



Anna Edwards-Stuart MA DPhil Called: 2002

Practice

Anna has an excellent reputation at the IP bar for being a diverse and successful junior, practising across all areas of intellectual property law ranging from pharmaceutical patents to complex trade mark matters and related contractual disputes as well as damages inquiries and accounts of profits.

Recent patent trials and hearings have concerned pharmaceutical compound and medical use patents (including small molecules, salt forms, antibodies and biosimilars; first and second medical use patents; orphan drug designations), pharmaceutical formulations and dosing regimens (including modified release formulations, preparations for nasal inhalation), medical devices (including advanced wound dressings and auto-injectors), mechanical devices (including coffee machines, food packaging and wind turbines), artificial neuron networks and financial trading systems.

Recent trade mark and passing off trials and hearings have considered the scope of bad faith, the limits of passing off, the use of trade marks as Adwords, and non-traditional marks, and related to subject matter as diverse as medical devices, bandage clothing, branded clothing, energy drinks and the shape of chocolate. Recent design right cases have involved bandage clothing, tablet computers and vacuum cleaners. Recent copying cases have involved fabric and bed linen designs.

Anna has previously been singled out as a "Star of the Future" in the legal press and continues to impress as a proactive advocate with increasing experience acting in several hearings, trials and appeals as sole counsel. She is regularly instructed to act in the Patents Court and general Chancery and Commercial Divisions of the High Court (both at first instance and on appeal), the Court of Appeal, the Supreme Court, the Intellectual Property Enterprise Court, the Trade Mark Registry, the Copyright Tribunal and before the Appointed Person. She has also advised in proceedings before the EPO, the General Court and EUIPO, as well as in various ICC arbitrations and ICANN and Nominet disputes.

Anna has a strong scientific background, having studied in life sciences and biotechnology, and has a doctorate in molecular biology. She is therefore particularly well placed to advise clients in the life sciences field.

During 2019 Anna was appointed Standing Counsel for the Comptroller of Patents, Designs and Trade Marks.

What the directories say

"Anna Edwards-Stuart is highlighted for her responsiveness, pragmatic advice and strong written opinion work. She has experience of invalidation and infringement actions relating to patents and trade marks. She is regularly instructed by life sciences companies and draws praise for her work in cases concerning design right infringements. She is an authority on IPEC proceedings." - Chambers and Partners

"Anna Edwards-Stuart is one of the most gifted barristers; she is ferociously smart with some real common sense. She has a really good understanding of her clients and everyone loves working with her." "Anna is extremely bright and very hard-working; she is well on top of things in extremely complex cases." "As an experienced junior Anna is always a top choice. She is sensible and commercially focused, and is a strong advocate who is able to highlight the key issues in the case for her clients." - Chambers and Partners

"Anna is one of the best senior juniors at the IP Bar. She has a very economical and no-nonsense style of advocacy that works very well. Thoroughly organised and with a good eye for the issues that actually matter.



Anna works well with a range of personality types and gets along well with solicitor teams and clients." - Legal 500

"A tremendous barrister who is a true team player." "She is diligent, hard-working and gets on with the case with panache." "She is exceptionally bright, very thorough and good with clients while being firm with her advice." - Chambers and Partners

"She has razor-sharp intellect, a persuasive advocacy style and can answer points on her feet at incredible speed." - Legal 500



Qualifications

2003 Tenancy at 11 South Square 2002 Called to the Bar of England & Wales 2002-2003 12 Month Pupillage, 11 South Square Wolfson Scholar, Lincoln's Inn 2001-2002 Bar Vocational Course, Inns of Court School of Law Sir Thomas More Bursary, Lincoln's Inn 2000-2001 City University, Postgraduate Diploma in Law (CPE), 1997-2001 University of Oxford, Magdalen College, D.Phil (Molecular Biology) BBSRC Studentship 1994-1997 University of Cambridge, New Hall, MA (Natural Sciences) II:i Albert Howard Memorial Award

Significant recent & reported cases

Sky v SkyKick (Comptroller-General of Patents Designs and Trade Marks* as intervener)

Trade mark validity, bad faith

Sky sued SkyKick for trade mark infringement. SkyKick counterclaimed for invalidity. Before the Supreme Court SkyKick argued that the relevant parts of Sky's trade mark specifications had been applied for in bad faith being part of a strategy of applying for overly broad trade marks in respect of goods and services which Sky did not and not intention of trading in.

