

## The Court of Justice Recasts the EU Patent Term Extension System

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A legal framework providing for *de facto* patent term extension for pharmaceuticals has existed in the EU for over twenty years and a parallel one for agrochemicals for nearly fifteen. One might therefore be forgiven for thinking that by now the major features of this system were fairly well settled. However, the commercial importance of the products that it protects, being high value products in regulated sectors that have succeeded in securing a marketing authorisation, has meant that the system has attracted a disproportionate amount of litigation. The means by which such extension is achieved - the Supplementary Protection Certificate regime, and which combines concepts from both patent and regulatory law - is a matter of EU law and so is ultimately interpreted by a body - the Court of Justice of the EU - whose recent judgments in this field have upset settled expectations. The consequences of these judgments are still being worked through in the case law, but their origins lie in certain decisions made by national courts. This article traces how this situation came about and identifies some of the uncertainties that remain in the system.

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Patent term extension, beyond the 20 year minimum term mandated by TRIPS, for those patents that protect certain regulated products such as pharmaceuticals, is a feature of the patent systems of many countries, and is mandated by some Bilateral Trade Agreements.<sup>1</sup> In the EU such a system, the Supplementary Protection Certificate (SPC) regime, has existed for over twenty years for pharmaceuticals and for nearly fifteen years for agrochemicals. One might therefore be forgiven for thinking that its major features were by now fairly well settled. But case law from the Court of Justice of the EU (CJEU) in 2011 upset the settled expectations of practitioners, and the consequences of this are still being worked through in its more recent case law. Much of the problem lies in the manner in which the extension regime, which is interpreted nationally in the same tribunals as deal with patents, employs concepts drawn from regulatory law. Another lies in the fact that the SPC regime is a matter of EU law and so is ultimately interpreted by the CJEU, which has little or no background in or experience of patent law. But on closer analysis it can be seen that the CJEU was put by national courts in the situation of having to address certain 'hard cases' which were themselves a consequence of earlier decisions by national patent courts.

The SPC regime in the EU does not in fact, strictly speaking, extend patent term, but instead confers, on patentees, by virtue of two EU Regulations,<sup>2</sup> a separate right, the SPC, which is meant to be open to the same challenges to validity as an already granted patent ('the basic patent') and to be capable of enforcement in the same way as such basic patent, except that its scope is limited to a particular 'product' that is protected by that basic patent and that has also received a Marketing Authorisation (MA), either as a medicinal product or as a plant protection product. The reason for this indirect approach to protection lay in the fact that the SPC regime is a creature of EU law, in contrast to patents which in general are not, but are instead subject to the European Patent Convention, which is not an EU measure, and which did not at the time admit the possibility of patent term extension.<sup>3</sup>

The basic idea behind the SPC regime is straightforward. The holder of a patent in force in any EU country (or Iceland and Norway) that protects a 'product' is eligible, once that product becomes the subject of an MA as a medicinal product (or as a plant protection product) effective in the country in which that patent is in force, to secure an SPC. Such SPC comes into force on expiry of the basic patent and has the effect in practice of extending the term of such

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‘basic patent’, but in respect only of the product, by 5 years after expiry of such basic patent, or 15 years after the date of the first such MA in the EEA,<sup>4</sup> whichever is the shorter. The term of a medicinal product SPC can be extended for a further six months where the conditions of the Paediatric Use Regulation have been met.<sup>5</sup> Despite its conceptual simplicity interpreting the SPC regime has proved problematic, not only in ways that were foreseen at the outset, but also, more recently, in ways in which no-one had expected.

### **What Constitutes the First Marketing Authorisation for a Product?**

Eligibility for an SPC is addressed by Article 3 of each Regulation. That for medicinal products provides that:

‘A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) 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;
- (c) the product has not already been the subject of a certificate;
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.’

