SETTERWALLS

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Setterwalls Life Sciences Report

Affärskritiska rättsfall, nya EU-krav och ett skärpt juridiskt landskap – Setterwalls presenterar vårens viktigaste regulatoriska skiften inom life sciences.

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Sverige har en stark och internationellt erkänd position inom life sciences, med betydande bidrag till forskning, innovation och export inom bland annat läkemedel, bioteknik och livsmedel. Den innovationsdrivna och expansiva branschen står inför snabba och föränderliga juridiska krav som påverkar bolagens affärsförutsättningar i grunden.

Sedan 2011 har Setterwalls Advokatbyrå, en av Sveriges största och äldsta affärsjuridiska byråer, presenterat sin Life Sciences Report. Två gånger per år släpps rapporten, som samlar aktuella insikter för aktörer som verkar inom området, och den har kommit att bli en viktig källa till kunskap för branschen. Setterwalls kartlägger i rapporten avgörande rättsliga förändringar och domar som påverkar bolag i branschen, och vårens upplaga bjuder på viktiga medskick till bolag inom medtech, läkemedel, livsmedel och kosmetika.

Bland annat analyseras en ny dom som resulterat i en betydande bot för långa betaltider i livsmedelskedjan, en intressekonflikt mellan en ny typ av patentrelaterade anpassningar av produktinformation och utbytbarheten för generiska läkemedel, samt nya krav på bland annat verifiering och dokumentation av miljöpåståenden i marknadsföring när Green Claims-direktivet träder i kraft.

Välkommen till Setterwalls. En av Sveriges ledande affärsjuridiska byråer.

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Important decision on the distinction between marketing and non-commercial information in relation to medicinal products

By Helena Nilsson and Lovisa Dahl Nelson

Setterwalls has previously written about the significance of the distinction between marketing and freedom of speech, for example here. This distinction is of material importance as it determines which rules apply to communications in relation to medicinal products. A recent decision gives us reason to revisit this topic. The decision highlights the importance of pharmaceutical companies reviewing and, if necessary, correcting statements made to journalists, as the company may be held responsible for what is stated in the article.

Background

The Ethical Rules for the Pharmaceutical Industry in Sweden (LER) include rules regarding information from and marketing by companies, directed at healthcare professionals or the public. Non-commercial information, however, is protected by constitutional rules on freedom of speech and thus falls outside the scope of LER's rules on marketing of medicinal products.

The Information Examiner Committee (IGN), which monitors compliance with LER by pharmaceutical companies that are members of the Swedish Association of the Pharmaceutical Industry (LIF), can refer cases of a principled nature to the Information Practices Committee (NBL). IGN recently referred a case to NBL concerning the distinction between marketing and non-commercial information in relation to medicinal products. In this article we review NBL's decision (NBL 1136/2024).

In the case in question, a Swedish listed pharmaceutical company was contacted by a financial journalist writing an article about how the company would be affected in the U.S. market by an FDA approval of a competitor's product. The company's own product had received FDA approval but had not yet been approved in the EU. The article was a follow-up to a previous article on the subject, which also included comparisons between the two products. The questions were answered by the company's CEO, but according to the company, the article was independently written by the journalist and published in Dagens Industri without the company's knowledge or involvement.

NBL's Assessment

NBL began by noting the importance of company representatives being able to answer questions from journalists and provide information about the

"In the case in question, a Swedish listed pharmaceutical company was contacted by a financial journalist writing an article about how the company would be affected in the U.S. market by an FDA approval of a competitor's product."

company and its research. However, this must be done with discretion so that the information or statements provided are not unintentionally perceived as marketing of medicinal products, thus falling within the scope of LER.

NBL focused on the fact that the company's CEO made specific statements about percentages, compared different studies and presented information, including value judgments, in such a way that, in NBL's opinion, the statements conveyed a commercial purpose and were considered to refer to purely commercial conditions. The committee believed that the company could have satisfied its shareholders' and investors' interests by expressing itself differently. As a result, NBL found that the statements, based on a comprehensive assessment, constituted medicinal product information, making LER applicable.

Although the article had not been written by the company itself, it contained statements from the company's CEO. NBL emphasized that it is important for representatives of a pharmaceutical company to always take LER into account in their statements and own communication efforts. Companies should always ensure that they read and, if necessary, correct their statements, as the company may be held responsible for what has been conveyed. NBL assumed that the statements in the article were accurately reproduced and considered that the company should be responsible for the content of the article.

NBL concluded that the statements were in breach of LER. In the article, the company made a comparison between its own product and the competitor's product in a way that was considered misleading and in breach of LER. Furthermore, several of the statements were considered to be pre-launch information, since the article made information available to the public without the medicinal product having been given marketing authorization in Sweden.

NBL wanted to emphasize that there are no obstacles in LER against pharmaceutical companies responding to, or making, statements to journalists. However, the statements have to be made in such a way that they do not constitute medicinal product information or, if the statements are medicinal product information, that they comply with the rules in LER.

Dissenting Opinions

It is interesting to note that the decision contains dissenting opinions.

Six of the committee members pointed out that an interview situation cannot be equated with a press release written and reviewed by the company. An interview is a special situation where the person answers direct questions of various kinds (i.e. according to the so-called pull and not push principle), often unprepared and without time for preparation. The journalist is responsible for the article as a whole, and the questions asked.

These committee members also looked at the interview in its context and highlighted that it was a follow-up to another article where comparisons and figures regarding side effects etc. were presented, which were repeated in the current article. The members noted that it was not the pharmaceutical company that presented the data in the current article but that the data were already present in several previously published articles. The company was thus interviewed as a result of the already published articles and commented on direct requests. Additionally, these dissenting members believed that the interview and article dealt with an area of importance to the listed company. A company's CEO must, in this context, be able to answer questions from a financial journalist and give their view of the company's future, including about confidence in its products.

One committee member largely agreed with the six members' dissenting opinion but added that it is not possible to freely answer questions from journalists and make any claims about the company's products. Instead, companies should strive to communicate information that is accurate and maintains a high scientific standard. In her opinion, the statements were unacceptable as they did not meet the scientific standard expected of LIF's member companies. However, in view of the above-described circumstances the current statements could not be considered to be commercial information.

Comment

The decision shows above all that representatives of pharmaceutical companies should always take LER into account in media statements, even in situations where they are not proactive vis-à-vis the media but are responding to journalists' questions. Companies should ensure that they read and, if necessary, correct statements and assess whether the upcoming article falls within the scope of LER and, if so, ensure that the statements comply with this regulatory framework.

Setterwalls continues to monitor and report on the latest developments in the field. Our life sciences team has extensive experience in marketing of medicinal products – do not hesitate to contact us for guidance through the regulations!

When legal and important areas of interest collide – the impact of patent law on interchangeability

By Per Lidman and Jakob Losell

A company about to launch a prescription medicinal product must necessarily take several legal aspects into account. One such constantly relevant issue is which patent rights may affect the launch. Even if the relevant substance itself is not patent- protected by a third party, there may be patent rights in relation to, for example, a certain dosage regimen or a certain form of administration.

In some cases, patent-related issues may also spill over into other legal areas. The company launching the product may have ensured through various measures/limitations that the launch and sale of the product does not constitute any patent infringement, but as a result of these measures/limitations, it might face problems with the regulatory authorities.

