

# IP Cases With a Chemistry Flavour

Dr Robert Whittock, Barrister

26 November 2018



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# IP Cases: Chemistry Flavour

- **Drafting** – Edwards Lifesciences<sup>1</sup>
- **Priority & Disclosure** – Icescape<sup>2</sup>
- **Obviousness** – Actavis v ICOS<sup>3</sup>
- **Arrow Direction** – Glaxo v Vectura<sup>4</sup>

# Edwards Lifesciences v Boston Scientific

(19)   (11) EP 2 926 766 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 24.02.2016 Bulletin 2016/08 (51) Int. Cl.: A61F 2/01 (2006.01) A61F 2/24 (2006.01)

(21) Application number: 15167832.3 (22) Date of filing: 22.12.2004

(54) REPOSITIONABLE HEART VALVE  
NEUPOSITIONIERBARE HERZKLAPPE  
VALVE CARDIAQUE REPOSITIONNABLE

(64) Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR (72) Inventors:  
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• Argento, Claudio  
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• Hildebrand, Daniel  
Merilo Park, CA 94025 (US)

(30) Priority: 23.12.2003 US 746280  
23.12.2003 US 746942  
23.12.2003 US 746240  
23.12.2003 US 746872  
23.12.2003 US 746887  
23.12.2003 US 746120  
23.12.2003 US 746285  
15.07.2004 US 893151  
15.07.2004 US 893131  
15.07.2004 US 893143  
15.07.2004 US 893142  
21.10.2004 US 972287  
21.10.2004 US 971535  
05.11.2004 US 982692  
05.11.2004 US 982388

(43) Date of publication of application: 07.10.2015 Bulletin 2015/41

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC: 04815634.3 / 1 702 247

(73) Proprietor: Boston Scientific Scimed, Inc.  
Maple Grove, MN 55311-1566 (US)

(74) Representative: Peterreins Schley  
Patent- und Rechtsanwälte  
Soellstraße 2a  
81545 München (DE)

(56) References cited:  
WO-A1-95/28899 US-A1-2001 039 450

## Claim:

- Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an expandable cylindrical anchor (30) supporting a replacement valve (20), the anchor (30) having a delivery configuration and a deployed configuration, and at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.

EP 2 926 766 B1

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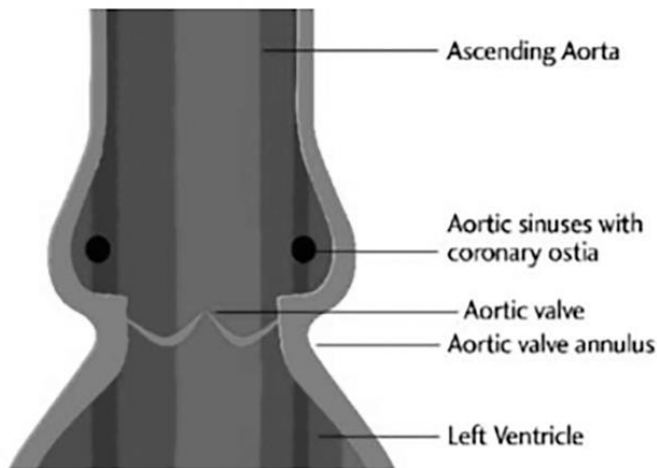
Printed by Jouve, 75001 PARIS (FR)

# Edwards Lifesciences v Boston Scientific

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an expandable cylindrical anchor (30) supporting a replacement valve (20), the anchor (30) having a delivery configuration and a deployed configuration, and at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.



# Edwards Lifesciences v Boston Scientific

'254 – 'bunched up'

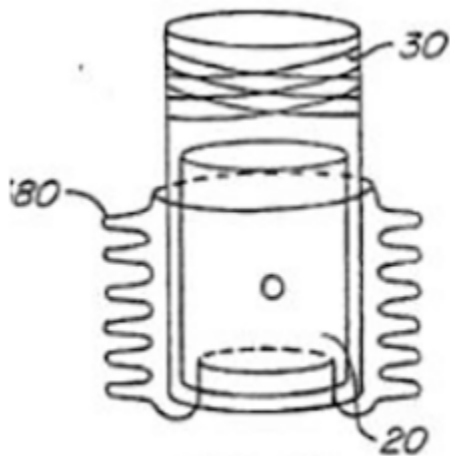


FIG. 23

## Claim:

1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

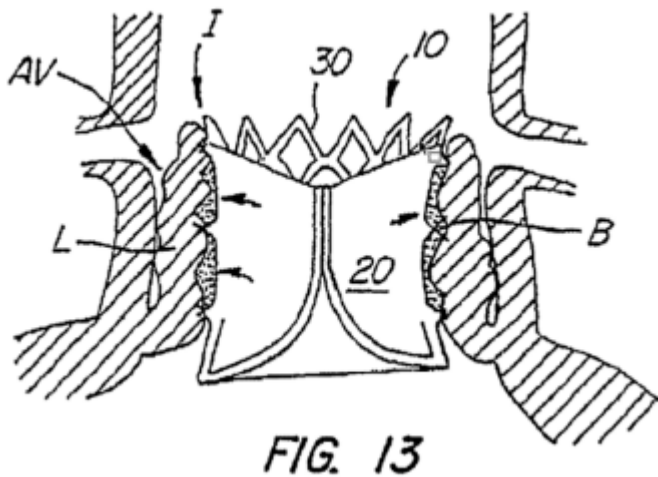
an expandable cylindrical anchor (30) supporting a replacement valve (20), the anchor (30) having a delivery configuration and a deployed configuration, and at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.

