Disembodied Embodiments: Medical Device Strategy for PCT and Foreign Applications

by

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This paper explores the problem of how to protect new medical technology, particularly under circumstances in which device protection may be viewed as unavailable, difficult to obtain, or insufficient. Under these circumstances, it becomes desirable to seek protection for methods that are practiced in using the device. Specifically, we address strategic considerations in seeking patent protection, for methods that may be practiced by medical devices, especially in the European Patent Office.

Let us consider an example taken from the real world, based on European patent application 03 726 057.[2] In this case, one aspect of novelty of the technology in question resides in use of a filter having a pore size that differs from the prior art. Here is a picture:

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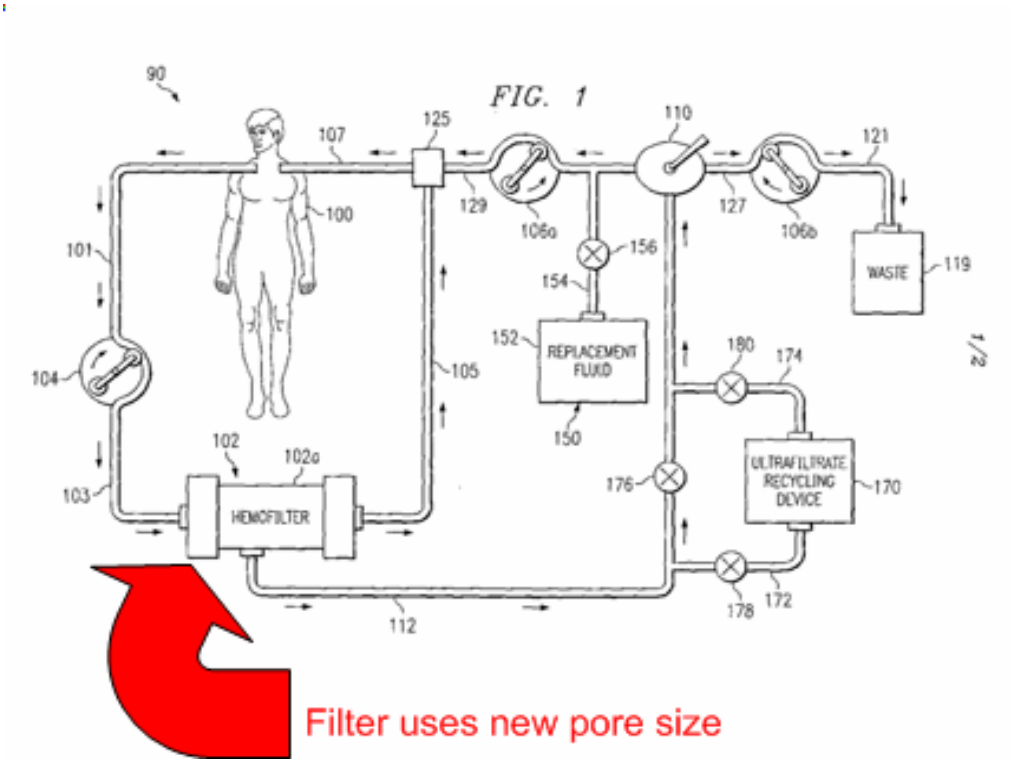
[2] The author had responsibility for a period of time in prosecuting this application in cooperation with Clive Froud, a European Patent Attorney, http://www.cfroud.co.uk. All information divulged in this paper concerning this application is based strictly on the public record available from the website of the European Patent Office.



A method claim directed to this technology, in a form similar to what appeared in the international application under the Patent Cooperation Treaty, is reproduced below.

12. A method of removing target molecules from a patient's blood, comprising:

circulating a stream of the patient's blood through a very large pore hemofilter having a nominal molecular weight cutoff greater than 150,000 Daltons to sieve the target molecules from the blood stream and the nominal molecular weight cutoff less than 1,000,000 Daltons to avoid removal of significant amounts of immunoglobulin and similar large molecules to prevent increasing the risk of opportunistic infection;

removing an ultrafiltrate containing the target molecules and target complex molecules from the blood stream using the hemofilter;

replacing the ultrafiltrate removed from the blood stream with a replacement fluid having clean target receptor molecules;

providing sufficient clean albumin to maintain adequate plasma oncotic pressure; and

providing the clean albumin and clean target receptor molecules to attract additional inflammatory mediators and toxins from tissue spaces and tissue binding sites in a patient.

We might ask whether anything is wrong with this claim structure for use in the United States Patent and Trademark Office. The answer is simply, "No."

