Date: 20080508

Docket: T-1822-97

Citation: 2008 FC 552

BETWEEN:

JOHNSON & JOHNSON INC.,
EXPANDABLE GRAFTS PARTNERSHIP
and CORDIS CORPORATION **Plaintiffs**
and

BOSTON SCIENTIFIC LTD./
BOSTON SCIENTIFIQUE LTÉE

Defendant

REASONS FOR JUDGMENT
[Confidential Reasons for Judgment issued on April 30, 2008]

LAYDEN-STEVENSON J.

[1] The introduction of stenting revolutionized the treatment of coronary heart disease. A stent is a medical device. It is inserted through the skin, usually into an artery, and is guided to an occluded or diseased body passageway requiring repair.

[2] The plaintiffs are the alleged successive owners of two Canadian patents. Both patents claim invention over a form of balloon-expandable stent. In this action, the plaintiffs assert that the defendant manufactured and sold a device, specifically a coronary artery stent, which infringed their patents. The defendant denies the allegation and contends, among other things, that the patents in suit are invalid. I conclude that one of the patents is valid and the other is not. I also conclude that the defendant's device does not infringe.

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Introduction

[3] Canadian Letters Patent No. 1,281,505 entitled “Expandable Intraluminal Graft, and Apparatus for Implanting an Expandable Intraluminal Graft” (the '505 Patent or the Palmaz Patent), naming Julio C. Palmaz as inventor, was issued to Expandable Grafts Partnership (EGP) on March 19, 1991.

[4] Canadian Letters Patent No. 1,330,186 entitled “Expandable Intraluminal Graft” (the '186 Patent or the Palmaz-Schatz Patent), naming Richard A. Schatz and Julio C. Palmaz as co-inventors, was issued to EGP on June 14, 1994.

[5] The '505 Patent generally relates to a graft or prosthesis, namely a stent, which is a device that can be used to expand and reinforce blood vessels. The stent is inserted into the lumen (channel) of a body passageway in its original diameter, delivered to an appropriate location within the body passageway, and then expanded to a larger, variable diameter controlled by the amount of force applied to the stent.

[6] The '186 Palmaz-Schatz Patent generally relates to an articulated graft or prosthesis, namely a stent, comprised of a plurality of tubular members which are connected together by one or more connector members. The Palmaz-Schatz stent is similarly inserted into the lumen of a body passageway in its original diameter, delivered to an appropriate location within the body passageway, and then expanded to a larger, variable diameter controlled by the amount of force applied to the stent.

[7] Johnson & Johnson, a United States corporation having its head office in New Brunswick, New Jersey (the parent company), is an umbrella corporation over its related and divisional companies.

[8] By a purchase agreement effective February 26, 1999, Cordis Corporation, a Florida corporation purchased by the parent company in the mid 1990s (Cordis), obtained the rights with respect to the '505 and '186 Patents from the now-defunct EGP.

[9] By assignment executed July 13, 1999, Cordis assigned its rights in the '505 and '186 Patents to Johnson & Johnson Inc., a corporation incorporated pursuant to the laws of Canada (Johnson & Johnson) and a consumer division of the parent company.

[10] Johnson & Johnson maintains that, from the date of issuance or reissuance of the noted patents until February 26, 1999, EGP had licensed Johnson & Johnson, through the source company Ethicon Inc. (Ethicon) of Somerville, New Jersey (presumably another of the parent company's corporations) to market the patented devices. Cordis then licensed Johnson & Johnson under the '505 and '186 Patents. Relying on section 55 of the *Patent Act*, R.S.C. 1985, c. P-4 (the Act), Johnson & Johnson claims to be a person claiming under the patentees, EGP and Cordis, from the date of issuance of the respective patents until July 13, 1999. Thereafter, Johnson & Johnson maintains that it has been the patentee.

[11] Since 1997, Boston Scientific has sold a device in Canada known as the NIR stent. Johnson & Johnson assert that Boston Scientific, by selling the NIR stent in Canada, has infringed upon the

rights of the plaintiffs, Johnson & Johnson, EGP and Cordis, without the license or consent of the plaintiffs.

[12] Boston Scientific denies the allegations of infringement and also contends that, by virtue of admissions made by the plaintiffs and their privies and findings of fact in litigation in other jurisdictions relating to patents which claim priority from the same United States applications as the patents in suit, the plaintiffs are precluded and estopped from alleging that the NIR stent infringes the patents in suit.

[13] Boston Scientific, by counterclaim, asserts that the alleged inventions described and claimed by the patents were obvious and lacked inventive ingenuity. Further, the “invention” of the '505 Patent was anticipated.

[14] The applications for the patents in suit were filed before October 1, 1989. Consequently, the provisions of the Act, as they read before that date, apply. For clarity and convenience, all references to the provisions of the Act throughout these reasons relate to, and should be taken to be, references to the Act as it read prior to October 1, 1989. There is no need to repeatedly designate the applicable provisions as “former” provisions and I do not intend to do so.

Background

[15] This non-contentious background is derived principally from the evidence of expert witnesses Doctors Buller and Cumberland. Their respective qualifications are discussed later in these reasons.

[16] Coronary heart disease is caused by narrowing or blockage of the coronary arteries which supply the heart muscle with blood. The usual cause of arterial narrowing is a gradual build up of fatty material in the arterial wall. The fatty deposits can become calcified and hardened thereby producing plaque. This process is known as atherosclerosis. The plaque can protrude into the lumen of the artery and narrow it (this is known as stenosis). As the lumen becomes progressively more narrowed, the stenosis can lead to a complete or partial blockage (occlusion). The heart muscle fed by the stenotic artery then becomes deprived of oxygenated blood. This may eventually result in chest pain (angina). If the lumen of the artery suddenly closes off, blood flow ceases and results in a heart attack (myocardial infarction) or death.

[17] Arterial disease affects other organs as well. For present purposes, we are concerned with cardiac heart disease (ischemia). Until 1977, there were only two treatments for ischemic heart disease: surgical coronary artery bypass grafting and drug therapy. Drug therapy is not relevant here.

[18] Surgery usually took (and takes) the form of open heart coronary artery bypass grafting (CABG). During this operation, a graft is sutured across the site of the occlusion, providing an alternative pathway for blood flow. The graft usually consists of a blood vessel taken from another part of the body, preferably an artery. The procedure constitutes major surgery and involves general anaesthesia and significant trauma for the patient.

[19] In 1964, Dr. Charles Dotter reported having treated arterial narrowing in the peripheral leg arteries by inserting a series of increasingly larger diameter catheters through the femoral (thigh) arteries and, using x-ray screening, pushing them through the narrowed or blocked section. This procedure was labelled “transluminal dilation”. It was performed under local anaesthetic. The label for insertion “through the skin” is percuntaneous. Dr. Dotter’s method was limited by the fact that a channel only as wide as the arterial entry site could be produced. Additionally, the technique could not be applied to any arterial territory remote from the entry site (such as a coronary artery) because it was known that flexibility would be necessary to negotiate the bends involved. Dr. Dotter’s paper entitled “Transluminal Treatment of Arteriosclerotic Obstruction” predicted eventual application of the technique to the coronary vessels.

[20] In 1977, after successful work in the peripheral arteries, Dr. Andreas Grüntzig first performed percuntaneous transluminal coronary angioplasty (angioplasty).

[21] This angioplasty procedure involves passing an outer catheter called a guide catheter through the skin (most often through the femoral artery in the groin or an artery in the arm) under x-ray control and steering it to the main coronary artery. Radio-opaque fluid, injected through the catheter, reveals the lumen of the vessels and their branches. A fine guidewire is passed through the catheter into the coronary branches and is steered, again under x-ray control, through the arteries to the diseased portion of the coronary artery. Over the guidewire, a catheter with a balloon is passed so that the balloon is placed at the site of the stenosis. Once in place, the balloon is inflated. This forces the occluded artery open, pushes back the plaque and deforms the arterial wall. The balloon

is then deflated and removed. Balloons of varying inflated diameters and lengths are used, typical dimensions being 2.5 - 4 mm inflated diameter and 20mm length.

[22] Angioplasty has the advantages of low morbidity, rapid recovery time and repeatability. It gained ground rapidly in the 1980s and 1990s. However, it also has associated complications. The method can involve occlusion (due to the tearing of the vessel wall, that is, the lining of the artery, specifically the endothelium) and consequent dissection in the endothelium creating a false passage or "flap" (which can close off the true lumen). This serious complication often requires emergency surgery. Additionally, restenosis (recurrence of the narrowing) can occur during the weeks or months after the procedure.

[23] During the 1980s, as a result of the problems associated with angioplasty, researchers explored several different alternatives, including lasers, atherectomy devices and stents. Stents act as a support in the artery.

[24] Dr. Dotter had tried implanting metal spirals in animal arteries but thrombosis (blood clotting) was a problem. He turned to coiled springs initially made of stainless steel and later, nitinol (an alloy made of nickel and titanium). This alloy is described as a "memory metal". Its physical properties are such that it can be fashioned into a particular shape at its "memory" temperature, cooled so that it then effects another shape, but when the "memory" temperature is applied to the metal, it returns to its first shape.

[25] In 1984, Maass et al. reported the use of spiral-shaped stents made of heat-treated steel alloy, configured as a double-helix spiral, torsion-reduced in diameter and transluminally inserted in the vena cava or aorta of dogs or calves. When wound tightly, the springs became narrow in diameter to allow them to be delivered into and through the lumen. Once released, they sprang back to their original size whereupon they pressed themselves against the vessel wall by elastic expansion.

[26] In 1985, Dr. Cesare Gianturco and co-workers reported their work with a stent (known as the Gianturco Z-stent), made of stainless steel wire formed in a zig-zag pattern, which they placed in major vessels of dogs. The stent features a metal wire folded numerous times such that it forms a spring-type, zig-zag pattern which springs open and expands upon being pushed from a catheter sheath. The sheath is then withdrawn. Once released from the sheath, the stent expands until the force of the stent on the walls of the vessel is in equilibrium with the force of the vessel wall on the stent. If the fully-expanded diameter is greater than that of the desired size of the lumen into which it is placed, it may cause undue injury to the vessel. This stent was not used in humans.

[27] Around 1986, the Wallstent became generally known. It is constructed of stainless steel braided wire mesh. It, too, is a self-expanding stent. It was held in a protective sheath and was implanted in dogs, mainly in the coronary arteries. The Wallstent is flexible and does provide some vessel support. However, its closed structure leads to side branch closure and the fact that it shortens on expansion (known as foreshortening) in an unpredictable fashion renders it less than ideal. Wallstent devices were also implanted in humans.

[28] During the 1980s, Dr. Julio Palmaz produced two balloon-expandable stent designs. One was made from soldered wire and another was characterized as a "slotted-tube" stent. Only the latter became commercially available. During 1986, the Palmaz stent became generally known to all those interested in interventional radiology and interventional cardiology. The Palmaz slotted-tube stent suffered from longitudinal inflexibility and the Palmaz-Schatz stent was introduced to overcome this difficulty. The Palmaz-Schatz stent consists of a series of Palmaz slotted-tube stents joined by a connector(s). In the 1990s, two major clinical trials, the Benestent and the Stress trials, were conducted in Europe and the United States at multiple centres on large numbers of patients. These trials tested the safety and efficacy of the Palmaz-Schatz stent as a treatment for coronary artery disease.

[29] Also during the mid-1980s, Dr. Roubin was working with Dr. Gianturco in the development of another stent, the Gianturco-Roubin balloon-expandable coil stent. It is a stainless steel length of wire formed into a coil. Practitioners in the field were aware of the Gianturco-Roubin stent by 1986. Although very flexible, its disadvantage is that it provides poor support and scaffolding to the vessel.

[30] Variations of coiled stent designs were subsequently developed. These were followed by a variety of stent designs typically described as second-generation and third-generation stents. The NIR stent was introduced in the late 1990s.

The Technical Experts

[31] Five technical experts provided evidence. A brief introduction to each of them is provided below.

Dr. Nigel Buller

[32] Dr. Buller, a medical doctor and cardiologist, appeared for the plaintiffs. Shortly before the trial, he returned to private practice after having been a consultant cardiologist and head of interventional cardiology at Queen Elizabeth Hospital in Birmingham, England. He continues to hold an academic appointment as senior lecturer in the cardiology department of the faculty of medicine at the University of Birmingham where he teaches general cardiology to undergraduates and interventional cardiology to postgraduates.

[33] Dr. Buller was part of the team that implanted the first coronary stent in the United Kingdom (the Wallstent). He was one of the clinical investigators in the Benestent trial in Europe and one of the first clinical investigators for the Guidant Multilink stent. On average, Dr. Buller performs approximately 200 stenting procedures each year.

[34] Dr. Buller proctored physicians in both the United Kingdom and the United States with respect to the use of balloon-expandable stents. He has served on the advisory boards of several manufacturers of coronary artery stents, has had direct involvement in research and clinical application of coronary artery stents and has had peripheral involvement in stent development.

[35] Dr. Buller has testified several times as an expert witness for Cordis and other Johnson & Johnson companies in patent trials in other jurisdictions regarding the Palmaz stent and related technology. He was declared an expert witness competent to provide opinion evidence regarding interventional cardiology, stents and stenting.

Dr. Richard Stringfellow

[36] Dr. Stringfellow, a mechanical engineer, holds an undergraduate science degree in civil engineering from Princeton University and a Master of Science and Ph.D. in mechanical engineering (with a minor in biomechanics) from the Massachusetts Institute of Technology (MIT). He completed a year of postdoctoral work at Brown University in Providence, Rhode Island. He testified for the plaintiffs.

[37] Since 2002, Dr. Stringfellow has been employed by TIAX LLC in Cambridge, Massachusetts, a firm that purchased the assets of his former employer Arthur D. Little, Inc. Throughout his employment, Dr. Stringfellow has been involved in a variety of engineering projects and has done consulting work with respect to medical devices, both surgical and implants. More particularly, he has consulted in relation to the analysis of blood processing centrifuges, suture wires, laparoscopic devices, bladder control devices, an accommodating intraocular lens, aneurism clips and stents.

[38] Dr. Stringfellow has significant expertise in Finite Element Analysis (FEA), a complicated computer analysis method used in the engineering field, which allows for the simulation and evaluation of the behaviour of complex structures.

[39] Dr. Stringfellow has previously testified as an expert witness for Johnson & Johnson, in litigation similar to this matter, in the United States. He has also performed duties, such as physical testing and FEA of various stents, to support other expert witnesses of Johnson & Johnson.

[40] Dr. Stringfellow was declared an expert witness competent to provide opinion evidence in mechanical engineering, particularly with respect to the mechanical behaviour of materials, including bending, plastic deformation, stresses and strains.

Doctor David Cumberland

[41] Although Dr. Cumberland was trained in interventional radiology, the majority of his practice has been in coronary angioplasty. He appeared as a witness for the defendant. In 1975, he was appointed consultant responsible for angiography service at Northern General Hospital in Sheffield, England. He began doing percutaneous balloon angioplasty in 1980 and began using stents in clinical practice in 1987 in collaboration with colleagues from the San Francisco Heart Institute. Dr. Cumberland began peripheral artery stent implantation in 1988 and has implanted various types of coronary stents in several thousand patients.

[42] In 1982, Dr. Cumberland founded the British Coronary Angioplasty Group (a discussion group for interventionists performing coronary angioplasty), the precursor to the present British Cardiovascular Intervention Society. Between 1983 and 1987, Dr. Cumberland founded many centres (in the technique of coronary angioplasty) in the United Kingdom, Scandinavia, India and the Middle East. He has been a lecturer and teacher of courses in coronary angioplasty in Britain,

Holland, France, the United States, Argentina, Australia and India. In 1994, he was appointed professor of interventional cardiology at Sheffield University where his work involved research into stents, specifically their deployment characteristics and the consequent vascular response.

[43] Dr. Cumberland has been the recipient of invitational fellowships from the Royal College of Physicians of Edinburgh, the Royal College of Surgeons of England, the American College of Cardiology and the European Society of Cardiology. In 2000, he retired to take up posts as consultant in cardiovascular intervention at a private hospital in Kuala Lumpur and visiting professor in the cardiology department at the university hospital. In 2003, he returned to Sheffield as consultant in cardiac intervention at Sheffield Northern General Hospital. He has held a chair in interventional cardiology and considers himself to be both an interventional radiologist and an interventional cardiologist.

[44] Dr. Cumberland has provided expert evidence on behalf of Boston Scientific in litigation similar to this in various countries. He was declared an expert witness competent to provide opinion evidence regarding interventional radiology, coronary intervention and therapeutic work in relation to stents and stenting.

Mr. Steven Opolski

[45] Mr. Opolski has a B.Sc. and an M.Sc. in mechanical engineering, with a specialization in mechanical design, and has completed some doctoral work. He testified for the defendant. He has been a senior technical consultant to NMT Medical Inc. (a manufacturer of a wide range of medical devices) of Boston, Massachusetts, since 1997. His consulting includes all aspects of design and

analysis of new products and enhancements to existing products and has included working with Cardio-Vascular Dynamic developing a balloon-expandable coronary stent. Mr. Opolski has designed and worked with medical devices, including stents, since 1988.

[46] Apart from two years service in the United States Army, from 1988 until 1997, Mr. Opolski was employed in various engineering and management capacities by C.R. Bard Inc. Bard (a manufacturer of medical devices) divided its products into cardiovascular, surgical and urological divisions. Mr. Opolski worked for the cardiovascular products division. In the early to mid-1990s, he worked on a nitinol self-expanding stent and was involved with the computer modeling and engineering development of various tests for pre-clinical evaluation for submission to the United States Food and Drug Administration (FDA).

[47] In the mid-1990s, Mr. Opolski was manager of a Bard "implant group" charged with the development of protocols and pre-clinical testing for a wide range of stents for the entire corporation. This included computer modeling, animal testing, fatigue testing and biocompatibility testing.

[48] Mr. Opolski is presently the president of Atlantic Engineering Inc. (Atlantic), an engineering consulting company, founded by him in 2003. He consults, through Atlantic, on engineering issues and engineering-related regulatory issues pertaining to various medical devices, particularly those that are permanently implanted in the human body. He additionally consults with companies requiring assistance in developing and applying for regulatory approval of medical devices.

[49] Mr. Opolski is a committee member of the American Society for Testing Materials (now ASTM International) initially tasked with developing standardized testing for balloon-expandable coronary stents. Its original mandate has been broadened to include stents in all areas of the body.

[50] Mr. Opolski has not performed consulting work for either Johnson & Johnson or Boston Scientific although he was an expert witness for Boston Scientific in litigation (which did not proceed to trial) involving Boston Scientific at the suit of Medtronic. He was declared an expert witness competent to give opinion evidence regarding mechanical engineering in the design, analysis and fabrication of interventional products, including stents.

Dr. Patrick Prendergast

[51] Dr. Prendergast has a Ph.D. in mechanical engineering. He is the director of the Trinity Centre for Bioengineering (TCBE) and a professor of bio-engineering at Trinity College, Dublin, Ireland. He has held post-doctoral fellowships in Italy and the Netherlands. He joined the faculty of Trinity College in 1995. He was Dean of Graduate Studies from 2003-2007 and was responsible for the admission, progression, and examination of all graduate (master and doctoral) students in the university. He was appointed director of TCBE in 2002. TCBE engages in research in the area of medical devices and medical device technologies in the schools of engineering, dentistry and medicine. It also provides master-level courses in bioengineering.

[52] Dr. Prendergast's interest in cardiovascular devices, particularly those with a biomechanical function such as stents, was piqued during the late 1980s and early 1990s when cardiovascular device manufacturers began to locate manufacturing facilities in Ireland to take advantage of tax and

other incentives offered at the time. His current responsibilities are to conduct research, develop a research strategy for TCBE, coordinate the research, and to teach and supervise graduate students.

[53] Dr. Prendergast is a prolific publisher. He is a recipient of research awards from the Europen Society of Biomechanics and the Royal Irish Academy. He is a member of the editorial board of several scientific journals including the *Journal of Biomechanics and Clinical Biomechanics*. He is the lead editor of "Finite Element Analysis of Medical Devices" which deals primarily with cardiovascular and orthopaedic medical devices. By invitation, he (with two colleagues) authored a paper "Stents" in the Encyclopaedia of Biomedical Engineering. He is past-president and current council member of the European Alliance of Medical and Biological Engineering and Science.

[54] Dr. Prendergast has completed research and work for Medtronic AVE (regarding its stents) through Enterprise Ireland, a state-funded initiative to encourage collaboration between local industry and research laboratories. Trinity College and Medtronic are funded by Enterprise Ireland to conduct research projects. This proceeding represents the first time that Dr. Prendergast has provided expert testimony in the litigation context. He was declared an expert witness competent to provide opinion evidence with respect to biomedical engineering with emphasis on the design, analysis and testing of implantable medical devices.

Stents Generally

[55] Strictly speaking, the general characteristics of stents constitute common general knowledge that a reader of the patents in suit would possess (in 1991) to give meaning to the words of the

patent. However, there is no dispute regarding the requisite attributes that stents must possess. I think it prudent to discuss the common characteristics at this point because the information is important, non-contentious and will provide a basis upon which to move to the issue of claim construction.

[56] First, a word or two about plasticity or plastic deformation, a concept that also factors into an understanding of stents. Deform means to alter or change. When force is placed on a typical metal, the metal will displace and then recover, that is, return to its initial configuration. When sufficient force is exerted to extend the metal beyond what is known as its elastic limit, the nature of the deformation changes and the properties that would normally bring the metal back to its original configuration go away. There is a permanent set to the material, which is called plastic deformation. In a nutshell, plastic deformation means that the shape of the metal is permanently altered.

[57] With respect to characteristics, the stent must be biocompatible in the sense that it works within the surrounding tissues, avoids overstressing the surrounding vessel wall and does not harm the patient. It must be structurally stable so that it will not disengage (migrate) from its placement in the lumen. That is, the stent must provide support (to keep the lumen open).

[58] Although some recoil is inevitable, elastic recoil of an expanded stent should be minimal. The stent must have sufficient scaffolding properties, that is, there should be minimal draping of the inner lumen between the struts (the metal parts) of the expanded stent. The stenotic material should not be so stressed that it could break off and cause an obstruction elsewhere.

[59] The shearing of the metal of the stent over the vessel wall should be minimized so the endothelium is not damaged. Although the stent will shorten longitudinally during expansion, foreshortening should be minimal.

The Claims in Issue

[60] The claims in issue in relation to the '505 Patent are claims 1, 4, 11, 12, 19 and 22. They are as follows:

> 1. An expandable intraluminal vascular graft, comprising:
>
> > a thin walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
> >
> > the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and
> >
> > the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.
>
> 4. The expandable intraluminal vascular graft of claim 1, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.
>
> 11. The expandable intraluminal vascular graft of claim 1, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.
>
> 12. An expandable prosthesis for a body passageway, comprising:
>
> > a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

19. The expandable prosthesis of claim 12, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

22. The expandable prosthesis of claim 12, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

[61] The claims in issue in relation to the '186 Patent are claims 1 and 5. Those claims state:

1. An expandable intraluminal vascular graft, comprising:

A plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen;

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

5. An expandable prosthesis for a body passageway comprising:

a plurality of thin-walled tubular members, each having a first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

> at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;
>
> each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and
>
> the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

[62] For practical purposes, the crux of this matter turns on claim 1 of each patent. Claim 1 and claim 12 of the '505 Patent describe the same structure. The difference between them is that the structure in claim 1 is restricted to use in the vascular system while the structure in claim 12 is not limited to any specific body passageway. Claims 4 and 11 relate to claim 1 while claims 19 and 22 relate to claim 12. Claim 5 of the '186 Patent is nearly identical to claim 1 of that patent. The only distinction is the location of application. While claim 1 is directed to an intraluminal graft, claim 5 is directed to an expandable prosthesis for a body passageway. I will have more to say about this later.

Reserve Ruling

[63] Eleventh-hour pre-trial motions regarding affidavits and witness statements resulted in Prothonotary Lafrenière's order, dated January 4, 2008, wherein he deferred objections to the admissibility of parts, or all, of various affidavits to the trial judge. I heard extensive argument in relation to the admissibility of Dr. Buller's "Reply Witness Statement", dated November 27, 2007. Rather than delay the witnesses and the progress of the trial, I reserved my ruling.

[64] Boston Scientific argues that the proposed testimony on construction and infringement on the "Buller Reply" does not constitute proper reply evidence. It notes that the testimony runs some 42 pages and is almost twice as long as Dr. Buller's initial report on those issues (23 pages). Boston Scientific submits that, in seeking to "reply" on the issues of construction and infringement, Johnson & Johnson is seeking impermissibly to split its case. Accordingly, such portions of the Buller Reply, namely paragraphs 3 to 116, ought to be struck.

[65] Resolution regarding some of the impugned paragraphs was achieved following the arguments. Johnson & Johnson voluntarily struck paragraphs 4 to 6, 7 (first half of the paragraph), 9, 14 (last 2 ½ lines), 15 (second-last sentence), 19, 21 (first sentence), 22, 28, 41, 42, 44 (third sentence), 58 (last portion of second-last sentence), 63, 66 (first sentence), 69 (first sentence and last portion of second-last sentence), 83 (first sentence), 89 (last three boxes of diagram), the first sentence of paragraphs 90, 99, and 109, and all of paragraphs 115 and 116.

[66] Mr. Justice Pelletier thoroughly canvassed the issue of proper reply evidence in *Halford et al. v. Seed Hawk Inc. et al.* (2003), 24 C.P.R. (4th) 220 (F.C.T.D.) (*Halford*). I adopt his comments and his synthesis of the law, at paragraphs 12 to 15 of his reasons. These are reproduced below:

> 12 This leads to the question of the proper scope of reply evidence. An indirect answer to this question is provided in *Allcock Laight & Westwood Ltd. v. Patten, Bernard and Dynamic Displays Ltd.* [1967] 1 O.R. 18 (C.A.) where the Ontario Court of Appeal had this to say about evidence which was sought to be led by way of reply:
>
> > It is well settled that where there is a single issue only to be tried, the party beginning must exhaust his evidence in the first instance and may not split his case by first relying on

> prima facie proof, and when this has been shaken by his adversary, adducing confirmatory evidence: *Jacobs v. Tarleton* (1848), 11 Q.B. 421, 116 E.R. 534. That case was considered by this Court and the principle therein enunciated was applied in *R. v. Michael*, [1954] O.R. 926, 110 C.C.C. 30, 20 C.R. 18. The rule is now so well settled that it requires no further elaboration. It is important in the trial of actions, whether before a jury or a Judge alone, that this rule should be observed. A defendant is entitled to know the case which he has to meet when he presents his defence and it is not open to a plaintiff under the guise of replying to reconfirm the case which he was required to make out in the first instance or take the risk of non-persuasion.

