PATENTS EXAMINATION BOARD

Subject:	The Drafting of Patent Specifications - Paper 2
Date:	October 2016
Time:	09h00 -13h00 (although candidates requiring extra time are entitled to an additional two hours)
Examiners:	J Fiandeiro V Williams
Moderator:	J D Whittaker

Attached is an instruction from your client detailing an invention.

You are required to draft a full patent specification for your client's invention. The full patent specification must include: (1) a background to the invention, (2) a summary of the invention, i.e. consistory clauses, (3) a brief description of the drawings, (4) a detailed description of the invention, (5) a set of patent claims, and (6) an abstract.

Marks will be allocated as follows:

- 50% of the marks will be allocated to the claims.
- 50% of the marks will be allocated to the rest of the specification.

In order to obtain a pass for this paper, candidates must obtain not less than 40% for each of these two sections.

Your client writes:

"I have developed an aneurysm repair method and device.

An aneurysm is an excessive localised swelling (corresponding to the upper part of attached Figure 2) of the wall of a blood vessel (the lower part of Figure 2). Aneurysms typically arise as a result of an abnormal, weak spot on the blood vessel, which causes an outward bulging or swelling of the blood vessel. An aneurysm can affect any vessel in the body, but is particularly serious when it forms within the brain. In such a case, if/when an aneurysm ruptures, blood escapes and damages surrounding delicate brain tissue. This is called a haemorrhagic stroke, and can lead to brain damage and death.

Brain aneurysms are often only discovered when they rupture. The aim, of course, is to treat brain aneurysms before they rupture. Currently, aneurysms are treated by means of open surgery "clipping." In this procedure, a neurosurgeon makes an incision in the skin over the head, makes an opening in the skull and dissects through the spaces of the brain to place a clip across the aneurysm where it extends from the blood vessel. This prevents the blood flow from entering the aneurysm in the first place. Although there have been considerable advances in open surgery techniques, open surgery "clipping" remains an invasive and dangerous procedure.

I have developed an aneurysm sealing device to provide a way of repairing aneurysms endovascularly i.e. from within the blood vessel itself. This is a far less invasive procedure, when compared to the open surgery clipping procedure described above.

As shown in Figure 1, in my preferred version, the device 10 comprises a dual catheter arrangement comprising an inner catheter 12 movable within an outer catheter 14, the outer catheter 14 acting as a sleeve. Fabric sheaths 16, 18 are

fitted to the dual catheter arrangement, and are joined together by a separator 20.

In particular, when looking at the orientation of the device 10 in Figure 1, the upper end of the sheath 16 is fitted to the upper end of the inner catheter 12, and the lower end of the sheath 18 is fitted to the upper end of the outer catheter 14. The fabric sheaths 16, 18 may be secured to the catheters 12, 14, respectively, with O-rings or any other fastening or bonding arrangement. The sheaths 16, 18 are typically compressible biocompatible fabric material sheaths 16, 18, which are arranged to deform in order to repair the aneurysm.

In use, the device 10 is partly inserted from within the blood vessel into the aneurysm, as shown in Figure 2, so that the sheath 16 is located within the aneurysm and the sheath 18 is located within the blood vessel; the separator 20 is thus positioned proximate the "neck" of the aneurysm.

The outer catheter 14 is then slid over the inner catheter 12, which compresses the fabric sheaths 16, 18 longitudinally so as to cause the sheaths 16, 18 to balloon outwardly in a fusiform fashion, as shown in Figure 3. As the outer catheter 14 continues to slide over the inner catheter 12, the sheaths 16, 18 shorten further to form an oblate spheroid shape (Figure 4) and then a discoid shape (Figure 5). As the longitudinal compression of the sheaths 16, 18 continue, the sheaths 16, 18 ultimately define a flattened disc-like shape (Figure 6). It is the final disc-like shape of the fabric sheaths 16, 18 that occludes the opening of the neck of the aneurysm, so as to seal off the aneurysm. The catheters 12, 14 may of course then be separated from the sheaths 16, 18 and removed, as indicated in Figure 6.

Although two sheaths are shown, with suitable modifications, I believe that it would be possible to achieve the same result with only one sheath i.e. sheath 16. However, by using two sheaths 16, 18 in series (one on either side of the

separator 20), as shown in the drawings, and compressing them simultaneously as described above, the opening of the neck of the aneurysm can be sealed by sandwiching the opening of the neck of the aneurysm between two discs of fabric, which would then simply be left *in situ*.

In the version described above, the fabric sheaths 16, 18 are manually compressed into the disc-like body. Depending upon the material of the sheaths 16, 18 and the particular application, it may be necessary to provide an internal connector of sorts to maintain the flattened disc-like shape shown in Figure 6. In this regard, the O-rings could be connected to each other, or the O-rings could be connected to the separator 20.

In an alternate version, the fabric used for the sheaths 16, 18 may have shape memory properties. In this version, the sheaths 16, 18 would be constructed to have a desired/required shape, similar to the flattened disc-like shape shown in Figure 6, when at rest. In use, the catheters 12, 14 may then be manipulated so as to stretch the sheaths 16, 18, under tension, into an extended sheath-like shape, of the type shown in Figure 1. Once the fabric sheaths 16, 18 have been positioned appropriately across the opening of the neck of the aneurysm, the sheaths 16, 18 may be allowed to relax, thereby allowing the fabric to spontaneously return to its original shape, which is the desired/required disc-like shape shown in Figure 6, by virtue of its shape memory properties.

Please prepare a patent specification for my invention."







