

EIP

The Concept of “Technical Character” becomes increasingly relevant for healthcare patents – Lessons from Recent EPO BoA Decisions

As patent attorneys practicing in the healthcare sector, we are encountering more and more inventions which straddle the life and computer science fields. AI and smart technologies are now a central feature in many medical technologies.

In claims incorporating the use of computer technology, a key consideration is that the invention must have “technical character”. The case law in this area typically concerns technologies which are far removed from the inventions arising in the healthcare and pharmaceutical sectors. However, recent decisions are highlighting that more and more cases that intersect digital and healthcare are now reaching the Boards of Appeal at the European Patent Office. The background technology in these decisions is more similar to what we see in our practice, providing a more relatable perspective on the technical character criteria than what has gone before.

T-1234/17; Use of physiological data in customised footwear design

T-1234/17 relates to use of physiological data from sensors to customise an item of sports footwear. In itself, the decision seems non-controversial, but it is worth discussing to highlight practice points to bear in mind when drafting applications for related healthcare technologies. The application was refused by the examining division, who found the claims to be insufficiently technical in character. At the outset of the appeal proceedings the claims were directed to a computer implemented method for customization of a piece of footwear. To summarise claim 1; data from sensors, including a time series of acceleration vectors is processed through a "data analysis module" which applies a "model of human physiology" to associate the data with a category of human gait (supination, pronation, over pronation or neutral); a customized design for the piece of footwear is then determined.

The Board took the view that the claimed invention came down to two mappings the first maps sensor acceleration data to gait category. The second maps the gait category to a "customized design". The Board considered whether the mere idea of mapping the acceleration data to gait category is technical; this is a question which arises in many inventions which involve mappings and algorithms, and so to guide the decision the Board referred to T 1798/13 (Forecasting the value of a structured financial product/SWISS REINSURANCE COMPANY LIMITED), in which it was held that it was not enough that a technical quantity in the form of a measured physical parameter (weather data). What matters is whether the algorithm reflects any additional technical considerations about the parameter such as its measurement; in that case there were none. They contrasted this with the decision taken in T 2079/10 (Steuerung von zellulären aufgebauten Alarmsystemen/SWISSRE) where the invention was seen to lie in the improvement of the measurement technique itself, which involved considerations about the sensors and their positions.

However, in the case in question, the claim only specified that the data "includes a time series of acceleration vectors" and that this data is "analyzed". There are no further details that could constitute technical considerations about the data or the sensors. The Board therefore considered that the mere idea of mapping acceleration data to gait category could not contribute to inventive step. However, if the claim had included details of a new implementation of the sensors, then this could have been acknowledged as inventive.

The Board went on to consider whether there was any technical character in mapping the gait category to customized design of the footwear. They pointed out that the claim language covers the example in the description of "assisted selection from a set of predetermined item configurations" which could be simply choosing a particular shoe

suitable for the user's gait, possibly with the help of a shop assistant. It could also mean to generate a customised graphic visualisation of the shoe with selected parameters. Hence it was a lack of detail in the claim and description which led the Board to conclude that there were also no real technical considerations involved in designing the customized footwear. Therefore, the aspects which had been argued to imbue the claims with inventive step were considered non-technical, and the claims to lack inventive step as a consequence. The appeal was dismissed.

Inventions concerning methods of using physiological data to customise patient experience is encountered often by patent attorneys working in the healthcare field. Examples include using sensor data to design a splint for physiotherapy, a medical implant, or use of wearables etc. Whilst the decision in T-1234/17 was not controversial; it serves as a useful reminder to ensure that inventive features which are appropriately technical are included in the application during the drafting stage, and also to draft fallbacks to exclude non-technical implementations (such as, in this case, assisted selection of footwear by shop assistants).

