MAUCHER JENKINS

Patent *issues*

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UK Supreme Court grasps nettle of doctrine of equivalents - Hugh Dunlop

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Patent litigation in China - Handong Ran

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UK SUPREME COURT GRASPS NETTLE OF DOCTRINE OF EQUIVALENTS

BY HUGH DUNLOP

Hugh Dunlop

In the case *Eli Lilly v Actavis UK Ltd* issued on 12 July 2017, the UK Supreme Court has overturned 35 years of English patent law by applying a doctrine of equivalents to find that Actavis's products directly infringe Eli Lilly's patent.

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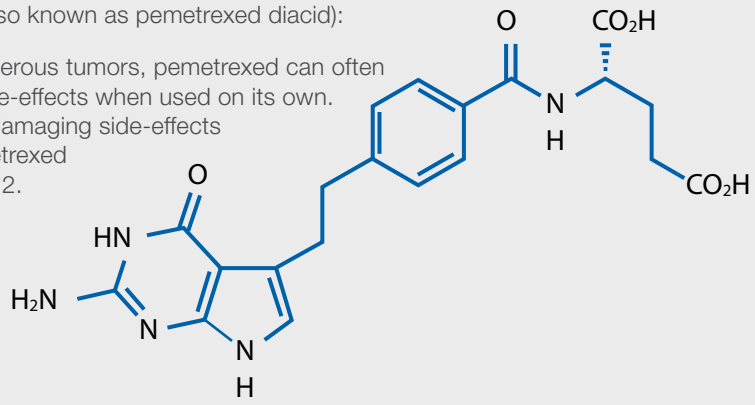
The Court has reformulated the "Improver" questions originally posed by Lord Hoffmann in *Improver Corp v Remington Consumer Products* (subsequently known as the "Protocol" questions). In doing so, the Supreme Court dealt with some important issues related to patent infringement, including the correct approach to the interpretation of patent claims (particularly in the light of the requirement under the EPC 2000 to take alleged equivalents into account) and also the extent to which it is permissible to make use of the prosecution history of a patent when determining its scope.

The interesting point about this decision is that a variant can now infringe when *"it varies from the invention (as claimed) in a way or ways which is or are immaterial"*, which may leave patent lawyers feeling cast further adrift on a sea of interpretive uncertainty.

Eli Lilly and Company ("Lilly") have marketed pemetrexed disodium as a cancer treatment under the brand name Alimta since 2004, and own European Patent No. 1 313 508 for the use of pemetrexed disodium in the manufacture of a medicament for use in combination with vitamin B12 (and, optionally, folic acid) for the treatment of cancer, due to expire in June 2021.

Pemetrexed, a member of a class of chemicals known as antifolates, contains two -CO2H units and, therefore, is an acid (hence it is also known as pemetrexed diacid):

Although known to have therapeutic effects on cancerous tumors, pemetrexed can often have seriously damaging (sometimes, even fatal) side-effects when used on its own. The essential disclosure of the patent was that the damaging side-effects could largely be avoided if a compound called pemetrexed disodium was administered together with vitamin B12. Pemetrexed disodium is known as a salt: it has two $-CO_2Na$ units instead of two $-CO_2H$ units and, when dissolved in water, the two sodiums separate from the rest of the molecule as positively charged cations, and the rest of the molecule becomes a negatively charged pemetrexed anion.



Actavis intended to market a generic pemetrexed product for the treatment of cancer, and sought declarations of non-infringement on the basis that the active ingredient in their generic product was pemetrexed diacid, pemetrexed dipotassium or pemetrexed ditromethamine and not pemetrexed disodium as claimed.

In 2014, Mr Justice Arnold held that Actavis's products did not infringe the UK, French, Italian or Spanish designations of the patent, either directly or indirectly[1]. That decision was partially upheld on appeal by the Court of Appeal, which took the view that there would be indirect infringement, but not direct infringement[2]. The court agreed with the judge's conclusion that the proper construction of the claim did not extend to pemetrexed diacid or any other pemetrexed salts *other than disodium* because the skilled reader of the patent would not have expected any of Actavis's pemetrexed salts to convert into pemetrexed solution when dissolved in an aqueous solution (*Improver v Remington* considered) and, on that basis, there could be no direct infringement by Actavis's dealing in the active ingredients of the generic product.

A solution made by dissolving pemetrexed dipotassium in plain water would not infringe because such a solution would contain only potassium ions and pemetrexed ions. However, Actavis's intended implementation was to dissolve and/or dilute each of the active ingredients in saline solution and, therefore, sodium ions would be present. The judge had dealt with this issue by accepting Actavis's submission that *"at no point is pemetrexed disodium used in the manufacture of a medicament by anyone"*. However, as the Court of Appeal explained, the skilled team would have understood from the patent that pemetrexed disodium was used to refer not only to the solid, but also to solutions containing sodium ions and pemetrexed ions with at least a 2:1 ratio. Further, the language of s 60(2) of the Patents Act 1977 did not require the supply of an element of the claim, but a means relating to an essential element. Consequently, the invention was put into effect when a pharmacist reconstituted or diluted the Actavis products in saline, because there was a stage in the course of that activity when pemetrexed disodium was present and used, which would amount to indirect infringement. Accordingly, the court disagreed with the judge on the issue of contributory infringement. It was common ground that there was no detectable difference in the laws of France, Italy and Spain on the approach to contributory infringement so it followed that the declarations of non-infringement should also be refused in those countries.

Lilly appealed to the Supreme Court on the issue of direct infringement, and Actavis cross-appealed against the rejection of their case that there would be no indirect infringement.

Decision

The Supreme Court unanimously allowed Lilly's appeal and dismissed Actavis's cross-appeal. Giving the lead judgment, Lord Neuberger said that as a matter of ordinary language, it was quite clear that the only type of pemetrexed compound to which the patent's claims expressly extended was pemetrexed disodium. In those circumstances, the Protocol on the Interpretation of Article 69 of the European Patent Convention ("the Protocol") was crucial to Lilly's contention that the scope of protection afforded by the patent extended to the Actavis products.

Lord Neuberger noted that *"the drafting of the Protocol bears all the hallmarks of the product of a compromise agreement"* which he said was unsurprising, given the *"inevitable conflict between the desirability of giving an inventor an appropriate degree of protection in a particular case and the need for clarity of principle as to the extent of such protection generally"*. There was also *"an unavoidable tension between the appropriateness of giving an inventor a monopoly and the public interest in maximising competition"*.

