Journal of Intellectual Property Studies
Vol. IV (1), January 2020, pp. 92-101

A DIFFERENT PERSPECTIVE ON THE ROLE OF DATA EXCLUSIVITY

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This article traces the history of data exclusivity in the European Union for animal pharmaceuticals and outlines how it has diverged over time from the data exclusivity regime for human pharmaceuticals. This trend has continued with the enactment in 2018 of a new system of data exclusivity for animal pharmaceuticals to take effect in 2022, which is reviewed in detail. The number and variety of different types of data exclusivity mandated by this latest revision of the regulatory data protection regime for animal pharmaceuticals shows how readily data exclusivity can be tailored to provide an incentive for securing regulatory approvals directed to various different ends which the legislation seeks to encourage - in this case either for certain otherwise neglected species of animal or for certain types of improvement, such as those resulting in a reduction in antimicrobial or anti-parasitic resistance. Whilst the inventions that underlie such regulatory approvals might also in some cases and in some jurisdictions be capable of being protected by patents, the "one size fits all" nature of the patent system precludes encouraging one type of invention over another. Moreover, even where patent protection may be available for such new applications, the effective patent term is significantly, and sometimes completely, attenuated by the time taken to secure such regulatory approvals. Data exclusivity, in contrast, provides a simple and straightforward way of providing the incentive for, and thereby improving the prospect of achieving, the purposes which the legislation seeks to encourage.

INTRODUCTION

This writer is, and has been for a long time,[1] an unabashed proponent of data exclusivity as a useful and beneficial intellectual property right, and of interpreting TRIPS Article 39(3), which mandates it, as requiring that a third party not be able, for a reasonable period of time, to rely on the technical data, such as clinical trials or field trials, filed by an earlier applicant in support of its application to secure the first regulatory approval to market a new pharmaceutical or agrochemical.

Data exclusivity, otherwise referred to as regulatory data protection, protects the investment made in generating the data, such as the results of clinical trials, required to prove to a regulatory authority that a product that has not previously been approved is adequately safe and efficacious. This is achieved by limiting, for a certain period of time, the extent to which potential competitors can rely on the existence of such data for their own commercial purposes. During such period these competitors cannot secure their own regulatory approval for their own version of such a product without independent generation of such data. The cost of such repetition, at least for small molecules (where, for example, for a pharmaceutical with only bioequivalence, all that a generic applicant

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[1] See Trevor Cook, Regulatory data protection in pharmaceuticals and other sectors, INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION HANDBOOK 437 (Anatole F Krattiger et al. eds., 2007).

need otherwise in general show is bioequivalence), is generally disproportionate to the benefits to a generic applicant of securing an approval that is independent of that secured by the earlier applicant.

Data exclusivity as an intellectual property right has evolved to the greatest degree, and has become of the greatest importance, in those highly regulated sectors in which demonstrating adequate product safety and efficacy is paramount, namely pharmaceuticals and agricultural chemicals. In these sectors the testing required to secure regulatory approvals for newly approved products has become ever more extensive, demanding and thus expensive. This is reflected by these two sectors being the subject of Article 39(3) of TRIPS.

However, data exclusivity also has potential application in other regulated sectors in which one must also show adequate safety and/or efficacy to seek a regulatory approval. Thus, for example in the European Union ("EU") one also finds data exclusivity for animal feed additives,[2] biocidal products,[3] chemicals,[4] novel foods,[5] and health claims for foods.[6] However, in such cases, as with data exclusivity for plant protection products,[7] third parties generally have a right of access to data as to trials on non-human vertebrates before the end of the data exclusivity period in order to avoid repetitive animal testing, provided they pay for such access, so the relevant legislation will provide for mechanisms to determine this in the absence of agreement.

