

What a Chemist Needs to Know... ... about Patents

Prepared for
SCI

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Infringement and Enforcement

What constitutes an infringement?

Infringement – Section 60(1) of the Patents Act 1977

“Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say—.

- (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
- (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;
- (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.”

Infringement – Section 60(2) of the Patents Act 1977

“Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.”

Infringement – Exceptions under the Patents Act 1977

Section 60(5)

Exceptions include acts

- (a) done privately and for purposes which are not commercial;
- (b) done for experimental purposes relating to the subject-matter of the invention
- ...
- (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or any other act which is required for the purpose of the application of those paragraphs

Infringement – Exceptions under the Patents Act 1977

The Bolar Exemption

Article 10 Directive 2001/83/EC

“1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

...”

Infringement – Exceptions under the Patents Act 1977

Section 64(1):

“Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention—

- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or
- (b) makes in good faith effective and serious preparations to do such an act,

has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act. “

Infringement – Exceptions under the Patents Act 1977

Section 64(2):

“If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may—

(a) authorise the doing of that act by any partners of his for the time being in that business, and.

(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.”

Infringement – Exceptions under the Patents Act 1977

Section 64(3):

“Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.”

Enforcement - What to consider

How long is a piece of string!

Enforcement

Your Legal Team

- Patent Attorneys
- Solicitors
- Barristers
- *People with Expertise*
- *People you can work with*
- *People who can work well together*

Enforcement

What is the infringement and where is it occurring? - Identifying all of the defendants and the relevant jurisdictions.

- Product or process or product obtained from a patented process?
- Sale, supply, manufacture, importation? Means essential?
- Use or a process, offering the use of a process?
- Who is carrying out each of the acts?
- Where are the acts occurring?
- What are the key pressure points, sales outlets, factory, distribution centres?

Enforcement – Which Jurisdictions

If multiple jurisdictions one needs to decide:

- Which jurisdictions to use (time to trial, experience and cost are key considerations)
- How to co-ordinate the different actions across Europe.
 - You do not want contradictions between the different cases, yet different procedures have different requirements.
 - You may want to control the timing between litigation in different countries to give you the greatest chance of the first victory (e.g. parallel litigation in Germany and the UK).
- Pick a firm to manage the action for you on a day to day basis?

Enforcement – High Court or IPEC

In the UK you need to decide whether to litigate in the High Court, or the Intellectual Property Enterprise Court “IPEC”.

- IPEC has a damages Cap of £500,000; but, has a costs exposure cap of £50K.
- IPEC will deal with ‘simple’ patent cases which require 2 days or less trial time.
- IPEC has a more ‘hands on’ and ‘up-front’ approach.

Enforcement

Is the Patent Valid?

- Is there time to road test the patent?
- Searches at the time of prosecution may not have been able to pick up obscure material that is now more accessible (e.g. consider the development of the internet over the last decade and what can now be found)
- Substantial defendants may well put a lot of effort into seeking to invalidate a patent where the infringement is (or could) make them a lot of money.
- Checking the validity before issuing could save you a lot of wasted time and money!

Enforcement – Questions to consider

Does the infringement you identify create a tension (squeeze) with validity?

- Does it stretch the claim language?
- Does it give rise to potential anticipation arguments?
- Does it give rise to insufficiency arguments (does the patent enable the alleged infringement)?

Enforcement

Can you find a relevant expert (specifically the UK)

- Finding an expert whose independent views match with your own is essential to any successful patent action.
- Necessary to provide input on Common General Knowledge.
- Necessary for any case on novelty and particularly inventive step over the prior art that will be thrown at you.

Enforcement

How much time do you have?

- Launch proceedings with an application for a preliminary injunction; or
- enter into dialogue to make the potential defendant aware of the infringement under a cease and desist type letter?

As well as time, you must also consider:

- Whether you can afford to give the relevant cross-undertaking if granted an injunction.
- Unjustified threats.

Enforcement

How do you prove infringement?