More specifically, it was clear from Article 1 of the Protocol that the scope of protection afforded to a patentee was not to be limited by the literal meaning of the claims. However, it was not at all clear how far a court was permitted to move away from the literal meaning. Secondly, it was apparent from Article 2 of the Protocol that there was potentially a difference between interpreting a claim and the extent of the protection afforded by a claim, and, when considering the extent of such protection, equivalents had to be taken into account, but no guidance was given as to precisely what constituted an *"equivalent"* or how equivalents were to be taken into account. As Lord Neuberger explained, three significant UK cases had considered the question of how far one could go outside the wording of a claim so as to enable the patentee to enjoy protection against products or processes which were not within the ambit of the actual language, construed in accordance with ordinary principles of interpretation.

[1] Actavis UK Ltd v Eli Lilly & Company [2014] EWHC 1511 (Pat)

[2] Actavis UK Ltd v Eli Lilly & Company [2015] EWCA Civ 555

Comment

This judgment says it is time to *"grasp the nettle"* of not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning.

As discussed in the present case, recent UK case law had moved away from any doctrine of equivalents or similar interpretive tool; Lord Hoffmann in *Kirin-Amgen* was openly sceptical of the doctrine of equivalents in the US and the pith and marrow doctrine in the UK, remarking that both *"were born of despair" and that "American patent litigants pay dearly for results which are no more just or predictable than could be achieved by simply reading the claims"*. After *Catnic*, the UK courts adopted a principle of construction, which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming. However, with the advent of Article 2 of the Protocol, came the need to take "due account" of any element which was equivalent to an element specified in the claims and the key limitation of the purposive construction theory is that it cannot protect an equivalent or variant that lies beyond the language of the claims. Another drawback of purposive claim construction is that unforeseeable technology arising after the patent is drafted might not be encompassed by the claim, depending on the generality of the language of the claim. Under purposive construction, an unforeseeable (or foreseeable) equivalent that cannot be found within the meaning of the language of the claim cannot infringe, which arguably places too much expectation on drafters of patent claims in the absence of significantly more guidance on patent scope. As Lord Neuberger noted in the present case, it is worth mentioning that Lord Diplock himself in *Beecham Group Ltd v Bristol Laboratories Ltd*[3] rejected a submission that *"[t]he increasing particularity with which claims are drafted… has made the doctrine [of pith and marrow] obsolete"*, but said that the doctrine *"still remains a part of patent law"*.

This decision is likely to make advising on patent infringement more difficult: practitioners will have to dust off earlier opinions and see if they need to be revised, and there may be a flurry of suits where companies thought they were safe and now find they may infringe.

[3] [1978] RPC 153, 200

PATENT LITIGATION IN CHINA

BY HANDONG RAN

There has been a noticeable step up in the value of patent lawsuits in China, combined with a readiness for the Chinese courts to recognize value in patents owned by foreigners and patents owned by non-practicing entities (NPEs).

Handong Ran

One clear example is the case of *Iwncomm v Sony,* in which the Chinese company Xi'an Iwncomm asserted a standards-essential patent (SEP) against Sony and was awarded approximately **£1 million** of damages and costs (approx. 95% damages and 5% costs).

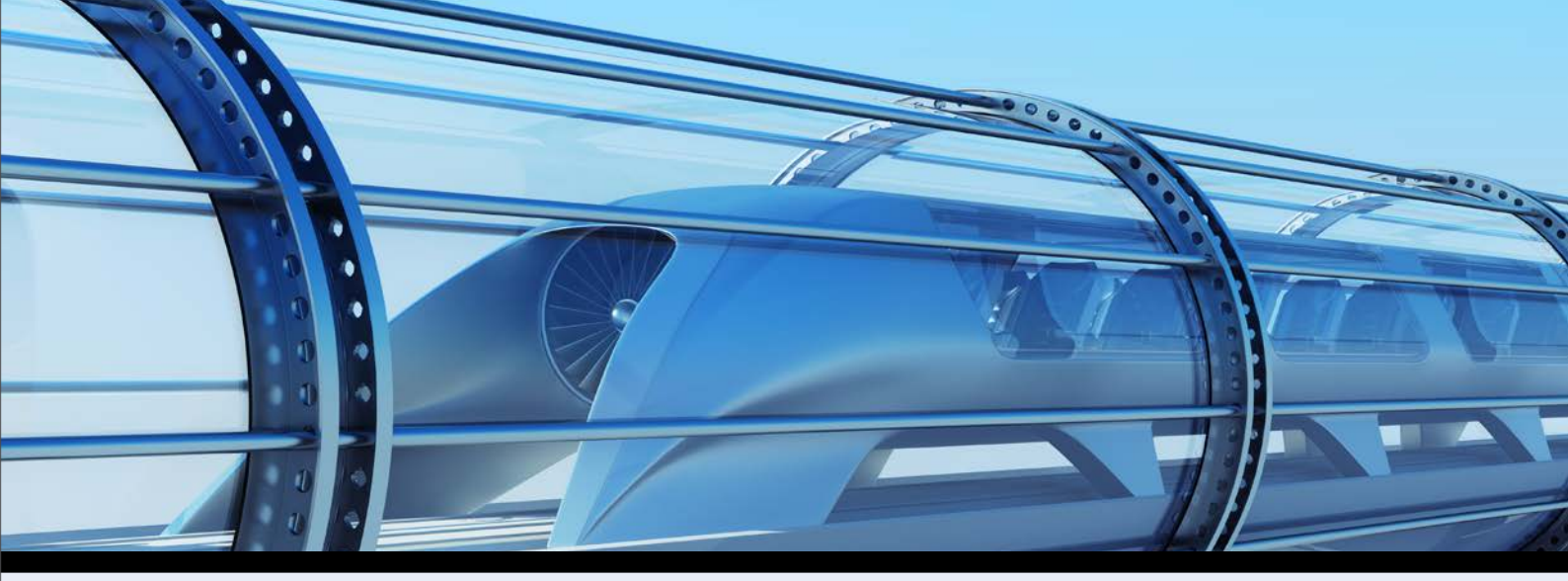
The patented feature related to WLAN Authentication and Privacy Infrastructure or "WAPI" and was mandated in every mobile phone in China. Sony admitted that the WAPI functionality was tested for purposes of authority to sell into the Chinese market, but attempted to argue that the actual feature was not used in production and that users do not use it after purchase. The patent had only method claims, so Sony were not direct infringers, but they were unsuccessful in various defences to indirect infringement.

