

INDEX

BIO-SCIENCE LAW REVIEW

VOLUME 14

CONTENTS

Subject Index	i
Countries and Institutions	ii
Contributors	iii
Contributions	iii
Case List	iv

Subject Index

BIG DATA

'Mining for gold': capitalising on data to transform drug development (Editorial) 1 3

BIOSIMILARS

Amgen v Sandoz: US Appellate Court rules that the information exchange contemplated by the Biologics Price Competition and Innovation Act of 2009 is optional (Case Comment) 6 240
Importance of certainty in the regulation of biosimilars (Article) 6 211

COSMETIC PRODUCTS

Nanomaterials

Nanomaterials in the EU Cosmetic Products Regulation 1223/2009 (Article) 6 223

DATA PROTECTION

'Mining for gold': capitalising on data to transform drug development (Editorial) 1 3
Publication of clinical trial data by the European Medicines Agency (Article) 3 67

GM CROPS

Economic loss

GM v organic farming: *Marsh v Baxter* (Case Comment) 2 48

Environmental impact

Humming a different tune? Commercial cultivation of GM crops in Europe (Article) 5 185

HEALTHCARE

Enforceability of NICE guidance and guidelines (Article) 5 179
Evaluating NICE: good value for money? (Editorial) 3 63

INTELLECTUAL PROPERTY

Plant varieties

Intellectual property protection of new varieties of plants in Sub-Saharan Africa: overview of existing regimes (Article) 3 75, 4 130

Plant breeding innovations: free access but not access for free.
A new approach to facilitating FRAND licences for plant-related patents (Article) 4 123

MEDICINAL PRODUCTS

CJEU rules on the requirements for protecting carrier proteins using Supplementary Protection Certificates (SPCs) (Case Comment) 4 159

NAGOYA PROTOCOL

Restrictions governing international trade in genetic resources enter into force (Case Comment) 4 163

NANOMATERIALS

Cosmetic products

Nanomaterials in the EU Cosmetic Products Regulation 1223/2009 (Article) 6 223

PATENTS

Antibodies

Patent protection for antibodies: the evolving challenges (Article) 1 9

Divisional application

Poisonous divisionals: any end in sight? (Article) 2 40

Experimental use exemption

Going full circle: Bolar in Europe and the UPC (Article) 2 31

Gene patents

Isolated nucleic acid sequences patentable in Australia: *D'Arcy v Myriad Genetics Inc* (Case Comment) 2 43

Indirect infringement

Skinny labelling and indirect infringement – consider being proactive: *Novartis v Sun* (Case Comment) 3 115

Obviousness

LEO's patent not 'obvious to try' because there was 'no reasonably optimistic expectation' of success regarding the claimed invention (Case Comment) 6 243

Patentability

Broccoli and tomato: free or not free? Decisions G2/12 and G2/13 of the Enlarged Board of Appeal (Case Comment) 4 167
European Court of Justice refines the meaning of 'human embryo' (Case Comment) 3 102
Patent protection for antibodies: the evolving challenges (Article) 1 9

Plant breeding

Broccoli and tomato: free or not free? Decisions G2/12 and G2/13 of the Enlarged Board of Appeal (Case Comment) 4 167

Plant breeding innovations: free access but not access for free.
A new approach to facilitating FRAND licences for plant-related patents (Article) 4 123

Supplementary Protection Certificates

- Article 3(a) SPC Regulation – guidance on obtaining SPCs based on functional claims: *Lilly v HGS* (Case Comment) 1 25
- CJEU rules again on combination SPCs – *Actavis v Boehringer* (Case Comment) 5 193
- CJEU rules on the requirements for protecting carrier proteins using Supplementary Protection Certificates (SPCs) (Case Comment) 4 159
- Meaning of ‘active ingredient’ for SPC protection is again uncertain: *Bayer CropScience AG* (Case 11/13) (Case Comment) 1 21
- Supplementary Protection Certificates for biologicals: some guidance from *Pharmaq v Intervet* (Article) 5 179

