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Young EPLAW Congress 2013

News from the SPC front



Christopher Stothers
Partner, London
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Overview

- It's all the UK's fault
- Don't worry, be happy
- Remember the kids

2

It's all the UK's fault
(but watch out for Germany!)

3

Early case law 1992-2010

- | | |
|-----------------------------------|-------------------------|
| ▪ C-350/92 <i>Spain v Council</i> | 13 July 1995 |
| ▪ C-181/95 <i>Biogen</i> | 23 January 1997 |
| ▪ C-110/95 <i>Yamanouchi</i> | 12 June 1997 * |
| ▪ C-392/97 <i>Farmitalia</i> | 16 January 1999 |
| ▪ C-127/00 <i>Hässle</i> | 11 December 2003 |
| ▪ C-31/03 <i>Pharmacia</i> | 19 October 2004 |
| ▪ C-207/03 <i>Novartis</i> | 21 April 2005 * |
| ▪ C-252/03 <i>Millennium</i> | 21 April 2005 |
| ▪ C-431/04 <i>MIT</i> | 4 May 2006 |
| ▪ C-202/05 <i>Yissum</i> | 17 April 2007 (Order) * |
| ▪ C-482/07 <i>AHP</i> | 3 September 2009 |
| ▪ C-66/09 <i>Kirin Amgen</i> | 2 September 2010 |

* = UK reference (3 of 12)

4

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Recent judgments 2011-2012

| | |
|--|----------------------------|
| ▪ C-195/09 <i>Synthon</i> | 28 July 2011 * |
| ▪ C-427/09 <i>Generics (UK)</i> | 28 July 2011 * |
| ▪ C-322/10 <i>Medeva</i> | 24 November 2011 * |
| ▪ C-422/10 <i>Georgetown</i> | 24 November 2011 * |
| ▪ C-518/10 <i>Yeda</i> | 25 November 2011 (Order) * |
| ▪ C-630/10 <i>University of Queensland</i> | 25 November 2011 (Order) * |
| ▪ C-6/11 <i>Daiichi Sankyo</i> | 25 November 2011 (Order) * |
| ▪ C-125/10 <i>MSD</i> | 8 December 2011 |
| ▪ C-442/11 <i>Novartis</i> | 9 February 2012 (Order) * |
| ▪ C-574/11 <i>Novartis</i> | 9 February 2012 (Order) |
| ▪ C-130/11 <i>Neurim</i> | 19 July 2012 * |

* = UK reference (9 of 11)

5

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Current references

| | |
|-----------------------------------|--------------------------|
| ▪ C-443/12 <i>Actavis</i> | [2012] EWHC 2545 (Pat) * |
| ▪ C-484/12 <i>Georgetown</i> | (NL Case AWB 10/4769) |
| ▪ C-493/12 <i>Eli Lilly</i> | [2012] EWHC 2857 (Pat) * |
| ▪ C-617/12 <i>AstraZeneca</i> | [2012] EWHC 2840 (Pat) * |
| ▪ C-TBC/13 <i>GlaxoSmithKline</i> | [2013] EWHC 619 (Pat) * |

* = UK reference (4 of 5)

But watch out for the plant protection references coming from Germany:

| | |
|---|-----------|
| ▪ C-210/12 <i>Sumitomo Chemical</i> | (DE Case) |
| ▪ C-477/12 <i>Hogan Lovells International</i> | (DE Case) |
| ▪ C-11/13 <i>Bayer CropScience</i> | (DE Case) |

6

Current references - issues

Issues to be decided:

- When is a product “protected” by the patent (technical contribution test?)
 - *Actavis; Eli Lilly*
 - **NB** *Eli Lilly also going to trial in UK - on whether an SPC can be filed on a third party MA*
- Can multiple SPCs be granted for different products “protected” by the same patent?
 - *Actavis; Georgetown*
- Is a Swiss MA which is automatically recognised in Lichtenstein a relevant authorisation, and if not what are the consequences?
 - *AstraZeneca*
- Can an adjuvant be an “active ingredient” or create a new “combination of active ingredients”
 - *GSK*

7

What one of the UK judges says

- If...the Court of Justice decides to overrule or qualify *Novartis*, I would request that it says so in clear and unambiguous terms, in order to avoid the need for yet another reference on this issue.

Arnold J, *AstraZeneca*, para 66

- Finally, I would observe that this is the third time in six months that I have had to refer questions of interpretation of the SPC Regulation to the CJEU. I do so with considerable regret. **That this should be necessary demonstrates the dysfunctional state of the SPC system at present. This is primarily due to the poor drafting of the SPC Regulation and to the failure of the European Commission, Council and Parliament to revise it to address the problems which have emerged. Matters have not been assisted, however, by the fact that the Court of Justice's recent case law interpreting the SPC Regulation has not provided the level of clarity and consistency that is required.**

Arnold J, *GSK*, para 86



8

Do the other UK judges agree?

- In my judgment, whatever might have been the position if *Pharmacia* and *MIT* had stood on their own, ***Yissum* is fatal to Neurim's case** on this appeal. Moreover, I consider that it means that **the interpretation of Article 3(d) is *acte clair***. If I were to refer a question to the Court of Justice on the point, I have no doubt that the Court would dispose of it by reasoned order

Arnold J, *Neurim*, para 49



- We consider that **Neurim's arguments** [on Article 3(d)] are not only tenable: in our view they **are right**...if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: **it will not be fit for purpose**. Whether that is so or not is clearly a matter for the EU's highest court.

