

# Bird & Bird & The Patent Review

2013 - 2014



May 2015



# Welcome

*In this Patent Review, we have set out in the following tables the decisions in patent validity and infringement actions from the first instance (PC and PCC/IPEC) and appeal courts for the calendar years 2013 and 2014. We have then summarised what we consider to be some of the more legally interesting decisions handed down over the last two years.*

## Recent developments in the English Patent Courts

### IPEC

On 1 October 2013, the Patents Court (PCC) was reconstituted as a specialist list in the Chancery Division of the High Court to form the Intellectual Property Enterprise Court (IPEC). The IPEC has a broad intellectual property (IP) subject matter jurisdiction which includes trade mark, design, copyright and other intellectual property rights, as well as patents. The IPEC may also hear proceedings which although primarily concerned with IP also concern other related subject matter. Like the PCC before it, the IPEC is intended to provide a less expensive jurisdiction with a more streamlined procedure than the Patents Court for IP actions; damages or account of profits are capped at £500,000 and recoverable costs are capped at £50,000. The more streamlined procedure, particularly the limitations on the extent of any disclosure and also the evidence that can be adduced at trial, combined with more pro-active case management and strict time limits on the length of any hearing, is intended to ensure a speedy (and hopefully cheaper) resolution of IP disputes.

### Judicial movement

In December 2013, HHJ Richard Hacon became the new permanent presiding judge of the IPEC. In May 2013, his predecessor Colin Birss had been appointed to be a High Court judge assigned to the Chancery Division; along with Richard Arnold he is one of two specialist patents judges assigned to patent actions with a technical complexity rating of 4 or more. As part of the Chancery Modernisation Review led by Lord Justice Briggs, a third patent judge has been proposed but not yet appointed.

In 2013, Lord Justice Floyd and Lord Justice Vos were appointed to the Court of Appeal. Along with Lord Justice Kitchin, they will normally be selected to hear appeals in patent actions against orders made by the first instance courts (the IPEC or the Patents Court).

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### Speedy trial

Since the mid-1990s, it has been an aim of the Patents Court to provide litigants with a jurisdiction in which they can expect actions to be brought to trial within 12 months of commencement. In the past couple of years, the time elapsing between commencement of the claim and the trial has been increasing. Various steps have therefore been taken to ensure that the

speed within which cases can be expected to come to trial, which is recognised as one of the advantages of the jurisdiction, is not lost.

A feature of litigation in the IPEC, namely a fixed-length trial, has been trialled (as a pilot scheme for some cases) in the Patents Court from 1 May 2014. A fixed-length trial is (as its name suggests) required to be completed within the period allocated to it. As a necessary corollary to the imposition of a trial of fixed length, the Patent Judges employ their enhanced case management powers, introduced on 1 April 2013 as part of the Jackson Reforms to civil procedure, in order to ration the parties' use of the court time and resources.

In January 2015, Mr Justice Arnold, as the senior of the two Patents Court Judges, announced that to achieve the long standing aim of patent actions being brought to trial (where possible) within 12 months of the claim being issued, a number of steps would be taken including (1) the use of more Deputy High Court Judges to hear patent cases; (2) greater use the court's case management powers to set limits on the length of trials and at the same time allocate fixed periods of time for the parties to cross-examine witnesses and argue their case orally at trials.

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# Patent action decisions: 2013

## *High Court (Patents) and Patents County Court Judgments on Validity and Infringement for 2013*

Judgment Date	Parties	Citation	Subject Matter and Patent(s)	Judge	Infringed?	Valid?	Appealed?
16/01/13	<i>Mastermailer Stationery v Everseal</i>	[2013] EWPC 6	Business Forms GB 2340073	HHJ Birss QC	No (DNI refused)	N/A	
05/02/13	<i>AP Racing v Alcon Components</i>	[2013] EWPC 3	Disc brake GB 2451690	HHJ Birss QC	Yes, as to 4 out of 5 products in issue	No – added matter	Yes
05/02/13	<i>Environmental Recycling Technologies v Upcycle Holdings</i>	[2013] EWPC 4	Plastics moulding process GB 2460838	HHJ Birss QC	N/A	Yes - as amended	
07/02/13	<i>Glenmark Generics v The Wellcome Foundation</i>	[2013] EWHC 148	Combination anti-malarial composition EP (UK) 0670719	Arnold J	N/A	No – obvious	
07/03/13	<i>Samsung Electronics v Apple Retail</i>	[2013] EWHC 467	Channel coding in mobile telephones EP (UK) 1005726 EP (UK) 1357675	Floyd J	Yes as to 726; N/A as to 675	No – x 2 – anticipated on loss of priority & obvious in any event	
07/03/13	<i>Samsung Electronics v Apple Retail</i>	[2013] EWHC 468	Methods of transmitting packet data in mobile phones EP (UK) 1714404	Floyd J	Yes	No – anticipated on loss of priority & obvious in any event	Appeal stayed pending EPO central amendment

Judgment Date	Parties	Citation	Subject Matter and Patent(s)	Judge	Infringed?	Valid?	Appealed?
15/03/13	<b>Hospira v Novartis</b>	[2013] EWHC 516	Dosing regime for administration of zoledronate for the treatment of osteoporosis  EP (UK) 1296689  EP (UK) 1591122	Arnold J	N/A	No – x 2 – all claims anticipated on loss of priority  689 – claims 1,2 and 5 insufficient;  122 – claims 1, 2, 6 and 7 insufficient	Yes
11/04/13	<b>Lizzanno Partitions v Interiors Manufacturing</b>	[2013] EWPC 12	Gasket for sealing between glass partitions  GB 2432617	HHJ Birss QC	Yes	Yes	
19/04/13	<b>Brigade v Amber Valley</b>	[2013] EWPC 16	Vehicle reversing alarm  GB 2318662	HHJ Birss QC	Yes	Yes - as amended	
22/04/13	<b>Nestec v Dualit</b>	[2013] EWHC 923	Capsule extraction device  EP (UK) 2103236	Arnold J	Yes, as to certain systems only	No – anticipated	
08/05/13	<b>Phil &amp; Ted's Most Excellent Buggy Company v TFK Trends For Kids</b>	[2013] EWPC 21	Baby buggy  EP (UK) 1795424	HHJ Birss QC	Yes	No – obvious	Yes
10/05/13	<b>Swarovski-Optik v Leica Camera</b>	[2013] EWHC 1227	Riflescopes  EP (UK) 1746451	Vos J	Yes	Yes	Yes
30/05/13	<b>OOO Abbott v Design &amp; Display</b>	[2013] EWPC 27	Shop display panel  EP (UK) 1816931	Birss J (sitting as judge of PCC)	Yes	Yes	Yes

