On the Pulse is brought to you by the Bristows Life Sciences Team. On a regular basis we comment on issues affecting those with an interest in the Life Sciences - changes to law, recent cases and market trends. The Team is led by Edward Nodder and Sally Field. This month, On the Pulse is edited by Sahar Shepperd.

This January issue of On the Pulse provides an overview of the most recent and significant developments that affect the Life Sciences industry. At the UK level, we comment on the recently published full text of the decision of the Office of Fair Trading in Reckitt Benckiser in which Reckitt Benckiser was held to have abused its dominant position by withdrawing its Gaviscon Original product from the NHS prescription channel. Following a lengthy consultation process, the signs are that the UK Government has listened to the concerns expressed by stakeholders with respect to the Patent Box regime for the UK. In this edition, we report on the UK Government's response to this consultation. At European level, we report on the cases of Medeva and Georgetown before the Court of Justice of the EU (CJEU) that concerned the interpretation of provisions of an EC Directive that dictates the conditions for when an SPC can be obtained. In addition, we also consider the decision handed down by the CJEU in the joined cases of Philips and Nokia in which the CJEU clarifies the circumstances under which imitation goods in transit between non-member states may be detained by EU customs authorities. We then comment on the CJEU's decision in Merck Sharp and Dohme Corp, in which the CJEU assesses if it is possible to obtain a zero term supplementary protection certificate. We also report on the General Court's interpretation of the Paediatric Regulation in Nycomed with relates to obtaining a waiver from the obligation to conduct paediatric studies. Finally, we comment on the Advocate General's opinion on whether the European Commission (EC) is liable to pay financial compensation to Artegodan after the CJEU previously held that the EC had exceeded its competence.

**The lessons of the Reckitt Benckiser case**

David George

The OFT recently published its decision fining Reckitt Benckiser £10.2m for abuse of dominance committed through the withdrawal of its Gaviscon Original product from the NHS prescription channel. This article assesses what lessons the industry can learn from the case

The OFT has recently published its infringement decision against Reckitt Benckiser ('RB'). This case is of interest for a number of reasons:

- it is the first completed UK decision affecting the pharmaceutical industry in the wake of the European Commission’s Pharmaceutical Sector Inquiry Report;
- it is also the first time that the OFT has used the early resolution agreement procedure to bring an investigation to a close,

We previously commented on the significant regulatory implications of the RB decision in an article published in the 20 October 2011 edition of Scrips.

**UPCOMING EVENTS:**

- 25/01/2012: BioSimilars Forum
- 26/01/2012: BIA Annual Gala Dinner
- 22/02/2012: EU Pharma Law Forum
The abuse RB was accused of concerned the deliberate withdrawal of its soon to be off-patent “Gaviscon Original” product from the NHS prescription channel prior to the assignment of a generic name for it. RB continued supplying its on-patent “Gaviscon Advance” product through NHS channels with the practical effect that a doctor who searched for “Gaviscon” on the NHS database would find no generic alternative to the on-patent product.

Internal documents revealed that RB’s staff thought that the de-listing would mean doctors would be more likely to write prescriptions for the on-patent product than (cheaper) generic alternatives to the off-patent product. The OFT found that RB’s actions amounted to an abuse of dominance contrary to Article 102. The OFT’s decision relied very heavily on RB’s internal documents to establish the infringement.

The RB case reveals the great breadth of the abuse of dominance concept: companies can abuse their dominance through actions which are (in all other respects) entirely lawful from a regulatory standpoint.

The key lessons to draw from the case are:

- the importance of monitoring the company’s market position vis-à-vis rivals. This will allow the company to assess whether it might hold a dominant position and hence whether Article 102 might apply to its actions.
- the importance of understanding the impact of the company’s actions on rivals; in particular, an action which impedes rivals might potentially be considered anticompetitive unless the impediment can be objectively justified.
- the importance of raising competition law awareness at all levels within a company. First, management and staff should have sufficient awareness of competition law to be able to raise potential concerns with legal advisers early on. Second, genuinely innocuous documents can appear suspicious if read out of context, an awareness of competition law can help staff use appropriate terminology so that this is less likely to happen.

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**Corporation tax reform - Patent Box - An Update**

**Samuel Rippon**

Following a lengthy consultation process, significant progress is being made on a patent box regime for the UK and the signs are as we report in this article that the Government has listened to the concerns expressed by stakeholders.

