

Medical Patent Law

- The Challenges of Medical Treatment

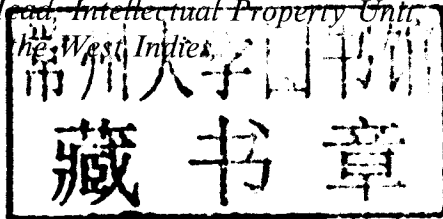
Eddy Ventose



Medical Patent Law – The Challenges of Medical Treatment

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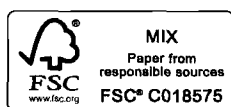
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List of abbreviations

Courts and Tribunals

Court of Appeal of England and Wales	CA
Enlarged Board of Appeal of the European Patent Office	EBA
Federal Court of Australia	FCA
High Court of Australia	HCA
High Court of England and Wales	HC
New Zealand Court of Appeal	NZCA
Patent Appeal Tribunal	PAT
Patent Office Board of Appeal (US)	POBA
Technical Board of Appeal	TBA

Legislation and Conventions

United Kingdom Patents Act 1977	1977 Act
European Patent Convention 1973	EPC 1973
Trade Related Aspects of Intellectual Property Rights	TRIPs
Medical Procedures and Affordability Act 1996	MPAA
Patent Convention Treaty	PCT
Genomic Research and Diagnostic Accessibility Act	GRDA

Organisations and Bodies

America Medical Association	AMA
European Patent Office	EPO
US Patent and Trademark Office	USPTO
World Medical Association	WMA

Others

Cornish, Llewellyn and Aplin, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (7th edn, Sweet and Maxwell, London 2010)

Bently & Sherman, *Intellectual Property Law* (3rd edn, Oxford University Press, Oxford 2008)

Base Proposal on the Revision of the European Patent Convention Munich (29 Nov 2000) MR/3/00 Rev

EC Directive on the Legal Protection of Biotechnological Inventions 98/44/EC of 6 July 1998, (1998) OJ L213/13

Cornish, Llewellyn and Aplin, *Intellectual Property*

Bently & Sherman, *Intellectual Property*

Base Proposal 2000

Biotech Directive

Foreword

Since its inception in the Statute of Monopolies, modern patent law has been remarkably adroit in adapting to the changing needs of inventors and industry. But changes in innovation and in the developed economies over the last 50 years have arguably put more acute pressures on the conceptual framework of the law than any it has encountered in its history. Those pressures have revealed how fragile are some of the distinctions – such as that between invention and discovery – that patent law has always taken for granted. They have pushed policy makers and lawyers back to the much contested, and often contradictory, justifications for the grant of the patent monopoly, even though those justifications have often had to be retrofitted onto the existing structures of the law.

One of the interesting things about those pressures is that they have often brought into the spotlight curious byways of the law; they have made issues that might once have been thought to be of merely scholarly interest commercially vital. It is in the consideration of these issues that the contradictions of patent law and policy have often become most plain.

In this way, enormous changes in the economics of the health system, in the way in which doctors regard their professional calling, and in patterns of healthcare innovation, together with contemporary expectations that all (or at least most) innovation should be rewarded, have put huge strain on the exclusion from patentability (however technically it may be achieved) of methods of medical treatment. The conceptual basis of that exclusion, while not robust, draws upon many other fundamental assumptions in the law of patents and, properly examined, opens up many of those assumptions themselves for further consideration.

This book is a careful, timely, and thorough treatment of what is therefore a question, not only of increasing commercial importance, but also of enormous intellectual interest. As its author teases out the policy underpinnings of the exception and the arguments against it, we get not only a helpful guide to this area of the law and its development, but a deeper understanding of patent law as a whole. I have no doubt that it will be of great interest not only to researchers and academics, but to practitioners and policy makers as well. Dr. Ventose is to be congratulated on a significant contribution to a growing and complex area of the law.