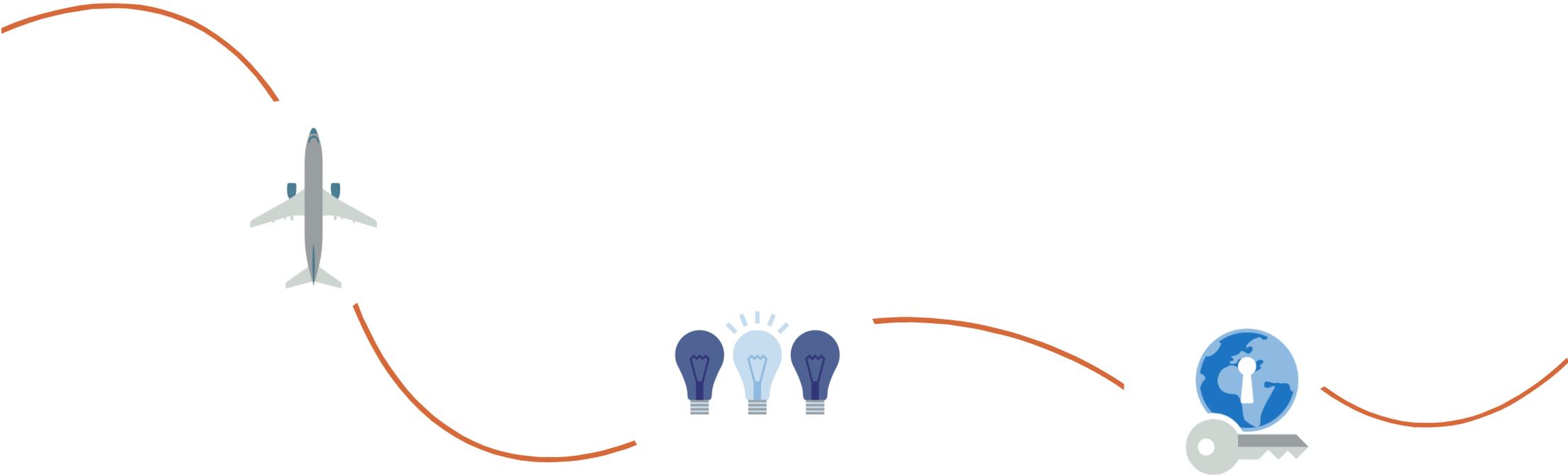
Judgment Date	Parties	Citation	Subject Matter and Patent(s)	Judge	Infringed?	Valid?	Appealed?
14/06/13	Master Distributor v SDL Hair	[2013] EWPC 31	Heating units for hair rollers GB 2472483	Meade QC	No	N/A	
25/06/13	Eli Lilly v Janssen Alzheimer Immunotherapy	[2013] EWHC 1737	Monoclonal antibodies EP (UK) 1994937	Arnold J	Yes	No – insufficient	
09/07/13	Merck Sharp Dohme v Teva Pharms	[2013] EWHC 1958	Non-nucleoside reverse transcriptase inhibitor EP (UK) 0582455 SPC/GB00/035	Birss J	Yes	Yes	
10/07/13	HTC v Gemalto	[2013] EWHC 1876	Using a high level programming language with a microcontroller EP (UK) 0932865 Smart card reader EP (UK) 0829062	Birss J	No as to 865 Yes as to 062	865 – claim 3 - yes; claims 1, 8, 15 and 18 – no - obvious on loss of priority; claims 1 and 15 – no - anticipated on loss of priority 062 – no – anticipated; obvious	Yes
16/07/13	Scopema v Scot Seat Direct	[2013] EWPC 32	Tilting device for a seat back EP (UK) 2121377	Wilson QC	No	N/A	Yes
31/10/13	HTC v Nokia	[2013] EWHC 3247	Modulator structure for a transmitter and a mobile station EP (UK) 0998024	Arnold J	Yes	Yes	Yes

Judgment Date	Parties	Citation	Subject Matter and Patent(s)	Judge	Infringed?	Valid?	Appealed?
07/11/13	Manvers Engineering v Lubetech Industries	[2013] EWHC 3393	Equipment for catching oil leakages  GB 2428032	Mann J	No	Yes	
03/12/13	Adaptive Spectrum v BT	[2013] EWHC 3768	Controlling the way a digital subscriber line (DSL) operates  EP (UK) 2259495 EP (UK) 1869790	Birss J	495 – No 790 – Yes	495 – Yes 790 – Yes	Yes
12/12/13	Smith & Nephew v Convatec Technologies	[2013] EWHC 3955	Silverisation of gel forming fibres used in wound dressings  EP (UK) 1343510	Birss J	Yes, as to development experiments;  No, as to commercial process	Yes	Yes
20/12/13	Blue Gentian v Tristar Products	[2013] EWHC 4098	Expandable garden hose  EP (UK) 2490276	Birss J	Yes	Yes	Yes

## Court of Appeal Judgments on Validity and Infringement in 2013

Date	Parties	Citation	Subject matter	Judge Upheld?	Infringed?	Valid?
23/01/13	<b>Omnipharm v Merial</b>	[2013] EWCA 2	Flea treatments EP (UK) 0881881 GB 2317564	Yes (only 564 in issue)	N/A	564 – no - insufficient
21/02/13	<b>Regeneron Pharmaceuticals v Genentech</b>	[2013] EWCA 67	Use of VEGF antagonists EP (UK) 1506986	Yes	Yes	Yes
30/04/13	<b>AstraZeneca v Teva</b>	[2013] EWCA 454	Sustained release formulation of quetiapine EP (UK) 0090364	Yes	N/A	No - obvious
03/05/13	<b>HTC v Apple</b>	[2013] EWCA 451	User Interfaces EP (UK) 2098948 EP (UK) 2964022	Yes, except as to one claim of 948 on excluded subject matter	N/A	948 – yes as to one claim; others obvious  022 – no - obvious
29/07/13	<b>Generics v Yeda</b>	[2013] EWCA Civ 925	Copolymer-1 EP (UK) 0762888	Yes	DNI refused	Yes
30/07/13	<b>Sudarshan Chemical Industries v Clariant Produktke</b>	[2013] EWCA Civ 919	Polymorph of pigment known as PY 191 EP (UK) 1170338	Yes	N/A	No – obvious; added matter
11/12/13	<b>Microsoft v Motorola Mobility</b>	[2013] EWCA Civ 1613	Synchronisation of multiple mobile devices EP (UK) 0847654	Yes	No	No - obvious

Date	Parties	Citation	Subject matter	Judge Upheld?	Infringed?	Valid?
19/12/13	<i>Hospira v Novartis</i>	[2013] EWCA Civ 1663	Dosing regime for administration of zoledronate for the treatment of osteoporosis  EP (UK) 1296689	Yes	N/A	No – anticipated on loss of priority
20/12/13	<i>Virgin Atlantic Airways v Jet Airways (India)</i>	[2013] EWCA Civ 1713	"upper class" seating system  EP (UK) 1495908	Yes	No	Yes



# Patent action decisions: 2014

*High Court (Patents) and Intellectual Property Enterprise Court Judgments on Validity and Infringement for 2014.*