# Edwards Lifesciences v Boston Scientific

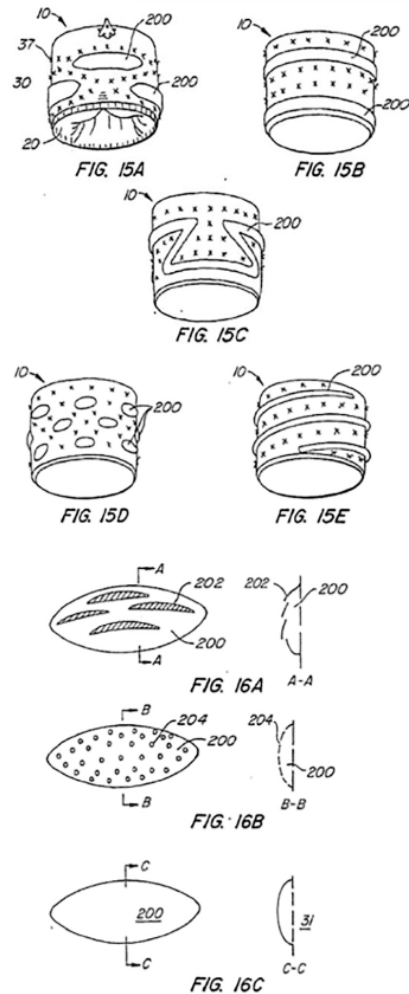
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1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an expandable cylindrical anchor (30) supporting a replacement valve (20),  
the anchor (30) having a delivery configuration and a deployed configuration, and  
at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.



# Edwards Lifesciences v Boston Scientific



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1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

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# Edwards Lifesciences v Boston Scientific



US006015431A

**United States Patent** [19] [11] **Patent Number:** **6,015,431**  
**Thornton et al.** [45] **Date of Patent:** **Jan. 18, 2000**

[54] **ENDOLUMENAL STENT-GRAFT WITH LEAK-RESISTANT SEAL.**

[75] Inventors: **Troy Thornton**, San Francisco; **Lilip Lau**, Sunnyvale, both of Calif.

[73] Assignee: **Prograf Medical, Inc.**, Palo Alto, Calif.

[21] Appl. No.: **08/773,479**

[22] Filed: **Dec. 23, 1996**

[51] **Int. Cl.**<sup>7</sup> **A61F 2/06**

[52] **U.S. Cl.** **623/1; 623/12; 606/194**

[58] **Field of Search** **623/1; 12; 606/108; 606/192, 194, 195**

[56] **References Cited**

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(List continued on next page.)

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 W095/21592 8/1995 WIPO  
 W0 96/26695 10/1995 WIPO

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Katzen, B. et al.: "Initial Experience Performing Combined Surgical/Interventional Procedures in the Interventional Suite", *Journal Of Endovascular Surgery—The Official Journal Of The International Society For Endovascular Surgery*, 1996; p. 467.

Chuter et al.: "Bifurcated stent-grafts for AAA: 3 year follow-up"; Abstracts from the Seventh International Course on Peripheral Vascular Intervention; J. Endovas. Surg. (1996) p. 458.  
 Derenne, JP et al.: "Endoluminal Treatment Of Abdominal Aortic Aneurysm with the Corvita Endovascular Graft, Results of a Single-Center, Prospective Feasibility Study of 90 Patients"; *Journal Of Endovascular Surgery—The Official Journal Of The International Society For Endovascular Surgery*; 1996; pp. 460-461.  
 Blum, U. et al.: "Dacron Endografts for Infraaortic Abdominal Aortic Aneurysms: 2 Year Follow-Up"; Springer, vol. 20, No. 1; Jan./Feb. 1997.

*Primary Examiner*—Bruce E. Snow  
*Attorney, Agent, or Firm*—Morgan & Finnegan LLP

[57] **ABSTRACT**

An implantable medical device has a tubular member and a sealing member secured to an outer surface of the tubular member. The tubular member is expandable to engage an endolumenal wall and has a lumen for providing an artificial conduit for flow through an endolumenal space defined by that wall. The seal member excludes flow around the tubular member between the outer surface and the endolumenal wall. One suitable tubular member for use in the present invention is a stent-graft which may be bifurcated for use in protecting vascular wall malformations adjacent to vascular bifurcations against endolumenal pressure and flow. The seal member may be a flange that is oriented on the outer surface at one end of the tubular member as a one-way valve against flow. Multiple seal members may be used, either on opposite ends of the tubular member or in series at one end thereof. Where anchors are used to secure the tubular member to the endolumenal wall, the seal member is positioned to protect against flow through leakage paths formed at localized areas of deformation in the tubular wall adjacent to the anchors. One or more seal members may also be used with two or more tubular members to prevent flow through endolumenal spaces that remain open to flow due to gaps between the multiple, parallel tubular members.

23 Claims, 29 Drawing Sheets

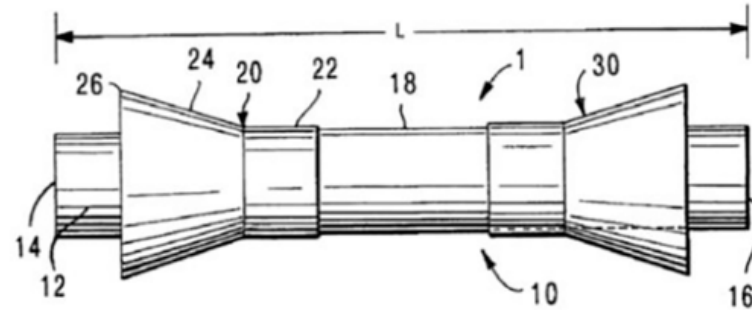
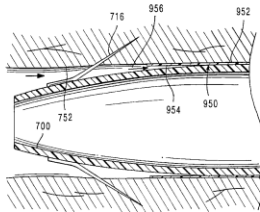


