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Editorial

The UK courts have been busy since our last newsletter, issuing several judgments of great importance to the pharma industry in particular but with broader application regarding contributory infringement and the relevance of the prosecution history. In this edition we discuss these cases as well as a recent US judgment in the hotly competitive field of wearable tech. We also provide updates relating to unitary patent fees and Unified Patent Court fee consultation.

A warm welcome to our new readers, particularly those acquaintances made at the recent British Private Equity and Venture Capital Association High Growth Conference.

Editor:
Neil Nachshen

Events

12 August 2015
Global Patent Applications - Info Tech, Webinar
Nicholas Malden willco-host this IPO (Intellectual Property Owners Association) webinar.

22 September 2015
Software Patents Seminar, London, UK
Ian Harris will be talking about 'Patent Protection for Software-Related and Business-Related Inventions in EU/US'.

25 September 2015
London Design Festival, London, UK
Jonathan Jackson will be speaking about design protection at the V&A during this annual festival.

27-29 September 2015
IPO Annual Meeting, Chicago, US
D Young & Co will be attending the IPO's 43rd annual meeting.

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Strategic patent enforcement / infringement

Jawbone and Fitbit flex their IP muscles

Is this the start of a wearable fitness IP litigation marathon?

In recent years many smartphone manufacturers have battled one another in IP disputes to try and gain a commercial advantage in a rapidly expanding market. At the peak of Samsung and Apple's IP battle there were around 50 IP disputes globally. Following maturity in the sector, whilst little skirmishes continue, the battle is far less fierce than it once was.

A new IP war?

In June 2015, two wearable technology market leaders locked horns in what could be the start of a new global controversy. Jawbone, the $3 billion valued company, hit Fitbit with a patent infringement suit, alleging that Fitbit is infringing three of its US patents. Jawbone is seeking both damages and an injunction to stop Fitbit from selling many of its products in the US.

The three patents relate to various technical features within fitness and health tracking bands:

1. US 8,446,275 relates to the app which receives and processes the data from a smartband.
2. US 8,073,707 relates to the combination of the smartband and the app for reporting physiological information to the user.
3. US 8,398,546 relates to the combination of the smartband and the app, but this time for managing a user's weight.

The final two patents were purchased in April 2013 as part of the $100 million take-over of the Pittsburgh based wearable tech pioneer BodyMedia by Jawbone's parent company, AliphCom. As market leaders, both Jawbone and Fitbit have invested vast amounts of money in R&D and protected this investment with patents. In fact, Jawbone says it has spent more than $100 million on R&D and has hundreds of patents. Fitbit hits back saying it too "independently developed and delivered innovative product offerings". Fitbit says it has more than 200 patents and patent applications of its own and that it would "vigorously defend itself against these allegations". This suggests a counter suit is quite possible, and perhaps we should brace ourselves for a new IP war: both these companies clearly understand how to use their investment in patents in both an offensive and defence manner.

Given that the dispute has arisen in another fast paced market, could the dispute between Jawbone and Fitbit take a different path to that of Apple and Samsung?

Let's look at the IP held by each participant in this dispute. EnvisionIP has released analysis of the types of patents owned by Jawbone and Fitbit in the US, highlighting a marked difference between each company's approach to IP, in particular patents.

The first difference is in how each company obtains its IP rights. Jawbone acquired 147 of its 156 US patents when it took over BodyMedia. Most of Fitbit's IP has been generated in-house, with a seemingly much smaller proportion being acquired.

The second difference lies in where each company considers the innovation in their products to be. Roughly half of Jawbone's patents are design patents, protecting the look of the product. This follows the quirky design of many of Jawbone's products, such as the fitness bands that clasp over the wrist and the unique surface decoration which runs through many of its products. On the other hand, Fitbit has just over 10% of its portfolio concentrated on the look of the product and a much larger percentage (over 50%) protecting the software within the app and the wearable device.

> As Fitbit has focussed on protecting the functionality (rather than appearance) of its products, Fitbit can assert its IP against unique functionality of a wearable device rather than its particular form-factor.

This puts Fitbit in a very strong bargaining position in counter-suing in an emerging market where stopping a competitor

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Jawbone hit Fitbit with a patent infringement suit in June 2015

device from having certain functionality can quickly erode market share.

Indeed, one can speculate that this composition of IP may partly explain why Jawbone has brought this suit in the first place. In what on the face of it seems a counter-intuitive move, Jawbone may have struck first as it wished to protect itself from future patent disputes with Fitbit. The logic is quite simple: if Jawbone brings a patent infringement suit early, Jawbone and Fitbit can negotiate a settlement where they each agree to cross licence their patents to one another. This early agreement allows Jawbone to cease worrying about Fitbit's seemingly larger utility patent portfolio and instead to focus on the risks brought as giant companies such as Google, Apple, Sony, Qualcomm and the like enter the wearable technology market, as each of these have much larger patent portfolios than Jawbone and Fitbit combined.

Alternatively, of course, this suit could have been brought for more conventional reasons. Fitbit has just launched its first IPO and bringing an infringement action against a company about to launch an IPO is not uncommon. This is for two main reasons. The first is because the uncertainty associated with a suit like this can negatively impact the IPO and thus harm your competitor. Secondly, after an IPO, companies tend to be cash rich, meaning that they are wealthy targets.

