

The patentability of diagnostic and surgical methods in the European Patent Office

Decisions G1/04 and G1/07 address the extent to which a diagnostic method and a method involving an invasive intervention on the body are excluded from patentability under the EPC.

Background

Decision G1/04 of the Enlarged Board of Appeal clarifies that the exclusion of diagnostic methods from patentability should be interpreted narrowly and sets out a rigid framework for assessing whether or not an invention is excluded from patentability.

Decision G1/07 of the Enlarged Board of Appeal provides guidance on the extent to which methods which involve an invasive intervention on the human or animal body are excluded from patentability as surgical treatments. G1/07 is a less prescriptive decision than G1/04 and leaves the precise boundaries of the exclusion to be resolved by the Technical Boards of Appeal on a case-by-case basis.

This practice note gives an overview of those two decisions, and also considers how some of the principles have been interpreted subsequently by the Technical Boards of Appeal.

The European Patent Convention provides specific exclusions from patentability (Article 53(c)) for methods for treatment of the human or animal body by surgery or therapy, and for diagnostic methods practised on the human or animal body.

Decision G1/04

In G1/04, following conflicting decisions from the Technical Boards of Appeal¹, the Enlarged Board, reached a narrow interpretation of the exclusion, and held that a claimed diagnostic method is excluded from patentability only if it includes all of the following steps:

- (i) Examination of the patient and collection of data;
- (ii) Comparing the data with standard values;
- (iii) Noting deviations from the standard values; and
- (iv) Making the diagnosis (i.e. the mental step that involves attributing any deviation from standard values to a particular clinical picture, enabling the choice of therapy to be determined),

with the requirement that any of steps (i) to (iii) which are of a technical nature must all be practised on the human or animal body.

The type of interaction with the human or animal body is irrelevant to patentability: visual observation, X-rays and invasive techniques all qualify as "practised on the human or animal body".

The identity of the person required to perform the method is also irrelevant: the method may be performed by a doctor, vet, support staff, the patient

itself or an automated machine, without impacting on patentability.

If any of steps (i) to (iv) are absent from the claim, the method is not excluded from patentability. Thus, methods which lead to intermediate results but fall short of providing a complete diagnosis, for example, claims to "A method for obtaining blood pressure measurements (or other physical quantities)..." are allowable. The Board did, however, stress that in certain cases it will not be possible to circumvent the exclusion simply by omitting from the claim one of steps (i) to (iv) if that step is essential to the invention as inferred from the specification as a whole.

Claims relating to methods in which one of the technical steps (i) to (iii) is practised *ex vivo* should also avoid the diagnostic methods exclusion, for example if a blood sample were taken from the body and then analysed *in vitro*.

A number of decisions subsequent to G1/04 interpreted these principles, illustrating the availability and importance of method claims for protecting inventions in the diagnostics field. In decision T330/03, a claim directed to "A method for measuring at least one parameter of a sample (e.g. glucose levels in blood)..." was deemed to lead only to intermediate results, rather than a decision on treatment,



and was not therefore excluded from patentability. In decisions T9/04, T41/04 and T504/03, the method claims in question were deemed allowable for similar reasons. On the other hand, the method claim of T125/02 was considered to fall within the exclusion from patentability since all of the steps (i) to (iv) were either present in, or derivable from, the independent claim, and because the sole technical step required the human subject to be present in order to exhale air.

Decision G1/07

Decision G1/07 was concerned more specifically with the patentability of steps involving a physical intervention with the human or animal body. In particular, the Enlarged Board considered whether an intervention step in a patentable diagnostic technique could exclude that method from patentability as encompassing a method of surgery even if that step was not per se aimed at maintaining life and health².

The claims under consideration in G1/07 encompassed an invasive magnetic resonance imaging (MRI) method in which delivery of the contrast agent to a patient was via direct injection into the heart. The Enlarged Board established that an imaging method, in which maintaining the life

and health of the subject is important, and which comprises an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise, is excluded from patentability as “*a method for treatment by surgery*”.

The Board clarified that it was the **nature** of the physical intervention that determined whether a method was excluded from patentability. It felt unable to give an authoritative definition of what constitutes an excluded surgical method (instead leaving the Technical Boards to decide on a case-by-case basis), and **indicated that methods involving only a minor intervention and no substantial health risks may not be excluded**. Given the advances in safety and the routine nature of certain invasive techniques, the Enlarged Board concluded that it would be incorrect to exclude all such methods from patentability.

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¹ T385/86 (BRUKER/Non-invasive measurement) interpreted the diagnostic exclusion narrowly, and held that a method was excluded only if its result makes it immediately possible to decide on a particular course of medical treatment. It also required the claimed method to contain all the steps involved in reaching a medical diagnosis. The method would also be excluded if any one step required a doctor. In contrast, T964/99 (CYGNUS/Diagnostic method) interpreted the exclusion broadly and held that a method was excluded if it contained at least one step which was (a) of a diagnostic character, and (b) practised on a living human or animal body, and that the identity of the person performing the method was immaterial.

² This issue had already been explored in a number of decisions. T182/90 and T35/99 concluded that the nature of the intervention with the human or animal body was decisive in assessing whether a method constitutes an excluded “surgical method”. On the other hand T1102/02 and T383/03 suggested that the purpose of the intervention was of importance.