Swiss form claims

- English Court of Appeal rules on the construction of Swiss form patent claims in *Warner-Lambert v Actavis* (Case Comment) 5 201
- Warner-Lambert v Actavis*: the end of the beginning? (Article) 6 214
- Warner-Lambert v Actavis*: what are the limits of Swiss form claims? (Case Comment) 3 107

Transdermal patches

- Novartis’ patent on a transdermal therapeutic system for the administration of rivastigmine found invalid, clearing the way to ‘generics’ to the Exelon Patch (Case Comment) 5 196

PHARMACEUTICAL PRODUCTS

Development

- Evaluating NICE: good value for money? (Editorial) 3 63
- ‘Mining for gold’: capitalising on data to transform drug development (Editorial) 1 3

PLANT VARIETIES

- Intellectual property protection of new varieties of plants in Sub-Saharan Africa: overview of existing regimes (Article) 3 75, 4 130
- UPOV and the plant variety protection system: a case study of Colombia (Article) 6 234

TRADE SECRETS

- Trade secrets: Council agrees general approach for trade secret proposal (Case Comment) 1 17

Countries and Institutions

AUSTRALIA

Biosimilars

- Importance of certainty in the regulation of biosimilars (Article) 6 211

GM crops

- GM v organic farming: *Marsh v Baxter* (Case Comment) 2 48

Patents

- Isolated nucleic acid sequences patentable in Australia: *D’Arcy v Myriad Genetics Inc* (Case Comment) 2 43

COLOMBIA

Plant varieties

- UPOV and the plant variety protection system: a case study of Colombia (Article) 6 234

COURT OF JUSTICE OF THE EUROPEAN UNION

- CJEU rules again on combination SPCs – *Actavis v Boehringer* (Case Comment) 5 193

- CJEU rules on the requirements for protecting carrier proteins using Supplementary Protection Certificates (SPCs) (Case Comment) 4 159
- European Court of Justice refines the meaning of ‘human embryo’ (Case Comment) 3 102
- Meaning of ‘active ingredient’ for SPC protection is again uncertain: *Bayer CropScience AG* (Case 11/13) (Case Comment) 1 21

EUROPEAN COUNCIL

- Trade secrets: Council agrees general approach for trade secret proposal (Case Comment) 1 17

EUROPEAN FREE TRADE ASSOCIATION (EFTA) COURT

Supplementary protection certificates

- Supplementary Protection Certificates for biologicals: some guidance from *Pharmaq v Intervet* (Article) 5 179

EUROPEAN PATENT OFFICE

Patentability

- Broccoli and tomato: free or not free? Decisions G2/12 and G2/13 of the Enlarged Board of Appeal (Case Comment) 4 167
- Patent protection for antibodies: the evolving challenges (Article) 1 9

EUROPEAN UNION

Cosmetic products

- Nanomaterials in the EU Cosmetic Products Regulation 1223/2009 (Article) 6 223

Data protection

- Publication of clinical trial data by the European Medicines Agency (Article) 3 67

GM crops

- Humming a different tune? Commercial cultivation of GM crops in Europe (Article) 5 185

Nagoya Protocol

- Restrictions governing international trade in genetic resources enter into force (Case Comment) 4 163

Nanomaterials

- Nanomaterials in the EU Cosmetic Products Regulation 1223/2009 (Article) 6 223

Patents

- Going full circle: Bolar in Europe and the UPC (Article) 2 31
- Plant breeding innovations: free access but not access for free. A new approach to facilitating FRAND licences for plant-related patents (Article) 4 123
- Poisonous divisionals: any end in sight? (Article) 2 40

GERMANY

Patents

- Going full circle: Bolar in Europe and the UPC (Article) 2 31

NETHERLANDS

Patents

- Skinny labelling and indirect infringement – consider being proactive: *Novartis v Sun* (Case Comment) 3 115

SUB-SAHARAN AFRICA

Plant varieties

- Intellectual property protection of new varieties of plants in Sub-Saharan Africa: overview of existing regimes (Article) 3 75, 4 130