The damages award included **treble damages** on account of bad faith demonstrated by Sony in the course of licence negotiations. The damages award was arrived at as a licence fee of 1 RMB per phone (the exact number of phones sold was registered with the Chinese Ministry of Industrial and Information Technology). That fee was based on comparable licences to others.

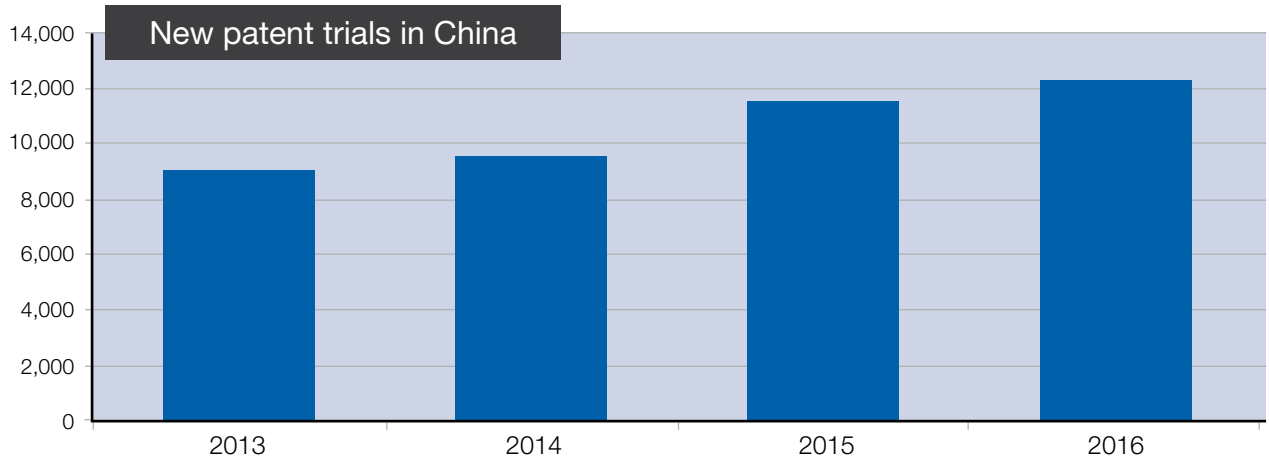
Sony's negotiating behaviour included refusal to sign Iwncomm's NDA before accepting claim charts, and the Beijing Court took the view that Sony were unreasonably dragging out the negotiation (often referred to as "hold-out" behaviour). For this reason, the Court awarded damages of 3 RMB per phone and an injunction against further unlicensed sales by Sony.[1]

Another example of high-value award for patent infringement is *Beijing Watchdata System v Hengbao* decided on 8 December 2016. In that case, the Beijing IP Court awarded damages of **RMB 49 million** and attorney fees of **RMB 1 million** (equivalent to **£5.8m** or **$7.6m** at present rates). The Court found that Hengbao infringed the product and method claims of Beijing Watchdata System's patent CN100542088 for USB keys used for bank transactions. That remains the highest compensation awarded by the court.

[1] This summary is based on a report of the case at 45 CIPA No.7-8 [2017], 39-43



Even setting aside these high-value cases, the average award for patent damages has risen from RMB 0.45m in 2015 to RMB 1.38m in 2016[2]. The number of patent lawsuits is on the increase too, as shown in the following chart:



It is reported that there are more than 20 SEP disputes pending before the Beijing IP Court[3].

Overall, the success rate for patentees is high at 66.5% (higher for utility models and design patents).
The reconciliation rate is 27%.

Foreign IP owners fare only slightly worse than the average. The proportion of the "successful" patent infringement litigation cases of the foreign-invested enterprises involved in the past five years is 50.7%.

We have additional data upon request.

[2] Source: Presentation by Yao Bingbang, Judge of Nanjing Intermediate Court, presented to CPAC on 6 September 2017
[3] Press conference of Court Vice-President Chen Jinchuan 22 March 2017

Comment

China is no longer seen as merely finding its way in dealing with patent disputes, and is now seen as an important forum for disputes between international companies battling over the Chinese market.

It remains difficult in many cases for a foreign entity to succeed over a local manufacturer when there may be jobs at stake within the jurisdiction of the court, but there have been various high-level political speeches and initiatives to impress on the courts the need to be impartial and recognize the rights granted under Chinese patents, regardless of whether those rights are in the hands of a local or foreign entity or a practicing or non-practicing entity.

The *Iwncomm* litigation contains some salutary lessons for anyone (patent holder or prospective licensee) involved in SEP license negotiations in China. Hold-up by the rightholder or hold-out by the putative infringer can be punished severely by the Chinese courts.

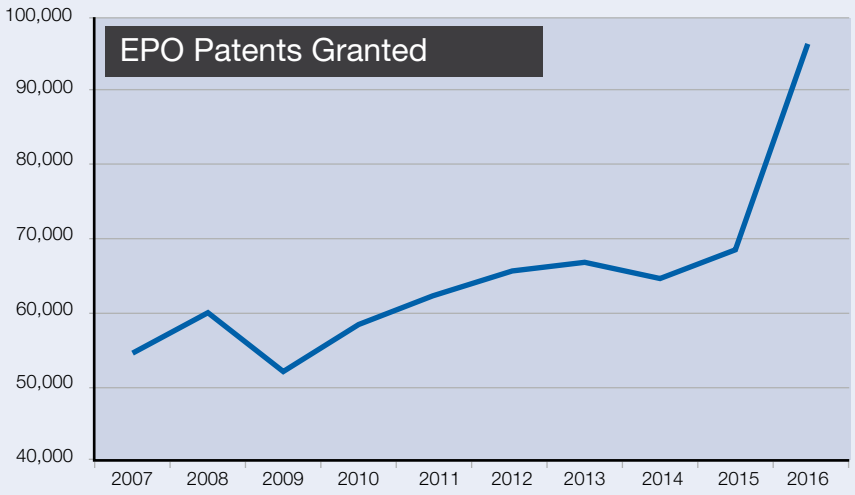
EPO INCREASES ITS OUTPUT

BY DR. JOHN PARKIN

Dr. John Parkin

The European Patent Office showed a significant increase in its output across its various functions. In particular, the number of patents proceeding to grant showed a 40% increase.