Judgment Date	Parties	Citation	Subject Matter and Patents	Judge	Infringed?	Valid?	Appealed?
15/01/14	<b>Eugen Seitz v KHS Corpoplast</b>	[2014] EWHC 14 (Pat)	Valves in the blowing station of moulding machines  EP (UK) 1271029	Roth J	Yes	Yes	
10/02/14	<b>Collingwood Lighting v Aurora</b>	[2014] EWHC 228 (Pat)	Lighting unit with solid state lighting element and fire resistant housing  GB 2475649	Roth J	Yes	Yes	
28/02/14	<b>Jarden Consumer Solutions v SEB</b>	[2014] EWHC 445 (Pat)	Fryer with automatic fat coating  EP (UK) 2085003	Arnold J	Yes – claims 10, 11 and 13	Yes – claims 10, 11 and 13	Yes
05/03/14	<b>Kennametal v Pramet Tools</b>	[2014] EWHC 565 (Pat)	Cutting inserts held in revolving cutter bodies and used to remove metal  EP (UK) 1897643	Henry Carr QC	No	No – obvious	Settled before appeal but opposed by Comptroller Appeal dismissed

Judgment Date	Parties	Citation	Subject Matter and Patents	Judge	Infringed?	Valid?	Appealed?
06/03/14	<b>F H Brundle v Richard Perry</b>	[2014] EWHC 475 (IPEC)	Fence bracket GB 2390104	HHJ Hacon	No	Yes	Permission to appeal refused by Court of Appeal
26/03/14	<b>Starsight Telecast v Virgin Media</b>	[2014] EWHC 828 (Pat)	Electronic television program schedule guide system and method EP (UK) 1763234 Merging multi-source information in a television system EP (UK) 0821856	Arnold J	234 - No 234 (as amended) – no 856 - No	234 – no - obvious; added matter\ 234 (as amended) - no - obvious \ 856 – no - obvious; anticipated	
10/04/14	<b>Hospira v Genentech</b>	[2014] EWHC 1094 (Pat)	Antibodies treatment EP (UK) 1210115 EP (UK) 1308455	Birss J	No x2	115 - no - obvious 455 – no - obvious	Yes
01/05/14	<b>Environment Defence Systems v Synergy Health</b>	[2014] EWHC 1306 (IPEC)	Manufacturing barrage units for flood defences EP (UK) 2393989	HHJ Hacon	N/A	No - obvious	
15/05/14	<b>Actavis v Eli Lilly</b>	[2014] EWHC 1511 (Pat)	Anti-cancer drug EP (UK) 0432677	Arnold J	No	Yes	Yes
15/05/14	<b>Rovi Solutions v Virgin Media</b>	[2014] EWHC 1559 (Pat)	Interactive television services EP (UK) 0862833	Mann J	No	No – obvious	Yes (pending)

Judgment Date	Parties	Citation	Subject Matter and Patents	Judge	Infringed?	Valid?	Appealed?
22/05/14	Generics (trading as Mylan) v Richter Gedeon	[2014] EWHC 1666 (Pat)	Emergency contraceptive pill, Levonorgestrel.  EP (UK) 1448207	Sales J	N/A	No - obvious	Yes (pending)
20/06/14	Koninklijke Philips Electronics v Nintendo of Europe	[2014] EWHC 1959 (Pat)	Wii Computer game console  EP (UK) 0808484 EP (UK) 1573498 EP (UK) 2093650	Birss J	484, 498 & 650 - Yes	484 – no – obvious  498 & 650 (as amended) - yes	
27/06/14	Farrow Holdings Group v Secretary of State for Defence	[2014] EWHC 2047 (Pat)	Blasting apparatus for cleaning ship hulls.  GB 2344348 (on appeal from UK IPO)	Birss J	N/A	No – obvious	
03/07/14	Nampak Plastics Europe v Alpha	[2014] EWHC 2196 (Pat)	Plastic milk bottle  GB 2494349	Birss J	No – DNI granted (summary judgment)	N/A	Yes
14/07/14	Rovi Solutions Corporation v Virgin Media	[2014] EWHC 2301 (Pat)	Video-on-demand "relocate feature"  EP (UK) 1327209	John Baldwin QC	N/A	No – obvious	Yes (pending)
22/07/14	AGA Medical v Occlutech	[2014] EWHC 2506 (Pat)	Medical device for occluding defects in the atrial septum of the heart  EP (UK) 0957773	Roth J	Yes	No – anticipated; obvious	

Judgment Date	Parties	Citation	Subject Matter and Patents	Judge	Infringed?	Valid?	Appealed?
22/08/14	William Mark v Gift House International	[2014] EWHC 2845 (IPEC)	Improved simulation of movement for flying fish toy  GB 2482275  GB 2483597	HHJ Hacon	275 – yes - claim 1 only  597 – yes - claims 1 and 2 only	275 - yes  597 – only claim 2	Yes (pending)
02/09/14	Teva v Astra Zeneca	[2014] EWHC 2873 (Pat)	Combination of formoterol and budesonide in a single inhaler for asthma.  EP (UK) 1085877	Sales J	N/A	No – obvious	Yes (pending)
22/09/14	CompactGTL v Oxford Catalysts	[2014] EWHC 2951 (Pat)	Catalysts for use in Fisher-Tropsch process  EP (UK) 1206508  EP (UK) 1206509	Arnold J	508 – yes - claims 1 & 6  509 – yes - claims 1, 7, 9, 16	508 & 509 - Yes	Yes (limited to process claims) (pending)
06/10/14	Teva v Leo Pharma	[2014] EWHC 3096 (Pat)	Psoriasis treatment ointment  EP (UK) 1178808  EP (UK) 2455083	Birss J	Yes x 2	No x 2 – both obvious	Yes (pending)
21/11/14	Hospira v Genentech	[2014] EWHC 3857 (Pat)	Breast cancer drug Herceptin  EP (UK) 1516628  EP (UK) 2275119	Birss J	N/A	119 – no - obvious  628 (as amended) - yes	Yes (pending)
08/11/14	Vringo Infrastructure v ZTE	[2014] EWHC 3924 (Pat)	Mobile Communications  EP (UK) 1212919	Birss J	Yes	Yes – as amended	

Judgment Date	Parties	Citation	Subject Matter and Patents	Judge	Infringed?	Valid?	Appealed?
01/12/14	<b>Idenix Pharmaceutical v Gilead Sciences</b>	[2014] EWHC 3916 (Pat)	Sovaldi (sofosbuvir) – treatment of Hep C virus  EP (UK) 1523489	Arnold J	Yes - claims 1, 5-7, 21 & 24	No – all claims except 20 & 37 anticipated; all claims obvious and insufficient; claim 4 – also added matter	Yes (pending)
18/12/14	<b>Adaptive Spectrum v BT</b>	[2014] EWHC 4194 (Pat)	DSL technology (broadband access network)  EP (UK) 1869790	Birss J	Yes - DNI refused	N/A	Yes (pending)

### *Court of Appeal Judgments on Validity and Infringement in 2014*

Date	Parties	Citation	Subject matter	Judge Upheld?	Infringed?	Valid?
28/01/14	<b>AP Racing v Alcon Components</b>	[2014] EWCA Civ 40	Disk brake calipers in high performance motor vehicles  GB 2451690	No	Yes, as to 4 out of 5 products in issue	Yes
28/02/14	<b>Scopema v Scot Seat Direct</b>	[2014] EWCA Civ 187	Tilting device for a seat back  EP (UK) 2121377	Yes	No	N/A
16/04/14	<b>Phil &amp; Ted's Most Excellent Buggy Company v TFK Trends for Kids</b>	[2014] EWCA Civ 469	Baby buggies  EP (UK) 1795424	Yes	Yes	No - obvious
15/05/14	<b>Swarovski-Optik v Leica Camera</b>	[2014] EWCA Civ 637	Riflescope: telescope mounted on a rifle  EP (UK) 1746451	Yes	Yes	Yes