13 The conclusion which I draw from this passage is that evidence which simply confirms or repeats evidence given in chief is not to be allowed as reply evidence. It must add something new. But since the plaintiff is not allowed to split its case, that something new must be evidence which was not part of its case in chief. That can only leave evidence relating to matters arising in defence which were not raised in the plaintiff's case in chief. But even this is subject to a limitation which is expressed in the following passage from Sopinka et al. The Law of Evidence in Canada 2nd Edition at p. 882:

> Should reply evidence be excluded if the point in respect of which contradictory evidence is sought to be adduced in reply arose in cross-examination of the other parties' witness rather than their evidence in chief? In *Mersey Paper Co v. Queens (County)* [(1959) 18 D.L.R. (2nd) 19 (N.S.C.A.)], The Nova Scotia Court of Appeal considered this to be an unjustifiable technical distinction. It is submitted that, at least in civil cases, it would depend on whether the matter was part of the plaintiff's case and one which might have been adduced in the plaintiff's case-in-chief. A plaintiff cannot leave part of its case until cross-examination of the defendant's witnesses and then when that goes badly make up for it in reply.
>
> Although the authorities are not entirely clear on this point, the better view is that reply evidence that conforms with the principles stated above can be adduced as of right. There is, however, a discretionary power vested in the trial judge to admit such evidence, notwithstanding that it may not be the proper subject of reply.

> 14 Consequently, I believe that the following principles govern the admissibility of reply evidence:
>
> > 1 - Evidence which is simply confirmatory of evidence already before the court is not to be allowed.
> >
> > 2 - Evidence which is directed to a matter raised for the first time in cross examination and which ought to have been part of the plaintiff's case in chief is not be allowed. Any other new matter relevant to a matter in issue, and not simply for the purpose of contradicting a defence witness, may be allowed.
> >
> > 3 - Evidence which is simply a rebuttal of evidence led as part of the defence case and which could have been led in chief is not to be admitted.
>
> 15 To these principles, I add one further. Evidence which is excluded because it should have been led as part of the plaintiffs' case in chief will be examined to determine if it should be admitted in the exercise of my discretion.

[67] My rulings with respect to the impugned paragraphs are guided by the noted principles.

[68] The following paragraphs of Dr. Buller's Reply are inadmissible: the remainder of paragraph 7 (summarizes the testimony of defence witnesses); paragraph 11 (constitutes repetition of Dr. Buller's first witness statement); the remainder of paragraphs 14 and 15 (either repetition, a summary of the testimony of witnesses, or both); paragraphs 18, the remainder of paragraphs 21, 27, 29, 30 and 38 (summarize the testimony of witnesses and Dr. Buller's disagreement with that testimony); paragraphs 39 and 40 (repetitions of the first report); paragraphs 43 and 44 (summaries of witnesses' statements); paragraph 54 and the first part of paragraph 58 (summary of testimony and Dr. Buller's disagreement with it); paragraph 59 (repetition of the first report); paragraphs 67, 68, the remainder of paragraph 69, paragraphs 76-

83, 90, 95, 97, 99 106, and the remainder of paragraph 109, (summarize the testimony of witnesses and repetition).

[69] Other paragraphs are also inadmissible. The information in paragraph 8 was not expressly set out in Dr. Buller's first report, but his position in this respect was clear during cross-examination. The paragraph is "simply confirmatory" of his original position and is not valid reply evidence.

[70] Paragraph 10 utilizes the AAA graft described in the 1991 Parodi and Palmaz article to proffer an example of a balloon-expandable tubular member, as part of a larger device. This goes to Dr. Buller's interpretation of the word "comprises" in claim 1 of the '505 Patent, specifically that it permits the graft to include other components (beyond the tubular member), with the result that the tubular member need not function on its own. In short, the paragraph's objective is to establish that the tubular member in claim 1 is not always the graft. Johnson & Johnson claim that the paragraph is simply replying to Boston Scientific's assertions that a non-elongate ring (the ring of half-slots) would not function as a stent and that the tubular member must be elongate. I will have more to say about the "functioning" and "elongate" issues in due course. However, Johnson & Johnson's submission does not transcend the hurdle that an issue in reply, raised in the party's case-in-chief, should be dealt with in the case-in-chief: *Halford* at para. 13. Dr. Buller discussed the meaning of the term "comprises" at paragraph 38 of his first report. He could, and should, have continued and included his evidence that, if other elements were present with the tubular member, the tubular member need not function as the stent.

Moreover, paragraph 10 is directed to an issue that is relevant to Johnson & Johnson's theory of infringement of the '505 Patent. Therefore, it is not valid reply.

[71] Paragraphs 12 and 13 consist of a discussion regarding the different numbers assigned to the tubular members in the patent's description and preferred embodiment. These paragraphs go to a matter similar to that of paragraph 10, that is, the tubular member(s) in the '505 and '186 Patents do not have to function as "the stent" on their own. For the reasons stated in relation to paragraph 10, this is not proper reply evidence. Moreover, it was information that was available to Dr. Buller from the outset.

[72] Paragraphs 51-53 go to the issue that I previously discussed in relation to paragraph 10 and are inadmissible for the same reason.

[73] Paragraph 33 discusses matters that are beyond the designation of Dr. Buller's expertise and is therefore inadmissible. Paragraph 50 speaks to the "building block" of rings, a matter that was clearly raised in Dr. Buller's first report. If he was aware of other stents, which employed this "building block", he could and should have referred to them in his first report. This is not proper reply evidence.

[74] Paragraphs 55-57 are basically confirmatory of evidence contained in Dr. Buller's first report: the "smoothness" of the wall surface relates to the ability to deliver the stent. It is not proper reply evidence.

[75] Paragraphs 60-66 (except paragraph 63, which was voluntarily struck) are directed to the topic that half-slots are not fully bounded by metal. This goes to the position advanced in the first report that both half-slots and full slots are slots. It is not valid reply evidence.

[76] The articles referred to in paragraph 84 are new. However, they address the point that the NIR stent is composed of rings. Therefore, they should have been included in the first report. The evidence in paragraph 87-89 speaks to the same topic and is not valid reply evidence.

[77] The statements in paragraphs 85 and 86 as well those in paragraphs 100-105 are inadmissible because they are hearsay. The comments in paragraphs 91-94 are beyond the parameters of Dr. Buller's designation of expertise and are inadmissible on that basis.

[78] I reach a different conclusion with respect to the comments in paragraph 96. Boston Scientific characterizes the contents of this paragraph as being beyond the scope of Dr. Buller's expertise. I do not think that is necessarily so. The paragraph contains a discussion of lines drawn on a flexed stent to demonstrate that certain parts of the stent remain parallel. It is a visual analysis of a stent. This paragraph (as well as others surrounding it that relate to "function") is in reply to Boston Scientific's evidence that the NIR stent is uniformly flexible (unlike stents made pursuant to the '186 Patent). The statement is therefore valid reply to that point. However, to the extent that Dr. Buller's opinion (that the NIR stent is not uniformly flexible) relates to the argument that the NIR stent is composed of short tubular members connected by flexible connectors, such evidence ought to have been included in the first report because it is a topic that, initially, was raised by Johnson & Johnson. Paragraph 98 illustrates Dr. Buller's effort to

equate “uniform flexibility” with the portrayal of the NIR stent as rings and connectors and is not valid reply.

[79] Paragraph 107 is not admissible. The information goes to the increased flexibility of the Palmaz-Schatz stent over the Palmaz stent. It should have been in the first report.

[80] Paragraphs 108, 110, and 111 are beyond Dr. Buller’s designation of expertise and are inadmissible on that basis. I disagree with Boston Scientific that paragraphs 112-114 are similarly inadmissible. These paragraphs discuss the results of certain studies concerning various stents and the likelihood of restenosis on their deployment. The information responds to Dr. Cumberland’s evidence about vessel support.

[81] This leaves paragraphs 16, 17, 20, 23-26, 28, 31, 32, 34-37, 45-49, and 70-74. These paragraphs relate to Boston Scientific’s proposed construction that a tubular member must be elongate and that a short ring would not function as a stent. This proposed construction responded to Johnson & Johnson’s position that, while a tubular member must be cylindrical and hollow, no other characteristics are contemplated by the patents in suit. The question is whether Johnson & Johnson ought to have anticipated this position and put evidence to refute it in its case-in-chief.

[82] Johnson & Johnson claims that, although this question concerns the construing of the patent, it has direct implications on determinations with respect to infringement. According to Johnson & Johnson, it should not be expected to anticipate Boston Scientific’s position that

tubular members must be elongate and, particularly, that a short stent of half-slots would not function as a stent on its own.

[83] Boston Scientific argues that Johnson & Johnson had its "crack" at construction. It construed the patent and, after Boston Scientific proposed its construction, Johnson & Johnson seeks to disagree. Its statement that the tubular member does not need to be elongate is equivalent to its evidence-in-chief that the tubular member can be a short ring. Johnson & Johnson is saying the same thing in a different way. Having had its chance to construe the patent, Johnson & Johnson should not be given a second opportunity to repeat or confirm its original construction. Further, evidence which is simply a rebuttal of evidence led as part of the defence case, and could have been led in chief, is prohibited.

[84] I have some misgiving regarding Johnson & Johnson's position that it was "genuinely surprised" by Boston Scientific's construction of a tubular member as elongate. It is arguable that Boston Scientific's Further Fresh as Amended Statement of Defence and Counterclaim should have put Johnson & Johnson on notice because of the "claims broader" allegations. On the other hand, Johnson & Johnson did not require evidence regarding the requisite length of a tubular member in order to advance its construction or infringement arguments. Additionally, the rule that prohibits evidence which is simply a rebuttal of evidence led as part of the defence is, in my view, a difficult one to apply. I am inclined to give Johnson & Johnson the benefit of the doubt and to rule that (except for paragraphs 28 and 31) the remaining paragraphs are admissible as proper reply evidence. If I am wrong, then I exercise my residual discretion to admit them.

[85] Paragraphs 28 and 31, broadly speaking, reply to Boston Scientific's argument that a tubular member should be elongate. Paragraph 28 states, because the tubular member has "ends" does not mean it is "elongate". Paragraph 31 states the same thing regarding a "plurality of slots". Although these paragraphs are replying to the construction of tubular members as elongate, they do not add anything new or change Johnson & Johnson's original proposed construction. This is not valid reply; it is merely confirmatory of the evidence-in-chief with a bit of a "spin".

[86] Indirectly, paragraphs 10, 12 and 13 could be said to relate to the issues of "elongate" and "function". However, these paragraphs have been determined to be inadmissible for other reasons and those rulings stand.

[87] Notwithstanding my rulings of inadmissibility, I have examined the evidence. Had I concluded that it constitutes proper reply evidence, its content would not have affected my conclusions with respect to validity and infringement.

Claim Construction

The Law

[88] The companion Supreme Court of Canada decisions in *Free World Trust v. Électro Santé Inc.* (2000), 9 C.P.R. (4th) 168 (S.C.C.) (*Free World Trust*) and *Whirlpool Corp. v. Camco Inc.* (2000), 9 C.P.R. (4th) 129 (S.C.C.) (*Whirlpool*) remain the seminal authorities regarding claim construction. There, the Supreme Court examined and analysed the existing jurisprudence then

synthesized and articulated the principles applicable to patent construction. Notably, the Court held that claim construction is antecedent to issues of validity and infringement. The principles set out below, although emanating from voluble jurisprudence, are discussed in and are derived from *Free World Trust* and *Whirlpool*.

[89] The claims of a patent receive one and the same interpretation for all purposes. Since construction is antecedent to the analysis of infringement or validity, the first task of the trial judge is to construe the claims of the patents at issue. Here, as noted earlier, the applications for the patents at suit were filed prior to October 1, 1989. Consequently, the claims are to be construed as of the dates that the patents were issued. The relevant date for the '505 Patent is March 19, 1991, and for the '186 patent, it is April 14, 1994.

[90] The Supreme Court endorsed a "purposive construction" to enable the terms in the claims to be given the meaning intended by the patentee based on a reading of the claims in the context of the patent as a whole. The claims are to be construed with "a mind willing to understand, not by a mind desirous of misunderstanding". The words chosen by the patentee should be read in the sense the inventor is presumed to have intended and in a way that is sympathetic to accomplishment of the inventor's purpose, express or implicit, in the text of the claims. The patent ought not to be construed malevolently but need not be construed benevolently. The claims may be broader in scope than the preferred embodiment, but may not be broader than what is disclosed or taught in the disclosure. Moreover, while the claims must be construed with reference to the entire disclosure, the patentee is not permitted to expand the scope of the monopoly specifically expressed in the claims "by borrowing this or that gloss from other parts of the specification".

[91] The inventor's intention is manifested in the patent claims as read and understood by the addressee, that is, by a person skilled in the art. The patent should be construed from this perspective. The average person skilled in the particular art of the patent is not a grammarian or etymologist and does not indulge in a meticulous and verbal analysis. Rather, an informed interpretation is accomplished by having regard to the common knowledge shared by competent ordinary workers in the art having the skills required to practice the invention.

[92] While claim construction is a question of law, expert evidence is admissible to determine what the common knowledge was at the time of the patent. Expert evidence may also be presented as to the meaning of words used in the claims. The expert's role is not to interpret the claims of the patent but to put the trial judge in the position of being able to do so in a knowledgeable way. The words and phrases used in the claims must be construed in the context of the specification as a whole, without resort to extrinsic evidence.

[93] This purposive construction promotes adherence to the language of the claims and, in turn, achieves fairness and predictability. The claims of a patent perform a public notice function by setting out the scope of the monopoly, so that the public may know where it may go with impunity. Claim construction analysis gives meaning to the words and phrases of the claims and identifies the particular words or phrases in the claims that describe what the inventor considers to be the "essential" elements of the invention.

[94] Guided by these principles, I turn to the construction of the claims in this matter.

The '505 Patent

[95] For ease of reference, claim 1 is again reproduced.

> 1. An expandable intraluminal vascular graft, comprising:
>
> > a thin walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
> >
> > the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and
> >
> > the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

[96] The '505 Patent describes the field of the invention as follows:

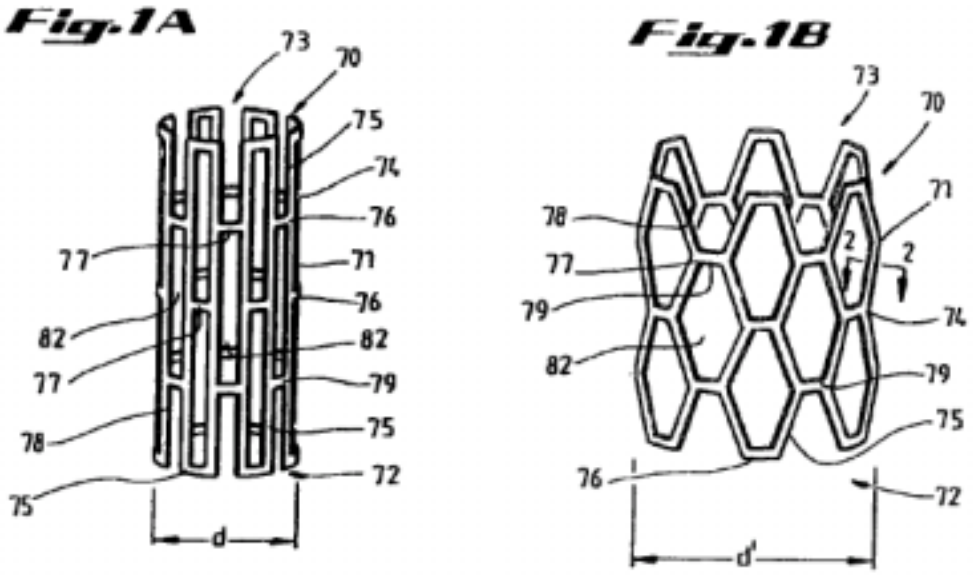
> The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

[97] The parties agree that the patent is addressed to a manufacturer of medical devices. This manufacturer would rely upon the advice of engineers, more specifically engineers with some expertise in the design, construction and analysis of medical devices, particularly those that are inserted in the human body. The engineers, in turn, would be dependent upon the input of interventional cardiologists or radiologists. Thus, for practical purposes, the person skilled in the art

with respect to the patents at suit is a team of mechanical engineers and interventional cardiologists or radiologists.

[98] I heard the expert testimony of three mechanical engineers (Doctors Stringfellow and Prendergast and Mr. Opolski) and two interventional cardiologists (Doctors Buller and Cumberland, the latter is also qualified in interventional radiology). My task would be simple had they agreed as to the meaning of the terms contained in the patent. Alas, it was not so. Some terms are rigorously contested. That said, there are words and phrases that are not in dispute. It seems sensible to begin with the non-contentious terms. In so doing, I will refer to the evidence of the witnesses, where necessary. References to the evidence of a single witness are for convenience only and are not indicative that the evidence of that witness is to be preferred over that of another, unless expressly so stated. Further, I note that the defendant takes no issue with the "proposed claim constructions that [the plaintiffs] gave yesterday with regard to the non-contested phrases and terms" (transcript, pp. 4696, 4697). Some critical terms such as "comprising", "tubular member" and "slots" will be addressed later.

[99] "Expandable" means capable of opening up or out, or becoming greater in size. Figure 1A in the preferred embodiment of the '505 Patent shows a structure that has a relatively small diameter. Figure 1B shows the structure after it has been expanded to a larger size, that is, of a diameter larger than that of Figure 1A. This depicts something that is expandable.



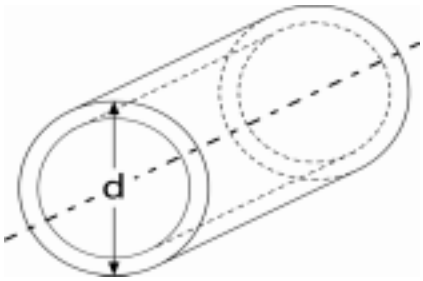
[100] "Vascular" typically relates to the blood. The claims of the patent in suit are not limited to use of the device within the coronary artery. The invention is very broad and covers use in all and any body passageways (Dr. Buller, transcript, p. 402). Thus, the plaintiffs propose that, in the context of this patent, the term "vascular" means "relating to tubes conveying bodily fluids, such as blood vessels". I agree with that construction.

[101] "Body passageway" is specifically referred to at page 11 of the patent disclosure. There, it states that the term "encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system". The experts agree, and I concur, that "body passageway" includes any duct within the human body, including blood vessels.

[102] "Graft", according to the expert testimony, means the same thing as "prosthesis" and "stent". The disclosure, at page 11, states that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention". Dr. Buller related that the term "intraluminal vascular graft" as used by Dr. Palmaz in the '505 Patent would, by 1991, be well-known as a stent. In his introduction to the '505 Patent, Dr. Palmaz calls out some prior art stents, which he says are intraluminal vascular grafts (transcript, p. 269). By 1991, the term of art for a balloon-expandable stent was a "stent" and has remained so. All these devices for intraluminal delivery and remote treatment, both self-expanding stents and balloon –expandable stents, were and are referred to as "stents" (transcript, pp. 320, 321).

[103] Thus, the term "graft" includes a stent, that is, a device used to support a body passageway. The term "prosthesis" includes a balloon-expandable stent.

[104] "First diameter" refers to the diameter of the stent before it is expanded. It is illustrated in the figure below (from Dr. Buller's Witness Statement) where the diameter is represented as d.



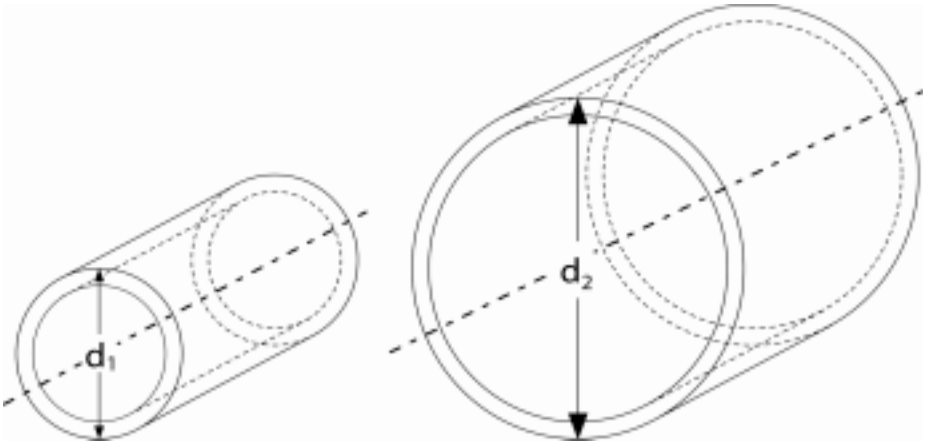
The phrase simply means that each tubular member has a first diameter.

[105] The first diameter must be such that it "permits intraluminal delivery of the tubular member into a body passageway having a lumen". Dr. Buller explained that this means "within the lumen".

He described “intraluminal delivery” as a term of art meaning delivery by a non-surgical procedure. Intraluminal delivery is the means by which a device can be delivered to a distant, remote point to treat a body passageway through the passageway itself, rather than through surgical opening (Dr. Buller, transcript, p. 293). Thus, intraluminal delivery means that the tubular member arrives at the desired location in the body passageway by being passed within and along the inside of the body passageway. Dr. Prendergast, in his description of the first diameter of the Palmaz stent, said “[it] is the diameter in the delivery state, which permits delivery of the stent into a body passageway having a lumen” (Dr. Prendergast, Expert Report).

[106] I construe the phrase to mean that the first diameter permits the placement of the tubular member at the desired location by passing it within and along the inside of a body passageway.

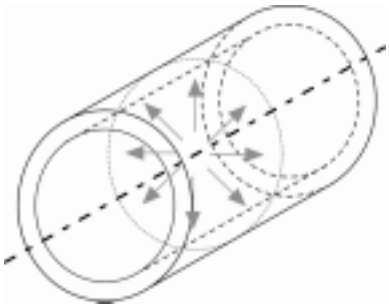
[107] “Second expanded and deformed diameter” refers to the diameter of the tubular member after it is expanded into a new, larger shape. The diagram (again from Dr. Buller’s Witness Statement) depicts the expansion from outer diameter d1 to d2.



[108] The concept of “deformation” has been discussed earlier in these reasons. It means permanent change. The disclosure states that the term means that the material from which the stent is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make it ('505 Patent, p. 15). A skilled person reading the patent would understand that the term “deformed” is used to explain that the metal of the stent must be plastically deformed to permanently maintain its second diameter. Otherwise, the stent would spring back to where it was (Dr. Prendergast, transcript, p. 2799). Therefore, the phrase means that the tubular member has a second diameter that is permanently larger in size than the first diameter.

[109] In relation to coronary artery stents specifically, the diameter of a stent (before it is inflated) is about 1 mm (Dr. Strauss, transcript, p. 194). The stent is expanded to about 3 mm, the degree of expansion being controllable. The range for the diameter of an expanded stent would be 2.5 mm to 4 m., sometimes larger. (Dr. Cumberland, Expert Report and transcript, pp. 1129-1131).

[110] The second diameter is produced “upon the application from the interior of the tubular member of a radially, outwardly extending force”. This term is understood to mean a force directed outwardly from the inside of the tubular member as illustrated by the arrows in the figure from Dr. Buller’s Witness Statement reproduced below. The arrows represent a force from the inside pushing outwards. Although the diagram gives the impression that it is merely at one point along the length, the force would be along the entire length of the tubular member and it is this force that would produce the permanent bending or plastic deformation which enlarges the tubular member from the first diameter to the larger second diameter. (Dr. Buller, transcript, p. 300).



[111] The preferred way of achieving this force is to use an angioplasty balloon inflated to high pressure. By placing an angioplasty balloon inside the structure and blowing it up to high pressure, the force required to permanently bend or plastically deform the device is produced. (Dr. Buller, transcript, pp. 300, 301). This would be the normal situation with respect to coronary artery stents. However, the patent does not require that the force be produced by a balloon. It also allows for the force to be produced by a series of mechanical levers. Dr. Cumberland believes, on reading the claim as a whole and in light of the description found in the patent, that it is apparent that the expansion of the graft is intended to be in the radial direction so that the graft can come into contact with the vessel wall (Dr. Cumberland, Expert Report).

[112] I construe this phrase to mean “upon the application of a force pushing radially outward”.

[113] This force, which expands and deforms the tubular member, is “variable and dependent upon the amount of force applied to the tubular member”. The evidence indicates that these terms mean that the second diameter can be varied, depending upon the amount of force applied to the tubular members. By adjusting the pressure in the balloon, the final dimension of the stent can be correspondingly adjusted. Inside the patient, “you can adjust the final diameter by cranking up the pressure in the balloon, or by changing to a larger balloon and then making the device even larger”

(Dr. Buller, transcript pp. 250, 251). This provides control over the final dimensions of the stent. When Dr. Sigwart intensified the pressure (beyond that generally applied) to fully expand the Wallstent, his technique became known as the "Swiss Kiss" (Dr. Cumberland, Expert Report).

[114] Consequently, this phrase means that the second diameter is variable and dependent upon the amount of force applied to the tubular member.

[115] This variable force, which expands and deforms the tubular member, must be such that it will "expand the lumen of the body passageway". The disclosure informs us that "it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts as previously described" ('505 Patent, pp. 16, 17). Because the device is designed to remain in the body, it is evident that it is intended to expand and scaffold the lumen of the body passageway.

[116] This concludes the discussion on most of the non-contentious terms and phrases. The word "intraluminal" as it is used in claim 1 in relation to the "expandable intraluminal vascular graft" (or stent) is the subject of some debate. The plaintiffs' experts maintain that the term is intended to mean the placement of the device at the desired location in the body passageway by being passed within and along the inside of the body passageway.

[117] This view is based on the reasoning that “lumen” means the “cavity of a tubular organ, such as a blood vessel or intestine”. Although I previously equated the “lumen” to the “channel” of the passageway, either description (cavity or channel), in my view, is appropriate. The plaintiffs say that the prefix “intra” means within. Therefore, “intraluminal” means the cavity of a tubular organ such as a blood vessel or other body passageway (Witness Statements of Drs. Buller and Stringfellow, Exhibits 3 and 4 respectively). On the last point, I do not understand the defendant’s experts to say otherwise. The divergence in opinion arises as a result of Dr. Buller’s reliance on the introduction to the '505 Patent.

[118] Dr. Buller opines that, in the introduction, Dr. Palmaz explains “intraluminal vascular grafting”. In providing examples of prior art, he instructs the reader that this is a process of delivery, along a body passageway, to obviate the need for surgery. Dr. Palmaz taught that this whole field of development was to avoid subjecting patients to conventional open surgery and to allow for intraluminal delivery (sometimes called “percuntaneous treatment”) to avoid such major surgery. Percetaneous means through the skin. Cutaneous is skin, and “per” means going through it. According to Dr. Buller, this procedure is done through the skin to distinguish it from a major, open surgical procedure. Thus, he understands the patent to be teaching that the device is delivered to the lumen and expanded there, in contrast to a surgical graft, which is used to bypass or replace a part (transcript, pp. 225, 268, 322).

