Pharma Report

Retrospective view of legal developments in Norway

Winter 2026 Edition

Introduction

Dear reader

As legal advisors with a passion for the pharmaceutical sector, Haavind has for several years published Pharma Report, providing an overview of some of the prominent legal developments in the pharmaceutical sector in Norway. In this report, we are happy to present a summary of some of the most significant cases which occurred in 2025.

In this edition, you can read about the endgame of MSD's attempt to limit their patent for a medicinal product used for the treatment of diabetes, as well as the Norwegian take on the rivaroxaban case. You can also read about pharmaceutical advertising, and whether a pharmaceutical company is allowed to provide "gifts" supplied via physicians to patients. You can also read about whether those troublesome decisions from Decision Forum can actually be appealed to by a pharmaceutical company, or if such attempts are futile.

As a leading law firm on healthcare and life science in Norway, our team continuously and closely monitors legal developments relevant to the pharmaceutical sector. If you wish to discuss how your business can meet the legal challenges of this innovative and highly regulated sector, you are always welcome to contact us.

Kind regards

Håkon Austdal

Haavind

Content

Haavind

About the author

Håkon Austdal

Specialist Counsel

Håkon is the author and editor of Haavind's Pharma Report. He specializes in regulatory affairs and intellectual property rights (IP), particularly focusing on the healthcare and life sciences sector.

He assists pharmaceutical and biotechnology companies with a variety of services, including regulatory advice, management, licensing and enforcement of intellectual property rights, complaints on administrative decisions, pharmaceutical advertising and interaction between healthcare personnel and healthcare organizations as well as various commercialization and R&D agreements.

Håkon is an experienced patent litigator, having been involved in some of the largest patent disputes concerning medicinal products in the recent years. He is also a member of EPLAW.

In addition to a law degree, Håkon also holds a bachelor's degree in pharmacy and has work experience from various pharmacies as well as the Norwegian Medicinal Agency (now Medical Product Agency).

Håkon is recognized in several international rankings, such as a Leading Associate by Legal 500 in the category Intellectual Property, Rising Star by IP STARS, Recommended Individual in IAM Patent 1000 and Recommended Individual in World Trademark Review 1000.

THE END OF THE NEVER-ENDING LIMITATION STORY

A decision from the Supreme Court marks the end of what for an IP practitioner would be the equivalent of a blockbuster crime fiction.

Background

Merck Sharpe & Dohme (MSD) is the holder of the now expired patent NO321999. The patent concerned compounds which are inhibitors of the dipeptidyl peptidase-IV enzyme (DP-IV inhibitors), which are directed in the treatment or prevention of e.g. diabetes.

The patent expired on 5 July 2022. However, MSD held two supplementary protection certificates (SPCs) with basis in the patent, one for the substance sitagliptin (which expired 23 September 2022 due to a pediatric extension) and one for the combination of sitagliptin and metformin (which expired 8 April 2023).

On 29 January 2020, i.e. prior to the expiry of the patent, MSD filed for a limitation of the patent at the Norwegian Industrial Property Office (NIPO). In essence, MSD requested two dependent claims to also include metformin in addition to the compound claimed in claim 1 (which includes, inter alia, sitagliptin). The motivation for this seems obvious, since SPCs for combinations of active ingredients have been subject to numerous cases at the European Court of Justice, and it could be argued that the SPC for the combination of sitagliptin and metformin would, based on case law from the CJEU, not fulfil the requirements of the SPC Regulation, in particular Article 3a (that the product must be protected by the basic patent).

Round 1 – The Norwegian Industrial Property Office

However, NIPO initially refused the application for amendment. The stated reason was that the proposed amendments did not constitute a “real” patent limitation since the independent claim 1 was not amended. As such, NIPO argued that the requirements of section 39a of the Norwegian Patent Act, which allows for amending the claims so that the protective scope of the patent is limited, was not fulfilled.

In addition, NIPO reasoned that the amendments in the two claims used features from the application as filed, but that these features were removed in the granted patent, and that these were amendments which are in violation with section 19 second paragraph and section 39 b first paragraph of the Norwegian Patent Act.

Round 2 - KFIR

MSD complained on this decision to the Norwegian Board of Appeal for Industrial Property Rights (KFIR), in addition to filing a subsidiary claim set. The essence of MSD's argument was that there was no legal basis for requiring an amendment of an independent claim in order for the patent limitation to be real. In addition, MSD pointed out that NIPO itself had accepted amendment only of a dependent claim in an earlier case.

On 16 September 2021, KFIR came to the same conclusion as the NIPO, but with another reasoning. KFIR alleged that the proposed amendments opened for protection of combination products, and that this would constitute an extension rather than a limitation of the protective scope of the patent, compared with the granted patent, since the formulation of the claims would open for a protection of combination products not protected by the granted patent. As such, KFIR refused the limitation.

Round 3 - Oslo District Court

MSD brought an action against KFIR's decision before Oslo District Court. MSD argued that KFIR's decision was based on an illogical conclusion. There was no extension of the scope of the patent, since claim 1 already covered all combinations with sitagliptin and any other active substances. The proposed amendments in the dependent claim would limit the scope of the claim from all combinations to a narrower selection of combinations. According to the decision, one of the KFIR members who rendered the original decision agreed with this position during the witness hearing.

The Office of the Attorney General, which represented KFIR, mainly argued that the amendment, if granted, would mean that MSD strengthened its legal position regarding the validity of the SPC for the combination product, and that this would have an effect on a potential assessment of the validity at a later stage. Since the original patent, according to the Attorney General, provided little support for combinations, this meant that MSD would be placed in a position where they obtained *"something more than what they previously had."*

In its ruling of 10 March 2022, Oslo District Court agreed with MSD that KFIR's reasoning was illogical when concluding that the proposed amendments included an extension of the protective scope of the patent. The court also agreed with KFIR that an amendment of the patent would increase MSD's legal position, but whether this should be allowed through patent limitation requires an assessment of the conditions for patent limitations, which had not been assessed by KFIR.

On the topic regarding the fact that the description of the combination product in the original application was removed, the District Court expressed some acknowledgment of KFIR's concern that MSD could maintain "individual protection" for the combination. However, the court pointed out that the question of allowing an amendment had to be assessed on whether the amendment had support in the description and if it occurred in the original basic documents. Consequently, the court revoked KFIR's previous decision.

Round 4 – 2nd time at KFIR

On 5 May 2022, KFIR rendered a new decision on the matter. KFIR upheld its rejection of the patent amendments. In accordance with the District Court's conclusion, KFIR acknowledged that the proposed request for limitation did constitute a real limitation of the protective scope of the patent, and that the requirements of section 39 a were fulfilled.

However, KFIR also referred to that while both the PCT-application and the Norwegian application as filed contained references in the description which formed basis for both sitagliptin and a combination product, the description was removed in the granted patent. KFIR then stated that since the amendments in the dependent claims, where features from the application as filed, lack description in the granted patent, these amendments were in violation with the Patent Act section 39 b first paragraph.

Round 5 – 2nd time at Oslo District Court

On June 3 2022, MSD brought the second dismissal of KFIR to the courts, citing both procedural errors and reasons for incapacity for two of the members of KFIR. This time however, the Office of the Attorney General decided to make a quick process, and in the reply agreed with MSD's claim that this decision was invalid. As such, Oslo District Court on 25 July 2022 once again revoked KFIRs decision to refuse patent limitation.

Round 6 – 3rd time at KFIR

One might normally be right in that third time is a charm, but not when it comes to patent limitation at KFIR. KFIR again on 1 December 2022 rejected the limitation, citing that the amendment did not represent a genuine limitation of the patent's protection. The alternative set of claims was also rejected, as it could not be granted in its entirety.

And on 12 December, MSD once again brought KFIRs decision before the courts.

Round 7 – Procedural issue at Oslo District Court

During the case preparation before the District Court, KFIRs attorney pointed out that the SPCs in question had now expired – as such, it was argued that MSD no longer had any interest in the case, and that the case should be dismissed. This was also the conclusion of Oslo District Court on 21 April 2023.

MSD appealed that decision to Borgarting Court of Appeal.

Side show - MSD submits infringement claim against three generic competitors.

On 19 May 2023, MSD filed a lawsuit against 3 generic competitors which prior to the expiry of the SPC for the combination of sitagliptin and metformin had launched generic versions of a combination drug. All generic competitors replied that the claim for infringement would have to be dismissed, since the SPC for the combination product was invalid, cf. the SPC Regulation Article 3a.

Over the years, there have been numerous decisions from the CJEU concerning the interpretation of the requirement in Article 3a of the SPC-Regulation, in which circumstances a product is "protected" by a basic patent. A key decision concerning the validity for SPCs of combination products is CJEU's decision C-121/17 (Teva UK & Others), which states two conditions in order for the product to be protected by the basic patent:

"– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."

The generic firms pointed out that this was not the case concerning the active ingredient metformin, which was not mentioned specifically in the claims of NO321999. Consequently, the generic firms argued that the SPC that MSD held for the combination of sitagliptin and metformin was invalid.

At this time, there were also pending cases before the CJEU concerning the interpretation of Article 3a and 3c. The case between MSD and the generic companies was ultimately stayed, both because of these cases and because of the pending limitation case.

Round 8 – Procedural issue at Borgarting Court of Appeal

Unlike the District Court, the Court of Appeal admitted the limitation case, referring inter alia to the submitted lawsuit initiated by MSD as grounds. And thus the case was brought back to the District Court.

Round 9 – 3rd time at Oslo District Court.

Third time is a charm – but for whom? A new decision from the District Court came 3 March 2024. At this point, the essence of the case was that MSD wanted to amend two of the dependent claims of the basic patent, clearly motivated by securing compliance for the combo-SPC with article 3a of the SPC-regulation. NIPO on the other hand, argued that this is not a real limitation of the patent scope, since you only limit the dependent claims. The independent claim 1, which inter alia concerned sitagliptin, would from a patent law perspective also protect against sitagliptin in combination with metformin. But this is not necessarily the case from an SPC-law perspective, cf. the case law of CJEU on Article 3a.

The question was thus how should section 39a of the Norwegian Patent Act be interpreted. The Court found that if looking at the preparatory works for the provision, it was quite clear that for administrative patent limitation, there must be a genuine reduction in the protective scope of the patent (i.e. a limitation of dependent claims would not constitute such a reduction). However, the preparatory works also makes it clear that section 39a is a parallel to article 105a of the European Patent Convention, and thus the

question was whether there were legal sources which indicate another perspective.

The District Court found that the wording of Article 105a is similar to section 39a, and the wording itself indicated that there is a requirement for a genuine reduction. The court also referred to the revision of the EPC from 1999 (CA/PL 29/99), where it was stated that it may be necessary to limit the granted patent if due to e.g. prior art not being taken into account *"the extent of the protection conferred is too great. Using the limitation procedure, patent proprietors may themselves reduce the extent of the protection claimed in a manner which is binding, and thus generally preclude disputes over the validity of a patent.".* This indicated to the District Court that the purpose of the EPC Article 105 was also the same as that stated in the preparatory works concerning section 39a.

On the other hand, the District Court also referred to EPO's guidelines for administrative limitations, where it is stated that *«The term «limitation» is to be interpreted as meaning a reduction in the extent of protection conferred by the claims. Mere clarifications or changes made to protect a different subject ("aliud") are not to be considered as limitations."* The guidelines state that limitation of a dependent claim only, without any independent claim being limited, is acceptable. The guidelines however also state that *"it is not permissible to introduce non-limiting amendments in the description or in the claims that are not a consequence of the limitation of the claims (for example tidying up unclear claims, making amendments to improve the patent or cosmetic changes). Likewise, adding dependent claims in limitation is not permissible if not directly caused by the limitation introduced in the claims."*

While the court acknowledged that this opened for EPC Article 105a being interpreted to allow amendment of the dependent claims only, the Court nevertheless found that the amendments desired by MSD in this case were an attempt to "improve the patent", and that such amendments were not allowed. The court also referred to the fact that the guidelines at this point had been criticized in legal literature.

MSD had referred to several examples where Examining Division had allowed amendment of the dependent claims only. However, this did not sway the District Court, and found that little emphasis could be placed on these, also because they were not reasoned. Another argument by MSD was that the result of this interpretation would be

that a patent holder of a Norwegian patent would be in a worse position than a holder of a European patent. The court agreed that this was indeed the consequence, and could be unreasonable, yet it did not alter the interpretation that other and more decisive legal sources provided basis for.