In a remarkable prediction, Fitbit noted in its IPO filing in May 2015 that it operates in a "highly competitive" market and that "competition in [the] market will intensify in the future".

IP strategies in the wearable tech market

Clearly, it is imperative that a company in the wearable tech space protects all novel aspects of its products. In the case of Jawbone, for example, the surface decoration applied to many of its products is unique and thus capable of design protection.

With regard to protecting novel functionality, it is important where possible, to include claims that cover the software running on the wearable device without reference to the wearable device itself. This enables the patent proprietor to sue the manufacturer of the software or the wearable device for direct infringement of their patent. On the other hand, if the set of claims is unnecessarily directed to only a combination of both the smartphone and the wearable device then the patent proprietor would be restricted to suing any competing manufacturer for contributory infringement, which is less desirable.

Of course, once a company has secured IP, commercial value needs to be extracted from it. Looking back to the smartphone wars, one way in which Samsung and Apple tried to extract value was to use the courts to try and block one another from selling in different markets. This however had limited success. Typically, by the time the court had decided to grant an injunction stopping the sale of a particular product, that product was already outdated and sales were consequently limited, reducing the impact of the injunction considerably.

Furthermore, although there were some huge damage awards (most notably the $1 billion award to Apple which was subsequently reduced on appeal), the cost of the legal wrangle and awards to the other side ate into pay outs for damages considerably. On reflection, are there better ways of extracting commercial value from IP in the wearable tech space?

Court proceedings are a very powerful tool. However, the options open to the court in terms of settlement are quite limited. The court can order damages and injunctions stopping the sale of competing products in a public proceeding. However, the downside of this is that the cost consequence to both parties of a full trial, although less than it once was, is still high. Also, as most defendants will challenge the validity of the IP, if such a challenge is upheld, the IP right holder will not only lose the dispute but may also lose their IP right. One common approach to settlement out of court in the electronics sector is, of course, cross licencing, as noted above.

Other dispute resolution mechanisms are possible which do not preclude subsequent court actions should the need arise. One such mechanism is mediation. Mediation is a negotiation between the disputing parties with a neutral third party assisting the negotiation to reach settlement. This type of dispute resolution is cheaper than litigation and allows broader commercial discussions to be had. This is particularly useful for companies in fast growing markets such as wearable technology in that many more options are open to the participants to resolve the dispute. Rather than the limited (albeit powerful) mechanisms open to a court, participants can be creative in settling the terms of a resolution, to involve all aspects of the company. Further, resolution can be reached quite quickly after the mediation process has commenced. This is particularly useful in a fast-paced market such as wearable technology.

So, as Jawbone and Fitbit dust off their IP gloves and throw their first legal punches, it will be interesting to see if the dispute actually escalates to the global war of Apple and Samsung. It may well be that their competitive strategies will allow both sides to take a different tack.

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‘True Top 4’ fee schedule
EPO announces decision on unitary patent fees

Whilst the introduction of the unitary patent is likely to be several years away, the question of how much unitary patent (UP) renewals will cost is relevant now as these are likely to affect applications already pending before the European Patent Office (EPO).

The EPO has now answered this question with an announcement on 24 June 2015 that unitary patent renewal fees will be set using the so-called ‘Top 4’ fee schedule. This schedule matches existing EPO renewal fees in the early years, before tracking the renewal costs of four of the most frequently validated EP states in later years.

EPO President Benoît Battistelli commented: “I am confident that [this] strikes a positive balance, ensuring that the fees represent a real cost saving to the user and also providing a healthy operating budget for the EPO and the participating member states. This is another major step in achieving truly uniform patent protection in Europe.”[1]

> In this article we investigate whether this really does represent a cost saving to the user, and if so whether this is sufficiently compelling to adopt the unitary patent over the current bundle of European patent rights.

Current renewal fee scheme

The EPO levies annual renewal fees starting with the third year after filing an EP application. The fees are paid directly to the EPO while the application is pending, and are paid to the national patent offices of validated states after grant (with 50% of these renewal fees then returning to the EPO).

These national fees increase annually, but a proprietor can manage their renewal costs by successively dropping those states where costs exceed perceived benefits. Consequently it is commonplace for patents to be widely validated at grant, but to geographically narrow to a small number of high GDP or strategically important states over time. As a result, a proprietor has considerable control over the renewal costs of their portfolio.

Unitary patent renewal fee scheme

The EPO will again levy annual renewal fees starting with the third year after filing an EP application, based on the ‘Top 4’ fee scheme shown in the table below. The EPO will retain 50% of the fee and share the remainder between the member states of the unitary patent scheme, most likely on a pro rata basis reflecting the current rate of validations. Unlike the current scheme, a proprietor cannot reduce fee payments by dropping states over time; the unitary patent is all-in or all-out. However it is important to note that both the current scheme and the unitary patent scheme will co-exist (not least to service non-members of the unitary patent scheme), and entry into the unitary patent scheme has to be actively requested within one month of grant.

Comparison of the schemes

Under the current scheme, the top three validating states are the UK, France and Germany, with each of Austria, Belgium, the Netherlands, Spain, Sweden, and Switzerland making a creditable claim to be 4th.[2] However since neither Spain nor Switzerland will participate in the unitary patent scheme, we will limit ourselves to a consideration of these four remaining states.