[119] The defendant’s experts take the view that the word “intraluminal”, when it is used to describe the vascular graft, describes the intended location. Dr. Cumberland claims that to import intraluminal delivery into the description of the graft imports “in part a meaning that would not have

been taken by a person skilled in the art either in 1991 or 1994". He maintains that, in this context, "intraluminal" means that the tubular member is placed within a body passageway, such as a blood vessel. The term is intended to specify where the devices are used rather than their method of delivery (Dr. Cumberland, Expert Report). It does not presuppose any particular delivery (Dr. Cumberland, transcript, p. 1151). Mr. Opolski's view is that the addition of the "intraluminal" qualifier helps direct the skilled person as to where the device is to be used and conveys that the graft will be within the lumen of the vessel (Opolski Expert Report).

[120] The word "intraluminal" appears twice in claim 1. At the outset, it describes the vascular graft. Later, when the first diameter is addressed, it states that the first diameter permits "intraluminal" delivery. Hence, at one point "intraluminal" modifies the word "graft". In this sense, it describes the graft itself and therefore, in this patent, its placement. However, "intraluminal" is also used a second time to modify the "delivery" of the graft. Because the adjective is used to describe different words, the question is whether it is to be given different meanings for its different contexts.

[121] As cautioned in *Whirlpool*, when a patent issues, it is an enactment within the definition of "regulation" in subsection 2(1) of the *Interpretation Act*, R.S.C. 1985, c. I-21. It must be given such interpretation according to section 12 of the *Interpretation Act* "as best ensures the attainment of its objects". Intention is manifested in words, whose meaning should be respected, but words themselves occur in a context that generally provides clues to their interpretation and a safeguard against their misinterpretation.

[122] Although the defendant concedes that terms are generally to be given the same meaning throughout the claims, it is said that because of the manner in which the claims are expressed, such is not the case here.

[123] In my opinion, the interpretation of this term underscores the rationale behind *Whirlpool* and *Free World Trust*. When regard is had to the patent as a whole, that is, in context, the patent speaks to the "invention" as an alternative to conventional vascular surgery. It discusses percuntaneous insertion into a blood vessel. In more than one instance, it addresses delivery by way of catheter to the desired location. None of the devices discussed as prior art involved open surgery. Angioplasty itself was hailed as an alternative to surgery. The discussion of angioplasty and its disadvantages in the disclosure refers to the necessity of having a surgeon on call in the event of [complications].

[124] It seems to me that one of the most fundamental aspects of the '505 Patent is that it avoids the requirement of open surgery. The foundation or premise upon which the device rests is intraluminal delivery. Thus, notwithstanding that the adjective "intraluminal" at the outset of the claim modifies the vascular graft, in my view, it is implicit that it is an "intraluminal" graft that is to be delivered "intraluminally". This notion is reinforced by the inclusion of the word "intraluminal" modifying the word "delivery" in claim 1. To determine otherwise, in the context of this patent, would indeed run afoul of Justice Binnie's admonition that a "grammatical" approach is to be avoided. Further, I cannot conceive of one reading the patent in its totality and not appreciating that "intraluminal" is intended to describe both the device and the delivery. To so construe the word does not broaden what is taught or disclosed in the disclosure. I prefer the evidence of Dr. Buller in this respect.

[125] Accordingly, I construe the word “intraluminal” to mean both the placement and the delivery of the device, the delivery being the passing of the stent within and along the inside of the body passageway. That said, I agree with the plaintiffs that nothing much turns on this construction. The device ends up in the lumen in any event.

[126] The debate occurs in relation to the “tubular member” portion of the claim. Claim 1 refers to “an expandable intraluminal vascular graft, comprising”:

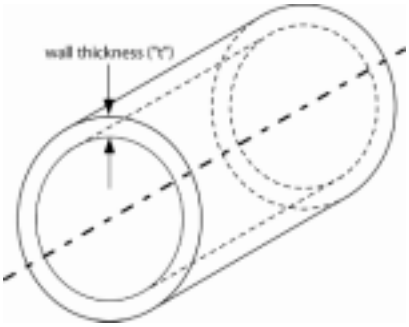
> A thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member.

[127] There is some common ground in relation to the terms “first and second ends”, “wall surface”, “thin-walled” and “substantially uniform thickness”.

[128] The “first and second ends” are understood by all to mean that the tubular member has two ends – one at each end of the tubular member. The phrase means that each tubular member has two ends.

[129] The reference to wall surface is a reference to the wall of the tubular member. It is the surface of the tubular member (made of the material from which the tubular member is made). It is “disposed” or located between the two ends of the tubular member.

The wall thickness is illustrated as “t” in the diagram below.



[130] Dr. Stringfellow explained that the term “thin-walled” is “used in terms of what the stent is used for”. If it is “thin enough for the function of the stent, then it is considered thin-walled”. The stent’s purpose “is to scaffold the artery and allow blood to pass through. So, if it’s not thin-walled, it will block that passage of blood through; so it has to be thin enough so that the blood can freely flow through it” (transcript, p. 680). The phrase “thin-walled” means that the wall of the tubular member is thin.

[131] “Substantially uniform thickness” was explained to mean that the thickness of the wall of the tubular structure (represented as ‘t” in the diagram above) is mostly the same throughout. In the diagram, the radial dimension “t” is exactly the same both circumferentially and longitudinally. The diagram represents a structure with precise uniform thickness. The claim requires that the wall surface of the tubular member have “substantially uniform thickness”.

[132] I concur with the expert evidence and conclude that this phrase should be construed as meaning that the wall thickness of the tubular member is mostly the same throughout.

[133] There is also agreement that “tubular” means “tube-like”. Being “tube-like” requires that the structure be cylindrical and hollow. Whether it must also be elongate is a matter of debate that will be discussed later.

[134] Before embarking upon a discussion regarding the areas of controversy, dependent claims 11 and 22 require attention.

These claims read as follows:

> 11. The expandable intraluminal vascular graft of claim 1, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.
>
> 22. The expandable prosthesis of claim 12, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

[135] The term that is not embraced by the construction of claim 1 is the word “smooth”. The disclosure refers to the word “smooth” at page 15 where (referring to the stent in the second, expanded diameter) it states that the outer surface, which would be in contact with the body passageway, should be relatively smooth. Although the patent indicates that the smooth surface “will be hereinafter described in greater detail”, there is no further description or definition.

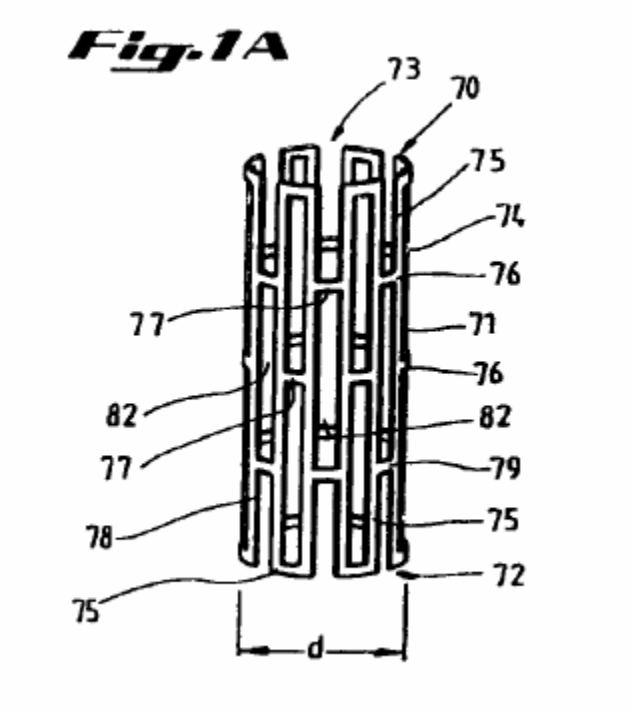
[136] It is clear that claims 11 and 22 of the '505 Patent require that the outside of the wall of the tubular member be a smooth surface when the tubular member has the first diameter. As Dr. Stringfellow noted, “smooth” is a relative term. The question is whether it is smooth enough for the job for which it is intended.

[137] Leaving aside the details of the explanations provided by the expert witnesses, the bottom line for each of them is that the tubular member has to be smooth enough to get into the body and be tracked along the arteries to its ultimate location, without causing damage. That is, although the tubular member may have some slight ridges or bumps, it must be smooth enough to be delivered intraluminally.

[138] Consequently, I construe the word “smooth” to mean smooth enough in the first diameter to permit intraluminal delivery.

[139] The controversy that exists in relation to the remaining words and phrases arises as a result of Dr. Buller’s theory regarding the tubular member. Synoptically, Dr. Buller opines that the building block of the Palmaz stent is a ring of half-slots and that each ring of half-slots is a tubular member. The defendant characterizes Dr. Buller’s proposed claim construction as one that is designed to find infringement.

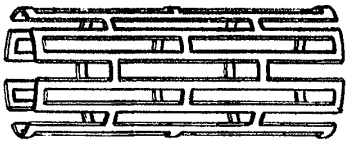
[140] Before examining the perspectives of the parties in detail, it is important to understand Dr. Buller’s position. Although he testified at length in this respect, I am satisfied that the essence of Dr. Buller’s opinion in this respect is captured in his Witness Statement. My summation of his thesis, at this point, is derived largely from that statement as amplified by his evidence in chief (transcript, pp. 281-288, 326-338). It assists if Fig. 1A of the preferred embodiment is reproduced.

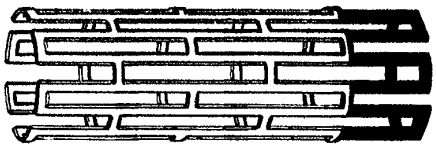


[141] Dr. Buller's position hinges on a paragraph found at page 14 of the '505 Patent, which reads:

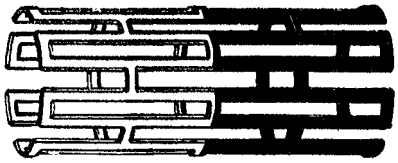
> Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of the tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

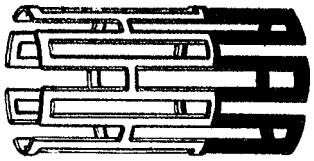
[142] Dr. Buller claims that, following these directions, the length of the stent could be made longer or shorter. He proposes a methodology by which this lengthening or shortening could occur. He asserts that the stent illustrated in FIG 1A of the '505 Patent would be made longer by turning the half-slots at one end of the stent into whole slots as indicated in the diagram below.



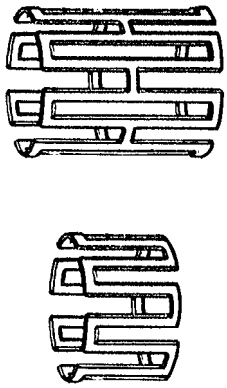


[143] Similarly, he claims that the stent could be made shorter by removing a half-slot from the end of the stent as shown in the diagram below (Fig. 1A less one half-slot).





[144] The stent could be made shorter still by removing further sets of half-slots until only a ring made of half-slots remains as shown by the two diagrams that follow.



[145] According to Dr. Buller, the ring of half-slots, shown in the lower diagram above, is the building block of the stent of the '505 Patent and is a tubular member as he understands the term to be used in the patent. It is a tubular member because the ring of half-slots is hollow, generally cylindrical and therefore tube-like.

[146] I should note that Dr. Stringfellow agrees with Dr. Buller in the sense that they, together, provide a table of definitions evidencing their consensus as to the meanings of the words and phrases contained in the claims of the impugned patent. However, aside from this table of definitions (Witness Statements, exhibits 3 and 4 respectively), Dr. Stringfellow's evidence is largely devoted to the issue of infringement. He does endorse Dr. Buller's building block "ring" concept, but it is clear to me, and I find as a fact, that the notion of the building block "ring" is Dr. Buller's (in accordance with his interpretation of the patent). Dr. Buller's opinion is, in short, that a tubular member can be a ring of half-slots.

[147] The defendant vehemently contests the building block "ring" postulation. Boston Scientific's expert witnesses maintain that the claims of the '505 Patent do not contemplate a ring of

half-slots or a tubular member with half-slots disposed in its wall surface. They assert that a slot must be bounded on all sides and a tubular member must be elongated and function as a stent. Moreover, a ring of half-slots is not a tubular member and it does not contain slots.

[148] In the end, the resolution turns on the meanings to be ascribed to “tubular member” and “slots” in claim 1.

[149] My analysis of these issues includes consideration of the evidence provided by the expert witnesses. Specific references to transcript pages will not be provided because, in many instances, the same propositions were advanced repeatedly. Such references would prove cumbersome and would unduly interrupt the flow of the discussion. It should be apparent, in due course, that the positions taken by the various witnesses are both considered and assessed. I summarize the positions of the parties with respect to each of the contested terms. My analysis and determinations will follow only after the evidence and arguments have been reviewed.

[150] Drs. Cumberland and Prendergast, and Mr. Opolski, for Boston Scientific, share the view that the tubular member in clam 1 of the '505 Patent is the functional graft (or stent), without a coating or anchor. The graft must include a tubular member and must be capable of functioning, as described in the patent, with one tubular member only. In brief, these experts interpret claim 1 as a reference to a single tubular member. They also say that the tubular member should be elongate to properly function as a stent, that is, the length of the stent is sized appropriately to scaffold a lesion in an artery. Boston Scientific notes Dr. Buller’s evidence that the Palmaz stent came in a variety of lengths, all of which were longer than 7 mm. Dr. Cumberland cautions that if the tubular member

were too short, there is a risk that it could tilt upon expansion. If a stent tilted upon expansion, it would not perform its supportive function. Moreover, it would lie in the blood stream, "with thrombosis being a likely result".

[151] With respect to "elongate" this means that the structure has a length notably greater than its diameter. The Boston Scientific witnesses say that, although the claims do not specify a length for the tubular member, length is implicit because the claim describes the tubular member as having two parts or components: a wall surface and two ends. It is said that a skilled person would understand from this that the tubular member is not a ring.

[152] Boston Scientific's experts maintain that the tubular member is to be distinguished from a ring (the latter has a length less than its diameter, or an aspect ratio of less than 1). There is no magical line to determine the length of a tube versus a ring. However, the requirement for stability and the requirement for scaffolding is understood from the patent. The ring of half-slots (the "building block") is not elongate, could not be considered to be a tubular member and would not function as a stent. It would be either too short to act as a scaffold along the length of the stenotic region, or, if it were stretched to sufficient length, it would be too flexible and would collapse under the compressive force of the vessel wall. The ring of half-slots would not be sufficiently long to push open the artery in a way that would allow blood to flow through the vessel again.

[153] Further, a ring of half-slots (the "building block") would be prone to instability. Once the aspect ratio is less than 1, the stability is compromised (the lower the aspect ratio, the lower the stability). When the ring of half-slots is expanded, its aspect ratio is about 0.25 (like a wedding

band) and a skilled person would not consider it to be tubular. Most lesions in the vascular system are about 10 mm in length. Typically, cardiologists want the stent to be slightly longer than the lesion so that the stent may extend somewhat on either side of the lesion. A tubular member that does not meet the basic functional requirements of a stent cannot be within the scope of the patent, which clearly relates to an implantable medical device. Once expanded, the ring of half-slots will be approximately 1 mm in length and 4 mm in diameter, hence the aspect ratio of approximately 0.25.

[154] In sum, on this point, the Boston Scientific expert witnesses maintain that the ring of half-slots does not provide scaffolding because it is not long enough to deal with the lesion on its own. Further, it would not provide protection against flaps or plaque coming down. The skilled person would know that the ring of half-slots would not function by itself.

[155] Next, the Boston Scientific experts maintain that the '505 Patent does not teach a ring of half-slots. There is no description, no illustration and no inference regarding such a ring. Since there is no hint, suggestion or teaching of a ring of half-slots in the patent, Boston Scientific contends that it is not open to me to construe the invention broader than it is disclosed.

[156] Moreover, based on the language of the patent, the shortest that the '505 Patent graft could be is one complete slot long. The patent depicts a stent that is 2 slots long. The structure of the '505 Patent is described clearly in slot lengths. Although it could be longer or shorter than the tubular member shown in Figure 1A, this is in reference to slots. Therefore, the skilled person would conclude that while the tubular member can be various lengths, the language of the patent and the

functional requirements dictate that there be at least one complete slot in the stents described and claimed in the Palmaz patent.

[157] The plaintiffs dispute Boston Scientific's allegations. Drs. Buller and Stringfellow consider tube-like to mean hollow and generally cylindrical, but not necessarily elongate. If the tubular member is hollow, there is space inside the cylinder where blood can pass through. A circular cylinder is an example of a tubular structure that extends along a line known as the longitudinal access. Not all the attributes of a tube must be present for an object to be tube-like or tubular. Dr. Stringfellow unequivocally states that there is no magical dimension at which a structure ceases to become a ring and is then considered a tube.

[158] Johnson & Johnson's position regarding the capacity of the ring of half-slots to function as a stent emanates almost exclusively from Dr. Buller. Dr. Stringfellow considered that he was not qualified to respond to many of the questions regarding the efficiency of a ring-like tubular member in the practice of interventional cardiology.

[159] Dr. Buller points to the prior art of the '505 Patent and says that there is specific reference to intraluminal endovascular grafting as involving the use of a "tubular prosthetic graft". It describes structures which previously have been used as intraluminal vascular grafts as including "expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern". This is the Gianturco Z-stent. The larger diameter Z-stent (referred to in the Wallace article and relied upon by the defendant for purposes other than construction) had a length to diameter ratio of 0.625:1. Thus, in

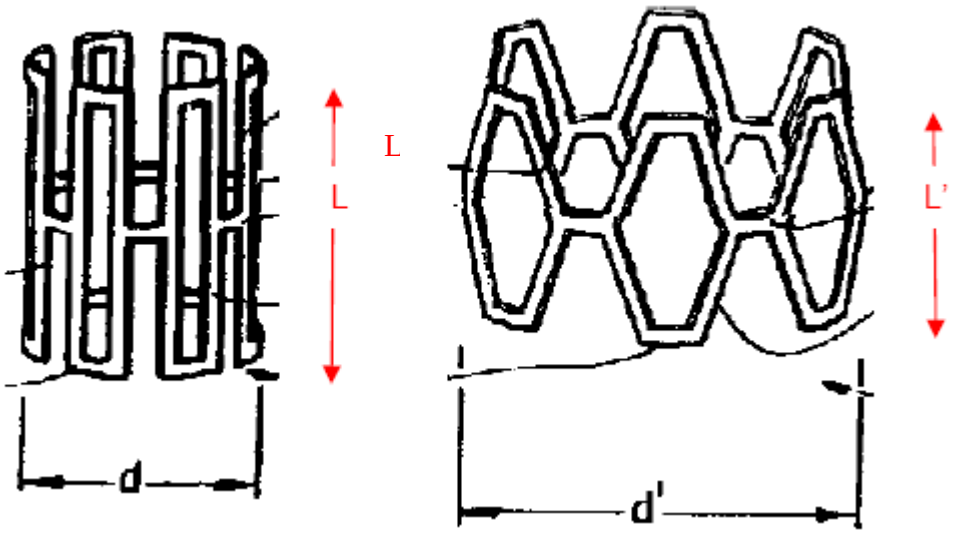
March of 1991, Dr. Palmaz was including devices having a length to diameter ratio of 0.625:1 within his meaning of the term “tubular”.

[160] Dr. Buller notes that the AVE Micro Stent PL, the first generation of AVE’s commercial stent, had short tubular rings which, alone, or in tandem supported a lesion. Johnson & Johnson claims that Mr. Opolski, on cross-examination, agreed that a Palmaz ring could work just as well as a Microstent PL 4 mm long. He also agreed that the patent does not say how many longitudinal parts are in the device. Further, ear grommets are somewhat more than 1 mm long and at least 1 mm in diameter. Dr. Prendergast acknowledges that his paper refers to a grommet generically as a ventilation tube. His paper sets out ranges for the dimensions of the ventilation tubes. For the low-level, the length of the device is 1.08 mm and the diameter or inner bore is 1.3 mm. Therefore the aspect ration (length to diameter ratio) of this tube is less than 1 (0.83:1). These devices for the eardrum have flanges, like ridges, to stabilize them in the anatomical position.

[161] In response to Dr. Cumberland’s evidence relating to the difficulties associated with inserting stents in tandem (in sequence), Dr. Buller states that many times, he has enlarged lesions by using, in sequence, balloon-expandable stents that were shorter than the totality of the lesion. He is aware of his colleagues having done likewise. In a high-quality catheter laboratory, Dr. Buller has not encountered problems visualizing the stent on x-ray screening (as Dr. Cumberland stated), with gaps between the stents, or with an excessive overlap of the stents.

[162] Johnson & Johnson additionally dispute the claim of the Boston Scientific witnesses that the shortest tubular member of the '505 Patent is one complete slot long. Dr. Buller maintains that if the

tubular members illustrated in Figures 1A and 1B of the patent were shortened to be one complete slot long, they would appear as indicated in the diagram below. The expanded tubular member would have a length (L) much small than its diameter (d).



[163] As for Dr. Prendergast's FEA, Johnson & Johnson contend that the choice of a 15 mm long ring of half-slots would not have been a practical choice for a ring of half-slots that would work. It says that Dr. Prendergast acknowledges that he was not, in any way, attempting to make a Palmaz ring 15 mm long that would work. Rather, he was trying to make a 15 mm-long ring to use as a point of comparison to one that was shorter. That is, he was trying to measure the effect of lengthening the ring (building block) to illustrate, examine and quantify, the extent to which a lengthened ring will recoil after expansion. Shorter rings have higher resistance to elastic deformation. Therefore, there would be less recoil if the ring were made shorter.

[164] Johnson & Johnson emphasizes that the '505 Patent expressly provides, at page 14, that the graft can be made longer or shorter, as desired, than what is illustrated in the patent. It states "[a]lthough the graft, or posthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired".

[165] To summarize Johnson & Johnson's position, its witnesses maintain that tubular means tube-like (having at least some, but not necessarily all characteristics of a tube). It means hollow and generally cylindrical, but need not be elongate. It need not be elongate in order not to tip or tumble and it need not be long enough to span a lesion on its own. In the context of the '505 Patent, "tubular" need not be elongate.

[166] The second major point of contention relates to the "slots" of the Palmaz Patent. The '505 Patent describes "slots" extensively and provides detail regarding what the slots are and how they are formed and arranged. Claim 1 of the '505 Patent requires a plurality of slots formed in the wall of the tubular member (depicted in Figure 1A as 71).

[167] It appears to be common ground that "plurality" means more than one and "formed therein" means that the slots are formed within the wall surface. Dr. Buller agrees that the term "formed therein" means that the slot is defined by the metal surrounding it.

[168] It is also agreed that the slots of the '505 Patent are elongate since the patent describes the shape of slots as being substantially longer than wide. Dr. Prendergast states that for the tubular

member to be able to expand as intended, the longitudinal length of the slots must be substantially greater than their width (which is in the circumferential direction).

[169] Similarly, there is no great debate about the fact that the slots are disposed (located) substantially parallel to the longitudinal (lengthwise) axis of the tubular member. As Dr. Prendergast explains, slots running in the longitudinal direction will expand circumferentially. Slots that are narrow or oriented other than longitudinally would not facilitate circumferential expansion of the stent.

[170] The dispute centers on the meaning of the word “slot”, specifically whether it refers to a complete slot, or to both a complete slot and a half-slot. Boston Scientific, for a variety of reasons, claims that it refers to a complete slot, which is fully enclosed (by the metal surrounding it). Johnson & Johnson claim that “slot” includes half-slot and that each slot need not be fully enclosed. The evidence is lengthy and it will be necessary to examine it in some detail.

[171] Boston Scientific witnesses note that the patent describes starting with the tube and making slots in the tube. It teaches that the tubular member has a wall surface that extends from one end of the tubular member to the other, with slots formed therein. At page 13 of the '505 Patent, the “surrounding” of the slots is described as follows:

> Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends 72, 73 of tubular member 71, as seen in FIG. 1A.

The Boston Scientific experts claim that a tubular member must have one complete slot in it to fit within the patent.

[172] The Palmaz Patent describes rectangles and elongated oval openings. Boston Scientific says that both are closed structures, bounded on all sides. An elongated oval, by definition, is a structure that has material all the way around it. Further, a slot has connecting members at each end, therefore it is closed. Looking at the patent as a whole, the skilled person would understand from the patent that a slot is bounded on all sides by metal.

[173] Dr. Prendergast notes that there is nothing in the patent to suggest that a "slot" within a tubular member could be anything other than bounded on all sides. The introduction of the term "half-slot" for the alternating openings at the ends reinforces that the "slots" are bounded on all sides. The existence of the half-slot (not bounded on all sides and located at the ends) is inevitably due to the complete slots. Dr. Cumberland refers to the patent's description of slots as having both longitudinal members and short transverse connecting members. Hence, the slots are enclosed. Mr. Opolski maintains that the patent always refers to the entire opening – not part of the opening – as the slot. The language "slots formed therein" tells the skilled reader that the slots have to be fully enclosed by wall elements.

[174] Further, the Boston Scientific experts opine that the term "slot", as it is used in the Palmaz Patent, refers to an opening that is substantially regular in shape. If the slots are not of the same general size and shape, then it would be expected that the expansion of the stent would not be uniform, but irregular. Moreover, if there is only a half-slot, there are not two ends to the structure

and connecting member 77 does not exist. A structure of only half-slots does not have any connecting members. To eliminate slots (as complete slots) is to eliminate the connecting members. The only slots 82 labelled in Figure 1A are two complete slots 82.

[175] The Boston Scientific experts note that half of a slot is not bounded and is located at the ends. The '505 Patent (page 14) states that, regardless of how many complete slots there are in the tubular member, the tubular member will have half-slots at both ends:

> Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71.

[176] Thus, the ends of the tubular member are alternating between two things: full slots and half-slots. Without the alternating openings at either end of the stent, a circumferential band of metal would be formed thereby preventing expansion of the tubular member or stent. A skilled person would recognize this fact.

[177] The Boston Scientific experts also discuss the patent's description of the staggering of the slots, by offsetting, so that there are openings at the ends of the stent. This allows for the radial expansion and it constitutes an effort, by the inventor, to explain how the invention works on a practical basis. The staggering of slots circumferentially is necessary to enable the tubular member to expand. Otherwise, a band of metal would be formed. When the tubular member of Figure 1A is expanded, it's going to have the hexagonal pattern that is seen in Figure 1B.

[178] The crux of Boston Scientific's position is that the word "slot" in the '505 Patent refers only to a complete slot. A complete slot is elongate, is bounded by metal on all sides, and has a longitudinal axis substantially parallel to the tubular member.

[179] Johnson & Johnson's expert, Dr. Buller, holds an opposing view. Dr. Buller claims that page 14 of the '505 Patent, with reference to Figure 1A, refers to "alternating slots", "complete slot" and a "half-slot":

> Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bound by members 78, 79, at both the first and second ends, 72, 73 of the tubular member 71.