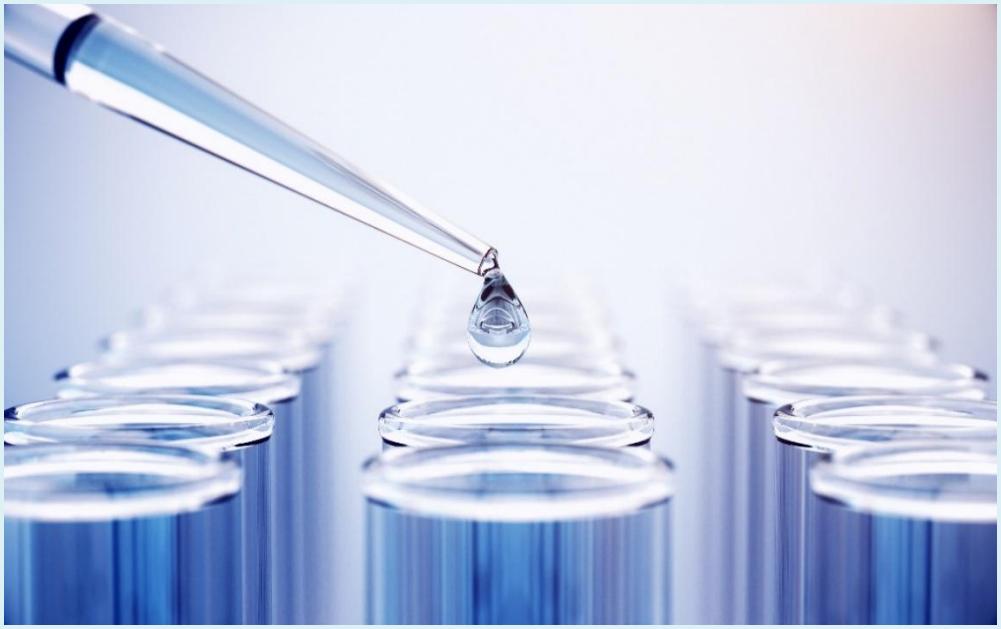
Consequently, the District Court acquitted KFIR, and the decision not to allow the patent amendment were upheld.

Round 10 – 1st time in Borgarting Court of Appeal

MSD appealed the District Court's decision, and on 21 October 2024, Borgarting Court of Appeal rendered its decision.

Like the District Court, the Court of Appeal found that KFIRs decision should be upheld, i.e. that section 39a requires that there is a genuine limitation of the patent claims, i.e. that the dependent claims cannot be limited alone. This was largely based on the same assessment as the District Court.

A question which arose was whether EPC Article 105a was of material or administrative character, and whether Norway from an international law perspective was obligated to follow it (cf. Protocol 28 of the EEA-Agreement). The Court of Appeal did not find it necessary to assess this in detail, since it found that section 39a of the Patent Act and Article 105a of EPC shall be interpreted in the same manner.



Having now battled for nearly 4 years on the interpretation of section 39a, MSD decided to appeal to the Supreme Court.

Plot twist – new case law from CJEU

In the meantime, in December 2024, new case law from CJEU emerged on Article 3a of the SPC-regulation. In Joined Cases C-119/22 and C-149/22 (Teva and Clonmel). In this decision, additional premises for when a product is protected by the basic patent according to Article 3a came to light. According to the CJEU, it is not sufficient that the product is expressly mentioned in the claims in order for the product to be protected. It is also necessary that the product "fall under the invention covered by that patent at the filing date or priority date", from the point of view of the skilled person and in light of the description and drawings. Or as stated in the decision para 64: *"If the mere mention, even if an express mention, of a product in those claims were to suffice, without the patent specification disclosing how that product constitutes a technical feature required for the solution of the technical problem disclosed by that patent, this would make it possible to obtain an SPC for a product which is not the result of the research which led to the invention protected by the same patent."* In para 70, it is also stated that if *"(…) 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, it may be concluded that the combination of those two active ingredients necessarily falls under the invention covered by that patent."*

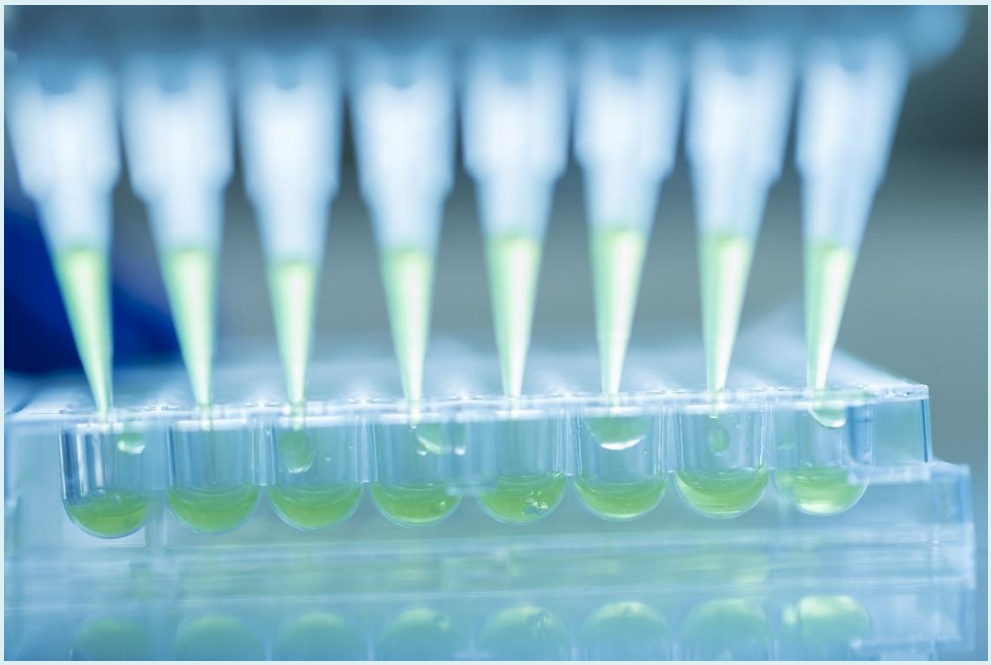
Round 11 – The Supreme Court's decision

Surprisingly, the Supreme Court admitted the decision, which is rare for cases concerning patent law. And when a decision has been lost in two instances, that is perhaps a signal once again that third time is a charm? Would MSD after more than 5 years of battle finally be awarded with its request for patent limitation?

The Decision from the Supreme Court came on 26 June 2025. Like the Court of Appeal and the District Court, the Supreme Court reviewed the same legal sources already presented. Norwegian sources where quite clear on what a limitation should constitute. But the reason for admission to the Supreme Court was no doubt the potential conflict with the interpretation of EPC.

Concerning the decisions from the Examining Division which had granted limitation of the dependent claims only, the Supreme Court found that this is not extensive case law – 23 cases had been presented over a span of more than 10 years – and they were not reasoned. Nevertheless, the Supreme Court found that the wording in the guidelines and the cited case law suggested that a request to the EPO for the limitation of a dependent claim in isolation is likely to be accepted. The question, then, was which implications this would have for the interpretation of section 39a of the Patents Act.

The Supreme Court pointed out that it follows from Article 4 of Protocol 28 that the EFTA States shall comply in their law with the "substantive provisions" of the European Patent Convention. The Supreme Court considered that Article 105a was not a substantive provision under Protocol 28. The Supreme Court referred to that the provision is found in Part V of the EPC, governing the «Opposition and limitation procedure», rather than in Part II on «Substantive patent law», which contains the core provisions on patentability, entitlement and the legal effects of patents and patent applications. Furthermore, the Supreme Court stated that while it is true that the limitation of a patent has substantive implications, the same can be said of other provisions outside Part II, such as those governing the handling of invalidity oppositions.



Furthermore, the Supreme Court stated that Article 105a does not impose obligations on national law, unlike provisions of a purely substantive nature. Noting that Article 105a was only introduced into the EPC during the 2000 revision; that is, after the EEA Agreement was concluded, the provision was not among those considered when the EEA Agreement was entered into. In the view of the Supreme Court Norway had thus not, through the EEA Agreement, undertaken an obligation to adopt the same rules for administrative patent limitation as those set out in the EPC.

The next question for the Supreme Court was thus whether the presumption principle requires that section 39 a must be interpreted in the same manner as Article 105a of the EPC. The principle entails that Norwegian law must, as far as possible, be interpreted in conformity with our international obligations. The Supreme Court pointed out that Article 105a concerns the EPO's handling of European patents and does not obligate the Contracting States to adopt identical national rules.

Could nevertheless a consideration of legal uniformity lead to a different result? The Supreme Court stated that considerations of legal uniformity are particularly compelling with respect to substantive patent provisions, but they also carry weight for other provisions with a clear substantive aspect, such as the possibility of patent limitation. The Supreme Court pointed out that for European patents validated in Norway, the patent holder may obtain a limitation based on EPO practice by submitting a request to the EPO, which has effect for the European patent as such, and thereby also for the national patent, see section 66 b subsection 2 of the Patents Act. It could be argued that it should not be decisive whether the application is decided by the EPO or by NIPO.

The Supreme Court then stated that equal treatment of European patents, regardless of whether the case is decided by NIPO or the EPO, is only one aspect of the consideration of legal uniformity. Another aspect concerns legal uniformity with the national patent laws of other countries. The same patent is often granted in multiple countries, even when it is not a European patent. The information on foreign law presented in this case shows that there was no common approach to the issue at hand.

The Supreme Court found that it was significant on the one hand how clear the domestic sources are, and on the other hand, how authoritative the interpretation of the EPC is, and whether this corresponds to the patent laws of other countries. The Supreme Court pointed out that the legislature has not always chosen the alternative that aligns with the EPC, with reference to a divergent solution regarding the consequences of missing a deadline, cf. section 72 of the Patents Act. On the topic in question, the Supreme Court found that the legislature had not conducted a comparable assessment in the present context.

In the view of the Supreme Court, the background appeared to be that the Ministry assumed that the EPO evaluates whether a genuine limitation of the patent exists, and that the preparatory works therefore did not address the considerations for or against allowing the amendment of a dependent patent claim in isolation. The same applied to factors that may be particularly relevant to the underlying purpose of the amendment request – namely to safeguard an SPC approval in the light of the requirements established by the CJEU. The Supreme Court then stated that in *"a technical field such as this, one that governs private law rights while also considering societal interests,"* (…) *"there is good reason to exercise caution before extending the statutory provision beyond its wording and the considerations explicitly addressed by the legislature."*

The Supreme Court concluded that section 39a of the Patent Act must be understood to mean that the scope of patent protection must be genuinely limited. The provision therefore does not allow for a dependent patent claim to be limited in isolation.

Comments

The Supreme Court decision marks the final end of a case complex spanning over 5 years of what must be considered as a rather unique case. The important question for patent holders is whether it is possible to amend only the dependent claims of a Norwegian patent. The answer to this question, based on this decision, is no. As such, attempts to post grant amend dependent claims to ensure that a subsequent SPC for a combination product granted on the same basic patent as a mono product in order to ensure compliance with article 3a of the SPC Regulation will not be successful in Norway.

From a patent law perspective, the Supreme Court decision makes a final clarification. However, from an SPC Regulation perspective, several questions remain.

If the Supreme Court had come to the opposite conclusion, and allowed the amendment, a question would have been whether the SPCs were still valid in light of Article 3a. The decision from the CJEU in December 2024 (Joined Cases C-119/22 and C-149/22) would have been key in the following case between MSD and the generic suppliers.

Another question, which is also unclear, is whether it is compliant with Article 3 of the SPC Regulation to amend the basic patent *after* an SPC has been granted. It follows from Article 3 that the four conditions (including the criteria in 3a) must be fulfilled *"at the date"* of the application of the SPC. It is not uncommon that patent holders therefore amend their patents prior to an SPC being granted. However, does the fact that an amendment of a patent has retroactive effect, mean that the criteria *"protected by a basic patent in force"* was fulfilled *"at the date"* of the application for the SPC in the sense of the SPC Regulation? That question will have to be answered another time.