Taking the average of the four-state scenarios, the unitary patent renewal scheme is significantly more expensive until around year seven, but then tracks the average fairly faithfully from around year ten. However, it’s worth noting that the EPO’s average pendency to grant is five years[5]; consequently an applicant will typically pay EPO renewal fees up to the fifth or sixth year anyway. Consequently in practice the comparative difference in renewal fees between the ‘Top 4’ scheme and national fees in the early years has less impact than the raw figures in this table would suggest. Hence for those who typically file in three or four European states covered by the unitary patent scheme, the ‘Top 4’ fee schedule is likely to represent good value as an alternative to national renewal fees, whilst for those who validate widely, clearly there are significant savings to be made.

Translation and administrative costs

Currently for the top three states of DE, FR and GB, no translation costs are incurred beyond the mandatory translation of the claims into the three EPO languages at grant, which applies regardless of the states being validated. With respect to the fourth state in our example, if the patent was in German, Austria has no translation requirements, whilst if the patent was in English, the Netherlands and Sweden have no translation requirements.

By contrast, in addition to the mandatory claims translations at grant, the unitary patent requires a translation of the full text of the patent into English (if prosecuted in French or German) or, if prosecuted in English, a translation into an official EU language of the applicant’s choice (which can be selected, for example, to be relevant to a competitor or to the seat of the relevant central unified patent court for the subject matter of the patent). Whilst this could represent a sizeable increase in cost at grant for those applicants only filing in three or four states, it again represents a considerable saving for those who validate more widely, and particularly in states outside the London Agreement.

There is an assumption that the official fees at grant will not change, because the decision to use the unitary patent option can be taken up to one month after grant; however in these circumstances the additional translation of the application is likely to incur a separate page fee, raising the possibility for a supplementary grant fee to also be levied.

Meanwhile, the administrative costs of renewal in four states is comparatively small in relation to the fees themselves; it remains to be seen at what level service providers will set the administrative cost of paying a unitary patent renewal fee, but it is likely to be higher than that of a single state renewal to reflect the greater liability of the service provider in the event of error, and

Further information

To keep up to date with all our unitary patent (European patent with unitary effect) and Unified Patent Court articles and commentary, please visit and bookmark our website unitary patent page: www.dyoung.com/unitarypatent.

The 'Top 4' UP scheme, compared with common combinations of validated states

Year	EPO Pending	Top 4 Granted UP	DE, FR, GB, Granted EP	DE, FR, GB, AT	DE, FR, GB, BE	DE, FR, GB, NL	DE, FR, GB, SE
1	0	0	0	0	0	0	32
2	0	35	36	36[3]	36	36	84
3	465	105	106	106[4]	141	106	166
4	580	145	106	106	156	146	214
5	810	315	224	224	289	324	365
6	1,040	475	328	432	412	488	501
7	1,155	630	426	634	526	646	621
8	1,265	815	552	865	677	832	790
9	1,380	990	670	1,087	815	1,010	941
10	1,560	1,175	798	1,320	968	1,198	1,101
11	1,560	1,460	986	1,612	1,181	1,486	1,321
12	1,560	1,775	1,204	1,935	1,424	1,804	1,572
13	1,560	2,105	1,440	2,275	1,690	2,140	1,851
14	1,560	2,455	1,696	2,636	1,986	2,496	2,140
15	1,560	2,830	1,980	3,024	2,310	2,880	2,456
16	1,560	3,240	2,294	3,442	2,664	3,294	2,803
17	1,560	3,640	2,604	3,857	3,014	3,704	3,145
18	1,560	4,055	2,924	4,281	3,379	4,124	3,508
19	1,560	4,455	3,234	4,800	3,734	4,534	3,851
20	1,560	4,855	3,540	5,315	3,985	4,940	4,189
Total	**23,855**	**35,555**	**25,148**	**37,987**	**29,387**	**36,188**	**31,651**

their financial exposure in paying a larger single fee. Again, those who validate more widely may see a more significant saving.

The future

The proposed 'Top 4' fee schedule comes with one very important caveat – it is subject to review in four years' time. This is significant for the simple reason that the unitary patent can come into effect only once twelve states have ratified the agreement – meaning that initially 50% of the renewal fee will be divided between twelve national offices. However, as additional states join the scheme, this same fee may eventually be shared between twice as many countries. As a result, it seems sensible to assume that the fee schedule will increase ahead of inflation over the next decade and may eventually increase by 50% or more in real terms.

Conclusions

For those who typically file in three or four states covered by the unitary patent scheme, the 'Top 4' fee schedule represents good value, providing coverage in a significant number of additional states for significantly less than the cost of one additional state under the current system, although it should be recognised that the renewal fees may increase in four years' time. Nevertheless, it seems reasonable to consider a portfolio comprising a mixture of conventional bundled European patent and unitary patents in complementary subject areas, to balance geographical coverage with resilience to risk.

Meanwhile for those who typically file in many states (for example ten or more), the renewal and translation savings will be large. For these proprietors, the potential savings suggest that it may be worth considering a patent review process to identify 'tier 1' and 'tier 2' patents at grant where possible, and use the unitary patent scheme as a cost-effective warehousing option for lower value/risk cases.

We have reviewed the unitary patent renewal fee solely on the basis of cost; the changes in risk associated with the unitary patent – which need to be weighed against these costs – will be the subject of a further article[6].