[180] In his view, the patent teaches half-slots and to suggest otherwise is to ignore the clear language of the disclosure. Alternating slots include half-slots. At the ends of the tubular members, there are half-slots. The half-slots are bordered by elements 78 and 79. Thus, the '505 Patent calls out that "slots" include "whole slots" or "complete slots" and "half-slots". Both are called "slots". According to Dr. Buller, it is important that the patent says that "complete slots" and "half slots" are both slots – they are just different types of slots. The wall surface extends from one end to the other and the half-slots are clearly within that surface. Therefore, the alternating or half-slots are in the wall surface of the structure. Thus, both the full (complete) slots and the (open) half-slots are within the wall surface. Because "alternating slots" of "half-slots' are referred to as such, they are then "slots" as that term has been used by Dr. Palmaz in the '505 Patent.

[181] Dr. Buller says that members 78 and 79 bound the half-slots at the ends. Member 79 in Figure 1A and 1B is indicated to be the same as connecting member 77. Members 77 and 79 define a boundary of the half-slots in the end rings of the device illustrated. The half-slots do not have material fully surrounding them and therefore not all slots in the patent have material fully surrounding them. “Complete slots” do, but half-slots do not. Specifically, in the introduction to the '505 Patent, in the general section, the patent says nothing about the slot being closed at the end.

[182] Disagreeing with Dr. Prendergast that the slots must be of the same general size and shape, or substantially regular in shape, Dr. Buller provides examples of balloon-expandable stents which he claims establish otherwise. He specifically refers to the BSC Express stent, the ACS (Abbott) Multi-Link stent and NIR Conformer stent. He provides photographic images of the BSC Express stent and the ACS (Abbott) Multi-Link Ultra stent.

[183] Regarding the staggered slots, Dr. Buller notes that page 13 of the '505 Patent uses the word “preferably”:

> Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71.

[184] Because the sentence says “preferably” not “necessarily”, it is an option and “we don’t have to have it”. Further, in relation to the “ends”, page 7 of the patent, in the section entitled “Summary of the Invention” states:

> Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

[185] Again, the word “may” indicates that the staggering is permissible, but not necessary. Significantly, according to Dr. Buller, Drs. Prendergast and Cumberland and Mr. Opolski considered the single complete slot device to be an embodiment of the '505 Patent. There are no offsets in such device. Thus, the staggering is not necessary or essential. Reference to page 13 is further illustrative in this respect:

> Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82.

[186] Clearly, asserts Dr. Buller, slots 82 refer to complete slots. In the “Summary of the Invention” section of the '505 Patent, there is no requirement that each slot have first and second ends with a connecting member disposed at the first and second ends.

[187] In sum, Dr. Buller’s opinion is that the tubular member could include complete slots and half-slots. Both are called slots. This interpretation is consistent with that adopted by the United States Court of Appeal for the Federal Circuit in respect of the “corresponding U.S. patent” (*Cordis Corp. v. Boston Scientific et al*., U.S.C.A.F.C., January 7, 2008 - Exhibit P-108-S) where it was determined that “the term ‘slots’ as used in claim 23, refers to both complete slots and half slots”.

[188] The final point of divergence concerns the word “comprising”. At the outset of Claim 1, the invention is introduced as “[a]n expandable intraluminal vascular graft, comprising”. Much has been said, particularly by the plaintiffs, in relation to the word “comprising”.

[189] Johnson & Johnson notes that terms such as “comprising”, “consisting of” and “consisting essentially of” are transitional words or phrases used at the beginning of a claim to join the preamble to the claim elements. Relying on *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.* (1974), 17 C.P.R. (2d) 97 (S.C.C.), the plaintiffs say “comprising” is no vaguer than “includes”.

[190] The Johnson & Johnson expert witnesses, Drs. Buller and Stringfellow, consider the word “comprising” to mean “includes”. Dr. Buller claims that it means “includes, but not limited to”. Therefore, and in accordance with the evidence of Dr. Stringfellow, if the claimed graft or prosthesis in the '505 Patent comprises or “includes” nothing more than the tubular member, then the tubular member would be the graft or prosthesis and would have to function as a graft or prosthesis. Yet, if the tubular member is only part of the graft, it need not function as a graft or prosthesis on its own. The United States Court of Appeal for the Federal Circuit, in the *Cordis* decision noted earlier, interpreted the word “comprising” as being “open” rather than “closed”. That is, “comprising” does not mean “consisting of”.

[191] The plaintiffs censure the defendant’s witnesses for providing an ambiguously inconsistent approach to what “comprising” means. On the one hand, Boston’s experts say it means “includes, but is not limited to” or “has”, while on the other hand they say that the word means “is”. All of the defendant’s witnesses took the position that the tubular member described in Claim 1 of the '505 Patent had to be able to function as a graft or prosthesis. The plaintiffs say that this is not so.

[192] According to the plaintiffs, if “comprising” means includes, then the graft or prosthesis can have parts other than a tubular member. Although the graft or prosthesis as a whole must still function as such, the tubular member part of it need not function as the graft or prosthesis on its own. Since it need not function on its own as a graft or stent, the tubular member in the '505 Patent can use the rest of the structure of the graft or stent to support it. To bolster this reasoning, the plaintiffs provide examples of various grafts that incorporate a balloon-expandable tubular member as part of the larger graft, in particular a Pardoi & Palmaz AAA (abdominal aortic aneurysm) graft.

[193] In sum, the plaintiffs claim that “comprising” means “including but not limited to”. They say that the tubular member can either be part of or all of the claimed graft or prosthesis in the '505 Patent.

[194] Boston Scientific, on the other hand, insists that, in the '505 Patent, the tubular member (with the additional features described in the claims) is the stent. Dr. Prendergast states that the term “comprises” or “comprising”’ means that elements, other than those specifically identified, can be included. However, the device must not require such additional elements in order to function as a graft or prosthesis.

[195] Moreover, Claim 4 of the patent refers to “the tubular member”. It is referring to the same tubular member of claim 1. Claim 4 simply adds a further limitation and is not changing “the tubular member” of claim 1. Claim 4 refers to “the tubular member” in the singular. It is talking about the same (one) tubular member that is referred to in claim 1.

[196] Dr. Palmaz refers to a “plurality” in relation to “slots” in claim 1. Nowhere in the '505 Patent does he refer to a plurality of tubular members.

[197] To summarize Boston Scientific’s position, it is said that, in a claim where a device is said to be “comprised by” or “comprising”, the claim must include those elements that are essential to the working of the invention, as described. Nothing else should be necessary to make the invention work.

Analysis

[198] Before turning to the construction of the contested words and phrases, some observations regarding the testimony of the expert witnesses in this area are in order.

[199] I place little weight on the plaintiffs’ submission that Dr. Cumberland’s credibility was compromised because his responses to questions during a proceeding in the United States differed from his answers (to the same questions) given in this proceeding. I found Dr. Cumberland’s explanations for the discrepancies to be thoughtful and reasonable.

[200] The procedure and approach in the United States differs from that in Canada. There, the claims of the patent are construed during a Markman hearing. The file wrapper is given significant emphasis whereas extrinsic evidence, while within the discretion of the judge, is regarded as less reliable than the prosecution history in determining how to read the claim terms. Generally, the construction is concluded without the benefit of expert testimony. Witnesses at

trial are confined to the definitions contained in the Markman Order. That is not the situation in Canada.

[201] The result is that responses to questions in the United States are, of necessity, premised on the Markman definitions. There, although expert witnesses may not subscribe to, or even agree with, the meanings assigned to specific terms or phrases, they must nevertheless apply those meanings when testifying. Dr. Buller (the plaintiffs' expert witness) encountered a similar difficulty in responding to questions asked of him.

[202] Overall, I found the expert witnesses to be generally credible. However, there are degrees of credibility. Dr. Stringfellow is eminently qualified, but his evidence (with the exception of the table of definitions arrived at in collaboration with Dr. Buller) was primarily directed to the issue of infringement. Should I determine that Dr. Buller's building block "ring" theory is flawed (Dr. Stringfellow endorsed the concept), then much of Dr. Stringfellow's evidence regarding construction is rendered of little assistance.

[203] Both Drs. Cumberland and Buller have extensive experience regarding coronary artery stents. Both have provided evidence in analogous litigation in the United Kingdom and the United States. Their evidence was helpful, particularly regarding the use and properties of coronary artery stents in general. That said, on the matter of claim construction of contentious terms, I did find Dr. Buller intransigent, particularly during cross-examination. He evaded questions that could expose any frailties in his theory and was intent on reiterating his views, when he deemed it necessary, irrespective of whether those views were responsive to the

questions at hand. In short, Dr. Buller's repetitive emphasis on those areas favourable to his interpretation and his reluctance to respond to certain questions asked of him was most unhelpful. While Dr. Buller could, and should, have been of great assistance (which is the function of an expert witness), he fell short in this respect. Although well-qualified, his credibility was compromised as a result of his responses, or lack of them.

[204] Although Mr. Opolski's evidence was also helpful, his tendency toward verbiage led to confusion. In many instances, several paragraphs could (and should) have been compressed into a few sentences. While I found Mr. Opolski credible, his evidence and the manner in which he gave it was not without difficulty.

[205] Dr. Prendergast, on the other hand, was most effective. In terms of degrees of credibility, I place him at the top of the range. While there may be isolated instances where I rely on the evidence of another witness, overall, in areas of inconsistency among the experts, I prefer the evidence of Dr. Prendergast. His qualifications are impeccable, he has devoted his life (to date) to academia and research, and he has no previous involvement in this, or analogous, litigation. He was forthright, fair and reasonable in answering all questions asked of him, both during examination-in-chief and cross-examination. In all instances, he answered thoughtfully and directly. He, in my view, exemplifies the requisite characteristics and qualities of an expert witness.

[206] I also note that the submissions regarding the construction of the contentious terms of the '505 Patent were rendered more complex because of the existence of the '186 Patent. Counsel for

both parties, while conceding that I could not utilize the '186 Patent to inform my construction of the '505 Patent, nonetheless frequently vacillated from one to the other. The expert witnesses did likewise. While it seems to me that my task would be far easier if regard could be had to the '186 Patent (an improvement of the '505 Patent) to assist in ascertaining the meaning of the '505 Patent, given the law discussed earlier, I do not believe such an option is available. Consequently, my construction of the '505 Patent is totally independent of the '186 Patent.

[207] The debate regarding the word “comprising” arose at the trial. The affidavits of Drs. Buller and Stringfellow indicate that “comprising” means “includes”. During his testimony, Dr. Buller emphasized that by “includes”, he means “includes, but not limited to”. Although Dr. Cumberland states that he reads “includes” as meaning “consists of”, he also says that it is fair to say that it could mean “includes, but not limited to”. Mr. Opolski is more equivocal and would restrict any items in addition to those delineated in claim 1 to those described elsewhere in the claims (coating and anchors). Dr. Prendergast’s view is that, although the graft could have other elements, it must not require such additional elements in order to function as described and intended in the patent.

[208] I agree with and accept Dr. Prendergast’s view. The meaning of the word must be derived from the context of the patent. Section 34 of the *Patent Act* reads:

Patent Act R.S., 1985, c. P-4 (pre October 1, 1989)	*Loi sur les brevets* L.R., 1985, ch. P-4 (avant le 1er Octobre 1989)
34. (1) An applicant shall in the specification of his invention	34. (1) Dans le mémoire descriptif, le demandeur : a) décrit d’une façon exacte et

(a) correctly and fully described the invention and its operation or use as contemplated by the inventor;	complète l'invention et son application ou exploitation, telles que les a conçues l'inventeur;
(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it;	b) expose clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'objet de l'invention;
[…]	[…]
(e) particularly indicate and distinctly claim the part, improvement or combination that he claims as his invention.	e) indique particulièrement et revendique distinctement la partie, le perfectionnement ou la combinaison qu'il réclame comme son invention.
(2) The specification referred to in subsection (1) shall end with a claim or claims stating distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege.	(2) Le mémoire descriptif se termine par une ou plusieurs revendications exposant distinctement et en termes explicites les choses ou combinaisons que le demandeur considère comme nouvelles et dont il revendique la propriété ou le privilège exclusif.

[209] I do not disagree with the construction adopted by the United States Court in the *Cordis* case that a graft "comprising" a tubular member does not equate to a graft "consisting" of a

single member. However, if the U.S. definition means that another element (that is essential to the functioning of the graft) can be added, then, in my view, that element must, to receive patent protection, be included in the claim. That is what Canadian law requires.

[210] Johnson & Johnson maintains that the tubular member in the '505 Patent can use the rest of the structure of the graft or stent to support it. Again, I do not disagree. My question is: what is there in the '505 Patent claims that would support it? None of the plaintiffs' witnesses were responsive in this respect. Rather, they pointed to examples of other grafts (such as the Parodi & Palmaz AAA graft) where the tubular member was merely a part of the graft. Many hypothetical questions were asked of the defendant's experts regarding the Dacron sleeve of the Parodi & Palmaz graft. These explorations are of limited assistance in addressing the context in which the word "comprising" appears in the '505 Patent. The same is true for the other examples provided by the plaintiffs. Those examples must be viewed in the context of the patents applicable to them.

[211] The plaintiffs say that if a device includes one thing, "surely a device with more than one thing can be said to include that one thing". That may well be so. The specific examples proffered by the plaintiffs were "two or three tubular members in tandem", or "two tubular members connected". My assessment is that if more than one tubular member is required for the graft to function, then the claim must provide for it. Similarly, if the connector connecting two tubular members is required for the functioning of the graft, then the connector would have to be delineated in the claim.

[212] The plaintiffs concede that the tubular member can be the claimed graft or prosthesis in the '505 Patent. I conclude that it is more likely than not that this is what is intended. While the plaintiffs are correct that a dependent claim cannot narrow the scope of an independent claim, there is a presumption of claim consistency, that is, the same words are given the same meaning throughout the claims. Independent claims must be interpreted in a manner that is consistent with the claims that are dependent upon them. When regard is had to the claims of the '505 Patent, each claim that refers to a tubular member (which in claims 2 through 11 is the tubular member in claim 1) refers to “the tubular member” expressed in the singular rather than the plural. This constitutes, in my view, a compelling indication that the tubular member discussed in claim 1 is a single tubular member.

[213] In sum, while I agree with the plaintiffs that “comprising” should be construed as meaning “including, but not limited to”, if the graft requires a specific element in order to function, that element must be found within the claim. Essential elements must be claimed.

[214] Turning to the meaning of the word “slot”, the arguments have been detailed earlier and I do not intend to repeat them. I am cognizant and mindful of the plaintiffs’ admonition that the words “preferably” and “may” are permissive and not mandatory. Similarly, I am aware that the ambit of the monopoly claimed cannot be diminished merely because, in the disclosure, the patentee has described the invention in more restricted terms than in the claim itself. Nor should the claims be limited to the specific examples or embodiments described in the patent. I regard these principles as aids to assist in arriving at a determination as to the proper meaning to be

given to the word “slot”. The ultimate exercise remains one of ascertaining the patentee’s intention on a reading of the patent as a whole.

[215] There is no debate that both terms, “slots” and “half-slots”, appear in the disclosure portion of the patent. The claims, however, refer only to “slots”. The meaning to be accorded the term “slots” is crucial. It is my view that the word “slots” in claim 1 means a complete slot. It does not include a half-slot. I arrive at this conclusion for a variety of reasons.

[216] The patent is replete with references to “slots”. These “slots”, as taught by the patent, are formed within the wall of the tubular member. They are defined as encompassing an opening whose length is substantially greater than its width, such as an “elongated oval opening”. The uncontroverted evidence is that an oval (or a rectangle as depicted in Fig. 1A) is, by its nature, fully bounded on all sides.

[217] In the preferred embodiment, the “slots” are assigned the number 82. The content of the disclosure, where the preferred embodiment is discussed, uses the terms “slots” and “slots 82” interchangeably. Notably, slots 82 are complete slots.

[218] At page 13 of the patent (Detailed Description of the Invention), it states that “each slot will have first and second ends with a connecting member 77”. The openings at the ends of the tubular member (I will say more about these later) do not have first and second ends 77 because one side of the opening at each end of the tubular member (as contrasted with the end of the slot) is open. Although the plaintiffs argue that this language refers only to the preferred embodiment

and thus is not a required characteristic, I do not find that submission persuasive. The word "preferably" appears at various times throughout the disclosure thereby indicating that the language that follows is not mandatory. However, the reference with respect to first and second ends on page 13 of the patent is not prefaced by the word "preferably".

[219] It is useful to examine the context in which the word "half-slots" actually appears in the patent. Notably, despite profuse references (in excess of 40) throughout the patent to the term "slots", the reference to "half-slots" appears only once, at page 14, where the ends of the tubular members are being described. That reference reads:

> Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of graft 70 could be made longer or shorter as desired. Use of the term "slot" encompasses an opening whose length is substantially greater than its width, such as an elongated oval opening.

[220] This reference, in my view, when regard is had to the patent as a whole, is intended to describe the ends of the tubular member (to which I indicated I would return). The word "half-slots" is used so that the reader is able to distinguish the "slots" referred to throughout the patent from the "half-slots" that are found only at the ends of the tubular member. As Dr. Prendergast and Mr. Opolski note, and I accept, the skilled reader would recognize that alternating openings at either end of the stent are necessary. Otherwise, a circumferential band of metal would be formed and would prevent expansion of the tubular member or stent.

[221] There is no disagreement that complete slots are bounded on all sides (unlike half-slots). My conclusion that “slots” means complete slots is, in my opinion, reinforced by other claims of the '505 Patent.

[222] Both dependent claims 5 and 6 refer to the “expandable intraluminal vascular graft of claim 1”. Claim 5 refers to the slots having a substantially rectangular configuration in the first diameter and a substantially hexagonal configuration when the tubular member has the second, expanded diameter. Claim 6 refers to slots having a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter. The evidence is clear that a half-slot would not expand into a hexagon or parallelogram; it would expand into a trapezoid or triangle. The plaintiffs say that a dependent claim cannot be used to narrow the scope of the broader claim. I agree with that proposition. However, I do not see that claims 5 and 6, which specifically refer to the “slots” recited in claim 1, do any such thing. They simply confirm that the slots referred to in claim 1 are indeed bounded on all sides. Were it otherwise, they could not expand as indicated in the claims. Slots that are bounded on all sides are complete slots. Thus, the “slots” in claim 1 are complete slots.

[223] I find Dr. Buller’s proposed definition of the word “slots” to be one that is contrived to accord with his theory of the building block “ring”. In discussing the patent language that requires slots to be formed within the tubular member, he begins from the premise that “half-slots” are “slots”. From there, he works in reverse and says because half-slots do not have

material fully surrounding them (are not bounded on all sides), this negates any requirement that "slots" be bounded on all sides. For the reasons previously discussed, I reject this approach.

[224] I have not forgotten the plaintiffs' request that I construe the phrase "slot" in the same manner as it was construed in the United States. I respectfully decline to do so for essentially the reasons that I have provided earlier when I addressed the word "comprising".

[225] I also reject Dr. Buller's building block "ring" theory. There is no indication, let alone description, in the patent regarding a ring of half-slots as the building block of the invention. Nor does the patent suggest, let alone teach, that the shortening or lengthening of the graft or prosthesis is to be accomplished through manipulation (Dr. Buller uses the word "orientation") of a ring of half-slots.

[226] Moreover, I accept the opinions of the expert witnesses Drs. Cumberland, Prendergast and Mr. Opolski (Dr. Stringfellow did not express any opinion in this regard) that in all likelihood, a ring of half-slots would be too short for a typical lesion, would not provide appropriate scaffolding, and would be prone to tilting upon deployment. These experts (Cumberland, Prendergast and Opolski) were unanimous in their view that the shortest permissible length of a functional Palmaz stent is a one "slot" (meaning a complete slot) stent.

[227] The plaintiffs do not confront this non-functional aspect head-on and I am left uncertain as to whether they dispute that the half-slot device would not work. Johnson & Johnson does, both in reply and during cross-examination of witnesses, refer to a stent manufactured by AVE

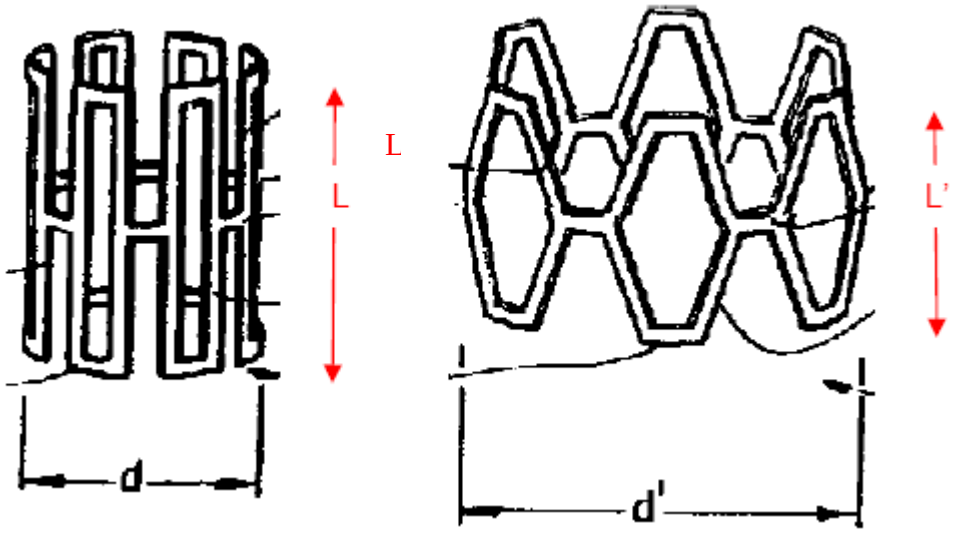
(the Microstent PL), which was 4 mm in length and had no openings that were bounded on all sides. However, that reference does not resolve the problem. First, Boston Scientific's witnesses do not acknowledge that the Microstent PL functioned well. Indeed, Mr. Opolski, when asked if the half-slot ring could function as well as the Microstent PL, responds "just as well or just as poorly". It seems to me that the Microstent PL (on the evidence before me) did not fare well and was not regarded as a functional stent. Moreover, and more importantly, there is insufficient evidence (actually there is none beyond Dr. Buller's references by name) regarding any of these allegedly "short functional stents".

[228] The remaining contentious issue is that of the tubular member being "elongate". Again, I do not intend to reiterate the arguments that have been previously detailed. The argument centres on the word "tubular" (which means tube-like) and whether a stent, having an aspect ratio of less than 1, is functional. There was much debate about this at the trial. Various pipes, tubes and tubing were examined. It is fair to say that, although no one was able to draw a magical line in the sand as to when a tube becomes a ring, the aspect ratio of 1 is regarded as extremely significant.

[229] It is common ground that the slots must be elongate. The question is whether the tubular member or stent must also be elongate. The patent, on its face, does not mandate that the tubular member be elongate. The defendant argues that it does so by implication.

[230] On the basis of the evidence (which was restricted to coronary artery stents) I am inclined to think that it is more probable than not that a coronary artery stent would not function well if its

aspect ratio were less than 1. At the same time, the defendant's expert witnesses are unanimous that a one-slot stent falls within the parameters of the '505 Patent. Johnson & Johnson opines that a one-slot Palmaz stent would have a length "much smaller than its diameter". This allegation is supported by a pictorial diagram that was reproduced earlier and, for convenience, is again depicted here.



[231] The difficulty is that the diagram does not purport to be drawn to scale, there are no measurements provided, and there is virtually no evidence to explain the statement.

[232] At the end of the day, I am satisfied that a tubular member that is not elongate would certainly not function well as a coronary artery stent. I am uncertain as to whether it would be totally non-functional. I do not regard the inquiry as one where I must determine whether one functions better than the other. Rather, it is whether the invention functions. My primary concern here is that the patent itself is not confined to coronary artery stents. As earlier noted,

the invention is intended for various other body passageways. At page 11 of the '505 Patent, there is reference to use in the esophagus, the intestine, the bile ducts and other areas of the body. It may well be (or may not) that appropriate scaffolding in these areas would require a stent of a larger diameter than those in the coronary arteries. At pages 16 and 17 of the '505 Patent, there is further reference to the invention being used to intraluminally reinforce other body passageways or ducts.

[233] In the absence of some indication in the patent that the tubular member itself (rather than its slots) must be elongate, I am not prepared to construe the word “tubular” as requiring that the tubular member must be elongate in all cases. It must, however, be cylindrical and hollow.

[234] This concludes the construction of the contentious issues. In relation to the construction of “comprising” and “slots”, I find that the plaintiffs’ proposed interpretations seek to broaden the invention beyond that which is described and intended.

[235] As for the essential elements, it is common ground that all the elements of claim 1 of the '505 Patent are “essential” to making the invention work in the way described by the disclosure. Nothing in the claims is superfluous or non-essential to the working of the invention.

The '186 Patent

[236] As stated previously, the claims in issue in the '186 Patent are claims 1 and 5. For ease of reference, those claims are again reproduced below.

1. An expandable intraluminal vascular graft, comprising:

A plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen;

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

5. An expandable prosthesis for a body passageway comprising:

a plurality of thin-walled tubular members, each having a first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

[237] The described invention of the '186 Patent is precisely the same as that of the '505 Patent.

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

[238] It is common ground that the '186 Patent is an improvement of the '505 Patent. It introduces a “connector” between the tubular members to ameliorate an identified problem of inflexibility. At page 5 of the '186 Patent, this issue of “inflexibility” is discussed. It states that problems may present if the length of the required graft (in relation to the length of the body passageway which requires repair) cannot negotiate the curves or bends of the body passageway. Specifically, it says that:

> Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes (pp. 5, 6).

[239] The disclosure, also at page 6, states that the invention “provides the necessary flexibility to negotiate the bends and curves in the vascular system”.

[240] The “Summary of the Invention” refers to the improvement over the invention of the '505 Patent as follows:

> In accordance with the invention, the foregoing advantages have been achieved by the present expandable intraluminal vascular graft. The present invention includes a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member; <u>at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members</u>; each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and the tubular members having a second, expanded and deformed diameter, upon the application of a radially, outwardly

> extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway. (my emphasis)

[241] The only difference between claim 1 and claim 5 of the '186 Patent is the location of the application. Both require that the graft or prosthesis contain more than one thin-walled tubular member and a connector member disposed between adjacent tubular members to flexibly connect the adjacent tubular members.