Judgment pending.

Exelogen v University of Birmingham* [2023] EWHC 1523 (Comm)

Breach of contract, loss of a chance

Prof Sinclair had identified an existing drug, exenatide, as a potential new treatment of idiopathic intercranial hypertension in the course of her research at the University of Birmingham. The University entered into an agreement with Exelogen Inc pursuant to which Exelogen were granted an exclusive right to negotiate for a licence of the University's intellectual property. However, in breach of the option agreement the University entered into negotiations with a third party to commercialize exenatide.

Exelogen sued the University for breach of contract. Other claims for misuse of confidential information and unjust enrichment were abandoned during the trial. Exelogen claimed in excess of \$60m for breach of contract being the net profit it claimed it would have made for bringing exenatide to market under licence from the University. For such a "lost opportunity" claim to succeed, a claimant has to establish (i) that the lost opportunity was real rather than speculative, (ii) that the breach of contract caused the loss in chance, and (iii) the value of that lost chance.

The University did not dispute that it had breached the option agreement, but argued it had no choice given Exelogen's inability to raise any funding. The University argued that the claim was speculative, given Exelogen's failure to raise any funding, which the University submitted was because of Exelogen's failure to develop a persuasive commercialization plan for the treatment of IIH with exenatide.

The Judge dismissed the claim, holding that Exelogen's purported lost opportunity was merely speculative given its lack of progress in obtaining funding.

Teva v Astellas* & Sandoz v Astellas* [2023] EWCA Civ 880 Patent validity, obviousness

This was appeal by Teva and Sandoz following a trial before Meade J in which he upheld the validity of Astellas' patent and SPC protecting the use of mirabegron for the treatment of OAB and granted Astellas relief for infringement ([2022] EWHC 1316 (Pat) – see summary below).



The generics argued that the judge had erred in principle because he did not correctly apply the law as stated in <u>Pozzoli</u> and <u>Philips v Asustek</u>. The CA rejected this argument for two reasons. First, because the judge's reasoning was that the patent was not obvious in the light of the prior art and accordingly the principle in <u>Philips v Asustek</u> was not engaged. Second, the CA held that the generics' argument was in reality a "more subtle variant" of the argument rejected by the House of Lords in <u>Conor</u>. Having conceded that the patent made it plausible that mirabegron is effective for the treatment of OAB this argument failed.

Teva and Sandoz have applied for permission to appeal to the Supreme Court.

Sandoz v BMS* & Teva v BMS* [2023] EWCA Civ 472

BMS owns a patent and corresponding SPC for the compound apixaban. Apixaban is a factor Xa inhibitor and used for the treatment for thromboembolic disorder. Sandoz and Teva each sought to revoke the patent on the ground of insufficiency on the basis that the patent did not make it plausible that apixaban would have any useful factor Xa inhibitory activity. The patent (and SPC) were invalidated by Meade J in April 2022 ([2022] EWHC 822 (Pat)).

BMS argued that the present case was factually dissimilar from the Supreme Court's decision in <u>Warner-Lambert</u>, not least because the patent disclosed a novel compound and not merely a medical use of a known compound, and that the recent EPO decision G2/21 supported a finding of validity. The CA held that it was bound by the Supreme Court's decision in <u>Warner-Lambert</u> and that the G2/21 decision did not justify a departure from <u>Warner-Lambert</u>. A patentee is required to demonstrate that the patent discloses some scientific rationale to support an assertion (explicit or implicit) of efficacy. Although experimental data is not necessarily required, a bare assertion is insufficient.

BMS has applied for permission to appeal to the Supreme Court.

Siemens v GE [2022] EWHC 3034 (Pat)

Patent validity, construction, obviousness, territoriality.