Date	Parties	Citation	Subject matter	Judge Upheld?	Infringed?	Valid?
09/10/14	<b>Nampak Plastics v Alpha</b>	[2014] EWCA Civ 1293	Plastic milk bottle GB 2494349	Yes	No	N/A
22/10/14	<b>HTC v Gemalto</b>	[2014] EWCA Civ 1335	Smart phones EP (UK) 0932865	Yes	No	Yes - claim 3 only
11/11/14	<b>Adaptive Spectrum v BT</b>	[2014] EWCA Civ 1462	DSL technology (Broadband access network) EP (UK) 2259495 EP (UK) 1869790	Yes as to 790 No as to 495 claim 6	495 – yes - claim 6 only 790 – yes	495 – yes - claim 6 only 790 - yes
17/12/14	<b>Jarden Consumer Solutions v SEB</b>	[2014] EWCA Civ 1629	Fryer with automatic fat coating EP (UK) 2085003	No	No	Yes – partially
06/02/15	<b>Hospira v Genentech</b>	[2015] EWCA Civ 57	Anti-cancer drug Herceptin EP (UK) 1210115	Yes	No	No - obvious



# Case summaries

## Our selected cases from 2013 and 2014

### Substantive Law

#### Allowability of Product by Process Claims

##### *Hospira UK Ltd v Genentech Inc [2014] EWHC 3857 (Pat), Birss J.*

Genentech's patents related to formulations of the breast cancer drug sold under the name Herceptin. The active ingredient of Herceptin is an antibody known as trastuzumab. Patent protection for trastuzumab itself had expired. The patents related to lyophilised (freeze-dried) formulations of certain antibodies one of which was trastuzumab.

Genentech had applied to amend the claims of both patents and did not defend the validity of the unamended claims as granted.

Hospira argued that all of the claims (as proposed to be amended) were obvious, or, if not obvious, were insufficient. Hospira also contended that proposed amendments should not be allowed on four grounds: extension of the scope of protection; a specific point on product by process claims; lack of clarity; and added matter.

The Judge held that the proposed amendments were not allowable because of the specific point on product by process claims as well as added matter and in any event the claims as proposed to be amended lacked inventive step.

In the course of dealing with the proposed product by process claims, the Judge considered the case law of both the UK courts and the EPO from which he derived the following principles:

*"(i) A new process which produces a product identical to an old product cannot confer novelty on that product. To be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product.*

*(ii) This rule is a rule of the law of novelty. It is not a principle of claim construction. Although in effect the rule treats "obtained by" language as "obtainable by"*

*language, nevertheless as a matter of claim construction a claim to a product "obtained by" a process means what it says. That will be the relevant scope of the claim as far as infringement and sufficiency are concerned.*

*(iii) Although normally a patent was drafted by the inventor in words of his own choosing, the EPO will not permit overt product by process language unless there is no other alternative available. By no other alternative, they meant no other way of defining a particular characteristic of the product in question."*

The Judge also held that because by virtue of section 75(5) of the Patents Act he was required to have regard to any relevant principles applied under the EPC in considering whether to allow an amendment; in considering the proposed amendments in this case to create product by process claims, he should follow the principles applied by the EPO as to whether to allow a product by process claim. In doing so, the Judge held on the facts that the proposed amendments should be refused because they did not allow the reader to identify all the attributes of the product conferred by the process conditions. To identify one attribute was not sufficient if the reader would understand there was likely to be an indefinite class of further attributes to which the product by process language also applied.

*Appeal floating May – November 2015.*



## Invalid Claim to Priority

Three Court of Appeal cases (the two below and *Samsung v Apple* discussed at p.20) and one first instance case have considered revocation of patents on the basis of an invalid claim to priority and consequent invalidity over intervening pieces of prior art.

### *Hospira and Generics (trading as Mylan) v Novartis [2013] EWCA Civ 1663, Court of Appeal*

Novartis's patent related to the use of a bisphosphonate known as zoledronate for the treatment of, amongst other things, osteoporosis.

The issue arose in the context of proceedings brought first by Hospira UK Limited and then also by Generics (UK) Limited (trading as Mylan) for revocation of the patent. Both companies wished to market products falling within claim 7 of the patent. Claim 7 contained a combination of features directed to (1) the drug (2) the fact that the drug was intended for the treatment of osteoporosis (3) the mode of administration (intravenous) (4) the range of dosage sizes (2 – 10 mg) and (5) the dosing interval (about once a year).

Arnold J held that the claim to priority for claim 7 was invalid and as a consequence of that loss of priority, claim 7 was invalid over a disclosure in an intervening publication. Novartis appealed only in relation to the Judge's finding that claim 7 of the patent was not entitled to claim priority. It was conceded that claim 7 would be invalid if it was not entitled to claim priority because of the disclosure in the intervening publication.

The Court of Appeal dismissed the appeal. They held that

*"Put in a nutshell, the problem for Novartis in seeking to establish that claim 7 is entitled to priority from [the priority document] is that the disclosure of the [priority document] is either too general or too specific. If one focusses on the disclosure about zoledronate, the "2 – 10 mg once a year" passage tells the skilled reader nothing about dosage range for any particular method of administration. It also does not tell the reader about the dosage range for any particular condition, such as osteoporosis. It teaches that 4 mg, once a year, administered intravenously to patients with post-menopausal osteoporosis is effective but nothing about what other doses could be used at that dosage interval."*

The Court found that the expert evidence adduced at the trial did not displace their view that there was no

disclosure in the priority document of once a year dosing by intravenous administration to treat osteoporosis. Therefore the Court of Appeal held that the invention in claim 7 was not disclosed in the priority document and as such was not entitled to claim its priority date.

### *HTC Corporation v Gemalto S.A. [2014] EWCA Civ 1335, Court of Appeal*

Gemalto's two patents related to computers and their programming, specifically the use of high level programming language with a microcontroller. The Judge had concluded that the 865 patent was not infringed by the HTC devices (a variety of smartphones and a tablet computer) and that only claim 3 (and its dependent claims) survived the attack on its validity. The Judge had also concluded that the 062 patent was wholly invalid.

Gemalto appealed against the decision that the 865 patent was not infringed by the HTC devices. HTC cross-appealed against the decision that claim 3 of the 865 patent was valid.

The appeal turned on the construction of the term *"microcontroller having a set of resource constraints and comprising a memory"*. The Judge had held that the normal way in which the term was used in the art and also the way in which the term was used in the 865 patent required there to be a chip having some memory on it. The Court of Appeal in fact adopted an even narrower construction of the term holding that it required all of the memory to be on the chip as a result of which they too like the Judge held that it was not infringed by the HTC devices. The appeal was therefore dismissed.