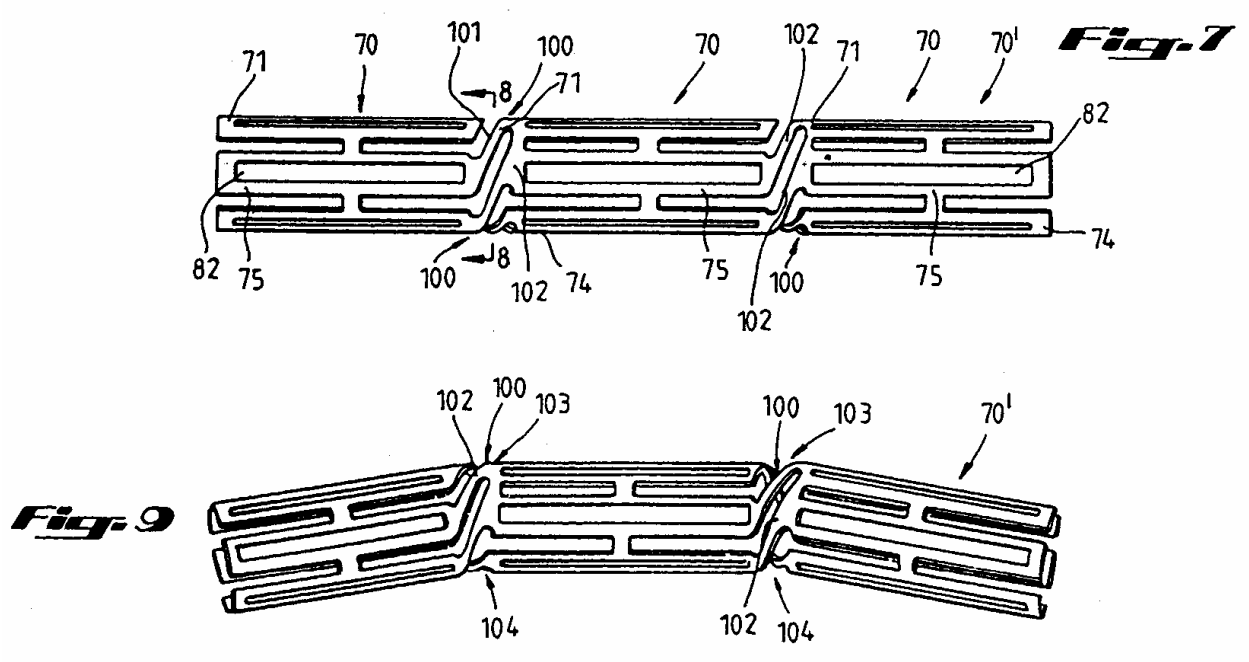
[242] Additionally, claim 1 of the '505 Patent and claim 1 of the '186 Patent are substantially the same, except that claim 1 of the '186 Patent also includes:

- a plurality of tubular members; and
- at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members.

[243] The evidence of the expert witnesses indicates that the '186 Patent teaches that a flexible graft can be created by joining inflexible tubular members together with a connector. In the '186 Patent, the tubular member is part of the overall stent. The tubular members (as well as the connector in some instances) provide a scaffolding function.

[244] The tubular members of the '186 Patent are “quite inflexible”. They are both depicted and described in the patent as being of the kind disclosed in the '505 Patent. Figures 1A and 1B of the '186 Patent are identical to Figures 1A and 1B of the '505 Patent.

[245] Figure 7 of the '186 Patent exhibits a preferred embodiment which has three tubular members with connectors between them. Figure 9 is the same structure in its curved format.



[246] The complete graft, comprised of tubular members and the connector(s), is labelled 70' (70 prime). The connectors are the articulation points between the adjacent tubular members (as described at page 25 of the patent). As Dr. Prendergast explained, the connector acts as a kind of hinge to enable the graft to go around sharp corners and negotiate the bends.

[247] Claims 2, 3, 6 and 7 of the '186 Patent (not in issue) claim at least one connector that is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Claims 4 and 8 (not in issue) claim at least one connector that is spiral.

[248] There is general agreement among the expert witnesses, and I concur, that the '186 Patent is comprised of the tubular members that form the subject matter of the '505 Patent joined together by a connector(s). Consequently, only the terms “plurality”, “connector” and “to flexibly connect” need be construed.

[249] I conclude that “plurality” means more than one. There must be at least two. Therefore, the graft or prosthesis of the '186 Patent has more than one tubular member. The “connector” member is located between adjacent tubular members. Its function is to connect the tubular members. In the case of the spiral connector, the evidence indicates that it also assists in scaffolding the artery. To “flexibly connect” means that the adjacent tubular members are flexibly joined together, that is, articulation is provided by the connector.

[250] Dr. Cumberland’s uncontroverted evidence is that all features of the '186 Patent would be considered by the person skilled in the art to have been intended to be essential elements of the device since they are related to how the device is intended to function. In the absence of any evidence to the contrary, I agree with Dr. Cumberland that all elements of the '186 Patent are essential elements.

[251] Insofar as the evidence of Doctors Buller and Cumberland (with respect to whether the language of the patent differentiates between “graft” or “prosthesis” and “tubular member” or uses the terms interchangeably) is concerned, I prefer the opinion of Dr. Cumberland over that of Dr. Buller and conclude that the terms are intended to be, and are, used interchangeably in the

'186 Patent. It necessarily follows that the '186 Patent is comprised of multiple tubular members, or stents, which are the subject of the '505 Patent, joined together by the connector(s).

[252] I have three additional observations before leaving this area. Having construed the '505 Patent independently of the '186 Patent, I find it surprising that the plaintiffs would suggest, in proposing a construction for “comprising” in the '505 Patent, that claim 1 of the '505 Patent could include a connector between two tubular members and still come within claim 1 of the '505 Patent.

[253] Second, I note Dr. Palmaz’s evidence (regarding the '186 Patent) that, while working with Dr. Schatz and during their discussions, Dr. Palmaz recognized that he would try to choose the shortest stent segments possible to get maximum flexibility. The shortest tubular member discussed in the '186 Patent is one that is one-slot long. While I have not factored this information into my construction analysis in relation to the '505 Patent, it reinforces my conclusion.

[254] My third observation is that I am left with the impression that a piece of the puzzle is missing. Dr. Palmaz testified that Dr. Schatz is the inventor named in a United States patent regarding the “boxcar” connector (a single connector to provide flexibility between tubular members). Dr. Palmaz further testified that there is a corresponding Canadian patent in relation to that connector. He also stated that he did not like that particular connector.

[255] When I pressed counsel for clarification as to how the '186 Patent could encompass an "invention" (the '186 Patent was stated to be broad enough to include the single "boxcar" connection) for which there is an existing patent wherein another individual is the named inventor, the response I received was that inventorship is not in issue here. While that may be so, I do not find that the plaintiffs squarely addressed the issue arising out of Dr. Palmaz's evidence in this respect.

[256] This completes the claim construction of the patents in suit. I propose to address the issue of validity before turning my attention to the issue of infringement for the simple reason that, should I find one or the other, or both, of the patents in suit invalid, the issue of infringement dissipates. Claims which are invalid cannot be infringed. However, Boston Scientific contends that issue estoppel arises with respect to both infringement and validity. Consequently, it is necessary to address that issue first.

Estoppel

[257] Boston Scientific contends that, by virtue of admissions made by the plaintiffs and their privies and findings of fact in litigation in other foreign jurisdictions relating to patents which claim priority from the same United States application as the Palmaz patents, the plaintiffs are precluded and estopped from alleging that the NIR stent infringes the Palmaz patents and from denying that the patents in suit are invalid. It seeks to do so through application of the doctrine of issue estoppel.

[258] Issue estoppel is one of two forms of *res judicata*. It arises where a cause of action may be different, but some point or issue of fact has already been decided. The pre-requisites to found issue

estoppel are well known. A detailed description of the doctrine and its application may be found in *Angle v. Canada (Minister of National Revenue)*, [1975] 2 S.C.R. 248 and *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 SC.R. 460 and need not be repeated here.

[259] Eight "lawyer" witnesses testified in relation to this issue. One provided factual evidence. The others were declared expert witnesses in patent law (generally) for their respective jurisdictions. The designations were nuanced to reflect the expertise and experience of each of the individuals in question. These witnesses spoke of proceedings in the United Kingdom, the Netherlands, France and the United States. Each spoke of the proceedings and determinations in his or her country.

[260] In support of its arguments, Boston Scientific refers to the comments of Madam Justice Sharlow, then of the Federal Court Trial Division, in *Connaught Laboratories Ltd. v. Medeva Pharma Ltd*. (1999), 4 C.P.R. 508 (F.C.T.D.) (*Connaught*) aff'd. (2000), 4 C.P.R. (4th) 521 (F.C.A.), specifically those at paragraphs 25, 26, 29 and 31 as follows:

> In the final analysis, the validity of a patent granted by the laws of Canada cannot be determined by the legal regime in another country
> …
>
> However, I do not understand why inconsistencies in findings of fact made by different tribunals should be tolerated if they can be avoided without offending the substantive law of procedural norms. Connaught is simply attempting to argue in this case that it is wrong in principle for Medeva to be permitted to take inconsistent positions on specific questions of fact that are in issue in this case and that have already been litigated elsewhere.
> …
>
> …Any plea of res judicata or a related principle adds complexity, because they compel the Court to consider difficult issues as to the nature of the prior proceedings and the precise significance of particular conclusions reached in the course of those proceedings.
> …

> It is also worth noting that the problem of complexity may be viewed in different ways. Patent litigation is already complex, in this Court and in every court that deals with patents. Ultimately, patent litigation may be simplified by principles that permit or require, in appropriate cases, the adoption of findings of fact in foreign proceedings. But this will never happen unless, in this case or another one, the Court undertakes an examination of the arguments that would open the door for establishing such a principle. (my emphasis)

[261] No further authority is cited by Boston Scientific, although the following excerpt from *Kirin-Amgen Inc. & Another v. Boehringer Mannheim GmbH & Another v. Jannsen-Cilag Limited*, [1997] F.S.R. 289 (Eng. C.A)(*Kirin-Amgen*) is cited in Justice Sharlow's reasons:

> …I envisage cases where issue estoppel will arise in patent actions. For instance, the same issue can arise in different countries of the world, for example whether a particular scientific effect occurs when the invention or a manufacturing process is carried out or how an infringing product is made, or the properties of a product or its composition. Thus this judgment should not be taken as concluding that issue estoppel has no place in patent actions. To the contrary, I believe that it does in appropriate cases. (my emphasis)

[262] Justice Sharlow's comments in *Connaught* occur in relation to an appeal from a prothonotary's decision to strike portions of a pleading purporting to rely on the findings of foreign jurisdictions to support a finding of *res judicata*. Justice Sharlow allowed the appeal on the basis that, "in principle, there is no reason to conclude that a plea of issue estoppel cannot be based on a foreign judgment, although inevitable difficulties will arise in establishing the conditions for its application." I regard it as settled law that pleadings that are worthy of the Court's attention should not be struck. In *Kirin-Amgen*, although noting that there may be circumstances in which issue

estoppel can arise with respect to the findings of a foreign jurisdiction court, the Court declined to apply the doctrine.

[263] In the end, whether to apply issue estoppel, even in circumstances where all the conditions are met, is a matter of discretion. Because I do not consider that this is an appropriate case to apply issue estoppel, I see little merit in reciting a lengthy and detailed description of the various proceedings (with their attendant discrepancies) from the foreign jurisdictions.

[264] The evidence reveals that the decisions from the United Kingdom, the Netherlands, the United States and France are not consistent. In other words, the courts of the foreign jurisdictions did not arrive at the same outcomes. Notably, that was not the situation in *Connaught*.

[265] An admission made in a foreign proceeding, which is expressly stated to be for the purpose of that proceeding only, cannot, in my view, be relied upon to establish that very fact in another proceeding, in another jurisdiction.

[266] I agree with Boston Scientific that the law of the United Kingdom "most closely resembles that of Canada". Notwithstanding, there are distinctions. More specifically, with respect to the patents in issue in the United Kingdom, European Patent 0335341 (EP '341) is an improvement of the invention claimed in European Patent 0221570 (EP '570). However, EP '570 is not the "corresponding" patent for the '505 Patent. Rather, it corresponds to Canadian Patent No.1338303 (the '303 Patent), which is not in issue. The claims of EP '570 and EP '341 are similar to, but not identical to, the claims of the '505 and '186 Patents.

[267] Moreover, Mr. John Thomas, a pre-eminently qualified legal expert, cautions that the term "corresponds" is not one of precision. He states that patents are "among the most complex legal documents that can be produced". He notes that there are language differences that render understanding of foreign laws very complex. Differences in practice and procedure result in "distinctions among these claims".

[268] Further, claim construction is a question of law and is antecedent to issues of infringement and validity. Infringement and validity determinations are made by reference to the claims, as construed. Boston Scientific does not suggest (nor could it) that *res judicata* applies to claim construction.

[269] The trial of this matter spanned six weeks. Many witnesses testified, most of them experts. Given the duration of the trial, the length of time that it has been pending, the preparation entailed, and the fact that it was a battle "hard fought", it seems appropriate, to me, that my determinations be made on the merits.

[270] The foregoing factors, in my view, are sufficient, in and of themselves, to lead me to conclude that I should not apply issue estoppel in this proceeding.

Validity

Anticipation (Novelty)

[271] Boston Scientific asserts that the '505 Patent lacks novelty because it was anticipated, or made known to the public, prior to the relevant time. To succeed, Boston Scientific must demonstrate that the invention described in the patent was described in any patent, or in any publication printed in Canada (or in any other country) more than two years before the inventor filed his patent application (paragraph 27(1)(b) of the Act). The statutory provision requires that the invention be "described in the prior document" and that this document be "a patent or any printed publication".

[272] The priority date for the '505 Patent is November 7, 1985. Dr. Palmaz authored two monographs, the "1980 Monograph" and the "1983 Monograph", which according to Boston Scientific, describe the invention claimed in the '505 Patent in a manner that renders the invention anticipated. Since both Monographs are beyond the two-year window (the critical date is November 7, 1983), they have the potential to anticipate the '505 Patent.

[273] In relation to the 1980 Monograph, Boston Scientific maintains that it discloses a balloon-expandable stent as taught in the '505 Patent. Specifically, Boston Scientific points to text on page 5 of the Monograph which states:

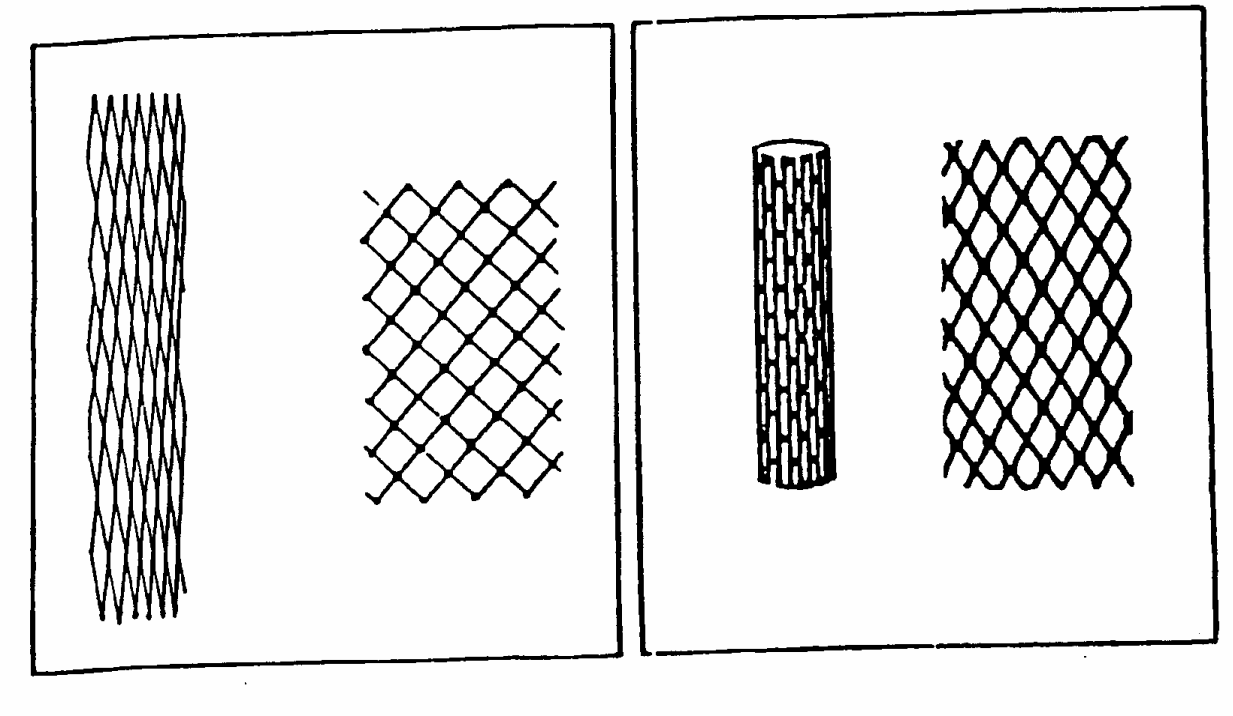
> The fractured atheromatous material may be contained against the vessel wall by placing an intraluminal tubular structure which may be expanded at one time with the stenotic lesion. The tube should be mounted on the balloon and introduced in the artery with it. Once it is in place the balloon insuflation would expand the tube and the steontic lesion together. The tube should have memory properties so as to oppose the elastic recoil of the wall. The tube

> would at the same time, maintain the lumen, avoid dislodgement of atheromatous material and give structural support to the wall.

[274] Mr. Opolski testified that a skilled person reading the 1980 Monograph would understand the Monograph (as a whole) to be talking about an alternative to balloon angioplasty, basically stenting. With respect to the noted passage, he claims that a medical device manufacturer would understand the text to be describing a tubular device that is balloon-expandable and delivered intraluminally (typically in the femoral artery) and then threaded up to the desired location (usually the site of the lesion). Additionally, the manufacturer would understand that the expansion of the tube would be controlled by the balloon and that, once expanded, the tube should scaffold the lesion, maintain the expanded diameter, and be relatively stiff.

[275] Dr. Cumberland, in his concurring opinion, believes that Dr. Palmaz clearly states in the 1980 Monograph that he wishes to use the balloon to simultaneously dilate the lesion and the tubular structure. The structure will then act to support the lumen and will stay expanded because it is plastically deformed.

[276] Boston Scientific also refers to Figure 1 on page 6 of the 1980 Monograph, specifically, the box on the right-hand side of Figure 1. Figure 1 depicts two boxes, a left-hand box and a right-hand box, as shown below:



[277] There is no consensus as to what the boxes in Figure 1 display. Mr. Opolski's general interpretation is that each box shows a version of the tubular structure (on the left) and a view of a portion of that version, after expansion, unrolling and flattening (on the right). This is because the text of the Monograph describes how the wires in the left-hand side of the left-hand box are welded together so that, upon dilation with the balloon, the wires will not slip over each other, but will bend and expand. Dr. Cumberland opines that each box shows a balloon-expandable metallic prosthesis in its unexpanded form (on the left) and in its expanded form (on the right). He notes that the expanded form in the right-hand box has thicker struts than the expanded form in the left-hand box and he describes the left-hand figures as having a "trellis-type structure".

[278] Although the text of the 1980 Monograph describes fashioning a stent from mesh and welding it together, according to Mr. Opolski, only the version shown in the left-hand box of

Figure 1 is made from the wire mesh. The right-hand box depicts a version which has a “grid-like pattern of rectangular openings which would not be possible to obtain with wire mesh”. Mr. Opolski (the only witness qualified in the fabrication of intervention products) maintains that he does not know how to make a wire structure at a scale that would work in any artery. He believes that a skilled person would know that there are different ways to make any given device. You can either weld pieces together or start with something larger and cut pieces out.

[279] Both Mr. Opolski and Dr. Cumberland believe that a medical device manufacturer, looking at the structure in the right-hand box, would conclude that it had been made by cutting openings into a hollow tube. Boston Scientific notes that when Dr. Palmaz showed this Monograph to a biotechnologist-technician (Dr. Shulz), Dr. Shulz immediately knew how to manufacture this tube.

[280] For Dr. Cumberland, the right-hand box of Figure 1 clearly shows an expandable, thin-walled, cylindrical, smooth tube of uniform thickness with staggered slots in it. The openings are rectangular in shape and are parallel to the longitudinal axis of the structure (and are therefore slots). The tubular structure in the right-hand box of Figure 1 is the same as Figure 1A of the '505 Patent.

[281] Dr. Palmaz testified that “the box on the right-hand side depicts a tubular-slotted configuration without welds”.

[282] In summary, Boston Scientific contends that all elements of the '505 Patent are present in the 1980 Monograph. The only element that Dr. Buller (the plaintiffs' expert) claims is absent from the Monograph is the '505 Patent's requirement that the wall surface have a "substantially uniform thickness". Boston Scientific claims that, by taking this position, Dr. Buller attributes to the skilled worker too great a reluctance to consider whether Figure 1 might not also indicate features beyond that described in the text of the Monograph. Moreover, it says that Dr. Buller acknowledges that a hollow tube would necessarily have a "wall surface having a substantially uniform thickness". Dr. Cumberland's view is that the tube on the left side of the right-hand box appears to be of uniform thickness. Therefore, the 1980 Monograph discloses all elements of the '505 Patent.

[283] With respect to the 1983 Monograph, Boston Scientific's experts, Mr. Opolski and Dr. Cumberland, opine that, the 1983 Monograph (like the 1980 Monograph) describes a balloon-expandable stent which is deformed upon expansion. The 1983 Monograph speaks directly to the illustrations in the Figure on page 5 of this Monograph (agreed by all to be identical to Figure 1 from the 1980 Monograph). The 1983 Monograph describes the right-hand box of Figure 1 as containing an "expandable metal tube with longitudinal fissures". It also states that "the tube could initially be a thin walled silver, tantalum or stainless steel continuous tube in which alternating fissures such as shown in Figure 1 have been done".

[284] Dr. Cumberland states that this language confirms what is clear from Figure 1 in the 1980 Monograph (that the device depicted in the right-hand box is an expandable, thin-walled, cylindrical, smooth tube of uniform thickness with staggered slots formed in it, the slots being

parallel to the long axis of the tube). Mr. Opolski adds that it would also be clear that the stent is manufactured by cutting slots in a tube. The slots are rectangular in shape with the long dimension parallel to the longitudinal axis of the tube and upon expansion, the tube has a larger diameter with deformation of the slots.

[285] Dr. Cumberland notes that the concept of “wall thinness” is articulated in the 1983 Monograph as follows: “The prosthetic tube wall should be adequately thin so as to avoid reducing the lumen of the tubular structure to be dilated by excessively increasing the total wall thickness”. The 1983 Monograph further states that the slotted tube carries an advantage over the wire mesh tube in that the tube will be thinner and smoother than the wire mesh, allowing easier introduction and positioning.

[286] Boston Scientific emphasizes that Dr. Buller could identify only one difference, between the information provided in the 1983 Monograph and that contained in the '505 Patent, that is, the phrase from the patent’s disclosure stating that the graft can be made longer or shorter, as desired. Boston Scientific contends that, since the length of the stent is not addressed in the claims of the patent, this “feature” is irrelevant to validity. In sum, its position is that the 1983 Monograph would allow a device manufacturer to design and manufacture the slotted-tube stent, as claimed in the '505 Patent.

[287] For the plaintiffs, Johnson & Johnson counter that the 1980 Monograph does not disclose all essential elements of the claims under consideration in the '505 Patent. Dr. Buller states that the 1980 Monograph refers only to wire and wire meshes. All further characteristics described in

the Monograph relate to the wire-mesh tube. The 1980 Monograph does not mention making anything from a pre-existing, solid, stainless-steel tube.

[288] Dr. Buller believes that a person skilled in the art, reading the 1980 Monograph around 1980-1983, having no knowledge that Dr. Palmaz had considered making a stent from a stainless steel tube, would conclude that the illustrations in Figure 1 were rough depictions of the mesh tubes described in the text. The left-hand and right-hand boxes are simply two different configurations of wires with a crisscross design. The central difference between them is simply that the figures in the left-hand box appear to be hinging (apparent from the difference in angle between the lines on the two figures) whereas the intersection of the wires on the diagrams in the right-hand box have been welded and, therefore, are forced to bend. Dr. Buller maintains that if one were to weld wires together and then compress the structure to a smaller size, one ends up with openings that appear much more rectangular. Comparing the diagrams in the right-hand box to Dr. Palmaz's woven, wire-mesh tube prototypes reinforces this conclusion. The wires in these prototypes are bending rather than just hinging. They no longer look like the simple crisscross drawing in the left-hand box of the Monograph.

[289] According to Dr. Buller, Mr. Opolski arrives at his conclusion that the device in the right-hand diagram of Figure 1 was made from a solid tube with openings in it with the benefit of hindsight. To give such an interpretation to Figure 1 forces the skilled person to ignore the text about woven-wire structures.

[290] Further, the description of the wire mesh in the 1980 Monograph leads Dr. Buller to conclude that the mesh is at least two wires thick where the wires crisscross. Therefore, the device in the Monograph does not exhibit one of the essential elements of the '505 Patent: uniform wall thickness. Moreover, unlike the '505 Patent, the 1980 Monograph does not expressly teach that the outer surface of the device should be smooth. Page 5 of the Monograph suggests that the displacement of the tube might be prevented by giving it a fenestrated or corrugated surface and requires that the device be covered with a “vascular prosthetic material” such as porous polyurethane. Thus, the Monograph neither teaches using the metal on its own nor discloses something that is integrally formed. Dr. Buller reiterates his view (discussed earlier in the claim construction portion of these reasons) that the '505 Patent (unlike the 1980 Monograph) teaches that the tubular member can be part of a graft or prosthesis. The Monograph does not differentiate between graft, prosthesis and tubular members.

[291] In all, the plaintiffs submit that it is possible to make a wire-mesh device having a rectangular, uniform pattern of openings as illustrated in the left-hand diagram of the right-hand box in Figure 1. In support, they point to the trial exhibits of commercially available wire-mesh (chicken wire) that was pulled into a rectangular pattern (Exhibits P 55-57).

[292] The plaintiffs’ submission in relation to the 1983 Monograph is skeletal. Dr. Buller notes that the '505 Patent states that the graft or prosthesis can be made longer or shorter, as desired, and this feature is not described in the 1983 Monograph. Making the device shorter makes it easier to deliver to more tortuous vessels and allows for the use of the “ring” structure as a basic tubular element.

Analysis

[293] *Beloit Canada Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289 (F.C.A.) remains the seminal authority regarding the test for anticipation. There, Mr. Justice Hugessen stated:

> [A]nticipation must be found in a specific patent or other published document; it is not enough to pick bits and pieces from a variety of prior publications and to meld them together so as to come up with the claimed invention. One must, in effect, be able to look at a prior, single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention.

[294] This passage was cited with approval by the Supreme Court in *Free World Trust*. Notably, *Beloit* and *Free World Trust* were concerned, as are we, with former provisions of the Act.

[295] In affirming that the '505 Patent is not anticipated by either of the Monographs, the plaintiffs refer to *Reeves Brothers Inc. v. Toronto Quilting and Embroidery Ltd.* (1978), 43 C.P.R. (2d) 145 (F.C.T.D.) (*Reeves*) where the Court identified several requisite factors to support a finding of invalidity on the ground of anticipation (the Reeves test). *Beloit* and *Free World Trust* were decided subsequent to *Reeves* and neither relies on the Reeves test. However, since *Reeves* has not been specifically overruled, I will bear its factors in mind.