Siemens alleged infringement of its patent relating to the location of bearings in wind turbines. GE denied infringement *inter alia* on the basis that its wind turbines were to be installed at Dogger Bank which was outside the territorial scope of the Patents Act 1977.

Meade J held that the patent was obvious over one of the prior art citations and not infringed. Further the acts that were to take place at Dogger Bank were said to be outside the territorial scope of the Patents Act.

Permission to appeal has been granted by the Court of Appeal.

Astellas* v Teva and Sandoz [2023] EWHC 2571 (Pat)

Patent validity, construction, obviousness, infringement

Astellas alleged that the generic mirabegron tablets proposed to be launched by Teva and Sandoz infringed its patent. The patent claimed a pharmaceutical composition for modified release with a particular formulation and dissolution profile. Both Teva and Sandoz counterclaimed to revoke the patent alleging it was obvious in the light of three prior art citations and insufficient. Teva did not contest infringement. Sandoz did not admit infringement, contending that on its true construction the claim requires the formulations to reduce a food effect which must be demonstrated by a comparison of differences between the *in vivo* parameters (AUC and C_{max}) in the fed and fasted state between the defendant's generic mirabegron tablets and a conventional release formulation. As these data were not available Sandoz argued that the allegation of infringement had not been proved.

Following trial before Mr Justice Mellor, the Patent was found to be valid but not infringed by Sandoz. The court also held that, if the Judge was wrong on the issue of construction, the Patent would be invalid for obviousness over two prior art citations relating to oral controlled absorption systems.

Sandoz v BMS/Pfizer* & Teva v BMS/Pfizer* [2022] EWHC 1831 (Pat)

Patent validity, obviousness, lack of a technical contribution



Apixaban, trade name ELIQUIS, is a successful drug for treating thromboembolic disorders. This trial concerned various patents from the same family relating to formulations of apixaban. Sandoz/Teva argued that the Patents are obvious over various prior art citations and/or lacked a technical contribution.

Meade J held that all the patents were held to be invalid for lack of an inventive step over one of the prior art citations.

Permission to appeal has been granted by the Court of Appeal.

Alcon* v Pharmathen [2022] EWCA Civ 845

Patent validity, obviousness

This was an appeal of the judgment of Meade J ([2021] EWHC 1026 (Pat)) in which he held that Alcon's patent for the use of a prostaglandin $F2\alpha$ analogue (fluprostenol isopropyl ester) for the treatment of glaucoma and ocular hypertension was valid and infringed. The appeal related to the Judge's findings regarding the obviousness attack and its interplay with an insufficiency squeeze.

The appeal was dismissed.

Teva v Astellas* & Sandoz v Astellas* [2022] EWHC 1316 (Pat)

Patent validity, obviousness

Teva and Sandoz each sought to revoke a patent of Astellas which claimed the use of mirabegron as a treatment for overactive bladder. By the time of the trial Teva and Sandoz relied on a single prior art citation, an Australian patent application referred to as 288, which Teva and Sandoz argued rendered the patent obvious, together with an insufficiency squeeze. Infringement was not disputed.

Meade J held that he patent was held to be valid and infringed.

Permission to appeal was granted by the trial judge. The appeal was dismissed in July 2023 ([2023] EWCA Civ 880 – summarized above). Teva and Sandoz have sought permission to appeal to the Supreme Court

Sandoz v BMS* & Teva v BMS* [2022] EWHC 822 (Pat)

Patent validity, insufficiency (lack of plausibility), Agrevo obviousness

Apixaban, trade name ELIQUIS, is a successful drug for treating thromboembolic disorders. Sandoz and Teva each alleged that BMS' patent protecting apixaban was insufficient because it did not contain any experimental data demonstrating that apixaban was an effective inhibitor of factor Xa, a key enzyme in the coagulation cascade. Sandoz and Teva also alleged that the patent was obvious over a single prior art citation.

The patent was held to be invalid by Meade J.

Permission to appeal was granted by the Court of Appeal. The appeal was dismissed in May 2023 ([2023] EWCA Civ 472 – see summary above). BMS have sought permission to appeal to the Supreme Court.