Traditionally, patents have provided the means by which such new products are protected. Nevertheless, patents provide only indirect protection for such innovation by protecting, for example, the invention of a new compound, a new form or formulation of such compound (or, in some jurisdictions, a new use of an existing compound), rather than showing to the regulatory authority that a product containing such compound is sufficiently safe and effective to merit regulatory approval. Such invention will often occur a long time, and sometimes a very long time, before the product which is protected by the patent secures such approval, resulting frequently in significant or

[2] Reg. 1831/2003, of the European Parliament and of the Council of Sept. 22, 2003, on additives for use in animal nutrition, art. 20, 2003 O.J. (L 268) 29, 43.
[3] Reg. 528/2012, of the European Parliament and of the Council of May 22, 2012 concerning the making available on the market and use of biocidal products, art. 59 to 64, 2012 O.J. (L 167) 1, 123.
[4] Reg. 1907/2006, of the European Parliament and of the Council of Dec. 18, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, art. 25, 2006 O.J. (L 396) 31.
[5] Reg. 2015/2283, of the European Parliament and of the Council of Nov. 25, 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation No 258/97 of the European Parliament and of the Council and Commission Regulation No 1852/2001, art. 26, 2015 O.J (L 327) 1, 22.
[6] Reg. 1924/2006, of the European Parliament and of the Council of Dec. 26, 2006 on nutrition and health claims made on foods, art. 20, 2006 O.J. (L404) 9.
[7] Reg. 1107/2009, of the European Parliament and of the Council of Oct. 21, 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, art. 59 to 62, 2009 O.J. (L 309) 1, 50.

sometimes complete attenuation of the patent term, which is rarely fully or sometimes completely compensated for by patent extension schemes even in the countries which provide for it. Patents are also subject to the unpredictability of patent law, which provides for many grounds of attack on their validity, such as anticipation, obviousness, insufficiency and added matter. For such attacks on patent validity to succeed, these need not bear any relation to the qualities of the compound in question as a regulated product and so, for purely formal reasons for example the protection provided by patents can be wholly vitiated.[8]

In contrast, data exclusivity is not subject to such vagaries and is instead linked directly to the very activity which it is sought to protect that of proving that a product is sufficiently safe and efficacious to merit regulatory approval. It is important for this purpose to decouple data exclusivity from the concept of the protection of confidential information as for example addressed in TRIPS Article 39(2). Otherwise the increasing trend internationally towards transparency of clinical trial and other data filed in support of applications for regulatory approvals could undermine it.

This writer also recognizes that the issue of data exclusivity has become in some quarters a contentious one. He suggests, however, that much of the discourse surrounding data exclusivity has been clouded when it has been addressed in the context of human pharmaceuticals as has usually been the case by the undeniably important issue of access to medicines.[9]

It is hoped in this article to decouple the issue of data exclusivity from that controversy and to discuss how it has application in regulated areas other than medicinal products for human use. Accordingly, the article focuses, as a case study, on the recently enacted revision of the EU legal regime applicable to veterinary pharmaceuticals. What is especially interesting about this particular example is the demonstration it provides of how data exclusivity can be tailored to provide an incentive for certain trials to be undertaken. The trials in question are directed towards securing approvals for certain types of use which are regarded as desirable and deserving of encouragement, showing that data exclusivity has a flexibility which the "one size fits all" patent system cannot readily match.

[8] Such as, in Europe, the failure during the priority year adequately to perfect the title to the right to claim priority from the first patent application filed for an invention in favor of those who subsequently file a patent application internationally claiming priority from that first filing. This is an error which in Europe cannot be remedied after the event, but is often only discovered very much later, and so will often expose the resultant patent to attacks on validity based on anticipation and/or obviousness over references filed during the priority year which can then become damaging and sometimes fatal prior art. See for example - T 0577/11-EPO Technical Board of Appeal, Apr. 14, 2016; T 1201/14 - EPO Technical Board of Appeal, Feb. 9, 2017; and T 0725/14 - EPO Technical Board of Appeal, Jan. 21, 2019.

[9] See for example Srividhya Ragavan - The Significance of The Data Exclusivity Debate and Its Impact on Generic Drugs - Journal of Intellectual Property Studies Vol 1, p 131 (2017)

Although the EU data exclusivity regime for veterinary medicinal products, which dates back to 1990,[10] corresponded initially to that for human medicinal products,[11] the two regimes started to diverge in 2005 and will diverge further with effect from 2022 as a result of legislation specific to veterinary medicinal products that was enacted in 2018.[12]

Initially both data exclusivity regimes required EU Member States to confer either 6 or 10 years of data exclusivity, other than for certain types of pharmaceutical, such as proteins produced by recombinant DNA technology, or ones authorized by the precursor to the centralized procedure, for which 10 years was mandatory in all EU Member States.