FIG. 1

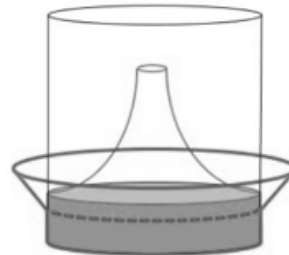


Figure 32: Example of a Thornton seal combined with a THV, showing the seal (red), skirt (blue), stent (black) and valve (green)

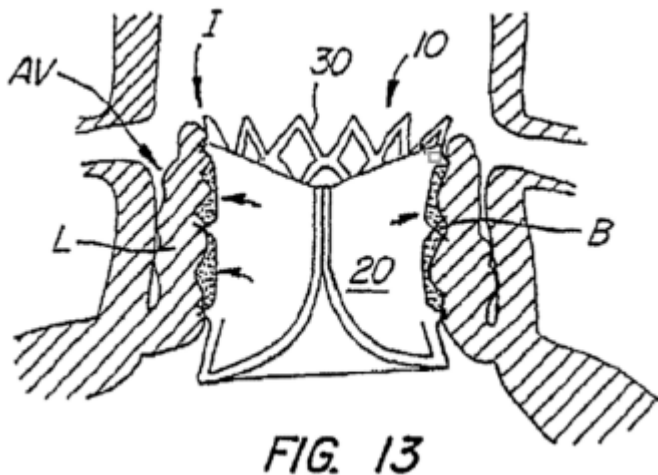
## Prior Art - Thornton

# Edwards Lifesciences v Boston Scientific

## Claim:

1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an expandable cylindrical anchor (30) supporting a replacement valve (20), the anchor (30) having a delivery configuration and a deployed configuration, and at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.



## Court of Appeal, 28 March 2018, Floyd LJ:

'49...the requirement for a sac in claim 1 is not so broad as to encompass any cavity...the term "sac" ...means a bag-like cavity providing a substantial degree of enclosure'.

'50...one would not get the idea of a sac forming a seal in the deployed configuration from Thornton'.

**Claim 1 of '766 was valid**

# Icescape Ltd v Ice-World International BV


(11) 1022998  
 Bureau voor de Industriële Eigendom Nederland  
(12) C OCTROOI<sup>20</sup>

(21) Aanvraag om octrooi: 1022998
(51) Int.Cl. 7  
F28F9/26, F25C3/02  
(22) Ingediend: 24.03.2003

<p>(41) Ingeschreven: 27.09.2004 I.E.</p> <p>(47) Dagtekening: 27.09.2004</p> <p>(45) Uitgegeven: 01.12.2004 I.E. 2004/12</p>	<p>(73) Octrooihouder(s): Finhoeks B.V. te Baarn.</p> <p>(72) Uitvinder(s): Wilhelmus Adolffus Johannes Marie Hoeks te Baarn</p> <p>(74) Gemachtigde: Ir. A. van Westenbrugge c.s. te 2502 LS Den Haag.</p>
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(54) **Mobiele warmtewisselaar en systeem voor het verschaffen van een ijsbaan voorzien van een dergelijke warmtewisselaar.**

(57) De uitvinding heeft betrekking op een mobiele warmtewisselaar, omvattende: ten minste één samenstel van ten minste twee ten minste in hoofdzaak starre leidingen voor doorvoer van een eerste medium, en een de twee leidingen aaneenschakelend koppellement, en met het samenstel verbonden toevormiddelen en afvoermiddelen voor toevoer respectievelijk afvoer van het eerste medium, waarbij het eerste medium is ingericht voor opwarming respectievelijk afkoeling van een het samenstel omgevend tweede medium. De uitvinding heeft tevens betrekking op een samenstel ten gebuike in een dergelijke mobiele warmtewisselaar. De uitvinding heeft voorts betrekking op een systeem voor het verschaffen van een ijsbaan voorzien van een dergelijke mobiele warmtewisselaar.



Winter 2003/2004 - prior use Belgium, Netherlands, Germany and Portugal.

NL C 1022998

De inhoud van dit octrooi komt overeen met de oorspronkelijk ingediende beschrijving met conclusie(s) en eventuele tekeningen.

# Icescape Ltd v Ice-World International BV


 Bureau voor de Industriële Eigendom Nederland  
 1022998  
 C OCTROOI<sup>20</sup>

21 Aanvraag om octrooi: 1022998  
 22 Ingediend: 24.03.2003  
 51 Int.Cl. 7  
 F28F9/26, F25C3/02

41 Ingeschreven: 27.09.2004 I.E. 47 Dagtekening: 27.09.2004 48 Uitgegeven: 01.12.2004 I.E. 2004/12	73 Octrooihouder(s): Finhoeks B.V. te Baarn. 72 Uitvinder(s): Wilhelmus Adolfus Johannes Marie Hoeks te Baarn 74 Gemachtigde: Ir. A. van Westenbrugge c.s. te 2502 LS Den Haag.
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54 Mobile warmtewisselaar en systeem voor het verschaffen van een ijsbaan voorzien van een dergelijke warmtewisselaar.  
 57 De uitvinding heeft betrekking op een mobiele warmtewisselaar, omvattende: ten minste één samenstel van ten minste twee ten minste in hoofdzaak starre leidingen voor doorvoer van een eerste medium, en een de twee leidingen aaneenschakelend koppellement, en met het samenstel verbonden toevoermiddelen en afvoermiddelen voor toevoer respectievelijk afvoer van het eerste medium, waarbij het eerste medium is ingericht voor opwarming respectievelijk afkoeling van een het samenstel omgevend tweede medium. De uitvinding heeft tevens betrekking op een samenstel ten gebuike in een dergelijke mobiele warmtewisselaar. De uitvinding heeft voorts betrekking op een systeem voor het verschaffen van een ijsbaan voorzien van een dergelijke mobiele warmtewisselaar.