One such problem relevant in Sweden concerns the issue of *interchangeability* or *generic substitution*. Typically, for a launch of generic medicinal product in Sweden to be commercially attractive, it is of great importance for it to be placed in the same interchangeability group (Sw. *utbytbarhetsgrupp*) as the reference medicinal product. This as the latter, depending on the functionality of the prescription system, will be the one prescribed by the physicians.

According to the Swedish Medicinal Products Act (**the Act**), the Swedish Medical Products Agency (**the Agency**), when a marketing authorisation has been granted for a medicinal product, must decide whether the product is interchangeable with another – primarily the reference product. The Act further states that medicinal products are interchangeable only if they can be considered equivalent. In practice, medicinal products have been considered ”equivalent” provided that they:

(a) are approved as medicinal products;

(b) contain the same active ingredient(s);

(c) contain the same amount of the active ingredient(s);

(d) have the same form of preparation; and

(e) have been assessed as bioequivalent/therapeutically equivalent.

This list of requirements generally does not cause any concerns to generic companies. However, there is an additional (potential) obstacle to overcome, and that is the Agency’s *remaining overall assessment* of the generic medicinal product’s *effect and safety*. In other words: even if the generic and the reference product are equivalent in the meaning of the Act, there may be differences that, in the opinion of the Agency, constitute obstacles to interchangeability.

On its website, the Agency lists several examples of such differences that could constitute obstacles to interchangeability, one of which is that *”some essential part of the product information is missing or contradictory”*. Differences in product information can thus be considered an obstacle to interchangeability, even if the products as such are equivalent. As initially indicated, generic companies are sometimes forced to make adjustments to the product information to avoid patent infringement – a concept known as ”skinny labelling”. The legislator has foreseen this, and a marketing authorisation can thus be granted for a generic even if its product information differs from the reference product’s information, provided that the difference is due to patent law considerations. Hence, Article 11 of Directive 2011/83 stipulates the following:

For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.

But: In this situation, the generic company risks getting caught between two different regulations. On the one hand, an adjustment of the product information (SmPC + package leaflet) must be made to avoid patent infringement. On the other hand, the adjustments to the product information may result in the Agency finding reasons to place the generic medicine in a separate interchangeability group (even if the generic product is equivalent to the reference product), on the basis of the aforementioned exception: that, in the opinion of the Agency, *some essential part of the product information is missing or contradictory*.

Patent law considerations may thus push the generic company into a kind of regulatory dead end. However, it should be borne in mind that the differences in product information must have an impact on the *effect or safety* of the generic medicine for the difference to constitute an obstacle to interchangeability. In a recent case at the Administrative Court in Uppsala, a generic company appealed the Agency's decision not to place its generic product in the same interchangeability group as the reference product. The generic company had been granted marketing authorisation for a medicine provided in capsule form – same as the reference product – and all the requirements (a) – (e) above were fulfilled.

However, to respect a patent regarding a special form of administration for patients with swallowing difficulties – e.g. breaking the capsule and mixing the capsule contents with a teaspoon of apple sauce (with nothing else, and no more or less than a teaspoon) – it was stated in the package leaflet for the generic that it should not be used by patients with swallowing difficulties. This represented a difference from the reference product's package leaflet, according to which the primary message was the same – the capsules were to be swallowed whole and not to be taken together with any foodstuff, *but also* that patients with swallowing difficulties could break the capsules and mix the contents with a teaspoon of apple sauce. The Agency argued that this difference posed a safety risk, as patients with a swallowing difficulty receiving the generic might administer the capsule contents using a different type of food (or different amount) than what had been confirmed as safe in clinical studies. To make the point more clearly, the patient's absorption of the relevant active substance could be strongly affected if taken with food (the concentration of the active substance increased, which could potentially lead to serious side effects). According to the Agency, patients could thus potentially suffer serious side effects. Consequently, the Agency found that

there was an obstacle to interchangeability, despite the products being equivalent. The Agency in its appealed decision ignored *inter alia* the facts that:

- The prescribing physicians have a duty to inform about differences and in relation to a medicinal product which could potentially cause dangerous side effects if taken together with food and especially for patients with swallowing difficulties, this duty could be expected to be fulfilled;
- The prescribing physicians have, if they believe that the difference is relevant, a duty and opportunity to block generic substitution at the pharmacies in the prescription;
- The pharmacists expediting against the prescription have a duty to inform about differences and in relation to a medicinal product that could potentially cause dangerous side effects if taken together with food, and especially in the case of patients with swallowing difficulties, this duty could be expected to be fulfilled;
- The patients would have to ignore the information they have been given and ignore the clear warning texts in the generic product information; and
- The patients, who must have had a previous habit of breaking capsules of the reference product and mixing the contents with a teaspoon of apple sauce, would in order to be exposed to a safety concern, suddenly in contrast with the strong warnings and previous information and habit, break the capsules and mix the contents with *other foodstuffs or other quantities*. Notably, if they broke the capsules and mixed the contents with a teaspoon of apple sauce, there was no identified risk. On the contrary, the products were considered equivalent.

As mentioned, the Agency's decision was appealed to the Administrative Court in Uppsala. However, the appeal has been withdrawn as the patent-related issue was resolved. Hence, it remains uncertain how this type of collision between two legal areas – patent law and the regulatory provisions on interchangeability – should be dealt with. In the present case, there were the safety concerns in relation to the underlying general preference of generic competition to be assessed and respected. These latter are not typically interests that are weighed against each other, but the effects of their application and effectiveness must be considered. Notably, in Sweden, effective market access relies heavily on the interchangeability/substitution system.

In summary, on the one hand, one could or perhaps even should respect the Agency's rather far-reaching safety concerns but on the other hand, marginally relevant patent rights could, although respected, indirectly be allowed to effectively delay generic competition. If this is acceptable is probably not possible to have a firm opinion on at a general level but the circumstances in the individual case should and must be considered and the safety concerns realistic and objective.

A walk-through of the latest CJEU case law on the SPC regulation

By Johanna Henningsson

In 2024, the CJEU delivered two rulings on the interpretation of Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (the SPC regulation):

- **Case C-181/24, relating to the designation of a marketing authorisation (MA) under Article 3(d), and**
- **Joined Cases C-119/22 and C-149/22, relating to the concept of "protected by a basic patent" in accordance with Article 3(a), as well as the relationship between Article 3(a) and (c).**

This article summarizes the findings of the CJEU in its latest rulings.

Order of the CJEU of 16 July 2024 in Case C-181/24 – can a revoked marketing authorisation be considered the first authorisation in accordance with Article 3(d)?

Facts and circumstances

- In 2010, the claimant obtained a first MA for a medicine containing the active ingredient A. Later, in 2019, this MA was revoked.
- In 2021, the claimant obtained a second MA for a different medicine, containing the same active ingredient A. The claimant applied for a Supplementary Protection Certificate (**SPC**) in Hungary on the basis of this later MA, dedicating the active ingredient A as the product in accordance with the SPC regulation. However, the Hungarian Intellectual Property Office (**IPO**) rejected the application.

As the reader acquainted with the SPC regulation is aware – article 3(d) states that the MA which forms the basis for the application should be the first MA to market the product in question:

- "(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product."

As the active ingredient A had been authorized in 2010, the Hungarian IPO ruled that the second MA was not the first MA for the product, i.e. the active ingredient. However – the English language version of Article 3(b), to which Article 3(d) refers, provides that a *valid* MA must exist on the day the application for an SPC is lodged:

- "(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;"

The same goes for *inter alia* the German, French and Swedish language versions. The claimant therefore argued that the second MA was indeed the first MA for the active ingredient A in accordance with article 3(d), as this was the only valid MA on the day on which the application for the SPC was made.

