Index

Access to medical procedures 48–52
  case against patent protection 50
  control, question of 50–52
  demand and supply, dynamics of 51–52
  increased costs of health care 52–53
  meanings 49
  methods of medical treatment 48–50

Actavis v Merck 361–372
  Court of Appeal 362–364
  ‘different medical condition’ 368
  distinct and different medical condition 366
  first instance 361–362
  novel technical features 363
  obviousness 364–365
  precedent 371
  which novelty? 370–371

Animals 101–112
  agricultural methods 102
  application by TBAs 103–104
  EBA 111–112
  ectoparasitic infestations of pigs 103–104
  immunostimulation 107–108
  incidental objectives 106–111
  increased meat production 108–109
  industrial application 101–106
  legislative history 104–105
  method of treatment by therapy 109–110
  reformulation of exclusion 106
  surgical methods 111–112
  therapy, meaning 110

Arguments against patent protection 41–70, 443–444
  access to medical procedures 48–52
  case against patent protection 50
  control, question of 50–52
  demand and supply, dynamics of 51–52
  increased costs of health care 52–53
  meanings 49
  methods of medical treatment 48–50
  breach of patient’s privacy 68–69
  disclosure 69
  right to privacy 68–69
  code of ethics 61–62
  compulsory licences 53–58
  Act of 1977 54–55
  case for 56
  costs, and 57
  intellectual property rights 53
  limitations 57–58
  meaning 53
  public health, and 55–56
  emotive arguments 41–42
  Hippocratic Oath 61–62
  methods of medical treatment 63–65
  specific to medical profession 63–64
  incentive structures 66–68
  alternative 67
  methods 43–45
  pharmaceutical products 43–45
  physician liberty and autonomy 58–60
  factors affecting judgment 59
  physician/patient relationship 60–61
  products 43–45
  public health implications 45–58
  rationale for exclusion 42
  right to health 46–48
simple methods of treatment 26