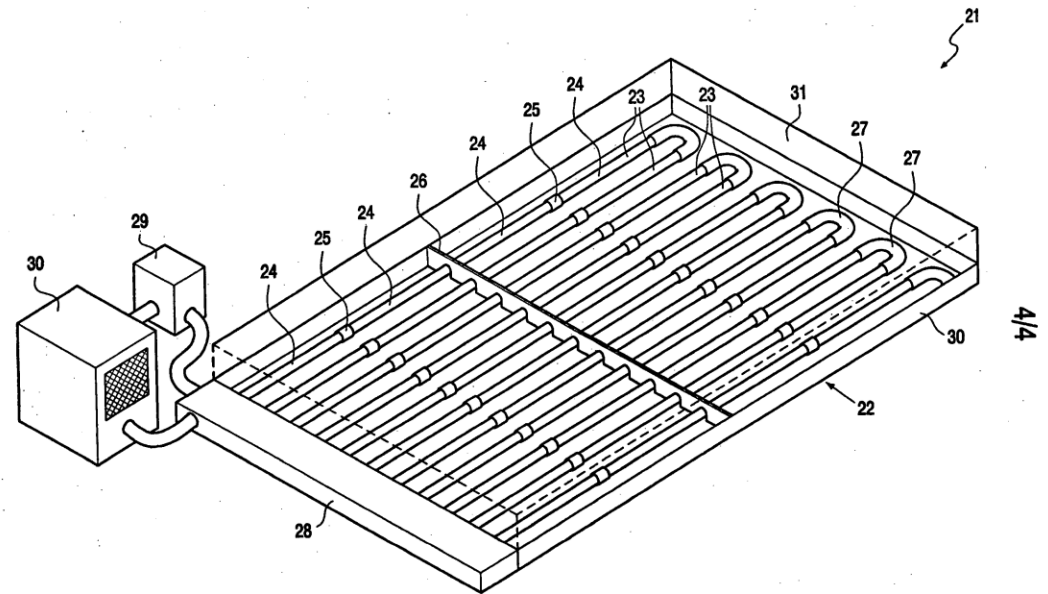


FIG. 6

# Icescape Ltd v Ice-World International BV



(11) EP 1 462 755 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 03.06.2009 Bulletin 2009/23

(51) Int Cl: F28F 9/26 (2006.01)

(21) Application number: 04075909.4

(22) Date of filing: 22.03.2004

(54) **Cooling member for a mobile ice rink**  
 Kühlelement für eine mobile Eisbahn  
 Élément de refroidissement pour une patinoire mobile

(84) Designated Contracting States:  
 AT BE BG CH CY CZ DE DK EE ES FI FR GB GR  
 HU IE IT LI LU MC NL PL PT RO SE SI SK TR

(74) Representative: van Westenbrugge, Andries  
 Nederlandsch Octrooibureau  
 Postbus 29720  
 2502 LS Den Haag (NL)

(30) Priority: 24.03.2003 NL 1022998

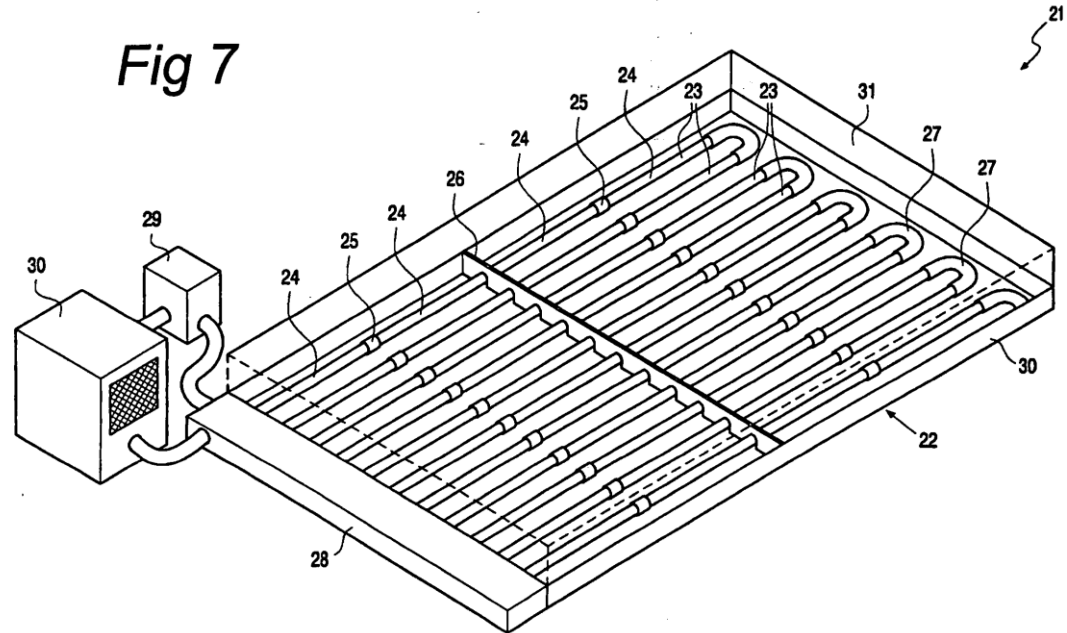
(56) References cited:  
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 FR-A- 2 677 262 FR-A- 2 802 292  
 GB-A- 252 516 GB-A- 2 051 340  
 US-B1- 6 253 558 US-B1- 6 334 439

(73) Proprietor: Ice-World International B.V.  
 3741 LM Baarn (NL)