The CJEU's reasoning

Despite the reference in Article 3(d) to the MA defined Article 3(b), the CJEU concluded that it clearly follows from the wording of Article 3(d) that the condition is based on an objective chronological criterion which designates the MA granted on the earliest date, regardless of whether it is still in force. This conclusion is further supported by the context in which Article 3(d) is set, the objectives pursued by the EU legislature and the legislative history of the SPC regulation.

According to the CJEU, the four conditions laid out in Article 3 are independent and cumulative. Hence, they cannot be merged. Article 3(d) therefore refers to Article 3(b) only in order to identify the MA which must satisfy the additional and independent

condition of the former provision. A contrary interpretation would lead to confusion of the two conditions by merging the concept of "MA" with the concept of a "valid MA". That confusion of the two conditions is not intended is further supported by Article 8 of the same regulation. Article 8 provides that the MA set out in Article 3(b) be specified. If this is not the first MA, the first MA is to be identified. If Article 3(d) only referred to a valid MA, this would, according to the CJEU, have been specified in Article 8.

It should also be noted that the Explanatory Memorandum to the proposal of the (former) SPC regulation states that only the first MA for the product in question should be considered – regardless of whether the product is granted several MAs due to differences in pharmaceutical form, dose, composition, indications etc. In addition, the CJEU stated in C-443/17 and C-673/1 that the legislature, by establishing the SPC regime, did not intend to protect all pharmaceutical research giving rise to the grant of a patent and the marketing of a medicinal product, but to protect only research leading to the first MA for an active ingredient as a medicinal product. This objective would be undermined if only MAs in force were considered. If this interpretation was held to be correct, the holder of several MAs would be given the power to choose which version of the product to favour – an order that, in the view of the CJEU, clearly does not accord with the choice of the EU legislature.

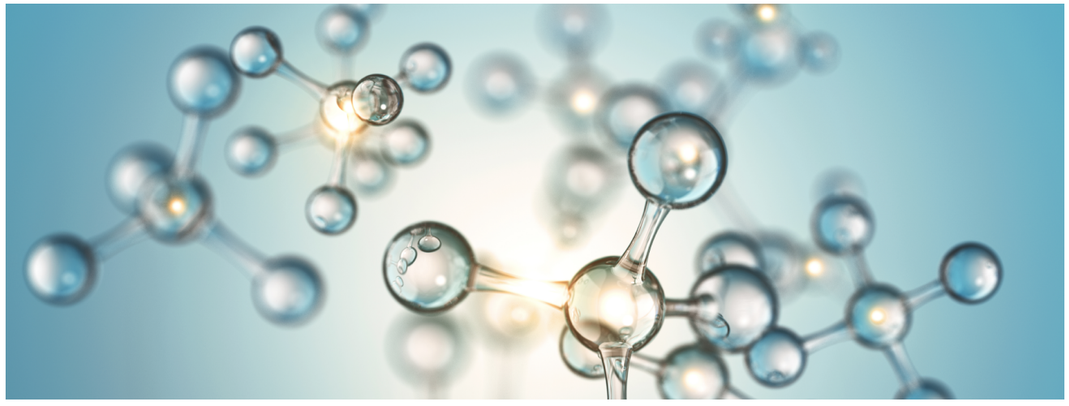
In summary, it is therefore not sufficient to refer in an application for an SPC to the earliest *valid* MA for a product. Article 3(d) refers to the earliest MA in chronological order – regardless of whether that MA is in force on the day of the application for the SPC.

Judgment of the CJEU of 19 December 2024 in Joined Cases C-119/22 and C-149/22– under what circumstances are the conditions of Article 3(a) and 3(c) met?

Introduction

Facts and circumstances

In Finland, the patent proprietor had obtained a first SPC for the single active ingredient A. Later, the patent proprietor obtained a second SPC in Finland relating to the combination of the active ingredients A and B. A generic company initiated legal proceedings to invalidate the SPC for the combination of A and B. The generic company argued inter alia that the SPC had been granted in breach of Article 3(a), since one of the active ingredients, namely A, was known and had been used to treat the same disease for decades before the granting of the basic patent. In addition, the generic company argued that the SPC had been granted in breach of Article 3(c), as the patent proprietor had previously been granted an SPC for the active ingredient A as such.



A substantially analogous dispute arose in Ireland, where the patent proprietor had obtained an SPC for a combination of the active ingredients A and B. Previous to this, the patent proprietor had obtained an SPC for A alone.

The preliminary ruling

Article 3(c) – the uncertainties in previous case law

The referring courts questioned whether Article 3(c) of the SPC regulation precludes the grant of an SPC for a product consisting of two active ingredients A + B where:

- the active ingredient A has already alone been the subject of an earlier SPC and is the only one disclosed by the basic patent, and
- the other active ingredient B was already known at the filing date or priority date of the basic patent.

The questions arose because the CJEU – in particular, in previous cases C-443/12 and C-577/13 – had somewhat confused the requirements of Article 3(c) with the requirements of Article 3(a). In those cases, the CJEU concluded that it should be determined whether a product has previously been subject to an SPC based on what the basic patent designates as the 'core inventive advance' and the 'subject matter of the invention'. However, in relation to Article 3(a) the CJEU has subsequently, at least according to some interpretations, abandoned the relevance of 'core inventive advance' for the interpretation of Article 3(a).

The CJEU's reasoning

The CJEU initially stated that the meaning of the term 'product' as defined in Article 1(b) of the SPC regulation must be determined. It follows from the definition of the term 'product' that whether two 'products' are different or not depends solely on the comparison of the active ingredient or ingredients. If one of the 'products' to be compared is a combination of two active ingredients A+B, it must be regarded as being a different 'product' from the 'product' consisting only of the active ingredient A or B. Hence, the CJEU concluded that the strict definition of the term 'product' is not dependent on the context in which it is relied on. Therefore, an SPC for the combination of active ingredients A and B cannot be refused due to the fact that ingredient A or B has previously been subject to an SPC alone.

In line with the finding that the term 'product' is independent of the context in which it is used, the CJEU concluded that the four conditions laid down in Article 3 are cumulative. While Article 3(a) seeks to delimit the material scope of the SPC by reference to the basic patent, Article 3(c) lays down a separate condition that seeks to limit the temporal scope of the additional protection conferred on a given 'product'. As a result, the basic patent cannot be given any weight in the interpretation of whether an SPC has previously been granted for the 'product'. As such, Article 3(a) is irrelevant in terms of the interpretation of the condition laid down in Article 3(c). The test of whether the condition laid down in Article 3(c) should consist solely of determining what 'product' protection is sought for, and then determining whether an SPC has previously been granted for the product in question.

Article 3(a) – the uncertainties in previous case law

With regard to Article 3(a), the referring courts first questioned whether it is sufficient that the 'product' for which protection is sought is explicitly mentioned in the claims of the basic patent. In addition, the Irish court referred a question to the CJEU specifically referring to the situation where the basic patent claims a combination of the novel ingredient A and the previously known ingredient B. In such a situation, the court questioned whether the combination could be protected by an SPC despite the fact that ingredient B was available in the public domain.