treatment regimes 25–26

rationales 9–10

rent dissipation theory 27–31

Grady and Alexander on 27–30

methods of medical
treatment 28–31

reward/desert 31–34

endocrine therapy 33

identity of creator 34

methods of medical
treatment 33–34

philosophical difficulties 32

value of product to society 33–34

Australia

judicial determination of exclusion 434

public interest 446

Commonwealth

manner of new manufacture see Manner of new manufacture

Contraceptive methods 97–100

feminine hygiene device 99–100

LHRH composition 97

manner of new manufacture see also Manner of new manufacture

arrangement of pills on card 317–319

hormonal drugs 316

method of medical treatment, whether 316

pack claims 316, 317–320

process claims 316

royal prerogative 317

setting limits 320–321

method of treatment by therapy, whether 97–98

personal use 98–100

susceptible to industrial application, whether 98–100

Cosmetic methods 89–96

acceptable form of claim 95–96

anti-snoring means 94

appetite suppressant 91

cleaning plaque 93–94

industrial application 94–95

meaning 90
methods of medical treatment, and 170–175
‘non therapeutic’, meaning 173–174
omission of step 181–182
surgical methods, and 168–182
use of 175–176
when allowed 175–176
wording of claims, and 171
Dosage regimes
Patents Act 1977 see Patents Act 1977
Enlarged Board of Appeal (EBA)
animals, and 111–112
disclaimers, and 180–181
MEDI-PHYSICS/Treatment by surgery, and 140–148
surgical methods, and 123–124, 136–138, 153
therapeutic methods, and 85–87
EU Biotech Directive 221–223
aim of 221
methods of medical treatments 221–222
morality, and 222–223
ordre public 222–223
European Patent Office (EPO)
jurisprudence 436–442
diagnostic methods 439–440
generic diagnostic testing 224–227
legislative history 436
medical treatment 5–6
second and further medical uses 440–442
surgical methods 438–439
therapeutic methods 436–438
United Kingdom courts, and 442
Excluded surgical step 158–168
applicable national laws 161–162
diagnostic methods 160–161
existence of surgical steps in claim 159–161
insertion of device into human body 162–163
interaction with body 158
MEDI-PHYSICS/Treatment by surgery 165–168
method for conditioning gas 163
non-surgical steps, and 159–160
ratio legis 161–162
surgical steps defined as excluded surgical treatments 162–164
surgical steps not defined as excluded surgical treatments 164–165
Genetic diagnostic testing 223–227
challenge 228
EPO jurisprudence 224–227
morality, and 223–227
nucleic acid 224–226
ordre public, and 223–227
socio-economic consequences of patenting 226–227
Hippocratic Oath 61–62
methods of medical treatment 63–65
specific to medical profession 63–64
Judicial determination of exclusion 433–436
Australia 434
New Zealand 434
United Kingdom 433–434
PAT 434
United States of America 435–436
Manner of new manufacture 287–331
Australia 321–330
ethical considerations 324
law 299
public policy 323
vendible test 322–323
biological subject matter 301–304
biotechnological subject matter 301–304
commercial object requirement 297–298
Commonwealth 321–330
contraceptive methods 315–321
arrangement of pills on card 317–319
hormonal drugs 316
method of medical treatment, whether 316
pack claims 316, 317–320
Index

process claims 316
royal prerogative 317
setting limits 320–321
diagnostic methods, and 291–292
defaith, and 293–294
demise of commercial object requirement 299–301
economic rationale of patent system 300–301
ethical grounds 308–315
extraction of lead 297
medicine, meaning 288
micro-organisms 302–303
morality: emerging concept 309–311
morality: legal justification 311–314
morality: necessary or hindrance, whether 314–315
morality, relevance 308
nature of exclusion 288–295
New Zealand 321–330
EISAI 327–329
new use claim 325–326
novelty 326
public policy 324–325
second medical indication 327–329
second medical use patents 325–329
Swiss-type claims 327,329
Patent Office Practice 287, 304–307
Act of 1977 307
contraception 305
Examiners, role of 307
improved wool yield 304–305
PAT, role of 307
procedure 306–307
reduction of gastric secretion 306
public policy grounds 308–315
rationale for exclusion 295–315
sound treatment 302–303
Statute of Monopolies 296
statutory interpretation 296–304
statutory regime 296
test for general patentability 300
treatment in animals 293–295
treatment in humans 289–292
vendible product 298
widening conception of manufacture 298
Medical treatment
EPO jurisprudence 5–6
future of medical patents 7–8
patent protection 1–2
arguments 2–5
direct control 5
public health, and 3–4
patentability 6–7
Medicine
meaning 288
New medical technology 112–116
DNA technology 113–114
gene therapy 113–115
germline gene therapy 114–115
somatic gene therapy 114–115
stem cell therapy 115
therapeutic cloning 113–115
New Zealand
economic rationale 446
judicial determination of exclusion 434
manner of new manufacture see Manner of new manufacture
Patent Appeal Tribunal
judicial determination of exclusion 434
Patent Office Practice, and 307
Patents Act 2004 332–373
basis of origin of exclusion, and 333–334
comparison with pre-1977 law 333–338
interpretation 332–333
revision of EPC, and 332
Patents Act 1977 334–338
Actavis v Merck see Actavis v Merck
animals, treatment of see also Animals 336
application of exclusion 338–344
defining therapy 339–340
ex post facto rationalisation 338–339
inherent contradictions 339
method of treatment by therapy 339–342
pharmaceutical inventions 338
taxol 340–342
Bristol-Myers Squibb, and 361–370
cosmetic methods 337–338
diagnostic methods 336–337, 343–344
dosage regimes 356–372
Actavis v Merck 361–372
issues for courts 357
second medical treatment 357–360
further reformation of exclusion 335–336
humans, treatment of 336
industrial application 335
invention 334–335
methods of treatment by surgery 342–343
new law of patents 334
reformulation of exclusion 335
second and further medical uses 345–356
applying requirements of Swiss-type claim 353–355
codification of EISAI/Second medical indication 355–356
current UK approach 348–353
desire to achieve conformity 347–348
doctrinal issues 346–356
dosage regime 352–353
EISAI 345–346
manufacture of medicament 353–354
new therapeutic application 354–355
novelty in end result 350–351
only first medical use protected 346
pharmaceutical inventions 347
principle, matter of 347
reaffirmation by Court of Appeal 349–353
reluctant application by Jacob J 348–349
second medical indication 345–346
Swiss-type claim 351–352
taxol 349–353
Public health considerations 433
Royal prerogative contraceptive methods and 317
Second and further uses see also
Second and further medical uses claims allowable, whether 252–253
‘compounds’ 232
devices 246–254
dosage regimes 255–285
controversy over 255–256
decisions of TBAs 279–280
defining 280–281
 differences between EPC 1973 and EPC 2000 281–282
end of Swiss type claims 282–283
EPC 1973 261–269
EPC 2000 259–261, 269
first medical uses 273–274
new technical effect 281
relationship with medical treatment exclusion 271–273
second and further medical uses 256–259
specific uses under EPC 2000 274–277
Swiss-type claims 277–279
EISAI 235–237
EPO jurisprudence, and 440–442
extending reach of EISAI principle 244–246
administration of vaccine to sero-positive pigs 244–245
initial exclusion 234–235
instruments 246–254
claims allowable, whether 252–253
recent changes 253
legislative history 230–234
new medical technology 285–286
not applicable to products which are not medicaments 251
Index

