The Protection of Proprietary Data in Novel Foods – How to Make It Work

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Nocumentum documentum – learn from your mistakes. One would expect that the golden rule expressed in this Latin proverb applies not only to the management of companies but equally to the European law-making process, certainly in times of Better and Smart Regulation. Like so often in real life, aspiration and reality do not always meet. A recent example of this is Article 24 of the European Commission´s proposal on a revised Regulation on novel foods[1].

I. The concept of data protection in the Regulation

Article 24 introduces the concept of data protection to the field of novel foods. According to Recital 23 of the draft Regulation its purpose is to stimulate research and development within the agri-food industry and to protect the innovators' investment in gathering the information and data provided in support of an application for a novel food. The need for such a protection arose from the Commission´s decision to shift from individual, applicant-related authorisations to generic authorisations with effect erga omnes. As a consequence, without some kind of protection for the investment in scientific studies supporting the application submitted by the initial applicant, the incentive for food business operators to seek novel foods approval would likely have been low. The European Commission therefore chose to replicate the data protection provision in Article 21 of Regulation (EU) No. 1924/2006 on Nutrition and Health Claims (NHCR).

Similar to Article 21 of the NHCR, Article 24 of the draft Regulation sets three conditions that must be met by scientific data in order to be eligible for data protection:

- the newly developed scientific evidence or scientific data was designated as proprietary by the prior applicant at the time the first application was filed;
- the novel food could not have been authorised without the submission of the proprietary scientific evidence or scientific data by the prior applicant; and
- the prior applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was submitted.

II. The European Commission´s understanding of data protection

While at first glance this might seem a reasonable construct, a closer look reveals significant weaknesses. The shortcomings originate not so much in the text of the provision itself but in the interpretation that was given to it by the European Commission in the context of the Nutrition and Health Claims Regulation. The Commission´s position was for the first time expressed in Recital 10 of Decision 2009/980/EU[2] and draws the line between published and unpublished data with the cut-off point being the date of submission of the application. According to the Commission, any publication of data prior to the submission date forfeits the applicant´s right to data protection. The concept certainly has the advantage of being easy to implement. Further, it means protection cannot be granted for any data that has already been in the public domain before Article 21 of the NHCR became effective. It is questionable though whether these benefits outweigh the disadvantages

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1 COM(2013) 894 final.

2 Commission Decision of 17 December 2009 authorising a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granting the protection of proprietary data under Regulation (EC) No. 1924/2006 of the European Parliament and of the Council, OJ L 336, p. 55.

which come with the approach. For one it can lead to a delay in publication of results and increase the probability of duplication of studies since other researchers might not be aware of the work that was done by the applicant. There is also an increased likelihood that studies would not be published at all because in the majority of cases the scientific substantiation of a claim will require more than one study to ensure that the initial results can be reproduced. Not least is that it is not compatible with the scientific assessment concept used in the United States which creates a new barrier for international trade.

The subsequent analysis aims to show that the Commission´s interpretation of Article 21 NHCR and Article 24 of the draft Novel Foods Regulation is not compelling from a legal point of view, and to provide an alternative solution that would be more friendly to research and development in the food sector, thus enhancing the effectiveness of the provision.

III. Data exclusivity in other Community legislation and ECJ jurisprudence

First of all, the text of Articles 21 and 24 respectively are silent about what exactly is meant by the exclusive right of reference to the proprietary data that is submitted by an applicant. The wording suggests that the applicant must have some kind of ownership of the data that authorizes him to exclude others from the use of that data. This concept of exclusive rights is commonly used in other fields of law, e.g. the ownership of property, and typically the existence of such exclusive rights is visible to the public. It is therefore only logical if provisions on data protection that existed prior to the adoption of Regulation (EU) No. 1924/2006 did not make a distinction between data that had been published at the time of the application and data that was unpublished, e.g. Article 20 para. 1 of Regulation (EC) No. 1831/2003[3], Articles 12 and 13 of Directive 98/8/EC[4], Article 14 of Regulation (EC) No. 726/2004[5] or Article 16 of Regulation (EC) No. 2065/2003[6]. The concept of data protection must be strictly distinguished from what is known as confidentiality. While confidentiality aims at protecting the competitive position of the applicant against the conscious or inadvertent disclosure of sensitive commercial information, data protection in the context of Article 21 NHCR (and the other legal acts stated above) is about the right to commercially exploit the scientific data that has been generated. For this reason, it seems more adequate to use the term "data exclusivity" than "data protection".