On the cross-appeal, the issue turned on whether the priority document disclosed *"a converter for post-processing the compiled form into a minimized form"*. It was conceded by Gemalto that if claim 3 was not entitled to claim priority then it was invalid over the disclosure in an intervening publication.

The Court of Appeal emphasised that although the question to be determined when considering a claim to priority was *"what was disclosed to the skilled person not what was made obvious to him by the priority document for example in the light of the common general knowledge"*, this did not mean that the priority document should be read in a vacuum. The knowledge and background of the skilled person should be taken into account in deciding what the priority document discloses.

The priority document itself disclosed a particular method of compacting the application program,

namely namespace mapping. The question was whether this disclosure was sufficient to support a claim which was wide enough to encompass all compaction methods.

The Judge had held that if the skilled team who were given the priority document "*decided to reduce the size of the application for time and space efficiency using techniques apart from the namespace map [they] would not think that they were doing anything different from the principles of general application the inventors of the priority document have taught.*" The Court of Appeal agreed with him rejecting Gemalto's criticisms of his reasoning and as a result the cross-appeal was also dismissed.

### *Nestec SA & Ors v Dualit Ltd & Ors [2013] EWHC 923 (Pat), Arnold J.*

The Nestec case addressed for the first time in England the issue which has become known as 'toxic' or 'poisonous' priority namely a claim which fails to claim priority is then held invalid as a result of the priority document having been subsequently published and thereby being deemed to form part of the state of the art for the purpose of novelty.

Nestec's patent related to a coffee extraction system. Nestec alleged that Dualit had infringed the patent by supplying coffee capsules which were compatible with Nestec's Nespresso coffee machines. Dualit denied infringement and counterclaimed for revocation on several grounds including lack of entitlement to priority coupled with an anticipation attack based on the disclosure in a deemed intervening publication, namely that of the priority document itself. The case also raised an issue as to partial priority i.e., affording different priority dates to different parts of a patent claim.

Dualit put forward two reasons why claim 1 of the patent was not entitled to claim priority from the priority document. First, claim 1 of the patent covered several different arrangements in which the housing to receive the capsule was contained, only one of which was disclosed in the priority document. Second, claim 1 of the patent covered several different orientations of the capsule in its intermediate position relative to the extraction axis, at least two of which were not disclosed in the priority document.

The Judge held that claim 1 was not entitled to claim priority or even partial priority from the priority document for both reasons. The claim to partial priority was rejected on the basis that the arrangements or orientations which claim 1 covered were not disclosed as clearly defined alternatives.

Having held that claim 1 was not entitled to claim priority, the Judge went on to hold that the claim lacked novelty over the priority document which having been published was therefore deemed to form part of the state of the art pursuant to section 2(3) of the Patents Act 1977 (corresponding to Article 54(3) EPC – novelty-only prior art effect of post-published patent applications having an earlier priority date).

*Appealed but settled.*

## Construction and Relevance of Numerals in Patent

### *Jarden Consumer Solutions (Europe) Limited V. SEB SA & Groupe SEB UK Limited, [2014] EWCA Civ 1629, Court of Appeal*

SEB's patent related to food frying machines known as dry fryers. Jarden manufactured the Breville Halo Health Fryer (the "Halo"), which competed with SEB's product, the Tefal Actify fryer (the "Actifyer").

The Judge held that claims 1, 3 and 8 of the patent were invalid, claims 1 and 3 would have been infringed if they had been valid and claims 10, 11 and 13 were valid and had been infringed. Jarden appealed against the Judge's finding of infringement of claims 10, 11, and 13.

Jarden's primary contention on the appeal was that the Judge misinterpreted the term "the main body" as including the lid of the fryer mainly on the basis that he had wrongly made use of numerals in the Patent to construe its meaning. Jarden argued that its Halo fryer did not infringe the Patent, properly construed, because the claims required the main heater to be located in the main body whereas the Halo's main heater was entirely located in its lid.

The Court of Appeal held that the Judge's construction of the term main body so as to include the lid was wrong. In the first place, they held that the Judge had fallen into error by allowing the numerals used in the specification to influence the construction of the claim in violation of Jacob LJ's clear instruction against so doing in *Virgin Atlantic Airways Ltd v. Premium Aircraft Interiors UK Ltd* [2009] EWCA Civ 1062. However, having held that the Judge had fallen into error in this way, the Court of Appeal considered itself free to consider the matter afresh. Although the Court of Appeal accepted that the use of the language in the patent was not entirely consistent, nevertheless they considered that paying close attention to the process of construction set out in *Virgin Atlantic*, the Judge

was wrong to conclude that the main heater mounted in the main body could include a main heater mounted in the lid.

As a result, they allowed that part of Jarden's appeal.

## Infringement of Swiss Form Second Medical Use Claims: Need for Subjective Intention

### Interim Injunction

#### *Warner-Lambert LLC v Actavis Group PTC EHF and others [2015] EWHC 72 (Pat), Arnold J.*

Warner-Lambert marketed pregabalin, a prescription-only drug, for three different indications under a single registered trade mark, Lyrica. Patent protection for the drug itself had expired but Warner-Lambert owned a patent relating to the second medical use of pregabalin for pain relief (being one of the three indications for which the drug was marketed). Actavis had applied for a marketing authorisation for a generic version of pregabalin limited to the other two indications.

Warner-Lambert was concerned that the generic drug would nevertheless be dispensed for the patented indication because most prescriptions are written generically and very few prescriptions state the indication for which the drug has been prescribed. Warner-Lambert also argued that because a generic version of a branded drug is usually cheaper than the branded product, pharmacists have a strong commercial incentive to dispense the generic version of the branded drug unless positive steps are taken to prevent this from occurring.

Warner-Lambert sued Actavis for patent infringement and at the same time sought an interim injunction requiring Actavis to take specific actions to prevent its generic version of the drug being dispensed to patients who had been prescribed the drug for the patented indication. It was common ground that although the injunction being sought was mandatory rather than prohibitive in nature the test to be applied was the same namely the principles laid down in *American Cyanamid v Ethicon* [1975] AC 396.

The first issue to be determined by the Court therefore was whether there was a serious issue to be tried. The second medical use claims in the patent were in the "Swiss form" i.e., "use of substance X for the preparation of a medicament (or pharmaceutical composition) for treating indication Y". Swiss form

claims are regarded as purpose-limited process claims. Warner-Lambert's primary claim for infringement therefore was under section 60(1) (c) of the Patents Act 1977 namely, the offer for sale and sale of a generic drug being a product obtained directly by means of the process the subject of the claim. There was no dispute that if Actavis carried out the process of the claims then their generic product would be a product obtained directly by means of the patented process. The dispute centred on whether the manufacture of pregabalin would fall within the scope of the claims and that dispute in turn centred on the meaning of the words "for treating ... pain." It was common ground that the word "for" in a Swiss form claim meant "suitable and intended for". It was also common ground that the generic product obtained by the use of pregabalin for the preparation of a pharmaceutical composition was *suitable* for treating pain. The issue to be decided by the Judge was whether the generic product obtained by the use of pregabalin for the preparation of a pharmaceutical composition was *intended* for treating pain. To answer that question, the Judge had to answer two other questions: whose intention was relevant and what was meant by intended.