Much of the case law in the first 15 years or so of the medicinal products SPC regime reflected controversies over what constituted the first MA for a particular product, as, in addition to affecting eligibility under the transitional provisions that applied to those medicinal products that were already on the market when the Regulation came into force,<sup>6</sup> this affected eligibility for an SPC under Article 3(d),<sup>7</sup> and assuming such eligibility, the term of such SPC under Article 13 of each Regulation, as this is keyed to the first MA in the EU.<sup>8</sup>

### **The Status of Products that are Combinations of Actives**

However, the question of what constitutes the first MA for a given product has proved in recent years to be particularly problematic where the product is a combination of actives. Article 1(b) of the medicinal

products Regulation defines a ‘product’ as an ‘active ingredient or combination of active ingredients of a medicinal product,’ on a literal reading of which one might think that a fixed dose combination of actives A plus B should be treated as a completely different ‘product’ for the purposes of Article 3 from its constituent actives, consistent with the regulatory approach for medicinal products. Doing so presents no especial difficulty, or hardship, with small molecules, where typically the grant of an MA for a single active medicinal product will precede that for those comprising combinations with that active. This allows the active, where appropriate, and subject to the other provisions of Article 3, to secure SPC protection, so that an authorisation for one active component of the combination does not allow one to secure an SPC on the combination, or preclude one later securing an SPC for the combination separately. Likewise, in those rare cases in which the MA for a medicinal product comprising a combination of actives precedes that for one of comprising one of those actives, the earlier SPC for the combination had been thought not, subject to the other provisions of Article 3, to preclude a later SPC for the individual active on its own. This indeed was how for many years Article 3, and in particular Article 3(c) was interpreted, although in the meantime case law was also developing at a national level which took a restricted view as to when, for the purposes of Article 3(a), a combination product was ‘protected’ by a basic patent in force.

### **Does the Basic Patent Protect the Product?**

Such national case law under Article 3(a) eschewed a pure patent infringement type analysis in determining whether a product that was a combination of actives was ‘protected’ by a patent, and held that a patent which would only be infringed because of the presence of one element of the combination was not to be regarded as a basic patent that ‘protected’ the combination in the sense of Article 3(a).<sup>9</sup> However such national case law never articulated precisely what more (short of having a claim to the precise combination in issue) was required than that a patent be infringed for it to be eligible as a basic patent for a particular combination of actives, leaving the question to be asked of the CJEU in Case C-322/10 *Medeva* and C-422/10 *Georgetown University*.<sup>10</sup>

Unfortunately for the development of the jurisprudence under the Regulations, the particular

cases that were eventually referred to the CJEU on this issue concerned the rather special situation of vaccines, the regulatory framework for which favours as medicinal products, where available, vaccines against multiple strains of pathogen over those against single strains. So the first MA for patented vaccine is rarely for a vaccine against a single strain but is instead generally for such vaccine in combination with a number of other vaccines against other strains. This presented difficulties under the accepted interpretation of Article 3(a), as although a patent protecting the invention of a vaccine effective against a particular strain of pathogen might well envisage its being authorised in a medicinal product in combination with vaccines against other strains, no patent claim set could ever realistically be expected to enumerate all other potential components of such combination. At the same time however Article 3(b) required on its face that the ‘product’ the MA for which gave rise to eligibility for an SPC be the particular combination of actives the subject of such MA, rather than only a one or some of the actives making up such combination.

The CJEU recognised that this situation would have meant that the SPC regime did not deliver its intended incentive for research for the particular type of medicinal product the subject of the references to it. Like the national courts it did not adopt an infringement test under Article 3(a), albeit for a different reason, namely the fact that patent claim scope is not harmonised at an EU level, and so the concept of ‘protected’ should be given an autonomous meaning. Instead it adopted a more flexible approach to what constituted a ‘product’ for the purposes of Article 3(b). Thus it held that despite its literal wording the requirements of Article 3(b) could be met where the medicinal product the subject of the marketing authorisation contained active ingredient(s) other than the active ingredient(s) ‘protected’ by the basic patent. However, in eschewing an infringement approach to Article 3(a) the CJEU held that for an active ingredient to be ‘protected’ by a patent such active ingredient must be ‘specified’ or ‘identified’ in the wording of the claims of the basic patent, without clarifying what it meant by this.