The EU regulatory regimes for both veterinary medicinal products and medicinal products for human use, including their data exclusivity regimes were extensively revised with effect from late 2005, and such data exclusivity regimes remain in effect to the present day.[13]

For medicinal products for human use, this revision introduced the "8+2+1" system of data exclusivity, which applied to all authorizations from such date granted by the Member States and to authorizations secured via the centralized route. Although this allowed an application for a generic marketing authorization for a medicinal product to be filed once 8 years had passed after the date of the first marketing authorization for the active in that medicinal product. A generic marketing authorization based on such application could not be granted less than 10 years after the date of the first marketing

[10] Council Directive 90/676/EEC, of Dec. 13, 1990, amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products, 1990 O.J. (L 373) 15. This amended Directive 81/851/EEC, inter alia, to introduce a data exclusivity regime by way of qualification to the requirements of Article 5(10), which was subsequently re-enacted as Article 13(1)(a)(iii) of Directive 2001/82/EC of the European Parliament and of the Council of Nov. 6, 2001, on the Community code relating to veterinary medicinal products, art. 13(1)(a)(iii), 2001 O.J. (311) 1.

[11] Council Directive 87/21/EEC of Dec. 22, 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, 1987 O.J. (L 15) 36). This amended Directive 65/65/EEC inter alia, to introduce a data exclusivity regime by way of a qualification to the requirements of Article 4(8) which was subsequently re-enacted as Article 10(1)(a)(iii) of Directive 2001/83/EC of the European Parliament and of the Council of Nov. 6, 2001, on the Community code relating to medicinal products for human use, 2001 O.J.(L 311); as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, 2003 O.J. (L 33) 6730, 40.

[12] Reg. 2019/6, of the European Parliament and of the Council of Dec. 11, 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, 2019 O.J. (L 4) 43, 167 (EU).

[13] Directive 2001/82/EC of the European Parliament and of the Council of Nov. 6, 2001 on the community code relating to veterinary medicinal products, 2001 O.J. (L 311) 1, was amended by the Directive 2004/28/EC, of the European Parliament and of the council of March 31, 2004 O.J. (L 136) 1; and for medicinal products for human use Directive 2001/83/EC on the Community code relating to medicinal products for human use was amended by Directive 2004/27/EC, of the European Parliament and of the Council of March 31, 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, 2004 O.J. (L 136) 34, 57.

authorization for that active, hence providing the "8+2" aspect of the system. The "+1" aspect of the system added an extra year of protection, for all indications, beyond the standard 10, or "8+2" years, where, during the first 8 years of protection, the holder of the original marketing authorization secured an authorization for "one or more therapeutic indications which, during the scientific evaluation prior to their authorization are held to bring a significant clinical benefit in comparison with existing therapies."[14]

For veterinary medicinal products, the revisions resulted in a data exclusivity regime for such products which differed in three respects from that for human medicinal products, although in overall structure, the two regimes are almost identical.[15] These differences, discussed below, can be seen as constituting an initial attempt to tailor the data exclusivity regime for veterinary medicinal products to provide extra incentives for studies undertaken in order to secure marketing authorizations applicable to specific species, or to further species.

The first such tailored incentive is the provision of 13 years rather than 10 years of protection for veterinary medicinal products for fish or bees (or other species designated in accordance with a specific procedure, although this has never been invoked).[16]

The second and third tailored incentives are specific to marketing authorizations for veterinary medicinal product for food-producing species. In these species, an applicant for a marketing authorization faces the additional burden of investigating the level of residues of the veterinary medicinal product in issue in food from such animal and its effect on humans who eat such food, and of establishing a maximum residue level for such products in such food. The second tailored incentive involves extending the term of protection for an existing authorization from 10 years by one-year increments to no

[14] Directive 201/83/EC of the European Parliament and of the Council of Nov. 6, 2001 on the community code relating to medicinal products for human use, 2001 O.J.(L 311); as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, fourth para of art. 10(1), 2003 O.J. (L 33) 30,40.

[15] Directive 2004/28/EC, of the European Parliament and of the Council of Mar. 31, 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, art. 5,13 & 13(c) of Directive 2001/82/EC correspond closely to those for medicinal products for human use in Articles 6 and 10 to 10c of Directive 2001/83/EC, as amended by Directive 2004/27/EC of the European Parliament and of the Council of March 31, 2004 O.J. (L 136) 34, 54. There is also an Article 13d in Directive 2001/82/EC as amended by Directive 2004/28/EC, of the European Parliament and of the Council of Mar. 31, 2004 O.J. (L 136) which has no corresponding provision in Directive 2001/83/EC as amended by Directive 2004/27/EC which establishes a specific derogation from the need to provide full data when seeking a marketing authorization that is expressed to be only applicable in exceptional circumstances.