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Notes

1. dycip.com/epoupfees
2. Notably, this doesn't reflect the GDP of EP member states, since Italy and Turkey both have GDPs greater than Austria, Belgium, Sweden, Switzerland and the Netherlands; however the top validated states typically have a strategic value, for example in terms of Austria's close relationship with Germany, or the significant volume of imports into the EU through the Netherlands.
3. Only France charges a renewal fee for the second year.
4. France and Germany only; the UK starts charging with the fifth year.
5. See dycip.com/iptstats13, page 68, footnote 43; average pendency to grant is 36 months after allocation to an examiner, in turn typically six months after publication of the search report. For some technology areas, the pendency is notably longer.
6. The main risk is of unitary revocation of the patent, compared to per-state revocation for national rights. A related risk arises from the (possibly unwanted) broader geographical scope triggering more searches and oppositions of granted patents. A further perceived risk is the associated commitment to the as-yet untested unified patent court.

Actavis v Eli Lilly
Contributory infringement found on appeal for Actavis

After judge Arnold J declared that Actavis was not infringing Eli Lilly's European patent in France, Italy, Spain or the UK[1] the Court of Appeal have now taken a broader approach to the construction of the claims and found that Actavis are contributory infringers[2]. Additionally, the Court of Appeal have warned **against** relying on the prosecution history of the patent to construe the claims.

Background

Eli Lilly's Patent (EP 1 313 508 B1) granted on 18 April 2007 with both Swiss-type claims and purpose-limited product claims directed to the use of pemetrexed disodium. The Swiss-type claim read (emphasis added):

> "Use **of pemetrexed disodium in the manufacture of a medicament for use in combination therapy** for inhibiting tumor growth in mammals, wherein said medicament is to be administered **in combination with** vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin, perchlorate, azidocobalamin, chlorocobalamin or cobalamin."

At first instance in the Patents Court, Arnold J granted Actavis declarations of non-infringement (DNI) in France, Italy, Spain and the UK for generic products containing pemetrexed diacid, pemetrexed dipotassium or pemetrexed ditromethamine. Arnold J concluded that there was no direct or contributory infringement and that applying the infringement laws of France, Italy and Spain would lead to the same result as the application of English law.

In coming to this conclusion Arnold J relied on the prosecution history of the patent. He stated that "consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement". During prosecution of this case, Eli Lilly had narrowed the claims to pemetrexed disodium in order to overcome clarity, sufficiency and added matter objections.

Eli Lilly appealed and in the Court of Appeal, Lord Justice Floyd gave the only reasoned judgement.

Claim construction: prosecution history

Unlike Arnold J, however, Floyd LJ did not rely on the prosecution history to construe the claims. He explained that he had "difficulty" endorsing Arnold J's reasoning because:

- it assumes that the skilled reader will always read the prosecution history; and
- it suggests that the story told by the prosecution history will assist the court in preventing abuse of the system.

Floyd LJ also noted that patent offices are usually concerned with patentability not scope of protection.

Claim construction: improver questions

Floyd LJ instead made reference to the established case law on claim construction and to the teachings of the patent specification.

Pemetrexed disodium is an antifolate and LJ Floyd noted that there were several passages in the patent where the use of "**the** antifolate" rather than "**an** antifolate" was indicative that the invention was not concerned with the use of antifolates as a class, but with the use of a specific antifolate. He thus concluded that it was clear that the claims were limited by the term "pemetrexed disodium".

LJ Floyd acknowledged that English courts do not apply a general doctrine of equivalence to the construction of patent claims, but that this "does not mean that the existence of equivalents which have no material effect on the way the invention works has no bearing on the proper, purposive interpretation of a patent claim". This is borne out by the 'improver' or 'protocol' questions which ask:

1. Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
2. Would this have been obvious at the date of publication of the patent to a skilled reader? If no, the variant is outside the claim. If yes?
3. Would the skilled reader nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

As will become clear from the discussion below, one of the key issues in the present case was question (2). LJ Floyd stressed that this question asked what would be obvious "in the sense of immediately apparent" to a skilled reader reading the patent in light of his common general knowledge.

Direct infringement

Floyd LJ agreed with Arnold J that Actavis did not directly infringe Eli Lilly's patent. He decided that the claim did not extend to cover the use of other pemetrexed salts because, like Arnold J, he was not convinced that the second or third improver question had been answered positively.

Whilst Actavis' active ingredients would not have had a material effect on the way the invention worked, Floyd LJ agreed that this would not have been obvious to the skilled reader. The skilled reader would not have been able to predict whether a particular salt form could be made and/or what its properties would be once it was made, eg, whether the salt would be sufficiently soluble to effectively treat the disease.

Floyd LJ explained that the latter is important for a Swiss-type/purpose-limited product claim because these claims include the step of manufacturing a medicament for treating a disease. The claim therefore requires that the manufactured medicament is to some extent effective for treating the disease.

Notes and further information

1. *Actavis UK Ltd & Ors v Eli Lilly & Company, [2014] EWHC 1511 (Pat)*
2. *Actavis UK Ltd & Ors v Eli Lilly & Company, [2015] EWCA Civ 555 (25 June 2015)*
3. *Grimme Maschinenfabril v Scott, [2010] EWCA Civ 1110*

Contributory infringement

Floyd LJ, however, came to the opposite conclusion for contributory infringement.