Dr. Michael Spence
The Vice-Chancellor and Principal
University of Sydney

Preface

The idea that the issue of excluding methods of medical treatment from patent protection could have generated enough material on which to write a thesis, let alone a book, would have startled anyone 10 or so years ago. But the question of patent protection for methods of medical treatment, which comprises therapeutic methods, surgical methods and diagnostic methods, has been debated and resolved with different results in Europe, the United States and some Commonwealth countries. The rationale for the exclusion from patent protection – one might say justifiably so – is to ensure that the activities of physicians when they treat their patients are not hampered by patents. The notion of a physician being able to secure a patent on a life-saving medical treatment has perhaps most potently put the idea of patent protection for such treatments beyond question. The exclusion for methods of medical treatments in Europe is seemingly here to stay, whereas in the United States the courts have revived the debate of whether they should be excluded from patent protection.

This book is divided into 11 chapters. Chapter 1 is the introduction. Chapters 2 and 3 examine the arguments of principle and policy that are usually made for and against patent protection for methods of medical treatment. What then marks the difference between the availability of patent protection in some countries and the lack thereof in others? Article 27(3)(a) of the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement provides that Members may exclude from patent protection diagnostic, therapeutic and surgical methods for the treatment of humans or animals. So either way, there would be compliance with this agreement. Sitting on the fence on this important issue is not comforting for those medical or veterinary practitioners, patients, inventors and pharmaceutical companies who all have a vested interest in the patentability or otherwise of methods of medical treatment. The arguments made in these two chapters put the debate in an appropriate context.

Chapters 4–6 deal with the exclusions from patentability under the European Patent Convention (EPC), namely, therapeutic methods, surgical methods and diagnostic methods respectively. It is in these three chapters that the fascinating legal framework for the exclusion of methods of medical treatment, which is found in a single provision, Article 53(c) EPC, is to be found. The scope of the exclusion and how it is to be

interpreted in light of competing considerations have, therefore, taken centre stage in Europe. The Technical Board of Appeal (TBAs) of the EPC have been delineating the scope of the exclusion in the last 38 years and the Enlarged Board of Appeal of the European Patent Office (EBA) has had to intervene in delineating the scope of the exclusion on four occasions: 1985 (second medical uses); 2004 (diagnostic methods); 2010 (surgical methods); 2010 (dosage regimes), with the effect that many of the troubling issues have been laid to rest by these decisions. Chapter 7 follows suit with an examination of the vexed question of patent protection for second and further medical uses, including that relating to dosage or treatment regimes under the EPC. Where appropriate, these chapters will also examine the exclusion in light of new technological advancements in medical treatments and considers other EPC exclusions that might be implicated in respect of these new technologies.

Chapter 8 considers the historical basis for the exclusion in the United Kingdom before 1977, examining its jurisprudential bases over the years, concluding with an examination of the position in New Zealand and Australia whose patent legislation is still based on pre-1977 UK patent law. Chapter 9 continues the examination of UK law by examining how UK courts have applied the decisions of the TBAs and the EBA relating to the exclusions (therapy, surgery and diagnosis), second and further medical uses and, most recently, dosage or treatment regimes. Chapter 10 considers the position in the United States of America, namely of the US Patent and Trademark Office (USPTO), legislative intervention and recent examination of the issue of patenting diagnostic methods by the Federal Circuit and the Supreme Court.

This book originated from my thesis completed as part of my doctorate at the University of Oxford between 2001 and 2004. The thesis has now been substantially expanded, revised and completely reworked to form this book. I wish to thank the Clarendon Fund Scholarship which funded my doctoral research. I am grateful for my supervisor, Dr Michael Spence, Vice-Chancellor and Principal of the University of Sydney, for his excellent supervision and my examiners, Dr Justine Pila and Dr Jenifer Davis, for their constructive comments. Special thanks to Chantal, Dimitrios, Faye, Gareth and Matt, for their unfailing support and encouragement throughout.