As the reader may be aware, the CJEU has had to deal with a great number of referrals relating to the interpretation of Article 3(a). In short, this number of referrals (described by the Advocate General as "the long winding road") started with C-392/97. In that case, the CJEU concluded that the interpretation of Article 3(a) should be made in accordance with national patent law. This line of reasoning has since been abandoned, and the CJEU concluded in C-121/17 that the conditions in Article 3(a) are fulfilled if the skilled person considers that:

- The combination of active ingredients necessarily, in light of the description and drawings in the basic patent, falls within the scope of the invention protected by the basic patent.
- Each of those active ingredients can be specifically identified in light of all the circumstances disclosed in the basic patent.

While the conditions following the decision in C-121/17 may as such be clear, it has not been certain whether both conditions always apply or whether the condition relating to the scope of the invention should only be applied in situations where each of the active ingredients are not explicitly mentioned in the claims of the basic patent.

The CJEU's reasoning

The CJEU concluded that the conditions laid down in C-121/17 constitute a two-stage test. The first step is to determine whether the skilled person on the priority date would consider the 'product' to be falling within the scope of the invention protected by the basic patent. The second step is to determine whether the skilled person, on the priority date, would have been able to identify the 'product' in the patent claims.

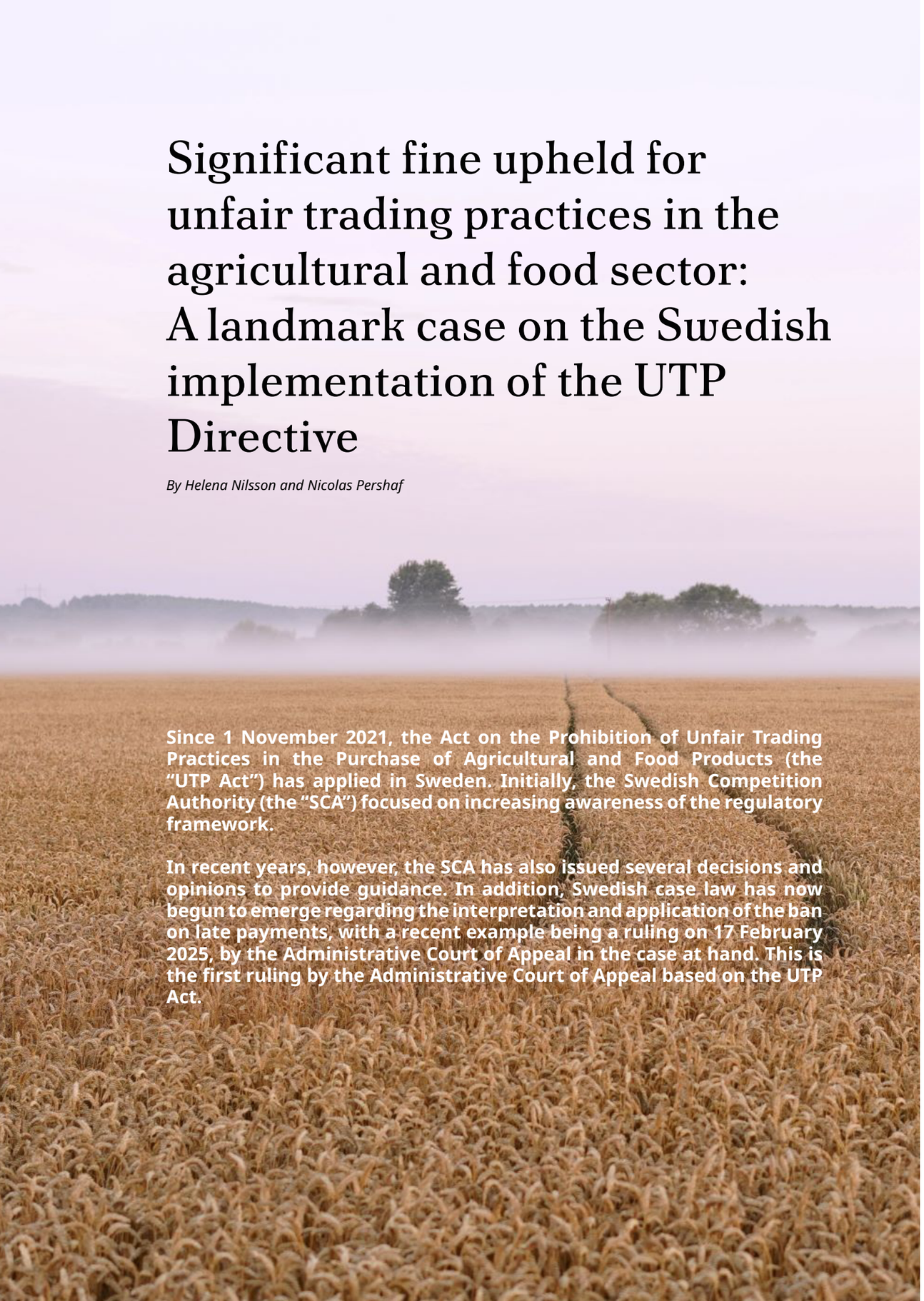
Hence, the two-stage test is of general application and should be applied regardless of whether the 'product' is explicitly mentioned in the claims. This reasoning, according to the CJEU, is supported by the fact that the protection conferred by an SPC is not intended to broaden the protection conferred by the basic patent.

With regard to the question asked specifically by the Irish court, the CJEU initially concluded that the two-stage test established in C-121/17 is to be applied regardless of whether one of the ingredients were previously available in the public domain. In a situation where a combination is indeed expressly mentioned in the claims, the interpretation of whether Article 3(a) is met will naturally be focused on whether the combination falls within the scope of the invention. To answer this question, it is necessary to determine whether the patent discloses how a combination explicitly mentioned in the claims is a feature required for the solution of the technical problem.

However – and it is worth mentioning – the CJEU concluded that a combination of a novel and a previously known ingredient may indeed be made subject to an SPC. This requires that the basic patent discloses that the combination of the two active ingredients has a combined effect going beyond the mere addition of the effects of those two active ingredients and which contributes to the solution of the technical problem. If so, it may be concluded that the combination of those two active ingredients necessarily fall under the invention covered by that patent.

Significant fine upheld for unfair trading practices in the agricultural and food sector: A landmark case on the Swedish implementation of the UTP Directive

By Helena Nilsson and Nicolas Pershaf



Since 1 November 2021, the Act on the Prohibition of Unfair Trading Practices in the Purchase of Agricultural and Food Products (the "UTP Act") has applied in Sweden. Initially, the Swedish Competition Authority (the "SCA") focused on increasing awareness of the regulatory framework.

In recent years, however, the SCA has also issued several decisions and opinions to provide guidance. In addition, Swedish case law has now begun to emerge regarding the interpretation and application of the ban on late payments, with a recent example being a ruling on 17 February 2025, by the Administrative Court of Appeal in the case at hand. This is the first ruling by the Administrative Court of Appeal based on the UTP Act.

The regulations concerning unfair trading practices stem from the UTP Directive [1]. The directive aims to address the imbalance of bargaining power between suppliers and buyers in the agricultural and food supply chain, which can lead to unfair trading practices that often deviate from good commercial conduct, and where weaker parties are forced to bear disproportionate economic risks.

The UTP Act implements the UTP Directive in Sweden and aims to provide a protective framework for suppliers, ensuring fair treatment in their commercial transactions. It applies to purchases of agricultural and food products where either buyer or supplier is established in Sweden, and where the buyer has an annual turnover of more than two million euros or is a public authority in the European Union. Importantly, the legislation does not extend to transactions where the buyer is a consumer, focusing instead on the commercial relationships that have the potential to impact broader market dynamics.