On 6 December 2011 the Treasury published a response to its June 2011 consultation on a proposed patent box regime for the UK. On the same day, draft legislation to implement the regime was released for comment, together with a technical note on the draft legislation published by HMRC.

As a brief recap, the regime is intended to tax certain profits arising from patented technologies at a reduced rate of just 10% rather than the mainstream corporation tax rate (currently 26%). A number of concerns were raised about the narrow scope of the patents to be included and the complicated calculation methods that were to be used to determine which profits were to be included in the patent box and which were not.

In our *article* dated 24 August 2011 we commented on the consultation document and some of the concerns that were aired in relation to the proposals set out in that document now seem to have been addressed.
The amendments to the proposed regime include: extending the regime to patents granted by certain other EU national patent regimes; extending the period for which profits generated before a patent was granted can be included in the regime from 4 years to 6 years; and making some important changes to the technical aspects of the calculation of the profit to be included in the regime, including simplification of the divisionalisation rules and a simpler calculation for small claims.

It is encouraging that the Government has listened to the concerns of the industry and advisers and chosen to take new policy decisions based on the responses it has received. The Treasury will accept comments on the draft legislation that has been published until 10 February 2012 and, based on the results of the last consultation, it would not be a surprise if further amendments were made to the regime before it is phased in over a 5 year period from April 2013.

Supplementary Protection Certificates for combination products - the CJEU decisions in Medeva and Georgetown

Katie Hutchinson, Laura Reynolds

In this article, we report on the cases of Medeva and Georgetown in which the CJEU considered the interpretation of an EC Directive that dictates the conditions for when an SPC can be obtained.

On 24 November 2011, the CJEU rendered its decisions in the cases of Medeva (C-322/10) and Georgetown (C-422/10), on referrals from the English Courts concerning the interpretation of Article 3 of the Supplementary Protection Certificate (SPC) Regulation. Article 3(a) states that an SPC can be granted if the product defined as an active ingredient or combination of active ingredients is “protected by a basic patent in force.” Article 3(b) outlines a further criteria whereby it is necessary that “a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate”. Provided these and other conditions are met, a patentee is entitled to obtain an SPC.

Medeva concerned applications for SPCs for products containing combinations of active ingredients where the patent relied upon under Article 3(a) specifically disclosed only some of the active ingredients which were contained in the product which was to be the subject of the SPC. The main issue before the CJEU in respect of Article 3(a) therefore was whether the product, in this case a combination of active ingredients, was “protected by a basic patent.” On this matter, the CJEU held that the Regulation should be interpreted as precluding the grant of an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate. The result is that it is not possible to obtain an SPC for a combination product e.g. A+B on the basis of a patent which only specifies A in the claims. Any SPCs previously granted in these circumstances are likely to be deemed invalid.

Both Medeva and Georgetown also asked a question on the interpretation of Article 3(b). In particular, the CJEU was asked to determine whether it is possible to obtain an SPC for an active ingredient or combination of active ingredients where the marketing authorisation (“MA”) relied upon was not only for that active ingredient or combination of active ingredients but also included other active ingredients. In effect, the CJEU was asked whether Article 3(b) is satisfied where the applicant is seeking, for example, to obtain an SPC for A on the basis of a patent for A and a MA for A+B. In contrast to its approach on Article 3(a), the Court opted for a broad construction of Article 3(b). The Court therefore held that it should be possible to obtain an
SPC for A on the basis of an MA for A+B.

The decisions above have been followed by Reasoned Orders from the CJEU in relation to the further references the English Courts made in relation to Articles 3 of the SPC Regulation. These subsequent references, Yeda (C-518/10), Daiichi (C-6/11) and Queensland (C-630/11), all followed the reasoning of the Medeva and Georgetown references.

The decisions may not however be the final word on the interpretation of Article 3. Notably, the decisions raise further questions. In particular, what does “specified in the wording of the claim” mean? How much detail is required in the patent claim to fulfil this criterion e.g. is a Markush formula sufficient to obtain an SPC for a product? In addition, in its decisions the CJEU makes comment on the earlier Biogen decision which is authority for the proposition that the SPC Regulation permits one SPC to be granted per product per patent. Some appear to interpret the decisions that the SPC Regulation may only allow one SPC per patent. However the most natural way of reading the Medeva and Georgetown decisions is that the CJEU did not intend to depart from previous case-law and any other interpretation could create serious injustice.