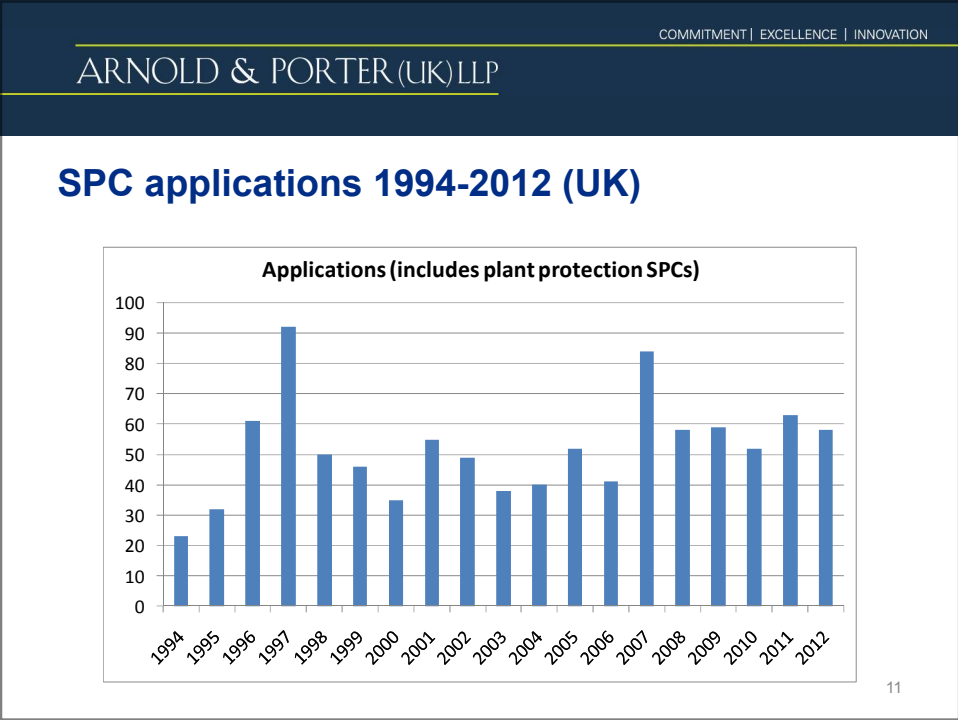
Jacob LJ, *Neurim*, paras 28-30



9

Don't worry, be happy
(SPC life isn't so bad)

10



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SPC grant and challenge 2008-2013 (UK)

- Decisions on grant 221
 - Granted 181 (82%)
 - Rejected 12 (5%)
 - Withdrawn 21 (10%)
 - Surrendered 7 (3%)

- Fate after grant 212
 - Expired 200 (94%)
 - Invalidated 12 (6%)

12

So don't worry, be happy

- Very few SPC applications are rejected (even in the UK)
- Very few are invalidated (even in the UK)
- Most SPCs serve their purpose (even in the UK)
- Cases and references are at the edges (even in the UK)

13

Don't forget about the kids
(they need drugs too)

14

Paediatric Regulation 1901/2006

- Obligation to carry out paediatric studies
- 6 month extension of SPC as “reward”

- Patent + extended SPC – MA + up to 15½ years
- Data exclusivity – MA + up to 11 years
- So paediatric extension will increasingly be “last to expire” right
- MA more important for products authorised late (less than 5½ years before patent expiry)

15

We aren't there yet (UK stats 2008-2012)

- | | |
|-----------|----|
| ■ Lodged | 19 |
| ■ Granted | 15 |
| ■ Pending | 4 |

16

What do the judges have to say about this?



Roth J: "...I have to say even [as] someone who has looked at quite a lot of regulations from the EU, it is not the easiest one to follow."



Kelyn Bacon: "My Lord, I am in full agreement with you and I would entirely agree this is the most difficult regulation I have ever had to construe. It is very tortuous, but that is how it works."

Dr Reddy's v Warner-Lambert, transcript

17

But no reference!

- "Further, although as I have stated it is very possible that the court will decide to make a reference at the conclusion of the trial, I am not convinced that such reference will be necessary"

Roth J, 28 June 2012, para 9

- "I should add that although this is a question of the proper interpretation of the Paediatric Regulation, I see no need to refer this question to the European Court of Justice for a preliminary ruling."

Roth J, 20 Dec 2012, para 73

18

Change on the horizon? 5 year report

- EMA report published 8 July 2012
 - 682 PIPs evaluated by end 2011
 - 29 completed by end 2011
 - 11 SPC extensions granted by end 2011
- Consultation launched 19 September 2012
- Consultation closed 28 November 2012
- Responses published 16 January 2013
- Commission report due 26 January 2013 (or “2013”)

19

What about the *Neurim* case?

- Melatonin was authorised:
 - 2001: to improve sheep reproduction
 - 2007: human insomnia
- Neurim had patent for the second medical use and sought an SPC based on the 2007 MA
- ECJ held: SPC applications for second medical uses are permitted where the later patent doesn't cover the earlier MA
- Doubt already cast on scope (*AstraZeneca*)

20

How does *Neurim* relate to paediatrics?

- Filing a “speculative” SPC *post-Neurim* may have consequences for paediatric studies
- If you are entitled to an SPC and seek new indications for old products (pre-Jan 2009), you may be required to complete paediatric studies
- But SPC applications may take time to decide, so a failed application could be very costly

21

Conclusions

- All the legislation is a mess
...but the system still works reasonably well
- The UK judges get very excited about it
...but why do (some) think the ECJ will help?
- Listening to talks about this is painful
...but just wait until FRAND after lunch!

22

Any Questions?

Christopher Stothers
Arnold & Porter (UK) LLP
christopher.stothers@aporter.com
+44 (20) 7786 6226