This approach to Article 3(a), which may well have reflected some understandable ignorance on the part of a tribunal which has no experience of the variety of different ways in which patent claims to pharmaceuticals may be formulated, put immediately

into question the issue of whether SPCs could be secured for single active products where, as is often the case, there are no relevant claims of the basic patent that list specific chemicals but the only relevant claims are for example in ‘Markush’ form or expressed functionally. This issue was addressed to a degree two years later by the CJEU in Case C-493/12 *Eli Lilly v Human Genome Sciences*<sup>11</sup> which held that to be treated as ‘protected’ it was not necessary for the active ingredient to be identified in the claims of the patent by a structural formula, but that where it was it had to be possible ‘to reach the conclusion on the basis of those claims, interpreted *inter alia* in the light of the description of the invention ... that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question,’ a test that still leaves much room for uncertainty. Such uncertainty is exacerbated by another observation made by the CJEU in that case, to the effect that the refusal of an SPC application for an active ingredient which is not specifically referred to in the claims may be justified where the holder of the patent in question had ‘failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients.’ Its justification for this is that ‘if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective’ of the SPC Regulation, an observation which on its face would appear to suggest that a basic patent which is licensed to the holder of the MA can less readily be said to ‘protect’ the product in issue than one that is held by the holder of the MA, a situation that surely cannot have been intended.

Meanwhile in other references to it the CJEU has started to address some of the consequences of its having in effect rewritten Article 3(b) to address the special situation of vaccines. Thus having held, consistent with this, from the perspective of enforcement, that an SPC for a single active could be asserted against a combination product where the basic patent permitted of this,<sup>12</sup> it held in Case C-443/12 *Actavis v Sanofi*<sup>13</sup> that one could not

secure, on the same basic patent, an SPC for a combination of actives where one of those actives had already been the subject of an SPC that could be asserted against such combination, a not uncommon situation with small molecules, thus reducing the scope in practice for securing an SPC on a combination of actives that would endure beyond an SPC on one of such actives. However it also held, in Case C-484/12 *Georgetown University*,<sup>14</sup> another vaccine case, that one could secure an SPC on an active that had already been the subject of an SPC on the same basic patent but in combination with other actives.

### Prospects for the Future

The recent history of this one particular aspect of the medicinal products SPC Regulation as recounted above, and which is still far from resolved,<sup>15</sup> identifies only one area of controversy as to the interpretation of the Regulations, albeit one that has a fundamental effect on their operation. Several other controversies under the Regulations than those here outlined have been resolved, but many uncertainties remain. Some are in consequence of the decisions of the CJEU or the observations it has made in the course of reaching such decisions, as noted above in Case C-493/12 *Eli Lilly v Human Genome Sciences*, but others have yet to give rise to a controversy that is referred to the CJEU. Given the situation which has been reached with the references under the Regulations to the CJEU it is hardly surprising that it has been reported that at one of the recent hearings on an SPC reference the CJEU asked the representative of the European Commission whether it was proposing to revise or recast the Regulations. However, the Commission will have no illusions as to the risks of the untoward consequences of reopening the Regulations given the strength of the commercial interests at stake, so a legislative fix in the near future would seem unlikely. Thus it seems that over time the strict wording of the Regulations will ever less reflect their reality as interpreted by the courts.

### References

- 1 For example Article 10.36 of the Free Trade Agreement between the European Union and its Member States and the Republic of Korea – OJEU L127 14 May 2011 p 6.
- 2 Regulation (EC) 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152 16.6.2009, p, 1), replacing on consolidation Regulation (EEC) 1768/92, and Regulation (EC) No 1610/96 of 23 July 1996 concerning the creation of a supplementary

protection certificate for plant protection products (OJ L 198, 8.8.1996, p. 30).