• DATABASE WPI Section Ch, Week 199243  
 Derwent Publications Ltd., London, GB; Class  
 H03, AN 1992-355493 XP002260014 - & SU 1 664  
 693 A (BELO KIROV TECHN INST) 23 July 1991  
 (1991-07-23)

(72) Inventor: Hoeks, Wilhelmus A. J. M.  
 3743 DC Baarn (NL)

Fig 7



EP 1 462 755 B1

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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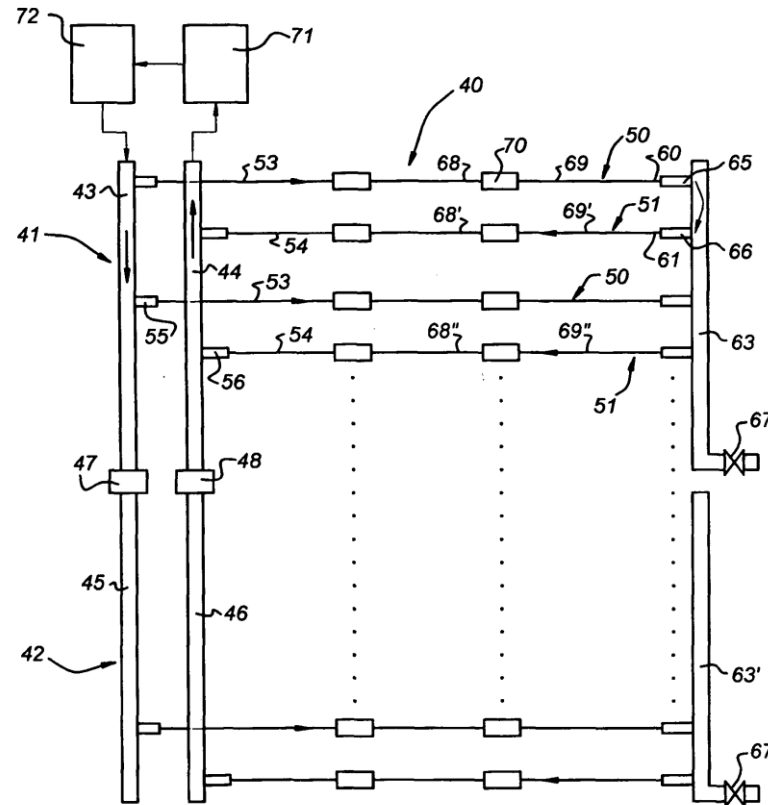
# Icescape Ltd v Ice-World International BV



**EUROPEAN PATENT SPECIFICATION**

- (19) Europäisches Patentamt  
European Patent Office  
Office européen des brevets
- (11) **EP 1 462 755 B1**
- (12) **EUROPEAN PATENT SPECIFICATION**
- (45) Date of publication and mention of the grant of the patent: 03.06.2009 Bulletin 2009/23
- (51) Int Cl.: *F28F 9/26 (2006.01)*
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- (74) Representative: van Westenbrugge, Andries  
Nederlandsch Octrooibureau  
Postbus 29720  
2502 LS Den Haag (NL)
- (30) Priority: 24.03.2003 NL 1022998
- (43) Date of publication of application: 29.09.2004 Bulletin 2004/40
- (56) References cited:  
EP-A- 1 031 809                      FR-A- 2 502 896  
FR-A- 2 677 262                      FR-A- 2 802 292  
GB-A- 252 516                        GB-A- 2 051 340  
US-B1- 6 253 558                      US-B1- 6 334 439
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(1991-07-23)
- (72) Inventor: Hoeks, Wilhelmus A. J. M.  
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**Fig 8**





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EP 1 462 755 B1

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 Nederlandsch Octrooibureau  
 Postbus 29720  
 2502 LS Den Haag (NL)

(30) Priority: **24.03.2003 NL 1022998**

(43) Date of publication of application: **29.09.2004 Bulletin 2004/40**

(73) Proprietor: **Ice-World International B.V.**  
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(72) Inventor: **Hoeks, Wilhelmus A. J. M.**  
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 GB-A- 252 516                        GB-A- 2 051 340  
 US-B1- 6 253 558                      US-B1- 6 334 439

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EP 1 462 755 B1

1. Cooling member (21, 40) for a mobile ice rink provided with:

- a feed manifold (43, 45) extending in a transverse direction and a discharge manifold (44, 46), and
- a number of longitudinal pipes (50, 51) which extend transversely to the manifolds and can be connected at a first end (53, 54) to a manifold (43, 44, 45, 46), two longitudinal pipes (50, 51) in each case being in fluid communication with one another at a second end (60, 61) via a connector (27, 63), so that a fluid path is formed from the feed manifold (43, 45) to the discharge manifold (44, 46) via the two connected longitudinal pipes (50, 51),