As regards the first question, the Judge held that the relevant intention was that of the manufacturer (not as Warner Lambert contended the intention of the person who disposes of the generic product).

As regards the second question, the Judge held that intended in this context meant subjective intention on the part of the manufacturer that the drug should be used for the patented indication (not as Warner-Lambert contended that it was sufficient if it was foreseeable that it would be likely to dispensed for treating the patented indication).

The court noted that cases from other EU jurisdictions supported the proposition that subjective intent was required and it held that the word "for" in Swiss form claims imported a requirement of subjective intention on the part of the manufacturer that the medicament or pharmaceutical composition would be used for treating the specified condition.

The Judge refused to grant the interim injunction. There was no serious issue to be tried as Actavis would not infringe the patent by marketing the drug for the permitted indications. As the relevant claim was to a process of manufacture, infringement would require a subjective intention by Actavis, as the manufacturer, that the drug would be used for treating the patented indication. While Actavis might foresee that the product might be prescribed for the patented use, it did not have the requisite intention.

As Warner-Lambert had not relied on any allegation of subjective intention on the part of Actavis in support of its application for an interim injunction, the Judge therefore concluded that there was no serious issue to be tried and dismissed the application.

NB. At the hearing, Warner-Lambert indicated an intention to apply to amend its claim so as to plead a case of subjective intention which application was permitted at a subsequent hearing.

*On 10 February 2015, the Court of Appeal granted Warner-Lambert permission to appeal against Arnold J's refusal to order an interim injunction. That appeal has been fixed to be heard at the end of April 2015.*

## Remedies

### A novel approach

*Warner-Lambert v Actavis Respondent NHS Commissioning Board Interested parties: Teva, Generics UK, Dr Reddy's Laboratories, Consilient Health, Sandoz, Department of Health, [2015] EWHC 485 (Pat), Arnold J.*

Following the approach taken by the Judge at the hearing of Warner-Lambert's previous application for a mandatory interim injunction against Actavis, on 16 February 2015, Warner-Lambert's solicitors wrote to NHS England stating that Warner-Lambert intended to make an application to the Court for an Order requiring NHS England to issue guidance to Clinical Commissioning Groups (CCGs) on the basis that other steps agreed by Warner-Lambert and Actavis in respect of the CCGs and pharmacists might not be sufficiently effective to achieve the desired objective, namely to prevent generic pregabalin from being prescribed for the patented indication of treating pain. In response, NHS England noted that whilst NHS England was an innocent bystander in the present dispute and was therefore unwilling for various reasons to issue guidance of its own motion, it would not oppose an application by Warner-Lambert for an Order requiring it to issue guidance provided certain conditions were met. Warner-Lambert duly made the application.

At the hearing, the Judge ordered NHS England to issue guidance along the lines requested by Warner-Lambert. The Judge considered that the Order was proportionate, did not create barriers to trade and also contained appropriate safeguards in compliance with Article 3 of the Enforcement Directive.

One issue before the court was the ambit of the cross-undertaking in damages. Warner-Lambert argued that it was sufficient for the cross-undertaking to be given in favour of NHS England and the Department of Health. Actavis, Teva and Dr Reddy's as interested parties requested that the benefit of the cross-undertaking should be extended to each of their respective group companies to compensate them for the lost profits on their lost sales of generic product should the patent be held invalid.

Paragraph 5.1A of the Practice Direction 25A states that "*When the court makes an order for an injunction, it should consider whether to require an undertaking by the applicant to damages sustained by a person other than the respondent, including another party to the proceedings or any other person who may suffer loss as a consequence of the order.*"

The principles to be applied when addressing this question were considered by Birss J. in *Actavis Group PTC EHf v Boehringer Ingelheim Pharma GmbH & Co KG*. Applying those principles to the case before him, the Judge ordered that the cross-undertakings be extended to the group companies of the three interested parties.

## Damages on a Cross-Undertaking

There have been several decisions over the past few years dealing with various issues arising on a cross-undertaking in damages given as a pre-requisite to the grant of an interim injunction.

*The nature of an illegality defence to a claim on a cross-undertaking*

*Laboratoires Servier v Apotex Inc [2014] UKSC 55, Supreme Court*

In 2006, Servier was granted an interim injunction against Apotex for infringement of a UK patent relating to a crystalline form of perindopril erbumine, an ACE inhibitor, used for treating hypertension and cardiac insufficiency. The injunction was obtained on Servier giving the cross-undertaking in damages i.e., an undertaking to comply with any order the court might make if it should later find the injunction had been wrongly granted to compensate Apotex for any loss it had suffered in the meantime. At full trial, the patent was held to be infringed but invalid and the injunction was discharged.

Meanwhile, in separate proceedings in Canada, the Canadian patent relating to the compound itself (the NCE patent) was held valid and infringed, and Servier was granted a final injunction against Apotex. In the

UK, the NCE patent had expired in 2004 but the corresponding Canadian NCE patent did not expire until 2018.

In the UK action, following the decision that the crystalline form patent was invalid, Apotex claimed compensation for the loss it had suffered by the wrongful grant of the injunction. It was agreed that the damages under the cross-undertaking fell to be assessed on the basis that but for the injunction Apotex would have sold an additional 3.6 million packs of tablets. Notably however the perindopril erbumine for the product sold in the UK would have been manufactured by Apotex in Canada.

In the proceedings to assess Apotex's damages, Servier argued it was against public policy for Apotex to recover damages in respect of sales of a product the manufacture of the active ingredient of which in Canada would have been "turpitude" as it constituted an infringement of the Canadian NCE patent. At first instance, Servier succeeded on its "illegality defence". However, on appeal, the Court of Appeal disagreed on the basis that the infringement of a foreign patent was not considered to be "turpitude".

The Supreme Court dismissed Servier's appeal. It pointed out that the illegality defence was a general rule of law based on public policy. "Turpitude" meant a criminal act or at least quasi-criminal act because only acts in these categories engage the public interest and it is the public interest which underlies the illegality defence. Patent infringement, being a tort or civil wrong, offended against private interests rather than the public interest. The only relevant interest affected was that of the patentee and that was sufficiently vindicated by the availability for damages for the infringement in Canada. There was no public policy which could justify the forfeiture of Apotex's right to be compensated in the UK.

*The measure of damages on a cross-undertaking.*

### *AstraZeneca AB & Anor v KRKA, d.d Novo Mesto and Consilient Health Limited [2014] EWHC 84 (Pat), Sales J.*

The interim injunction in question had been ordered against Consilient back in 2010 preventing them from marketing a generic version of A-Z's proton pump inhibitor sold under the brand name Nexium. As a result of A-Z subsequently losing an infringement action commenced against Ranbaxy on the same patent, they concluded that they would not win the action on the same patent against Consilient and applied to have the injunction discharged.

The Judgment is of interest insofar as the Judge had to consider the merits of the various approaches that could be used in trying to determine the damage caused by the lost opportunity to enter a pharmaceutical market.

The Judgment is also of interest insofar as the Judge relied heavily on the evidence about the decisions that Primary Care Trust Medicine Managers would have made when considering recommending the change from an originator product to a branded generic product. By contrast, the Judge was fairly dismissive of the evidence from the experts on how the market for a pharmaceutical behaves upon generic entry.