not falling within ratio legis of ESAI/second medical indication 249–251
origin 234–237
Second and further medical uses see also Second and further uses
Patents Act 1977 see Patents Act 1977
reform of EPC 254–255
‘substance’ 232–233
Swiss-type claims see Swiss-type claims
treatment regimes 255–285
controversy over 255–256
decisions of TBAs 279–280
differences between EPC 1973 and EPC 2000 281–282
end of Swiss-type claims 282–283
EPC 2000 259–261
first medical uses 273–274
new technical effect 281
relationship with medical treatment exclusion 271–273
second and further medical uses 256–259
specific uses under EPC 2000 274–277
Swiss-type claims 277–279
SET patent 18–20
funding 19
Surgical methods 117–183
animals 121–122
biotechnology, and 122
broadening of definition 183
cosmetic methods 148–153
beautifying human body 150–151
EBA in MEDI-PHYSICS/Treatment by surgery 153
purpose test 149–151
removal of excess hair 150
technical features of claims 151–153
tightening skin surface 151–152
defining 124–138
dental treatment 155–156
diagnostic method 154
disclaimers see also
Disclaimers 168–182
EBA in CYGNUS/Diagnostic method 136–138
EBA, referral to 123–124
EPO jurisprudence 438–439
exception 131–132
excluded surgical step 158–168
applicable national laws 161–162
diagnostic methods 160–161
existence of surgical steps in claim 159–161
insertion of device into human body 162–163
interaction with body 158
MEDI-PHYSICS/Treatment by surgery 165–168
method for conditioning gas 163
non-surgical steps, and 159–160
ratio legis 161–162
surgical steps defined as excluded surgical treatments 162–164
surgical steps not defined as excluded surgical treatments 164–165
expansive definition 125
hair removal method 121
interpretive criteria 155–157
intervention on structure of organism 156–157
issues relating to 118
legislative history 119–123
MEDI-PHYSICS/Treatment by surgery 138–148
apparatus for skin resurfacing 142
broad or narrow construction of exclusion 143–144
decision of EBA 140–148
decision of TBA 138–140
hair removal method 142
legal analysis 146–148
literal interpretation 140–141
ratio legis of exclusion 141–143
redefining methods of treatment by surgery 144–146
treatment by therapy 141
medical practitioners, involvement of 153–155
narrow interpretation 126–127
non-insignificant 129–130
pericardial access 124
physician, role of 153–155
polarized 129Xe 123–124
purpose of intervention 132–136
ratio legis 132–134
relevance 134–136
reason for exclusion 117
significance 157
surgery, meaning 128–129
therapeutic treatment, and 130–131
travaux preparatoires 120
treatment, meaning 125–126
Swiss-type claims 237–244
acceptable form 242–244
adsorbent, use of 238–239
anti-tumoural agent 242–243
L (-) carnitine 241
manufacture of medicament 238–239
new therapeutic application 239–242
requirements 237–244
sea lice infestation 242
serotonin receptor 240–241
Therapeutic methods 71–116
animals see Animals
contraceptive methods see
Contraceptive methods
cosmetic methods see also Cosmetic
methods
defining 75–78
EPO jurisprudence 436–438
implantable devices 78–88
application 86
blood assistance method 84–85
EBA 85–87
need for functional link or
nexus 79–80
not patentable 80–81
pacemaker 81–84
patentable 81–85
rapid acquisition resonance
imaging 87
therapeutic effect 88
involvement of medical
practitioners 88–89
legislative history 73–75
maintenance of health 77–78
medical treatments 73
methods of therapy 73–74
new medical technology see New
medical technology
‘physical methods’ 74
restoration of health 77–78
scope of exclusion 75–77
therapy, meaning 74–75
treatment by therapy,
meaning 72–73
Therapy
meaning 74–75, 75–76
Treatment by therapy
meaning 72–73
TRIPs Agreement 47, 54