[296] In accordance with *Beloit*, the issue is whether one can look at the 1980 (or the 1983) Monograph and find all the information which, for practical purposes, is needed to produce the

claimed invention. It is useful to review the '505 Patent to determine precisely what must be contained in a piece of prior art in order to anticipate the invention. The claims of the '505 Patent teach:

- an expandable, intraluminal, vascular graft
- comprising a thin-walled tubular member
- the tubular member has first and second ends
- the tubular member has a wall surface disposed between the first and second ends that is of a substantially uniform thickness
- the wall surface has a plurality of slots formed therein
- the slots are disposed substantially parallel to the longitudinal axis of the tubular member
- the tubular member has a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen
- the tubular member has a second expanded and plastically deformed diameter
- upon application of a radially outwardly extending force, the second diameter is variable.

[297] Boston Scientific argues that, although we acquire information regarding the basic structure and configuration of the stent and a general description of its use (how it is placed on a catheter and inserted and expanded) from the '505 Patent, we gain no information on how to manufacture the stent other than starting with a thin-walled stainless steel tube. Further, there is scant information regarding what the stent looks like, its size, or how it is made (other than Figures 1A and 1B and the “Description of Device” section of the disclosure). Although this

may be so, the inquiry (as articulated in *Beloit*), is not concerned with information that is not found in a patent. Rather, it engages the question whether a prior art document discloses all of the essential elements of an invention, such that the invention is rendered invalid.

[298] The 1980 Monograph begins by reviewing Dotter's (and others') work in percutaneous transluminal angioplasty. It describes the conditions for the procedure, its statistical success and some of the associated complications. As an alternative to balloon dilatation, page 5 of the 1980 Monograph sets out the concept of using a tubular device that could be implanted intraluminally and expanded at one time with the stenotic lesion. Mr. Opolski's report addresses this particular passage and I agree that this portion of the Monograph discloses an expandable, intraluminal tube.

[299] Given the discussion of the tube's expandability and the phrase "the tube would give structural support to the wall", it is arguable that the skilled person would also gather the tube has a first diameter and a second, expanded diameter (the latter is expected to be maintained). It is less clear whether this passage reveals that the tube would plastically deform because it specifically states that the tube should have memory properties (conjuring images of memory metal that was set to a specific diameter before insertion). The Monograph continues and says that the "memory of the tube may be obtained by an inner deformable wire mesh consisting in crisscrossed structure with welded crossing points". There is no explicit discussion requiring the tube to have "slots", or openings of any kind, although such openings could be understood from the words "wire mesh" (since a mesh is not solid) and from the diagrams in Figure 1.

[300] Nor does the text directly describe Figure 1. It refers only to wire and wire-mesh structures (all witnesses agree in this respect). Consequently, absent Figure 1, there is no information revealing the making of this device from a rolled-up piece of metal to create a tubular structure with a wall surface that is “slotted” and uniformly thick (two essential elements taught in the '505 Patent). The relevant question is whether these two elements are elucidated in the diagrams in Figure 1. In my view, they are not.

[301] The House of Lords faced a similar question in *C. Van der Lely N.V. v. Bamfords Ltd.*, [1963] R.P.C. 61 (*Van der Lely*). Lord Reid stated, at page 71, that the Court should not attempt to interpret a diagram for the purpose of determining anticipation, but should rely on the evidence of the skilled person. “The question is what the eye of the man with appropriate engineering skill and experience would see in the photograph and that appears to me to be a matter for evidence. Where the evidence is contradictory the judge must decide”.

[302] In *Van der Lely*, Lord Reid found that a skilled person would look at a picture of a raking machine and infer that it was “ground driven” instead of “gear driven” despite that it was not clear, from the picture, which was the case. The finding was justified by factors such as the speed at which the magazine stated that the machine can travel, the absence of an elaborate system of gears, and so on. Additionally, Lord Reid noted that the machine had at least one new feature and it would attribute “too great a reluctance to the skilled man” if one believes that he would not consider whether the photograph might not also indicate other features which were novel in agricultural machines.

[303] I agree that the Court must rely, to a large extent, upon the opinions of expert witnesses as to the correct interpretation of diagrams for the purpose of anticipation. However, whereas the Court in *Van der Lely*, found that the skilled person would infer, from an ambiguous diagram, the information necessary to anticipate the asserted claims, I make no such finding in this case.

[304] Dr. Cumberland and Mr. Opolski assert that a skilled person would immediately understand the right-hand box of Figure 1 to be illustrating a device made from a tube in which slots had been cut. Dr. Buller's opposing opinion is that the skilled person would interpret the right-hand box of Figure 1 as depicting a second wire-mesh configuration because this is solely what the text of the 1980 Monograph relates to. Although I understand that the right-hand box is depicting a slotted tube device (as Dr. Palmaz testified), I am not convinced that a skilled person, at the relevant time, would inevitably come to this conclusion and would manufacture the device shown in the right-hand side by cutting holes in a tube.

[305] The entire text of the 1980 Monograph is based upon a discussion of wire mesh. To construct the tube from a rolled-up sheet of metal, in which slots have been cut, goes against the writing and teaching in the Monograph. Dr. Buller claims that, even if Figure 1 depicts a slotted-tube stent, it can still be a tube with slots without having uniform thickness (being made of crisscross wires). He says: "[t]hey are all representing tubular structures with slots in them, but it is just a question of how it is made and what features it has". Indeed, Dr. Cumberland acknowledges that the illustrations are merely "stylized depictions of what Palmaz was showing and certainly not a blueprint or a technical drawing".

[306] Dr. Cumberland and Mr. Opolski concur that a skilled person would understand such slots to take on a hexagonal pattern when expanded. That is not what is depicted in the right side image of the right-hand box of Figure 1. The pictorial representation of the openings, expanded in a different shape, would lead the skilled person away from the "slotted tube' configuration as would the concept of increasing the thickness of metal on such an intraluminal device. Mr. Opolski is explicit that, at the relevant time, a skilled person would view "more metal' as something to avoid.

[307] Much debate centered on whether it was possible to make the structure (in the right-hand box) from a wire mesh. The plaintiffs produced a large tube made of commercial chicken wire and succeeded in obtaining Mr. Opolski's admission that it was indeed a "wire mesh tube with rectangular openings". Mr. Opolski maintains that he does not know how one would make such a structure to the small scale required of an intraluminal graft and even if it were possible, such a structure would not permanently deform. In the end, not much turns on this discussion. If, looking at the right-hand drawing, a skilled person would conclude that it could not be made with wire mesh, that conclusion lends support to the assertion that the person could also reason that it must be made from a tube. However, it does not guarantee it.

[308] Mr. Opolski acknowledged on cross-examination that if someone showed him the right-hand box of Figure 1 and told him that it was made out of wire, he could potentially make it by repeatedly welding little pieces of wire onto a long, straight piece of wire. I cannot discount the possibility that a skilled person, after reading the description of wire mesh, would attempt to

make the right-hand box diagram using this method. If such a method were employed, there would be no way to ascertain whether the device would have a smooth outer surface or a uniform wall thickness.

[309] In 1980, Dr. Palmaz (a leader in this field) had no idea how to construct the tube to the scale and specifications necessary for it to deform and maintain the lumen. How is it then that other skilled persons would view this diagram, in 1981, and in the context of the text on wire mesh, and immediately understand how to fashion this device to have all of the essential elements of the '505 Patent? How can it be said, for certain, that the skilled person would select a piece of metal and roll it into a tube that had a uniform thickness and a smooth surface? In my view, to suggest that the skilled person would come to these conclusions every time employs the benefit of hindsight as well as the knowledge that Dr. Palmaz had considered making stents in such a way.

[310] Mr. Opolski attests, in his evidence-in-chief, that the verbiage and descriptions between the 1980 Monograph and the '505 Patent are a little different, but that the “key kernel” concept of what he would need is there (in the 1980 Monograph). This statement strikes me as describing the 1980 Monograph as a signpost on the way to the invention, rather than the flag where the invention is planted. A “key kernel” does not qualify. The piece of prior art must contain all of the information necessary to result in the claimed invention, every time.

[311] All experts, to some extent, have varying opinions regarding the illustrations in Figure 1. For instance, despite Dr. Cumberland’s testimony that the right-hand side of the left-hand box in

Figure 1 shows an expanded view of the figure in that box, he agreed, on cross-examination, that it could also be a close-up view of the figure on the left, or a diagrammatic representation of wire mesh. Ultimately, the illustrations in Figure 1 are ambiguous. If the experts disagree, in their interpretations of the diagrams, it is highly likely that persons skilled in the art would disagree as well. As a result, it cannot be said that the skilled person would fabricate the device protected by the '505 Patent "in every case and without possibility of error".

[312] As for Boston Scientific's argument that Mr. Schulz immediately knew that there were many ways to make the slotted-tube stent shown in the right-hand box of Figure 1 (implying that skilled persons reading the monograph would equally know how to fashion the slotted-tube stent), I do not find it persuasive. As noted by the plaintiffs, Mr. Schulz had, before him, materials other than the 1980 Monograph. Dr. Palmaz testified that he showed Mr. Schulz his cardboard model which, in my view, clearly demonstrates that Dr. Palmaz was seeking to make a tube from a flat sheet with slots cut out of it. The test for anticipation dictates that it is the 1980 Monograph alone that is determinative. That document does not provide information that, for purposes of practical utility, is equal to that of the '505 Patent.

[313] Turning to the 1983 Monograph, it begins by detailing the different types of stenotic lesions that can be found in various arteries and the success rate of intraluminal dilatation on these stenoses. It notes that the failure of balloon dilatation is usually due to elastic recoil of highly fibrous lesions. The 1983 Monograph outlines the work others have accomplished with percutaneous placement of grafts and denotes the problems with it, specifically the coils made of

heat sensitive alloy and the plight of not being able to control the reshaping of the coil after deposition.

[314] The 1983 Monograph (like the 1980 Monograph) suggests the solution of an expandable tube which will be introduced percutaneously mounted on an angioplasty balloon catheter. It includes a diagram identical to Figure 1 of the 1980 Monograph. However, the text of the 1983 Monograph speaks directly to Figure 1 describing the right-hand box as showing "an expandable metal tube with longitudinal fissures…the tube could initially be a thin walled silver, tantalum or stainless steel continuous tube in which alternating fissures such as shown in Fig. 1 have been done". This content, in conjunction with Figure 1, is sufficient to inform a skilled person to cut elongate slots out of a tube. The 1983 Monograph goes so far as to specify that this could be done with electronic or laser etching.

[315] The 1983 Monograph contemplates the thinness of the wall since it notes that the prosthetic tube wall should be adequately thin (so as to avoid reducing the lumen). The document also says that the tubular device in the right-hand box will be smoother and thinner (in its unexpanded state) than the wire mesh device, thereby allowing easier introduction and positioning before inflation. Thus, the skilled person would be given the indication that the wall surface of the tube is relatively smooth and thin.

[316] The one comment that Dr. Buller makes in relation to the 1983 Monograph is that it fails to address the capacity (articulated in the '505 Patent) to make the Palmaz stent longer or shorter. In fact, the 1983 Monograph suggests that, in the vascular system, tube lengths should be limited

to probably no more than 4 cm. Significantly however, a particular length of stent (or the freedom to adjust the length) are not essential elements in the '505 Patent claims and need not be disclosed in prior art documents.

[317] Assisted by the opinions of the experts, it seems to me that the 1983 Monograph discloses the essential elements of the '505 Patent for practical purposes. Although I detect other omissions from the 1983 Monograph, they have not been identified by the plaintiffs' expert and I therefore assume that they are not relevant to this inquiry. I will say no more in that respect.

[318] Since the 1983 Monograph discloses the '505 Patent, I must now determine whether the 1983 Monograph is a "publication printed in Canada or in any other country" as contemplated by paragraph 27(1)(b) of the Act. Regard must be had to the circumstances under which the 1983 Monograph was disclosed to decide whether this document has the quality of a "printed publication".

[319] In large part, the facts surrounding Dr. Palmaz's disclosure of the 1983 Monograph are not a matter of dispute. The discord centers on the conclusion to be drawn from those facts. The evidence reveals that the 1983 Monograph was disclosed to a much lesser degree than the 1980 Monograph. Although Dr. Palmaz attempted to enter into various contractual agreements with medical device manufacturing companies, he testified that he used the 1980 Monograph in these commercial interactions.

[320] The 1983 Monograph is a revision of the 1980 Monograph. Dr. Palmaz testified as to his dissemination of the 1983 Monograph. He states that he sent the document to two individuals (Dr. Reuter and Joe Peters) at the University of Texas Health Science Centre. He also sent a copy of the 1983 Monograph to Werner Schulz (the technician with whom he met with after writing the 1980 Monograph). Dr. Palmaz accepted a position at the University of Texas Health Science Centre in 1983. At some point in 1984, he provided a copy of the 1983 Monograph to the Patent Committee of the University of Texas Health Science Centre and to his patent agent, Ben Tobor. In late 1984 or early 1985, he made an arrangement with Albert Windeler, a dentistry professor, to make the first slotted-tube prototypes with an EDM machine. During this process, he gave a copy of the 1983 Monograph to Professor Windeler.

[321] In Canada, a document is "published" if it has become generally available, without restriction, to at least one member of the public. The person or persons receiving the document (to be categorized as members of the public) must have no special relationship to the author of the publication: *Xerox of Canada Ltd. v. IBM Canada Ltd.* (1977), 33 C.P.R. (2d) 24 (F.C.T.D.) at p. 85 (*Xerox*).

[322] Mr. Justice Gibson, in *Owens-Illinois Inc. v. Koehring Waterous Ltd*. (1978), 40 C.P.R. (2d) 72 (F.C.T.D.) at p. 89 (*Owens-Ilinois*), aff'd. and indexed as *Koehring Canada ltd. v. Owens-Illinois Inc. et al.* (1980), 52 C.P.R. (2d) 1 (F.C.A.) (*Koehring Canada*) set forth a similar test when he stated:

> I am of the view that to constitute publication within the meaning of s. 28(1)(b) of the *Patent Act*, there must be general availability without restriction or putting it another way, there must be no inhibiting fetter so as to make the concept of the invention

> unavailable to the public and that, therefore, s. 28(1)(b) of the *Patent Act* being a substantive statutory bar of anticipation to the issuance of a patent is not applicable unless there is dissemination of the secret of the concept of the invention to the public, and further that the party asserting publication within this statutory meaning has the onus of proving publication.

[323] The parameters of a "special relationship" are not fully fleshed out in the jurisprudence. In *Xerox*, the Court noted that it might be a relationship that "smacks of a joint-venture" and in *J.M. Voith GmbH v. Beloit Corp.* (1989), 27 C.P.R. (3d) 289 (F.C.T.D.) (*J.M. Voith*), there was argument that a "special relationship" existed between a seller and its customers or potential customers.

[324] Of the various individuals to whom Dr. Palmaz gave a copy of his 1983 Monograph, the defendant appears to categorize only one as falling beyond the category of special relationship. That person is Werner Schulz. Boston Scientific contends that there is no evidence that the disclosure to Mr. Schulz was meant to be in confidence. I disagree.

[325] The defendant led no evidence to establish that the 1983 Monograph had been utilized, by those to whom it was given, in such a way as to leave the impression that it had been disclosed without confidence. The 1983 Monograph was not shopped around to companies, nor was it distributed at conferences (as in *Koehring Canada* and *J.M. Voith*). The distribution of the 1983 Monograph to Mr. Schulz (the one individual outside the Health Centre forum) and who was contacted by Dr. Palmaz (initially at the suggestion of Dr. Palmaz's colleague) for assistance to Dr. Palmaz (as to how he could have the invention fabricated) hardly seems, to me, to be akin to publishing the document.

[326] Dr. Palmaz testified, and I accept his evidence, that he had a general recollection that there was a statement of confidentiality in his discussions (of the Monographs) with individuals (I draw a distinction between the discussions with individuals and the discussions with medical device manufacturers in relation to the 1980 Monograph). His meeting with Mr. Schulz entailed showing Schulz his materials and asking him "how can we make these things", clearly indicative of one seeking advice and assistance. My view (and I so find) is that Dr. Palmaz approached Mr. Schulz in a way similar to the manner in which he approached his colleagues at the hospital, that is, to obtain their advice and thoughts on his idea or concept. It is evident, from Dr. Palmaz's evidence, that Mr. Schulz did not take Dr. Palmaz's idea as his own. The Monograph's contents remained very much Dr. Palmaz's work. Nor is there any indication that Mr. Schulz was free, or entitled, to use Dr. Palmaz's invention. Dr. Palmaz's evidence in this respect is uncontroverted. The defendant has led no evidence to the contrary.

[327] While Dr. Palmaz's treatment of his 1980 Monograph was less than stellar in terms of ensuring its confidence, the same cannot be said of the 1983 Monograph. In any event, the burden is on the defendant to establish that there was a publication of this Monograph (that it was in the public domain) and I conclude that it failed to discharge this burden. Based on the evidence, I do not find, nor do I infer, that there was 'publication" of the 1983 Monograph within the meaning of section 27 of the Act.

[328] In view of my finding that the 1983 Monograph was not "published", I need not decide whether the copies of the Monograph constitute a document that was "printed". The law on

printed publications relates to printing and distribution technologies that may be outdated in today's word. However, given my findings on "published", it is neither necessary, nor appropriate, for me to consider whether an evolution in the law on printed publication is desirable. I turn now to the issue of obviousness.

Obviousness

[329] As mandated by *Beloit*, determination of whether an invention claimed in a patent is obvious requires that one ask whether the skilled technician would, in light of the state of the art and common general knowledge as of the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. This is reputed to be a difficult test to satisfy.

[330] The crucial date for assessing obviousness is the claimed date of the invention. There is agreement on the law that, in this case and for each of the patents in suit, the date is the earlier of the priority date or the "invention date" itself, as established by the evidence at trial. There is, however, some confusion regarding the evidence of the "invention date".

[331] It seems that, on discovery, the plaintiffs informed the defendant that they were relying on February 23, 1978 (the Grüntzig lecture) as the earliest date of invention for the '505 Patent. The "invention date" for the '186 Patent was stated to be late 1985 or early 1986. In closing submissions at the end of trial, the plaintiffs claimed that "in order to keep with international comity", they were relying on the priority dates for the patents (November 7, 1985 for the '505 Patent and March 28, 1988 for the '186 Patent).

[332] When Boston Scientific addressed this inconsistency, the plaintiffs suggested that it was for the Court to determine the proper invention date under Canadian law. Johnson & Johnson's last-stated position is that "it may be as early as 1978 and 1985-1986, but no later than the priority dates listed above".

[333] Boston Scientific's concern is that it prepared its case on the understanding that the plaintiffs were relying on the earlier dates. If the question of obviousness is now to be determined as of a later date, there may be additional prior art available that could be relevant to the issue of obviousness. I understand Boston Scientific's worry. However, in view of the evidence and my ultimate conclusion regarding the date of invention, I do not believe that Boston Scientific is prejudiced in any way.

[334] Although Dr. Palmaz testified that he first "came up" with the idea of a balloon-expandable stent in February of 1978 (after hearing a lecture by Dr. Grüntzig on the problems of balloon angioplasty), I do not find that February of 1978 is the proper invention date as the term is defined by the jurisprudence. *Koehring Canada* holds that, to establish a date of invention prior to the filing date of an application, it must be demonstrated that the invention was "reduced to a practical and definite shape either by a written or oral description of it that would enable a person skilled in the art to make it or in the case of an apparatus, by the apparatus having been actually made".

[335] In *Christiani & Nielsen v. Rice*, [1930] S.C.R. 443 (*Christiani*), the Supreme Court of Canada stated (at page 456) that "date of invention" means the date at which the inventor can prove

he has first formulated, either in writing or verbally, a description which affords the means of making that which is invented.

[336] *Ernest Scragg & Sons Ltd. v. Leesona Corp*., [1964] Ex. C.R. 649 (*Ernest Scragg*) provided further clarification as follows :

> Thus, the statement in the Christiani v. Rice case (supra) to which I have referred should not be interpreted as laying down a rule that proof that an invention was made at an asserted date must be confined to evidence that a written or oral description of it had been formulated at such date. It may also be proved, in the case of an invention of an apparatus, that the apparatus was made at such date or, in the case of an invention of a process, that the process was used at such date. The essential fact to be proved is that at the asserted date the invention was no longer merely an idea that floated through the inventor's brain but had been reduced to a definite and practical shape. (emphasis added)

[337] Dr. Palmaz testified that, after attending the Grüntzig lecture, he commented to his colleague and mentor, Dr. Reuter, about the possibility of inserting some sort of internal scaffold to solve the problems of balloon angioplasty. Although this marked the genesis of Dr. Palmaz's idea, it is clear that his "invention" was not fully formulated at that time. Dr. Palmaz was unsure how to go about fashioning the device. On his own, he experimented with various materials (pins, copper) and attempted to weave these materials around pencils to create an interwoven mesh. He then soldered the criss-cross points to prevent hinging. These early prototypes were 3 cm long and 8 mm in diameter. That is, they were much larger than the dimensions of what later became the '505 Patent. Dr. Palmaz estimates that it was two or three years before he moved on to "implantable quality materials such as stainless steel 316L" and started making stents in various diameters.

[338] I find that these initial endeavours were based on an idea floating around in Dr. Palmaz's head and constituted trial and error attempts to make a workable apparatus. The 1980 Monograph was written during this period but it related to a woven-mesh structure rather than the slotted-tube apparatus claimed in the '505 Patent. I have previously determined that the 1980 Monograph does not anticipate the '505 Patent. Nor do I believe that it can be used to establish the date of invention. As noted, during this time frame, the slotted-tube stent was simply an idea in Dr. Palmaz's head. It had not been "made" as is required to demonstrate a date of invention. In fact, Dr. Palmaz testified that he did not know how to make the device because it required techniques that were not within his reach.

[339] Dr. Palmaz learned that he was able to make his prototypes of the slotted stent only in 1983 (after he met with Werner Shulz) and came to know of the EDM (electro-mechanical discharge machining) technique. Dr. Palmaz states that it was early 1985 when he had dentistry professor, Albert Windeler, use the EDM machine at the University of Texas Health Science Centre to make the apparatus that is the subject of the '505 Patent invention.

[340] In my view, the appropriate date of invention is the date of Dr. Palmaz's second Monograph (May 18, 1983). I concluded earlier that this document discloses the invention and therefore constitutes a "description which affords the means of making that which is invented". It may fairly be said that any conclusions on obviousness of the '505 Patent should be determined as of May 18, 1983 and, based on the evidence adduced, I find May 18, 1983 to be the date of invention.

[341] For the '186 Patent, Boston Scientific submits that the date of invention is March of 1986. Dr. Palmaz testified that the idea of the '186 Patent occurred to him on a plane trip with Richard Schatz, after he (Dr. Palmaz) saw the luggage carts moving around the airport. Viewing the carts enabled him to realize that he could move away from "straight segments". Correspondence dated March 17, 1986, from Dr. Palmaz to Richard Bowman (an EDM manufacturer), outlining the concept of what later became the Palmaz-Schatz stent, was tendered as Exhibit P-99. The second page of the letter is a photocopy of a cardboard model of a flexible stent made up of tubular members with connectors between them. Dr. Palmaz states that this letter was sent days after the plane trip and that Mr. Bowman made prototypes of what became the Palmaz-Schatz Patent a few weeks after the letter was sent. On the evidence, I find the date of invention for the '186 Patent is March or April of 1986.

[342] The two pieces of prior art, specifically the 1985 Radiology article and the February 1986 Wallace article, relied upon by Boston Scientific to demonstrate the obviousness of the '186 Patent, were in existence by that date. However, the two articles that Dr. Buller references, in response to Boston Scientific's arguments on obviousness, are dated later than March of 1986 (the Charnsangavej article, November 1986 and the Duprat article, 1987). These latter articles do not constitute prior art at the relevant date.

[343] In contrast to determinations of novelty, when evaluating the inventiveness of a patent, the Court is entitled to look at all patents and other publications that would have been available to the public at the relevant time. After considering such documentation and information, the Court must decide whether the resulting "mosaic" leads directly to the invention: *Illinois Tool Works Inc. v.*

Cobra Fixations Cie (2002), 20 C.P.R. (4th) 402 aff'd. (2003), 29 C.P.R. (4th) 417 (F.C.A.) at para. 100.

[344] In *Janssen-Ortho Inc. v. Novopharm Ltd*. (2007), 59 C.P.R. (4th) 116 (F.C.A.) (*Janssen-Ortho*), the Federal Court of Appeal itemized relevant factors for consideration in the obviousness analysis: the nature of the invention; the appropriate hypothetical skilled person; the body of knowledge the skilled person would be expected to know and/or be able to find out as well as the "climate" in that field at the time the alleged invention was made; the motivation to solve a recognized problem; and, the time and effort involved in the invention. Secondary factors include the commercial success of the invention and any recognition or awards received by the patent's inventor.

[345] Boston Scientific asserts that both the '505 and the '186 Patents are obvious, the '505 in view of United States Patent 3,756,744 (the Ersek Patent) and the '186 due to the "Radiology" and "Wallace" articles as well as the knowledge of a skilled person at the relevant time.

The '505 Patent

[346] Boston Scientific witness Dr. Cumberland opines that the '505 Patent is obvious in light of the Ersek Patent because Ersek teaches a deformable tubular mesh-like sleeve (with uniformly spaced and staggered openings), which is secured in place by expansion, the degree of which is determined by an outwardly extending force. Since the Ersek Patent issued in April 1972, it forms part of the prior art in existence at the time of the '505 Patent's invention date.

[347] The “tubular mesh-like sleeve” or the “fixation sleeve” is the central component of the Ersek Patent. By providing controlled expansion, the sleeve is mean to affix a graft more quickly than conventional methods of suturing. The sleeve is fashioned from a sheet with slits, which is stretched to open the slits and to expand the metal sheet in a direction perpendicular to the longitudinal axis of the slits themselves, so that they become diamond-like apertures. The sheet is then spot-welded to form a tubular sleeve.

[348] As noted, the Ersek sleeve can be expanded. When used for the fixation of heart valves, the sleeve is pre-assembled in the expansion tool (a device with resilient rings that compress and extend an outward force to the interior of the sleeve) and then introduced by way of incision in the aorta and passed along the lumen of the aorta to the required position. Dr. Cumberland claims that the device is placed intraluminally and then expanded. He says that it is sufficiently thin-walled for delivery in its first, unexpanded diameter and would be useful as an intraluminal vascular graft because it can be expanded with minimal encroachment on the lumen. The more the expansion tool’s trigger is squeezed, the more the disks will bulge and the more the tubular sleeve will expand.

[349] The described procedure results in the implantation of the sleeve into the vessel wall. The tubular sleeve contains ribbon-like members that protrude into the vessel lining (to encourage the lining to proliferate through the open lattice work of the tubular sleeve) with the result that (after expansion) there is little metal coming into contact with the bloodstream itself. Despite these ribbon-like members, Dr. Cumberland asserts that column 3, line 13 of the Ersek Patent indicates that the surface is meant to be smooth. In his testimony, he clarifies, “if you don’t like the projecting edges you can just smooth them off”.