Following the Supreme Court's decision, the case between MSD and the generic companies concerning infringement of the SPC has been settled and withdrawn. Our law firm represented one of these generic companies in the proceedings against MSD.

WHEN COOLER HEADS PREVAIL

Can pharmaceutical companies "give patients gifts" through a prescribing physician?

Background

On 26 May 2025, the Norwegian Medical Product Agency (NOMA) rendered an administrative decision against Novartis for the breach of the rules of advertising for medicinal products. The reason for the decision was that Novartis made it possible for healthcare personnel to order cooling bags and cooling elements via an online site. The cooling bags and cooling elements were intended to be supplied by the healthcare personnel to patients which were prescribed Aimovig (erenumab), a drug used for the treatment of migraine.

Initially, NOMA had in an advance notice alleged that the non-compliance was with section 13-10 of the Norwegian Medicinal Product Regulation. Section 13-10 first paragraph prohibits to offer gifts, benefits etc. in the promotion of a medicinal product to healthcare personnel, unless such gifts or benefits have an insignificant value or are related to the practice of the healthcare personnel. This provision implements Article 94(1) of Directive 2001/83/EC. However, in the actual decision, NOMA abandoned non-compliance based on this decision and instead argued that the action constituted a breach of section 13-4 of the Regulation. Section 13-4 prohibits advertisements of prescription medicinal products to the public, which mirrors the prohibition of the Directive Article 88(1) litra a.

Novartis submitted a complaint about the decision. Novartis pointed out that the cooling bags were reserved for healthcare professionals, not the public. Only healthcare personnel could order them and after a specific assessment distribute them to patients. There was also no communication between patients (i.e. the public) and Novartis at any time.

Novartis first argued that NOMA had interpreted the term "advertising" wrong, based on the definition of section 13-1 of Regulation. The definition in the Norwegian Regulation is "*any form of information outreach, campaigns, advocacy and other measures intended to promote the prescription, dispensing, sale or use of medicinal products"*. In the decision, NOMA had argued that with regard to "other activities", businesses who have a financial interest in the sale or use of the medicinal product will normally be considered to have an advertising purpose when engaging in such activity. In other words, NOMA argued that "other activities" normally would be prohibited because they had an advertising purpose because a pharmaceutical company was behind the activity.

Novartis pointed out that this was incorrect and not in line with the definition of the Directive Article 86. Novartis also pointed out that it had never been the intention of Novartis that the distribution of cooling bags should promote the prescription of Aimovig og promote Novartis as a pharmaceutical manufacturer, and that the purpose was that the product should be stored and transported in a safe and appropriate manner to ensure proper use and effectiveness, as well as to prevent damage and destruction.

Novartis also pointed out that any activity a pharmaceutical company does cannot be considered as advertising, referring to the EU court's decision C-316/09 (MSD). This decision concerns information about a medicinal product published on MSD's website, but it does state that from the wording of the Directive Article 86(1), *(…)the purpose of the message constitutes the fundamental defining characteristic of advertising, and the decisive factor for distinguishing advertising from mere information"* (para 31). The decision also clarifies that whether *"dissemination of information has a promotional objective must be determined by undertaking a detailed examination of all the relevant circumstances of the case(…)"* (para 33). The decision further outlines that although it is undeniable that the manufacturer of the medicinal product has a financial interest in marketing its product, the fact that the manufacturer disseminates such information itself cannot, as such, lead to the conclusion that it has an advertising purpose. For such a factor to be a conclusive factor, it is also necessary that the conduct, action and approaches of the manufacturer disclose its intention to promote, via such dissemination, the prescription, supply, sale or consumption of that medicinal product. (para 34).

A further argument by Novartis was a decision previously made by the Ministry of Health and Care Services (i.e. the appellate instance for the administrative decision. In that case, a pharmaceutical company had previously supplied a food diary to be distributed by physicians to patients in relation to a weight loss drug. In that decision, the Ministry stated that since the pharmaceutical company had a marketing authorization, this could justify classifying the printed material distributed as advertising. However, the food diary contained no written or verbal references to or images of medicinal products, nor did it contain any information about diseases or references to drug treatment. The only element linking the food diary to the pharmaceutical company was a small company logo on the last page. After an overall assessment, the Ministry found that the food diary did not constitute advertising.

The Ministry's decision

On 26 August 2025, the Ministry revoked the decision of NOMA.

In its assessment, the Ministry held that section 13-4 of the Regulation holds three conditions: It must be a question of "advertising", for a "prescription drug" and "directed to the general public".

That Aimovig was a prescription drug was undisputed. When it came to whether the activity was directed towards the general public, the Ministry supported NOMAs view that the provision cannot be interpreted to mean that there must be direct contact between the complainant and the general public. If this was the case, it would open the door for circumvention of the provision. As such, distribution of the cooling bags does not lose its character of being directed at patients because the distribution is carried out by healthcare personnel. The Ministry also pointed out that the cooling bags were intended for patients. Consequently, the condition of "directed at the general public" was also fulfilled.

The decisive factor was thus whether the distribution of the cooling bags could be considered as advertising. The Ministry here pointed out that the definition of advertising sets out two requirements – there must be an activity, and there must be an intent.

Concerning activity, the option "other measures" was considered broad and allowed for a range of activities, and based on a literal

interpretation of the wording, the Ministry found that distribution of cooling bags fell under this option.

Concerning intent, the Ministry first pointed out that it was not necessary for the action to actually lead to an increase in prescription, dispensing, sale or use. However, the wording itself does not provide any further guidance for assessing the intent requirement.

The Ministry then pointed out that the rules in the regulation implement the rules in Directive 2001/83/EC, and that the Directive and related case law would be relevant to the interpretation. In this respect, the Ministry referred to the previously mentioned passages from the C-316/09 (MSD).

The Ministry clarified that it follows from this decision that it is a relevant factor in the overall assessment that a pharmaceutical company is behind the dissemination, but it is not decisive for the assessment. The case illustrates that the decisive factor is the intention behind the activity, and that a comprehensive assessment must be made of all relevant circumstances that may shed light on this intention.

The Ministry then turned to its previous decision concerning the food diary, which in that decision was described as *"a notebook with columns for recording, among other things, daily food intake and physical activity as an aid in connection with the treatment of obesity."* In that decision, after a comprehensive assessment, the Ministry had concluded that since the pharmaceutical company had a marketing authorisation for weight loss drugs, the distribution of the food diary was to be considered as advertising. However, the lack of any written and verbal references to images of medicinal products, or any information concerning disease or references to drug treatment, made it clear that the activity was not sufficient to be considered as illegal advertising.

Similarly for this case, the Ministry held that the fact that Novartis has a marketing authorization for the drug Aimovig was an argument for considering the distribution of cooling bags as advertising. However, like the food diary, the cooler bag did not contain any written or verbal references to drugs, disease information, or drug treatment.

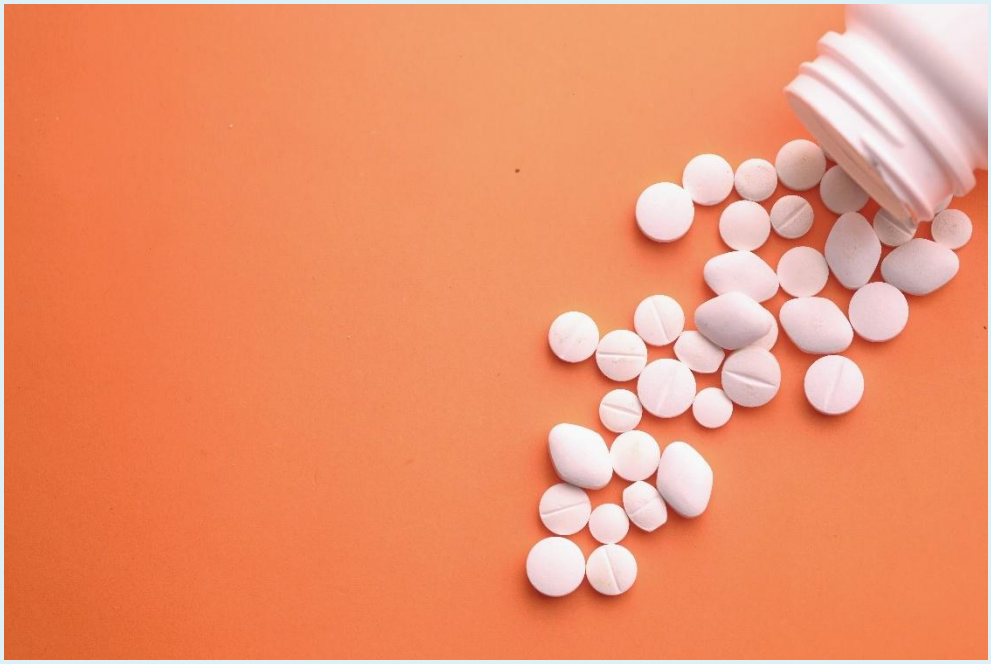
An argument NOMA had presented was that there was significant difference in the factual circumstances of the two cases, and that the cooler bag had a *"commercial context not present"* in the food diary case. The cooler bag had *"a clear link"* to the product Aimovig. The Ministry here pointed out that the same can be said about the food diary and the weight loss drug, and it could therefore not see that such a "commercial context" was absent in that case, and therefore not valid argument for viewing the facts in this case differently.

NOMA had also argued that the design of the cooler bag was irrelevant to the assessment, and it was the act of distribution that constituted illegal advertising. The Ministry pointed out that according to the CJEU in case C-316/09, all relevant circumstances must be considered.

One aspect of the case was that the previous decision from the Ministry was rendered at a time when the definition of "advertising" in the Regulation was different. A linguistic amendment was made in the wording in 2020. While NOMA had argued that the amendment was a linguistic clarification and an update of the wording, and not a change in the substantive legal situation, NOMA nevertheless argued that even though the amendment did not constitute a "tightening", the new rules provided for a more detailed assessment of activities that may have a commercial purpose. This was shut down by the

Ministry, simply stating that this was not reflected in either the consultation paper of the amendment or other reference by NOMA. When it was not the intention to change the rules substantially, there was no basis for deviating from previous practice. The Ministry further reiterated that it did not agree with NOMA's argument that there were significant differences in the factual circumstances of the two cases.

Consequently, the Ministry found that the distribution of the cooling bags did not meet the conditions for "advertising" in section 13-1 of the Regulation, and thus the activity was not advertising for a prescription drug under section 13-4. The previous decision from NOMA was thus revoked.



Comments

The decision from the Ministry illustrates clearly that concerning advertisements, the Ministry follows both EU case law and its own previous practice. In that respect, the revocation of NOMA's decision does not come as a surprise. A clear differentiation must be made between advertising and advertising for a medicinal product.

A key takeaway from the decision is that NOMA had argued that the distribution of material goods differs substantially from the distribution

of health and disease information in printed form or via digital channels, as cooling bags and cooling elements are commercially available equipment that patients must obtain themselves. The distribution of such goods would result in direct financial savings for the patient. This could in NOMA's view create a relationship of loyalty between the patient and the drug, and in the long-term lead to increased prescribing if other patients became aware that this offer is only available when a given drug is prescribed. If NOMA had succeeded with this attempt to distinguish the cases, the door could have been shut for pharmaceutical companies to provide many physical goods which could aid the patient. However, as the Ministry did not place any weight on this argument, such a principal difference cannot be established. In other words, it's all in the intent.

ONCE DAILY AT THE THIRD ATTEMPT – THE RIVAROXABAN CASE

Sandoz A/S vs. Bayer Intellectual Property GmbH – Borgarting Court of Appeal 29 July 2025

Introduction

Bayer Intellectual Property GmbH ("Bayer") is the holder of patent NO 344 278 ("NO'278"), which concerned a once daily dosing regimen for the active substance rivaroxaban for the prevention of thromboembolic diseases, in the form of a rapid release tablet. Rivaroxaban is an anticoagulant agent (Factor Xa-inhibitor) which is marketed by Bayer under the trade name Xarelto. NO'278 mirrors the European Patent EP 1 845 961 (EP'961). EP'961 had been subject to opposition proceedings in the EPO, but was upheld by the Board of Appeal.