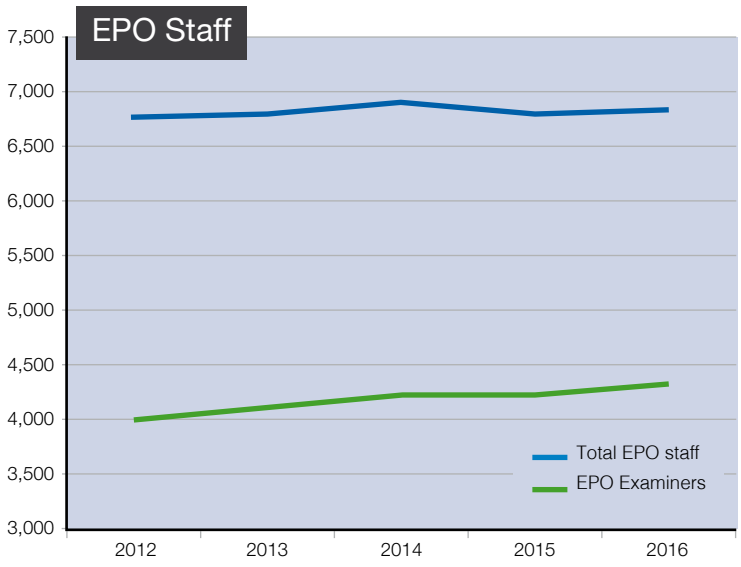
Anecdotal indications are that this merely represents a focus on “easy” cases. For example, if applications in which the European Search Report shows only “A” category citations are given top priority. But we believe there is a genuine improvement in productivity at the office.



Output of search reports, first examination reports and oppositions are also showing significant improvements.

The historical trend of outcomes of opposition proceedings remains; around one third of patents survive opposition in amended form, one third are revoked and in one third of cases the opposition is rejected.

Of particular note is that, according to EPO figures, the backlog of work has fallen by 25% over the last two years – i.e. the total months of work in the backlog (searching, examination and opposition) has dropped from 19.5 months at the end of 2014 to 14.7 months at the end of 2016.



EPO aims for 12 months average examination time by 2020

The EPO says, in its 2016 Annual Report, that the time taken to conclude the examination procedure is already falling and has announced an aim to bring this down to 12 months on average by 2020.

The Office is achieving these impressive results with an increase in numbers of Examiners but no increase in total staff.

UNWIRED PLANET V HUAWEI

– THE FRAND INJUNCTION

BY JAMES CROSS

James Cross

Having granted Unwired Planet a final injunction to restrain infringement of two standard essential patents (SEPs) by Huawei in the case *Unwired Planet v Huawei* (reported in Spring 2017 Patent Issues), the High Court has now ruled on remedies[1]. The decision to grant an injunction allowing the parties to come back to court after final relief has been granted is unusual.

[1] Unwired Planet v Huawei [2017] EWHC 1304, issued on 7 June 2017

In this judgment, Mr Justice Birss decided the terms of the final injunction which should be granted and stayed pending appeal. He found that this new type of IP injunction – a FRAND (fair, reasonable and non-discriminatory) injunction – should be in normal form to restrain infringement of the relevant patent(s), but ought to include a proviso that it would cease to have effect if the defendant entered into a FRAND licence. If, as in this case, the FRAND licence was for a shorter duration than the lifetime of the relevant patents, then the injunction should also be subject to an express liberty to enable either party to return to court in future to address the position at the end of the term of the FRAND licence. In addition, the court made a declaration that the form of the licence finalised a few weeks after the main judgment (the Settled Licence) represented the FRAND terms in the relevant circumstances that existed between the parties. It was also ruled that Huawei had to make a payment on account of costs of £2.9 million, in order to cover some of Unwired Planet's costs of the non-technical trial and permission to appeal was granted to Huawei on three issues, and to Unwired Planet on one issue.

It was common ground that some sort of declaration should be made about the Settled Licence but there was a dispute about the terms. Birss J decided that the correct declaration would be: *"the licence annexed to the judgment represents the FRAND terms applicable between the parties in the relevant circumstances"*.

As Huawei had maintained throughout the proceedings that they were not prepared to enter into a global licence with Unwired Planet on the basis that such a global licence would not be FRAND as a matter of competition law, the draft terms of the injunction remained undecided after the main judgment.

In this latest judgment, the terms of a new injunction – a FRAND injunction – were decided. Normally in English law, once final relief has been granted by the court, the parties are not entitled to come back to court in future even if circumstances change, which runs contrary to the unusual terms in the FRAND injunction. The flexible nature of the FRAND injunction in the form granted in this judgment allows parties to come back to court at the expiry of the FRAND licence; as Birss J said *"the court should not pre-judge at this stage what should happen if or when the FRAND licence ceases to have effect"*.

UPDATE ON BOLAR EXEMPTIONS IN EUROPE

BY DR. EDWARD RAINSFORD

Dr. Edward Rainsford

The "Bolar exemption" allows the use of patented products for the purposes of providing the clinical trial and experimental evidence required for obtaining regulatory approval. This allows a pharmaceutical manufacturer to obtain regulatory approval for a generic version of a patented drug prior to expiry of the patent. The manufacturer is therefore able to sell the approved generic drug immediately after expiry of the patent rights.

As has been reported, different countries within the European Union have taken different approaches to implementing the European Directives relating to the Bolar exemption. In 2014, the UK made a major change to its approach to the Bolar exemption to allow not just testing for generic versions of patented drugs but also testing for innovative drugs.

Ireland also broadened its approach to the Bolar exemption in recent years. However, despite initially being proposed, an exemption for health technology assessment was not implemented.

A summary of the differences between different European countries is set out in the table below:

	Exempted acts		
	Exemption is limited to activities relating to marketing approval of generic medicines, bioequivalents and biosimilars	Broader exemption for any act required for marketing approval, as well as acts relating to innovative medicines	Further exemption for Health Technology Assessment (e.g. for drugs that already have marketing approval)
Marketing authorizations in the EU only	Belgium, Cyprus, Greece, Netherlands and Sweden	Bulgaria, the Czech Republic, Estonia, Finland, France, Hungary, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain	
Marketing authorizations inside or outside the EU or European Economic Area (EEA).		Austria, Germany, Denmark, Ireland, Italy and UK	UK

One grey area relating to the Bolar exemption is whether a company is free to market and sell a generic version of a patented drug explicitly for use in testing under the exemption. The Düsseldorf Appeal Court in the case of *Astellas Pharma Inc v Polpharma S.A. Pharmaceutical Works* referred several questions relating to this issue to Court of Justice of the EU (CJEU) in case C-661/13. However, these questions were withdrawn prior to being answered by the CJEU.