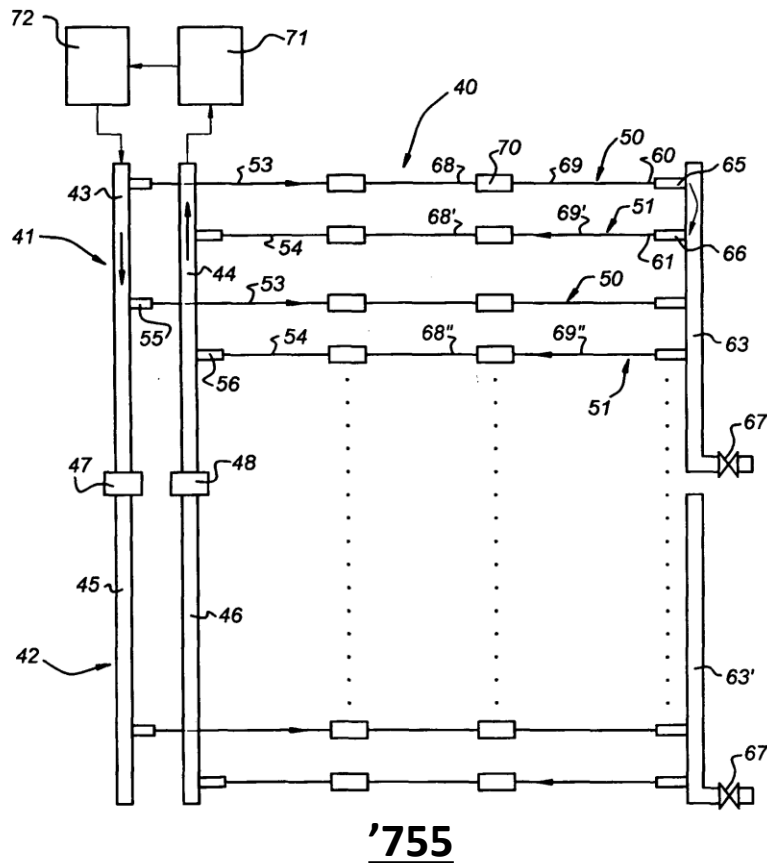
**characterised in that**

the cooling member comprises at least two elements (41, 42), each with a feed manifold (43, 45) and discharge manifold (44, 46) and a number of longitudinal pipes (50, 51) connected thereto, wherein each longitudinal pipe comprises at least two rigid pipe sections (3, 12, 16, 24, 68, 69) that are connected to one another via a joint member (4, 13, 17, 25, 70, 132, 133) such that they are fluid-tight, and wherein by moving the joint members (4, 13, 17, 25, 70, 132, 133) a first series of parallel pipe sections (68, 68', 68'') can be placed in a transport position with respect to a second series of parallel pipe sections (69, 69', 69'') connected thereto, in which transport position the two series of pipe sections (68, 68', 68''; 69, 69', 69'') are at an angle with respect to one another or are positioned on top of one another, and can be placed in an operational position in which the two series of pipe sections (68, 68', 68''; 69, 69', 69'') extend in the extension of one another, wherein the first and the second element (41, 42) can be placed in the operational position alongside one another such that the feed and discharge manifolds (43, 44, 45, 46) of the elements extend in the extension of one another in the transverse direction,

wherein the feed and discharge manifolds of the two elements are provided with a coupling member (47, 48) to make a fluid-tight connection between the respective feed and discharge manifolds of the first and the second element.

# Icescape Ltd v Ice-World International BV

Fig 8



**Court of Appeal** 10 October 2018


Lord Kitchin:


- Joint elements (70) – novel & inventive feature  
- Enabled folding of the unit
- Skilled person appreciate 2 x figure 6 to ↑ width  
**BUT** No express or implicit disclosure of:
  - two joined together OR
  - features A, D or E of Claim 1
- Claim to priority must fail.
- ❖ Common ground use prior to date of application.

'755 Patent Invalid



# Actavis v Icos


 Europäisches Patentamt  
 European Patent Office  
 Office européen des brevets

(19)  (11) **EP 1 173 181 B1** ←

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent: 15.10.2003 Bulletin 2003/42

(51) Int Cl.7: **A61K 31/4985**, A61P 15/10

(86) International application number: PCT/US00/11129

(81) Application number: 00926367.4

(87) International publication number: WO 00/066099 (09.11.2000 Gazette 2000/45)

(22) Date of filing: 26.04.2000

(54) **COMPOSITION COMPRISING PHOSPHODIESTERASE INHIBITORS FOR THE TREATMENT OF SEXUAL DYSFUNCTION**  
 ZUSAMMENSETZUNG ZUR BEHANDLUNG SEXUELLER FUNKTIONSTÖRUNGEN DIE PHOSPHODIESTERASE-5 INHIBITOREN ENTHALTEND  
 COMPOSITION COMPRENANT DES INHIBITEURS DE LA PHOSPHODIESTERASE POUR TRAITER LES DISFONCTIONNEMENTS SEXUELS

(84) Designated Contracting States: **AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE**  
 Designated Extension States: **AL LT LV MK RO SI**

(30) Priority: 30.04.1999 US 132036 P

(43) Date of publication of application: 23.01.2002 Bulletin 2002/04

(73) Proprietor: Lilly Icos LLC  
 Wilmington, DE 19801 (US)

(72) Inventors:  
 • PULLMAN, William, Ernest  
 Carmel, IN 46032 (US)  
 • WHITAKER, John, Steven  
 Woodinville, WA 98072 (US)

(74) Representative: Richardson, Kate et al  
 Forrester & Boehmert,  
 Pettenkoferstrasse 20-22  
 80336 München (DE)

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EP 1 173 181 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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# Actavis v Icos

(19)  (11)  **EP 1 173 181 B3** 

(12) **NEW EUROPEAN PATENT SPECIFICATION**  
After limitation procedure (B3-2)

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15.10.2003 Bulletin 2003/42

(45) Date of publication and mention of the limitation decision:  
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(51) Int. Cl.:  
A61K 31/4985 (2006.01) A61P 15/10 (2006.01)

(86) International application number:  
PCT/US2000/011129

(87) International publication number:  
WO 2000/066099 (09.11.2000 Gazette 2000/45)

(54) **COMPOSITIONS COMPRISING PHOSPHODIESTERASE INHIBITORS FOR THE TREATMENT OF SEXUAL DYSFUNCTION**  
ZUSAMMENSETZUNG ZUR BEHANDLUNG SEXUELLER FUNKTIONSTÖRUNGEN DIE PHOSPHODIESTERASE-5 INHIBITOREN ENTHALTEND  
COMPOSITION COMPRENANT DES INHIBITEURS DE LA PHOSPHODIESTERASE POUR TRAITER LES DYSFONCTIONNEMENTS SEXUELS