[350] According to Dr. Cumberland, the sleeve is intended as a fixation device but would have been suitable as a stent in some vessels as it would clearly be capable of supporting the vessel wall. In support, he points to Figure 1 of the Ersek Patent where it is apparent that the device is, at least in part, expanded against the aortic wall so that it is partly in the aorta and partly in the graft. The portion of the fixation sleeve that is against the vessel wall is supporting the vessel wall (exactly the function of a stent).

[351] Boston Scientific contends that if a skilled person had seen the Ersek Patent, the Palmaz stent would be an obvious device. It notes Dr. Palmaz's testimony that he conceived the idea for his slotted-tube stent after seeing a piece of expanded metal (another name for masonry metal), the material from which the Ersek Patent can be made. Boston Scientific also claims that, in a 1991 article "Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysm" (the Parodi article), the Palmaz stent is shown to have been used in patients in the treatment of AAA (one of the stated purposes of the Ersek device). Although Dr. Cumberland agreed, during cross-examination, that most of what is suggested in Ersek is meant to be performed during an open operation, he feels that a skilled worker would imagine other expanding means for intraluminal catheters and that the Parodi article procedure might be considered a hybrid between surgery and percuntaneous angioplasty art.

[352] A final point advanced by Boston Scientific is the re-examination of United States Patent 4,739,762 (U.S. '762 Patent). It is said that the U.S. '762 Patent was re-examined in view of the Ersek patent and that claim 13 (with identical wording to claim 1 of the '505 Patent) was cancelled.

[353] In summary, Boston Scientific's position is that the Ersek Patent discloses a fixation device that can be used in the same manner as the Palmaz stent to anchor an AAA graft. It includes:

- an expandable tubular sleeve made of open work metal
- the open work metal has slots formed in its wall surface
- the tubular sleeve has an unexpanded diameter which permits it to be placed within the lumen of a body passageway
- it can be expanded to a larger, variable and permanently deformed diameter by an outwardly extending force in order to make the sleeve fit within the lumen
- the tubular sleeve exerts no outward radial force when in its expanded diameter
- it can be smoothed to facilitate entry

[354] In addition to these similarities, Boston Scientific notes that Dr. Buller agreed that the skilled person would know that, by widening the slits in Ersek to form slots, the open area of the metal would be increased. Therefore, according to Boston Scientific, the alleged invention of the '505 Patent is an obvious modification of Ersek.

[355] Johnson & Johnson's argument outlines evidence with respect to the non-obviousness of both the '505 and the '186 Patent (in view of the Ersek device). I will confine my summary of its position to the '505 Patent since Boston Scientific restricted its arguments to this patent.

[356] Johnson & Johnson maintain that it would not have been obvious to a skilled person (at the relevant time) to change the Ersek Patent into the graft as described and claimed in the '505 Patent.

Dr. Buller (and Dr. Cumberland) testified that the Ersek Patent was never commercialized and was never used on a patient. In Dr. Buller's opinion, the intention behind the device was to accelerate major surgery by permitting an implanted graft to be stapled in place rather than laboriously suturing it to the body. It was to be used to attach a prosthetic device to the transplant situs; it was never meant to be used on its own.

[357] Further, Johnson & Johnson claims that the Ersek device fixes itself into the tissue wall by way of a "plurality of longitudinally extending ribbon-like undulating portions" (claim 1) that twist to extend angularly relative to the perimeter of the sleeve. The twisting of these ribbons causes the wall thickness of the sleeve to vary by a factor of at least two and thus, the wall thickness is not uniform. This twisting is desirable because it provides a multitude of narrow projecting edges (along the sleeve's surface) which become embedded into the tissue wall (upon expansion of the sleeve) resulting in very little metal being exposed to the bloodstream.

[358] The Ersek Patent states that "the edges may be cuffed if desired or simply smoothed to facilitate entry". Dr. Buller believes that this refers to smoothing or cuffing (hemming) the jagged, circumferential ends of the sleeve in order to allow the fixation device to enter the severed end of the aorta. It does not refer to smoothing the entire surface of the Ersek sleeve. To do so would be contrary to the teaching of the patent (to embed the ribbons into the tissue).

[359] These narrow projecting edges point outwardly and inwardly. Johnson & Johnson contends that the edges render the Ersek device completely unsuitable for use as a coronary stent because it could injure and possibly rupture the vessel and the balloon (if a balloon were used for delivery).

The sharp protruding ribbons, along with its overall size, prevent the Ersek device from being delivered intraluminally, as required by the '505 Patent. It cannot be said that the Ersek device has a "first diameter" that permits intraluminal delivery. Rather, the diameter generally matches the diameter of the tissue to which it is being connected.

[360] Moreover, the delivery device described in the Ersek Patent can only be used intra-operatively and not percutaneously. Although the patent states that a variety of expanding devices may be used, Dr. Buller notes that there are no obvious alternatives. The delivery device has a "pistol, grip handle" and a "trigger-like operating lever". When the lever is pulled, the device expands the sleeve "in one stroke" and only certain portions of the sleeve expand. Thus, the force applied to the sleeve is not controllable and the entire Ersek device does not take on a "second diameter". Because it is sized to match the implant and designed to embed (edge-on) into the vessel wall, it does not expand the lumen, nor does it support it structurally.

[361] Last, Johnson & Johnson submits that it is incorrect to say that the Parodi article describes Palmaz stents being used for the same purpose as the Ersek device because the Palmaz stent was not used as a "staple-like device". Although the '505 Patent uses the word "embed', there are different uses for this word. In the Palmaz Patent, the word "embed" refers to expanding a stent against the vessel wall so that it is "nicely in contact". The Ersek device is actually embedded into the vessel wall.

[362] To summarize, Johnson & Johnson takes the position that the Ersek device is missing a number of elements taught in the '505 Patent, specifically:

- intraluminal delivery
- a first diameter to allow for intraluminal delivery
- a second diameter (for the entire graft)
- a second diameter that is variable
- an increase to the opening of the vessel
- structural support for the vessel
- smooth outer surface
- substantially uniform wall thickness

Analysis

[363] My earlier claim construction regarding the '505 Patent defines the nature of the invention for the purpose of obviousness. I determined the hypothetical skilled person to be a team of mechanical engineers and interventional cardiologists or radiologists. The question now is whether this hypothetical team (with an understanding of the common general knowledge and in particular, the Ersek Patent) would come directly and without difficulty to the invention as defined by the claims in the '505 Patent. I have thoroughly reviewed the evidence and the submissions and I conclude that the answer is no.

[364] The Ersek Patent (or simply “Ersek”) is entitled “Method for Fixing Prosthetic Implants in a Living Body”. The patent’s description reveals that it exists within the field of major surgical operations. All witnesses agree that the purpose of the device is to accelerate open surgery by quickly connecting a transplant with body tissue through the use of a sharp-sided metal sleeve rather

than by stitches. In contrast, the underlying basis and purpose of the '505 Patent is to obviate the need for surgery.

[365] The Ersek Patent, like the '505 Patent, includes a tubular device made from a sheet of metal. However, the nature of these tubular devices is markedly different. The Ersek describes stretching and expanding the metal sheet to create the twists to the undulating flat ribbon-like portions, which project and are desirably not flattened out. I accept Dr. Buller's opinion that the patent's discussion of "cuffing or smoothing the edges" speaks to the circular ends, which will be forced into the implant and not to smoothing the entire surface because it would be contrary to Ersek's teaching. Dr. Cumberland agreed that the Ersek cannot be described as a low profile device without protrusions.

[366] In view of the evidence with regard to how the Ersek device embeds itself into the vessel wall, I am unable to conclude that the surface of the tubular sleeve is "smooth" as this element has been defined for the purpose of construing the '505 Patent. That is, it is not smooth enough for intraluminal delivery. The surface of the tubular sleeve is not smooth. More importantly, the tubular sleeve does not have a uniform thickness due to the rotation of the ribbon-like material, a fact that was also acknowledged by Dr. Cumberland.

[367] The Ersek device is not passed through the lumen to its intended location so it is not surprising that it does not have a first diameter which allows for intraluminal delivery before expansion. Its diameter is set, external to the patient, at a measurement that coincides with the diameter of the lumen. Its sleeve is expanded in one thrust and only where the doughnut-like rings

press against it. I reject Dr. Cumberland's suggestion that Dr. Ersek must have intended for the entire sleeve to expand and that this could happen by altering the number of rings on the barrel of the gun. There is no indication in the Ersek Patent that the entire sleeve must expand. Moreover, the preferred embodiment depicts the expansion device with two rings, indicating that the sleeve will expand only in those two sections.

[368] Regarding the range of expansion issue, I have significant difficulty with Boston Scientific's position that the expansion device of the Ersek provides a range of expansion similar to the balloon expansion of the '505 Patent. Dr. Buller did agree that the more one squeezes the trigger of the Ersek expansion device, the more the rings will bulge. Although this is technically accurate, Ersek teaches the expansion of the tubular sleeve "in one stroke" to embed the projected metal edges into the tissue.

[369] The '505 Patent, on the other hand, teaches that (depending on the needs of the patient) the degree to which the stent should expand and the amount of force it should exact against the lesion and the artery wall can be controlled. There is no doubt that both the Ersek device and the Palmaz stent expand quickly. To the untrained eye, both may appear to be expanded in "one stroke". It is what is taught by the Ersek Patent and the purpose of the device that is crucial. I found Dr. Buller's testimony, on cross-examination, on this point persuasive. He notes that if an Ersek device were in use by a surgeon, the surgeon would "not be looking at it on an x-ray or visualizing it. There is no purpose in adjusting it".

[370] Rather than making close contact with the lining of a vessel wall, the Ersek tubular sleeve is meant to implant itself into the surrounding tissue. The patent states, “since the sleeve becomes incorporated into the tissue wall, no foreign material is left in contact with the blood”. This implantation occurs through the use of an expansion tool, which “forces the fenestrations of the sleeve into the wall of the aorta to achieve a leak-proof union”. Although I do not necessarily agree that the Ersek device is “stapling” (as the word is commonly used), it is evident that the device is intended to penetrate the vessel wall immediately. Dr. Cumberland, when pressed on cross-examination, acknowledged that the part of the device that renders it not “staple like” is its failure to curve around the underside (like the prongs on an office stapler).

[371] The Palmaz stent scaffolds the artery and, even after expansion, metal remains exposed. Over time, the stent will usually become covered with a layer of endothelium and grow to be “part” of the vessel wall. This is a gradual process. Both Dr. Palmaz and Mr. Opolski testified that the general attitude in the field, at the pertinent time was to minimize the amount of metal used in devices that were meant to remain inside the body. The evidence also indicates that Dr. Palmaz’s designs were initially met with skepticism. It seems to me that it would be most unlikely that a skilled person would read Ersek and directly conceive of expanding a similar metal sleeve in the artery, yet not embed the metal into the tissue, for it would ignore the general attitude at the relevant time (“the less metal, the better”).

[372] There is also the issue of the ability to expand the artery. Dr. Cumberland acknowledges that there is neither discussion nor reference in the Ersek Patent with respect to expanding the lumen. Nor is the purpose of the Ersek device to dilate and support diseased vessels. I accept

Dr. Buller's evidence that the Ersek device is not intended to scaffold the vessel wall and that its concept is substantially different from what a skilled person would be looking for in terms of an intraluminal stent (a smooth surface to facilitate delivery and support the vessel wall upon expansion).

[373] I question whether the relevant skilled person would necessarily be aware of a patent in the general field of suturing devices, which appears to be outside the general area of angioplasty and intraluminal stenting. The skilled person is assumed to be reasonably diligent in keeping abreast of advances in the field to which the patent relates: *Whirlpool*, at paragraph 74. However, the skilled person is not expected to go outside the art in the field: *Eli Lilly & Co. v. Marzone Chemicals Ltd.* (1977), 37 C.P.R. (2d) 3 aff'd. 37 C.P.R. (2d) 37.

[374] Boston Scientific also points to a 1991 article co-authored by Dr. Palmaz (the Parodi article) in which the Palmaz stent is described for treating an AAA in the same way that the Ersek Patent teaches. Dr. Cumberland states that the "Palmaz stent was in fact used in patients for the same purpose as the Ersek device, that is, at each end of the graft in the intraluminal treatment of abdominal aortic aneurysm". It is not immediately apparent to me what I am to take from this. Dr. Cumberland's statement does nothing to enlighten me.

[375] The Parodi article reports the results of a study of animal experimentation and initial clinical trials exploring the feasibility of the use of the Palmaz stent in the treatment of AAA. I note that the Ersek Patent teaches no overlap between the Dacron graft and the blood vessel; the two abut ends. In the Parodi article, a friction seal is created by expanding the stent inside the Dacron graft then

pushing the Dacron against the wall of the aorta. In other words, the graft goes inside the severed blood vessel (this is not the case in Ersek). The Palmaz stent does not have a multitude of projecting edges. Therefore, it holds the graft in place (in the aorta) in a manner different than the Ersek device.

[376] More importantly, the Parodi article is dated 1991 (some eight years after the date of the invention of the '505 Patent). This inquiry (whether the invention of the '505 Patent was obvious in view of the Ersek Patent) is concerned with the state of affairs at the relevant time (May 18, 1983). In *Janssen-Ortho*, Madam Justice Sharlow stated, at paragraph 26:

> …I find it difficult to envisage a situation where a subsequently recognized advantage to a claimed invention would be of any assistance in determining whether inventive ingenuity was required to make it. I can imagine a situation where the commercial success of an invention is attributable to a subsequently recognized advantage, but that would not assist the inquiry as to inventive ingenuity. I recognize that it is impossible to imagine every possible situation, but given the current state of the jurisprudence I would be inclined to give this factor no weight except in the most extraordinary case.

[377] I find that reasoning to be apposite to this issue and I subscribe to Justice Sharlow's view. The Parodi article does not assist me in determining the obviousness of the '505 Patent and I accord no weight to it in that regard. Further, I take nothing from Dr. Palmaz's use of the word "embed" in the 1983 Monograph. First, the word is to be read in its context, a proposition well known to, and repeatedly advanced by, Boston Scientific throughout the trial of this matter. The meaning of the word "embed" in the context of 1983 Monograph bears no similarity to its meaning in the context of the Ersek Patent. In any event and, at the risk of redundancy, it is the obviousness of the '505 Patent that is in issue. The '505 Patent does not speak to embedding the metal in the tissue surface.

[378] I also place minimal weight on Boston Scientific's references to the re-examination proceedings in relation to the U.S. '762 Patent. In the absence of specific evidence relating to the relevant file wrapper or the circumstances of the proceeding, the generalized comment that claim 13 was cancelled "in view of Ersek" is of little assistance to me. All the more so when regard is had to Boston Scientific's repeated representations regarding the dissimilarities between Canadian and United States patent law.

[379] The secondary factors of commercial success and meritorious awards indisputably point toward the "inventiveness" of the '505 Patent although caution is warranted in assigning undue weight to them because they relate to facts arising after the date of the invention.

[380] Dr. Palmaz testified, and other witnesses confirmed, that the limitations of balloon angioplasty were recognized as a problem. The history of angioplasty and its restrictions evidenced a "long-felt need" for the invention. I accept Dr. Palmaz's motivation regarding the conception of his stent. The Palmaz stent, at the time, functioned better than other devices in the field aimed at remedying the same problem. The evidence of commercial success tendered by Johnson & Johnson was directed primarily to the '186 Patent. However, numerous articles cite Dr. Palmaz as the inventor of the balloon mounted stent, which is the subject of the '505 Patent. Dr. Palmaz is the recipient of many prestigious awards recognizing his work in this regard.

[381] It is important, in my view, to distinguish between a prior invention that renders a later idea obvious and one that triggers an inventor to think of a new (and equally inventive) concept. I regard

the Ersek Patent, at its highest, as being in the latter category. While the Ersek Patent has characteristics or elements that could trigger ideas for those searching for an alternative to coronary bypass surgery, for the foregoing reasons, it does not follow that, after seeing the Ersek Patent, the skilled person would directly and without difficulty (and without employing an "inventive step") arrive at the '505 Patent.

The '186 Patent

[382] Boston Scientific does not allege that the '186 Patent was anticipated. It does contend that the '186 Patent is an obvious improvement, or alteration, of the '505 Patent. Mr. Opolski states that a medical device manufacturer, as of 1986, would have considered the use of a connector to flexibly connect two rigid structures together to be a common design choice. He provides "real-life" examples (railway trains, subway cars) where a connector flexibly connects two rigid structures. He explains that, by making the rigid elements shorter, using more of them, and using connectors between them, the flexibility of the overall structure is enhanced.

[383] Dr. Cumberland and Mr. Opolski refer to the Wallace article, which they claim demonstrates that stents can be used individually or, that two stents can be connected by a wire strut and inserted together. According to Dr. Cumberland, the positioning of the two stents in Figure 3 of the article teaches that the bridge (strut) allows the two stents to be flexible (relative to one another), while at the same time, preventing migration. It is not totally clear from Figure 3 whether the flexibility occurs because the bridge itself flexes, or if flexibility occurs at the junction of the stent and the metal bridge. Regardless, Dr. Cumberland states that it would have been apparent to a

person skilled in the art, upon reading this article, that two Palmaz stents could be connected by means of a metal bridge.

[384] In the Radiology article, Dr. Palmaz (and colleagues) discuss the lack of longitudinal flexibility of the wire mesh stent configuration. They state that the graft is limited to use in straight arterial segments. Curved arteries require the use of short graft lengths. The article indicates that problems, experienced with an excessively long graft, can be solved by using "shorter grafts or grafts in tandem". Dr. Cumberland claims that the meaning of "tandem" is not clear and offers two possibilities: mounting two grafts simultaneously on a balloon; or, implanting grafts separately, adjacent to one another.

[385] In Dr. Cumberland's opinion, neither arrangement is satisfactory. There are risks associated with multiple stents on one balloon. One stent may displace and migrate to another arterial territory or, the movement of the stents relative to each other during passage may cause gaps, or overlaps, between them. The process of placing separate stents, one at a time, is difficult and time-consuming. Moreover, it subjects the vessel to greater trauma. The plain and simple solution is to join the stents together with a single strut as a flexible connector. Dr. Cumberland notes that such a device was introduced as the Palmaz-Schatz stent. The Palmaz-Schatz stent solved the rigidity aspect of the original Palmaz stent and the attendant restrictions discussed in the Radiology article.

[386] Dr. Buller sees no ambiguity in the phrase "grafts in tandem" (in the 1985 Radiology article). He feels that a skilled person would understand the phrase to refer to the placement of two or more grafts end-to-end on the same angioplasty balloon. The solution to the problem of

inflexibility proffered in the Radiology article was to use shorter graft lengths. There was no motivation to search for another solution. Because of the desire to minimize the amount of metal being put in the coronary arteries, one would not have been inclined to add metal (in the form of connectors) to the structure.

[387] Dr. Buller maintains that the Wallace article states only that two stents were connected by a wire strut. It provides little description of the connected stents. Increased flexibility is not an advantage of the design cited in the Wallace article. The article's abstract hints at the reason for connecting the stents: "because of stent migration, designs are being tested to develop stents with greater stability". Dr. Buller refers to the "Charnsangavej Radiologoy" article (by members of Dr. Gianturco's group), wherein the use of shorter Z-stents is suggested for the treatment of a long stenosis. The rationale is that shorter stents can provide greater expansile force and can help prevent the two Z-stents from de-stabilizing. Dr. Buller concludes that the purpose of connecting two Z-stents was to improve the stability of the device during delivery, not to promote flexibility.

[388] He further explains that, due to the nature of Z-stents as self-expanding springs, their orientation can change when they are ejected from the catheter. Joining two stents together permits greater stability and control because the second stent remains inside the catheter while the first stent expands. Unlike Palmaz's balloon-mounted stents, the Z-stents are expelled from the catheter by pushing. Any connecting strut must have axial rigidity to transfer the pushing force, stabilize the first stent released, and hold the Z-stents at the correct distance from one another. The struts depicted in Figures 2 and 3 of the Wallace article support this rigidity requirement since the wire of the struts appears thicker than the wire of the stents (and therefore is more rigid).

[389] Moreover, without knowing the relative configuration of the Z-stents in Figure 3 prior to insertion, Dr. Buller says that one cannot conclude that the alignment of the stents demonstrates the use of the strut to flexibly connect the stents. Even if the Wallace article taught one to connect stents, it did not teach the connection of other things (namely tubular members) in the way that the '186 Patent teaches. Therefore, it would not have been apparent to the skilled person, upon reading the Wallace article, to provide longitudinal flexibility to a balloon-expandable slotted-tube stent by flexibly connecting two or more tubular members together.

[390] Nor, in Dr. Buller's opinion, would it have been a common design choice to flexibly connect two rigid structures. In this respect, he refers to the sequence in which AVE introduced various stent products. First, AVE commercialized relatively short, non-connected rings mounted on a balloon. It then moved to connect the rings at the four adjacent points of each ring. It was only after the introduction of these two products that AVE introduced the GFC stent with one connection between adjacent rings.

[391] Relying primarily on the Duprat article, Dr. Buller notes that when the Gianturco group moved to the development of a balloon-expandable stent, it did not adopt the connected struts of the Z-stents. Instead, it used a spiral-coil design. Dr. Buller claims that this indicates that Gianturco did not consider the previous teachings in the Z-stent art to have any flexibility (including the connected Z-stents). The use of a connector to flexibly connect two stents was not the solution directly arrived at by Dr. Gianturco's team. Therefore, joining two stents together with a single strut as a flexible

connector would not have been a solution that occurred immediately and without creative thought to a person skilled in the art in the mid-1980s.

Analysis

[392] The Radiology article describes the biological reaction that occurs (in the arteries of animals) in relation to Dr. Palmaz's woven-wire stent. Boston Scientific contends that the article demonstrates Dr. Palmaz's early recognition regarding the inflexibility associated with his longer grafts. Shorter and/or multiple grafts "in tandem" were considered as possible solutions to this limitation.

[393] The improvement of the '186 Patent is the connection of two or more tubular members, with connectors, to allow flexibility. In my view, the Radiology article, on its own, reveals that Dr. Palmaz recognized the inflexibility of his longer grafts from early on. It also illustrates that Dr. Palmaz's solution to this problem was to shorten the grafts and use shorter grafts together. It does not demonstrate that connecting the short grafts would be obvious.

[394] Dr. Cumberland believes that the inherent problems of using short grafts in tandem would make connecting the grafts an obvious step. Although I find his evidence that these problems would occur credible, the fact that the "unconnected shorter grafts" solution would be faulty does not diminish its legitimacy as the first-conceived solution. Mr. Opolski agrees that making a stent short may permit it to get around curves more easily and that AVE's first product was shorter (unconnected) stents.

[395] Johnson & Johnson points to element 85 of the '505 Patent (a retaining mechanism to keep the stent on the balloon) and notes that early versions of the NIR stent had “socks” to keep the NIR stent on the balloons. I understand Johnson & Johnson to be saying that Dr. Palmaz had other ideas for keeping multiple stents (in tandem) on a balloon during delivery and that the idea of connectors is not obvious.

[396] Therefore, I disagree with Boston Scientific that connecting the stents was obvious, based on the Radiology article alone. That said, a consideration of the known limitations of the '505 Patent, in conjunction with other pieces of prior art and the general knowledge of the skilled worker at the time, ultimately leads me to conclude that the '186 Patent is invalid for obviousness.

[397] The Wallace article relates to the use of Z-stents in the trachea and bronchi (airway passages) of dogs and its clinical application in two patients. It states that “the stents were used individually, or two stents were connected by a wire strut and inserted together”. What would a skilled person understand from these wire strut connectors in terms of the invention of the '186 Patent?

[398] I have given considerable thought to Dr. Buller’s opinion that the purpose of the strut connector is to assist in releasing and expanding the stents in a more controlled, stable fashion. In the end, I do not accept it. The Wallace article says little regarding the release of the stents except for the comment, “when the stent remained in the outer catheter, its position could be altered, but once released only slight adjustments could be made”. The justification for Dr. Buller’s opinion is derived primarily from the Charnsangavej article. That article discusses the potential for

minimizing migration with the use of two stents (connected by a wire strut) by releasing the lead strut while the other stent remained in the catheter. The difficulty is that the article does not form part of the prior art at the relevant date.

[399] I do not believe that the skilled person would understand the wire strut connector in the Wallace article to be serving a function related exclusively to stability. I accept Dr. Cumberland's evidence that the excerpt from the article's abstract, which discusses "developing stents with greater stability" speaks to other work that was focused on the problem of stents migrating over time after being placed in the body. Dr. Buller acknowledges, in cross-examination, that this text is referring to future articles (where barbs were added to stents) and not to the stability of the stents in their release from the catheter.

[400] I consider it inconceivable that, upon reading this piece of prior art, the skilled person would not immediately grasp the concept that multiple stents can be connected and inserted into the body together. The fact that a Z-stent will migrate less upon expansion, if it is attached to a second Z-stent that remains in the catheter, does not detract from the general notion of connecting multiple stents. I reject Johnson & Johnson's submission that connecting stents in the Wallace article is "so far removed from the teaching in the '186 Patent of connecting multiple tubular members". Although the individual tubular members are not the "stent" claimed by the '186 Patent, the '186 Patent is nonetheless an improvement of the '505 Patent. Essentially, the '186 Patent teaches the connection of multiple '505 Patents together to create the '186 Patent. Claim 9 of the '186 Patent (not in issue) teaches to connect multiple prostheses (stents) not tubular members. In other words, tubular members and stents are equated (or interchangeable). The skilled worker would be so

aware. Moreover, Dr. Buller concedes, on cross-examination, that the Z-stents of the Wallace article are hollow and cylindrical and therefore meet his definition of tubular member.

[401] All witnesses agree that it is difficult to draw conclusions from the Figures in the Wallace article, specifically as to whether the stents had shifted position relative to each other as between Figures 3A and 3B.

