Haavind

Pharma Report Summer 2022

Retrospective view of legal developments in Norway

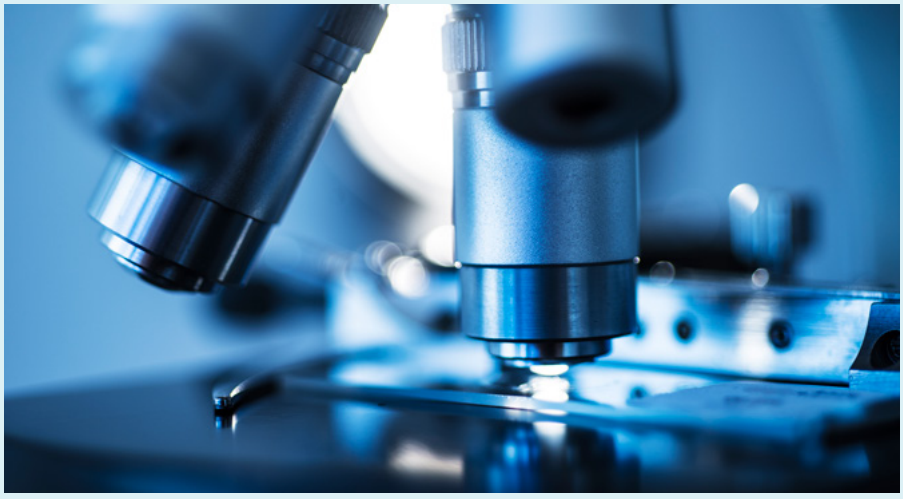
Introduction

Dear reader

Since 2016, Haavind has published Pharma Report, a biannual publication on some of the legal developments for the pharmaceutical sector in Norway. As legal advisers with a passion for the pharmaceutical sector, we are happy to present some of the cases in yet another eventful period for the pharmaceutical industry. As usual, our cases include topics in both regulatory affairs and intellectual property rights.

Sanctions in the healthcare industry has been a hot topic this year, and in this Summer Edition of Pharma Report, you can read about the new sanction regime on pharmaceutical advertising, as well as the attempted sanction regime for physicians. You can also read about the new reimbursement scheme for PCSK9-inhibitors, and the latest cases on intellectual property within the pharmaceutical industry.

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.



Content

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Håkon is the primary 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, patent litigation, 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.

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Norwegian Supreme Court refuses leave to appeal for validity on patent

Can appeals for patent cases really be determined by simplified and written procedure? Yes, according to a new decision from the Supreme Court.

Background
In the previous edition of Pharma Report, we reported on Oslo District Court's decision in a patent case between Orifarm Healthcare and Neurim Pharmaceuticals regarding a patent for the use of melatonin for the treatment of primary insomnia. The patent in question (NO334 788) had a rather complicated procedural background in Norway.

First, the grant of the patent was accepted by the Norwegian Industrial Property Office (NIPO) in 2014, but this decision was later invalidated in 2016 based on lack of novelty due to an opposition. Neurim subsequently appealed this refusal to the Norwegian Board of Appeal for Industrial Property Rights (KFIR), which first maintained NIPO's refusal. However, Neurim brought KFIR's decision to Oslo District Court, which invalidated the decision in 2018. After a renewed procedure at KFIR, the patent was maintained in amended form.

The patent was nevertheless challenged by the generic manufacturer Orifarm, alleging invalidity due to lack of both novelty and inventive step as well as invalidity due to insufficient disclosure. In its decision of 17 August 2021, Oslo District Court ruled that the patent was invalid due to lack of inventive step. Orifarm was also awarded damages.

Unsurprisingly, Neurim appealed the District Court's decision, both regarding the question on validity and the awarded damages.

Refused leave to appeal
The main rule is that an appeal over a decision shall be brought before the appeal court if the value in question exceeds NOK 250,000 or the matter concerns ideal interests. However, Norwegian courts have the possibility to refuse leave to appeal against a decision if the court finds it clear that the appeal will not succeed, and refusal may be limited to certain claims or grounds of appeal, cf. the Civil Procedure Act Section 29-13 second paragraph. This refusal shall be interpreted strictly, and the requirement pursuant to case law is that there is a high degree of certainty that the District Court's decision will not be overturned after the appellate hearing.