Contributory infringement is assessed under section 60(2) of the Patents Act 1977 which states that a person infringes if they supply or offer to supply in the UK, the means relating to an essential element of the invention, for putting the invention into effect when the person knows that those means are suitable for and intended to put the invention into effect in the UK.

> In the present case, contributory infringement was alleged because each of Actavis' active ingredients would be dissolved and/or diluted in saline before administration to the patient. The result is thus a solution containing pemetrexed ions and sodium ions.

Arnold J held that this did not give rise to contributory infringement because pemetrexed disodium per se was not used in the manufacture of the medicament. Floyd LJ, however, disagreed.

Floyd LJ noted that the patent was not limited to solid pemetrexed disodium, but included solutions containing pemetrexed ions and sodium ions.

He also highlighted that section 60(2) refers to a means **relating to** an essential element of the invention, and that in the present case this clearly included a means for releasing pemetrexed ions into solution. The invention is thus put into effect when a pharmacist makes up the solution using Actavis' active ingredients because there comes a stage when pemetrexed disodium is present and is used.

In coming to this conclusion, Floyd LJ referred to the earlier Court of Appeal case:

Activis was found not to directly infringe Eli Lilly's patent at first instance and on appeal

Grimme Maschinenfabril v Scott[3], where the court recognised that the "essential means" of section 60(2) did not have to be something which could be used without alteration. Pemetrexed dipotassium was therefore a means relating to an essential element of the invention.

Consequently, Actavis were refused their DNIs under English law. DNIs were also refused for France, Italy and Spain since there are no detectable differences in their approach to contributory infringement.

It is interesting to note that the Court of Appeal's conclusion on contributory infringement contradicted that of the Düsseldorf Court of Appeal (Oberlandesgericht Düsseldorf) for the German designation of the patent. Floyd LJ reasoned, however, that the German court appeared in the judgment to understand "pemetrexed disodium" as describing only that substance in solid form.

Comments

Although no decision was made by the Court of Appeal as to the admissibility of the prosecution history, Floyd LJ's comments give some guidance as to the Court of Appeal's position on this issue. Reassuringly this is the status quo in that the prosecution history has little weight when construing the claims of a patent in the UK. This is good news for applicants, patent proprietors and practitioners. Care should, however, still clearly be taken when making amendments and arguments during prosecution.

This case also contributes to the ongoing development of the law on contributory infringement of second medical use claims. See the article on page 10 of this newsletter for further discussion of the dispute between Warner-Lambert and Actavis on the scope of section 60(2) for Swiss-type claims.

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Unified Patent Court
Fees consultation

Further information
To keep up to date with all our unitary patent (European patent with unitary effect) and Unified Patent Court articles and commentary, please visit and bookmark our website unitary patent page: www.dyoung.com/unitarypatent.

In our June 2015 newsletter, we reported on the launch of the consultation on the fee regime for the Unified Patent Court (UPC). We have since had some time to review that consultation and while it will have closed for comment by the time this newsletter is published, we share some of our thoughts with our readers. We have been actively participating in the responses on behalf of several organisations, and although some views differ, overall there are large areas of agreement on the key aspects.

Value-based fees

As is well known, the UPC fee regime will have both fixed and substantial value-based fees. This is expressly provided for in the UPC Agreement and is said to be necessary in order for the UPC to be self funding. However, substantial value-based fees are an alien concept to EU jurisdictions save Germany, which has a well-established scheme. This scheme is understood to work reasonably well and it is our understanding that there are comparatively few disputes over valuation in Germany (although there are some).

That is not the same thing of course as saying it is popular with users, nor does it necessarily follow that there will similarly be few disputes over valuation in the UPC. We rather doubt that will be the case bearing in mind that most users and advisers come from jurisdictions without this sort of scheme. It is therefore somewhat disappointing that the Preparatory Committee was unable to issue draft valuation guidelines in the consultation, although it is clear that there will be some in due course. We understand this is because the draft could not be agreed in time for the consultation. It seems pretty clear to us that the basis upon which cases will be valued is fundamental to being able to comment on whether the fee regime is appropriate and it needs to be made clear as soon as possible what that basis will be. Reasonable people will differ over valuation.

We would also note that as currently presented, value-based fees will apply to infringement claims and counterclaims, declarations of non-infringement, damages actions and appeals. Values are also relevant for costs recovery (see below). It is unclear however whether the same value will apply in each case, nor whether so many value-based fees are actually necessary for the running of the court. We have been suggesting (a) a single valuation only and (b) no more value-based fees than absolutely necessary. A large case that goes to a damages enquiry and appeal could attract value-based fees in the region of €660,000 (or €880,000 if there is duplication of fees in a declaration of non-infringement/infringement action – which we think is a bad idea). These do indeed seem rather high, although we would note that they are rather lower than value-based fees in Germany in a similar case.

Fee reductions

The UPC has long been promoted as a cost-effective answer to patent enforcement difficulties across Europe. It has also been promoted as a forum in which SMEs may be able to enforce their rights effectively. It is recognized however that with a value-based fee regime, the UPC could in fact prove to be rather expensive for such entities, perhaps prohibitively so. To try to address this conflict, the fee proposal sets out two alternatives for fee reduction.