Original Beauty Technology Company Ltd & ors* v G4K Fashion Ltd & ors [2021] EWHC 3439 (Ch) Damages inquiry in an unregistered design case

This was the damages inquiry in an unregistered design case involving two fashion brands: House of CB (the Claimants) and Oh Polly (the Defendants). A liability trial was heard towards the end of 2020: see [2021] EWHC 294 (Ch).

Oh Polly had sold 15,393 garments which infringed House of CB's unregistered UK and/or Community design rights. House of CB claimed "standard damages" on two bases: (i) lost profits where Oh Polly's sales had substituted for sales which would have been made by House of CB; and (ii) "user principle" damages where sales substitution had not taken place. Oh Polly accepted that it was liable to pay "user principle" damages, but not damages for lost profit. House of CB sought c. £275,000 in standard damages, while Oh Polly maintained that only c. £15,000 was due.



The liability trial had determined that House of CB was entitled to additional damages. House of CB sought a "top up" award of additional damages to take the total to c. £500,000. Oh Polly's position was that additional damages should be calculated as an "uplift" on standard damages of 20% (on Oh Polly's case coming to c. £3,000).

The Court held that House of CB was entitled to standard damages under both heads claimed. It determined that 20% of Oh Polly's infringing sales would have been made by House of CB had the infringing garments not been available, and awarded damages for lost profit accordingly; on the remainder of sales a reasonable royalty was awarded of 10% of Oh Polly's net sales with a guaranteed minimum royalty of £4,000 per design. Standard damages were awarded in the sum of c. £150,000.

In relation to additional damages, the Court determined that an award of £300,000 was appropriate, having regard to the scale of the infringement and its flagrancy, and the need to punish and deter the Defendants from further infringements. This represents the largest reported UK award of additional damages in a design right (or copyright) case.

Permission to appeal was granted by the Court of Appeal. The case settled shortly before the hearing of the appeal.

Teva* v Bayer [2021] EWHC 2690

Patent validity, obviousness, claim construction

Teva sought to revoke a single claim of Bayer's patent to clear the way for its generic product. The claim was to the tosylate salt of a known compound (sorafenib). Teva argued that the tosylate salt was obvious. Bayer denied that the tosylate salt was obvious and further argued that, on its true construction, the claim required that the tosylate salt be suitable for oral administration.

Mellor J held that the claim was invalid.

Permission to appeal was granted by the Court of Appeal. The case settled shortly before the hearing of the appeal.

Fibrogen v Akebia & Astellas v Akebia [2021] EWCA Civ 1279

Patent validity, insufficiency

This was an appeal of the findings of insufficiency and the obviousness of the Family B patents in the judgment of Arnold LJ ([2020] EWHC 866 (Pat)).

Birss LJ Arnold LJ had construed the claims incorrectly and applied the wrong test. Birss LJ held that the correct approach is to ask whether it is possible to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim. In determining the scope of the claim compounds Birss LJ distinguished between two types of functional limitations: those that determine the scope of the claimed class and those that describe the technical effect to be achieved by the claimed compounds. He set out the following three-step approach:

- (1) Identify what it is which falls within the scope of the claimed class;
- (2) Determine what it means to say that the invention works (i.e. what is it for?);
- (3) Answer the question whether it is possible to make a reasonable prediction the invention will work with substantially everything falling within the scope of the claim.

By this approach so-called step 1 functional features define the scope of the claimed compounds which are then assessed for plausibility rather than asking whether all compounds with the claimed structural features will have the claimed functional features. Accordingly Birss LJ found that the claims were not insufficient.

The appeal in respect of the finding that the Family B Patents were obvious was dismissed.

The Supreme Court have granted Akebia permission to appeal. The appeal will be heard in 2024.

Renaissance Technologies v Comptroller General of Patents, Designs and Trade Marks* [2021] EWHC 2113 (Ch) Patentability

The UKIPO held that the Appellant's patent application was excluded from being patentable under section 1(2) of the Patents Act 1977 as (1) a method for doing business and (2) a program for a computer, as such. Accordingly, the Appellant's patent application was refused pursuant to section 18(3) of the 1977 Act. The patent application related to a computer-based financial trading system. The application sought to avoid problems associated with latency by providing a plurality of servers co-located on or near the relevant financial exchanges and sending trade instructions containing smaller orders with an execution time enabling them to be received by the exchanges substantially simultaneously.

