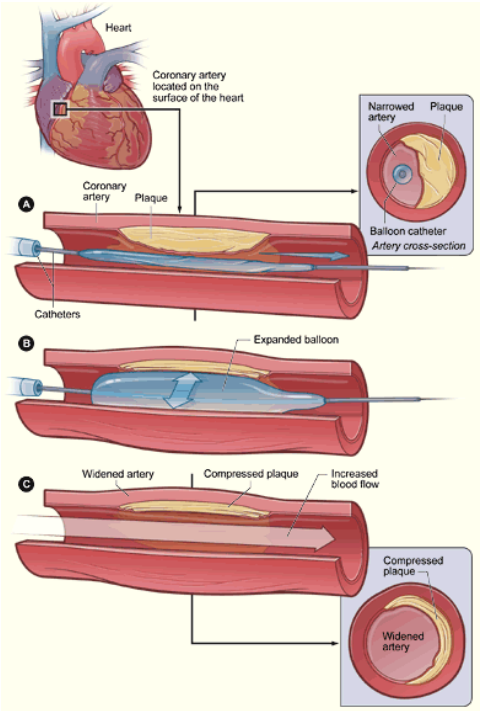
JAUIP 2016 Summer IP Seminar (Practitioner Course)

Fundamentals of Dispute Resolution in Japan and the United States

Fact Pattern

I. Introduction

Messi Medical, Inc. (Messi), a U.S. medical device company, owns U.S. and Japanese patents drawn to features of balloon dilatation catheters: U.S. Patent No. 9,xxx,333 and JP3xxx555. Each of the two patents has a single claim with the identical scope and the same disclosure. Balloon dilatation catheters are typically used in coronary angioplasty procedures to remove restrictions in coronary arteries. Messi also manufactures and sells balloon dilation catheters worldwide.



Ronaldo Cardiovascular Co. (Ronaldo) is a major Japanese manufacturer of catheters used in coronary angioplasty procedures, and its balloon dilation catheter product, “DuoLumen,” is most widely used balloon dilation catheter in the world. Ronaldo and Messi are competitors in the field of balloon dilatation catheters.

Messi filed suit against Ronaldo in the United States District Court for the Northern District of California and Tokyo District Court, charging Ronaldo with infringement of Messi’s U.S. and Japanese patents.

II. Messi's U.S. and Japanese Patents

The present invention relates to a dilatation balloon catheter having a guide wire lumen extending through a balloon of the catheter, which is most widely used for angioplasty. Typically, a catheter with a balloon is used to guide the balloon through the vascular system to a position near a stenosis, and the balloon is inflated by supplying fluid through an inflation lumen in the catheter to stretch the artery and press the lesion into the artery wall, to reestablish blood flow through the artery. There has been a continuing effort to reduce the profile and shaft size of the catheter so that the catheter not only can reach but also can cross a very tight stenosis. A dilatation catheter must also be sufficiently flexible to pass through tight curvatures in the coronary arteries. A further requirement of a dilatation catheter is its "pushability," which involves the transmission of longitudinal forces along the catheter so that a physician can push the catheter through the vascular system and the stenosis.

Two commonly used types of dilatation catheters are referred to as "over-the-wire" catheters and "non-over-the-wire" catheters. An over-the-wire catheter is one in which a separate guide wire lumen is provided in the catheter so that a guide wire can be used to establish the path through the stenosis. The dilatation catheter can then be advanced over the guide wire until the balloon on the catheter is positioned within the stenosis. One problem with the over-the-wire catheter is the requirement of a larger profile and a generally larger outer diameter along the entire length of the catheter in order to allow for a separate guide wire lumen therethrough.

A non-over-wire catheter acts as its own guide wire, and thus there is no need for a separate guide wire lumen. One advantage of a non-over-the-wire catheter is its potential for a reduced outer diameter along its main shaft. However, one disadvantage is the inability to maintain the position of the guide wire within the vascular system when removing the catheter and exchanging it for a catheter having a smaller (or larger) balloon diameter.