The prohibited practices are categorised into those that are always prohibited (blacklisted) and those that are prohibited unless explicitly agreed (greylisted).

Prohibited trading practices

The following practices on the part of a buyer of agricultural and food products are prohibited according to Section 5 of the UTP Act:

- payment later than 30 days,
- cancellation of an order with less than 30 days' notice,
- unilateral changes to certain terms of a supply agreement,
- requiring payments from the supplier that are not related to the sale of the products,
- requiring the supplier to pay for the deterioration or loss, or both, of the products, where such deterioration or loss is not caused through the negligence or fault of the supplier,
- non-compliance with the supplier's request for written confirmation of the terms of a contract,
- commercial retaliation against a supplier who exercises their contractual or legal rights, and
- requiring compensation from the supplier for the cost of customer complaints relating to the sale of the products.

As regards to the date from which the payment term in (a) (and which is subject to scrutiny by the Administrative Court of Appeal in the present judgment) is to be calculated, the UTP Act distinguishes between contracts where the products are to be delivered on a regular basis and when they are not.

1 Directive (EU) 2019/633 of the European Parliament and of the Council of 17 April 2019 on unfair trading practices in business-to-business relationships in the agricultural and food supply chain.

In the case of a contract providing for delivery of products on a regular basis, the 30-day payment term starts from the end of an agreed delivery period, or the date on which the amount payable is set, whichever occurs later. In the case of a contract that does not provide for delivery of products on a regular basis, the 30-day payment term starts on the date of delivery or the date on which the amount payable is set, whichever occurs later. If it is the buyer who determines the payable amount, the payment term shall always commence from the end of the delivery period or the date of delivery, as applicable.

Permissible trading practices with prior agreement

The following practices by buyers of agricultural and food products are prohibited, unless clearly agreed in advance between buyer and supplier, as provided for in Section 12 of the UTP Act:

- returning unsold products to the supplier without paying for them,
- returning unsold products without paying for their disposal,
- requiring payment as a condition for the storage, display or listing of the supplier's products, or for making such products available on the market,
- requiring the supplier to pay for the marketing of the products by the buyer, and
- requiring the supplier to pay labour costs for furnishing premises used for the sale of the supplier's products.

Background to the case

Setterwalls has previously reported on the matter here.

Following a tip to the SCA in December 2021, the authority initiated a formal investigation into a fruit and vegetable wholesaler's (the "**Company**") trading practices. Specifically, the tip alleged that the Company applied payment periods longer than 30 days, in breach of the UTP Act.

As part of its investigation, the SCA requested information and documents from eight suppliers. In seven of the agreements examined, the SCA discovered that the Company had applied payment terms of 40 days after the enactment of the UTP Act. The SCA's investigation revealed that the Company made late payments to six of the eight suppliers on at least 612 occasions between 1 November, 2021 and 24 February, 2022. These delays ranged from 4 to 23 days beyond the 30-day period after the invoice date. The total amount of these late payments was approximately SEK 2,837,000. Additionally, the Company used contractual terms specifying payment periods exceeding 30 days with a total of 290 suppliers.

Furthermore, email correspondence between the Company and a number of its suppliers in connection with the UTP Act entering into force showed that the Company had not adjusted its payment periods, despite being informed by the suppliers that the payment periods exceeded those permitted by the UTP Act. The Company justified its position to its suppliers by asserting that existing contract terms apply until renegotiated.

On initiation of investigation by the SCA, the Company manually updated the agreements with its suppliers and revised the payment terms.

In October 2023, following a comprehensive investigation by the SCA, the authority issued its decision in the matter, concluding that the Company had violated the prohibition on late payments, having on several occasions paid suppliers later than the payment times applicable under the UTP Act. On this basis, the SCA imposed a fine of SEK 5,000,000 on the Company. In its decision, the SCA notably provided guidance on how to calculate the fine and this was the first case under the UTP Act in which the SCA imposed a fine.

> "The fine was deemed sufficiently effective and dissuasive, and also proportionate."

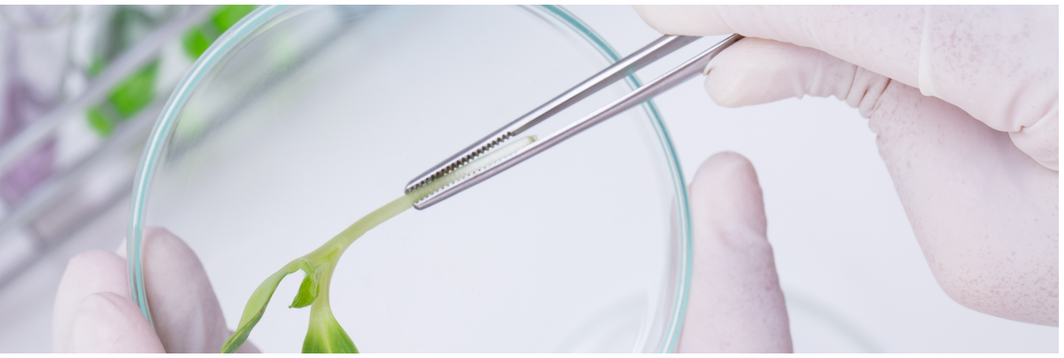
The Company appealed the decision to the Administrative Court.

Proceedings before the Administrative Court

Initially, it should be noted that the Company admitted that by failing to adjust its payment terms in time, it had breached Section 5 of the UTP Act.

Against this background, the main issue in the case was not whether the Company had breached the UTP Act, it was instead whether a fine was appropriate and whether the fine had been correctly determined.

The Company argued that the fine was excessive, and that the violation was not intentional. It also emphasised that the Swedish legislator had not implemented a transitional provision for older contracts to bring them into line with the new legal framework. It highlighted the fact that



the violation occurred shortly after the law came into effect and was corrected within a month, suggesting that a reasoned dismissal or an injunction would have been more appropriate than the sanction imposed. The Company further pointed out that initial enforcement actions were supposed to focus on guidance and self-regulation. The Company argued that its violation was of a minor nature, involving small amounts and short delays in payments, with minimal economic damage to suppliers. It criticised the lack of a proportionality assessment in the decision, deemed the sanction disproportionate and noted that similar violations in other EU Member States resulted in much lower penalties. It also claimed that the lengthy processing period of 22 months violated the Company's rights under Article 6.1 of the European Convention on Human Rights.

The Administrative Court rejected the Company's appeal, ruling that the fine imposed by the SCA was justified and well-balanced, and that there were no grounds for reducing it. The fine was deemed sufficiently effective and dissuasive, and also proportionate. The Administrative Court considered that the Company's arguments did not give rise to any other assessment. Finally, the Administrative Court added that it found that it was clear from the SCA's decision that the principle of proportionality had been taken into account in all necessary respects.

The Company appealed against the Administrative Court's judgment at the Administrative Court of Appeal.

Proceedings at the Administrative Court of Appeal

In the Administrative Court of Appeal, the Company essentially presented the same arguments as in the Administrative Court, adding inter alia that if the Administrative Court of Appeal did not set aside the fine for other reasons, it should examine whether Article 1.4 of the UTP Directive has direct effect, possibly after a preliminary ruling from the Court of Justice of the European Union. In particular, the Company argued that the unconditional and precise time limit in the article aimed to give companies sufficient time to adapt existing agreements.