The appeal was dismissed.

Alcon v Pharmathen [2021] EWHC 1026 (Pat)

Patent validity, obviousness

This case began as a claim for patent infringement. The defendants submitted to an interim injunction and the proceedings were stayed pending determination of the validity of the patent at the EPO. The EPO upheld the patent. The defendants then sought to lift the stay of the English proceedings with the intention of invalidating the UK designation of the patent and claiming under the cross-undertaking given by the claimants in obtaining the interim injunction. The sole issue was whether the use of fluprostenol (a prostaglandin F2- α analogue) was obvious as a treatment for glaucoma.

Meade J dismissed the claim to revoke the patent. That decision was upheld on appeal ([2022] EWCA Civ 845).

Original Beauty Technology & ors v Oh Polly & ors [2021] EWHC 294 (Ch)

Unregistered design right infringement, passing off

The Claimants (House of CB) and Defendants (Oh Polly) are rival fashion brands selling bodycon and bandage dresses, styles made famous by celebrities such as Kim Kardashian. House of CB claimed that Oh Polly copied 91 of its garments, thereby infringing UK and EU unregistered design right. House of CB also claimed that Oh Polly had copied its business model, social media, marketing, packaging and presentation (using the same models and the same locations for photoshoots) such that consumers would be deceived into thinking that Oh Polly was a sister brand of House of CB, thus passing off. Mr David Stone (sitting as a Deputy High Court Judge) held that some garments infringed design right and awarded additional damages given the flagrancy of the infringement.

The claim for passing off was dismissed: House of CB had proved its case in relation to goodwill in some of the pleaded indicia but had not established that sufficient members of the relevant public had been deceived into thinking that Oh Polly was a sister brand of House of CB.

Lenovo (Singapore) PTE Ltd v Comptroller General of Patents, Designs and Trade Marks* [2020] EWHC 1706 (Pat)

Patentability

The UKIPO held that the Appellant's patent application was excluded from being patentable under section 1(2) of the Patents Act 1977 as (1) a method for doing business and (2) a program for a computer, as such. Accordingly, the Appellant's patent application was refused pursuant to section 18(3) of the 1977 Act. The patent application related to a method of avoiding 'card clash' when paying with contactless payment devices such as credit cards.

The appeal was allowed.

Akebia Therapeutics Inc* v Fibrogen; Astellas v Akebia* [2020] EWHC 866 (Pat)

Patent validity, insufficiency, plausibility, undue burden, conceptual uncertainty, obviousness, patent infringement by equivalence, patent infringement by off-label use

Fibrogen's patents concerned the use of an enzyme inhibitor to treat various anaemias. The patents fell into two families (A & B) and included claims to classes of and single compounds. Akebia, for whom I acted, sought revocation of the patents on the grounds of insufficiency and obviousness. Astellas (the licensee) counter-sued for



infringement. Arnold \square held that the Family A patents involved inventive step but, to the extent that they covered classes of compounds, were insufficient. He held that the claims to classes of compounds would have been infringed on a literal basis, but dismissed the infringement claim based on equivalence to the single compound. The Family B patents were obvious. There was insufficient threat of infringement of the Family B patents.

The Court of Appeal reversed the findings of insufficiency ([2021] EWCA Civ 1279). The Supreme Court has granted permission to appeal.



Teva UK Ltd v Chiesi Farmacutici SpA* [2020] EWHC 1311 (Pat)

Patent infringement, strike out

Teva sought to revoke various patents owned by Chiesi relating to inhalers for a combination of beclomethasone and formoterol. Chiesi inferred from this that Teva was seeking to clear the way for its own generic inhalers and counterclaimed for infringement on this basis. Chiesi pressed for disclosure (alternatively a product description) in respect of Teva's product in the usual way. Teva's response was to apply to strike out the counterclaim on the basis there was no evidence it threatened or intended to commit an infringing act, alternatively that it was an abuse of process being advanced for a collateral objective, i.e. to have access to Teva's commercial plans. In the alternative Teva sought to stay the infringement claim for reasons relating to competition law.