[16] Directive 2004/28/EC, of the European Parliament and of the Council of Mar. 31, 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, art. 13(1), 2004 O.J. (L 136) 58, 84.

more than 13 years, keyed to extending the scope of the marketing authorization to another food producing species.[17]

The third tailored incentive concerns an exception to data exclusivity by which an application for a marketing authorization can be made that relies on published literature after ten years' well-established veterinary use of the product in the EU. The incentive applies to an applicant who plans to rely upon published literature in support of an application for marketing authorization for use on a food-producing animal but for which no maximum residue limit has been set. Such an applicant has therefore to conduct suitable trials in order to get a maximum residue limit determined. Further, such an applicant is entitled to three years' data exclusivity in respect of that trial data, running from the date the consequent marketing authorization is granted.[18]

VETERINARY MEDICINAL PRODUCTS - THE NEW EU REGIME AND ITS BACKGROUND

In 2014 the European Commission, which is responsible for initiating EU legislation, adopted a proposal for a new Regulation on veterinary medicinal products,[19] and proposed as part of the reform extending various data exclusivity periods. It explains the thinking behind this proposal as follows:

> ‘‘This part also regulates the “protection period” applying to technical documentation submitted in order to obtain or amend a marketing authorization. It addresses the characteristics and specificities of the veterinary sector. Experience has shown that the needs of the veterinary sector differ substantially from those of the human sector. Also, the drivers for investment differ for the human and veterinary medicines market, for example in animal health there is more than one species, creating a fragmented market and necessitating major investments to add other animal species. Therefore, the provisions in this proposal to stimulate innovation cannot be considered as a model for the human medicines market. The protection arrangements prevent applicants for a generic product from referring to the documentation submitted for the reference product. Data provided to extend the generic product to another animal species should also be protected according to the same principle.”
>
> “Extending the protection periods provided for in Directive 2001/82/EC should create incentives and stimulate innovation in the animal health sector. The current

[17] Directive 2004/28/EC, of the European Parliament and of the Council of Mar. 31, 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, art. 13(5), 2004 O.J. (L 136) 58, 84 (Such new authorization(s) must be granted within the five years of the grant of the initial marketing authorization, and the holder of the marketing authorization holder must also have applied for the determination of the maximum residue level to be established for the species covered by the authorization, and which determination must be made before a marketing authorization for a veterinary medicinal product for food-producing animals can be granted).

[18] Directive 2004/28/EC, of the European Parliament and of the Council of Mar. 31, 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, art. 13a, 2004 O.J. (L 136) 58, 84.

[19] See pages 4 and 5 of the Explanatory Memorandum accompanying ‘Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products, COM (2014) 558 final, (Sept. 1, 2014) 4, 5; - Also for relevant aspects of the Proposal itself see art. 33 - 36.

ten-year period would be maintained for the initial marketing authorization. In order to encourage industry to extend already authorised products to other species, a further one year would be added for any extension of the veterinary medicinal products to another species (up to a maximum of 18 years)."

"In order to encourage the animal health industry to develop products for minor species, increased protection will apply: 14 years for the initial marketing authorization for a minor species, and 4 additional years for an extension to a minor species."

"So as to secure data protection, any application for an extension must be submitted at least 3 years before expiry of the data protection period. This ensures that companies can place a generic product on the market immediately after expiry of the protection period for the reference product. Product developments for bee medicines will receive increased data protection because of the small size of the market for bee medicines and the lack of effective medicines to treat diseases in bees. The protection applying to environmental data would be the same as that for safety and efficacy data.''

These proposals were enacted in December 2018, largely as originally proposed, in Regulation 2019/6 setting out the new legislation for veterinary medicinal products, and will take effect as from January 2022.[20] Recital 33 to Regulation 2019/6 recognises the importance of data exclusivity:

(33) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorization or to establish a maximum residue limit for pharmacologically active substances of the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, in particular on veterinary medicinal products for minor species and antimicrobials, so that it is ensured that the necessary veterinary medicinal products are available in the Union. For that reason, data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection, however, should be limited in time in order to allow for competition. Similar protection of investments should be applied to studies supporting a new pharmaceutical form, administration route or dosage that reduces the antimicrobial or antiparasitic resistance or improves the benefit-risk balance.