It has now been reported in the Wall Street Journal that the UK National Health Service (NHS) has secured a supply of a generic version of the anti-HIV drug Truvada from Mylan NV at a much reduced price than that of the patent owner Gilead Sciences Inc. The reason this is allowable is because the NHS is supplying the drug to patients as part of a clinical trial. This move has been noted by some commentators as unconventional for the NHS and it has been speculated that it may have been sparked by the NHS losing a UK Court of Appeal case in which the NHS was deemed to have the resources to pay for Truvada and was compelled to start providing the drug[1].

The Bolar exemption is set to remain an important issue for European pharmaceutical companies.

If and when the unitary patent system comes into effect, there is the possibility that these differences in national implementation of the exemption will give rise to different outcomes depending on the residence of the applicant. A unitary patent shall have the same effect across all participating member states (UP Regulation Art. 5.2), but what that effect is in a given state depends not on the law of that state but on the law of the state of residence of the applicant (Arts 5.3 and 7.1). It is possible that the legislative intent of the states with broad exemptions may be circumvented by applying for European patents in the name of a company registered in a state with a narrow exemption and declaring such patents as having unitary effect.

[1] In *National Aids Trust v National Health Service Commissioning Board (NHS England)* (Rev 1) [2016] EWHC 2005, Mr Justice Green ruled that NHS England had "erred in deciding that it has no power or duty to commission" pre-exposure prophylaxis (PrEP), a treatment which involves HIV negative people taking an antiretroviral drug to avoid getting HIV. The NHS appealed and lost.

PATENTING GUIS IN THE UK

BY HUGH DUNLOP

Graphical User Interfaces (GUIs) lie on the boundary of what is patentable in Europe, as they can fall foul of the computer program exclusion or the presentation of information exclusion. In a recent decision of the UK Intellectual Property Office (O/246/17 *Fisher-Rosemount Systems' Application*), a patent application was allowed for a GUI used to control a process control system such as a chemical or petroleum installation.

The UK Patents Court has developed five "signposts" from *HTC v Apple*, to apply when considering whether a computer program makes a relevant technical contribution. The Applicant in Fisher-Rosemount argued that the first of these signposts was applicable.

Hugh Dunlop

Five helpful signposts, to apply when considering whether a computer program makes a relevant technical contribution:

1

Whether the claimed technical effect has a technical effect on a process which is carried on outside the computer.

2

Whether the claimed technical effect operates at the level of the architecture of the computer - that is to say whether the effect is produced irrespective of the data being processed or the applications being run.

3

Whether the claimed technical effect results in the computer being made to operate in a new way.

4

Whether the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer.

5

Whether the perceived problem is overcome by the claimed invention as opposed to being merely circumvented.

Critical to the question was an element of the claim that read:

> "data is receivable by [an] executable graphical element such that an updated control algorithm or data is [manually or automatically] generated and transmitted to the process plant for execution or use in controlling the process plant based on the received data."

The Hearing Officer concluded that changing which "gadgets" (graphical elements) are displayed has a direct causal link to the control of the process plant. This was so whether the data generated and transmitted was generated automatically or manually. The contribution was more than the presentation of information as such, since reconfiguring the display automatically affects the control of the plant. Accordingly, the invention was not excluded from patentability.

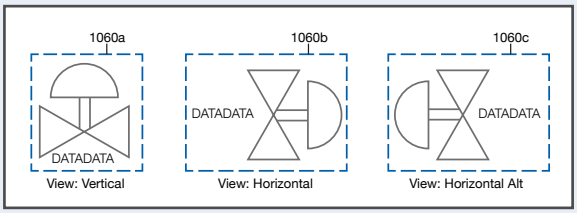


Fig. 12 from GB patent application 1505495.0:

"a display, Graphical Element Module or Gadget may contain dynamic behavior to allow the operator to see the process data, navigate through the process data, or change the process data."

Comment

In Autumn 2013 **Patent *issues***, we discussed EPO Guidelines on the subject of GUIs. The EPO applies the *"Comvik"* approach by excluding the ease of use of a GUI as merely "easing the cognitive burden" and as therefore being non-technical. EPO examiners consider whatever other technical contribution may remain and ask whether this is inventive under the problem-solution approach.

Although the law is the same before the UKIPO and the EPO, the approach taken by the UKIPO is governed by the interpretation imposed by the UK Patents Court, which has a slightly different approach to the computer program exclusion. Before considering inventive step, the UKIPO applies a *per se* test for exclusion (referred to as the *Aerotel* test and discussed in Spring 2007 **Patent *issues***).

This *per se* approach can make the UKIPO a difficult forum for patenting computer programs, but in this decision it can be seen that provided certain signposts are present, the *per se* hurdle can be overcome, and then the inventive step hurdle is much easier, meaning the UKIPO may in some cases be an easier forum than the EPO.

It may be noted, however, that in a parallel decision (O/455/17) relating to another patent application of the same applicant, the applicant presented a claim to a general method and system, within a GUI, of linking graphical representations of entities with graphical representations of related entities, to enable navigation within the GUI, arguing that it was not limited to process control systems. The Hearing Officer in that case was not persuaded that the contribution was at the level of the hardware-software interface. The contribution made by the invention was a way of linking of graphical representations of related process entities to allow the navigation between those graphical representations to occur. It was a contribution at the level of, and directed to, navigation in a graphical program environment. For this reason none of the "signposts" applied and the application was refused under both the computer program exclusion and the presentation of information exclusion.

"FUJIFILM" DECLARATION

BY DR. JANET STRATH

Dr. Janet Strath

In our Spring 2017 edition of **Patent *issues*** we wrote about "Arrow" declarations and how they are a defence against submarine divisional patent applications. An "Arrow" declaration is a court declaration that a certain product was known or obvious at a particular date – i.e. that a party is free to make and sell its product notwithstanding a certain pending patent application, because any claims that might validly be granted would not be infringed. The remedy is named after the case of ***Arrow Generics v Merck***, in which the High Court declared that a certain generic pharmaceutical was known or obvious at the priority date of certain divisional patent applications.

Now, in *Fujifilm v Abbvie Biotechnology*[1], Mr Justice Henry Carr has granted a similar declaration for particular dosage regimens for biosimilar adalimumab products that Fujifilm intend to launch in Europe. A twist in this case, however, is that there was no pending UK patent application in existence. Abbvie had withdrawn the UK designation for their EU patent for the dosage regime (presumably to try to avoid UK jurisdiction and avoid any Arrow declaration).