Refusal to allow appeal in a patent case concerning validity where the district court was appointed with expert lay judges has to our knowledge newer occurred before. Nevertheless, on 21 December

2021, Borgarting Court of Appeal issued its decision to refuse to allow appeal against the District Court's decision regarding the question of validity. Instead, the court decided to review the case via a written and simplified procedure. Although "simplified" may be a bit misleading when reviewing the extent of the written decision.

In its decision, which consists of twenty pages, the Court of Appeal reviewed the legal standards for refusing appeal and stated that there is nothing principally wrong with refusing leave to appeal in patent cases, even if expert lay judges are often appointed in such cases. In practice, however, the subject in these cases and the need for expert lay judges will often mean that a court of appeal does not have the basis for finding that an appeal cannot succeed. In this case, however, the court found that it had such sufficient basis.

The court then proceeded to perform a specific assessment, using the well-known problem solution approach. The court found that the closest prior art was an article called Haimov 1995, which was considered the closest prior art by the District Court. Referring to the specific assessment done by the District Court, which the Court of Appeal found to be correct, the Court of Appeal concluded that the invention "clearly did not fulfil the requirements of inventive step", and that it was correct of the

District Court to invalidate the patent. The Court also considered the commercial success of the invention, and that KFIR came to another conclusion, but found that this did not affect the conclusion.

The court also assessed Neurim's allegations regarding the parallel situation in EPO and the parallel proceedings in the UK but found that the fact that the EPO and the court in the UK had come to another conclusion did not change the court's assessment.

The court proceeded to state that an oral hearing would not have resulted in a different outcome. The Court of Appeal assessed that it was not necessary to provide evidence for the court during an oral hearing in order to establish what, at the time of the application, was the prior art and if it from this could be found whether the skilled person would find the invention obvious. The Court of Appeal stated that the case did not concern questions of principle, and that the factual circumstances were not disputed. The disagreement between the Parties was what the skilled person would have concluded from the prior art. The Court of Appeal found that it had sufficient basis to conclude in this particular case.

The Supreme Court's decision
Neurim appealed the Court of Appeal's decision to the Supreme Court, which on 23 March reached its decision. The arguments from Neurim were that the Court of Appeal had based its decision on a "too low threshold" when refusing the leave to appeal. Furthermore, Neurim also alleged that the reasoning of the Court of Appeal was not sufficient, and that it was not proper to determine the appeal by a written and simplified procedure without assistance from expert lay judges or other experts.
The Supreme Court first assessed the question of whether the court had used a too low threshold. Finding that the Court of Appeal had clearly stated the legal basis for refusing leave to appeal, and that this was correct. The Supreme Court concluded that the application of the law gave no merit to using a too low threshold.

On the argument that the Court of Appeal had failed to provide a sufficient reasoning. The Supreme Court here stated that it found that the Court of Appeal had provided a thorough reasoning of its refusal and pointed to the fact that Neurim's allegations were referred to over five pages, and that the reasoning demonstrated

that the Court of Appeal had been aware of the alleged errors pointed out by Neurim. The Supreme Court also found that it was clear that the evaluation left the impression that there was no doubt that the Court of Appeal had performed an individual and genuine assessment.

Regarding the last argument by Neurim, that it was not proper to refuse leave to appeal, the Supreme Court was divided. The majority stated that the technical character of these cases results in the appointment of expert lay judges, but that it is not an "exemption free rule" that such experts must be appointed, and that the degree of such expertise may vary from case to case. The majority here also referred to the fact that Neurim before the District Court alleged that it was not necessary to appoint expert lay judges.

The majority also emphasized that the Parties agreed on the factual circumstances and the legal basis and found that the question of inventive step were not so emphatically technical that it would be improper for a court to assess without assistance from expert lay judges or expert witnesses. Emphasis was also placed on the fact that the District Court's decision was clear and precise, and that the Court of Appeal had access to written declarations by the Parties' expert witnesses.

The majority of the Supreme Court also emphasized that the question of invalidity of the patent did not raise any principal questions, that there was no new evidence that had not been assessed by the District Court. The Supreme Court also pointed out that although the patent undoubtedly had a financial impact for Neurim, the patent would nevertheless lapse in August 2022, i.e. in a relatively short time.