(84) Designated Contracting States:  
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE  
Designated Extension States:  
AL LT LV MK RO SI

(30) Priority: 30.04.1999 US 132036 P

(43) Date of publication of application:  
23.01.2002 Bulletin 2002/04

(60) Divisional application:  
03023276.3 / 1 415 652

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WO-A-97/03675 WO-A-99/59584

- DATABASE WPI Section Ch, Week 200029 Derwent Publications Ltd., London, GB; Class B02, AN 2000-339026 XP002152606 & WO 00 20033 A (EISAI CO LTD), 13 April 2000 (2000-04-13)
- ISRAËL M: "VIAGRA: THE FIRST ORAL TREATMENT FOR IMPOTENCE", PHARMACEUTICAL JOURNAL, PHARMACEUTICAL SOCIETY, LONDON, GB, vol. 261, 1 August 1998 (1998-08-01), pages 164-165, XP000919343 ISSN: 0031-6873
- GOLDENBERG M M: "SAFETY AND EFFICACY OF SILDENAFIL CITRATE IN THE TREATMENT OF MALE ERECTILE DYSFUNCTION" CLINICAL THERAPEUTICS, US, EXCERPTA MEDICA, PRINCETON, NJ, vol. 20, no. 6, 1998, pages 1033-1048, XP000853855 ISSN: 0149-2918



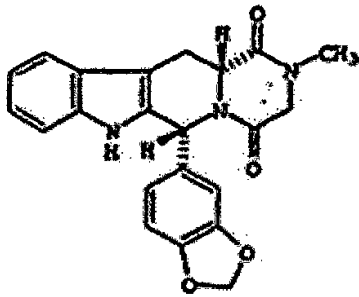
Amended 25.03.15 in the IPO

EP 1 173 181 B3

# Actavis v Icos

## '181 Claims:

1. A pharmaceutical unit dosage composition comprising 1 to 5mg of a compound having the structural formula:



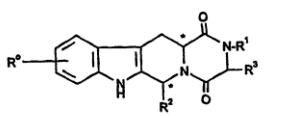
7. The dosage form of claim 6 wherein the condition is a sexual dysfunction.

10. Use of a unit dose containing 1 to 5mg of a compound having the structure...



Amended 25.03.15 in the IPO

# Actavis v Icos

<b>PCT</b> WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)			
(5) International Patent Classification <sup>6</sup> : <b>A61K 31/495</b>	<b>A1</b>	(11) International Publication Number: <b>WO 97/03675</b>	(43) International Publication Date: 6 February 1997 (06.02.97)
(21) International Application Number: PCT/EP96/03024 (22) International Filing Date: 11 July 1996 (11.07.96)		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(30) Priority Data: 9514464.8      14 July 1995 (14.07.95)      GB		<b>Published</b> <i>With international search report.</i>	
(71) Applicant (for all designated States except US): LABORATOIRE GLAXO WELLCOME S.A. [FR/FR]; 43, rue Vineuse, F-75116 Paris (FR).		(72) Inventor; and (75) Inventor/Applicant (for US only): DAUGAN, Alain, Claude-Marie [FR/FR]; Laboratoire Glaxo Wellcome S.A., Centre de Recherches, Z.A. de Courtaboeuf, 25, avenue de Quebec, F-91940 Les Ulis (FR).	
(74) Agents: FILLER, Wendy, Anne et al.; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).			
(54) Title: USE OF CGMP-PHOSPHODIESTERASE INHIBITORS TO TREAT IMPOTENCE			
(57) Abstract The use of compounds of formula (I)			
(6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2,1':6,1]pyridine[3,4-b]indole-1,4-dione, (S), (R), (12aR)-2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2,1':6,1]pyridine[3,4-b]indole-1,4-dione, and physiologically acceptable salts and solvates thereof, in the treatment of impotence.			

## Prior Art - Daugan

### Obviousness:

- Inventive step – not obvious to a skilled person having regard to the state of the art

### Daugan discloses:

- the idea of using PDE5 inhibitors for ED
- 2 compounds (A + B). A = tadalafil
- Example of 50mg dose tablet
- Doses of A + B – 0.5 to 800mg per day

# Actavis v Icos

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61K 31/495	A1	(11) International Publication Number: WO 97/03675
(21) International Application Number: PCT/EP96/03024	(22) International Filing Date: 11 July 1996 (11.07.96)	(43) International Publication Date: 6 February 1997 (06.02.97)
(30) Priority Data: 9514464.8 14 July 1995 (14.07.95) GB	(71) Applicant (for all designated States except US): LABORATOIRE GLAXO WELLCOME S.A. [FR/FR]; 43, rue Vimeuse, F-75116 Paris (FR).	(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LI, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(72) Inventor; and (75) Inventor/Applicant (for US only): DAUGAN, Alain, Claude-Marie [FR/FR]; Laboratoire Glaxo Wellcome S.A., Centre de Recherches, Z.A. de Courtaboeuf, 25, avenue de Quebec, F-91940 Les Ulis (FR).	(74) Agents: FILLER, Wendy, Anne et al.; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).	Published With international search report.
(54) Title: USE OF CGMP-PHOSPHODIESTERASE INHIBITORS TO TREAT IMPOTENCE		
(57) Abstract The use of compounds of formula (I) (6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyridis[3,4-b]indole-1,4-dione, (6S, 12aR)-2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyridis[3,4-b]indole-1,4-dione, and physiologically acceptable salts and solvates thereof, in the treatment of impotence.		