T 0752/19 - The “unbroken technical chain fallacy” applied to a second medical use claim

In the healthcare and pharmaceutical fields, the outcome of using data or AI technology often has a clear physical endpoint in affecting healthcare outcomes, therefore, in contrast to inventions in the software field, it could be expected that features having true technical character would be readily available to include in MedTech/Pharma claims. However, a recent decision T 0752/19, highlights that in cases where the advantage of an invention can be seen to lie in modifying the behaviour of a patient (or consumer), we should be alert to the possibility that the invention could be considered non-technical in some instances.

T 0752/19 invokes the “unbroken technical chain fallacy” in relation to a second medical use claim. The concept of the “unbroken technical chain” was coined by the Board in T 1670/07, in which it outlined a range of common arguments that patent attorneys typically raise when contesting objections concerning the technical character of inventions.

The claims in T 0752/19 related to a combination of drugs (Ticagrelor for use in a treatment of Acute Coronary Syndrome or myocardial infarction, in combination with

acetyl salicylic acid) and a computer programme product. The second medical use of the combination therapy was already known at the priority date of the application, therefore the steps undertaken by the computer programme were relied upon for inventive step. To summarise, claim 1 specified that the computer programme product asked a set of questions, ultimately providing feedback to the patient. The appellant argued that the computer programme increased patient compliance with treatment and noted that improved patient compliance had been acknowledged as the technical effect of the claims in a previous decision, T 0970/12.

The Board, however, pointed out that the improvement in patient compliance in the decision referred to by appellant was brought about by a direct improvement of the pharmaceutical composition in question. In contrast, there was no improvement to the pharmaceutical composition in the case in suit. Improved patient compliance could be recognised as the overall technical effect of the distinguishing features of claim 1 only if it were shown to arise objectively in an unbroken technical chain from the intrinsic properties of the claimed pharmaceutical formulation. In general, in a pharmaceutical formulation exhibiting improved patient compliance, the intrinsic properties of the improved pharmaceutical formulation either lead to fewer side effects or make the administration of the pharmaceutical formulation into the patient's body easier, thus objectively lowering the risk of discontinuation or interruption of the therapy regimen.

Any improved patient compliance in the case at hand, is instead the result of a "broken technical chain" (see T 1670/07, point 11 of the Reasons), namely an alleged chain of technical effects starting with information provided to a patient which is then broken by the patient's mental activities. In the case at hand, the possible final technical effect of improved patient compliance brought about by a computer program generating and presenting patient-specific feedback is conditional on the patient's mental activities and so cannot be used to establish an overall technical effect. This is analogous to the information provided on a package insert, rewarding the patient, or providing a wall chart with check boxes, which would also not produce any technical effect in an unbroken technical chain.

The Board contrasted this with the scenario in the previous case referred to by appellant (T 0970/12) in which an unbroken technical chain could be traced starting from "the addition of hyaluronic acid or a salt of ester thereof with a low molecular weight or an intermediate weight at a concentration of between 0.01% and 1%, instead of quinine sulfate" to an inhalation formulation, which led to "better local tolerability, with a reduction in the inflammatory component affecting the mucosa of the airways", which in turn led to "a lower risk of discontinuance of the treatment", ending thus in "good patient compliance" (see point 2.3.1 of the Reasons).

Interestingly, in the case at hand, the computer program which was in accordance with claim 1 had received EU approval as a medical device, and appellant argued that this was clear evidence of technical character, given the technical hurdles for regulatory approval. The Board was dismissive of this argument stating, "regulatory approval of a device has no relevance to the assessment of its patentability in accordance with the EPC" (reasons 2.6).

The Board concluded that the distinguishing features of claim 1 of the main request did not have any overall technical effect and thus did not involve an inventive step and the appeal was dismissed.

The outcome of this appeal is unsurprising to many who would have suspected the claims could run foul of the EPO's requirements for patentability. Nevertheless, it is interesting to see the "unbroken technical chain fallacy" appear in a Board of Appeal decision relating to Pharma, and it will undoubtedly be useful to have the guidance of such a decision in relation to technologies we encounter in practice.

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