The wording of Article 21 of Regulation (EC) No. 1924/2006 does not exclude an interpretation that allows consideration of data published prior to the submission of an application to be proprietary, provided that the ownership of the data still exists at the time the application for authorisation of a claim (or a novel food) is made. Such an interpretation would even be more coherent with other existing Community legislation[7]. It is also supported by the ruling of the Court of First Instance (now General Court) in the Alpharma case[8]. The Court held that the legal provision of Article 9c para. 1 of Directive 70/524/EEC regarding the authorisation of feed additives, which read "the scientific data and other information in the initial dossier submitted for the purpose of the first authorisation may not be used for the benefit of other applicants for a period of 10 years", granted the applicant a specific right that came close to an intellectual property right[9]. Given that according to Article 7 of Directive 70/524/EEC the interpretation of the pharmacological, toxicological and eco-toxicological data relating to a feed additive could in no event be considered confidential, it is quite likely that some of the scientific data concerning the safety of the additive was already in the public domain at the time the application for an authorisation was made. Even if that should not have been the case it must be noted that the Court did not make any distinction between published and unpublished data in its ruling.

3 Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 268, p. 29.

4 Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 123, p. 1; the Directive has been replaced by Regulation (EU) No. 528/2012 but the concept of data protection (now in Articles 59 and 60) remained unchanged.

5 Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, p. 1.

6 Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods, OJ L 309, p. 1.

7 See notes 4-7 above.

8 Case T-70/99, judgement of 11 September 2002.

9 Case T-70/99, judgement of 11 September 2002, para. 90.

However, it is not only precedent but also the purpose of the data exclusivity provision that calls for an equal treatment of published and unpublished data.

IV. The purpose of data exclusivity provisions

Article 1 of the NHCR states that its main objective is to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. It seems that the question whether data that was published prior to the submission of an application for authorisation of a claim should benefit from data exclusivity under Article 21 or not would not have any impact on the level of consumer protection that is achieved by the Regulation. It should, however, be noted that a legal environment that encourages publication of scientific data is more likely to contribute to a high level of consumer protection than a framework that incentivises companies to delay the publication of scientific data or not to publish it at all.

The main purpose of the data exclusivity provision of Article 21/24 can be found in Recital 32 of the NHCR and Recital 23 of the draft Regulation on Novel Foods:

> "In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation."

Recital 32 of the NHCR further adds:

> "This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials."

Any interpretation of Article 21/24 must therefore ensure that research is stimulated, the investment made by an innovator is adequately protected, and unnecessary repetition of trials is avoided.

V. Weaknesses of the European Commission's interpretation

Introducing a requirement that only studies and trials that have not been published at the time the application for authorisation of a claim is made will be considered to be eligible for data exclusivity would not serve these purposes. First and foremost, accepting only unpublished data forces potential applicants to withhold scientific data from publication until the application has been submitted. This contradicts the ethics of the scientific community, which requires a high level of transparency and timely publication of the results of clinical studies. In particular, it must be considered that in most cases at least two clinical studies will be required to substantiate a health claim. The typical timeline for conducting a clinical trial and compiling the results is between three and six months. As a consequence, researchers would have to commit to withholding scientific data from publication for a period of six to twelve months which many researchers would find difficult to accept. A result could be that food business operators might do more in-house research, thus putting funding of similar university research at risk and increasing the likelihood of duplicate studies. In addition, only considering unpublished data for data exclusivity is at odds with the approach taken by the United States Food and Drug Administration which only considers peer-reviewed, published data for the support of a health claim[10]. A food business operator who is active in both jurisdictions is forced to decide whether he wants to use a claim in the United States first and sacrifice data exclusivity in the EU or to launch in the EU and delay entry into the U.S. market until the data has been published in peer-reviewed journals.