The present invention is an over-the-wire dilatation balloon catheter having a guide wire lumen. As shown in FIG. 1, a balloon dilatation catheter 20 has a main shaft section 22, an intermediate sleeve section 24, and a balloon 26. In use, the main shaft section 22 is coupled to an inflation device (not shown) that provides or removes inflation solution to selectably inflate or deflate the balloon 26.

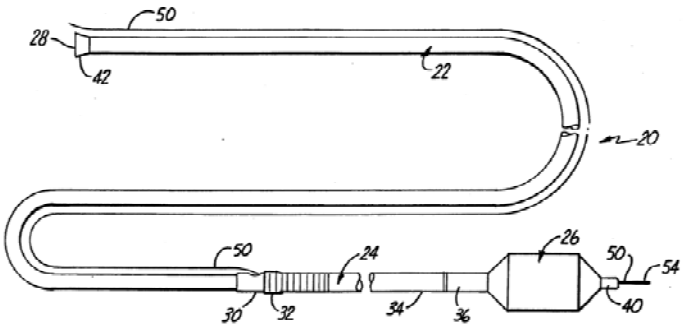


FIG. 1

FIG. 2 shows the intermediate sleeve section 24 and the balloon 26. FIG. 3 is a sectional view of the intermediate sleeve section 24 in FIG. 2. The intermediate sleeve section 24 extends from the main shaft section 22 and has an inner core tube 80 and an outer sleeve 82. The core tube 80 defines the guide wire lumen 52 extending through the catheter 20. The outer sleeve 82 is tubular and arranged coaxially with the core tube 80 to define an annular inflation lumen 104. The inflation solution from the inflation device travels through the annular inflation lumen 104 to inflate or deflate the balloon 26. The balloon 26 is connected to the intermediate sleeve section 24. An interior 106 of the balloon 26 is sealed and in fluid communication with the annular inflation lumen 104 within the sleeve section 24.

The intermediate sleeve section 24 and the balloon 26 of the catheter 20 allows the catheter 20 to have a reduced diamter size and to be very trackable and flexible in order to negotiate the tortuous coronary anatomy to and across the lesion. Moreover, this design allows the cathether 20 to be sufficiently stiff to enhance the “pushability.”

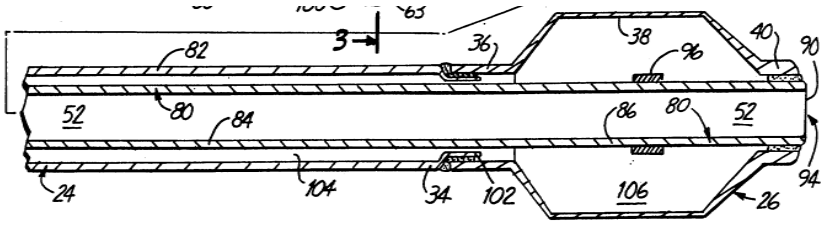


FIG. 2

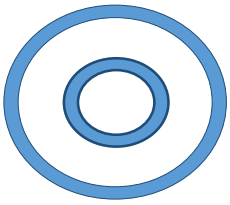


FIG. 3

Claim:

1. A balloon dilatation catheter comprising:

a main shaft section;

an intermediate sleeve section extending from the main shaft section, the intermediate sleeve section including an inner core tube having a guide wire lumen extending therethrough and an outer sleeve extending over the inner core tube to define an inflation lumen between the inner core tube and the outer sleeve, the inner core tube and the outer sleeve being arranged coaxially;

an inflatable balloon extending from the intermediate sleeve section and being in fluid communication with the inflation lumen.

III. Ronaldo's Product, "DuoLumen"

Ronaldo's balloon dilation catheter product, DuoLumen, has a similar structure to the subject matter of claim 1 and has a tube section, an intermediate tube section, and a balloon. The intermediate tube section of DuoLumen, however, has two tubes, each creating inflation lumen and guide wire lumen, respectively, and the two tubes are arranged side-by-side in the intermediate tube section of the catheter. The cross-section of the intermediate tube section of DuoLumen is shown in the figures below.