[1] *Fujifilm v Abbvie Biotechnology Ltd* [2017] EWHC 395

Explaining that the circumstances relied on in the present case were not the same as those in *Arrow Generics v Merck,* and were not the same as originally pleaded, Carr J went on to state that "describing these declarations as Arrow declarations is a potentially misleading shorthand, as the purpose of the declarations is different". The main purpose of an Arrow declaration was to provide a "Gillette defence" to allegations of infringement in the UK. However, in this particular case, Abbvie argued that it had "taken steps leading to the revocation of all patents which are or might have been in issue in these proceedings" and had "also given clear and unambiguous undertakings to the Court which are just as useful as the relief sought by the Claimants in the declarations". As a result, Abbvie contended, there was no need for a Gillette defence in the UK since there would never be any UK patent claims to the dosage regimens in question and, therefore, the declarations sought should not be granted because they did not serve a useful purpose.

However, Carr J found that the declarations would serve a useful purpose by:

- providing commercial certainty for FKB and SB/Biogen regarding the intended launch of their biosimilar adalimumab products;
- dispelling commercial uncertainty in the UK (and European) market, created by Abbvie's threats to enforce its patents against biosimilar competition anywhere in the world;
- providing clarity for third parties in the UK, which the judge considered to be necessary, given AbbVie's conduct to date, and was not provided by AbbVie's undertakings;
- protecting FKB and SB/Biogen's supply chain for the UK market; and
- promoting settlement on a European or even a worldwide basis, in that it would change the parties' negotiating positions because AbbVie would need to take account of the fact that the court had declared that it could not prevent the marketing of FKB and SB/Biogen's products, in spite of AbbVie's public statements to the contrary, which had extended to Europe in general.

Also, Carr J noted that the "Fujifilm declaration" was based on the facts of the present case and therefore may not be appropriate for generalisation.

Adalimumab, sold by AbbVie (a spin-off of Abbott Laboratories) is the world's top-selling drug. It is sold under the trade mark HUMIRA, and 2016 sales were $16.1 billion. Adalimumab is an antibody that binds to TNF and reduces inflammation. It is prescribed for rheumatoid arthritis, psoriasis, Crohn's disease and a host of other autoimmune diseases. HUMIRA's success also makes it a target for biosimilars competition.

HIGH COURT THROWS OUT CLAIM FOR LOSS UNDER THE 'UNLAWFUL MEANS' TORT

BY DR. JANET STRATH

Dr. Janet Strath

The UK High Court has been asked to consider (and has struck out) an unusual claim for damages arising from alleged "misleading or dishonest misrepresentations" to the European Patent Office.

The case concerned the pharmaceutical drug perindopril, a prescription-only medicine used as an angiotensin converting enzyme (ACE) inhibitor to treat high blood pressure, which Servier sold in the UK under the brand name "Coversyl". The basic protection for perindopril expired in 2006.

Servier had a later European patent for the alpha crystalline form of the perindopril salt, through which they sought to extend their monopoly in perindopril. The later patent was held invalid back in 2007[1] but only after Servier has been granted interim relief. In upholding the invalidity decision on appeal, Lord Justice Jacob referred to the patent as "the sort of patent which can give the patent system a bad name"[2].

Subsequently, the English Health Authorities commenced proceedings[3], seeking damages from Servier for a series of alleged breaches of both EU and UK competition law and a free-standing claim for the tort of unlawful means. Here we look at the 'unlawful means' tort.

[1] *Servier v Apotex* [2007] EWHC 1538
[2] *Servier v Apotex* [2008] EWCA Civ 445
[3] *Secretary for State for Health v Servier* [2017] EWHC 2006 (Ch)

The unlawful means claim

The English Heath Authorities (the claimants) alleged that the patentee had obtained the grant of the alpha crystalline patent, and defended it in opposition proceedings, by making misleading or dishonest misrepresentations to the EPO.

Under the heading "Abuse of the Patent System" the claimants stated that the patent application "contained express and implied representations that the alpha form was novel and implied representations that the alpha form was not obvious" and that representations were "repeated and/or further relied on" in contesting the opposition proceedings before the EPO and in the proceedings in the English courts in successfully obtaining interim relief. They alleged that the conduct of the patentee had caused elevated prices for perindopril, achieved at their expense, by virtue of them bearing the financial burden of reimbursement payments to pharmacists and doctors for perindopril dispensed and/or administered pursuant to the NHS.

Servier applied to strike out the free-standing claim for the tort of unlawful means on the basis that it disclosed no cause of action.

For an unlawful means claim to succeed, there must be "*acts intended to cause loss to the claimant by interfering with the freedom of a third party in a way which is unlawful as against that third party and which is intended to cause loss to the claimant*."[4] Such acts do not include acts which may be unlawful against a third party but which do not affect his or her freedom to deal with the claimant.

Servier (defending) submitted that the "third party" was the EPO and the English court and that there was no question of interference with their "freedom to deal" with the English Health Authorities or anyone else.

Mr Justice Roth concluded that, given that the EPO or English courts did not have any economic dealings with the English Health Authorities, it was clear that the claim for the tort of unlawful means was bound to fail, so it was struck out.

Being bound by Article 6(1) of the European Convention on Human Rights, the courts have to exercise caution before striking out a claim on a summary application. But in this case, even assuming all the facts in favour of the English Health Authorities, the issue raised was a pure point of law and was suitable for striking out.

[4] *OBG Ltd v Allen* [2007] UKHL 21

Comment

Unlike the US, the UK does not have a doctrine of "fraud on the patent office". However, the express or implied representations which lay at the foundation of the claimants' allegation of deceit were not hopelessly unarguable. Indeed, the judge assumed that the allegation of deceit was made out. He left these matters to be considered under competition (anti-trust) law rather than the economic tort of unlawful means. The competition law claim remains to be considered at trial.

Parties are not immunised against misleading or dishonest representations to the EPO as to the validity of a patent. Even if they do not give rise to a self-standing tort, they may give rise to other claims for damages. Misrepresentations to the court would, of course, be a very serious matter.

CHALLENGING UKIPO DECISIONS

BY REUBEN JACOB

Reuben Jacob

The UK Intellectual Property Office (UKIPO) can issue non-binding opinions on whether a patent is valid and/or infringed. The procedure allows an opponent to test validity or infringement issues without initiating full inter partes proceedings, but doesn't entirely avoid the risk of costs being awarded. This service has been available since 2005. There were 31 such requests in 2016, of which 21 were requests for opinions on validity, 9 on infringement and 1 on validity and infringement. Numbers for 2017 to date are similar.

Anyone can ask for such an opinion, but the patentee can request a review of the opinion.