UNIFIED PATENT COURT

Going full circle: Bolar in Europe and the UPC (Article) 2 31

UNITED KINGDOM**Healthcare**

Enforceability of NICE guidance and guidelines (Article) 5 179
Evaluating NICE: good value for money? (Editorial) 3 63

Patents

Article 3(a) SPC Regulation – guidance on obtaining SPCs based on functional claims: *Lilly v HGS* (Case Comment) 1 25
English Court of Appeal rules on the construction of Swiss form patent claims in *Warner-Lambert v Actavis* (Case Comment) 5 201
Going full circle: Bolar in Europe and the UPC (Article) 2 31
LEO's patent not 'obvious to try' because there was 'no reasonably optimistic expectation' of success regarding the claimed invention (Case Comment) 6 243
Novartis' patent on a transdermal therapeutic system for the administration of rivastigmine found invalid, clearing the way to 'generics' to the Exelon Patch (Case Comment) 5 196
Patent protection for antibodies: the evolving challenges (Article) 1 9
Warner-Lambert v Actavis: the end of the beginning? (Article) 6 214
Warner-Lambert v Actavis: what are the limits of Swiss form claims? (Case Comment) 3 107

Pharmaceutical products

Evaluating NICE: good value for money? (Editorial) 3 63

UNITED STATES**Biologics**

Amgen v Sandoz: US Appellate Court rules that the information exchange contemplated by the Biologics Price Competition and Innovation Act of 2009 is optional (Case Comment) 6 240

Contributors

Antcliff, Jenny (Case Comment) 1 25
Blakeney, Michael (Case Comment) 2 48
Bradbury, Simon (Book Review) 6 247
Carter, Ailsa (Article) 6 214; (Case Comment) 5 201
Cline, Helen (Editorials) 1 3, 3 63
Cohen, Liz (Article) 1 9
Dautlich, Marc (Editorial) 1 3
De Coster, Christoph (Article) 2 31
Duxbury, Pat (Case Comment) 5 196
Ellsmore, James (Case Comment) 2 43
England, Paul (Article) 2 31; (Case Comment) 1 21
Heimholt, Diana (Article) 3 67
Hill, Christian (Article) 5 182
Hutchinson, Katie (Case Comment) 5 193
Inman, Paul (Article) 6 214; (Case Comment) 6 243
Jackson, Stuart (Case Comment) 3 107
Jose, Sherine (Article) 6 234
Kailasanath, Vinita (Case Comment) 6 240
Kempton, Luke (Case Comment) 5 201
Kock, Michael A (Article) 4 123; (Case Comment) 4 167
Kuijpers, Gertjan (Case Comment) 3 115
Lee, Robert G (Article) 5 185
Lynch, Maeve (Case Comment) 3 102
Madar, Suzy (Article) 6 211
Maggs, Andrew (Case Comment) 6 243
Mahop, Marcelin Tonye (Article) 3 75, 4 130
Manheim, Bruce S (Case Comment) 4 163
Marsh, David (Case Comment) 6 240
Meade, Alexandra (Case Comment) 2 48
Mester, Gabor (Article) 2 40
Michel, Sara (Article) 2 40

Miles, John (Article) 5 179

Naylor, Tom (Case Comment) 2 43
O'Connell, Kim (Article) 6 211; (Case Comment) 2 43
O'Farrell, Jennifer (Case Comment) 4 159
Pears, Michael (Article) 5 179
Ramirez de la Piscina, Aratz (Article) 6 223
Ranson, Paul (Editorial) 3 63; (Article) 5 179
Rehmann, Wolfgang A (Article) 3 67
Reynolds, Laura (Case Comment) 5 193
Ribbons, Duncan (Case Comment) 3 102
Rieu, Vanessa (Article) 1 9
Roberts, Tim (Book Review) 2 57
Royle, Matthew (Article) 2 31
Shikoli, Aprinah Magarinah (Article) 3 75, 4 130
Tejan-Cole, Alhaji (Article) 3 75, 4 130
Ter Woort, Bertrand (Case Comment) 3 115
Watts, Jennifer (Case Comment) 1 17
Whitehead, Brian (Case Comment) 3 107