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Table of cases

Australia

Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) 50 FCR 1 4, 41, 44, 55, 64, 313, 322, 323, 334
Bristol-Myers Squibb Co. v FH Faulding & Co. Ltd (2000) 97 FCR 524; (2000) FCA 316 311, 321, 322, 323, 334
Joos v Commissioner of Patents (1972) 126 CLR 611 312, 313, 322, 323, 434
National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252; (1961) RPC 134 299, 322
Maeder v Busch (1938) 59 CLR 684 298, 302, 322, 323
Wellcome Foundation Ltd (Hitching's) Application [1980] RPC 305 322
Wellcome v Commissioner of Patents (1980) 30 ALR 510 322

Canada

Tennessee Eastman Co v Commissioner of Patents (1974) 30 DLR (3rd) 459 325

Israel

Wellcome Foundation Ltd v Plantex Limited [1974] RPC 514 44, 46, 297, 330

New Zealand

Pfizer Inc v Commissioner of Patents [2004] NZCA 104 2, 311, 324
Pfizer Inc v Commissioner of Patents [2005] NZLR 362 334
Pharmaceutical Management Agency Ltd v Commissioner of Patents [2000] 2 NZLR 529 321, 322, 324, 327, 328, 329
Swift and Company v Commissioner of Patents [1960] NZLR 775 322
Wellcome Foundation v Commissioner of Patents [1979] 2 NZLR 591; [1983] NZLR 385 55, 447
Swift and Company's Application [1961] RPC 147 294, 295
Swift & Co Application [1960] NZLR 775 324

United Kingdom

A & H's Application (1927) 44 RPC 298 308
Actavis UK Limited v Merck & Co Inc. [2008] EWCA Civ 444; [2008] RPC 26 25, 185, 255, 271, 282, 357, 361, 362, 365, 371, 372, 442
American Home Products v Novartis [2001] RPC 8 354, 355
Bayer AG (Meyer's) Application [1984] RPC 11 346

- Bio-Digital Sciences Incorporated's Application [1973] RPC 668 **291, 324, 336, 337**
- Blendax-Werke's Application [1980] RPC 491 **319, 320**
- Biogen Inc. v Medeva Plc [1997] RPC 1 **25, 114, 355**
- Boulton v Bull (1795) 126 ER 651 **287**
- Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc [1999] RPC 253 **10, 44, 50**
- Bristol-Myers Squibb v Baker Norton Pharmaceuticals Inc [2001] RPC 1 **185, 357**
- C & W's Application (1914) 31 RPC 235 **289, 333**
- Calmic Engineering Co. Ltd's Application [1973] RPC 684 **290, 291**
- Canterbury Agricultural College's Application [1958] RPC 85 **288, 293, 294, 304, 306**
- Ciba-Geigy AG (Durr's) Application [1977] RPC 83 **318**
- Consultants Suppliers Ltd's Application [1996] RPC 348 **355**
- Darcy v Allen (1602) 77 ER 1260 **287, 321**
- Douglas v Hello! Ltd [2001] QB 967 **68**
- Dow Corning Corp. (Bennett's) Application [1974] RPC 235 **319**
- Eli Lilly & Company's Application [1975] RPC 438 **291, 311–313, 333, 334, 434**
- GEC's Application (1942) 60 RPC 1 **297, 298**
- Gillick v West Norfolk and Wisbech Area Health Authority [1986] 1 AC 112 **59**
- Hoerrmann's Application [1996] RPC 341 **355**
- Hunter v Mann [1974] QB 767 **69**
- Imperial Chemical Industries Ltd (Richardson's) Application [1981] RPC 609 **355**
- John Wyeth and Brothers Ltd's Application and AG's Schering Application [1985] RPC 545 **240, 338, 362**
- L'Oreal's Application [1970] RPC 565 **318**
- Lee Pharmaceutical's Application [1978] RPC 51 **290, 334**
- London Rubber Industries Ltd's Patent [1968] RPC 31 **301, 303, 305, 316, 317, 319, 320**
- McManus Application [1994] FSR 558 **355**
- Merrell Dow Pharmaceuticals v N H Norton [1996] RPC 76 **349**
- Monsanto & Company v Merck & Co. Inc [2000] RPC 77 **353, 354**
- NV Phillips' Gloelampenfabrieken's Application (1954) 71 RPC 192 **294**
- Neva Corporation's Application [1968] RPC 481 **290, 302, 334**
- Organon Laboratories Ltd's Application [1970] RPC 574 **288, 317, 319, 320**
- Palmer's Application [1970] RPC 597 **290, 302, 303, 334**
- Pfizer Ltd's Patents [2001] FSR 16 **355**
- Prendergast's Applications [2000] RPC 446 **355**
- Puharich and Lawrence's Application [1965] RPC 395 **290, 291**