Against this background, the Company contended that there were strong indications that Sweden had not correctly transposed Article 1.4 of the UTP Directive into Swedish law, which was why the UTP Act, together with the principles of proportionality and equal treatment, should be interpreted in accordance with the UTP Directive in order to justify the setting aside of the fine.

For clarity, Article 1.4 of the UTP Directive states that supply agreements concluded before the date of publication of the measures transposing the directive in accordance with the first subparagraph of Article 13.1 shall be made to comply with the directive within 12 months of that date of publication.

In this regard, the SCA argued that Article 1.4 of the UTP Directive specifies the date by which Member States must ensure that the terms of supply contracts are in line with the substantive provisions of the UTP Directive. It is conditional upon Article 9.1 of the UTP Directive, which states that Member States may maintain or introduce stricter rules aimed at combating unfair trading practices than those laid down by the UTP Directive, and therefore has no direct effect. According to the SCA, the Swedish legislator had elected to apply the substantive provisions of the UTP Directive to all supply contracts at the time the UTP Act entered into force, which represents an application of the right conferred on Sweden under Article 9.1 of the UTP Directive.

The Administrative Court of Appeal agreed with the SCA's assessment ruling and, in view of the fact that Article 1.4 of the UTP Directive is conditional upon Article 9.1 of the same directive, found that the UTP Directive had been correctly transposed into Swedish law.

The Administrative Court of Appeal further agreed with the Administrative Court's ruling that there were grounds for imposing a fine and that there were no grounds for reducing the fine. On these grounds, the Administrative Court of Appeal dismissed the appeal.

The Company has appealed the judgment to the Supreme Administrative Court. The Supreme Administrative Court is yet to grant leave to appeal.

Concluding remarks

This is the first case decided by the Administrative Court of Appeal concerning the UTP Act. The case therefore sets a precedent and provides important guidance on when fines are appropriate and how they should be calculated. The case is a reminder of the strict obligations imposed by the UTP Act and the seriousness with which late payments and other unfair trading practices are viewed in Sweden.

The Company has appealed to the Supreme Administrative Court, which has yet to grant leave to appeal, leaving open the possibility of further judicial guidance on these issues.

Buyers and suppliers alike should pay close attention to the obligations set out in the UTP Act. Setterwalls has extensive experience working with the agricultural and food sector and is happy to assist with any questions you may have regarding the UTP Act.

Strengthening EU's medicine supply: The EU Commission's Critical Medicines Act proposal

By Lovisa Dahl Nelson and Filippa Jagorstrand

In recent years, shortages of medicines have become an increasingly urgent challenge within the EU. The pandemic, geopolitical tensions and a growing dependence on manufacturing outside the EU have exposed vulnerabilities in the supply chain for critical medicines. In response, on 11 March 2025, the European Commission presented a proposal for a new regulation—the Critical Medicines Act (CMA)—aimed at strengthening the EU's resilience and ensuring access to essential medicines in the EU.

The scope of the proposed regulation is primarily centred on the medicines that are identified as critical on the EU's List of Critical Medicines. The list, developed jointly by the European Medicines Agency (EMA), the European Commission and the Heads of Medicines Agencies (HMA), is formally established as part of the ongoing revision of EU pharmaceutical legislation, presented in April 2023. Critical medicines are those for which few or no alternatives are available, and where shortages pose a serious threat to patient health. They are medicines that must always be available in the EU to guarantee continuity of care, high-quality healthcare, and to protect public health across the EU. The category includes a wide range of medicines, from antibiotics and anticoagulants to cancer drugs and cardiovascular medicines.

The proposed regulation also aims to improve availability of other medicines of common interest, i.e., medicines other than critical medicines, which may not be affected by supply issues but are still not available to patients in three or more Member States, such as orphan drugs. However, not all rules in the act will be applicable to these medicines.

The Critical Medicines Act forms part of the EU's broader pharmaceutical strategy and complements the ongoing reform of the EU's pharmaceutical legislation.

The specific objectives of the initiative are as follows:

- To facilitate investment in manufacturing capacity for critical medicines and their active ingredients and other essential inputs within the EU.
- To reduce the risk of supply disruptions and strengthen availability by encouraging diversification of supply chains and resilience in public procurement procedures for critical medicines and other medicines of common interest.
- To leverage the aggregated demand of participating Member States through joint procurement procedures.
- To also support the diversification of supply chains to facilitate the establishment of strategic international partnerships.

The Swedish Government welcomes the Commission's proposal for a regulation on critical medicines, and its ambitions. The proposal is now being considered by the European Parliament and the Council, where it may be subject to numerous amendments and lengthy voting processes. It is therefore not yet possible to predict whether, when, or in what specific form the proposed regulation will come into force.

The Critical Medicines Act is a step towards achieving a more robust and autonomous pharmaceutical supply within the EU. The proposal aims to enhance the supply of essential medicines in the EU by minimising the EU's dependence on non-EU medicine suppliers, by incentivising supply chain diversification and boosting domestic manufacturing in the EU. Setterwalls is closely monitoring this matter and will provide updates as soon as there are any new developments.

Court ruling: Delivery of cosmetic products that do not comply with labelling requirements constitutes an unfair marketing practice

By Helena Nilsson and Nicolas Pershaf

Swedish regulations applicable to cosmetic products require labelling in Swedish, including details of specific precautions. In a recent ruling (2025-03-12, Case no. PMT 12383-21), the Swedish Patent and Market Court of Appeal (Patent- och marknadsöverdomstolen) examined Sweden's implementation of the EU E-commerce Directive and its interaction with Swedish marketing law and regulations concerning cosmetic products. This article delves into the Court's findings, focusing on the implications for cosmetics businesses operating within the EU.

Background

The Swedish Association of Chemical Products Suppliers (KTF) is an association of five industry organisations, including a trade association for companies that import, manufacture or market *inter alia* cosmetics and hygiene products. KTF filed a legal action against a German-based cosmetics company, claiming that the company was marketing and selling its products to the Swedish market through its website without complying with Swedish labelling requirements.

The EU Cosmetic Products Regulation mandates that cosmetic products must be safe for human health when used under normal or reasonably foreseeable conditions. This includes proper labelling to inform consumers adequately on, for example, specific precautions to be observed in use. However, the Swedish implementation of these regulations, as seen *inter alia* in the Swedish Regulation (2013:413) on Cosmetic Products, further requires this labelling to be in Swedish when products are sold to end-users on the Swedish market. KTF thus considered that the cosmetics company violated these requirements by marketing products without the necessary Swedish language labelling.

The E-commerce Directive vs Swedish marketing law in relation to online marketing claims

The core issue of the case was whether the Swedish E-commerce Act (implementing the E-commerce Directive) was applicable to the company's marketing and, if so, how this affected the applicability of Swedish marketing law in the matter.

The E-commerce Directive aims to remove obstacles to cross-border online services. The internal market clause is a key principle of the E-commerce Directive. It ensures that providers of online services are subject to the law of the Member State in which they are established, and not the law of the Member States where the service is accessible. Hence, in accordance with the Act, the "country of origin" principle (ursprungslandsprincipen) is to be applied, meaning that the rules of the country where the marketing originates from apply.

However, in Swedish marketing law, the primary principle applied is "the country of effect" principle (*effektlandsprincipen*). According to this principle, Swedish marketing law applies to marketing directed at the Swedish market. While not part of any formal piece of Swedish marketing legislation, the country of effect principle has been acknowledged in preparatory works of Swedish legislation and consistently applied by Swedish courts for decades. In this matter, a particular issue was thus how the principle of the country of effect relates to the country of origin principle.