The cases will now come back before the English Courts this year who will implement the rulings of the CJEU. It will be interesting to see if any guidance is given from the English Courts on the further questions the rulings have raised or whether a further reference from the CJEU is required to obtain this clarification.

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The CJEU clarifies the circumstances under which imitation goods in transit between non-member states may be detained by EU customs authorities

Simon Llewellyn

In the joined cases of Philips and Nokia, the CJEU decides whether imitation goods in transit between non-member states could constitute "counterfeit goods" under the Counterfeit Goods Regulation in the absence of evidence to suggest that the goods would be put on the market in the EU.

On 1 December 2011, the Court of Justice of the European Union ("CJEU") handed down its judgment in the joined cases of Koninklijke Philips Electronics NV (C-446/09) and Nokia Corporation (C-495/09) on referral from courts in England and Belgium on questions concerning the Counterfeit Goods Regulation (3295/94 and its successor, 1383/2003). While the judgment is disappointing for rights owners, as it will make the detention of certain imitation goods by customs authorities more difficult to secure, it provides important clarification on the circumstances in which goods in transit through the European Union ("EU") may be detained.

Reference by the Belgian Court

Belgian customs authorities had detained a batch of electric shavers from China which resembled a protected design of a shaver developed by Philips. Philips had subsequently brought an action against the manufacturer of the Chinese shavers for infringement of Philips' design and copyright, seeking damages for infringement, and destruction of the detained goods. The Belgian court referred a question to the CJEU on whether in order to determine if goods were infringing under Belgian law, it could apply the so-called "production fiction". The "production fiction" would have allowed the Belgian court, for the purposes of determining whether the shavers were infringing, to deem that the shavers were manufactured in the...
member state, because they were in temporary storage/transit in the member state. The CJEU held it could not - it would be necessary to prove both that the shavers would infringe an EU Intellectual Property Right and that putting them onto the market in the EU was envisaged.

Reference by the Court of Appeal (England and Wales)

Nokia had requested a judicial review of a decision by Her Majesty’s Revenue and Customs ("HMRC") not to detain counterfeit Nokia mobile phones that were at Heathrow airport, in transit between Hong Kong and Columbia. The HMRC had refused to detain the phones on the grounds that because they were in transit between two non-EU member states, and there was no evidence that the phones were to be diverted onto the EU market, the phones were not “counterfeit goods” within the meaning of the Counterfeit Goods Regulation, and therefore could not be detained. On appeal, the Court of Appeal referred questions to the CJEU on whether goods in transit between non-member states could constitute “counterfeit goods” within the meaning of the Counterfeit Goods Regulation, in the absence of evidence to suggest that the goods would be put on the market in the EU. In its judgment, the CJEU, stated that such imitation goods were not “counterfeit goods”. The CJEU confirmed that such goods could be classified as “counterfeit goods” if it could be proved, for example that they had been sold or offered for sale in the EU, or if it was apparent from the documents that diverting them to EU consumers was envisaged.

The judgment

The judgment represents disappointing news, as it confirms that for rights owners to secure the detention of imitation goods, they will have to inform customs authorities both that the goods are infringing and provide evidence that it is envisaged that the goods will be put on the market in the EU. More positively; however, in its judgment the CJEU also provided useful guidance on what might constitute evidence that it is envisaged that the goods will be diverted to EU consumers.

Some Positive News on Negative Term SPCs

Marina Vickers

Is it possible to obtain negative term SPC’s? The CJEU decides in Merck Sharp and Dohme Corp

On 8 December 2011, the Court of Justice of the European Union ("CJEU") delivered its judgment in Case C-125/10 (Merck Sharp & Dohme Corp), finally bringing certainty to the industry on the thorny question of whether it is possible to obtain a negative or zero-term supplementary protection certificate (“SPC”). The Court endorsed the views of Advocate-General Bot, [1] ruling that it is possible to obtain a negative term SPC where the period that has elapsed between the date on which the application for a basic patent was lodged and the date of the first marketing authorisation (“MA”) in the EU is less than five years.

Article 13(1) of Regulation 1768/92[2] (the “SPC Regulation”) provides that the duration of an SPC shall be the period of time that elapses between the filing of the basic patent application and the grant of the first MA to place the product on the market in the EU, reduced by a period of five years and subject further to a maximum duration of 5 years (plus the 6-month
extension under Regulation 1901/2006, the “Paediatric Regulation”). However, the SPC Regulation does not address the situation where the period between the date on which the basic patent was filed and the date the first MA was granted is less than 5 years. In Merck’s case, the first MA for Januvia (for the treatment and prevention of diabetes) was granted 4 years, 8 months and 16 days after the filing of the basic patent.