In Decision O/318/17, our Reuben Jacob successfully petitioned for review of one such opinion, and a modest costs award was made.

The UK IPO Hearing Officer reviewed Opinion 23/16 and concluded that the Examiner had made an error of principle and had been wrong to conclude that UK patent GB 2478028B was invalid. We represented Linpac Packaging Limited ("Linpac"), the patent proprietor.

The patent concerned containers suitable for use in packaging, storage, transportation and/or display of a product, such as fresh food or a medical product. A process for making a container was also claimed. Ingenium IP Limited had requested an opinion on validity in light of nine patent documents which included document D2 (listed on the search report for the PCT application, but not considered in detail) and document D9 (not previously considered).

The pertinent issues before the Hearing Officer related to:

- the construction of "substantially perpendicular" and "vertical" in the examiner's opinion; and
- whether D9 (US4538651A) clearly disclosed a sealing layer comprised of PP and/or PE.

An additional issue was raised, namely whether the examiner had been correct to disregard a machine translation (into English) of D2, but this was found to be irrelevant as an Australian equivalent of the D2 patent was available and had been considered.

The invention provided a solution to the difficulty of attaching an effective sealing film to a container made from polyethylene terephthalate (PET), without the need for complex sheet structures (expensive and difficult to recycle) and minimising the risk of food contamination. This was achieved by providing a layer of adhesive only to the upper surface of the flange of a PET tray in order to seal a multi-layer film comprising a polypropylene (PP) and/or PE seal layer. The figure below shows a cross-sectional view of a typical container according to the invention:

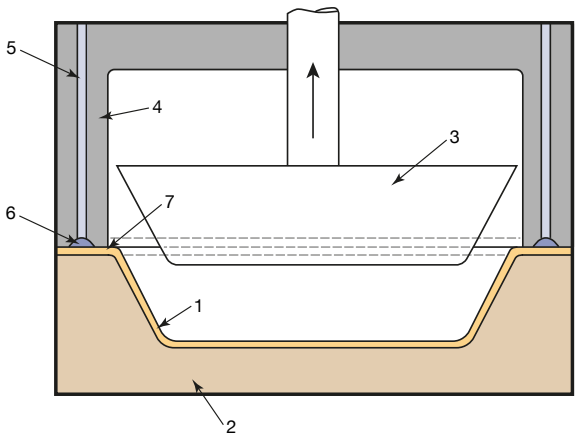
The one independent claim (claim 1) of the patent was the only claim discussed during the hearing (reproduced below, with the hearing officer's emphasis):

A container comprising a base and a continuous side wall extending **substantially perpendicular** to the base with a peripheral flange formed along the upper, in use, edge of the continuous side wall, wherein the base and the continuous side wall consist essentially of polyethylene terephthalate (PET) wherein a layer of adhesive is located on an upper, in use, surface of the peripheral flange and said layer of **adhesive does not extend onto the vertical, in use, surfaces of the continuous side wall and does not extend onto the base** wherein the container further comprises a lidding film which may be sealed to the peripheral flange to create a sealed space between the base, continuous side wall and lidding film; and wherein the lidding film is a **multi-layer film comprising a seal layer and the seal layer comprises polypropylene (PP) and/or PE**.

The construction of "substantially perpendicular" and "vertical"

The Examiner had applied the 'Windsurfing' test for inventive step, construed claim 1 of Linpac's patent and concluded that the terms "substantially perpendicular to the base" and "vertical, in use, surfaces" simply meant surfaces which extended away from the base to create a space. However, the Hearing Officer found that the Examiner had erred in his construction of these particular terms. As the Hearing Officer noted, "perpendicular to the base" would mean an angle of 90° between the side wall and the base, and "substantially" introduced a range either side of 90°. The Examiner's construction would encompass an extremely broad range of angles (such as 30° or 45°), which would include embodiments with side walls that could not be described as 'vertical' or 'substantially vertical' on any reasonable interpretation.

Based (at least in part) on his construction, the Examiner had concluded that D2 demonstrated a lack of inventive step in the patent. Noting that the side walls of the container shown in figure 1 of D2 (below) appeared to be 30° to the vertical, the Hearing Officer had significant doubt as to whether the Examiner would have formed the same opinion in relation to D2 had he not erred in his construction of the patent claim.



CHALLENGING UKIPO DECISIONS (CONT/…)