The Court thus examined both the Swedish implementation of the E-commerce Directive and its compatibility with EU law, as well as the scope of the coordinated field according to the Directive. The Court also submitted a request for a preliminary ruling to the Court of Justice of the European Union (CJEU).

The Swedish Court asserted that online marketing is part of the coordinated field

under the E-commerce Directive. Hence, the conclusion was that the country of origin principle (*ursprungslandsprincipen*) applies, and that Swedish marketing law rules cannot, as a general rule, be applied in relation to the online marketing for which the cosmetics company was responsible and which originated in Germany. Based on this conclusion the Swedish Court found that the Swedish Marketing Act did not apply to the cosmetics company's online marketing claims even though they were directed at Swedish consumers. This aspect of KTF's claim was therefore dismissed.

The E-commerce Directive vs Swedish marketing law in relation to delivery of products

The Swedish Court thereafter examined whether the deliveries of cosmetic products that did not meet Swedish labelling requirements was unfair and could be prohibited under Swedish marketing law. According to the E-commerce Directive, requirements applicable to goods as such are not part of the coordinated field. This means that safety standards, labelling requirements and product liability fall outside the scope of the E-commerce Directive. Thus, the principle of the country of effect (*effektlandsprincipen*) is applicable to labelling requirements.

Considering the broad scope of application given to the term "marketing" in the underlying EU law, the Swedish Court came to the conclusion that the delivery of a product constitutes a marketing measure within the meaning of the Swedish Marketing Act. The Court found that the delivery of a product that does not comply with labelling requirements is contrary to the principle of legality and therefore not in accordance with good marketing practice under the Swedish Marketing Act. As the marketing has significantly affected, or is likely to affect, the recipient's ability to make an informed business decision, the marketing was also considered unfair.

The cosmetics company's unfair marketing was prohibited, and each prohibition was accompanied by a substantial fine of SEK 1,000,000.

Concluding remarks

The Court's decision has implications for businesses, such as the cosmetic businesses, operating across borders within the EU. They must be aware that while the E-commerce Directive (and the Swedish E-commerce Act) facilitates the free movement of online services, it does not exempt them from complying with local requirements applicable to the goods as such (such as safety standards, labelling requirements and product requirements).

This case underscores the importance of understanding and navigating the complex interplay between e-commerce laws and product regulations in, for example, the cosmetics industry. Setterwalls is happy to help you navigate these rules.

EU introduces stricter rules on plastic food contact materials

By Helena Nilsson and Nicolas Pershaf

On 21 February 2025, the European Commission introduced amendments to existing EU regulations concerning plastic materials and articles intended to come into contact with food. The new regulation[1] aims to enhance safety, quality control and the use of recycled plastics in food contact materials. The changes took effect on 24 March 2025. In this article, Setterwalls provides a brief analysis of the key changes and their implications.

[1] COMMISSION REGULATION (EU) 2025/351 of 21 February 2025 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, amending Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, and amending Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food.

A key element of the regulation is the introduction of the concept and requirement of a “high degree of purity” for substances used in the manufacture of plastic materials and articles that may be present in the final plastic material, including those manufactured from waste. A substance is considered to have a high degree of purity if containing only minor amounts of non-intentionally added substances that meet specific conditions. The regulation also aligns with the concept of UVCB (substances of unknown or variable composition, complex reaction products or biological materials) as defined in Regulation (EC) No. 1907/2006. Only substances that comply with high-purity requirements will be permitted. This alignment facilitates the risk assessment for, and authorisation of, such substances.

The amendments also emphasise the importance of reprocessing plastic by-products and the use of recycled plastics. The regulation defines ”reprocessing of plastic” and sets out rules for the safe reprocessing of plastic by-products. It also specifies that substances manufactured from waste must be of a high degree of purity to ensure they do not pose a risk to human health. The use of recycled plastics is allowed in the manufacture of plastic materials and articles, provided they meet specific conditions.

The regulation also updates specific migration limits (SMLs), ensuring that hazardous chemicals do not leach into food at harmful levels.

Furthermore, to enhance consumer safety, the regulation mandates that manufacturers provide clear instructions regarding the use of plastic food contact articles. This includes information on how to prevent or slow down deterioration, observable changes indicating deterioration and warnings about specific damage or foreseeable misuse. The regulation also requires that plastic materials and articles intended for repeated use be accompanied by instructions for safe and appropriate use.

“It also specifies that substances manufactured from waste must be of a high degree of purity to ensure they do not pose a risk to human health. The use of recycled plastics is allowed in the manufacture of plastic materials and articles, provided they meet specific conditions.”

The regulation provides a transitional period for manufacturers to adapt to the new requirements. Plastic materials and articles complying with the previous regulations may continue to be placed on the market until 16 September 2026. However, manufacturers must inform users if a product from an intermediate stage of the manufacturing of plastic materials and articles or a substance intended for the manufacturing of such a product, material or article, and which is first placed on the market after 16 December 2025, does not comply with the new regulation and cannot be used to manufacture plastic materials and articles after the transition period.

The amendments introduced represent a step towards ensuring the safety and quality of plastic materials and articles intended for contact with food. By clarifying definitions, enhancing compositional requirements and promoting the use of recycled plastics, the regulation aims to protect human health and support sustainable practices.

It is important for all stakeholders to stay informed and adapt to these changes to ensure compliance. Please do not hesitate to reach out to Setterwalls if you have any questions.

Five steps to ensure Data Act compliance for IoT products and services within the MedTech sector

By Ebba Karlsson and Mathilda Ström

In December 2023, the new regulation on harmonized rules on fair access to and use of data (2023/2854; the "Data Act") was published in the Official Journal of the European Union, with most of the new requirements becoming applicable later this summer, on 12 September 2025. The new regulation aims to foster a competitive data market by making data, especially industrial data, more accessible. It will have an impact on many businesses, not least those within the MedTech sector.

The Data Act imposes design and manufacturing obligations on IoT products and services to ensure users have access by default to relevant data. It specifies when, how and on what terms data must be shared with users and other businesses. Additionally, it includes transparency requirements by mandating the pre-contractual provision of information to users about the data generated by connected products or related services.

Five essential steps to consider as part of your Data Act compliance project are described below.

Step 1 - Conduct a product and service inventory

Evaluate your business to identify which of your products and services could be classified as connected products and related services, thereby falling within the scope of the Data Act. For a product to be considered a connected product, it must be capable of obtaining, generating or collecting data concerning its use or environment and it must be able to communicate such data via, for example, the Internet or a cable. Examples of such products include a smart insulin pump or an asthma inhaler that collects data about its usage and can transmit this data over the Internet.

It is important to note that for a service, such as a mobile application, to be classified as a related service under the Data Act, it must have functions that have an impact on the operation of a connected product. For example, an application that merely displays statistics and an overview of the product's functioning, such as battery status, without controlling the product's operation, would not be classified as a related service under the Data Act.

Step 2 - Start mapping and categorising the data

Not all data needs to be shared. To determine which data falls under the requirements for sharing, a data holder should map and classify the data generated by, or in connection with, a connected product and a related service. In the case of connected products, data sharing requirements apply to product data generated through the use of the product and designed by the manufacturer to be retrievable. Data that is not retrievable, such as data immediately deleted upon creation for product functionality, typically does not need to be shared. In the example of a smart insulin pump, the historical records of insulin dosages administered by the user,

including the specific time and date of each dose, could be classified as product data subject to data sharing requirements.

