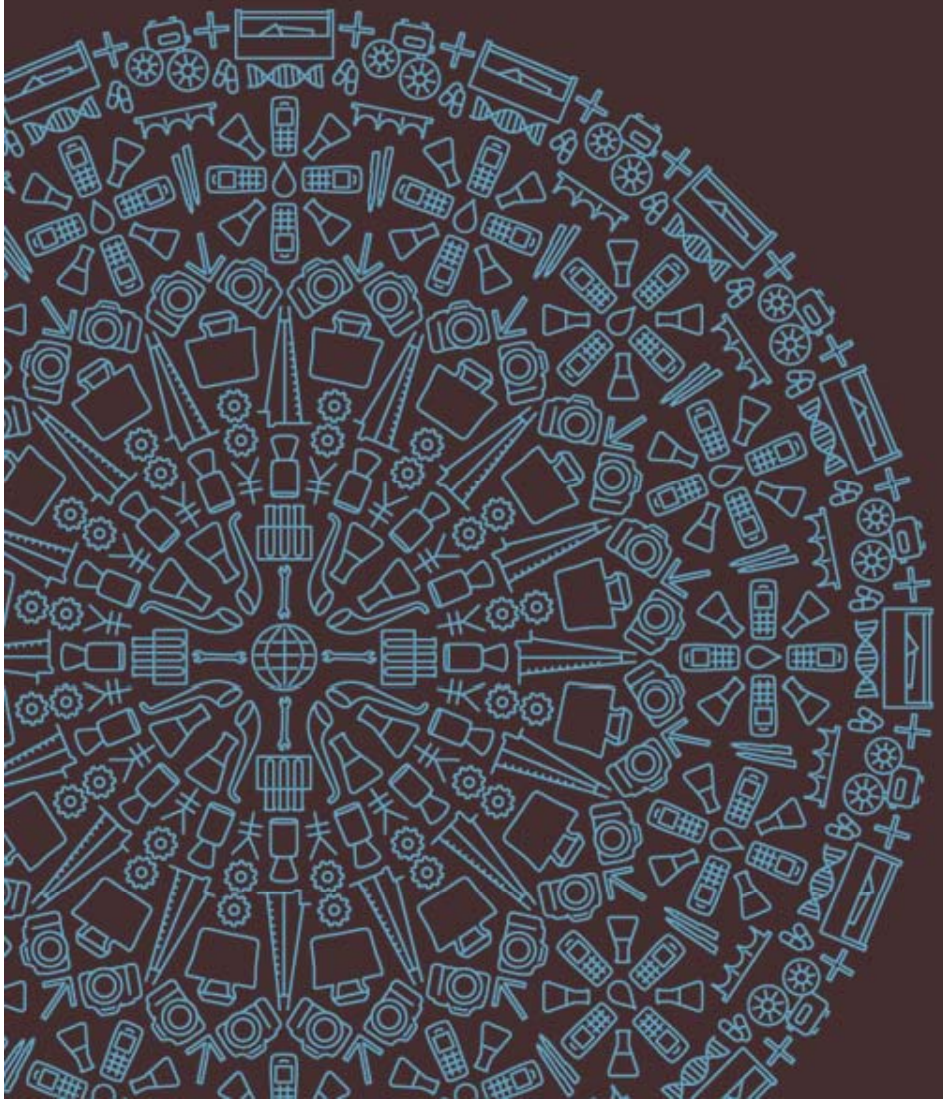

BRISTOWS

Fordham IP Conference 2012

Supplementary Protection Certificates

Some answers and more questions

PART TWO: The UK Reaction to Medeva and Other Issues

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London
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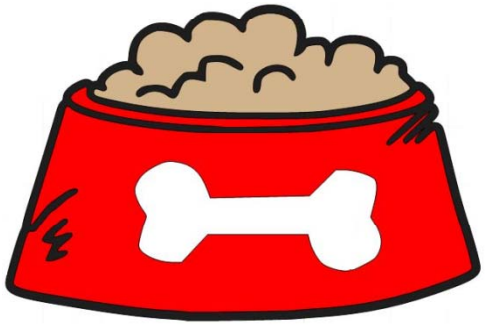
Agenda

- **The UK Reaction to Medeva**
- **The scope and effects of SPCs**
- **Other issues**

The UK Reaction to Medeva

- **WHY** has the CJEU taken this approach?

- **WHAT** does “specified in the wording of the claims” mean?



WHY?