Claim 1 of the patent stated as follows:

The use of a rapid-release tablet of the compound 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide for the manufacture of a medicament for the treatment of a thromboembolic disorder administered no more than once daily for at least five consecutive days, wherein said compound has a plasma concentration half-life of 10 hours or less when orally administered to a human patient.

In November 2022, the pharmaceutical company Sandoz filed an invalidity action against NO'278, alleging that the patent lacked novelty and inventive step. On 9 June 2023, Oslo District Court ruled in favor of Bayer, holding that the patent was valid. Sandoz appealed the decision.

Meanwhile, in April 2024, Bayer filed for preliminary injunctions against three generic competitors, including Sandoz and the pharmaceutical company Glenmark. Preliminary injunctions were awarded by the District Court ex parte in May 2024. Glenmark and Sandoz requested oral hearing in an attempt to revoke the decisions, and a joint oral hearing was held in August 2024. In September 2024,

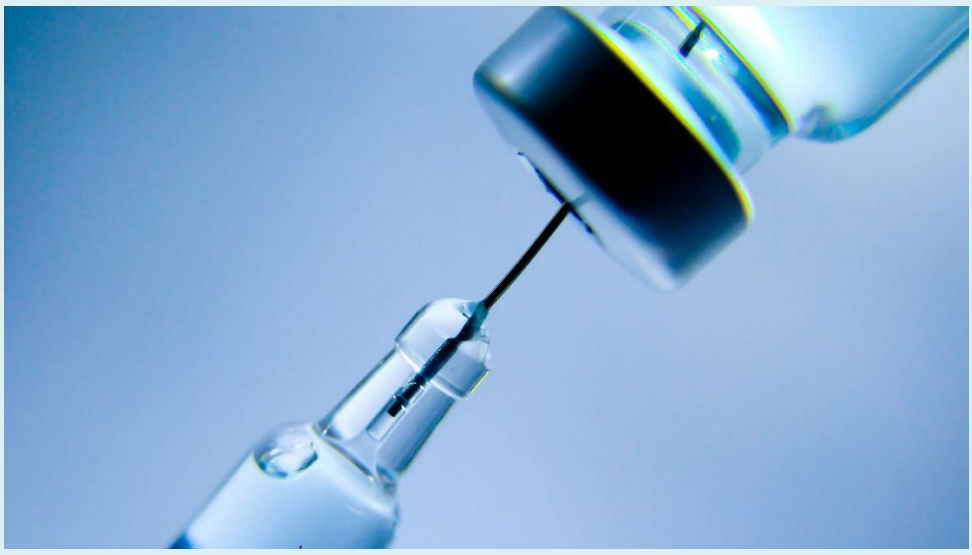
Oslo District Court once again ruled in favor of Bayer, and the preliminary injunctions were upheld.

During the autumn of 2024, Glenmark joined the case between Sandoz and Bayer as an intervener. Fast forward to May 2025, and the appeal hearing for the first invalidity decision from 2023 were held.

The arguments of the parties

Sandoz and Glenmark argued that the patent lacked novelty and inventive step, and thus was invalid. Before the District Court, the appellants presented the same cited art as before the District Court in support for invalidity, namely three sets of abstracts and conference posters from three phase I studies performed by Bayer concerning the clinical development of rivaroxaban. These were the Kubitza multiple dose study, the Kubitza single dose study and the Harder study. The Kubitza multiple dose study explicitly indicated that rivaroxaban (using the code name BAY 59-7939) was suitable for twice daily dosing, whereas the Harder study explicitly indicated that rivaroxaban was suitable for once daily dosing, as prescribed by the patent in dispute.

The abstract had previously been a part of the EPO proceedings, whereas the conference posters, which contained additional information. The conference posters, which were not part of these proceedings, had all been displayed at the same conference meeting in San Diego in 2023.



In addition to the conference posters, the appellants had discovered new potential prior art that resulted in invalidity. These were patient information leaflets presented to patients which participated in phase II studies concerning rivaroxaban, which had been presented prior to the priority date. Sandoz and Glenmark argued that these documents were publicly available at the priority date and that the patients who participated in the studies were not subject to any explicit or implicit confidentiality obligation. The appellant argued that this patient information was the closest prior art, or in the alternative, that this would be the previously mentioned conference posters

Bayer argued that the conference poster and abstract from the multiple dose study were the closest prior art, which were also the findings of the District Court. Bayer argued that in order to assess the therapeutic effect of the drug in the prevention and treatment of thromboembolic disorders, phase II and III studies in patients requiring treatment were necessary. A person skilled in the art would therefore have had no basis for assuming that rivaroxaban was suitable for once-daily dosing in the form of a rapid-release tablet. Nor would a person skilled in the art have assumed that such a dosing regime was safe, or had a reasonable expectation of success with it.

Bayer further argued that the Harder poster did not constitute an alternative closest prior art. It presented results from a non-mandatory phase I study that investigated pharmacodynamic parameters for rivaroxaban's effect on thrombus generation in healthy volunteers using experimental tests. The invention would not have been obvious based on the Harder poster alone or in combination with the posters from the Kubitza studies. There were no information or data in the Harder poster that would have given the skilled person a basis for conclusions about a possible dosing interval in phase II studies. The Harder poster therefore did not provide a basis for a reasonable expectation of success.

Concerning the patient information leaflets which had emerged, Bayer argued that this information was not publicly available before the priority date. The ethics committees and clinical investigators who participated in the phase II studies were subject to confidentiality. The patients who participated in the studies and received the information had a special relationship with Bayer. The information did not mention the active ingredient rivaroxaban, but only the code name used at that time ("BAY 59-7939") and does not refer to the

use of fast-release tablets or the safety and efficacy of the treatment. There was no "enabling disclosure" as the skilled person would not be able to clearly and directly deduce all the features of the invention from the patient information from the phase II studies.

Bayer further argued that the patient information did not provide a basis for a reasonable expectation of success in administering rivaroxaban once daily in a rapid-release tablet to provide safe and effective treatment of thromboembolic disorders. The skilled person would have assumed that the studies concerned modified-release tablets, given the short half-life.

The Court's reasoning

The Court of Appeal rendered its decision on 29 July 2025. Unlike the District Court, the Court of Appeal invalidated the patent.

In an extensive and detailed decision concerning both facts and law, the court began its assessment with the usual problem solution approach. The court explicitly stated that it did not take a position on whether the patient information from Bayer's phase II studies was publicly available before the priority date and thus whether it can constitute prior art. The Court of Appeal considered that the entries describing Kubitza SD, Kubitza FD and the Harder study, seen in conjunction with the abstracts from the same studies as published and exhibited in connection with the conference, constituted the closest prior art.

Unlike the District Court, the Court of Appeal considered that it would have been natural for the skilled person to assess the Harder poster and the Kubitza posters together. The Harder poster referred directly to the posters from Kubitza and there was consistency between the findings in the studies regarding the dose-dependent Factor Xa-inhibiting effect of rivaroxaban. The skilled person would also have seen that several of the authors behind the Harder poster/abstract were also the authors behind the Kubitza posters/abstracts. The posters were displayed close to each other at the conference and were presented on the same day. It was also clear that all three posters deal with the same active substance.

The court found that the skilled person would therefore have assumed that there was a connection between the studies and would have been motivated to read not only the Kubitza posters/abstracts,

but also the Harder poster/abstract and to view these in context. The fact that the Harder study was not a mandatory phase I study and did not measure pharmacokinetic parameters was of less significance in this context.

Concerning the objective technical problem to be solved, the Court of Appeal found that the term "treatment" encompasses both therapeutic and prophylactic (preventive) treatment of all types of thromboembolic disorders. The objective problem to be solved by the invention was thus to produce a safe and effective dosage regimen for the treatment of all types of thromboembolic disorders with the active ingredient rivaroxaban.

Concerning the decisive part, on whether the invention would have been obvious to the skilled person, the court systematically assessed the individual features.

Bayer had argued that the skilled person would not have understood that the code name BAY 59-7939 was rivaroxaban. The Court of Appeals disagreed, finding that the skilled person would have searched for the code name BAY 59-7939, and that such a search would have easily led to the chemical structure of BAY 59-7939, and that this substance was rivaroxaban.

Concerning the release profile, the claim described a "fast release tablet". One of the posters mentioned tablet. The court found that the skilled person would have concluded that the studies concerned oral administration of BAY 59-7939, mainly in tablet form. The Court of Appeal also found that if followed from common general knowledge that as a general rule, "tablet" is understood to mean a fast-release tablet, unless otherwise specified.

Nor did the feature "thromboembolic diseases" create any issues for the Court of Appeal, which found that it was is common knowledge within the field that the term "treatment" encompasses both therapeutic and prophylactic (preventive) treatment. It would therefore have been natural for the skilled person to try rivaroxaban in phase II studies for therapeutic and prophylactic treatment of thromboembolic disorders.

The key feature of the patent was the feature stipulating administration no more than once daily for at least five consecutive days. Here the Court of Appeal pointed to several issues in favor.

First, the court found that the information in the posters and abstracts from the phase I studies would have motivated the skilled person to initiate phase II studies. But since rivaroxaban was a new drug, the court also assessed that the skilled person would have been motivated to investigate which information was available on BAY 59-7939, and would therefore have become aware that Bayer had initiated phase II studies at the priority date. Similarly, the skilled person would have been aware that other pharmaceutical companies had initiated targeted development of direct-acting anticoagulants, including direct factor Xa inhibitors.

Second, the Court of Appeal found that the skilled person was aware of the clinical benefits for patients of a dosage form that requires only one daily dose, compared with regimens involving two or more daily doses. In the court's view, these advantages alone would have motivated the expert team to explore such a dosing regimen. However, the advantages would have had to be balanced against other considerations, in particular patient safety.

Third, and a contentious point between the parties, was knowledge of the therapeutic window, which the Court of Appeal found that was particularly critical for anticoagulants. On this point, the court relied heavily on the statements from the expert witnesses. Bayer's expert witness had argued that the balance preventing both thrombosis and hemorrhage was particularly demanding for anticoagulants, making clinical development challenging and associated with considerable uncertainty. The Court of Appeal agreed with this view, and that the skilled person would have approached phase II studies with caution. However, the court also stated that this risk should not be exaggerated, and in practice, there is always a certain risk associated with conducting phase II studies, including the risk of serious side effects that could not be predicted in phase I. The court here also pointed out that the skilled person was aware that Bayer had initiated phase II studies on rivaroxaban, and had presumably obtained approvals for these.

A further contentious issue was the significance of the half-life of rivaroxaban, and how the feature in the claim should be interpreted in this regard. This was a topic that was heavily discussed during the trial, since the half-life stated in the Harder poster differed from the half-life stated in the Kubitza-posters. The half-life of the Harder poster came from the study protocol from the Harder study and the Investigator's brochure. In later versions of the Investigator Brochure, the half-life was aligned with that stated in the Kubitza poster, but not updated in the study protocol. Bayer argued that this was an error, which was repeated in the phase II studies and was only discovered after these had been completed.

The Court of Appeal found it difficult to understand how this error could go unnoticed, and also that it was not discovered for the preparation of the Harder poster. But the final nail in the coffin was that this half-life was also mentioned in a letter to the Ethics Committee by the steering committee of a phase II study where this half-life was used as an argument for attempting OD dosing in patients.

However, the court also found that it was irrelevant whether it was an error or not. The question was how the skilled person would have dealt with the conflicting half-lives from the posters. The court found that the conclusions of the Kubitza studies (which stated a short half-life) would have been considered as more reliable. However, the skilled person would not have ignored the statement of a longer half-life in the Harder poster. The longer half-life would not have been deemed as an error, but the skilled person would have examined the pharmacokinetic and pharmacodynamic data from Kubitza SD and Kubitza FD in more detail in an attempt to understand why a different half-life was stated in the poster from the Harder study, and to see if there was anything to support the claim and possible suitability for once-daily dosing.

In the decision, the Court of Appeal then discusses in detail the interpretation of the figures which were shown in the posters. The parties disagreed on the interpretation of these. The court ultimately agreed with the view of the appellant's expert witnesses concerning that the data supported scientific basis for the claim of the half-life stated in the Harder study.