- 3 The amendments to the EPC to permit patent terms of more than 20 years from filing under the Act Revising Article 63 EPC of 17 December 1991 (OJ EPO 1992, page 1) did not take effect until 4 July 1997.
- 4 The European Economic Area, consisting of the EU plus Iceland, Liechtenstein and Norway. Liechtenstein lacks its own patent system, and Swiss patents extend to it, but by virtue of the effect in Liechtenstein of pharmaceutical marketing authorisations granted by Switzerland (which has its own SPC regime for Swiss patents), account is also taken of these authorisations for SPCs in the EU, despite Switzerland not being a member of either the EU or the EEA. The effect of a Swiss marketing authorisation in Liechtenstein is now delayed in order to reduce the adverse consequences of this for SPC term in the EU – see Joined Cases C-207/03 *Novartis* and C-252/03 *Millennium Pharmaceuticals* (ECJ 21 April 2005) and Case C-617/12 *AstraZeneca* (CJEU 14 November 2013).
- 5 Regulation (EC) 1901/2006 on medicinal products for paediatric use (OJ L 378 27.12.2006, p.1).
- 6 As in Case C-127/10 *AB Hassle v Ratiopharm* (CJEU 26 February 2002), holding that an authorization which did not in practice without more admit of entering the market was still an effective marketing authorization for such purposes.
- 7 Case C-31/03 *Pharmacia Italia* (CJEU 19 October 2004), holding that an earlier authorization for an active as a veterinary medicinal product still counted even where an SPC was sought on the basis of an authorization for a human medicinal product, so no SPC could be secured by reason of such subsequent authorization, although see also Case C-130/11 *Neurim* (CJEU 19 July 2012) where this consequence was avoided. Article 3(d) eligibility has also been addressed in the framework of the definition of ‘product’ in Article 1(b) to deprive new formulations, medical uses or vaccine-adjuvant combinations of previously authorized actives of SPC eligibility in Case C-431/04 *Massachusetts Institute of Technology* (CJEU 4 May 2006), Case C-202/05 *Yissum* (CJEU 17 April 2007) and Case C-210/13 *GlaxoSmithKline Biologicals* (CJEU 14 November 2013) respectively. Some eligibility issues have also been addressed under Article 2, namely Cases C-195/09 *Synthon v Merz* and C-427/09 *Generics (UK) v Synaptech* (CJEU 28 July 2011), holding that actives the subject of marketing authorizations secured within the territory of the EU, but which by reason of their age were not secured under the EU acquis, are outside the scope of the Regulations and so no SPC can be secured under subsequent authorizations for such actives.
- 8 If a marketing authorization is secured less than 5 years after the basic patent is filed, the calculation mandated by Article 13 results in a negative term for the SPC. This means that even if the Article 3 requirements are met no SPC is then available, unless the negative term is less than 6 months, as this can provide the basis for a positive term if and when the requirements of the Paediatric Use Regulation are met so as to extend the SPC term by 6 months – see Case C-125/10 *Merck Sharpe & Dohme* (CJEU 8 December 2011).

- 9 The first English case in which this approach to Article 3(a) was articulated (although the application in issue failed also under Article 3(b)) was *Takeda Chemical Industries SPC Applications (No 3)* [2003] EWHC 649, which notes that a Swedish court had come to the same conclusion in relation to a parallel SPC application.
- 10 Cases C-322/10 *Medeva* and C-422/10 *Georgetown University* (CJEU 24 November 2011). See also Cases C-518/10 *Yeda Research and Development*, C-630/10 *University of Queensland*, and C-6/11 *Daiichi Sankyo* (CJEU 25 November 2011) addressing, *inter alia*, the situation in which a product could only be said to infringe on a contributory infringement theory.
- 11 Case C-493/12 *Eli Lilly v Human Genome Sciences* (CJEU 12 December 2013).
- 12 Cases C-442/11 *Novartis v Actavis* and C-574/11 *Novartis Deutschland v Actavis* (CJEU 9 February 2012).
- 13 Case C-443/12 *Actavis v Sanofi* (CJEU 12 December 2013).
- 14 Case C-484/12 *Georgetown University* (CJEU 12 December 2013).
- 15 See for example pending Case C-577/13 *Actavis v Boehringer Ingelheim Pharma*, in which the CJEU is asked, *inter alia*, whether an amendment to the claims of a patent can have the effect of converting a patent which could not have served as basic patent for the purposes of Article 3(a) into one which could.