- Experiments?? Do you have time to run some tests prior to issuing to check you *can* prove infringement?

How are you going to prove validity?

- Further Experiments??

Enforcement – Customs Seizures

Customs Seizures

- An IP Rights Application for Action (AFA) under Regulation EU 608/2013
- Such applications can be submitted to HMRC for seizure on the UK Border or for seizure of goods at the borders of more than one Member State.
- Guidance can be found on the HMRC website in *Notice 34* at:

[http://customs.hmrc.gov.uk/channelsPortalWebApp/channelsPortalWebApp.portal?nfpb=true&pageLabel=pageLibrary>ShowContent&id=HMCE CL 00244&propertyType=document](http://customs.hmrc.gov.uk/channelsPortalWebApp/channelsPortalWebApp.portal?nfpb=true&pageLabel=pageLibrary>ShowContent&id=HMCE%20CL%2000244&propertyType=document)

Enforcement – Customs Seizures

- The Application requires you to provide information that should enable customs to identify the infringing shipments.
- The applicant must undertake to assume liability for the holder of the goods where, for example, the goods are seized, damaged or destroyed but later found not to infringe and IP rights.
- The applicant undertakes to pay ALL COSTS AND LIABILITIES incurred under the Regulation, including the costs of storage and handling of the detained goods.
- Where goods are seized, the applicant has 10 days for the date of notification of detention to decide whether the goods do indeed infringe, and if so whether to take action.

Facing Infringement Proceedings- What to consider

A similar piece of string!

Facing Infringement Proceedings

How important is the alleged infringement to you?

Can you work round it?

Do you have the time and money to contest the claim?

Is it worth your while to contest the claim?

At minimum get initial advice on the strength of the infringement claim and validity of the patent before deciding that you do not want to fight.

If cost risk is an issue can you transfer the case to IPEC?

Facing Infringement Proceedings

Assuming that you do want to argue the case... time is of the essence

- If you have been served with proceedings, you will only have 42 days to provide a defence. In the High Court these do not necessarily require a great deal of detail, but you will likely want to run an argument that the patent is invalid (if you can).

Facing Infringement Proceedings

- Quickly identify and assemble your legal team
- It is likely that the patentee will have picked the barristers that they want and will have already approached potential experts. You will be behind the game.
- Your own technical expertise will be important as a starting point to identify non-infringement arguments – you know your products – the legal team will understand how this applies to the language of the patent.
- You may also know of potential experts in the field.
- Start your legal team on prior art searches ASAP. Again you may well have an insight into the work carried out at the time.

The Road To Trial


What happens when the patent is enforced.

The Road to Trial - Pleadings

- Issue and Service of Claim Form, Particulars of Claim & Particulars of Infringement
- Service of Defence and likely a Counterclaim for invalidity
- Patentee may Reply to the Defence and will serve a defence to the Counterclaim.
- In the normal course of event there will then be a case management conference to determine the road to trial...
 - Disclosure
 - Experiments
 - Evidence
 - Dates

The Road to Trial – The Patents Court Guide and Model Directions

<http://www.justice.gov.uk/downloads/courts/patents-court/patent-court-guide.pdf>

 HM Courts & Tribunals Service		Issued December 2012 By authority of the Chancellor of the High Court	
The Patents Court guide			
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Amendments to statements of case

3. The claimants have permission to amend their claim form shown in red on the copy [annexed to the application notice/as signed by the solicitors for the parties/annexed hereto] and [to re-serve the same on or before [date]/and that re-service be dispensed with] and that the defendants have permission to serve a consequentially amended defence within [number] days [thereafter/hereafter] and that the claimants have permission to serve a consequentially amended reply (if so advised) within [number] days thereafter.

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<http://www.justice.gov.uk/downloads/courts/patents-court/patent-court-guide.pdf>

Further Information and Clarification

4. (a) The [claimants/defendants] do on or before [date] serve on the [defendants/claimants] the further information or clarification of the [specify statement of case] as requested by the [claimants/defendants] by their request served on the [defendants/claimants] on [date] [and/or]

(b) The [claimants/defendants] do on or before [date] serve on the [defendants/claimants] [a response to their request for further information] [do answer the requests in their request for further information] or clarification of the [identify statement of case] served on the [defendants/claimants] on [date].