- R (on the application of Quintavalle) v Secretary of State for Health [2002] 2 All ER 625 **222**
- Re Cementation Co Ltd (1945) 62 RPC 151 **307**
- Roussel-Uclaf v GD Searle and Co Ltd [1977] FSR 125 **55**
- Schering AG's Application [1971] RPC 337 **2, 45, 288, 292, 294, 300, 301, 305, 306, 309–311, 313, 316, 317, 319, 333–336, 338, 340, 434**
- Sopharma SA's Application [1983] RPC 195 **346, 347**
- Stafford Miller Ltd's Applications [1984] FSR 258 **324**
- Swift and Company's Application [1961] RPC 129 **294, 295**
- Swift and Company's Application [1962] RPC 37 **295**
- Teva Industries Ltd v Instituto Gentili SpA [2003] EWHC Civ 5; [2003] FSR 29 **10, 339, 352, 353, 357, 360**
- Unilever Ltd's (Davis's) Application [1983] RPC 219 **340, 342**
- United States Rubber Company's Application [1964] RPC 104 **289, 294**
- Upjohn Company (Robert's) Application [1977] RPC 94 **291, 305, 310, 312, 313, 333, 334**
- Virginia-Carolina Chemical Corporation's Application [1958] RPC 35 **305**
- Visx v Nidex Co. Ltd [1999] FSR 405 **338**
- Welcome Foundation Ltd (Hitchings's) Application [1980] RPC 305 **322**
- Young v Bristol Aeroplane Company [1944] KB 718 **371**
- United States**
- Abele, In re 684 F.2d 902 (Fed. Cir. 1982) **395**
- Adler v Montefiore Hospital Association (1973) 453 Pa 60 **59**
- Ariad Pharmaceuticals Inc. v Eli Lilly and Co. 560 F 3d 1366 (Fed. Cir. 2009) **409**
- Association of Molecular Pathology v US Patent and Trademark Office US District Court (Southern District of New York, 09 Civ 415, 29 March 2010) **413**
- AT&T Corp. v Excel Communications Inc. 172 F. 3d 1352 (Fed. Cir. 1999) **409**
- Bilski, In re 545 F.3d 943 (Fed. Cir. 2008) (en banc) **395, 400, 402, 404, 407–409, 413, 415, 416**
- Bilski v Kappos 130 S. Ct. 3218; 177 L. Ed. 2d 792 (2010) **7, 374, 375, 394, 409–413, 415, 416, 422, 423, 430, 431, 432, 435**
- Brinkerhoff, Ex parte (1883) reprinted in 27 JPOS 797 (POBA (1945) **375, 377–381, 431, 435**
- Classen Immunotherapies, Inc. v Biogen Idec 2006 U.S. Dist. LEXIS 98106 (D.Md., 16 August 2006) **402–404**
- Classen Immunotherapies, Inc. v Biogen Idec 304 Fed. Appx. 866 (Fed. Cir. 2008) **375, 412, 414, 416, 417, 430–432, 435**
- Cochrane v Deener 94 U.S. 780 (1954) **378**
- Diamond v Chakrabarty 447 U.S. 303 (1980) **3, 219, 393, 445, 446**
- Diamond v Diehr 450 U.S. 175 (1981) **393, 397, 410, 418**