Birss J dismissed the strike out application on both grounds and dismissed the application for a stay.

Ashley Wilde Group Ltd v BCPL Ltd* [2019] EWHC 3166 (IPEC)

Copyright, subsistence, infringement

Ashley Wilde manufactured and sold, inter alia, bedlinen for the 'Kylie Minogue At Home' including a range called Evangeline. BCPL manufactured and sold, inter alia, bedlinen for the 'By Caprice Home' brand named after Caprice Bourret, the highly successful model and reality television star. Ashley Wilde owned the copyright in an original artistic work, namely a prototype fabric for use in the Evangeline range, which was created by an employee. Ashley Wilde alleged that the Evangeline duvet cover was widely available in the UK and that BCPL or its designer had access to it and copied it to create the Amore range of bedlinen sold under the 'By Caprice Home' brand. BPCL averred that the Amore range was independently designed and so did not infringe. Ashley Wilde instructed an expert to support its allegation of copying.

The claim was dismissed at trial.

Quinn Packaging Ltd* v (1) Linpac Packaging Ltd (2) R. Færch Plast A/S [2019] EWHC 2119 (IPEC) Patent validity, obviousness

Quinn sought to revoke two patents, one in the name of Linpac and the other in the name of Færch. The case was unusual in that the co-defendants were unrelated companies, although the subject matter of their patents was very similar justifying a single claim to revoke both patents.

Both patents relate to the secure application of film lids to plastic containers in which fresh fruit, meat and fish are stored and displayed in supermarkets.

Quinn alleged both patents were obvious over a single piece of prior art, Ono. Linpac had proposed various amendments to the claims of the Linpac patent. Quinn alleged that the amendments did not cure the invalidity and were in any event impermissible as adding matter.

The Judge revoked both patents.

Glaxo Wellcome UK Ltd v Sandoz and Vectura* [2019] EWHC 2545 (Ch)

Passing off by use of a similar get up, passing off by equivalence

Glaxo sold its salmeterol/fluticasone combination product (under the name Seretide) in a purple inhaler. Following expiry of the relevant patent protection Sandoz launched a salmeterol/fluticasone combination inhaler. Although a different shape, Sandoz' inhaler was also predominantly purple. Both inhalers were prescription only medicines, prescribed for the treatment of asthma and COPD. Glaxo alleged passing off based on the "get up" of its inhaler. The case was put two ways: misrepresentation as to trade origin and equivalence. Glaxo also alleged that Sandoz (and Vectura the manufacturer of the device) had deliberately intended to deceive health care professionals and patients in developing a purple inhaler. The defendants argued that purple was chosen to indicate the active ingredients in keeping with an established practice of colour coding inhalers e.g. brown inhalers for maintenance therapy and blue inhalers for rescue therapy.

The claim was dismissed in its entirety.

Glaxo Group Ltd and ors v Vectura* [2018] EWCA Civ 1496

Patents, Arrow relief

This was appeal against the judgment of HHJ Hacon striking out Glaxo's claim for Arrow relief.

The appeal was allowed.

Glaxo Group Ltd and ors v Vectura* [2018] EWHC 3414 (Pat)

Patent validity, obviousness, insufficiency, infringement, Arrow relief

Glaxo sought to revoke five patents in the name of Vectura which related to methods for the manufacture of microparticles (composite active particles) for incorporation into pharmaceutical compositions to be used in inhalers. Although the subject matter of the claims was slightly different all involved the use of magnesium stearate. The patents were alleged to be obvious over various prior art citations and insufficient.

Arnold J held that Glaxo had not established that the patents were obvious over the prior art but that they were invalid on the ground of insufficiency. He also held that Vectura had not established that the patents were infringed by Glaxo, although Glaxo were entitled to an Arrow declaration because its process was obvious over the prior art citations.