- Until 2003, the UKIPO considered that “protected by a basic patent” meant “infringed”; but then in Takeda the English Court decided that the subject matter of the SPC had to be somehow disclosed in the basic patent. This led to a line of cases (Gilead, Astellas, Medeva, Yeda and Daiichi) and a cascade of references

- At the CJEU hearing in May 2011, the UK Government advocated the infringement test as the only clear and equitable solution.

WHY? (cont)

- The CJEU gave the following reasoning for its ruling (paragraph 25):

  "Moreover, it should be recalled that Article 5 of Regulation No 469/2009 provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) of the Regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent."

- The UK Judges regard the reasoning in Medeva as not intellectually satisfactory:

"Then, they go on in 25 to say, SPC, same rights as conferred by the basic patent. Then it says in 25: 'It follows that Article 3(a) of the regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent.' How exactly does that follow?"

"You miserable person!... But your Lordship is right, it does not follow as night follows day."

"It does not follow at all, does it?"

"Come on, I am trying to be nice." (Extract from the MedImmune transcript)

What does specified in the wording of the claims mean?

- A clear case: MedImmune v Novartis [Arnold J; February 2012]
  - ranibizumab not specified in wording of a research tool patent – no SPC
- But the Judge noted that further references were likely:
  - *"In particular, it is unclear precisely what is meant by "specified (or identified) in the wording of the claims". Does this mean that it is sufficient for the product to fall within the scope of the claim on its true construction, or is something more required and if so what? For example, is it sufficient, say, for the claim to incorporate a Markush formula which covers a large number of compounds one of which is the product in respect of which an SPC is sought? Is it sufficient for the product to be defined in functional terms? Even in combination cases, it is not clear to me how the test enunciated by the Court should be applied in a case like Gilead. Regrettably, therefore, it is inevitable that there will have to be further references to the CJEU to obtain clarification of the test."*

Other Issues

- What about enantiomers?
  - Is the UK Court of Appeal's decision in Generics v Daiichi [2009] still correct?
  - OR, should the original MA for the racemate (A+B) amount to the first MA for the enantiomer (A)?

	Patent	MA	SPC
Racemate	A+B 1990	A+B 1997	A+B 2012
Enantiomer (Daiichi)	A 2000	A 2006	A 2021
Enantiomer (post-Medeva)	A 2000	A+B? 1997	A? No SPC?!

Other Issues

One SPC per product per patent?

- Everyone assumes that the Medeva ruling did not intend to change the Biogen approach
  - "where a patent protects only a product, in accordance with Article 3(c), only one certificate may be granted for that basic patent" (Medeva)
  - Arnold J noted in Queensland that the UKIPO's view is that the CJEU did not intend to change the law as previously stated in Biogen and so there can be one SPC per product per patent (14 February 2012)
  - The Swedish Patent Office has issued a guidance note to the same effect.

The Scope and Effects of SPCs

- Once an SPC is granted, the Regulation provides as follows:

Article 4 – Subject Matter of Protection

"Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate"

Article 5 – Effects of the Certificate

"Subject to Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations"

The Big Issue – would an SPC for A be infringed by a medicine which contained A in combination with other active ingredients?

- The Co-Diovan Story

Active Ingredients:
- valsartan
- hydrochlorothiazide

- Challenge to the scope of Novartis' valsartan SPC by Actavis in early 2011
  - Did sales of Gx Co-Diovan infringe the valsartan SPC?
  - Preliminary injunctions granted against Actavis in UK (by consent); France; Germany; Austria; Norway – different interpretation by the Belgian Court
  - Reference to the CJEU by Floyd J. in July 2011

"Where a supplementary protection certificate has been granted for a product as defined by Regulation ... No 469/2009 for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:

(a) by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or

(b) only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient?"

- Basically, is an SPC for A infringed by sales of a medicine containing A+B?

Reasoned Order of the Court in Novartis v Actavis
(9 February 2012)

- *"Articles 4 and 5… must be interpreted as meaning that, where a 'product'… was protected by a basic patent… a supplementary protection certificate granted for that 'product' enables its holder… to oppose the marketing by a third party of a medicinal product containing that product for a use of the 'product' as a medicinal product, which was authorised before that certificate expired."*
- In other words, the SPC may be enforced in the same way as the patent
- Therefore an SPC for A is infringed by any medicine containing A, regardless of the presence of other active ingredients.

Further Issues

Decided

- Negative-term SPCs, possible in light of Regulation no. 1901/2006

(Merck Sharp & Dohme Corp)

Under Consideration

- Neurim – Article 3(d) – what is the "first authorisation to place the product on the market?"

For the Future

- Biogen – obtaining an SPC on another's MA

Thank you for your attention

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