The Court of Appeal also referred to the pharmacodynamic data of the Harder study, which the District Court had dismissed due to it being considered as experimental studies. The court believed that the skilled person would have assessed the pharmacodynamic data from the Harder study together with the data from the Kubitza studies, and concluded that rivaroxaban had an anticoagulant effect which lasted more than 24 hours after administration, measured by several parameters. The skilled person would thus have encouraged the expert team to include such a dosing regimen in their phase II studies.

The court thus found that there were no technical obstacles to such a once daily regiment being both safe and effective, and there was sufficient data in the posters to provide a reasonable basis for assuming that a daily dose could provide sustained effect throughout the day, with no indication of unacceptable bleeding risk. Although the risk of insufficient effects or bleeding could not be completely ruled out, based on the available information, the risk did not constitute an unacceptable health risk.

The skilled person would therefore reasonably have considered it safe and justifiable to conduct a phase II study that included once daily dosage. Consequently, it would also have seemed obvious to the expert team to initiate such a study, and the court ruled that the patent lacked inventive step.

Comments

The decision from the Court of Appeal stands out in both its description of the fact and its description of applicable law, making it a worthy case study for patent litigation afficionados. From a legal perspective, it is somewhat disappointing that the court completely skipped the parts on patient information leaflets, as the legal situation here is somewhat uncertain in Norway, and this decision could have been a chance to provide some clarity. However, this also emphasize the pragmatic approach Norwegian courts practice.

It is also worth mentioning that the case serves as an example of the fact that a decision from EPO's Board of Appeal does not hold particular sway with Norwegian courts when additional and supplemental evidence is presented.

Bayer did attempt to appeal the decision to the Supreme Court, but the case was not admitted. The Court of Appeal's decision thus marks the end of the rivaroxaban case in Norway. Similar cases have been ongoing in parallel in several jurisdictions, making this case a truly cross-border challenge for the parties involved.

A team from Haavind assisted Sandoz in both the District Court and in the Court of Appeal.

ADEXTIN – NOT TO BE CONFUSED WITH ATTENTIN

Pharmaceutical trademarks and the likelihood of confusion

Background

The pharmaceutical company Orifarm Generics (Orifarm) registered the word mark ADEXTIN in late 2023, for goods in NICE Class 5: Pharmaceutical and medical preparations, including those for the treatment of symptoms associated with ADHD.

In February 2024, an opposition was lodged by Medice Arzneimittel GmbH (Medice) against the registration of the word mark, based on alleged confusion with the previously registered word mark ATTENTIN. This mark was also registered for goods in NICE class 5, albeit for a broader selection of goods.

In October 2024, the Norwegian Industrial Property Office (NIPO) rejected the opposition and upheld the registration, concluding that there was no likelihood of confusion. NIPO found that there was a complete overlap with regard to goods.

With regard to the similarities of the mark, NIPO found that the words were approximately the same length and began and ended in the same way. The letter X, placed in the middle of the proprietor's mark, contributed to clear visual differences, as the opponent's mark did not have such a center point.

Phonetically, NIPO found that the marks had similarities due to the initial a sound and the same ending ("TIN"), as well as the same number of syllables and rhythm. However, the beginnings ("ADEX" and "ATTEN") would be pronounced differently. The marks thus had clear phonetic differences.

NIPO found that "ATTENTIN" resembles the word attention and could give rise associations with the meaning of this word but still had a normal degree of distinctiveness. On the other hand, the later mark ADEXTIN was considered to be a fantasy word and would not give rise to any such associations.

Medice filed an administrative complaint on NIPO's decision in November 2024 to the Norwegian Board of Appeal for Industrial Property Rights (KFIR). Medice argued inter alia that the marks had significant visual similarities, which in turn would give a similar overall impression. Both started with "A" and ended with "TIN." In addition, the letter "E" had a similar position in both marks. The presence of the letter "X" did not sufficiently weaken the visual similarities.

With regard to phonetic differences, Medice argued that despite the later mark using the letter X in the middle of the word, this would not result in in any significant phonetic difference in normal pronunciation. The middle parts "DEX" and "TTEN" merged in the general pronunciation and did not dominate the overall impression. This was reinforced by the fact that both marks have three syllables, which would lead to a similar rhythm when pronounced. Furthermore, Medice argued that the beginning of the marks would play an important role, as the syllables "AD-" and "AT-" sounded very similar. Both marks ending with "TIN" would also lead to almost identical pronunciations at the beginning and the end. Medice also pointed out that ATTENTIN was not a word to be found in dictionaries, and the absence of the letter "o" was sufficient to prevent it from being recognized as "attention."

Medice also pointed out that although healthcare professionals exercise a higher degree of attention than a normal end user, practice showed that confusion could still occur with regard to the goods in question. The patient's preferences could play an important role in the choice of medication. The high level of attention would not help if the end user had already confused ADEXTIN and ATTENTIN. Medice thus argued that the patient's perception of brands could thus influence the choices of the person dispensing the medicine.

Orifarm argued that there was no risk of confusion between the marks. The market would consist primarily of professional actors, such as doctors, psychologists, and other healthcare personnel. This would indicate a very high level of attention.

Orifarm further agreed with NIPOs evaluation that ATTENTIN was similar to "Attention", and was thus suggestive, whereas ADEXTIN was a fantasy word. There were thus no conceptual similarities. Concerning the similarities visually and phonetically, these were not significant The prefix ATTEN differed greatly from ADEX, both in

visual appearance and in pronunciation. Orifarm also agreed on NIPO's argument on the effect the letter X created.

KFIRs decision

In April 2025, KFIR reached its decision on the complaint, upholding the registration of ADEXTIN and thus agreeing with the conclusion of NIPO.

KFIR's decision initially refers to the key issues when assessing whether confusion exists, which is an overall assessment of in which both the similarity of the goods and the similarity of the signs are taken into account. KFIR also referred to the degree of distinctiveness of the earlier mark must be considered. The more distinctive the earlier mark is, the greater the likelihood of confusion will be.

Concerning the average consumer, KFIR referred to that the average consumer will normally perceive the marks as a whole, without examining the details, cf. also C-334/05 P Shaker, paragraph 35. KFIR also referred to that it must be considered that the average consumer will not normally have the opportunity to compare the marks side by side, but must rely on the image he has in his memory, cf. C-342/97 Lloyd.

The relevant public for the goods were found to be both ordinary end users and professionals such as doctors and pharmacists, and KFIR found that the level of attention for medicinal products is high, as the goods have medical and health-promoting purposes, cf. the General Court's decision T-502/11.

On the similarity of goods, the court concluded that the relevant goods were identical. The confusion assessment should thus be based completely on the marks themselves.

KFIR found that phonetically and visually, the marks were similar in that they had several identical letters and the same number of syllables and rhythm, namely A-DEX-TIN and AT-TEN-TIN. However, the marks nevertheless had clear phonetic and visual differences due to the consonants in the components "adex" and "atten". In addition to the consonants being visually different, the double consonant "t" and the consonants "d" and "x" in particular give ATTENTIN a sound that is quite different from ADEXTIN.

KFIR also found that the marks had no conceptual similarities, as they either appeared to be fantasy words or conveyed sufficiently different images. It was primarily within the field of ADHD that the marks could give associations. Based on relevant medical publications, KFIR found that the relevant public would consider ADHD to be an abbreviation for "Attention Deficit Hyperactivity Disorder" and knows that "dexamfetamine" was a drug used to treat ADHD. The average consumer would thus have to make a mental leap to realize that ATTENTIN could play on "attention". KFIR found that ATTENTIN had a normal distinctiveness, as well as that ADEXTIN could give rise to association with ADHD medicine.

However, KFIR still concluded that the two marks provided the necessary different impression. Decisive in this assessment was the differences in the phonetic differences as well as the visual differences, as well as the marks creating different conceptual ideas. A factor mentioned by KFIR is also that the suffix "-IN" is commonly used in the pharmaceutical area, referring to both insulin and penicillin.

Comments

The decision from KFIR serves as a recent example of how the similarity assessment between pharmaceutical trademarks is conducted by KFIR. What is particularly important to be aware of with regard to pharmaceutical trademarks is that the average consumer is held to have a high level of attention, which also follows from the decision, although not being specific why this is the case. This principle is, however, emphasized and nuanced in case law in the EU. For instance, in Case T-435/22 (Pascoe), the General Court held that "*It is apparent from the case-law, first, that medical professionals have a high level of attention when prescribing medicines."* Concerning end consumers, the General Court emphasizes that *"(…)in cases where pharmaceutical products are sold without a prescription, it must be assumed that those goods will be of concern to consumers who are deemed to be reasonably well informed, observant and circumspect, since those goods affect their state of health, and that those consumers are less likely to confuse different versions of such goods. Furthermore, even assuming that a medical prescription is mandatory, consumers are likely to have a high level of attention when the goods in question are prescribed, in the light of the fact that those goods are pharmaceutical products."* (para 34). In other words, whether the question trademark concerns a prescription drug or an OTC-drug, the average consumers attention level is heightened.

A similar view is held in the General Court's decision T-175/22 (Novartis), which also refuted the argument that it was necessary to draw a distinction between the general public and professionals with regard to the level of attention. In this decision, the General Court held that such an argument could not succeed, because *"(…) irrespective of their training and professional activity, the average consumers of the goods concerned, which have in common the essential purpose of being marketed on the recommendation of or through a medical professional and have a direct impact on health,*

are reasonably well informed and reasonably observant and circumspect and have a high level of attention, whether they are members of the general public or professionals" (para 23).

This is particularly important to keep in mind when assessing the probability of success of whether an opposition will succeed, since despite apparent similarities both visual and phonetically, the threshold for confusion will thus be high. Combined with the fact that it is common within the pharmaceutical area to use similar prefixes and suffixes, the threshold for confusion can be quite high.

WHEN PILLS PROMISE TOO MUCH

Several breaches in advertising of OTC-products were found amongst online pharmacies in a recent supervision.

Background

Online sale of medicinal products, in particular non-prescription or over the counter (OTC) products, has been on the rise for several years in Norway. It should then come as no surprise that this has also increased advertisements for OTC products by pharmacies online.

In 2025, NOMA increased its supervisory activities concerning OTC products, in particular with a campaign towards pharmacies. Several similar breaches were found amongst 15 different pharmacy websites. The breaches concerned the same medicinal products.

Analgesic containing paracetamol

The first infringement concerned an OTC-analgesic containing paracetamol (500 mg). The advertisements stated:

"[Brand name] is an over-the-counter, fast-acting medicine containing the active ingredient paracetamol. It is used for mild headache, toothache, menstrual pain, muscle pain and joint pain, and for fever with colds and flu. [Brand name] has a rapid effect as the tablets contain an excipient that contributes to faster absorption (by taking two tablets at the same time, preferably on an empty stomach)".

The breach? Failure to state that the product was approved for over-the-counter use for *short-term* mild to moderate pain and that patients should contact a doctor after 3 days of fever or 5 days of pain if he/she does not experience improvement or feels worse. As such, NOMA found that this constituted a breach of the Medicines Product Regulation section 13-6 second paragraph letter b, where it is stated that it is mandatory to include *"information necessary for the proper use of the medicinal product, including indications for use and important precautions and warnings."*

The same analgesic also had advertisements which stated:

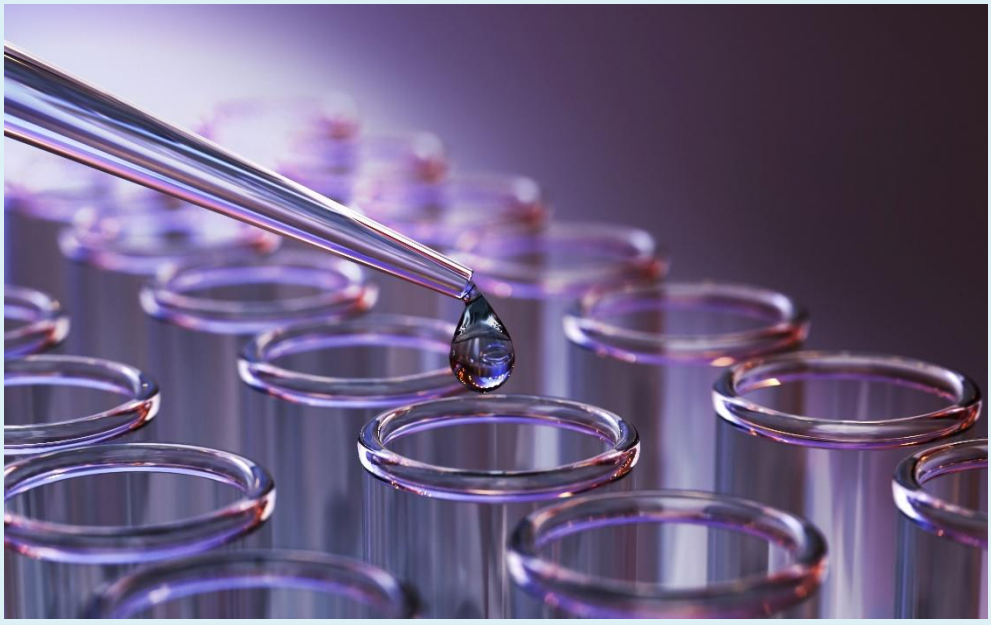
"Adults and children over 12 years (over 40 kg): 1-2 tablets up to 4 times a day. There should be at least 46 hours between each dose. Do not take more than 8 tablets in a 24-hour period".