The first provides for a rebate of part of the value-based fee where the case is settled or withdrawn at an early stage. As drafted however, we don't see how this can work because the value-based fee is not in fact payable, under the Rules of Procedure, until a relatively late stage. We also think that there is a large enough incentive to settle early as it is, since this could avoid the value-based fee entirely and obviously reduce costs generally.

The second provides a targeted fee waiver regime, under which certain entities, including SMEs, would not pay any value-based fees. This is rather more in keeping with the principles of the UPC, which include access to justice for SMEs. However, many have expressed concerns with the proposal since it is not means tested and instead is 'entity based' – in essence, if you qualify as a certain kind of entity you get the benefit. This could be open to abuse through corporate or other structuring, which must be avoided. Perhaps a means tested relief system, with disclosure requirements, would be better.

Costs recovery ceilings

The other area of significance in the consultation is the notion of cost recovery caps, to reduce the risk to litigants of exposure to the uncontrolled costs of the other side. The Intellectual Property Enterprise Court (IPEC) in London has a very strict regime of cost recovery limitation, which applies a maximum overall recovery of £50,000, with individual stages also subject to their own caps. This is not value based as such. It was brought in to limit the exposure of litigants to the risk of having to reimburse the other side's costs, over which they have no control. That risk was a substantial deterrent to smaller entities commencing proceedings in the UK and the new IPEC regime has been very effective.

The UPC fees consultation proposes something similar, although on a sliding scale based on case value. This introduces a further valuation issue. Will the same value as that used for the action itself be used? This makes sense, although as there is no value-based fee for revocation actions somehow valuation in these circumstances needs to be dealt with. It also raises the tricky question of how to value an invalidity action, an area in relation to which we know there are substantial disagreements. This makes the guidelines on valuation even more important.

Update on the Rules of Procedure

The Preparatory Committee of the UPC met on 10 July 2015 and discussed the 18th draft of the Rules of Procedure. From the report of that meeting on the UPC website, it seems the expectation is to have finalised the rules by October 2015. It was noted that there are some items to finalise, and these must include consequential changes arising from the fees consultation. For example, the rules currently do not provide for a value-based fee for an appeal, although the fees consultation clearly contemplates this. It will also be interesting to see how the opt out for conventional European patents is proposed to be administered prior to the coming in to force of the UPC Agreement, since currently that remains somewhat unclear.

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Numerical limits revisited
Smith & Nephew v Convatec

Notes and further information

1. *Smith & Nephew v Convactec [2015] EWCA Civ 607*
2. *It should be noted that this is far from being the only approach adopted in the EPO.*
3. *Kirin Amgen Inc v Hoechst Marion Roussel Ltd [2004] UKHL 46*
4. *PLG v Ardon [1993] FSR 197*
5. *Auchincloss v Agricultural & Veterinary Supplies Ltd [1997] RPC 649*
6. *Lubrizol v Esso [1997] RPC 195*
7. *TH Goldschmidt v EOC Belgium (25 January 2000)*

Numerical limits in patent claims are, it seems, always open to interpretation, despite numerous cases that have considered the issue. A recent case in the English Court of Appeal, Smith & Nephew v Convactec[1] serves to illustrate why. The case concerned a process for the silverisation of gel-forming fibres used in wound dressings. A key step in the process involved subjecting the gel-forming fibres to an agent which facilitates the binding of the silver to the fibres, wherein the according to the claim the agent must be present in a concentration between 1% and 25% of the total volume of treatment. The defendant wished to use a process that involved a concentration of binding agent which did not exceed 0.77%, and sought a declaration of non-infringement to that effect.

First instance decision

At first instance, the judge held that the proposed process did not infringe. He did so applying "significant figures" interpretation to the numerical limits in the claim. On that basis, the lower end limit was expressed to one significant figure and accordingly "1%" meant 0.95% - 1.4%. Thus 0.77% was below the claimed range. Interestingly, the upper end was expressed to two significant figures, and therefore 25% here meant 24.5%-25.4%. It is worth noting that the accuracy of deterination at the different ends of the claimed range would therefore have to be different, under this interpretation.

The Court of Appeal's approach

Convatec, having lost at first instance, appealed on the basis that the claim limits should be construed as being to the nearest whole number – thus 1% encompassed 0.5% and above, and therefore there was infringement at 0.77%. By contrast, Smith & Nephew contended that the claim limits should be interpreted precisely as 1% and 25%, with no rounding, an approach that has been adopted in a number of European Patent Office (EPO) decisions.[2]

The judge reviewed numerous UK and EPO decisions involving numerical limits.

Kirin Amgen Inc v Hoechst Marion Roussel

The judge stated that, under UK law, the principles of purposive construction in the leading UK decision on interpretation of patent claims generally, Kirin Amgen Inc v Hoechst Marion Roussel [3], applied equally to numerical limits as they do to any other claim integers. Two principles were particularly relevant to this issue:

1. The reader of the claim brings common general knowledge to that reading and understands that the purpose of the limit is to demarcate an invention.
2. The patentee will have chosen the words of the claim on the basis of skilled advice and therefore in so far as the patentee has cast their claim in specific rather than general terms, is likely to have done so deliberately.

PLG v Ardon[4]

A claim limit of "not less than 75%" was infringed where the relevant aspect of the accused product varied from 60% to above 75%, depending on where the measurement was taken. In the judge's view, this was a question of an immaterial variant rather than an expansive interpretation of a numerical limit, and it would be very rare for a numerical limit to be given such an expansive interpretation.