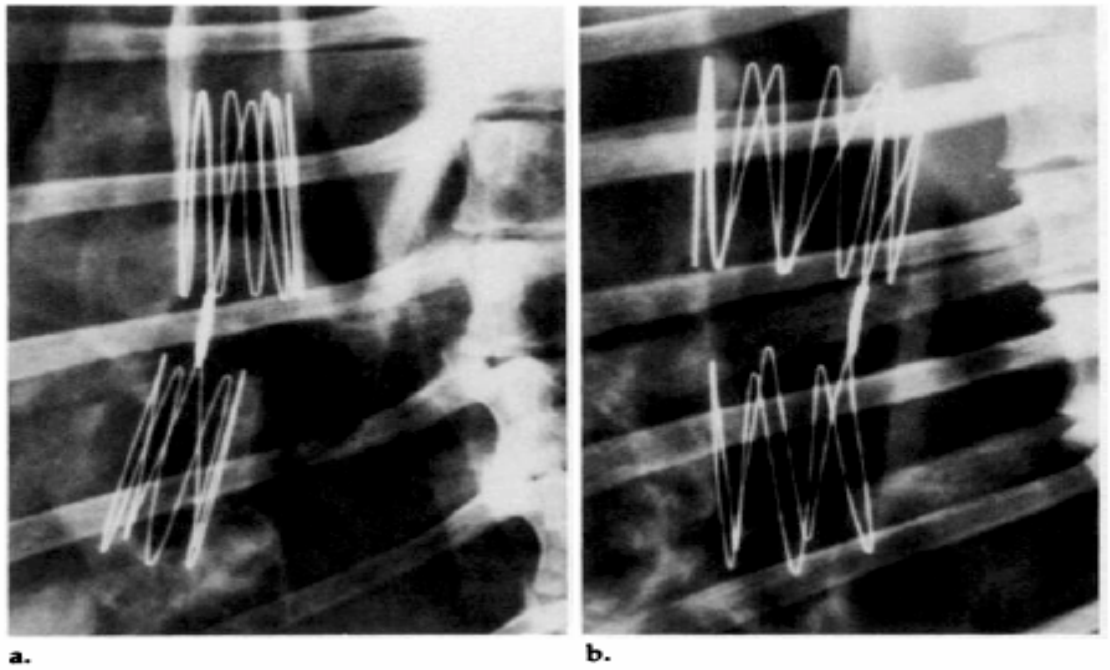


Figure 3. Combined endotracheal and endobronchial stent in a dog, immediately after placement **(a)** and 1 month later **(b)**.

[402] Although the text does not expressly discuss being "flexibly" connected to one another, in my view, it is more probable than not, that the articulation between the two stents (as can be seen in Figure 3A) demonstrates that the stents are flexing relative to each other. As Dr. Cumberland notes,

it is both unlikely and impractical that the stents would have been assembled in such a way, prior to insertion.

[403] Dr. Buller acknowledges that a person skilled in the art, beginning to examine balloon-expandable stents, would know "all about self-expanding stents" and would therefore know about the idea of connecting Z-stents together. However, he feels that the concern of thrombosis was so great that no one would have leaned toward adding metal, despite what was shown in the Wallace article because the experiments discussed therein were conducted in the airways.

[404] Although I accept that there were concerns about placing metal in the bloodstream (and Dr. Palmaz's original prototypes were met with scepticism), it is my understanding that, by the time Drs. Palmaz and Schatz discussed the creation of a flexible stent and made application for what became the '186 Patent, such concerns had somewhat dissipated. That is not to say that the apprehension regarding thrombosis had been eradicated. Rather, the industry was growing more comfortable with the notion of putting metal in the bloodstream by way of stents as evidenced by the numerous groups experimenting with various metal stent designs throughout this time frame. Only Dr. Buller raises this issue as a potential concern. Mr. Opolski, who was cognizant of the aversion to metal, did not see the connector as a problem in this respect. I do not find Dr. Buller's evidence to be persuasive.

[405] The issue of obviousness requires an examination of a "mosaic" of prior art and a determination of what would have been obvious to the skilled worker based on the totality of available information at the relevant time. I conclude that the idea or concept of adding connectors

to shorter versions of the '505 Patent stents was an obvious improvement. I arrive at this conclusion for a variety of reasons, including but not limited to: the inflexibility of the Palmaz stent was immediately apparent and solutions were sought to remedy it; numerous shorter stents were thought to give increased flexibility; the problems with migration, overlaps and gaps would have necessitated a means to keep multiple, shorter stents together; using connectors would have been obvious to the skilled person given the existence of not uncommon "real-life" examples where an articulation point is used between relatively rigid members to increase the overall flexibility of the structure; and, even if the idea of connectors would not have immediately occurred to the skilled person, the concept formed part of the prior art and public domain (the Wallace article).

[406] I should mention that, in arriving at my determination that the '505 Patent was inventive and the '186 Patent was not, I have considered the commercial success and recognition gained by these patents. Dr. Palmaz has been widely recognized as the inventor of the slotted-tube balloon-expandable stent. Millions of such stents have been sold. It is somewhat difficult to assess the apportionment of the financial and meritorious awards as between the '505 and the '186 Patents. This is understandable since the '186 Patent was the subject of the BENESTENT and STRESS trials. Those trials irrefutably established that balloon-expandable stents were an improvement over the process of angioplasty alone. Notwithstanding, my conclusion that the '186 Patent was obvious remains.

[407] The "invention" found in the '186 Patent is basically the addition of connectors to a previous invention, the Palmaz stent. The tubular members that are joined together to form the Palmaz-

Schatz stent are the tubular members that, individually, constitute the Palmaz stent of the '505 Patent. Dr. Buller, in testifying about his use of the '186 Patent with a single strut connector stated:

> On occasions I would require a shorter stent, and therefore it was not uncommon to use a very delicate pair of surgical scissors to cut the connector in the middle to create a shorter, what would essentially be a Palmaz stent. So it would be just under one half of what is shown in this picture, and that would create a short, 7mm long, Palmaz stent, and I used those on very many occasions too.

[408] In summary, and for the foregoing reasons, I conclude that the '186 is invalid for obviousness. In view of my determination, I need not address Boston Scientific's submissions with respect to "double patenting" or "claims broader" and I decline to do so.

Infringement

Overview

[409] A patent that is invalid cannot be infringed. Consequently, only the '505 Patent need be considered. Although at first blush the evidence and the arguments appear daunting, having thoroughly considered both, I note that there is much common ground between the parties.

[410] First and foremost, they agree on the law. Section 44 of the Act provides the patentee with the right to exclude others, for the term of the patent, from making, constructing or using the invention, or selling it to others to be used.

[411] Infringement is "any act that interferes with the full enjoyment of the monopoly granted to the patentee" or any activity that deprives the inventor, in whole or in part, directly or indirectly, of

full enjoyment of the monopoly conferred by law. The onus is on the patentee to prove infringement of such right: *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (*Monsanto*).

[412] After the claims are construed, infringement is determined by comparing the allegedly infringing device with the words of the claims, as properly construed: *Monsanto; Free World Trust*.

[413] For infringement, the allegedly infringing device must include all the essential elements of a patent claim. If an essential element is omitted or substituted in the defendant's device, there is no infringement: *Free World Trust; Whirlpool*.

[414] As earlier noted, the expert witnesses agree, and I concur, that all elements in claim 1 of the '505 Patent are essential elements. Further, should Boston Scientific's NIR stent be found to infringe the '505 Patent, then its activities constitute infringing behaviour. For ease of reference, the essential elements (comprising the expandable intraluminal vascular graft claimed in the '505 Patent) are:

- a thin-walled tubular member
- the tubular member has first and second ends
- the tubular member has a wall surface disposed between the first and second ends that is of a substantially uniform thickness
- the wall surface has a plurality of slots formed therein
- the slots are disposed substantially parallel to the longitudinal axis of the tubular member

- the tubular member has a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen
- the tubular member has a second expanded and plastically deformed diameter
- upon application of a radially outwardly extending force, the second diameter is variable.

[415] Additionally, there is no dispute that the NIR stent is a stent. It has the requisite characteristics of stents generally, and it functions as a stent. That is, the NIR stent is an intraluminal vascular device which expands to a larger diameter inside the lumen to support and scaffold an occluded vessel. The NIR stent could also be labelled a “graft” or “prosthesis” because the word “stent” (in the field of coronary artery angioplasty and stenting) is interchangeable with the terms “graft” and “prosthesis”. Further, the NIR stent is a type of balloon-expandable stent. Because it is delivered intraluminally, it has a sufficiently small initial diameter and is permanently deformed (with a balloon) to a larger diameter. Being a balloon-expandable stent, it is not self-expanding and does not exert any outward force, once expanded. Interventionists using the NIR stent have some control over the extent of the stent’s expansion by controlling the force applied to the balloon. In other words, the NIR stent’s second diameter is variable depending upon the amount of force applied.

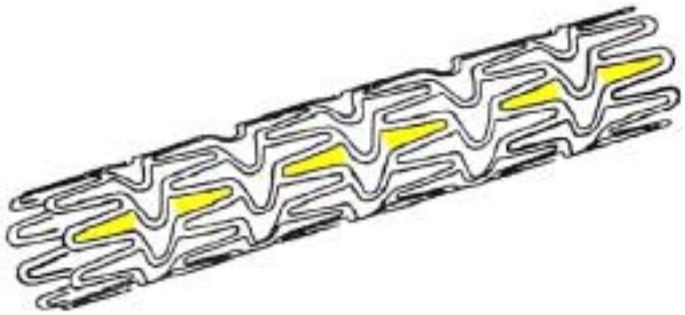
[416] The essential elements relating to the '505 Patent’s wall surface (thin with substantially uniform thickness) are qualities that allow any stent to function effectively and avoid harm to the patient. There is no debate as to whether the NIR stent’s wall surface has these qualities. Dr. Prendergast states that the outer surface of the NIR stent is smooth enough for intraluminal delivery.

A NIR stent is manufactured from a metal sheet that has a thickness of 0.004 inches and the thickness is uniform.

[417] In short, there is no quarrel about the NIR stent "being a stent". The relevant question is whether it infringes the '505 patent. The narrower issue is whether the NIR stent contains all the essential elements of the '505 Patent.

[418] Johnson & Johnson advance two theories with respect to infringement of the '505 Patent. Synoptically, they are:

(1) The entire NIR stent is a tubular member, with a wall surface (which contains a plurality of slots) between its first and second ends. This position is illustrated in the following diagram:



(2) Each section of the NIR stent between successive U-loops meets the definition of "tubular member" because it is hollow, cylindrical and contains a plurality of slots. Because of the word "comprising" in claim 1 of the '505 Patent, the monopoly can cover grafts that

are constructed by linking multiple tubular members. The diagram below depicts Johnson & Johnson's second position.

[419] Much discussion revolves around the "'nomenclature" used to describe the NIR stent. Boston Scientific maintains that the NIR stent is made up of "cells". Its witnesses assert that the repeating cell unit is the functional unit of the NIR stent. Johnson & Johnson, for the plaintiffs, contends that the NIR structure constitutes rings of "half-slots" and the "cells" are merely a visual analysis. Despite their differences in terminology, the parties agree that the NIR stent has horizontal loops (C loops) and that these loops contribute primarily to the scaffolding and supportive functions of the stent. They also agree that there are vertical pieces (U loops) that "go between" the horizontal loops and that they contribute, for the most part, to the NIR stent's flexibility. While Johnson & Johnson would group the C loops together to form zig-zag "rings", Boston Scientific would arrange two U loops with two C loops to form a "cell".

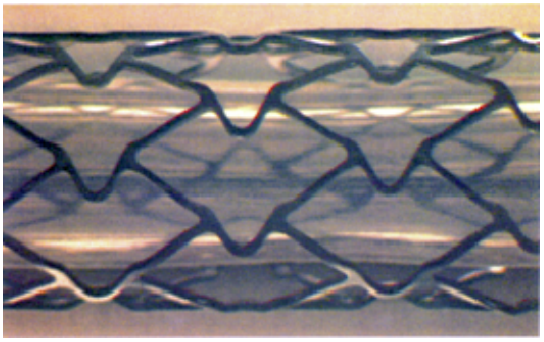
Analysis

[420] From one perspective, the stent has cells. From another, it has zig-zag rings, connected by vertical pieces. Visually, both can be true. In my view, the NIR stent functions in a manner that aligns itself best with the language used by Boston Scientific. However, I accentuate that the labels

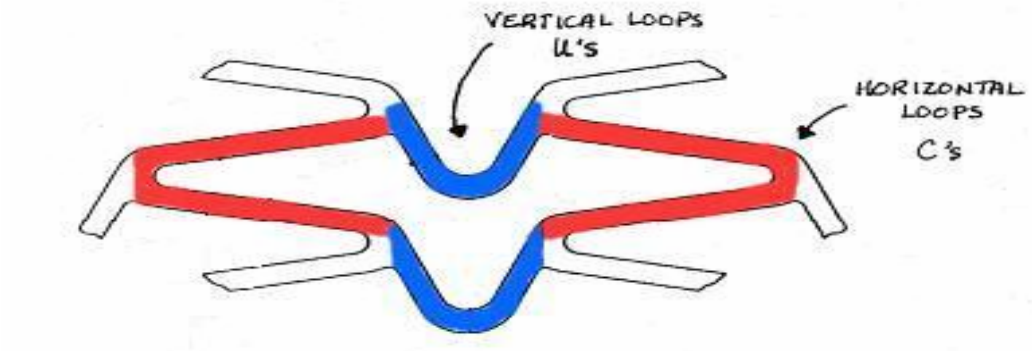
assigned, by others, to the specific components of the device are simply labels and I do not attach the same significance to them as do the parties.

[421] To appreciate the nature of the debate, an examination of the manner in which the NIR stent functions is warranted. The NIR is a second (or third) generation stent. Although it, like the Palmaz stent, has the basic characteristics of balloon-expandable stents, it has improved functional features as demonstrated by its geometry.

[422] The openings on the wall surface of the NIR stent are formed in what has been described as an “integrated cellular structure”. This repeating pattern of irregular-shaped cells is depicted in the diagram below. I emphasize that it may be equally fair to say that the pattern below shows zig-zag rings connected together. Changing the names of its parts does not alter the manner in which the stent functions, nor does it alter my determination regarding infringement.



[423] Each closed cell of the NIR stent is formed by a pair of opposite-facing horizontal or longitudinal “C” loops and a pair of vertical or circumferential “U” loops. One individual cell (with its components color coded) is set out below:

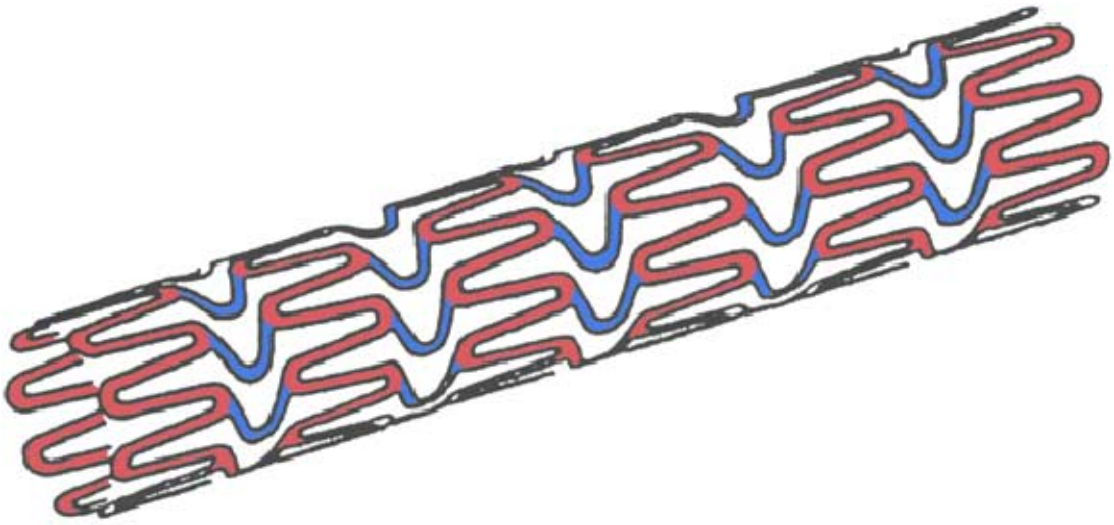


[424] The integration of each cell with those next to it provides the NIR stent with "uniform flexibility" (probably the most notable benefit over prior stent models). The evidence of the Boston Scientific expert witnesses indicates that the U loops and the C loops cooperate in order to allow for this level of flexibility. The NIR stent owes many of its functional characteristics (including the ability to flex longitudinally at any point along the length of the stent) to this sharing of structural elements between the cells. The Us and Cs permit "differential elongation" on bending. More specifically, the U loops close when on the inside of a bend and open on the outside of the bend to permit the outside of the curve to become longer. This enables the stent (as a whole) to flex (bend) along its entire length.

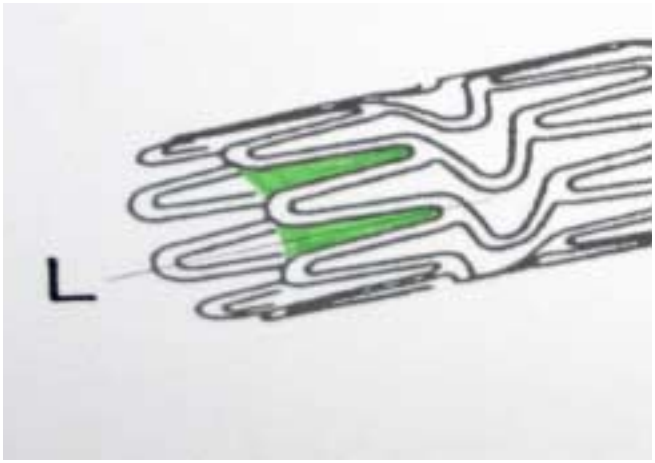
[425] There is no question that the U loops contribute more to the NIR stent's flexibility, as compared to the C loops. Yet, I agree with Boston Scientific that both the Us and the Cs assist in the stent's flexibility. Indeed, the U loops and C loops collaborate in all phases of the stent's use (not only in terms of uniform flexibility, but also by assisting to provide radial strength and scaffolding functions). As all witnesses acknowledge, the Palmaz stent (in contrast) is very rigid.

[426] The integrated cellular structure also permits the NIR stent to foreshorten to a lesser extent than the stent of the Palmaz Patent. The tendency of balloon-expandable stents to foreshorten is offset by the cooperation of the U and C loops. As the C loops expand, their length will diminish, but the U loops compensate by lengthening. Thus, the overall length of the stent is maintained.

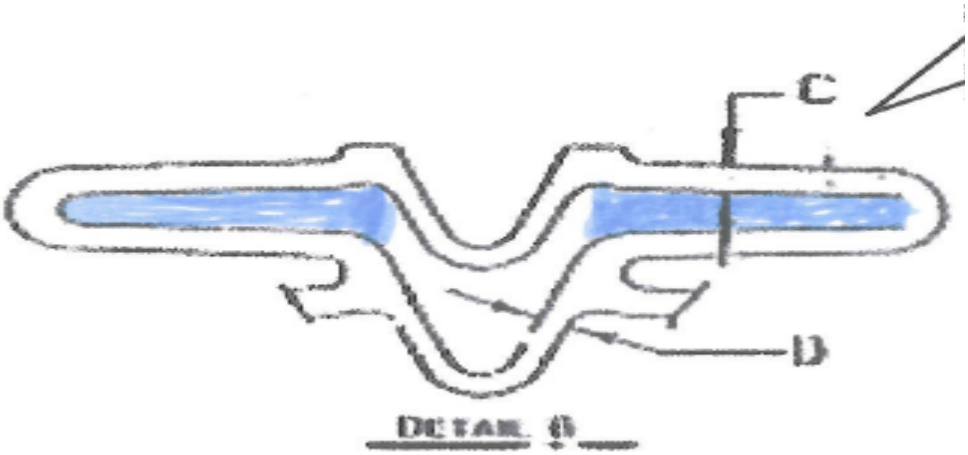
[427] Johnson & Johnson contends that the NIR stent has a plurality of "slots" as required by claim 1 of the '505 Patent. In support, it points to specific literature that refers to the NIR stent as a "slotted tube". (Notably, Boston Scientific does likewise in relation to its characterization of the NIR as being cellular and claims that the weight of the literature supports its view). The rationale underlying Johnson & Johnson's analysis of where the slots are located in the NIR stent is tied to the theory that the NIR stent is functionally divided into rings. These "rings" are illustrated, in red, in the diagram below.



[428] Johnson & Johnson points to the “openings” in the “rings” of the NIR stent and claims that these openings are the “slots” as shown by the green markings in the figure that follows.



[429] Further clarification in conceptualizing the portions of the NIR that Johnson & Johnson labels “slots” is provided by the blue portions of the diagram marked as Exhibit D-5.



[430] I have determined that the term “slot” (as it is used in the claims of the '505 patent) should be construed as meaning an elongated opening that is bounded on all sides, that is, a “complete slot”. Although the graft of the patent contains what the patent refers to as “half-slots” in the first

and second ends (I will say more about this later), these “half-slot” openings are not included in the term “slot”.

[431] The regions of the NIR stent that Johnson & Johnson attempts to label “slots” are open-ended. They cannot be “slots” (as I have construed this term). Although these regions in the NIR stent are longer than they are wide and are disposed generally along the longitudinal axis, they are not fully bounded on all sides. Therefore, they are not “slots”. I note (peripherally) that these regions are not staggered circumferentially, although this feature is not essential to the claims of the '505 Patent.

[432] Johnson & Johnson’s position is dependent upon the veracity of Dr. Buller’s building block Palmaz ring hypothesis. I have rejected that hypothesis because it is not one that is contemplated by the '505 Patent. Dr. Stringfellow’s evidence is not particularly helpful because it is premised on Dr. Buller’s thesis. Dr. Stringfellow provides no indication that he subjected Dr. Buller’s theory to any level of scrutiny. He merely endorses it. In contrast, the Boston Scientific experts provide cogent, detailed explanations and reasons as to why they reject the feasibility of the Palmaz ring theory. As previously stated, I conclude that Dr. Buller’s hypothesis is not sustainable. Moreover, I find that it is contrived to find infringement.

[433] The crux of my determination is that there are no complete slots along the longitudinal axis of the NIR stent. Dr. Buller acknowledged that this is so. The absence of “slots”, as the term is used in the '505 Patent (where it means complete slots), is inconsistent with the teaching of the '505

Patent. No embodiment of the '505 Patent would be made this way. Consequently, the NIR stent is missing an essential element from claim 1 of the '505 Patent.

[434] Also, first and second ends constitute an essential element of the '505 Patent. These ends are defined in great detail in the patent's disclosure such that they contain openings that are approximately half the size of complete slots. These half-slots alternate with the complete slots around the circumference of each "end" of the tubular member. This is evident from both the description of the first and second ends found on page 14 of the '505 Patent and from Figure 1A of the patent. In other words, the Palmaz Patent specifies that there will be "half slots" alternating with "slots" at each end of the tubular member. The NIR stent does not contain any "slots". Therefore, the first and second ends of the NIR stent are not the same as those of the '505 Patent.

[435] With respect to Johnson & Johnson's first "infringement analysis" (that the entire NIR stent is a tubular member), Boston Scientific does not disagree. However, the fact that the NIR stent is a tubular member does not eradicate the absence of "slots" in its wall surface. The absence of "slots" necessitates a conclusion of non-infringement.

[436] I have three observations regarding Johnson & Johnson's second infringement analysis. First, to accept it, I must also accept that each "ring" of the NIR stent is a tubular member. Tubular member has been defined as tube-like (cylindrical and hollow). As to whether a tubular member must be elongate, I concluded earlier that it is more probable than not that a coronary artery stent would not function well if its aspect ratio were less than one. In other words, a tubular member

should ideally be elongate and the “rings” of the NIR stent (a coronary artery stent), as defined by Johnson & Johnson, are not elongate.

[437] Second, I have found that, although the word “comprising” is non-exhaustive, claim 1 of the '505 Patent must contain everything necessary for the invention to function. That is, even if one assumes that a NIR ring is a tubular member, it must be capable of functioning on its own (as a stent) in order to come within the parameters of the '505 Patent. The NIR stent is an invention in which many “rings” (to use Johnson & Johnson nomenclature) are joined together in order for the stent to function in a particular way. Since the other “rings” are necessary to the functioning of the device, it is not correct to isolate one ring and then attempt to fit the entire NIR stent within claim 1 of the '505 Patent through use of the word “comprising”.

[438] Third, and most importantly, the second infringement analysis is totally discredited because of the absence of “slots” (as the term is understood in the '505 Patent). Even if I were to consider the NIR ring to be a tubular member and to consider that numerous tubular members can infringe the '505 Patent (and I do not), there are no “slots” in the NIR “ring”.

[439] Johnson & Johnson claims that all future stents (for example, Cordis, BX Velocity, AVE-S7, NIR) essentially copied the “rings” and connector structure of the '186 Patent. It is said that Johnson & Johnson initiated actions against Guidant and AVE for patent infringement of the '505 and '186 Patents. Guidant “settled” by taking a licence under these patents. Medtronic (which acquired AVE) did the same. Johnson & Johnson submits that such licences constitute evidence that these future stents have the same structure as the Palmaz-Schatz stent.

[440] There are no licences in evidence. Nor is there evidence as to the terms of the licences. Aside from fleeting references, there is no specificity whatsoever in this regard. Consequently, I accord very little (if any) consideration to these submissions.

[441] There is evidence that Johnson & Johnson, at one point, put together a proposal for acquiring the NIR design (Project Olive). At the time, Johnson & Johnson indicated that "the NIR is a superior stent design for both coronary and peripheral applications and has the potential to substantially replace the Palmaz and Palmaz-Schatz stents due to certain unique features". I take this statement to be indicative of the superiority of (and distinction between) the NIR stent and the Palmaz stent.

[442] To return to "nomenclature", the absence of "slots" in the NIR stent signifies that it is of no moment whether the NIR is "connected, zig-zag rings" or "integrated cells". The rings can be there and can be rigid. Indeed, most of the flexibility can come from the U loops. Notwithstanding, the NIR stent does not infringe the Palmaz stent.

[443] Johnson & Johnson's infringement theories appear to me to treat any stent that has an expandable zig-zag ring as infringing, irrespective of what the rest of the structure and its openings look like, and regardless of how they function. This approach stretches the '505 Patent to cover devices that Dr. Palmaz neither described, nor invented. The fact that the NIR stent performs essentially the same ultimate function as the Palmaz stent does not render it an infringement of the '505 Patent. The NIR stent (no longer marketed) was a new method by which to reach a similar

result. As Mr. Justice Binnie stated in *Free World Trust*, "[t]he ingenuity of the patent lies not in the identification of a desirable result, but in teaching one particular means to achieve it. The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desirable result".

[444] As stated earlier, because the '186 Patent is invalid, I need not address the issue of infringement in relation to it. However, even if I had determined that the '186 Patent was not obvious, since I reject Dr. Buller's building block Palmaz ring theory, and since the term "slots" in the '505 Patent means complete slots, the NIR stent could not infringe the '186 Patent in any event.

Conclusion

[445] The plaintiffs' claim of infringement will be dismissed. The defendant's counter-claim of invalidity with respect to the '505 Patent will be dismissed. The defendant's counter-claim of invalidity with respect to the '186 Patent will be allowed. Judgment will go accordingly.

[446] This is sufficient to dispose of the matter. Since the plaintiffs' infringement action is to be dismissed, the issues of remedies, ownership and licence do not arise.

[447] With respect to costs, I encourage counsel to endeavour to resolve the issue of costs by agreement. Success has been somewhat divided. Absent resolution, counsel are to serve and file written submissions (not to exceed five pages, double-spaced) within 35 days of the date of judgment. Responses to those submissions (not to exceed three pages, double-spaced) are to be served and filed within 10 days of service of the first submissions or within 45 days of the date

of judgment, at the election of counsel. I remain seized of this matter in relation to determination of the issue of costs.

"Carolyn Layden-Stevenson"
Judge

Ottawa, Ontario
May 8, 2008

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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