Contributions**EDITORIALS**

Evaluating NICE: good value for money? *Paul Ranson and Helen Cline* 3 63
'Mining for gold': capitalising on data to transform drug development *Helen Cline and Marc Dautlich* 1 3

ARTICLES

Enforceability of NICE guidance and guidelines
Paul Ranson and Christian Hill 5 179
Going full circle: Bolar in Europe and the UPC
Paul England, Matthew Royle and Christoph de Coster 2 31
Humming a different tune? Commercial cultivation of GM crops in Europe *Professor Robert G Lee* 5 185
Importance of certainty in the regulation of biosimilars
Kim O' Connell and Suzy Madar 6 211
Intellectual property protection of new varieties of plants in Sub-Saharan Africa: overview of existing regimes
Marcelin Tonye Mahop, Aprinah Magarinah Shikoli and Alhaji Tejan-Cole 3 75, 4 130
Nanomaterials in the EU Cosmetic Products Regulation 1223/2009
Aratz Ramirez de la Piscina 6 223
Patent protection for antibodies: the evolving challenges
Liz Cohen and Vanessa Rieu 1 9
Plant breeding innovations: free access but not access for free.
A new approach to facilitating FRAND licences for plant-related patents *Michael A Kock* 4 123
Poisonous divisionals: any end in sight? *Dr Sara Michel and Dr Gabor Mester* 2 40
Publication of clinical trial data by the European Medicines Agency *Diana Heimholt and Dr Wolfgang A Rehmann* 3 67
Supplementary Protection Certificates for biologicals:
some guidance from *Pharmaq v Intervet*
John Miles and Michael Pears 5 179
UPOV and the plant variety protection system: a case study of Colombia *Sherine Jose* 6 234
Warner-Lambert v Actavis: the end of the beginning?
Paul Inman and Ailsa Carter 6 214

CASE COMMENTS

Amgen v Sandoz: US Appellate Court rules that the information exchange contemplated by the Biologics Price Competition and Innovation Act of 2009 is optional *Vinita Kailasanath and Dr David Marsh* 6 240
Article 3(a) SPC Regulation – guidance on obtaining SPCs based on functional claims: *Lilly v HGS*
Dr Jenny Antcliff 1 25
Broccoli and tomato: free or not free? Decisions G2/12 and G2/13 of the Enlarged Board of Appeal *Michael A Kock* 4 167

CJEU rules again on combination SPCs – *Actavis v Boehringer Katie Hutchinson and Laura Reynolds* 5 193
CJEU rules on the requirements for protecting carrier proteins using Supplementary Protection Certificates (SPCs) *Jennifer O'Farrell* 4 159
English Court of Appeal rules on the construction of Swiss form patent claims in *Warner-Lambert v Actavis Luke Kempton and Ailsa Carter* 5 201
European Court of Justice refines the meaning of 'human embryo' *Duncan Ribbons and Maeve Lynch* 3 102
GM v organic farming: *Marsh v Baxter Alexandra Meade and Michael Blakeney* 2 48
Isolated nucleic acid sequences patentable in Australia: *D'Arcy v Myriad Genetics Inc Kim O'Connell, James Ellsmore and Tom Naylor* 2 43
LEO's patent not 'obvious to try' because there was 'no reasonably optimistic expectation' of success regarding the claimed invention *Paul Inman and Andrew Maggs* 6 243
Meaning of 'active ingredient' for SPC protection is again uncertain: *Bayer CropScience AG (Case 11/13) Paul England* 1 21
Novartis' patent on a transdermal therapeutic system for the administration of rivastigmine found invalid, clearing the way to 'generics' to the Exelon Patch *Pat Duxbury* 5 196
Restrictions governing international trade in genetic resources enter into force *Bruce S Manheim* 4 163
Skinny labelling and indirect infringement – consider being proactive: *Novartis v Sun Gertjan Kuipers and Bertrand Ter Woort* 3 115
Trade secrets: Council agrees general approach for trade secret proposal *Jennifer Watts* 1 17
Warner-Lambert v Actavis: what are the limits of Swiss form claims? *Dr Brian Whitehead and Stuart Jackson* 3 107