Auchincloss v Agricultural & Veterinary Supplies[5]

The judge agreed that as a general matter numerical limits were quite different to descriptive words when considering "variants". Consideration of variants sits more easily with a word such as "vertical" than it does with an expression such as "between 87.0° and 93.0°".

Lubrizol v Esso[6] & TH Goldschmidt v EOC[7]

The Court of Appeal had interpreted "at least 1.3" as including "1.25 and above" on the basis that 1.3 was expressed to two significant figures, and would have been interpreted as such by the skilled addressee using the conventions adopted by scientists. Similarly, in TH Goldschmidt v EOC a range of "pH 5 to 8" was interpreted as encompassing values from 4.6 to 4.9. Had the patentee wished to exclude such values, the claim could have been expressed as "5.0 to 8.0", and the skilled addressee would have known that measurement to this level of accuracy was conventional. The other UK authorities come to very similar conclusions.

In this case, the claimed range was expressed to different significant figures at each end. How therefore should it be interpreted? The judge set out five principles that he felt were of particular relevance to this kind of claim. Perhaps the most important are that the meaning and scope of a numerical range must be ascertained in the light of the common general knowledge and the context of the patent as a whole; and that the skilled person may understand from all of these circumstances that the degree of precision set out in the claim is intended to include all values within that range, stated to the same degree of precision.

Having reviewed the patent as a whole, the judge rejected the "exact values" approach contended for by the defendant. This was inconsistent with the description which set out a number of values stated to several decimal places – had "exactly 1 to 25" been intended, this would have been inconsistent with that disclosure. He also rejected the first instance judge's approach of applying significant figures to the ends of the claimed range. He noted the anomaly that there would be different degrees of precision at each end and hence asymmetry in the claim. On the evidence and having reviewed the patent, he considered the "nearest whole number" approach to be the right one. The numbers in the claim conveyed a degree of accuracy with which the skilled addressee needs to make a determination of the relevant concentrations, and this should logically be same at both ends of the claim. . Accordingly, the limits were interpreted as being to the nearest whole number, which therefore meant the range extended between 0.5% and 25.4%. There was therefore infringement.

The clear message from this decision is that there is no single applicable approach to interpreting numerical limits. Significant figures, exact values or whole numbers each have their place. Numerical limits will be construed in context, taking into account what the patentee will be understood to have been trying to convey by choosing to express the limits in the way they were. This involves considering such limits with care, both when claiming and considering the validity or infringement of such a claim.

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Could this be foreseen? Court of Appeal changes picture on second medical use claims in UK

The Court of Appeal have overturned the Patents Court's view on the issue of infringement of Warner-Lambert's Swiss-type second medical use patent for pregabalin.

> The Court of Appeal decided there was an arguable case of infringement, ruling that it merely needs to be foreseeable that a pharmaceutical could be used for the indication claimed in the second medical use patent.

This lowers the bar from the 'subjective intention' test in the Patents Court ruling and brings the UK courts more into line with those in the Netherlands and Germany.

Swiss-type claims

A Swiss-type claim takes the form "use of drug X in the manufacture of a medicament in the treatment of disease Y". Swiss claims avoid the exclusion from patentability of methods of treating the human body, as they are directed at pharmaceutical manufacturers and not doctors.

Pregabalin and its marketed indications

Pregabalin is the active ingredient of the Warner-Lambert (part of Pfizer) product Lyrica®. The drug is approved in the European Union (EU) for three medical indications: treatment of epilepsy and generalised anxiety disorder (GAD), both disclosed and claimed in the basic patent covering the active ingredient, and neuropathic pain, which is the subject of a later use patent having Swiss-type claims.

Following expiry of the basic patent and regulatory data exclusivity periods, Actavis and other generic manufacturers prepared to launch a generic version of pregabalin, Actavis' product was sold under the name Lecaent. The generic products were sold with a label only mentioning the epilepsy and GAD indications, and not mentioning the patented treatment of pain. This is known as 'skinny labelling' and is specifically permitted by the EU medicinal products Directive (2001/83/EC). Actavis also launched revocation proceedings against the neuropathic pain use patent.

The court must balance the rights of the patentee with those of the generic manufacturer

On notification of Actavis's plan to market Lecaent, Warner-Lambert counter-claimed for infringement – their concern being that physicians and pharmacists might prescribe and dispense the cheaper generic product for all indications, including off-label prescribing for the patented use of treating neuropathic pain. In advance of full trial concerning the validity of the use patent, Warner-Lambert applied to the court for an interim injunction requiring Actavis to take a series of steps to ensure its generic pregabalin product would not be dispensed for neuropathic pain.

First instance interim judgments in the UK, Netherlands and Germany

In the first instance case before the Patents Court in January, Mr Justice Arnold decided that there was no serious issue to be tried and therefore refused to grant an interim injunction.

Regarding direct infringement of claim 1 under section 60(1)(c) of the UK Patents Act which relates to infringement of a direct product of a process (this section applying as Swiss claims relate to a process of manufacture and not a product, the manufacturer being Actavis and not anyone else further downstream), the word "for" in Swiss-style claims was held to require an element of **subjective intention** on the part of the manufacturer that the medicament will be used for treating the specified condition (neuropathic pain). While Actavis could foresee that the product

might be prescribed for the patented use, Warner-Lambert failed to demonstrate Actavis had the required intention.