The Road to Trial – The Patents Court Guide and Model Directions

<http://www.justice.gov.uk/downloads/courts/patents-court/patent-court-guide.pdf>

Admissions

5. The [claimants/defendants] do on or before [date] state in writing whether or not they admit the facts specified in the [defendants'/claimants'] notice to admit facts dated [date].

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<http://www.justice.gov.uk/downloads/courts/patents-court/patent-court-guide.pdf>

Security

6. The claimants/defendants do provide security for the defendants'/claimants' costs for its claim/counterclaim in the sum of £[state sum] by [paying such sums into court] [specify manner in which security to be given] and that:
 - (i) in the meantime the claim [counterclaim] be stayed [and/or];
 - (ii) unless security is given as ordered by the above date, the claim [counterclaim] be struck out without further order with the defendants'/claimants' costs of the claim [counterclaim] to be the subject of detailed assessment if not agreed.

The Road to Trial – The Patents Court Guide and Model Directions

Lists of Documents

7. (a) The claimants and the defendants respectively do on or before [state date] make and serve on the other of them a list in accordance with form N265 of the documents in their possession custody or control which they are required to disclose in accordance with the obligation of standard disclosure in accordance with Part 31 as modified by paragraph 5 of the Practice Direction - Patents etc. supplementing Part 63.

(b) In respect of those issues identified in Schedule [number] hereto disclosure shall be limited to those [documents/categories of documents] listed in Schedule [number].

Inspection

8. If any party wishes to inspect or have copies of such documents as are in another party's control, it shall give notice in writing that it wishes to do so and such inspection shall be allowed at all reasonable times upon reasonable notice and any copies shall be provided within [number] working days of the request upon the undertaking of the party requesting the copies to pay the reasonable copying charges.

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<http://www.justice.gov.uk/downloads/courts/patents-court/patent-court-guide.pdf>

Experiments

9. (a) Where a party desires to establish any fact by experimental proof, including an experiment conducted for the purposes of litigation or otherwise not being an experiment conducted in the normal course of research, that party shall on or before [date] serve on all the other parties a notice stating the facts which it desires to establish and giving full particulars of the experiments proposed to establish them.

The Road to Trial – The Patents Court Guide and Model Directions

<http://www.justice.gov.uk/downloads/courts/patents-court/patent-court-guide.pdf>

9.
 - (a) The claimants/defendants are to afford to the other parties an opportunity, if so requested, of inspecting a repetition of the experiments identified in paragraphs [specify them] of the notice[s] of experiments served on [date]. Any such inspection must be requested within [number] days of the date of this order and shall take place within [number] days of the date of the request.
 - (b) If any party shall wish to establish any fact in reply to experimental proof that party shall on or before [date] serve on all the other parties a notice stating the facts which it desires to establish and giving full particulars of the experiments proposed to establish them.

The Road to Trial – The Patents Court Guide and Model Directions

Product or Process Description

11. (a) The defendants/claimants do provide a written description together with relevant drawings of the following [product(s)] [process(es)] to the claimants/defendants by [date].
 - i. [description of product or process];
 - ii. [description of product or process]; etc.
- (b) The description served under paragraph (a) shall be accompanied by a signed written statement which shall:
 - (i) state that the person making the statement is personally acquainted with the facts to which the description relates;
 - (ii) verify that the description is a true and complete description of the product or process; and
 - (iii) contain an acknowledgement by the person making the statement that he may be required to attend court in order to be cross-examined on the contents of the description.

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Technical Primer

12. The parties shall use their best endeavours to agree on or before [date] a single technical primer setting out the basic undisputed technology and shall on or before [date] indicate which parts of the technical primer are agreed to form part of the common general knowledge.