- Dick v Lederle Antitoxin Laboratories 43 F 2d 628 (DC SDNY (1930)) **378**
- Funk Bros. Seed Co. v Kalo Inoculant Co. 333 U.S. 127 (1948) **416, 417**
- Gottschalk v Benson 409 U.S. 63 (1972) **416**
- Grams, In re 888 F.2d 835 (Fed. Cir. 1989) **394, 408, 414, 422, 424, 428**
- Griffin, In re 285 F.3d 1029 (Fed. Cir. 2002) **395, 414**
- Kettering, Ex parte 35 USPQ 342 (POBA (1936)) **375, 381**
- Laboratory Corporation v Metabolite Labs 548 U.S. 926; 126 S. Ct. 2976; 165 L. Ed. 2d 990 (2006) **374, 393, 394, 396–402, 405–407, 414, 416, 417, 420, 430, 432, 435**
- Martin v Wyeth 96 F Supp 689 (DC DM (1951)) **379, 380, 431**
- Meyer, In re 688 F.2d 789 (Fed. Cir. 1982) **395, 414**
- Morton v New York Eye Infirmary 17 F Cas 879 (CC SDNY (1982)) **29, 375, 377, 378, 380**
- Pallin v Singer 36 USPQ 2d 1050 (US DCDY (1995)) **22, 374, 381, 382, 432, 435**
- Parker v Flook 437 U.S. 584 (1978) **7, 412, 416–419, 423, 427**
- Prometheus Laboratories Inc. v Mayo Collaborative Services (Invalidity Opinion, 2008 WL 878910) **405**
- Prometheus Laboratories Inc. v Mayo Collaborative Services 581 F.3d 1336 (Fed. Cir. 2009) **375, 404, 407, 412, 414–416, 422, 423, 430–432, 435**
- Prometheus Laboratories Inc. v Mayo Collaborative Services (No. 2) (dated 17 December, 2010) (Fed. Cir. 2010) **415, 422, 423, 425, 431, 432, 435**
- Roe v Wade 410 U.S. 113 (1973) **68**
- Scherer, Ex parte 103 USPQ 107 (POBA (1954)) **374, 375, 378, 380, 381, 431, 435**
- Schloendorff v Society of New York Hospital 105 NE 92 (1914) **59**
- State Street Bank & Trust Co. v Signature Financial Group Inc. 149 F. 3d 1368 (Fed. Cir. 1998) **399, 409**
- Wappler, Ex parte 26 USPQ 191 (POBA (1934)) **378**
- Zuckerberg v Blue Cross and Blue Shield 487 NYS 2d 595 (CC DNY (1985)) **59**
- European Patent Office**
- ABBOTT
LABARATORIES/Multiplex sensor and method of use (T 0330/03) **209, 211**
- ABBOTT
RESPIRATORY/Dosage Regime (G 02/08) **256, 259, 271, 275, 283, 284, 286, 441**
- AEROCRINE AB/Evaluation of a respiratory function (T 0125/02) **213, 214**
- ALINOMOTO/Feed for sows (T 1223/01) **110**
- ARS/Infertility (T 1074/06) **268**
- ASTA/Cytostatic Combination (T 09/81) [1979–85] EPOR B303 **235**
- BAYER AG (T 774/89) **76, 104, 105**

- BAYER/Immunostimulant
(T 780/89) [1993] EPOR
377 97, 107–109, 111
- BAYER/Nimodipin (I) (T 17/81)
[1979–85] EPOR B320 235
- BAXTER/Blood extraction
method (T 0329/94) [1998]
EPOR 363 84, 85, 88, 153,
163, 165, 191, 193, 199
- BETH ISRAEL HOSPITAL
ASSOCIATION/Method for
diagnosing Alzheimer's disease
(T 0143/04) 212, 215–217,
344
- BIOTRONIC/Heart monitoring
apparatus and method
(T 0598/07) 192
- BRUKER/Non-invasive
measurement (T 385/86) [1988]
EPOR 357 186, 189–198, 200,
204, 205, 209, 218, 344
- BRITISH TECHNOLOGY
GROUP/Contraceptive method
(T 74/93) [1995] EPOR
279 98–100
- CAMTECH AS (T 0005/04) 129,
162
- CANADY JEROME/Surgical
coagulation device
(T 1138/09) 72
- CODMAN/Second surgical use
(T 0227/91) [1995] EPOR 82
247–250, 343
- CSIR/Appetite suppressant
(T 0543/04) 173, 174
- CYGNUS/Diagnostic method
(G 01/04) [2006] EPOR 15 73,
89, 96, 107, 123, 125, 127, 130,
133, 136–139, 144, 148,
154–157, 160, 161, 164–167,
175, 178, 179, 185, 186, 196,
201, 202–205, 207–210, 213–
218, 220, 228, 276, 283, 343,
344, 370, 413, 414, 420, 439–441
- CYGNUS/Diagnostic method
(T 964/99) [2002] EPOR
272 186, 189, 195–200,
203–205
- DU PONT/Appetite suppressant
(T 144/83) [1987] EPOR 6 75,
76, 90–95, 97, 100, 107
- DUPHAR/Pigs II (T 19/86) [1988]
EPOR 10 76, 77, 244,–246,
265
- DURAMED
PHARMACEUTICALS/
Method of oral contraception
(T 1063/04) 98
- EISAI/Medicament for gastritis
(T 913/94) [2001] EPOR 362
241
- EISAI/Second medical indication
(G 05/83) [1979–85] EPOR
241 6, 26, 75, 76, 78, 90, 117,
126, 165, 171, 185, 230, 235,
236, 238, 240–245, 247, 248,
250–257, 259–268, 273, 74,
277–286, 321, 325–329, 345,
347–351, 354–357, 359, 360,
362, 364, 366–368, 371, 372,
440, 441
- ELA MEDICAL/Therapeutic
method (T 789/96) [2003] EPOR
23 82–84
- ELAN CORPORATION/Use of
nicotine (T 0584/97) 247, 264,
267
- ELI LILLY/Serotonin receptor
(T 241/95) [2001] EPOR
292 240
- EURO-CELTIQUE/
Thiazide diuretics (T
56/97) 247, 267
- EXERGEN CORPORATION/
Radiation detector
(T 1255/06) 209
- EXOMIS/Haloperoxide
(T 0292/04) 239, 247