This was also found to be breach of section 13-6, since the total dosage was higher than the maximum daily dose for children weighing between 40-50 kg (over 12 years of age) for over-the-counter use (3000 mg).

A third infringement was also held by NOMA for this product concerning a claim of fast effect. A claim in the advertisements stated:

[Brand name] provides a rapid onset of action and pain relief".

NOMA found that this claim was made without stating the source of the claim and without qualification. The package leaflet approved for over-the-counter use of the product stated that *"The rapid onset of action of [Brand name] tablets is only achieved by taking 2 tablets at a time"*. According to DMP, this did not support the claim that the product provides a rapid onset of action and pain relief.



Consequently, NOMA found that the advertisement implied that the effects of the medicinal product were guaranteed, and was in breach of section 13-6, third paragraph, letter b of the Medicinal Product Regulation, which prohibits information that *"suggests that the effects of the medicine are guaranteed, it is without side effects or is better than or as good as another treatment or medicine".*

Two allergy medicines

An OTC-antihistamine containing the active substance cetirizine used the statements:

- *"Relieves nasal and eye symptoms in seasonal or year-round allergies"*
- *"An over-the-counter medicine containing cetirizine, an antihistamine for the treatment of allergies"*
- *"Used to relieve symptoms in the nose and eyes due to seasonal or year-round allergies"*
- *"Can be used by adults and children over 6 years of age"*

However, NOMA reacted to the fact that the advertisement did not state that the product was approved for non-prescription use as *a short-term treatment* of eye and nose problems in allergies, e.g. pollen allergy adults and children ≥6 years, and that patients should contact a doctor if he/she does not experience improvement or feels worse after three days.

Consequently, the advertisement was deemed to not contain information necessary for the correct use of the medicine, and was therefore in breach of section 13-6 second paragraph letter b of the Regulation.

Similarly, failure to state that the use was intended for a short term was also an issue with an advertisement used for a histamine product containing fexofenadine.

The relevant claims stated:

"Non-prescription allergy tablets used for the treatment of allergic nasal and eye complaints in adults and children over 12 years of age. [Brand name] is an over-the-counter medicine containing the active

ingredient fexofenadine, an antihistamine, which is used to relieve symptoms of seasonal allergic eye and nose problems".

However, it did not state that the product was approved for non-prescription use as a short-term treatment of eye and nasal allergies, e.g. pollen allergies in adults and children >12 years and that patients should contact a doctor if he/she did not experience improvement or feels worse after seven days. Consequently, NOMA assessed that the advertisement did not contain information necessary for the correct use of the medicine, and was therefore in breach.

For this medicinal product, there was also a link to a video using English language, which inter alia stated *"Allergy relief in 30 minutes".* NOMA pointed out that this did not correspond with the product's package leaflet, which states: *"This medicine will start to relieve your symptoms within 1 hour and lasts for 24 hours".* It is stated in the decision that the video in question was from Youtube account named "[Brand name] Arabia", and NOMA points out that linking to foreign videos in a promotional aspect will be considered as governed by Norwegian legislation. The video was thus found to exaggerate the properties of the medicine, and was in breach of section 13-3, second paragraph, letter a of the Regulation, which states that all advertisements shall *"promote the rational use of the medicinal product by presenting it objectively without exaggerating its properties."*

Emergency contraception

The lack of necessary information in advertisements was a concern in advertisements of an emergency contraception containing ulipristal acetate. In several decisions against pharmacies, NOMA pointed out that there was no information from the "Warnings and Precaution" section of the package leaflet. Such information is intended to prevent patients from being exposed to unnecessary risk and must therefore be communicated in the advertisement itself so that people can consult their doctor or pharmacist before starting treatment with the medicine.

Lack of such information was considered a breach of the Regulation section 13-6 second paragraph letter b.

Medicine for heartburn and acid reflux

An advertisement stated in an online newspaper claimed that an OTC-product containing famotidine and calcium carbonate used a picture of the product and the following claim:

"Too much Christmas food? Quick relief for heartburn"

When clicking on the advertisement, readers were led to a webpage by an online pharmacy. NOMA considered that this statement implied that the effects of the medicinal product are guaranteed and is therefore in breach of section 13-6, third paragraph, letter b of the Regulation.

Furthermore, DMP argued that the advertisement did not contain readable information that clearly identifies the advertisement as an advertisement for a medicinal product, information necessary for the correct use of the medicinal product, including area of use and important precautions and warnings, as well as an invitation to the user to read the package leaflet or information contained on the package. The pharmacy did not agree, and pointed out that that the advertisement did include information about the medicinal product's use/area of use, precautionary rules and warnings, as well as encouragement to read the package leaflet. However, NOMA considered that this information, which is required, was not presented in a readable manner, and thus maintained the breach.

Comments

The abovementioned examples from the supervision demonstrate that with regard to claims on use and effect, the devil is in the details. The level of attention required when drafting a pharmaceutical advertising is high, and the margin for error is unforgiving. Minor errors or oversights that are easy to do when drafting an advertisement, as well as failing to include necessary information such as warnings or precautions could lead to reactions from NOMA.

SECOND MEDICAL USE PATENTS – THE USTEKINUMAB-CASE

Samsung Bioepis NL B.V. vs. Janssen Biotech, Inc. – Oslo District Court 27 February 2025

Introduction

The pharmaceutical company Janssen Biotech (Janssen) is the holder of European patent EP 3 883 606 (EP'606). The patent describes a method for dosing ustekinumab for the treatment of moderate to severe ulcerative colitis in humans. The method describes that a first dose is administered intravenously in week 0, and then by injection (subcutaneous) with a maintenance dose of 90 mg every 8 or 12 weeks, where the individual should be in corticosteroid-free clinical remission (CSFCR) for at least 44 weeks after week 0 of maintenance treatment.

Janssen markets a biological drug containing ustekinumab for the treatment of several different diseases, including psoriasis, Crohn's disease, and ulcerative colitis, under the trade name Stelara.

On 22 May 2024, Samsung Bioepis (Samsung) filed an action against Janssen, holding that EP'606 was invalid. Janssen filed a response to these allegations, as well as a counterclaim against both Samsung and Sandoz (which markets Samsung's products in Norway) requesting a preliminary injunction to prevent future sales.

The court hearing was held from 20-31 January 2025 at Oslo District Court.

The parties' arguments

Samsung argued that the patent lacked inventive step and argued that a person skilled in the art would have a reasonable expectation that ustekinumab would be effective in ulcerative colitis and provide corticosteroid-free clinical remission at the end of maintenance treatment. Samsung relied on cited art named "the Sand Slides". The Sands Slides presented data from the induction phase of a study called the UNIFI study, which lasted 8 weeks. The results showed

that ustekinumab had a real effect as induction therapy, with statistically significant results for all endpoints, including clinical remission at week 8, clinical response, improved health-related quality of life, as well as endoscopic healing and mucosal healing. Based on experience with the treatment of Crohn's disease with ustekinumab, a professional could expect ustekinumab to have a similar long-term effect on the treatment of ulcerative colitis, including clinical CSFCR. Samsung also referred to a study protocol (the UNIFI protocol), which had clinical CSFCR at the end of maintenance treatment as one of its endpoints.

Samsung also referred to the results of a separate study called the UNITI study, which concerned the use of ustekinumab for Chrohn's disease. This was a study using ustekinumab as a drug for Crohn's disease. The study showed that Stelara was a safe and effective drug for Crohn's disease, which did not cause side effects and had low "loss of response." Based on the results of that study, Stelara had been approved as a drug for Crohn's disease since 2016.

Based on Sand Slides and the results of the UNITI study on the use of ustekinumab for Crohn's disease, Samsung argued that the skilled person would expect CSFCR at the end of the maintenance phase.

Samsung further referred to a presentation (as well as an abstract and poster) providing results from a study by Professor Ochsenkühn, which showed long-term effects and that patients no longer use steroids after nine months. Samsung argued that the presentation strongly indicates that patients responded well clinically to treatment with ustekinumab.

A further support for Samsung was that the High Court of England and Wales had ruled that the patent did not have sufficient inventive step, using the Sand Slides as the closest prior art.

Janssen argued that at the priority date, there was no reliable knowledge to support the idea that ulcerative colitis could be treated by blocking IL-23. There was uncertainty associated with the consequences of blocking this cytokine. A person skilled in the art would not have had a reasonable expectation of success based on the information from the UNIFI protocol and the Sands presentation. There was no information to suggest that subcutaneous dosing of 90 mg ustekinumab every 8 or 12 weeks over 44 weeks would result in long-term CSFCR.

Janssen argued that the UNIFI protocol described the design of a phase III study. CSFCR at week 44 was listed as the last secondary endpoint in the UNIFI protocol. This indicates that it was considered very difficult to achieve and more difficult than other secondary endpoints. No phase II studies were conducted for ustekinumab in ulcerative colitis. This increased the uncertainty about the outcome of the phase III study, as it is not known whether the same dose would work in the different diseases

Janssen further argued that the Sands Slides showed promising short-term results for ustekinumab as induction therapy, but provided no information on the long-term effect or the effect of maintenance therapy, and gave no indication of the achievement of long-term CSFCR. The achievement of endoscopic and mucosal healing provided no further information than clinical remission.

A skilled person would not base their expectations on ustekinumab being approved for Crohn's disease or on the results obtained in the UNITI study. There is no general rule that drugs that work for Crohn's disease will also work for ulcerative colitis. Janssen also further argued that there was no definite correlation between the results in the induction phase and CSFCR achieved at the end of a maintenance study.

Janssen also argued that the Ochsenkühn documents could not be considered as prior art. In any event, this study was an undersized, retrospective, observational study without a placebo control group, and the skilled person would not have emphasized to the study.

The Court's reasoning

Oslo District Court rendered its decision on 27 February 2025.

With reference to case law from the Board of Appeal, Samsung had argued that where there is a protocol for a study, there will be an expectation of success, and that the examination was whether there exist other circumstances that indicate the opposite, i.e. that there is a reasonable expectation of failure. The Court was not swayed with this argument, and referred to Board of Appeals decision T 2963/13. The court found that there is no such automatic expectation of success even if a protocol for a study has been drawn up and it is known that it is also underway. The burden of proof is not reversed. However, this shows that the person conducting the study has such a strong expectation or hope of success that they are willing to invest considerable resources in exploring the possibility. This expectation may be based on preclinical trials or other scientific facts, which in themselves give the protocol weight in the assessment.

Concerning the decision from the UK, the Court referred to that the patent had been held invalid in light of the Sands Slides as the closest prior art. However, British law used a different approach to assess inventive step, and the court therefore found that it was not appropriate to go into further detail on that ruling. Instead, the court based its' decision on the well-known problem-solution approach.

On the properties of the skilled person, the court pointed out that there were disagreements between the parties as to whether the skilled person should have in-depth knowledge of inflammatory signaling pathways. The court found that the skilled person was an experienced clinician who specializes in the diagnosis and treatment of inflammatory bowel diseases and who was involved in clinical studies for the development of new treatments for inflammatory bowel diseases. The skilled person was also familiar with the underlying inflammatory signaling pathways that were believed to be involved in ulcerative colitis and Crohn's disease, respectively, at the priority date, but in the opinion of the court the skilled person did not need to have in-depth knowledge of the complexity associated with

the signaling pathways. The skilled person should be familiar with how clinical studies were designed, but did not need to have knowledge of failed and unpublished studies.