The Road to Trial – The Patents Court Guide and Model Directions

Written Evidence

14. (a) Each party shall on or before [date] serve on the other parties [signed] written statements of the oral evidence which the party intends to lead on any issues of fact to be decided at the trial, such statements to stand as the evidence in chief of the witness unless the court otherwise directs;
- (b) Each party shall on or before [date] serve on the other parties [signed] written statements of the oral evidence which it intends to lead at trial in answer to facts and matters raised in the witness statements served on it under paragraph (a) above;
- (c) Each party may call up to [number] expert witnesses in this claim and counterclaim provided that the said party:
- (i) supplies the name of such expert to the other parties and to the court on or before [date]; and
 - (ii) no later than [date]/[[number days] before the date set for the hearing of this claim and counterclaim] serve upon the other parties a report of each such expert comprising the evidence which that expert intends to give at trial.

How to Avoid Infringement

Avoiding Infringement

- Knowing the patent space – due diligence
- Declarations of non-infringement (confidence required)
- Can never guarantee safety

Unified Patent Court & Unitary Patent

Unified Patent Court & Unitary Patent

- Although a European Patent is valid in all EPO contracting states and is obtained under a single application process, once granted, any litigation is fragmented and takes place on a country by country basis.
- At sometime in the future (*potentially* as early as 2015) a new process will come into play.
- Inventors will have the option of applying for a Unitary Patent.
- This Unitary Patent can be litigated before the new Unified Patents Court.

[THIS IS A TALK IN OF ITSELF!]

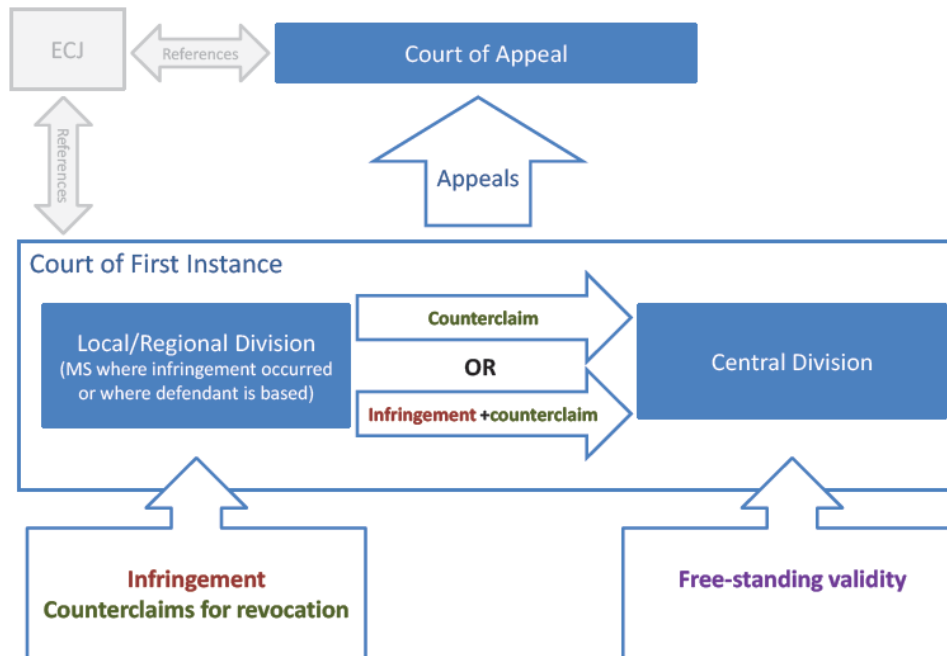
Unified Patent Court & Unitary Patent

- http://ec.europa.eu/internal_market/indprop/patent/faqs/index_en.htm
- Generally, cases will be brought either before:
 - a local division hosted by the Member State where the actual or threatened infringement has occurred or may occur (or the regional division in which this Member State participates);
 - or the local division hosted by the Member State where the defendant has his residence or place of business (or the regional division in which this Member State participates).