*Appeal part heard in February 2015.*

## Summary Judgment on Infringement

### *Nampak Plastics Europe Ltd v Alpla UK Ltd [2014] EWCA Civ 1293, Court of Appeal*

This was a relatively unusual case where summary judgment was granted to the claimant (putative infringer) in a patent action for a declaration of non-infringement.

The Nampak patent related to plastic milk bottles. Nampak had alleged that Alpla's bottle called the ECO 1 infringed the patent. Alpla denied infringement and contended that the patent was invalid. Alpla also produced a design called the ECO 2 (a modification of ECO 1) which it argued did not infringe the patent. Alpla brought a claim for a declaration of non-infringement (DNI) under Section 71 of the 1977 Patents Act in respect of the ECO 2 product and at the same time applied for summary judgment on that claim.

Summary judgment, a procedure by which all or part of a case can be disposed of without a trial where a claim or a defence to a claim has no real prospect of success, seldom succeeds in patent infringement actions. This is because in order to determine infringement, the Court needs to construe the claim and for that purpose, it needs to adopt the mantle of the person skilled in the art for which it normally needs expert evidence on the common general knowledge and the skilled person's understanding of the words in the claims at issue.

At first instance, the Judge held that the technology in this case was sufficiently simple for there to be no need to call expert evidence: the patent claims did not use terms of art and so the judge could proceed to

construe the claims without any expert evidence. The Judge said that a patentee could not resist an application for summary judgment simply by advancing unspecific assertions about the need for expert evidence: he or she needed to explain with at least some specificity what fact or what expert evidence or what common general knowledge is to be relied on. Generalities were not good enough. Further, the shape of the ECO 2 product could readily be understood and nothing had been put before the court to explain how the outcome of any infringement analysis would depend on the results of detailed measurement experiments as proposed to be conducted by the patentee. Therefore there was no need to prolong the commercial uncertainty by waiting for a trial. Accordingly, the Judge held that the ECO 2 product as depicted in the application for the DNI did not infringe and granted summary judgment.

The Court of Appeal upheld the decision of Mr Justice Birss. The Court of Appeal commented that it was not a complicated case and that the warnings in the authorities about the dangers of summary judgment in patent cases did not therefore apply with such force. Like the first instance judge, the Court of Appeal felt able to draw the necessary conclusions about the construction of the claim on the basis of the specification of the patent and was unable to see how these, or the conclusion relating to infringement, could be shown to be erroneous by subsequent evidence. It was for Nampak to have shown that there was at least some basis for supposing the contrary to be the case but it had failed to do so.

## Employees' Compensation

The bar to employees obtaining compensation under section 40 of the Patents Act 1977 is a high one. Few such employee compensation claims have succeeded. This is a further example.

### *Ian Alexander Shanks v Unilever plc and others [2014] EWHC 1647 (Pat), Arnold J.*

Professor Shanks was employed by a company within the Unilever group. He was responsible for an invention used in blood glucose testing kits which was the subject of a series of related patents. The patents were transferred to an associated company for a nominal consideration. For a period of time the patents were licensed to third parties operating in the field and finally the company that owned the patent was sold to a third party for £103 million.

In 2006, Professor Shanks commenced proceedings in the UK Intellectual Property Office (IPO) claiming compensation under sections 40 and 41. Following a

number of interim proceedings including an appeal to the Court of Appeal, the IPO concluded that although the benefit to Unilever from the patents was £24.5 million, it was not outstanding. It decided that if, contrary to its conclusion, the patents were of outstanding benefit, a fair share of the benefit for the Professor Shanks would be 5%. Both parties appealed to the High Court.

The Judge dismissed Professor Shanks's appeal upholding the IPO's decision that the patents were not of outstanding benefit to Unilever and therefore Professor Shanks was not entitled to compensation under section 40(1).

The Judge rejected Professor Shanks' argument that the IPO had decided that the benefit that Unilever obtained from the patents was not outstanding because of the large profits that Unilever ordinarily made in the course of its business. Overall, the Judge considered that the IPO had undertaken a multi-factorial assessment, which included a consideration of the benefit received by Unilever and the disparity between that benefit and the benefit that the Professor had received in the context of the size and nature of Unilever as an undertaking.

The Judge also held that the mere fact that Unilever had received a benefit from the patents in a manner and amount that was unusual for it (by licensing and selling the patents rather than by manufacturing) was not, in itself, an indication that the benefit was outstanding.

The Judge also held that Professor Shanks had not created a new product for his employer as Unilever never produced a blood glucose test. Nor did Professor Shanks produce a new income stream without any substantial input from his employer. Although Professor Shanks had made an invention, the income stream for the product incorporating the invention was largely generated by Unilever's licensing department with little input from the Professor.

As Professor Shanks' appeal was dismissed, the Judge did not have to make a decision on fair share. However, the Judge commented that, in the circumstances of this case, the benefit derived by Unilever from the patents would be the benefit net of tax.

NB. Section 40(1) was amended by the Patents Act 2004 to make compensation payable when the invention, and not just the patent, has been of outstanding benefit. However, the amendments only affect patents applied for after 1 January 2005 and were not relevant in this case.

## Central Amendment before the EPO

The European Patent Convention (EPC) allows a patentee to have the claims of its granted patent limited or to have the whole patent revoked, in either case for all designated states. Such a central amendment or revocation is deemed to have effect from the grant of the patent. Section 77(4) of the Patents Act 1977 gives effect to these provisions.

### *Samsung Electronics Co Ltd v Apple Retail UK Ltd [2014] EWCA Civ 250, Court of Appeal*

In the global dispute between Samsung and Apple relating to the iPhone and the iPad, Samsung had commenced patent infringement proceedings against Apple in respect of various of Apple's 3G enabled devices. The trial of the action had been divided into two parts and two separate Judgments were issued on the first two patents and the third patent.

Samsung had made unconditional applications to amend the patents before the trial. The Judge had found that each of the patents was not entitled to its claimed priority date and as a result was invalid for anticipation or obviousness by reason of a disclosure in an intervening piece of prior art and was otherwise invalid for obviousness.

Samsung appealed against the Judge's decision. At the same time, Samsung also filed applications for amendment centrally at the EPO (the EPO amendment applications). Samsung then applied to adjourn the appeal pending the determination of the EPO amendment applications. The EPO amendment applications were expedited and at the hearing of the application for an adjournment a decision from the EPO was expected within a few months. Samsung explained the delay in making the EPO amendment applications in the first place on the basis of the need to co-ordinate with parallel proceedings (in Germany, Italy and France).

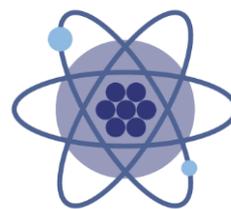
Apple made a cross-application for an order that, unless Samsung undertook to take no further steps in the EPO amendment applications proceedings, then the permission to appeal should be set aside, the appeal struck out and the patents revoked, in effect forcing Samsung to choose between the appeal and the EPO amendment applications.

