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# Corporate Intangibles Research and Development Manual

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# CIRD210170 - Patent Box: qualifying companies: qualifying IP rights: other rights to which Part 8A applies - Supplementary Protection Certificates and Marketing Authorisations

The scope of the Patent Box extends to rights similar to patents which relate to human and veterinary medicines, plant breeding and plant varieties. It is not the intention to limit the scope of the Patent Box as a result of the UK's exit from the EU, so UK equivalent rights have been included

from 1 January 2021 (see CTA/357BB), in addition to rights under EU law, which continue to qualify (see CTA/357BBA).

Supplementary Protection Certificates and Marketing Authorisations are listed here and plant breeders' rights, plant variety rights, and plant protection products with data protection benefits are included at CIRD210175 (https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird210175)

## 1.Supplementary protection certificates

Supplementary protection certificates ('SPC') are issued under Regulations (EC) 469/2009 and 1610/96 relating to medicinal and plant protection products respectively. This will also include any paediatric use extension: Article 36 of Regulation (EC) 1901/2006 extends the duration of an SPC issued under Regulation 426/2009 in respect of paediatric use medicinal products for six months. Therefore where this is the case, the company would continue to hold the SPC issued under Regulation 469/200 for an additional six months and hence continue to hold an IP right to which the Patent Box applies for that period.

"EU supplementary protection certificate" continues to mean a certificate issued under either of the regulations mentioned above. SPC Regulations are retained as UK law, under the domestic implementing provisions, preserving the existing rights with their current UK-only scope.

## 2.Medicinal and veterinary products with marketing authorisations and marketing or data protection

S357BB provided that companies granted marketing authorisation, for example medicinal products for human use under Regulation (EC)

726/2004 or Directive 2001/83/EC and who benefit from marketing protection by virtue of Article 14.11 of Regulation (EC) 726/2004 and Article 10.1 of Directive 2001/83/EC respectively will be treated as if they hold a right to which the Patent Box applies for the period of the marketing or data protection. This is ten years, extended by a further year in certain circumstances.

Companies granted a marketing authorisation which benefits from one year of data exclusivity under Article 10.5 of Directive 2001/83/EC, or an in-force one year prohibition on referring to the results of test or trials in relation to the product imposed by Article 74a of that directive, will be treated as if they hold a right to which the Patent Box applies for those one year periods.

As set out in Article 38 of Regulation (EC) 1901/2006, paediatric use medicinal products are also granted marketing authorisations under Regulation (EC) 726/2004 or Directive 2001/83/EC.Therefore companies will also be treated as holding a right to which the Patent Box applies during the periods of marketing protection for such paediatric use medicinal products.

As for medicinal products for human use, where a company is granted a marketing authorisation in respect of a veterinary medicinal product that benefits from marketing protection under Article 13.1 of Directive 2001/82/EC, it will be treated as if it holds a right to which the Patent Box applies for the period of the marketing protection, i.e. ten years, extended by a further three years in certain circumstances. Where veterinary medicinal products are authorised in accordance with Regulation (EC) 726/2004, they also benefit from the provision of marketing protection under Article 13.1 of Directive 2001/82/EC and therefore will also be treated as if they hold a right to which the Patent Box applies for the marketing protection period referred to above.

As the Veterinary Medicines Regulations 2011 implement Directive 2001/82/EC, where a marketing protection or prohibition under

Paragraph 11 or 12 of Schedule 1 to those Regulations is in force, it will also be treated as if it holds a right to which the Patent Box applies for the period of the marketing protection/prohibition.

Medicinal products designated as orphan medicinal products under Regulation (EC) 141/2000 benefit from a period of marketing exclusivity by virtue of Article 8.1 of Regulation (EC) 141/2000. Where this is the case, a company will also be treated as holding a right to which the Patent Box applies for the ten year period of the marketing exclusivity. This period is extended to twelve years if the orphan medicinal product is also a paediatric use medicinal product that meets the requirements set out in Article 37 of Regulation (EC) 1901/2006.Therefore where this is the case, the company would continue to benefit from marketing exclusivity under Regulation 141/2000 for an additional two years and hence continue to hold an IP right to which the Patent Box applies for that period.