## Before Birss J.

C contended '181 claims are obvious over Daugan:

- Dose ranging studies to find minimal effective dose
- 5mg dose would be obvious

D contended '181 claims not obvious over Daugan:

- Dose as low as 5mg
- Advantages of efficacy and low side effects
- Skilled team embarking on clinical project would have:
  - No reasonable prospect of success as to outcome
  - No reasonable basis for 5mg dose being efficacious
  - No reasonable basis for its benefits
  - Used higher doses for Phase II trials

Prior Art - Daugan

Claims 1, 3-11 - Valid and infringed

Appeal to Supreme Court  
Heard 19-20 November 2018

# Actavis v Icos

**Court of Appeal, 1 November 2017, Kitchin L.J.:**

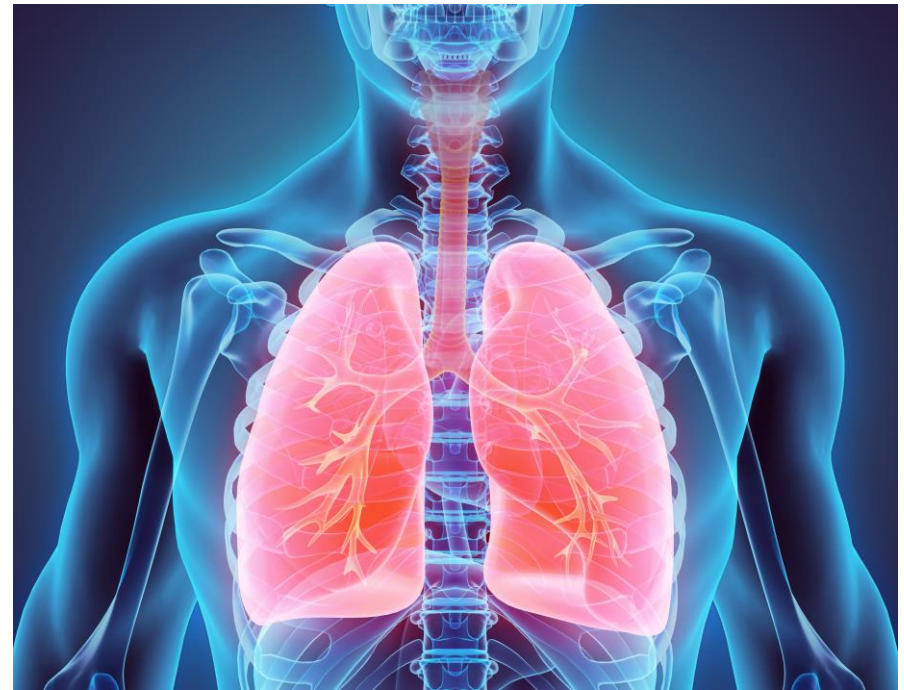
- **Pozzoli** – requires the identification of the difference between the disclosure of the prior art and the claims in issue:
  - Claim 1 – Daughan does not disclose a tablet containing 5mg of tadalafil.
  - Claims 7 and 10 – Daughan does not disclose 5mg daily dose of tadalafil or that such a dose is an effective treatment for sexual dysfunction.
- **MedImmune** – court must have regard to all the circumstances of the case when asking: was it obvious to the skilled but unimaginative addressee in light of the prior art and the common general knowledge to make a product...failing within the claim?
- **Generics v Novartis** – CoA gave guidance as to relevance of whether a particular route was obvious to try and skilled team's expectation of success.
- ❖ **Claim 1** - entirely obvious in light of Daughan.
- ❖ **Claims 7 and 10** - obvious - 'the claimed invention lies at the end of the familiar path through the routine pre-clinical and clinical trials' process'.



# Glaxo Group v Vectura Ltd

## Ellipta (inhalation)

- Asthma and COPD
- Vectura 5 patents, more to follow
- GSK – commercial uncertainty:
  - Seek Arrow Declaration



# Glaxo Group v Vectura Ltd

## Ellipta (inhalation)

- Arrow Declaration being sought by GSK:

(a) [GSK's] Processes, namely a process in which

- (i) lactose monohydrate and magnesium stearate are first blended together to produce a lactose/magnesium stearate pre-blend (“pre-blend”),
- (ii) micronized active ingredient combined with a portion of the Pre-Blend is then sieved to de-lump the active ingredient, and
- (iii) the remaining Pre-Blend is added and the whole batch further blended to produce an homogeneous blend, was obvious as of 30 November 2000 or at any date thereafter, and



# Glaxo Group v Vectura Ltd

## Ellipta (inhalation)

- Arrow Declaration being sought by GSK:

(b) [GSK's] Products insofar as they are the direct products of [GSK's] Processes (and save for the active ingredient therein, were obvious as of 30 November 2000 or at any date thereafter.

Court of Appeal June 2018 – reversed decision of HHJ Hacon to strike out Arrow Declaration

**High Court Trial – listed for ca. 19 November 2018**

# IP Cases: Chemistry Flavour

- **Drafting** – Edwards Lifesciences<sup>1</sup>

**Choice of words is very important**

- **Priority & Disclosure** – Icescape<sup>2</sup>

**Disclose invention in priority document**

**Prior use could invalidate the patent application if priority is lost**

- **Obviousness** – Actavis v ICOS<sup>3</sup>

**Test for inventive step**

- **Arrow Direction** – Glaxo v Vectura<sup>4</sup>

**May provide commercial certainty**

# Thank you! Any questions?

robert.whittock@hardwicke.co.uk

# References

1. *Edwards Lifesciences LLC v Boston Scientific Scimed Inc* [2018] F.S.R.29
2. *Icescape Ltd v Ice-World International BV* [2018] EWCA Civ 2219
3. *Actavis Group PTC EHF v ICOS Corp* [2017] EWCA Civ 1671
4. *Glaxo Group Ltd v Vectura Ltd* [2018] EWCA Civ 1496