The closest prior art for the court was a pragmatic choice, as the court chose the UNIFI protocol. The reasoning for this was that the Sand Slides was a presentation of the results from the first part of the UNIFI protocol, which includes both an induction phase and a maintenance phase. The UNIFI protocol therefore had to be viewed in light of the knowledge contained in Sand Slides

The Court formulated the technical problem is to provide effective treatment for patients with moderate to severe active ulcerative colitis that provides long-term CSFCR. The court added that developing a treatment method that ensures that patients achieve and maintain clinical remission without the use of steroids over a longer period of time has been a significant challenge in the treatment of ulcerative colitis.

In the specific assessment of whether the solution described by EP'606 was obvious, the court first stated that it was undisputed that no phase II studies had been conducted for ustekinumab in ulcerative colitis at the time of the priority date. However, in the study protocol, there was an explicit pointer on the that due to the similarities in the genetics and biology of UC and Crohn's disease, it was reasonable to assume that ustekinumab will also be effective in UC. The court thus found that it was reasonable to assume that ustekinumab will be effective in the treatment of ulcerative colitis.

The court found that since the dosages were not tested in a phase II study beforehand, this increased the uncertainty about the outcome of the phase III study, because it was not known whether the same dose would work in the different diseases. On the other hand, the UNITI study had showed that the doses in question were effective and safe for the treatment of Crohn's disease, and the patients did not experience any serious side effects.

The District Court found that the Sands Slides showed that ustekinumab had an effect on clinical remission, endoscopic healing, and mucosal healing, but that the results on clinical remission was low compared to studies of other biological drugs. Nevertheless, the court found that the Sands Slides showed very positive results, especially considering that treatment after only 8 weeks resulted in

highly significant mucosal healing. However, none of the results in Sands Slides showed which patients were on steroids during induction treatment and which were not.

At the priority date, there was no reliable knowledge from human studies to support the treatment of ulcerative colitis by blocking IL-23. However, the court pointed out that evidence had found that IL-23 could also be important in ulcerative colitis, based on studies of experimental colitis in mice and an increase in cells in patients with both Crohn's disease and ulcerative colitis. There was no evidence to suggest that inhibiting IL-12 would have negative consequences.

In its summary, the District Court stated that although Crohn's disease and ulcerative colitis were different diseases, they were known to share several inflammatory mechanisms. In studies of drugs where the induction phase has had a clinical effect on both diseases, maintenance studies show results such as clinical remission and CSFCR.

The court concluded that a professional could reasonably expect that treatment with ustekinumab would lead to CSFCR in the treatment of ulcerative colitis at the end of maintenance treatment in week 44. The patent therefore lacked inventive step. However, Janssen had submitted four alternative claim sets which the court had to assess. Neither of these were found to make any difference with regard to whether the patent held inventive step.

As the patent was held to be invalid, the court also acquitted Samsung and Sandoz in the request for a preliminary injunction.

Comments

Patent disputes between Samsung and Janssen has been ongoing in several jurisdictions in 2025, including in the Netherlands and in Switzerland, with various outcomes. As Stelara is a blockbuster drug for Janssen, it was expected that this decision would be appealed and that the case would be held by the appeal court in 2026.

While Janssen did appeal the decision of the District Court, the case was subsequently settled between the parties, and the parties submitted a joint pleading to the Court of Appeal. Consequently, the court ruled that Janssen is acquitted for the invalidity action. As such, the patent is thus still in force in Norway.

YOU SHALL NOT PASS – A TALE ON ATTEMPTING REVERSALS OF DECISION FORUM

Decision on use of medicinal products for hospitals are not subject to administrative complaint – but can they still be held invalid?

Introduction

In Norway, public funding and therefore access to new pharmaceutical medicinal products is divided between whether the product is intended for the primary healthcare or the specialist healthcare (in practice public hospitals). In the case of the latter, which is often the case of new and innovative medicinal products, such products are faced with a procedure which bears the unoriginal name "New Methods".

This system is based on health technology assessments (HTA) made by the Norwegian Medical Product Agency, but the cornerstone of the system is the general rule that until there exists a decision from board called "Decision Forum", new medicinal products and indications cannot be prescribed in the specialist healthcare. And the decisions of Decision Forum shall be made on the basis of the three prioritization criteria in the Specialist Health Services Act section 2-1a (2), namely benefit, resource use, and severity.

It goes without saying that when implementation of a new decision is rejected by Decision Forum, the first thought a pharmaceutical company would have is whether it is possible to appeal the decision if it disagrees with the outcome and/or reasoning.

However, the first hurdle in overcoming this obstacle is that the decisions from Decision Forum are not formally considered an administrative decision pursuant to the Public Administration Act. This precedence was established in 2016, when two pharmaceutical companies attempted this route, but where the complaints were refused by the Ministry of Health and Care Services. Ultimately, the Parliamentary Ombud for Scrutiny of the Public Administration (the

Ombudsman) issued a statement in 2018, stating that such decisions were not individual administrative decisions according to the Public Administration Act, but subject to the states private autonomy.

This principle also became statutory law in 2020 with a new provision in the Specialist Health Services Act section 4-4, which explicitly states that these decisions are not administrative decisions pursuant to the Public Administration Act.

But can these decisions nevertheless be considered as invalid in certain circumstances?

Inquiry on reversal of the decision

On 13 August 2025, a pharmaceutical company sent a petition for reversal of a decision made in 2023, but which the pharmaceutical company apparently became aware of in 2025. The backstory is rather peculiar, as the decision in question was a transfer of a number of medicinal products being transferred from national insurance funding (i.e. the system used for reimbursement in the primary specialist healthcare) to the funding of the specialist healthcare services. In the decision, Decision Forum set several conditions, including the following:

"The same price level as the price on which the decisions are based is assumed."

The pharmaceutical company was not involved in this decision, and as the medicinal product in question had been used since 2019 and continued to be used, there was no reason for alarm. After the funding was transferred to the specialist healthcare sector, the use became subject to tenders, which the pharmaceutical company participated in the following years.

Fast forward to 2025, and the pharmaceutical company ran into trouble, as it was rejected from the competition. The rejection was justified on the grounds that there was a significant deviation from one of the requirements in the tender, namely that *"For products introduced into the specialist health service through a decision by the Decision Forum for New Methods, the price offered must be in accordance with the decision."* This is a general requirement that the entity responsible for tenders for hospitals (tender authority) apply in tender competitions regardless of whether or not there has actually

been a decision by the Decision Forum. The rejection letter referred to the decision from Decision Forum in 2023 and stated that the offer of the pharmaceutical company was not in accordance with this decision.

The pharmaceutical company alleged that they became aware of the decision of Decision Forum through a letter from the tender authority more than two years after the decision was made, and do not know the price concerning this condition in the decision.

The pharmaceutical company naturally knew that the decisions from Decision Forum are not individual administrative decisions, cf. the Specialist Health Services Act section 4-4. Nevertheless, the company argued that section 35 of the Public Administration Act was a codification of general administrative law and could be applied to decisions other than individual administrative decisions, including those made by Decision Forum. It also followed from the previous statement from the Ombudsman, which had stated that the fact that there was no formal right to appeal did not mean that companies affected could point out errors in the process leading up to the Decision Forum's decision and request a new assessment. Furthermore, the doctrine of abuse of authority, rules on disqualification and requirement for a proper case management, could in principle be subject to appeal to the Ombudsman and subject to judicial review.

The pharmaceutical company then began the exercise of finding grounds for invalidity. The first was invalidity due to serious procedural errors. Here the pharmaceutical company pointed out the secrecy of the document, as well as the fact that it is common practice to negotiate a discount. Failure to do so in this case was *"a clear violation of the principle of equal treatment".* It was also *"a gross violation of the requirement for predictability."*

The pharmaceutical company also argued that the decision had to be considered as invalid due to a lack of legal basis. The argument here was primarily that Decision Forum did not have the legal authority to *"unilaterally set a price other than the maximum AUP as the basis for its decision."* It was clearly not within the private autonomy to *"unilaterally decide the discount at which suppliers should offer their products"*, and Decision Forum had *"no legal authority to dictate the price of a product offered by a private company."*

Finally, the pharmaceutical company argued that the decision was invalid due to incorrect factual assumptions. This argument concerned the price. But the company was at a disadvantage here, since it did not actually know the price referred to in the Decision Forum decision. However, the company stated that it was possible that the price referred to in the decision was the same price used by the pharmaceutical companies in the latter tender framework agreements.

The company pointed out that the price offered in a tender is always temporary, and is influenced by several factors, including the competitive situation and the terms and conditions of the tender, duration of contract etc. The pharmaceutical company argued that Decision Forum clearly could not *"unilaterally use a tender price at a randomly selected point in time as a permanent condition for introduction into the specialist health service."*

The company also argued that not only could Decision Forum reverse its decision, but it was obligated to do so. The company pointed out to the financial loss of being rejected from the tender competition. Beyond this point, the case had revealed a *"very worrying administrative practice"*. According to the company, the errors led to *"a decision being made to introduce a randomly selected price that is not anchored with the supplier. The supplier is*

not even aware of the price that has been used as a basis." And such *"use of public authority and purchasing power in a market with a monopoly-like character"* was argued to be unacceptable.

The response from Decision Forum

The response from Decision Forum came from the tender authority on behalf of the secretary of Decision Forum. The tender authority also referred to the fact that they were involved in both the decision and the tender referred to and thus were best qualified to deal with the request.

The tender authority systematically attacked the alleged invalidity reasons from the pharmaceutical company. Concerning procedural errors, the tender authority referred to that decisions on the introduction of medicines into the specialist health service fell under the state's private autonomy and were not subject to the rules of the Public Administration Act on individual decisions. Furthermore, citing the Ombudsman's opinion that the decisions were not governed by rules, and there were no established rules of procedure. The decisions had to be made on an assessment of the three priority criteria of benefit, resource use, and severity. This assessment was based on a professional judgement, and in principle not subject to judicial review. As the decision is thus an exercise of private autonomy, there were no procedural errors.

Concerning the lack of involvement of the pharmaceutical company, the tender authority stated that although the decision-making process normally involved interaction with suppliers, this did not mean that suppliers had a right to participate in the processes or in the preparation of the case basis for a decision. Furthermore, the decision in question was not a normal process in which a new drug was considered for introduction into the specialist health service. The decision was the result of a number of drugs being transferred from national insurance funding to health enterprise funding, and this unusual route justified the procedure by the decision, which entailed equal treatment with other drugs that were transferred.

Concerning the lack of legal basis, the tender authority stated that the argument from the pharmaceutical company assumed that the decision involved a unilateral determination of the price at which a pharmaceutical company must sell its products. This was an incorrect representation of what the Decision Forum's decisions are.

The Decision Forum sets the maximum price that hospitals can pay for the drug in question, cf. the express condition for introduction of the same price or price level as in the basis for the decision. When the public sector purchases goods and services, it does not exercise public authority.

On the last argument from the pharmaceutical company, concerning the incorrect factual assumptions, the tender authority stated that it was unclear from the inquiry what these might be and what the correct assumptions might be. However, the prices used by Decision Forum as a basis for their assessment are not regulated and therefore could not be relevant as grounds for invalidity. The decision was therefore not invalid due to incorrect factual assumptions.

Finally, the tender authority stated that it is the supplier's responsibility to ensure that the minimum requirements in the competition are met, and the pharmaceutical company could not be heard on the grounds that they were not aware of the decision. The decision had been open and available on the New Methods website since 2023, and it was the company's responsibility to keep up to date with new decisions. The company also had the opportunity to contact the tender authority for price guidance and request a reassessment of the medicinal product, if they so wished.

The Ministry gets involved

The pharmaceutical company did not accept this response to be the end of the road and requested that the Ministry of Health and Care Services reversed the decision made by Decision Forum. Also pointing out that in its view, Decision Forum did not consider the request for reconsideration but left this to a subordinate body (tender authority).

The pharmaceutical company argued that the Ministry like Decision Forum had a duty to reverse the decision in question. The company here referred to a statement from the Ministry of Legal Affairs, which described the duty to reverse invalid decisions made by public authorities.