- EXPANDABLE
GRAFTS/Surgical device
(T 0775/97) [2002] EPOR
24 **134, 152, 240, 249,
250**
- GENENTECH INC/IGF-I to
improve the neural condition
(T 0486/01) **245**
- GENENTECH INC/
Intrapulmonary delivery
(T 0138/95) **238, 252, 253**
- GENENTECH INC/Method of
administration of IGF-I (T
1020/03) **255, 259, 270, 357,
364, 365, 371, 372, 442**
- GEORGETOWN UNIVERSITY/
Pericardial access (T 35/99),
[2001] EPOR 169 **118, 124,
130–132, 134, 135, 137–139,
147, 157, 160, 162, 343**
- GENERAL ELECTRONIC
COMPANY (T 0530/93) **190**
- GENERAL
HOSPITAL/Contraceptive
method (T 820/92) [1995] EPOR
446 **76, 97, 171**
- HARVARD/Onco-mouse
(T 19/90) [1990] OJ EPO
476 **315**
- HOWARD FLOREY
INSTITUTE/Relaxin (T 272/95)
[1995] EPOR 541 **221**
- ICI/Cleaning plaque (T 290/86)
[1991] EPOR 157 **76, 93, 94,
97, 107, 108, 265**
- INTRAVASCULAR RESEARCH
METHOD (T 0948/95) **78**
- KANEGAFUCHI KAGAKU
KOGYO KABUSHIKI
KAISHA (T 0138/02) **238**
- KIRIN-AMGEN/Erythropoietin
(T 0787/00) **238, 258**
- KONINKLIJKE PHILIPS
ELECTRONICS NV/Medical
diagnostic imaging
(T 09/04) **86, 135, 159, 162,
164**
- KONINKLIJKE PHILIPS
ELECTRONICS NV/
Determining a dimension from
density distribution
(T 0504/03) **210**
- KOS LIFE SCIENCES
INC/Dosage regimen
(T 1319/04) **255, 256, 269, 372**
- L'OREAL/Cosmetic method
(T 1077/93) **152**
- L'OREAL/Procédé et appareil
pour la détermination de
caractéristiques d'un produit
cosmétique (T 0619/03) **210**
- LEO PHARMACEUTICALS
PRODUCTS LTD/EDTA-free
heparins (T 0532/96) **236, 160,
165, 213**
- LEXION/Method for conditioning
gas (T 0238/06) **160, 165, 213**
- LONZA/L-carnitine (T 80/96)
[2000] EPOR 323 **235, 241**
- MACRI/Down's syndrome
screening method
(T 0310/99) **200**
- MAI/Trigonelline (T 143/94)
[1996] EPOR 613 **242**
- MAQUET CRITICAL CARE
AB/Method for determining a
transfer function (T 1102/02)
86, 135, 162, 165, 212
- MAX-PLANCK/BDPI Phosphate
(T 0870/04) **222**
- MEDCO RESEARCH/Adrenaline
(T 0233/96) **245, 246**
- MEDI-PHYSICS/Treatment by
surgery (G 01/07) **85–88, 111,
115, 119, 120, 123, 127, 133,
137, 138, 140, 146, 148, 153,
155, 158, 161, 166, 168, 169,
175, 177, 180, 182, 183, 220, 343,
344, 354, 438**