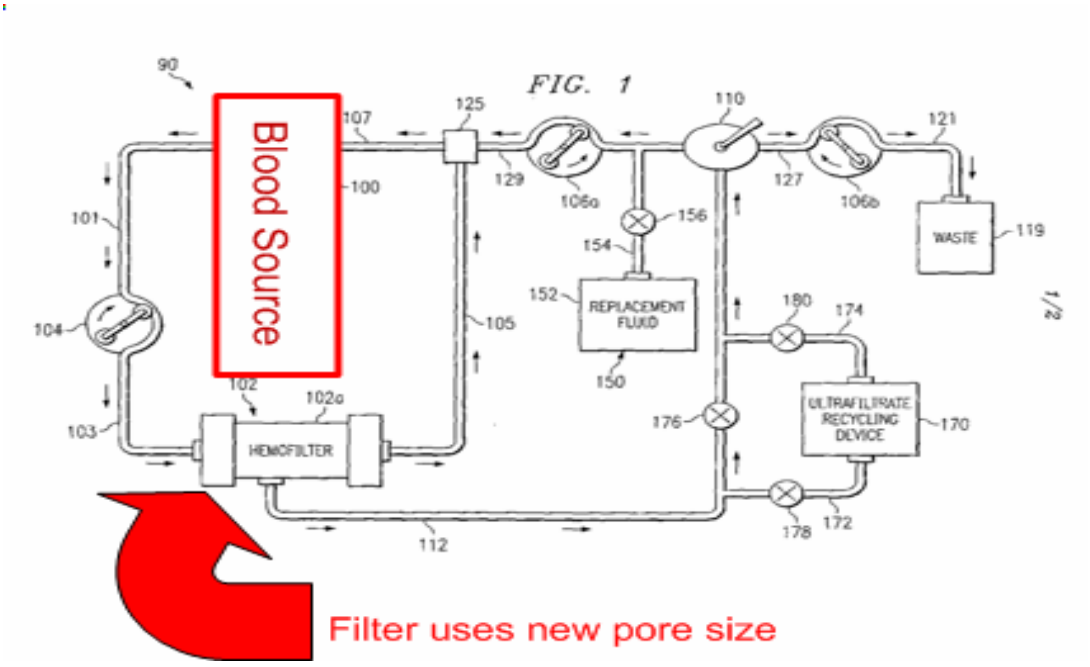
However, the claim structure ran into a problem in the European Patent Office. The European Patent Office objected to the claim: "Claim 12 is directed to a method for treatment of the human or animal body by therapy, which cannot be allowed under Art. 53(c) of the European Patent Convention."

The referenced section of the European Patent Convention reads as follows:

"53. European patents shall not be granted in respect of: …(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

How should one respond to such an objection? The apparatus performs a new method, but the method claim does not define patent eligible subject matter, according to the EPO. What has destroyed patent eligibility in the EPO? — It is the human body.

Accordingly, one way of attempting to restore patent eligibility is to remove from the claims that which destroyed patent eligibility to begin with, namely the human body. Accordingly, we can argue that the technology being claimed is not as pictured on the previous page but rather like this:



With this figure, the human body is gone, and in place of the human body is simply a blood source from which blood is removed and to which processed blood is returned. With a revised technological concept, may be presented a revised claim, with respect to which the human body has been correspondingly removed:

A method for removing one or more toxic substances from blood previously withdrawn from a patient, characterized in that the method comprises:

delivering the blood to a hemofilter having a molecular weight cutoff of greater than 150,000 Daltons and less than 1,000,000 Daltons so as to create a return stream and an ultrafiltrate stream;

transferring at least a portion of the ultrafiltrate stream;

providing the return stream for subsequent return to a patient; and

providing a fluid, containing target receptor molecules not contaminated with or bound with target molecules, for subsequent provision to a patient.

The revised claim was not happily received by the EPO: "The objection under Art. 53(c) EPC raised against former claims 12 to 15 which have been replaced by claims 1 to 12 presently on file is maintained, since claim 1 represents a medical method of treatment of the human or animal body by therapy although the applicant tries to hide the real nature of the method claimed by removing some features from claim 17 as published and claim 12 filed on 17.10.2005."

One might question how the examiner can determine what is "the real nature of the method claimed" and that "the applicant tries to hide" it. Moreover, the wording of the objection suggests that presenting the claim the first time around in the new language might have been successful, since "the real nature of the method claimed" would never have been shown to the examiner.

One might similarly imagine a slightly different approach to the claim while still keeping the human body out of the claim. We might have worded the claim this way:

A method for removing one or more toxic substances from blood from a blood source, characterized in that the method comprises:

delivering the blood from the source to a hemofilter having a molecular weight cutoff of greater thant 150,000 Daltons and less than 1,000,000 Daltons so as to create a return stream and an ultrafiltrate stream;

transferring at least a portion of the ultrafiltrate stream;

providing the return stream for subsequent return to the blood source; and

providing a fluid, containing target receptor molecules not contaminated with or bound with target molecules, for subsequent provision to the blood source.

How would these claims fare in the EPO? We cannot provide a definitive answer. Successor counsel withdrew the objected to claims. On the other hand, the EPO action suggests that claims drafted along these lines would have had a better chance for success if presented in that form initially rather than after amendment.

The present example suggests that an application to be filed outside of the United States, having method claims that may be rejected as directed to patent-ineligible therapeutic methods, can benefit from drafting revisions that remove the human body from relevant figures and claims. Hence, these considerations apply not only to applications to be filed in the European Patent Office but also to international applications to be filed under the Patent Cooperation Treaty. Preferably, the application with such kinds of claims can be constructed from the ground up in advance of filing, so as to obviate the need for amendment of an application that has already been filed.