Victoria Plum Ltd* v Victorian Plumbing Ltd [2016] EWHC 2911 (Ch)

Trade mark infringement, passing off, Google Adwords

Victoria Plum and Victorian Plumbing were competitors in the online bathroom retailing market. They had traded under similar names (Victorian Plumbing/Victoria Plumb) since about 2001. Victoria Plum claimed for trade mark infringement by Victorian Plumbing's use of its mark as a paid search term on Google in response to searches for the Victoria Plum's name but did not object to any other uses by Victorian Plumbing of its name for advertising and promotion. Victorian Plumbing argued that both parties should be entitled to advertise against searches for the other's name under the doctrine of honest concurrent use but made a conditional counterclaim for passing off by Victoria Plum if it was wrong.

Henry Carr J rejected the Victorian Plumbing's primary argument and held that neither party was entitled to bid on the other's name as a paid search term.

Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories (UK) Ltd and Sandoz Ltd* [2016] EWCA Civ 1053
Patent infringement

This was an expedited appeal of Arnold J's decision 2016] EWHC 1517 (Pat) () that Napp's patent for transdermal patches containing buprenorphine for pain relief was not infringed by Dr Reddy's and Sandoz' generic patches.

The appeal was dismissed.

Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories (UK) Ltd and Sandoz Ltd* [2016] EWHC 1517 (Pat) Patent infringement

Napp alleged that the generic transdermal buprenorphine patches to be sold by Dr Reddy's and Sandoz fell within the claims of two of their patents for such patches. The patents' claims specified the percentage ranges of particular materials (active and excipients). Dr Reddy's and Sandoz argued that their products fell outside the claimed ranges or that, if they did not, the claims were insufficiently precise. The issues included whether the percentages required were those used as ingredients in the manufacturing process or those measured in the final product and whether the numerical ranges should be interpreted as covering amounts outside the identified limits. There was also a dispute about how to determine infringement using statistical analysis of the results of sample testing (assaying being destructive).

The action was expedited and came to trial in early June, little more than 4 months after the claim was issued. After a three day trial with both technical and statistical evidence, Arnold J held that neither Dr Reddy's nor Sandoz' product infringed the claims.

Napp was given limited permission to appeal ([2016] EWCA Civ 1053).



Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co Ltd & Anor* [2015] EWHC 2973 (Pat)

Patent validity, added matter, insufficiency, loss of priority, anticipation and obviousness.

Merck sought to revoke Ono's patent (under which BMS was the exclusive licensee), with claims to anti-PD-1 antibodies which inhibit the immunosuppressive signal of PD-1 for cancer treatment. Merck raised a wide variety of attacks on the patent, including added matter, insufficiency, loss of priority, anticipation and obviousness. The case raised a number of points of legal interest including the role of plausibility in priority, novelty and sufficiency.

Merck had admitted that, if the patent were found valid, its proposed dealings in its product for treating melanoma would infringe. Unusually, Ono indicated that if it won its infringement case, it would not seek an injunction in the UK provided an appropriate royalty was paid by Merck, to be agreed or decided by the court.

In concluding that the patent was valid, Birss J held that the mouse models for cancer in the priority document (and the patent) provided support for the claimed invention, such that the Patent was entitled to its priority date. Further, because the skilled person would appreciate that these results would have broad application in treating cancer (because the PD-1 blockade effects the immune system, rather than being directed to an attribute of any particular type of cancer) it was plausible that the invention would be effective for treating a wide variety of cancers and so the claims were sufficient.

The Sofa Workshop Ltd v Sofaworks Ltd [2015] EWHC 1773 (IPEC)

Trade mark infringement, passing off

The parties were both retail chains selling sofas and soft furnishings who traded under their respective names. Validity and infringement of the mark "Sofa Workshop" were in issue on all grounds. There was evidence of actual confusion between the parties arising from the similarity of their names.

HHJ Hacon held that the registrations were invalid on the ground that they had not been used in a sufficient part of the EU (only UK use was established) and because the mark is inherently descriptive (although it had acquired distinctiveness in the UK) but would have been infringed if valid. The passing off claim succeeded.