- MEDI-PHYSICS/Treatment by surgery (T 0992/03) [2007] EPOR 32 **91, 118, 119, 137–139, 154, 157, 165, 169, 183**
- MEIJI/Feeds (T 438/91) [1999] EPOR 333 **76, 109**
- MELLES/Vital dyes for vitreo-retinal surgery (T 0566/07) **236**
- MIT/Perception of fatigue (T 0469/94) **78, 245, 246**
- MOBIL/Friction reducing additive (G 02/88) [1990] EPOR 73 **131, 248, 252, 327**
- NATIONAL DEVELOPMENT CORPORATION/Method of producing image information (T 400/87) **186, 193, 194**
- NATIONAL RESEARCH COUNCIL OF CANADA/Method of assessing tissue viability (T 0041/04) **210**
- NESTEC SA/High fibre composition (T 1002/09) **235, 284**
- NESTEC/Probiotics (T 0515/06) **247, 268**
- NEXINS RESEARCH/Apoptotic cells (T 1038/00) **193**
- NIPRO/Combined anti-inflammatory agent (T 0292/99) **241**
- NOGIER/Magnetic therapy (T 30/83) [1979–85] EPOR C755 **72, 76**
- NOVARTIS/Method of improving immune response (T 0485/99) **247, 265, 267**
- NOVARTIS/Transgenic plant (T 1054/96) **173**
- NOVARTIS/Transgenic plant (G 01/98) [2000] EPOR 303 **170, 177, 178**
- NYCOMED AS/Contrasting agent for NMR imaging (T 665/92) [1998] EPOR 206 **186, 193**
- OPTIMATA/Optimized drug delivery (T 1873/06) **82**
- PHARMA MAR/Aplidine (T 0385/07) **240, 255, 259**
- PHILIPS/Diagnostic method (T 45/84) [1979–85] C937 **192**
- PLANT GENETIC SYSTEMS/Plant cells (T 0356/93) **315**
- PPG/Disclaimer (G 01/03) [2004] EPOR 33 **168, 169, 173–177, 180–183, 439**
- PRAECIS/GnRH Antagonists (T 0380/05) **247**
- PROCTOR & GAMBLE/Gastrointestinal compositions (T 317/95) [1999] EPOR 528 **247, 261, 267**
- QUEEN'S UNIVERSITY KINGSTON/Controlling bleeding (T 893/90) **245**
- REDEKEN LABOARATORIES/Chelating (T 0453/95) **92**
- REICHART/Anti-snoring means (T 584/88) [1989] EPOR 448 **94**
- RORER/Dysmenorrhoea (T 81/84) [1988] EPOR 297 **77, 240**
- RHOMED INC/Radiolabeled antibodies (T 0606/96) **79**
- ROUSSEL-CULAF/Thenoyl peroxide (T 36/83) [1987] EPOR 1 **97, 235**
- ROUSSEL-UCLAF/Tetrahydropyridinyl-Indole Derivatives (T 43/82) [1979–85] EPOR B448 **235**
- SALMINEN/Pigs III (T 58/97) [1989] EPOR 125 **76, 109, 275**