Warner-Lambert had also initially pleaded indirect infringement under section 60(2) relating to supplying an essential means to put the invention into effect, but they did not press this point before the Patents Court. Following the initial decision, Actavis pleaded in a separate hearing for this point to be struck out completely. However, prior to the Court of Appeal hearing the Dutch and German courts both ruled in the patentee's favour on the issue of indirect infringement regarding similar 'skinny label' claims.

Interim appeal rulings

The Court of Appeal upheld the decision to refuse the interim injunction but took a different view on whether Warner-Lambert has an arguable case on direct infringement.

The Court of Appeal interpreted the claim that the skilled person would understand that the word "for" in the Swiss claim extended beyond simply making pregabalin, yet fall short of including the step of actually using pregabalin for treating pain (which would be an excluded method of treatment).

However, the Court of Appeal overturned the Patents Court's interim view that subjective intention was required on the part of the manufacturer to directly infringe the Swiss claim, and considered there to be an arguable case of direct infringement not only under section 60(1)(c), but also under section 60(1)(b).

> The Court of Appeal ruled that the skilled person would understand that, if the manufacturer knows or could reasonably foresee that some of the drug will intentionally be used for pain, the manufacturer is making use of the patentee's inventive contribution.

Therefore, the Court of Appeal considered it unnecessary for the purposes of direct infringement that the manufacturer has that specific intention.

The court did acknowledge that this test of reasonable foreseeability raises some difficult questions. For example, a manufacturer selling a medicine before the priority date sees an increase in sales in relation to the new use that the manufacturer does nothing to solicit or even actively discourages – is it right that the manufacturer is made an infringer on the basis that the increase in sales was foreseeable?

The court must also balance the rights of the patentee to enforce the second medical use patent with those of the generic manufacturer to lawfully market the product for the off-patent uses. The court proposes that the answer to these issues of potential unfairness lie in the relief that may be granted on a finding of infringement.

The Appeal Court also considered there to be an arguable case of indirect infringement. The court gave weight to the Dutch and German decisions which considered that indirect infringement could occur in the circumstances of the case.

Based on their finding of threatened or actual infringement of the process claim under section 60(1)(b), the court also found that dealings downstream in the direct product of the process could also be infringements under section 60(1)(c).

Regarding indirect infringement under section 60(2), significantly the Court of Appeal found that the person supplying the means to put the invention into effect (with the requisite knowledge that it could be used for the stated indication) and the person who intentionally uses it for that indication need not be the same person. Therefore, the Court of Appeal ruled that there was an arguable case that the Swiss claim could be indirectly infringed if pregabalin is manufactured by one person with that knowledge and supplied to another who intentionally uses it for the treatment of pain.

For these reasons, the Court of Appeal allowed Warner-Lambert's appeal against the striking out of the indirect infringement aspect of their claim and allowed this point to proceed to full trial.

In the first instance proceedings, all parties agreed that the best solution to the problem, at least for interim purposes, was for the National Health Service (NHS) to give guidance regarding prescription.

> The Patents Court issued an interim order to the NHS to prescribe pregabalin by the brand name Lyrica® for pain, but by its generic name for the non-patented indications of epilepsy and GAD. This guidance was subsequently issued by the NHS.

Warner-Lambert made further arguments before the Court of Appeal to attempt to overturn this (based on fears that the guidance may be ineffective or not be followed), but the Court of Appeal refused to interfere with the Patents Court's findings of fact and dismissed their appeal on this point.

What happens next?

The full trial was held at the Patents Court at the end of June 2015.

Both issues will probably be appealed, so the Court of Appeal will likely consider this matter once again.

In view of the fundamental issues this case raises regarding interpretation and infringement of second medical use claims, the matter may be further appealed to the Supreme Court.

We will keep you informed of developments in this long-awaited case.

Authors:
Kirk Gallagher & Garreth Duncan

And finally…

D Young & Co event

London Design Festival
Are you protecting your designs?

First staged in 2003, the London Design Festival is one of the world's most important annual design events. The festival programme is made up of over 350 events and exhibitions staged by hundreds of partner organisations across the design spectrum and from around the world.

"During the 9-day period visitors will be able to see a series of exciting and beautiful installations interacting with our world-renowned collections and historic spaces; take part in innovative design workshops; and hear from the best international designers working today to motivate, provoke and discover new creative ideas." Dr. Martin Roth, Director of the V&A.

> D Young & Co is pleased to be a festival partner and will present a free design seminar to take place at the V&A.

Our talk will take place at the V&A, and will be followed by an opportunity to speak with patent, trade mark, design and copyright advisors, who will be on hand to answer IP questions. The V&A will be open until 10pm as an extended Friday opening during the festival.

IP design seminar and IP Q&A
V&A seminar room 1, Friday 25 September
D Young & Co's IP law experts will be presenting this design focused seminar, perfect for those involved in all aspects of design and its commercialisation. Partner Jonathan Jackson, European Patent Attorney and European Design Attorney, will provide delegates with the IP information needed to protect and enforce designs (and for agencies, those of their clients).

The seminar will be of interest to companies and individuals involved in the creative design industry, particularly product and packaging design, design engineering, brand and corporate identity, 2D and 3D design, graphic and digital design and creative marketing solutions.

For further information please see www.dyoung.com/event-ldwdesigns.

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