With regard to the situation in the EPO and the UK, the majority stated that it is not extraordinary that decisions in patent cases go in different directions in various jurisdictions, also referring to that the patent was not upheld in Sweden.

The majority thus found that the Court of Appeal's decision to refuse leave to appeal was proper.

The minority came to the opposite conclusion. The minority emphasized that the evaluation of inventive step is discretionary and, in this case, required competence within the fields of medicine and/or pharmacy, and that the Court of Appeal did not have such expertise. The District Court did have such expertise with the expert lay judges but did not consider whether it was clear that KFIR's grant of the patent was invalid.

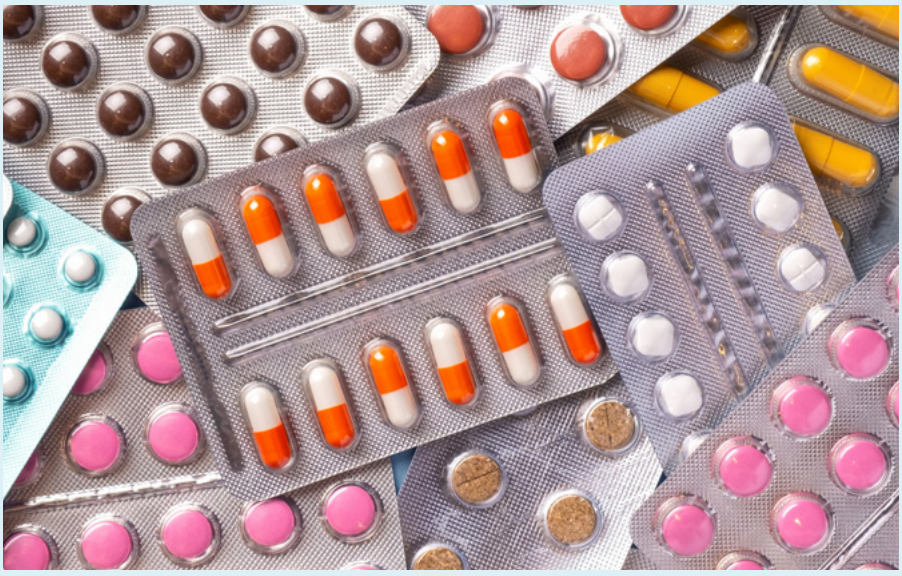
Also pointing to the so-called "Swingball-doctrine", which states that the courts shall be reserved in overturning decisions made by the patent authorities, it would require a significant proper basis to not allow an appeal on a decision on the validity of a patent. The minority here also pointed to the fact that there was dissenting opinion on the grant of the patent in KFIR, and the situation in the EPO.

Comments
As previously stated, this is the first time that a first instance decision on the validity of a patent has been refused leave to appeal. From a Norwegian patent law perspective, this is thus a landmark decision, and both the decision of the Court of Appeal and the decision of the Supreme Court should be of significant interest to Norwegian patent practitioners. The case also demonstrates that although in most cases the technical aspects of a case would result in an appeal hearing with expert lay judges, this is by no means any guarantee as such, and would have to be assessed on the specific circumstances in the individual case. The part of the District Court's decision concerning damages awarded to Orifarm is still subject to appeal.

Haavind's team represented Orifarm with the refusal to allow for appeal and also represents Orifarm in the appeal case concerning damages.

Tender on PCSK9-inhibitors – paving the way for a new reimbursement model for medicinal products?

A new reimbursement model is on the horizon for expensive medicinal products in Norway. But will it be for the benefit for the patients or the public health budget?



Background
Somewhat simplified, the Norwegian system for reimbursement can be split into two different categories. Medicinal products offered in specialist healthcare, which is financed by the public hospitals, and medicinal products offered in primary healthcare, where reimbursable products are financed by the National Insurance Scheme.

The two categories have until recently lived separate lives. Medicinal products in the specialist healthcare sector are subject to tenders. On the other hand, in order for a medicinal product offered in primary healthcare to be reimbursable, it must be placed on a reimbursement list, where the product can be subject to either pre-approved reimbursement, individual reimbursement or reimbursement for contagious diseases. This system is popularly referred to as the "blue prescription regime". The majority of medicinal products subject to reimbursement in primary care are pre-approved for reimbursement.