- SCHERING/Combination therapy
HCV (T 0036/04) **247, 268**
- SEE-SHELL/Blood flow
(T 182/90) [1994] EPOR
320 **118, 127–132, 134, 135,
138, 139, 143, 148, 150, 151,
160, 163, 343**
- SEQUUS/Liposome composition
(T 04/98) [2002] EPOR
371 **247, 263, 267**
- SERENO/HCG (T 51/93) **247,
265**
- SEPRACOR INC/Method and
composition for treating
hypertension (T 1031/00)
246
- SIEMENS/Diagnostic method
(T 83/87) [1988] EPOR
365 **186, 190, 195, 199**
- SIEMENS/Flow measurement
(T 245/87) [1989] EPOR
241 **80, 81, 83, 85, 88, 171**
- SIEMENS/Pacemaker
(T 0426/89) [1992] EPOR
149 **81, 83**
- SMITHKLINE BEECHAM
CORPORATION/Treatment of
ovarian cancer (T
1001/01) **268, 269**
- STERLING/S(+)-ibuprofen
(T 315/98) [2000] EPOR
401 **241**
- STIMTECH/Transcutaneous
electrical nerve stimulation
(T 94/83) [1979–85] EPOR
C811 **79**
- SQUIBB/Prostaglandin analogs
(T 0825/94) **241**
- TEIJIN LIMITED/Bone
evaluation method
(T 0775/92) **193**
- TELETRONICS/Pacer (T 82/93)
[1996] EPOR 409 **80, 82, 158–
160**
- TEXAS/Amendments (J 10/84)
[1979–85] EPOR A213 **72, 76**
- THE AUSTRALIA NATIONAL
UNIVERSITY/Method and
apparatus for early detection of
glaucoma (T 1197/02) [2007]
EPOR 9 **165**
- THE GENERAL HOSPITAL
CORPORATION/Hair removal
method (T 383/03) **134, 135,
139–143, 149, 159, 343**
- THE PRESIDENT AND
FELLOWS OF HARVARD
COLLEGE/ Method for
producing transgenic animals
(T 315/03) (OJ 2006, 15) **223**
- THERAPEUTIC
SUBSTITUTES/Anti-tumoural
agent (T 958/94) [1997] EPOR
417 **242, 243**
- THERMAGE/Apparatus for skin
resurfacing (T 1172/03) **129,
133, 135, 136, 142, 151, 152,
251, 252**
- THOMPSON/Cornea (T 24/91)
[1996] EPOR 19 **76, 88, 89,
154, 159, 172**
- THOMPSON-CSF/
Tomodensitometry (2)
(T 208/83) [1979–85] EPOR
C917 **192**
- THOMPSON-CSF/
Tomodensitometry (1) (T 61/83)
[1979–85] EPOR C763 **192**
- ULTRAFEM/Feminine hygiene
device (T 1165/97) [2002] EPOR
384 **76, 97, 99, 100, 136, 154,
200**
- UNIVERSITY OF
CALIFORNIA/Lung cancer
dated (T 629/98) **238, 258**
- UNIVERSITY OF
MANITOBA/Lung ventilator
device (T 0592/98) **76**

- UNIVERSITY OF TEXAS/DNA
damaging agents (T 0036/04)
247, 285
- UNIVERSITY OF UTAH/Breast
and ovarian cancer
(T 1213/05) **222, 224, 227**
- UNIVERSITY OF
UTAH/Method of diagnosis
(T 0080/05) **220, 222, 227**
- UNIVERSITY OF
UTAH/Mutation (T 0666/05)
219, 220, 226
- UROLOGIX INC/Apparatus for
surgical treatment (T 0634/02)
79
- VERICORE/Sea lice infestation
(T 0708/02) **242, 246, 47, 268**
- WAVE ENERGY
SYSTEMS/Mycobactericide
(T 0051/99) **76**
- WARF/Stem cells (T 1374/04)
[2006] EPOR 31 **222**
- WARF/Use of embryos (G 02/06)
[2009] EPOR 15 **127**
- WEIGHT WATCHERS/Slimmer's
calculator (T 0537/04) **173**
- WELLCOME/Pigs I (T 116/85)
[1988] EPOR 1 **76, 97, 103,
110, 197, 202**
- WISCONSIN ALUMNI
RESEARCH FOUNDATION/
Rapid acquisition resonance
imaging (T 0266/07) **86, 87**
- ZAIDAN/Benanomicin A
(T 0853/94) **243**
- ZYMOGENETICS/
Hematopoietic receptor
(T 0898/05) **222**
- European Court of Justice**
- C-428/08 Monsanto Technology
LLC v Cefetra BV and others
(Argentine State intervening)
[2010] All ER (D) 65 (Jul)
219