United Kingdom courts
EPO jurisprudence, and 442
United Kingdom Patents Act 2004 see Patents Act 2004
United States of America 374–432
applying Bilski v Kappos 422–430
applying machine-or-
transformation test 425–
428
diagnosis for curative
purposes 420
interpreting claims 423–424
mental step 429–430
natural phenomena 428–429
relevance of machine-or-
transformation test 422–
423
balancing of competing values and
interests 445
constitutional guarantee 392–393
constitutional power 392–431
creation of fever in human
body 379
diagnostic methods after Bilski v
Kappos 412–430
analysis of gene sequences 421–422
defining diagnostic
methods 413–415
mathematical formula 417–418,
419
laws of nature 416–417
Index

machine-or-transformation test 415–416
natural phenomena 416–422
process for curing synthetic rubber 418–420
diagnostic methods in Federal Circuit after Laboratory Corporation v Metabolite Labs 400–409
diagnostic methods in Federal Circuit before Laboratory Corporation v Metabolite Labs 394–395
diagnostic methods in Supreme Court 396–400
‘application of a law of nature’ 399
‘correlate’, meaning 396–399
‘natural phenomenon’ 399–400
‘process’ 399
public interest considerations 400
658 patent 396
Dick 378
ex parte Brinkerhoff 378–380
ex parte Scherer 374, 375
Federal Circuit 394–395
algorithm 394, 408
diagnostic claims 394–395
diagnostic methods after Laboratory Corporation v Metabolite Labs 400–409
fundamental principle 407
machine-or-transformation test 404
mental process 403–404
phenomena of nature 401–403, 406
transformation 407–408
‘warning’ steps 408–409
Genomic Research and Diagnostic Accessibility Act 390–392
contrary to spirit of MPAA 392
immunity from infringement 391
reason for 390
research on genetic sequences 391
retrospective application 391–392
infringement 390
inhaled ethers 375–376
initial exclusion 375–378
initial judicial determination 375–382
involvement of human body 380–381
judicial determination of exclusion 434
legal requirements of patentability 431
legislative history 383–384
legislative intervention 382–392
MPAA 382
MPAA 432
medical or surgical method 380
nature of exclusion in section 387(c) 384–390
cadavers 387
defendant 386
hybrid claims 389–390
legislative intention 385–390
medical activity 384–385, 386–387
patented use of composition of matter 387–389
three-pronged approach 385
patent protection reasserted 380–382
POBA 374
professional ethics 431
public policy 431
section 1, Patent Act 392–393
Senate Bill 1334 383
Supreme Court
categories of inventions eligible for protection 410
diagnostic methods after Bilski v Kappos 412–430
machine-or-transformation test 410–411
process, test for 411
standard for patentability in Bilski v Kappos 409–412
surgical instruments 377
USPTO 374