The Court of Appeal commented on the fact that (1) the Patents Act 1977 specifically contemplated the possibility of concurrent opposition or central amendment proceedings in the UK and in the EPO;

(2) save where opposition proceedings were pending, there was no prohibition on the filing of a central amendment application while infringement or revocation proceedings were pending, or in the period between a first instance judgment and an appeal in such proceedings, in any designated state; and (3) any decision by the EPO on a central amendment application would be directly effective in every designated state and that if allowed, the bundle of European patents would be deemed always to have been in their amended form.

In this case, the Court of Appeal decided that because the EPO amendment applications were likely to be concluded in the relatively near future, Samsung's pursuit of the EPO amendment applications was not an abuse of the process of the court nor was it an activity with which the court could properly interfere for any other reason. The EPO amendment applications might or might not be successful and it could not be predicted with any certainty what form the amendments would take if allowed, since their final form might depend on the dealings between Samsung and the EPO during the central amendment proceedings. They decided that an adjournment would not cause Apple any significant prejudice whereas a refusal of the adjournment might have resulted in the appeal proceeding on what might turn out to have been a false basis, with consequential waste of costs and time.

Accordingly, the Court of Appeal granted the application to adjourn the appeal until the outcome of the EPO amendment applications was known.



## Stay pending EPO proceedings

### *Actavis Group v Pharmacia LLC [2014] EWHC 2265 (Pat), Arnold J.*

Pharmacia applied for a stay of UK patent proceedings pending the final determination of parallel proceedings concerning the validity of the same patent before the EPO. Actavis opposed the application.

In support of its application for a stay, Pharmacia had offered undertakings (a) to seek expedition of the EPO proceedings, (b) not to seek an injunction against Actavis or its customers until the determination of the EPO proceedings and (c) only to seek damages of 1% of Actavis' net sales during the period from launch until the determination of the EPO proceedings if the Patent is held valid both by the EPO and by the English courts.

The principles applicable to an application of this nature had been restated recently by the Court of Appeal in *IPCom GmbH & Co KG v HTC Europe Co Ltd* [2013] EWCA Civ 1496).

The Judge at first refused to accede to the application and stay the proceedings. He said that although the competing considerations were finely balanced, in the end, he concluded that they favoured the refusal of a stay. The main reason in favour of his refusal was the fact that the EPO proceedings had only just begun. Even with expedition, it was likely that the EPO proceedings would take at least three years to resolve finally and possibly significantly longer. By contrast, the UK proceedings would be resolved finally in two years. This was therefore a case where the relative timings of the two sets of proceedings meant that commercial certainty was likely to be achieved in relation to the UK market at an earlier date if the UK proceedings were allowed to proceed (IPCom factors 8 and 10).

Refusal of a stay was also supported by the possibility that an English decision might promote a settlement (IPCom 9) and by the public interest in determining the validity of the Patent (IPCom 11). The risk of wasted costs was a factor that favoured the grant of a stay, but this was outweighed by the commercial uncertainty (IPCom 12).

After Judgment had been handed down, Pharmacia offered two additional undertakings in return for the grant of a stay of the UK proceedings, namely (i) not to seek an injunction in the UK against Actavis or its customers in relation to Actavis' sustained release pramipexole product during the life of the Patent and (ii) only to seek damages of 1% of Actavis' net sales in

the UK during the life of the Patent if the Patent was ultimately held valid by the EPO and valid and infringed by the English courts.

In view of these two additional undertakings, the Judge decided to grant a stay. He held that taking all of the factors set out in the *IPCom* decision into consideration, the overall balance now came down in favour of the grant of a stay.

## Cross-border declarations of non-infringement

### *Actavis UK Ltd and others v Eli Lilly & Co [2014] EWHC 1511 (Pat), Arnold J.*

Pemetrexed disodium, a cancer treatment marketed by Eli Lilly under the brand name Alimta, was protected by a basic patent extended by supplementary protection certificates (SPCs) expiring in December 2015. Lilly also owned a second medical use patent relating to the use of pemetrexed disodium in the manufacture of a medicament for use in treating cancer in combination with vitamin B12 which would not expire until June 2021.

Actavis wished to clear the path in France, Germany, Italy, Spain and the UK in relation to its generic pemetrexed product (not being the disodium salt) ahead of expiry of the SPCs based on the basic patent.

Accordingly, Actavis decided to commence proceedings in the UK for declarations of non-infringement (DNIs) in respect of each of the designations of the second medical use patent in those other countries as well as the UK.

The Judge had held previously that, in circumstances where there was no challenge to the validity of the foreign designations of a European patent, the English court had jurisdiction to entertain an action seeking DNIs of those foreign designations as well as the UK designation. This decision was upheld by the Court of Appeal ([2013] EWCA Civ 517).

Actavis subsequently discontinued the proceedings in respect of the German part of the European patent after a German first instance infringement court had held that the use of pemetrexed dipotassium would infringe the German designation of the European patent.

The Judge held that (1) the law applicable to the issue as to whether Actavis' proposed acts would infringe each of the non-UK designations of the European patent was the substantive patent law of the relevant country but (2) the law applicable to the grant of the

DNIs themselves was that of the forum itself; in this case, English law.

Even if that was wrong, however, the Judge held that the national rules of France, Italy and Spain would permit the grant of a DNI for each of their respective jurisdictions.

As regards the UK part of the European part, the Judge held that the use of the diacid (Actavis's lead candidate salt) would not infringe the claims of the patent. He did so using the framework of the so-called Improver Questions and on the basis that the skilled addressee of the patent was a team which included both an oncologist and a chemist and of the CGK of the skilled chemist regarding the predictability of the viability of different salt forms of the parent molecule, pemetrexed. The Judge answered Improver Questions 2 and 3 in favour of Actavis for a multiplicity of reasons including the way in which the patent had been prosecuted before the EPO.

In the course of his Judgment, his review of the authorities on construction included those dealing with the use of prosecution history as an aid to construction. He concluded that, although the courts had been directed to be cautious in doing so, nevertheless it was useful in some cases to consider the prosecution history in order to shed light on the meaning of the claim.

He then went on to consider the issue of infringement of the other designations of the European patent under the laws of each of the respective countries (France, Italy and Spain) and came to the same conclusion namely that the use of the diacid would not infringe those other designations in those respective countries.

The Judge expressly disagreed with the German first instance court's decision on (non-literal) infringement (based on the doctrine of equivalence). He set out a number of reasons for his disagreement including the fact that the German court had only considered the matter from the perspective of the oncologist and not also of the chemist and also that they had ignored the prosecution history.

As regards the grant of the DNIs themselves, applying English law, the Judge granted relief in respect of each of the parts of the European patent under its inherent jurisdiction on the basis that Actavis had clearly demonstrated that it had a real commercial interest in obtaining the declarations and they would serve a useful purpose. He also held that even if he was wrong as to the applicable law i.e., applying the national laws of each of France, Italy and Spain, the relief would still be granted.

Lilly's appeal against this decision was heard at the end of March 2015 and the Judgment from the Court of Appeal is expected to be handed down soon.

Interestingly, shortly before the hearing of the appeal, the German Court of Appeal reversed the decision of the German first instance court holding that the claim was not infringed (on a nonliteral basis) by the use of the dipotassium salt of pemetrexed.





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