It is a generally acknowledged principle of Community Law that in case of several possible interpretations of a provision, the interpretation should be chosen that leads to the highest effectiveness of Community Law (*effet utile*).[11]

While "exclusive right of reference" from its literal meaning can be understood as the ability to refer to scientific data or studies for any purpose, be it scientific or commercial, such an interpretation would not serve the purpose to avoid the replication of studies because it would exclude third parties from making use of the generated data for research purposes

10 FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm, last accessed 25 July 2014.

11 See recently ECJ, cases C-34/10 para. 50; C-128/09, para. 53 and C-403/08, paras. 163 and 175.

until an application for authorisation of a health claim is submitted by the owner of the data. Based on the considerations in Recital 32 an interpretation that limited the protection of the data to the commercial value created by the investment in the research would maximise the protection of the innovator's investment while allowing free use of the data for research purposes, thus reducing the need to replicate studies that have already been conducted. Consequently, the exclusive right of reference should only refer to the exploitation of the generated data for the purpose of supporting an application for authorisation of a health claim or novel food, not the use of this data for other purposes, in particular further scientific research. If that is the case, there is no need to restrict the protection of the commercial value of the data to unpublished data.

To ensure the highest effectiveness it would, to the contrary, even be desirable to encourage immediate publication. Such an interpretation would also serve the interest of universities that to a significant extent rely on funding of their research by third parties but would regard it as highly unethical not to publish the results of their research within a reasonably short timeframe of typically three to six months after completion of a study. If the publication of results had to be delayed just for the purpose of obtaining data exclusivity under Article 21/24, this could mean that many scientific journals would not accept papers on the conducted research for later publication. Moreover, researchers have already indicated that for this reason they would be very reluctant to engage in research that includes the generation of proprietary data.

As the possibility to get exclusivity for proprietary data was only created by Regulation (EC) No. 1924/2006, only data that has been published after the entry into force of the regulation can be eligible for this protection. A further requirement should be that the existence of the exclusive right of reference is properly documented by an agreement between the sponsor of the research (as the prospective applicant of the claims authorisation) and the researcher. The statement should indicate the owner of the exclusive right of reference and must also appear in the publication of the data in order to make the ownership of the data known to third parties.

The protection of data for which an exclusive right of reference is documented and which is published prior to the submission of an application will support future research rather than hinder it. Even if an owner of data decides to delay the submission of an application or not to submit an application at all, there would be no significant impact on the ability of other parties to use the results of the research. Non-commercial research will be supported by the fact that the data is published and that the exclusive right of reference is limited to the use of the data for commercial purposes that do not put any limitations on its academic use. If the data is supportive of a claim or the safety of a novel food that is considered to be of commercial relevance, it is likely that the owner of the data will proceed with the application unless the area is not of interest to him. In the latter case he will be interested to recover the cost of the research and will be willing to sell the data to a company that is interested in exploiting the claim. Given the significant cost of clinical research and the uncertain outcome of any new clinical study, an interested company would always prefer to buy data that is already available instead of having to reproduce this data through its own research.

If exclusivity is granted to data that has been published prior to the submission of an application there is obviously a risk that the exclusivity could block the use of the data for the substantiation of other claims or novel foods by third parties, in particular when the protected research is used as a starting point for further investigations on new claims or foods. However, this eventually is a question of whether the protected data is pertinent to the support of the second effect, and the same issue arises if the data is published after the application has been submitted. The question whether data exclusivity is justified or not is subject to judicial review by the Court of Justice of the European Union. A dispute around ownership of the data can arise independently of the question whether proprietary data was published prior to the submission of an application or not. Even if the data is unpublished, cases can be envisaged where a researcher ceases collaboration with a sponsor and continues to work with another party, which would almost inevitably result in a conflict around the ownership of the data. These limitations on the commercial use of the protected data for new claims or products by third parties though are similar to those in other fields where provisions on data exclusivity exist, like biocides or medicinal products. They do not depend on whether the data eligible for protection is unpublished or published.

VI. Conclusions

All this shows that possible concerns with regard to the consideration of published data for data exclusivity are either not inherent to the distinction between published and unpublished data or can be addressed satisfactorily if only data is considered that was published after the entry into force of the relevant Regulation.

In summary, it can be concluded that by choosing a narrow interpretation of what is comprised by the concept of data protection (or rather data exclusivity), the European Commission got itself into a legal cul-de-sac and created an environment that hardly incentivises innovation in the food sector. The good news is that with the revision of the Novel Food Regulation there is a potential escape route available that would allow the European Union to move to a more innovation-friendly approach. This would require the Commission to bite the bullet and change its current position. The reward would be an effective data exclusivity regime that stimulates research and is aligned with similar provisions in other areas of Community Law. Carpe Diem!