPC, would be impacted. Interestingly, in this connection the Board pointed to the guidelines for examination before the UKIPO where it reads that, pending clarification from the courts, it remains the practice of the UKIPO that if a claimed product can only be manufactured by performing a method of surgery then the claim to the product is objectionable under the UK section on exceptions to patentability. In such a case it will not be possible to work the invention without performing an excluded method.

So in summary, in T 1731/12 Board of Appeal 3.4.01 has terminated a long tradition of defining medical devices by means of functional statement, by giving much weight to a statement in a single EPO decision and by relying on guidelines for examination of a national patent office, if the functional statement results in defining the product such that it can only be obtained by means of a step of surgery or therapy.

For us, this decision creates uncertainty. It also leaves us with a few practice points until the uncertainty has been resolved. The problem with the functional statement was identified in the perceived fact that the claimed function could only be delivered in vivo and in situ. So as to avoid the problem, one could, of course, avoid such functional statements in a claim. In a further step, specifications could be drafted so that they describe alternative ways of delivering the function ex situ, possibly in a machine environment, for instance for testing or calibration purposes. Doing so, however, may well result in a claim which the EPO understands to embrace both, patent eligible and non-eligible subject matter. The current EPO approach to such claims is to request that the non-eligible subject matter be excised from the claim, possibly by means of a disclaimer. It will need to be evaluated if the resulting scope is still of commercial interest.

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