

GERMANY



**Maiwald Patentanwalts
GmbH
Munich**

Martin Huenges



*and
Dirk Buehler*

Patentability of diagnostic methods clarified

The Enlarged Board of Appeal has laid down the criteria that allow a practitioner to assess whether a diagnostic method is excluded from patentability under Article 52(4) EPC. In Opinion G1/04 of December 16 2005, the Board sets a liberal standard for the patentability of diagnostic methods.

G1/04 confirms that the method steps to be carried out when making a diagnosis consist of: (i) an examination phase, during which data are collected; (ii) comparing these data with standard values; (iii) finding any significant deviation, that is, symptoms, during the comparison; and (iv) attributing the deviation to a particular clinical picture, that is, the deductive decision phase. Steps (i) to (iii) are constitutive for making a diagnosis and may include technical and non-technical steps. Step (iv) is regarded as the diagnosis *stricto sensu*, which is an intellectual exercise by the medical practitioner or is made by a device.

G1/04 stresses that a method can only be excluded from patentability under Article 52(4) EPC if it claims *all* of the steps (i) to (iv).

The Board also referred to the danger of circumventing the patent exemption of Article 52(4) by omitting one of steps (i) to (iv) in a method claim. If a method claim is directed to a diagnostic method, all the steps are essential and must be included to comply with Article 84 EPC. If not all of steps (i) to (iv) are included, the claim should not be directed to a method of diagnosis, but for example, to a method of data acquisition or data processing.

Further, G1/04 made clear that the diagnostic character is not correlated with the participation of a medical or veterinary practitioner by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medical or non-

medical support staff, the patient, or an automated system.

Lastly, to be a diagnostic method exempted from patent protection, all of the method steps of a technical nature among the steps (i) to (iii) have to be performed on the human or animal body. The Board stated that any interaction necessitating the presence of the body fulfils this requirement. However, this means that, even if a method claim is directed to a method of diagnosis, and even if this claim comprises all these four steps, the method is not exempted from patentability if one of the steps preceding to the diagnosis *stricto sensu* is not performed on the body, for example, if body fluids are extracted and treated or analyzed in a device outside the human or animal body.