With regard to the price – all medicinal products in Norway intended for human use and subject to prescription requires maximum prices to be set prior to marketing. For the majority of products that are reimbursable under the National Insurance Scheme, the maximum price is also the reimbursement price, and the maximum prices would remain the basis for reimbursement until generic medicinal products became available, where automatic price cuts would be introduced (the so-called stepped price model).

However, the introduction of several novel and expensive treatments has complicated this fairly clear approach on reimbursable prices. In 2016, an amendment in the Norwegian Medicinal Product Act opened for reimbursement contracts with pharmaceutical companies, which in essence allowed a pharmaceutical company to offer confidential discounts in order for a product to be reimbursable, whereas the maximum price would remain. Such reimbursement contracts exist for at least 5 medicinal products.

Introducing tenders as a "test run"
Despite the introduction of "reimbursement contracts", using tenders as an option to reduce expenses of the National Insurance Scheme has until recently never been a possibility. However, with recently introduced amendments in the legislation, that is about to change.

With effect from 13 June 2022, several amendments in the Norwegian Medicinal Product Regulation have paved the way for including tenders when considering whether a product shall be subject to reimbursement by the public. The background for the amendments is that the Ministry of Health and Care Services in 2019 requested that the Norwegian Medicines Agency evaluated increased competition using tenders. This evaluation resulted in a recommendation to use tenders for a select group of medicinal products considered as therapeutically equal.

During Autumn 2021, the Norwegian Medicines Agency in collaboration with the Purchasing Entity for the public hospitals began the work on a pilot to allow for a tender for PCSK9-inhibitors, which is a group of novel LDL-cholesterol lowering medicinal products serving as an alternative to e.g. statins. From a cost perspective, the annual cost for a patient using PCSK9-inhibitors is significantly higher. According to a news article, the annual costs for the National Insurance Scheme for PCSK9-inhibitors prior to any offered discounts was MNOK 92 in 2020.

In June 2022, a tender was issued for PCSK9-inhibitors. The tender requires any bidders to provide prices for two patient populations – a limited group which is already subject to reimbursement today, and an extended group which will allow for more patients to receive treatment with PCSK9-inhibitors. The idea is thus that the tender may open for extending treatment with PCSK9-inhibitors to a larger patient populace/population if the tender offers provide sufficient cost-effective prices.

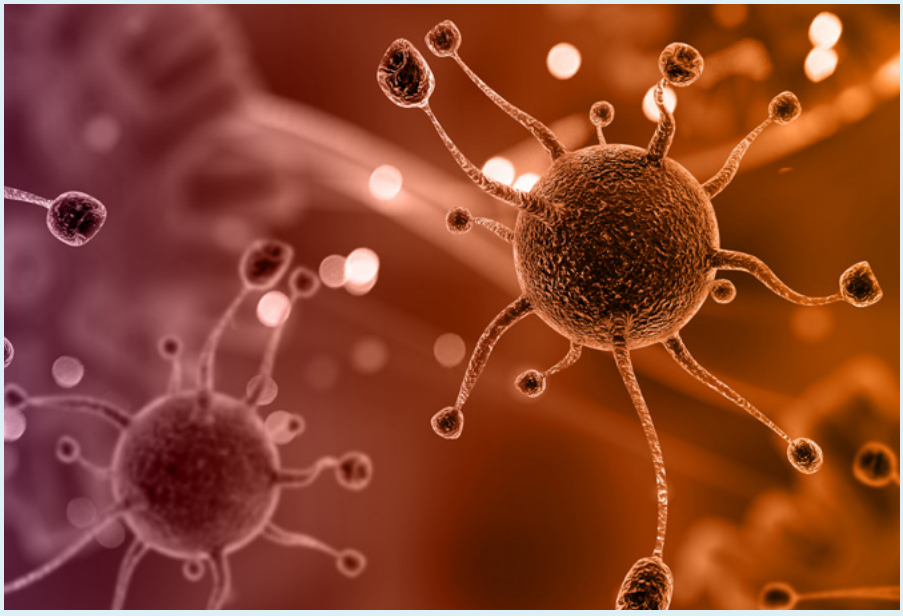
Pharmaceutical companies have until 14 September to submit tender offers. Contracts are expected to enter into force as of January 2023, with a possible 12 month extension.