Fresh Trading Limited v Deepend Fresh Recovery Limited & ors [2015] EWHC 52 (Ch)

Entitlement to a trade mark, copyright

This case concerned the copyright in the "Dude" logo – the cartoon face with a halo which is used by Innocent Smoothies. The 'Dude' was designed by a company called Deepend pursuant to an agreement under which it would be given shares in the company responsible for Innocent. No shares were ever given to Deepend and Deepend later went into liquidation. Some years later, Deepend Fresh Recovery Limited, the sucessor-in-title of Deepend's rights (if any) in the copyright, brought an action at OHIM seeking to revoke Innocent's trade marks for the Dude on the basis that it was the owner of copyright. OHIM initially found in Deepend Fresh Recovery Ltd's favour and Innocent appealed. However, the OHIM proceedings were stayed pending Innocent's High Court action for a declaration that it was the owner of copyright in the Dude (in law or in equity), alternatively that any claim against it for infringement was barred due to acquiescence.

The Judge held at trial that Innocent owned the copyright in equity and were thus entitled to an assignment of legal title from Deepend Fresh Recovery Ltd.

Boxing Brands v Sports Direct [2014] EWHC 91 (Ch)

Trade mark infringement, availability of an inquiry as to damages under a cross-undertaking

This was the latest instalment in a long running dispute between Boxing Brands Ltd (BBL) and the Sports Direct group of companies (Sports Direct) as to the ownership of and entitlement to use the mark QUEENSBERRY (see [2013] EWHC 2200). In November 2012 Sports Direct began offering various QUEENSBERRY branded clothing from their websites and selected stored. BBL, the proprietor of various trade marks for the words QUEENSBERRY and QUEENSBERRY RULES, obtained an interim injunction against Sports Direct restraining the use of the marks QUEENSBERRY and QUEENSBERRY RULES in relation to clothing and sporting equipment until trial. Equivalent



undertakings were given by BBL so as to preserve the status quo pending the trial. At the trial it was held that BBL's QUEENSBERRY marks for clothing were valid and had been infringed by the QUEENSBERRY branded clothing sold by Sports Direct. Following the trial it emerged that Sports Direct had intended to sell other QUEENSBERRY branded products which it claimed were covered by the cross-undertaking but which had not been dealt with at trial. A further hearing was ordered to resolve the dispute in respect of these products.

Birss J held that most of the products that Sports Direct had intended to sell did infringe BBL's trade marks, however a few did not. Of these items only two (corner pads and punch bags) had actually been ordered in advance of the injunction. Although these products were covered by the cross-undertaking Birss J. declined to exercise his discretion an order an enquiry as he was not convinced that Sports Direct had ever intended to launch a free-standing equipment range, let alone one limited to the products held not to infringe.

Boxing Brands v Sports Direct [2013] ETMR 48 & [2013] EWHC 2200

Trade mark infringement

Boxing Brands Limited (BBL), a company owned by Frank Warren and Robert Earl owned a number of trade marks for the word "QUEENSBERRY" covering clothing. In December 2012 BBL successfully obtained an interim injunction against Mike Ashley's Sports Direct group (Sports Direct) when it launched a range of clothing under the QUEENSBERRY brand. At the trial in July 2013, Sports Direct contended that the trade marks relied on were invalid. Sports Direct claimed that its predecessors in title, Messrs La Mura and Goodwin had used the QUEENSBERRY mark since 2004 in relation to a boxing enterprise in Bedford and that this use (and BBL's knowledge of that use) rendered the marks invalid pursuant to sections 47 and 5(4)(a) and/or 3(6) of the Trade Marks Act 1994.

Birss J held that whilst Messrs La Mura and Goodwin may have acquired a very local protectable goodwill in relation to the operation of gym, they had no goodwill in the word QUEENSBERRY as a boxing agency nor in relation to the sale of clothing. The claim based on bad faith was also rejected. Even though BBL knew that Messrs La Mura and Goodwin had been using the sign in some way, that was not enough to amount to bad faith. The mark was not registered for the purpose of preventing them from continuing their use of the mark and did not interfere with their limited rights under passing off. In the circumstances the filing of the trade mark in full knowledge of the earlier use was entirely acceptable commercial behaviour.

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