Whilst an SPC of negative duration is of no value in itself, such an SPC may be of use to the holder of a basic patent wishing to obtain the 6-month paediatric extension. Provided that the negative duration of the SPC is not more than 6 months, the patent holder will benefit from a paediatric extension – in Merck’s case the Court acknowledged that the SPC and the paediatric extension would together confer on the holder of the basic patent a period of protection of 2 months and 16 days that takes effect at the end of the lawful term of the basic patent. However, the Court ruled that where the duration of an SPC is negative, it cannot be rounded to zero (in other words, the patent holder will not be entitled to the full 6-month extension running from the expiry date of the basic patent). Indeed, the Court considered that such an approach would be contrary to the calculation rules laid down in Article 13(1) of the SPC Regulation. However, looking at the issue in light of the Paediatric Regulation, it is at least arguable that as long as the product benefits from a patent which qualifies for an SPC and the appropriate legal requirements have been fulfilled, the patent holder should be entitled to the 6-month extension running from the end of patent protection (i.e. a zero-term SPC).

Whilst allowing zero-term SPCs would have been the best outcome for the innovative pharmaceutical industry, the possibility to have a negative-term SPC is clearly very good news and may encourage companies to undertake paediatric research and development where they would not otherwise have done so – which is clearly in the interests of public health in the EU.

[1] See further the article of Maria Isabel Manley (Partner and Head of the Regulatory Practice of Bristows): ‘Where do we Stand on Negative and Zero Term SPCs: Analysis of the Views of Advocate-General Bot’; BioScience Law Review Vol 11 Issue 6 BSLR.

[2] Regulation 469/2009 codified and repealed Regulation 1768/92. However, Regulation No 1768/92 remained applicable to the present case.

Nycomed Danmark ApS v European Medicines Agency: Clarification of the obligation to conduct paediatric studies

Libby Amos

In this article, we report on the General Court’s interpretation of certain provisions of the Paediatric Regulation that relate to a waiver from the obligation to conduct paediatric studies

The General Court of the European Union has dismissed an application made by Nycomed Danmark ApS (Nycomed) concerning the European Medicine Agency’s (EMA’s) decision not to grant the company a waiver from the obligation to investigate the use of an imaging agent in children as required by Regulation EC 1901/2006 (the “Paediatric Regulation”). The case is unique in that it is the first time the Court has been called upon to interpret the Paediatric Regulation.

Legal Background

Article 7 Paediatric Regulation provides that all applications for marketing authorisation of new medicines must include the results of studies carried out in children of different ages in accordance with a paediatric investigation
plan (“PIP”). The proposal for the PIP must be submitted to the EMA’s Paediatric Committee (“PDCO”) who are responsible for agreeing or refusing the plan. However, Article 11(1)(b) provides that pharmaceutical companies may be entitled to a waiver in respect of the obligation to conduct paediatric studies, if they can provide evidence that the condition which the medicine treats only occurs in adults.

**Factual Background**

Nycomed developed an ultrasound echocardiography imaging agent (perflubutane) which was to be marketed under the trade name Imagify. Nycomed applied, in 2008, for a waiver from the obligation to submit the results of a PIP when applying for a marketing authorisation for Imagify. Nycomed stated that its intended indication for perflubutane was the diagnosis of coronary artery disease (“CAD”), which only occurs in adults.

The EMA rejected the waiver application on the grounds that the actual intended use of Imagify was not only for CAD, but to improve the visibility of blood flow in the heart muscle during an ultrasound scan to detect myocardial perfusion defects. Such defects are a sign of a range of underlying diseases and conditions (not solely CAD), including some that occur in children.

Following extensive correspondence between the parties, Nycomed ultimately filed an application at the General Court against the EMA’s decision refusing the waiver. Nycomed’s main plea was that the EMA had incorrectly interpreted the concept of ‘disease or condition for which the medicinal product is intended’ as provided in Article 11(1)(b) Paediatric Regulation. Nycomed understood this to mean: the intended use of the medicinal product as determined by the company that has produced it. A fundamental issue to be determined, therefore, was: does the indication for adults, as intended by the company, determine whether paediatric studies must be conducted, or can the PDCO extend the indication so that the relevant paediatric studies must be conducted if the PDCO can see a use for the product in the paediatric population?