From 1 January 2021, S357BBA and s357BB allow both EU Regulations and the equivalent UK rights to be treated as qualifying IP rights under the following circumstances:

A product benefits from EU marketing protection if —

- the product benefits from marketing protection by virtue of Article 14.11 of Regulation (EC) No 726/2004 (https://www.legislation.gov.uk/european/regulation/2004/0726) of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medical products for human use, or
- any of the following prohibitions is in force—

1. the prohibition on placing on the market a generic of the product imposed by Article 10.1 of Directive 2001/83/EC (https://www.legislation.gov.uk/european/directive/2001/0083) of the European Parliament and of the

Council of 6 November 2001 on the Community code relating to medicinal products for human use(21 (https://www.legislation.gov.uk/uksi/2019/818/made#f00021)),

2. the prohibition imposed by Article 8.1 of Regulation (EC) No 141/2000 (https://www.legislation.gov.uk/european/regulation/2000/0141) of the European Parliament and the Council of 16 December 1999 on orphan medicinal products(22 (https://www.legislation.gov.uk/uksi/2019/818/made#f00022)), and
3. the prohibition on placing on the market a generic of the product imposed by Article 13.1 of Directive 2001/82/EC (https://www.legislation.gov.uk/european/directive/2001/0082) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products(23 (https://www.legislation.gov.uk/uksi/2019/818/made#f00023)).

A product benefits from EU data protection if—

1. the product benefits from the data exclusivity conferred by Article 10.5 of Directive 2001/83/EC (https://www.legislation.gov.uk/european/directive/2001/0083) of the European Parliament and of the Council,
2. the prohibition on referring to the results of tests or trials in relation to the product imposed by Article 74a of that Directive is in force, or
3. data relating to the product benefits from data protection under Article 59 of Regulation (EC) No 1107/2009 (https://www.legislation.gov.uk/european/regulation/2009/1107) of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market. The reference to data in subsection does not include a study necessary for the renewal or review of a marketing authorisation

granted in respect of the product in accordance with Regulation (EC) No 1107/2009 (https://www.legislation.gov.uk/european/regulation/2009/1107).

Where a product benefits from EU marketing protection or data protection, it is the person who holds the relevant marketing authorisation in respect of the product who is to be treated for the purposes of this Part as having been granted a right to which this Part applies in respect of the product. The relevant marketing authorisation is the marketing authorisation by reference to which it is determined that the product benefits from marketing protection or data protection.

A product benefits from UK marketing protection if the following apply:

After UK transition,where the EU legislation has been revoked and restated within the Human Medicines Regulations 2012 or Veterinary Medicines Regulations 2013 and the directive is implemented under the domestic implementation provisions, S357BB provides that the following UK rights can be qualifying IP rights:

(i) a marketing authorisation under the Human Medicines Regulations 2012(16 (https://www.legislation.gov.uk/uksi/2019/818/made#f00016)) which has been granted in respect of the product and the period during which a generic of the product may be prevented from being sold by reason of regulation 51(8) of those Regulations has not expired;

(ii) an orphan marketing authorisation under the Human Medicines Regulations 2012 has been granted in respect of the product and the prohibition arising in connection with that authorisation under regulation 58D(1) of those Regulations remains in force;

(iii) a marketing authorisation to which paragraph 6 of Schedule 33A to the Human Medicines Regulations 2012 applies has been granted in respect of the product and the holder of the

authorisation continues to benefit from marketing exclusivity.

(iv) a marketing authorisation under the Veterinary Medicines Regulations 2013(17 (https://www.legislation.gov.uk/uksi/2019/818/made#f00017)) has been granted in respect of the product and the period during which an equivalent of the product may be prevented from being placed on the market by paragraph 11(3) of Schedule 1 to those Regulations has not expired.

(v) a marketing authorisation in respect of the product under the Human Medicines Regulations 2012 has been granted or varied in circumstances giving rise to the prohibition in regulation 51(16) or 64A(3) of those Regulations and that prohibition remains in force;

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