Comments
The pilot and the introduced amendments have met mixed reviews. On the one hand, an expected decrease in costs resulting in a possible patient population receiving treatment with PCSK9-inhibitors is welcomed. On the other hand, there is concern that the sole focus on cost containment signals a lack of value and understanding for innovation, contrary to one of the stated political goals concerning medicinal products. Furthermore, there is a concern that patients' access and doctors' autonomy are limited by introducing tender regimes where price is the sole concern. Allowing for tender competitions between "equivalent medicines" of the same category but with different active ingredients has also been criticized.

Depending on the experience of the pilot for PCSK9-inhibitors, other medicinal products may also be subjected to tender as a requirement for reimbursement in the National Insurance Scheme. Expected attention and potential candidates for future tenders will be direct oral anticoagulants (DOACs), calcitonin gene-related peptide (CGRP) inhibitors (novel migraine treatment) and sodium-glucose cotransporter-2 (SGLT2) inhibitors (lowering blood glucose levels).

Sanctions against wrongful prescriptions stopped after protests from physicians

Administrative fines against physicians prescribing medicines not fulfilling reimbursement requirements entered into force in January 2022. Less than a month later, the new regime was reversed.



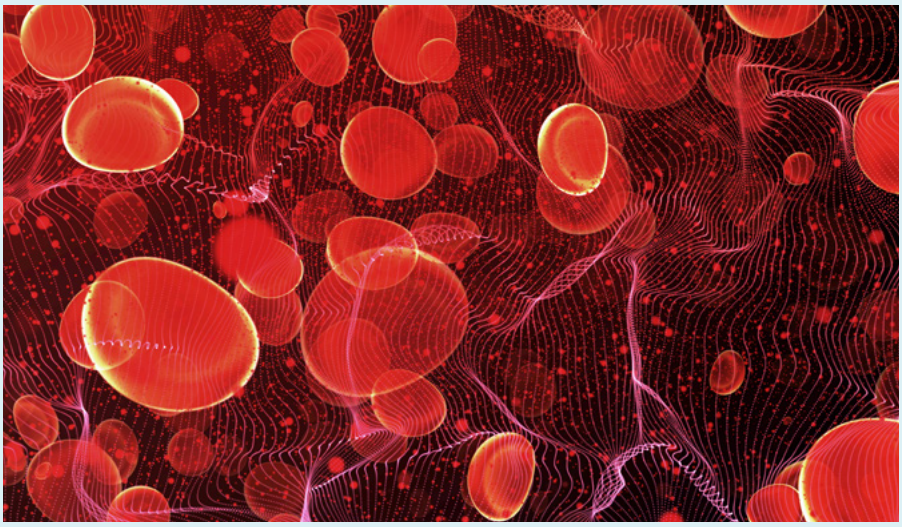
Background
A large part of the costs of medicinal products in Norway are reimbursed by the National Insurance Scheme, a system that is commonly referred to as «blue prescription». When prescribing medicines that are included in the "blue prescription" system, physicians are responsible for fulfilling the relevant requirements that follow from the relevant provisions in the Act on the National Insurance Scheme and its appurtenant regulations. Prescribing outside these requirements may result in increased financial expenses for the state, and to ensure adherence to the requirements and to ensure that the system is not misused is therefore a high priority for the health authorities.

Following a recommendation from the Office of the General Auditor of Norway to strengthen the possibility of sanctions against physicians who misused the "blue prescription" system in 2015, a proposal was presented in 2018 to include a provision in the National Insurance Scheme Act which would allow the Norwegian Health Directorate or an appointed delegate to issue administrative fines against physicians who intentionally or negligently prescribed medicinal products. This legislative proposal of introducing a new Section 25-6a to the Act was approved by the Norwegian Parliament in June 2019 but did not enter into force until 1 January 2022.

In September 2021, an amendment in the regulation on aid for expenses for important medicinal products (the blue prescription regulation) was approved. This amendment introduces a new Section 11a to the regulation, specifying that administrative fines against physicians could be up to 2 times the basic amount of the National Insurance Scheme, which amounts to NOK 222,954 (approximately EUR 22,000) as of May 2022. This amendment also entered into force on 1 January 2022.

The new Section 11a also referred to that a guideline would be made on when administrative fines should be issued, as well as how measuring out the fines should occur. The guideline stipulated, inter alia, that wrongful prescription where there is "a lower degree of guilt, where a lesser extent of errors have been discovered or the wrongful prescription in itself is considered as less serious", would be eligible for fines from approximately NOK 10,000 and up to NOK 50,000. The level of fines would increase with the degree of guilt.