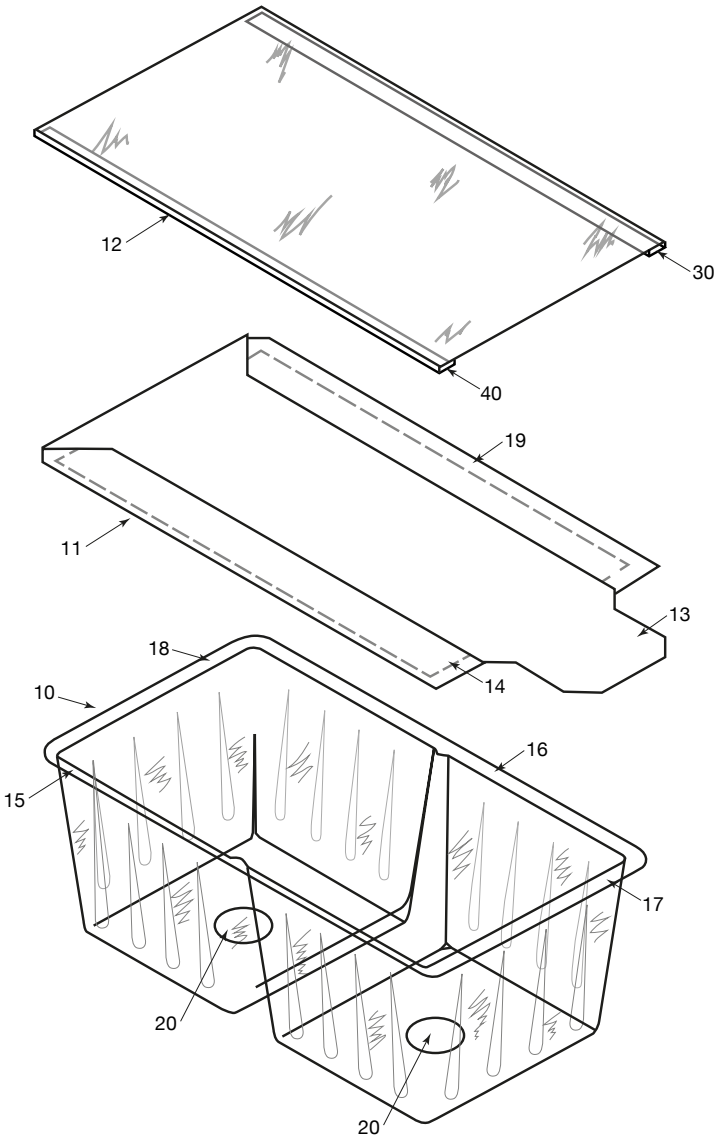
BY REUBEN JACOB

The sealing layer disclosed in D9

The Examiner's opinion concluded that claims 1, 15 and 21 of Linpac's patent lacked novelty having regard to D9 (US4538651A). The toner cartridge disclosed in D9 undoubtedly included most of the features required by claim 1 of Linpac's patent, but there was some disagreement concerning strip 11 (the middle item in the below figure). Strip 11 was composed of two layers: (i) a layer of randomly oriented, bonded polyethylene fibres, and (ii) a low surface energy layer consisting of nylon or PET. In use, the second layer would face the contents of the container. As stated in the opinion of the Examiner, it was not entirely clear whether the second layer extended over the whole of the (lower) surface of strip 11, and in particular whether it extended over the boundary area (19) where the strip would be adhered to the base (10). The Examiner concluded that the boundary area (19) was not covered by the nylon (or PET) layer - because it was said to be "of low surface energy". According, he found that the boundary or seal layer would comprise PE, by virtue of the polyethylene fibres of the upper layer.

We submitted to the Hearing Officer that the low surface energy layer had to extend across the whole surface of the strip. Ingenium disagreed. The Hearing Officer found our argument more compelling. He decided that the significant ambiguity surrounding features claimed in document D9 made it impossible to say for certain whether or not the PE layer described in D9 functioned as a sealing layer. In the absence of a clear indication in the disclosure, it was not apparent how the Examiner had formed his opinion on the issue.

In view of the decision he had reached on the construction of "substantially perpendicular" and "vertical", and the significant ambiguity of features disclosed in D9, the Hearing Officer concluded that the Examiner had made an error of principle, and had reached a conclusion that was clearly wrong. He ordered that Opinion 36/16 should be set aside in whole, thereby terminating the proceedings under section 73(1A) to revoke the patent, and he awarded Linpac a contribution of £750 towards their costs.



Team news

Welcome to:

Nicole Ockl who has started as a new Senior Associate in the trade mark team in Munich. Nicole is an experienced advisor on trademarks, design, copyright and unfair competition law and specializes in intellectual property litigation. Additionally, she is a Certified Lawyer for Intellectual Property Law as well as a trained mediator and assists parties in commercial disputes to find an amicable solution.

Stefan Siegel who has joined the firm's Wireless & Mobile Communications patent team in the Farnham office. Stefan has a BSc (Hons) in Physics and Philosophy, which included a year spent at University California Santa Barbara with a focus on French and Environmental studies.

Andrew van den Bent-Kelly who has joined the firm's Wireless & Mobile Communications patent team in the Farnham office.He is a technical assistant and has a degree in Physics with Astrophysics. After graduation, Andrew received a British Council scholarship to study in Tianjin, China, where he spent a year learning the language and now speaks Mandarin Chinese to a high level.

Congratulations to:

Matthew Yip who has qualified as a UK and European Patent Attorney (dual qualified) in June this year.

Oliver Poskett who qualified as a European Patent Attorney in June this year.

Out and about - external event attendance

Who	Details	When
Fiona Kellas	Technology Scotland Annual Dinner, Edinburgh	24 October
Phil Treeby, Reuben Jacob	APAA, Auckland, New Zealand	4-7 November
Katie Cameron, Tim Pendered	INTA Leadership Meeting, Washington DC, USA	7-10 November
Reuben Jacob	MEDICA 2017, Dusseldorf, Germany	13-16 November
Kana Enomoto	PTMG Spring Conference, Porto, Portugal	19-20 March
Katie Cameron, Tim Pendered, Angela Fox, Dr. Michael Nielen, Kana Enomoto	INTA, Seattle, Washington	19–23 May
Reuben Jacob	BIO International Convention, Boston, USA	4-7 June

Maucher Jenkins hosted events

Maucher Jenkins Partners	IP SHOWCASE BASEL, Switzerland	24 October
Johannes Lange	Free consultation for inventors (kostenlose Erfinderberatung) at the IHK Südlicher Oberrhein in Freiburg, Germany	2 November
Henrich Börjes-Pestalozza	Free consultation for inventors (kostenlose Erfinderberatung) at the IHK Südlicher Oberrhein in Lahr, Germany	21 December

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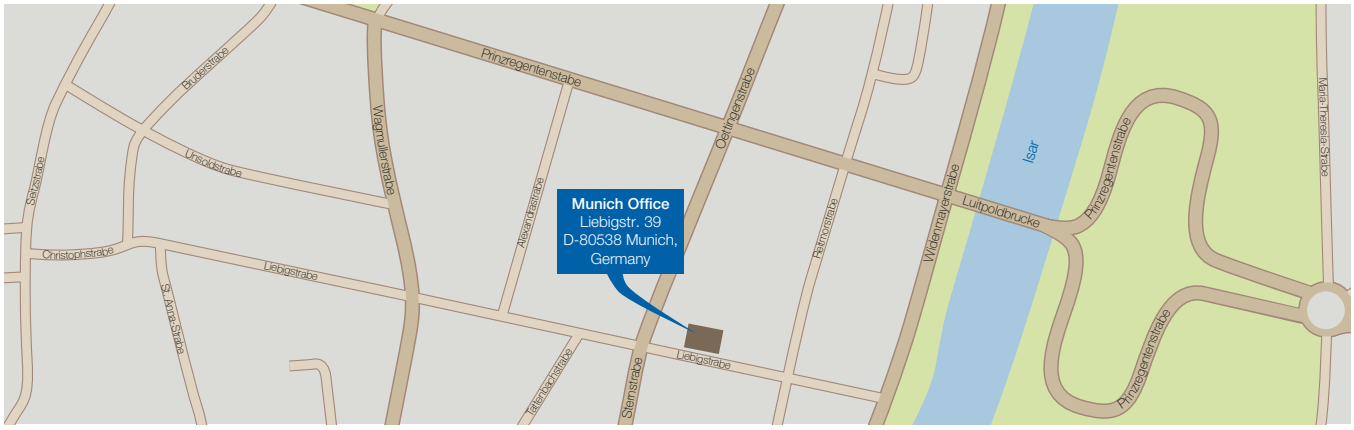
New Munich office location



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