Additionally, the level of data refinement affects sharing requirements. Only raw or source data and pre-processed data (i.e., data processed to make it usable or understandable) must be shared. “Inferred or derived data” (e.g. data refined through advanced processing or analytics) is generally exempt from sharing.

Step 3 – Prepare for sharing

It is advisable to begin evaluating the various options for enabling access to data based on the preferred setup for a specific product and to document all considerations for the purpose of being able to demonstrate this to a supervisory authority. The data holder should then establish routines and policies for managing data access requests from both users and third parties. A connected product or related service should ideally be designed to allow direct access to product and service data, including metadata. If direct access is not feasible, the data holder must provide ‘readily available data’ upon the user’s request. ‘Readily available data’ refers to data that the data holder can lawfully obtain without excessive effort. While direct accessibility is preferred by the legislator, it is not mandatory. Manufacturers or service providers can decide, on the basis of technical feasibility, costs, protection of trade secrets or intellectual property, and security maintenance, whether their products or services should be designed with access by default. If direct access is not possible, indirect access must be provided by making data available upon request. In the case of indirect access, the Data Act requires simplicity for the user. Wherever possible, requests should be enabled electronically, and data should be shared without undue delay and free of charge. Although the Data Act does not specify a timeline, the one-month limit stipulated in the GDPR might generally be used as a rule of thumb.

Step 4 – Transparency measures

The Data Act mandates the provision of pre-contractual information regarding data usage for connected products and related services. As regards connected products, the obligation lies with the seller, renter or lessor, who must provide information on, for example, the estimated volume of product data to be generated and the location of data storage. This information may be delivered via a stable URL, web link or QR code. In the case of related services, an equivalent obligation lies with the service provider.

The transparency obligations stipulated in the Data Act do not override the GDPR obligations for data controllers to inform data subjects about personal data processing. Both sets of obligations must be applied concurrently. Any changes in the information during the product’s lifetime or the contract period must be communicated to the user. To ensure timely compliance, it is recommended to start preparing the necessary pre-contractual information, focusing on both content and format to meet the standards required by the Data Act.

Step 5 – Contract inventory

The Data Act states that a data holder’s right to use any readily available product and related service data must be agreed upon in a contract with the user. Consequently, contracts must be prepared for such data usage. Additionally, contracts are needed for third-party recipients of data, which a data holder must share upon a user’s request. Such contracts must include fair, reasonable and non-discriminatory (FRAND) terms. It is also advisable to review and update existing supplier or distributor contracts to ensure back-to-back terms are in place and that the responsibility for providing pre-contractual information is assigned to the party directly in contact with the user.

To aid compliance with the Data Act, the EU Commission is creating and recommending non-binding model contractual terms (MCTs). While these MCTs are voluntary, they are intended to set a “best practice” standard. Data holders may use the MCTs as a foundation but should tailor them to meet specific needs. provide information about the

“Wherever possible, requests should be enabled electronically, and data should be shared without undue delay and free of charge. Although the Data Act does not specify a timeline, the one-month limit stipulated in the GDPR might generally be used as a rule of thumb.”

The Green Claims Directive – New rules regarding environmental claims

By Lovisa Dahl Nelson

The EU Commission adopted a proposal for a Directive on Green Claims in 2023, which is expected to be finally adopted in mid-2025. The proposal aims, among other things, to make green claims reliable, comparable and verifiable across the EU, and to protect consumers from greenwashing. The directive introduces stricter requirements as to how companies substantiate and communicate voluntary green claims to consumers.

As many companies in the life science sector use environment and sustainabilty statements — such as claims about eco-friendly production of pharmaceuticals, "green" medical devices and biodegradable diagnostic tests — the new directive will impact the life sciences industry and its marketing. In this article, we summarise some of the key points of the proposed directive that companies in the life sciences sector should be aware of.

Background

It has been found that many environmental claims made by companies were unreliable and consumer trust in them was extremely low. For example, it has been found that 53% of green claims give vague, misleading or unfounded information. With a proposed new law on green claims, the EU addresses "greenwashing", a practice where consumers risk being misled, as companies may have given a false impression of their environmental impacts or benefits. Against that background, the upcoming Green Claims Directive proposes the imposition of specific and binding rules on how claims must be substantiated, verified and presented.

Substantiation requirements

According to the directive, all green claims — including statements like "climate neutral", "sustainable production" and "biodegradable materials" — must be verifiable and based on scientific evidence. This means that companies must conduct an evaluation to substantiate their environmental claims. The assessment should, among other things, demonstrate that the environmental aspects covered by a claim are significant throughout the lifecycle of the products and should specify whether a claim applies to the whole or certain parts of a product. For example:

- A biotech company promoting a "sustainable fermentation process" must demonstrate the full environmental lifecycle benefits, not only in manufacturing but also in sourcing raw materials and waste management.
- A medical device manufacturer marketing a "low-carbon footprint" instrument must substantiate the claim through lifecycle assessments covering material extraction, production, usage and end-of-life disposal.

Moreover, companies must make evidence supporting claims easily accessible to consumers — for instance by using QR codes on packaging linking to detailed sustainability reports.

The proposal includes already existing trademarks, meaning that trademarks consisting of claims that could be considered as an environmental claim (for example, a green leaf) may be covered by the act. However, many are hoping for an exception for already registered trademarks, but this is not yet clear.

Verification requirement

A major shift is the mandatory third-party pre-verification of environmental claims. No marketing materials using green claims may be published without prior certification from an accredited body. If the body determines that the claim meets the requirements of the directive, a certificate of conformity is issued. The effect of the certificate is that companies are allowed to use the claim in commercial communication to consumers throughout the internal market, and the claim in question cannot be challenged by competent authorities in other member states.

The cost of verification will vary depending on claim complexity:

- The cost to verify a simple claim, e.g., regarding materials used in production, is estimated at EUR 500.
- A full lifecycle-based claim for the environmental footprint of one product could cost up to EUR 8,000.
- A claim regarding an entire organisation's environmental footprint could cost EUR 54,000.

As a result, companies must plan for additional costs and timelines in the go-to-market process. This requirement has faced criticism as it risks leading to increased costs, long processing times and increased administration for companies, which may discourage companies from communicating their sustainability initiatives – a phenomenon known as "green hushing". Despite the criticism, the EU Council has chosen to retain the requirement for prior approval but proposes a simplified process for certain types of environmental claims.

Penalties

Non-compliance could result in severe consequences, such as:

- Fines up to 4% of the company's annual turnover in the Member State concerned.
- Temporary exclusion from public procurement.

The EU Council has expressed concern about the proposed sanctions and believes that they may be too severe and difficult to enforce. Instead of imposing fixed fines, the EU Council has suggested that Member States should be allowed to decide for themselves which sanctions to apply and how to enforce them. This issue is still under discussion, and it remains to be seen which solution will be adopted in the final directive. The final rules on penalties are thus still under discussion, but Member States are expected to be allowed some flexibility in setting national sanctions.

Key steps for life science companies

In light of the upcoming rules, businesses should start preparing by:

- Mapping all environmental claims in marketing materials.
- Collecting scientific evidence for each claim, including full lifecycle analyses where necessary.
- Budgeting for verification costs and incorporating extra time into project planning.

Conclusion

The Green Claims Directive will change the way environmental claims are used in marketing in the EU. Companies that act early to align with the new rules will be better positioned to maintain compliance, strengthen brand trust, and differentiate themselves in an increasingly sustainability-focused market.

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