Protests from physicians
While the interest organization of physicians in Norway (the Norwegian Medical Association) during the consultative hearings of both the amendment of the Act and the amendment of the regulation had voiced its criticism against such sanctions, this did not deter implementation of the new rules. The turning point nevertheless occurred when the Norwegian Medical Association and its members received a letter from HELFO (an external agency under the Norwegian Health Directorate) informing of the new rules.



The reactions of the Medical Association and physicians were stern. Several physicians raised their voices in the media against such “punishments”, referring to that this would cause a “fear culture” where physicians would not report their own errors, and in cases of professional doubt on whether the criteria for reimbursement were fulfilled, the doubt would be to the patients’ disadvantage and for the benefit of the National Insurance Scheme.

To put matters into perspective, physicians pointed out that it is not uncommon for a physician to prescribe at least 50-60 medicinal products during a day, and that mistakes thus are bound to happen. Administrative sanctions as proposed was thus both disproportionate, but also the wrong cure.

The Norwegian Medical Association also criticized the Minister of Health and Care in a letter of 14 January 2022, where they also demanded that the Minister had to initiate actions to remove this change in the rules. The Medical Association pointed out that it would consider recommending to physicians to minimize prescriptions of medicinal products via the "blue prescription" system, which ultimately would mean that patients would have to pay the total expense themselves and seek reimbursement with HELFO directly. If this had become a reality, it would have resulted in a workload that would have overloaded HELFO, not to mention that some patients would likely not be able to pay for medicines since they would have to pay the actual price and not the reimbursed price at pharmacies.

The reversal
The implications presented by the Norwegian Medical Association spurred a lot of media attention, and subsequently political criticism, with demands to reverse the legislative amendments. During this political upheaval, the Minister of Health and Care Services stated that a process to change the regulation and guidelines and proposed amendments would be subject to a consultative hearing.

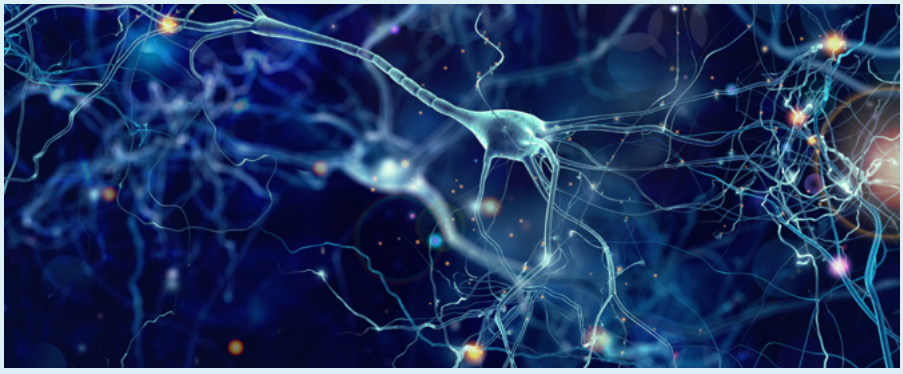
Several politicians found that this was inadequate and requested that the legal basis in the Act was also reversed. However, this would require parliamentary approval. As such, a proposal to instruct the Ministry to put forward a legal amendment to amend Section 25-6a in order to ensure that physicians could not be subject to violation fines for issuing wrongful prescriptions was made. However, the proposal was voted down by the Healthcare Committee of the Parliament in April this year. The main reason was in essence the signal from the Minister on the review and future consultative hearing of a revised regulation, and also pointing out that the legislative change in 2019 received full support from the Parliament.

Comments
Violation fines are usually included in legislation to act as a necessary deterrent to avoid breaches of legislation. The intent was similar in this case – the new rules were likely to act as a deterrent for any physicians who deliberately prescribe medicinal products in cases where the criteria for reimbursement are not fulfilled.

While the intention of these rules is understandable, the execution is not. The first problem is the maximum level of fines. While being an effective deterrent, the amount is exceedingly high given the situation of the physicians. The stated level of 2 times the basic amount stems from the fact that the consultative process of the amendment in the regulation was done with two other proposed amendments in other regulations which used the same level when sanctioning individuals. In hindsight, this was clearly not a good idea.