The periods of data exclusivity for veterinary medicinal products are set out in Articles 39 and 40 of Regulation 2019/6:

Article 39 - Periods of the protection of technical documentation

1. The period of the protection of technical documentation shall be:

[20] Reg. 2019/6, of the European Parliament and of the Council of Dec. 11, 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, 2019 O.J. (L 4) 43, 167 (EU).

(a) 10 years for veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats;

(b) 14 years for antimicrobial veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;

(c) 18 years for veterinary medicinal products for bees;

(d) 14 years for veterinary medicinal products for animal species other than those referred to in points (a) and (c).

2. The protection of technical documentation shall apply from the day when the marketing authorization for the veterinary medicinal product was granted in accordance with Article 5(1).

Article 40 - Prolongation and additional periods of the protection of technical documentation

1. Where the first marketing authorization is granted for more than one animal species referred to in point (a) or (b) of Article 39(1) or a variation is approved in accordance with Article 67 extending the marketing authorization to another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by one year for each additional target species, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the protection period laid down in point (a) or (b) of Article 39(1).

2. Where the first marketing authorization is granted for more than one animal species referred to in point (d) of Article 39(1), or a variation is approved in accordance with Article 67 extending the marketing authorization to another animal species not referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by four years, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the protection period laid down in point (d) of Article 39(1).

3. The period of the protection of technical documentation provided for in Article 39 of the first marketing authorization, prolonged by any additional periods of protection due to any variations or new authorizations belonging to the same marketing authorization, shall not exceed 18 years.

4. Where an applicant for a marketing authorization for a veterinary medicinal product or for a variation to the terms of a marketing authorization submits an application in accordance with Regulation (EC) No 470/2009 for the

establishment of a maximum residue limit, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of five years from the granting of the marketing authorization for which they were carried out. The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those tests, studies and trials.

5. If a variation to the terms of the marketing authorization approved in accordance with Article 67 involves a change to the pharmaceutical form, administration route or dosage, which is assessed by the Agency or the competent authorities referred to in Article 66 to have demonstrated:

(a) a reduction in the antimicrobial or antiparasitic resistance; or

(b) an improvement of the benefit-risk balance of the veterinary medicinal product,

the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection.

The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those studies and trials.

A common feature of these new provisions is the generally longer term of protection than the existing system that these provide. One can also compare this large number of tailored provisions with the three tailored provisions in the existing system discussed above. Article 39(1)(c) extends the 13-year period of protection for veterinary medicinal products for bees to 18 years. Article 40(1) through (3) extends the term of protection for each further authorization secured in respect of new species, but this is no longer limited to veterinary medicinal products for food producing animals and the maximum such protection available is extended from 13 years 18 years. Finally, Article 40(4) provides a simpler means, which is of much more general application of protecting studies involved in the establishment of a maximum residue limit, which protection is extended from 3 to 5 years.

Although Article 39(1) provides at present for 10 years as the shortest period of protection, it has a larger number of longer periods of protection than at present, keyed to the species for which the veterinary medical product is authorized or, in Article 39(1)(b) the type of product, in this case antimicrobial veterinary medicinal products containing an active not previously authorised for such products in the EU. Article 40(5) provides 4 years protection for variations resulting in two specific types of beneficial property which the legislation seeks to encourage where this arises as a result of a change to the pharmaceutical form, administration route or dosage of a previously authorized pharmaceutical.

CONCLUSION

The number and variety of different types of data exclusivity mandated by this latest revision of the regulatory data protection regime for veterinary pharmaceuticals in the EU shows how readily data exclusivity can be tailored to provide an incentive for securing regulatory approvals directed to various different ends but which the legislation seeks to encourage - in this case either for certain otherwise neglected species or for certain types of improvement, such as those resulting in a reduction in the antimicrobial or antiparasitic resistance. Whilst the inventions that underlie such regulatory approvals might also be capable of being protected by patents in some jurisdictions, the "one size fits all" nature of the patent system precludes encouraging one type of invention over another. Data exclusivity, in contrast, provides a simple and straightforward way of achieving this purpose.