**Decision of the General Court**

The General Court upheld the EMA’s decision not to grant the waiver. The General Court supported the EMA’s interpretation of the Paediatric Regulation, ruling that the indication that a company applies for is only a starting point for the PDCO’s assessment. The Committee should also take into account the properties of a medicine and consider its potential uses in children. The judgement noted that if Nycomed’s views were adopted, pharmaceutical companies would be able to obtain a waiver of their obligations under the Paediatric Regulation by simply restricting the scope of the indication of the medicinal products they develop so as to avoid conducting studies on children. As a result, one of the main objectives of the Paediatric Regulation, to produce suitably adapted medicinal products for the paediatric population, would not be achieved.

In the judgment, the General Court provides reassurance that this does not mean that the indication applied for by the applicant will not be taken into account. It will continue to be used as a starting point for the Paediatric Committee’s assessment. However, a waiver will only be granted, in the case of a diagnostic product, to those products which diagnose a sign of a condition which is both covered by the indication applied for by the applicant and also existing only in the adult population.

This judgment has been greatly anticipated by the pharmaceutical industry due to the additional time and financial implications imposed by the applicant being unable to restrict the indication of their product just for use in adults and being obliged to carry out paediatric studies. Nycomed has the right to appeal against the judgment. It will be interesting to see
The Artegodan saga: When is the European Union liable to pay financial compensation?

Sylvia Delbeuf

The Advocate General opines on whether Artegodan is entitled to receive financial compensation from the European Commission (“EC”) after the CJEU previously held that the EC had exceeded its competence.

The Advocate General’s opinion in Case C-221/10 is the latest instalment in the long-running Artegodan case, and concerns the European Commission’s liability for damages following the ruling of the Court of Justice of the European Union (“CJEU”, ECJ as it then was) that the Commission had exceeded its competence in adopting a Decision regarding the withdrawal of marketing authorisations (MAs) for certain medicinal products.

Advocate General Yves Bot acknowledged that the rules of competence between the EU and Member States confer rights to individuals, the violation of which engages the EU’s non-contractual liability. However, in the present case, the Advocate General concluded that although the Commission had violated the law, the breach was not “suffisamment caractérisée”, namely not clear cut and sufficiently serious to grant compensation to Artegodan.

Background

The Commission adopted a Decision in 2000 regarding the withdrawal of MAs for medicinal products containing “amfepramone”, a selective noradrenaline releasing agent that is used as an appetite suppressant. As a consequence, the German authorities asked Artegodan to withdraw its amfepramone product.

Following the ruling of the CJ that the Commission had exceeded its competence in adopting the Decision, Artegodan sought compensation from the Commission under Article 288 TEC (now Article 340 TFEU) for the damages it suffered as a consequence of the adoption of the unlawful Decision. According to Article 288 TEC, the EU’s non-contractual liability can only be engaged if the rule in question confers rights to individuals and if there is a serious and clear cut violation.

The General Court dismissed Artegodan’s claim for damages on the ground that the rules of competence did not confer rights to individuals, and therefore could not engage the liability of the EU for financial compensation. Artegodan appealed this ruling to the CJEU, submitting that the General Court had committed an “error of law” in holding that the rules of competence are not linked to individuals’ rights, and further that it assessed the nature of the violation too restrictively.

Legal analysis

According to the Advocate General, it is for the legislator of the European Union to decide in each case whether the Member States or a European institution has competence as this will affect the way individuals’ rights are protected. However, in order for the violation to be “significantly serious”, certain criteria need to be fulfilled. Indeed, the General Court explained that “the EU’s liability depends on the actions of an ordinarily prudent and diligent administration in similar circumstances” (point 62). Although the Commission did not have any margin of appreciation under the regulatory regime existing at the relevant time, the Commission’s mistake was an excusable one due to lack of clarity in the relevant legislation. The Advocate...
General therefore concludes that Artegodan's claim for financial compensation should be dismissed.

**Conclusion**

In summary, the case's interest lies in the possibility to engage the EU's liability for financial compensation. In principle, a violation of rules of competence can engage the EU's liability. However, whether financial compensation is payable depends on the Court's assessment as to whether the breach is significantly serious. No doubt all stakeholders are awaiting the CJEU's decision with interest as it will in particular influence the way the Commission conducts itself in its assessment of the interpretation of the legislation affecting the rights of third parties.