The Ministry responded on 13 November 2025, with a rather short reply. Stating that it was not the superior authority of Decision Forum and therefore could not assess the petition of reversal. Reference was made to section 4-4 of the Specialist Health Services Act which expressly states that such decisions are not to be regarded as administrative decisions.

However, despite this rather short and not so sweet reply, the Ministry did throw out a potential helping hand, stating that although *"decisions on which methods can be offered in the specialist health service are not to be regarded as individual decisions, the Ministry agrees that certain procedural requirements apply",* such as impartiality and the duty to provide guidance. Reference was made to the preparatory works of the Specialist Health Services Act. Furthermore, the Ministry referred to the statement from the Ombudsman that *"[t]he doctrine of abuse of authority, rules on disqualification and requirements for proper case processing will also, in principle, be subject to appeal to the Ombudsman and to judicial review."* The Ministry ended the letter with stating that if the company considered that there had been a breach of administrative law principles, it could complain to the Ombudsman as the appropriate body.

Comments

The outcome of this petition to the Ministry may seem rather obvious, in light of the Ministry's previous position which led to the statement of the Ombudsman. The decision nevertheless provides much needed clarity for pharmaceutical companies if they disagree with Decision Forum. Such complaints must be directed to the Ombudsman and not to the Ministry.

However, such a complaint might still be a futile endeavor. It does not change the fundamental principle that there is no judicial review of decisions made by the Decision Forum, as it is part of the private autonomy of the state. Finding any errors based on administrative law principles, as the pharmaceutical company attempted, quickly becomes an exercise of "theory not matching the reality", ending up with listing various principles and case laws which can quickly be dismissed due to the factual circumstances of the case. Whether the pharmaceutical company will attempt such a route remains to be seen.

RECENT DECISIONS FROM THE COUNCIL

When pharmaceutical advertising and tender requirements meet.

Introduction

Supervision of pharmaceutical advertising pursuant to the Norwegian Medicinal Product Regulation is a task for the Norwegian Medical Product Agency (NOMA). However, many pharmaceutical companies are also subject to industry guidelines on advertising due to their membership in the Norwegian Pharmaceutical Industry Association (LMI). Breach of compliance with these guidelines is subject to a self-regulatory Council for Drug Information (the Council), based on a complaint proceeding.

While self-regulatory, the Council is far from a paper tiger. In fact, a pharmaceutical company in breach of the advertising guidelines can be ordered to pay a "fine" up to NOK 400 000 (appr. EUR 35 000). In the recent years, there have been fewer decisions from the Council compared to those issued by NOMA. Nevertheless, these decisions are of interest to pharmaceutical companies seeking to be compliant in all aspects of advertising, and in 2025, the Council published three cases.

Case R0325 – "first choice for new patients"

In the first case, Sanofi submitted a complaint on Amgen concerning an advertisement for the medicinal product Repatha (evolocumab). Repatha is a so-called PCSK9 inhibitor, used to treat high cholesterol in patients who have not achieved sufficient effect with other types of cholesterol lowering products. Repatha is prescribed by a doctor and administered by the patient.

The backstory is that there was a tender for individual reimbursement for PCSK9 inhibitors in Norway, where Amgen's Repatha were listed first and Sanofi's Praluent were listed as second.

Sanofi's complaint concerned the use of the expression *"first choice for new patients"* used in an advertisement in a professional journal for healthcare personnel, as well as on

Amgen's website for healthcare personnel, and that this expression was misleading.

The context of the expression was that this was stated as *"Repatha is the first choice for new patients with the following threshold values"* followed by a table showing relevant patient groups and threshold values. The right-hand side of the advertisements used of a large circle with bold red letters stating "*Repatha is first ranked for new patients."*

Sanofi argued that the term *"*first choice" indicated an instruction that the drug *should* be chosen. According to the complainant, this gives an inaccurate impression because the reality is that the product is the first to be *considered*. Sanofi argued that it was misleading to talk about "first choice" and that the term left a false impression that the doctor has a duty to prescribe the drug, which created confusion among doctors. The term "first choice" creates a false impression of therapeutic superiority. The correct approach according to Sanofi would be to refer to the drug as "first-line" and to consider it first for new patients.

Amgen on their part pointed out that both NOMA and the tender authority responsible for the tender used the term "first choice" when describing the outcome of the tender. The tender outcome also meant that doctors cannot freely choose between the drugs that have been awarded contracts, but must consider Repatha first for new patients. This means that it was correct to refer to Repatha as the "first choice" for new patients.

Amgen further argued that "first choice" could not be interpreted as *"mandatory choice"* or "*the only choice*." On the contrary, the defendant believes that the term "first choice" indicates that there is also a second choice.

The Council found that based on a natural linguistic understanding, the term "first choice" meant *"the one that is chosen first"* and "the preferred/priority option." The Council agreed with that the term "first choice" could not be understood to mean *"the only choice"*, but clearly indicates that there are other options.

The Council generally agreed with Sanofi that the term used in advertising for specific drugs could easily give the impression of therapeutic superiority. In this case, however, it was clear that *"first*

choice for new patients" referred to a specific tender competition and thus to the award criteria in this competition. The Council assessed that the recipients of the advertising message would not perceive the claim that Repatha was "first choice for new patients" as a message of therapeutic superiority, but the product that should be chosen first for new patients. Repatha was the preferred, but not the only, option.

The message was also not misleading in light of the tender, where the criterion under the tender agreement was that orders should be placed in accordance with the ranking, so that the highest-ranked drug shall always be considered first when starting or changing treatment during the agreement period. Deviations from the ranking are only permitted if the highest-ranked drug cannot be used for medical reasons, if a dose increase is necessary that changes the cost/benefit assessment, or if there are delivery problems with the highest-ranked drug.

Consequently, the Council found that there was no breach of the guidelines.

Case R0125 – "one of two tender winners"

A separate case involving the two parties and medicinal products, but where the roles were reversed, was also published by the Council. This case concerns an advertisement in the same professional journal, for the medicinal product Praluent (alirocumab).

Amgen had complaint on the use of the claim " *Praluent - one of two tender winners*", and that this was contradictory to the tender result. Amgen's medicinal product Repatha was ranked first in the PCSK9 tender and should therefore be considered first for new patients. However, in Amgen's view, the advertisement conveyed an incorrect message that Praluent and Repatha should be treated equally when prescribing. The advertisement gave the impression that doctors were free to choose between the drugs without taking into account the tender ranking, which is not correct and misleading. Using this expression was therefore viewed as a breach of the guidelines.

Sanofi argued that the complaint fell outside the Council's jurisdiction because it concerns the interpretation and implementation of a public procurement process, and that the Council was not the appropriate forum for resolving disputes about how tenders should be interpreted or how healthcare professionals should apply such frameworks in practice.

Sanofi argued that the statement "*Praluent - one of two tender winners*" was correct, as Sanofi's bid was accepted and a contract was awarded. It was therefore objectively correct to say that Praluent was one of the winners of the tender.

Furthermore, it was not correct according to Sanofi that the advertisement suggested that prescribers could ignore the ranking requirements of the tender. Sanofi acknowledges that Repatha should be considered first for new patients. Sanofi believes that its communication is fully consistent with the interpretation of NOMA and the tender authority as expressed in their correspondence:

The Council first pointed out that there were no exceptions for cases where an alleged breach of the guidelines is based on the outcome of a public procurement process. The Council had also previously dealt with cases where allegations of breaches of

guidelines have been based on the outcome of public procurement processes. The complaint thus fell under the Councils jurisdiction.

Concerning the statement itself, there was no doubt that a claim of being "*one of two* tender winners" would be perceived as meaning that Praluent *shared* first place with another winner, i.e. that the tender had *two* winners. The tender operated with a ranking system, and entering into a contract did not mean that one was the "winner" of the tender. The tender had one winner. The statement was thus not factually accurate.

In the Council's opinion, the claim "*Praluent – one of two tender winners!*" also left the false impression that there were *two* winners of the tender. The advertisement also stated that "*Reimbursement terms remain unchanged and the choice of PCSK9 inhibitor does not need to be documented in the medical record*."

Sanofi had out that the reimbursement conditions for the two drugs were the same and that, according to the tender authority, the reimbursement conditions therefore did not impose any "*regulatory barriers to prescribing and make it easy for doctors to prescribe the drug that is right for the individual patient*."

However, the Council pointed out that prescribing physicians had to comply with the tender outcome. The highest-ranked drug must always be considered first when starting or changing treatment during the contract period. The advertisement in question presented Praluent as one of the winners of the tender and emphasized that the choice of drug did not need to be documented in the patient's medical record. The advertisement did not contain information that another drug should always be considered first for new patients.

In the Council's view, the advertisement was misleading. It did not convey the tender outcome in a truthful manner, and left a false impression that doctors are free to choose between drugs that have a framework agreement without taking into account the tender ranking.

The Council thus concluded with breach of the guidelines. The fine awarded was set to be NOK 100 000 (appr. EUR 8 750). In determining the level of the fine, the Council considered that the message had been communicated to a limited extent, and that the activity did not endanger the lives and health of patients.

Case R0225 – advertisements lacking mandatory information

The third case concerned advertising for the drug "Opdualag", a combination of the active substances nivolumab and relatlimab. Opdualag is a cancer drug used to treat advanced melanoma. The drug is marketed by Bristol-Myers Squibb

The case concerned seven different "banner advertisements" for Opdualag that have been published on a website. The case was initiated by the Secretary of the Council on their own accord. The Secretary argued that the advertisements lacked mandatory information and were therefore in breach of the guidelines section 7.2.

Section 7.2 of the guidelines states that advertisement must comply with public laws and regulations, and must contain:

> *a) relevant information that is complete and that corresponds with the summary of product characteristics approved by the Norwegian Medical Products Agency,*
>
> *b) prescription group*
>
> *c) price, and*
>
> *d) information on pre-approved reimbursement.*

An exception is made for so-called "reminder advertisements". However, such reminder advertisements can only contain the trade name, the name of the active substance and the name of the company. This was not the case with the seven banner advertisements for Opdualag. There was a link to mandatory information, but a link did not satisfy the requirement.

Bristol Myers Squibb acknowledged that the content of the advertisements exceeded the limits for both reminder advertising and ordinary pharmaceutical advertising, and that they therefore did not meet the requirements of the guidelines. It was explained that the breach was not intentional, but due to an internal misunderstanding regarding the use of a "one-click" link to mandatory information. The advertisements were removed immediately after Bristol Myers Squibb was made aware of the matter.

The Council concluded that there was a breach of section 7.2. However, the Council also pointed out that the advertisements did not fulfil the requirement that the advertisement shall be balanced, cf. section 7.1 of the guidelines. This inter alia includes that "*advertising shall be balanced with regard to the product's benefits and risks*" and that advertising "*must always balance positive messages about efficacy with relevant safety information that helps to prevent misuse of the medicinal product*".

The advertisements in question were short and did not contain much information. The advertisements contain the product name Opdualag, either as a logo or in the text, the medicinal product's area of use and/or efficacy claims. The advertisement did not contain any balancing information, including safety information. The advertisements were not balanced in terms of benefits and risks.

Concerning sanctions, the Council awarded a fine of NOK 200 000 (appr. EUR 17 500). The main reason for this was that even though there was a misunderstanding with regard to the use of a "one-click" link to mandatory information, there was no explanation for the lack of balance in the advertisements. The Council stated that the requirement that advertising must be balanced is one of the fundamental requirements that apply to pharmaceutical advertising, and violations of this requirement must always be considered serious. The fact that the same violation had been repeated in seven advertisements for the same medicinal product also influenced the size of the fine.

Comments

The "dual lane enforcement" of pharmaceutical advertising in Norway can be tricky to maneuver. While the areas overlap in some areas, a common area where the self-regulatory process is chosen by the complainant is where the advertisement of a competitor uses comparative elements in the advertisement. Such concepts are less likely to be a focus area for NOMA, but much more so for the Council. This may also give the impression that there is more "artistic room" for the advertisements compared to the more stringent requirements in the Medicinal Product Regulation. However, as illustrated by the abovementioned examples, the devil is in the details also for such details.

Haavind

Better understanding - better solutions