Unified Patent Court & Unitary Patent

- http://ec.europa.eu/internal_market/indprop/patent/faqs/index_en.htm
- Some cases will have to be brought before the “central division”, e.g. (direct) revocation actions, infringement actions if the Member State does not host a local division nor participates in a regional division, actions for declaration of non-infringement and actions concerning administrative decisions of the EPO.
- In other cases, the case may be brought or referred by a local/regional division to the central division, e.g. in cases in which the defendant has his residence in a third country, in cases in which both parties agree, in cases of counterclaims for revocation of patents or in cases in which a (direct) action for revocation is already pending before the central division.

Unified Patent Court & Unitary Patent



Source: UKIPO

Unified Patent Court & Unitary Patent

- The Central Division:
 - London will hear cases relating to chemistry, including pharmaceuticals, and the life sciences.
 - Munich will hear cases relating to mechanical engineering (IPC class F).
 - All other cases will be heard by the Paris central division.

Unified Patent Court & Unitary Patent

- A Unitary Patent will stand or fall in a single jurisdiction.
- Some large companies are not keen on using the Unitary Patent as it places valuable eggs in a single basket.
- The system could be prone to jurisdiction shopping:
- “Cases will be brought either before a local division hosted by the Member State where the actual or threatened infringement has occurred or may occur”
- Particularly where the system allows courts to bifurcate.

Unified Patent Court & Unitary Patent

- When Will this occur?

When will the "patent package" enter into force?

The two regulations entered into force on 20 January 2013. They will apply from 1 January 2014 or from the entry into force of the Agreement on a Unified Patent Court, whichever is the later date.

A link is thus made to the entry into force of the Agreement on Unified Patent Court which will enter into force:

- **either** on 1 January 2014
- **or** on the first day of the 4th month after the deposit of the 13th instrument of ratification or accession (whereby France, Germany and the United Kingdom must be included among these 13 states),
- **or** on the first day of the 4th month after the date of entry into force of the amendments to Regulation (EC) 1215/2012 (*Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 20.12.2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJEU L351/1 of 20.12.2010), including any subsequent amendments*) concerning its relationship with this Agreement

whichever is the latest.

In any event, together with the 25 EU Member States participating in enhanced co-operation, the EPO will take all necessary steps to ensure that it is ready to carry out the tasks entrusted to it as soon as the unitary patent system becomes operational.






- <http://www.epo.org/law-practice/unitary/faq.html>

Unified Patent Court & Unitary Patent

Unitary patent – ratification progress

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Member State	Participation in the enhanced cooperation on the unitary patent protection	Signature of the Agreement on a Unified Patent Court	Ratification of the Agreement on a Unified Patent Court
 Austria		 19.02.2013 ¹	 06.08.2013 ²
 Belgium		 19.02.2013 ¹	
 Bulgaria		 05.03.2013 ¹	
 Croatia			
 Czech Republic		 19.02.2013 ¹	
 Cyprus		 19.02.2013 ¹	
 Germany		 19.02.2013 ¹	
 Denmark		 19.02.2013 ¹	
 Estonia		 19.02.2013 ¹	
 Greece		 19.02.2013 ¹	
 Finland		 19.02.2013 ¹	
 France		 19.02.2013 ¹	 14.03.2014 ²
 Hungary		 19.02.2013 ¹	
 Ireland		 19.02.2013 ¹	
 Italy		 19.02.2013 ¹	
 Latvia		 19.02.2013 ¹	
 Lithuania		 19.02.2013 ¹	
 Luxembourg		 19.02.2013 ¹	
 Malta		 19.02.2013 ¹	
 The Netherlands		 19.02.2013 ¹	
 Poland			
 Portugal		 19.02.2013 ¹	
 Romania		 19.02.2013 ¹	
 Slovakia		 19.02.2013 ¹	
 Slovenia		 19.02.2013 ¹	
 Spain			
 Sweden		 19.02.2013 ¹	
 United Kingdom		 19.02.2013 ¹	

Unified Patent Court & Unitary Patent

A difficult decision for patentees

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