BOOK REVIEWS

Intellectual Property Law of Plants (Mark D Janis, Herbert H Jervis and Richard C Peet) *Tim Roberts* 2 57
Patent Term Extensions: USA, Japan, Germany, EU (Arne Markgraf, ed.) *Simon Bradbury* 6 247

Case List

Actavis v Boehringer (CJEU) Case C-577/13 12 March 2015 5 193
Actavis v Sanofi (CJEU) C-443/12 5 193
Amgen Inc. v Sandoz Inc. (United States) 2015 WL 1264756, *8–11 (N.D. Cal. Mar. 19, 2015), WL 4430108, *10–15 (Fed. Cir. July 21, 2015) 6 240

Arne Forsgren v Österreichisches Patentamt (CJEU) Case C-631/12 15 January 2015
Association for Molecular Pathology v Myriad Genetics, Inc (United States) 133 S. Ct. 2107 (2013) 2 45
Bayer/CropScience AG (CJEU) Case C-11/13 ECLI:EU:C:2014:2010 1 21
Cancer Voices Australia v Myriad Genetics Inc (Australia) (2013) 99 IPR 567 (15 February 2013) 2 43
D'Arcy v Myriad Genetics Inc (Australia) [2014] FCAFC 115 (5 September 2014) 2 43
Eli Lilly and Company Ltd v Human Genome Sciences, Inc [2014] EWHC 2404 (Pat) 18 July 2014 1 25
Generics v Yeda and Teva [2013] EWCA Civ 925 1 13
Generics UK v Daichi [2008] EWHC 1903 (Pat) 1 12
Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548 (Pat) 6 214
Georgetown University v Octrooicentrum Nederland (2013) WLR (D) 487 4 160
GlaxoSmithKline Biologicals SA and another v Comptroller-General of Patents, Designs and Trade Marks (CJEU) Case C-210/13 14 November 2013 1 21, 4 161
Hospira v Genentech (No 1) [2014] EWHC 1094 (Pat) 6 219
Hospira v Genentech (No 3) [2015] EWHC 1796 (Pat) 6 219
Hospira UK Limited v Genentech Inc, Patents Court [2014] EWHC 1094 1 16
International Stem Cell Corporation v Comptroller General (CJEU) Case C-364/13 3 102
Kirin-Amgen Inc. and others v Hoechst Marion Roussel Ltd and others [2004] UKHL 46 1 12
Marsh v Baxter (Australia) [2014] WASC 187 2 48
Massachusetts Institute of Technology (MIT) (CJEU) Case C-431/04 EU: C:2006:291 1 22
MedImmune Ltd v Novartis Pharmaceuticals UK Ltd [2012] EWCA Civ 1234, [2013] RPC 27 1 13
Neurim Pharmaceuticals (CJEU) Case C-130/11 ECLR:EU:C:2013:762 1 23, 4 160
Novartis AG v Sun Pharmaceutical Industries (Europe) BV (Netherlands) Court of Appeal of The Hague 27 January 2015, IEF 14599 3 112, 3 115
Oliver Brüstle v Greenpeace (CJEU) Case C-34/10 3 102
Pharmaq AS v Intervet International BV (EFTA Court) Case E-16/14 9 April 2015 5 179
Regeneron Pharmaceuticals Inc & Bayer AG v Genentech Inc [2013] EWCA Civ 93 1 13
Teva v LEO [2015] EWCA Civ 779 6 243
Warner-Lambert v Actavis [2015] EWHC 72 (Pat), [2015] EWCA Civ 556 3 106, 5 201, 6 214