The second problem is the guidelines, which allowed for too much discrepancy for the supervisory authorities. As an illustration, the approved (but now suspended) guidelines state that erroneous prescribing where there exists a lower degree of guilt, where a lesser extent of errors is revealed or the erroneous prescription in itself is considered as less serious, could be sanctioned with anything from one tenth to half of the basic amount, meaning fines in the range of NOK 22,000 to 55,000. Combined with an expectation that physicians have knowledge of the prescription rules and thus could easily be considered to be negligent in cases of violations, it is not hard to see why the physicians reacted as they did.

It remains to be seen how the Ministry of Health and Care will construe the amendment in the regulation and in future guidelines. A fair bet is that either will reflect that violation fines shall not be issued as a first sanction, and certainly not in cases where the level of guilt is low and the violation is considered less serious. In any event, the future proposals will be subject to a much larger degree of scrutiny than before, and the political outcry has also made it clear how extremely unpopular such fines would be.



A tale of patent limitations, combination products and SPCs

The road for pharmaceutical companies in securing patent limitation to strengthen SPCs is filled with obstacles and insecurities.

Background
Merck Sharpe & Dohme (MSD) is the holder of patent NO321999. The patent concerns 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 hold two supplementary protection certificates (SPCs) with basis in the patent, one for the substance sitagliptin (which expires 23 September 2022 due to a pediatric extension) and one for the combination of sitagliptin and metformin (which expires 8 April 2023).

On 29 January 2020, 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 the SPC for the combination of sitagliptin and metformin would, based on aforementioned case law, not fulfil the requirements of the SPC-Regulation, in particular article 3a.

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. These essentially disclosed in the original application, or that constitutes an extension of the scope of patent protection."

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 previously had accepted amendment only of a dependent claim in an earlier case.

In 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 that 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 - KFIR

On 5 May 2022, KFIR rendered a new decision on the matter. Somewhat surprisingly, 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 39 b first paragraph.

Round 5 – Oslo District Court
On June 3 this year, 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 agree with MSD's claim that this decision was invalid. As such, Oslo District Court once again revoked KFIRs decision to refuse patent limitation.

Comments
KFIR will now have to review (once again) the request for patent limitation, and whether third time is a charm remains to be seen. Regardless of the final outcome, this case illustrates the many challenges concerning SPCs for combination products. As stated before, the motivation for MSD seems crystal clear. However, it is necessary to differentiate between the playing rules for the patent institute and the rules on validity for SPCs. Whether an SPC is valid based on a patent application that did not "cover" the combination product due to the interpretations of the decisions of the CJEU is a different question than whether a patent holder during the term of the patent (and not the SPC) is allowed to amend the patent. To base the allowability of patent limitations based on potential and hypothetical scenarios on the validity of already granted SPCs is questionable practice, especially when those SPCs have yet to be challenged by any third parties.

Violation fines for breach on rules of advertising of medicinal products

Effective from 1 January 2022, the Norwegian Medicines Agency can issue violation fines for breaches on the rules of pharmaceutical advertising.

Pharmaceutical advertising in Norway has for several years been a two-headed beast. On the one hand, pharmaceutical companies which are members of the Pharmaceutical Industry Association in Norway (LMI) have to comply with the LMI Industry Rules, or else risking fines from the self-regulatory Board established by the Norwegian Medical Association and LMI. On the other hand, pharmaceutical advertising can also be sanctioned by the Norwegian Medicines Agency (the NMA), which has the order to stop an advertisement which violates the rules of the Norwegian Medicinal Product Act and the Norwegian Medicinal Product Regulation but cannot issue fines for breaches.

However, effective from 1 January 2022, new rules entered into force, allowing for the NMA to issue violation fines for breaches. The new regime of sanctions has been expected some time. The proposal to introduce violation fines can be traced back to 2017, when the Ministry of Health and Care Services proposed changes in several acts to allow supervisory authorities to impose such fines for certain breaches of the Medicinal Product Act, the Pharmacy Act and the Medical Device Act. While the legislative amendments were introduced as early as 2018, they did not enter into force until January 2022.

While the new sanction regime (which is based in Section 28a of the Medicinal Product Act) concerns breaches of various rules, the topic which has received most concern is how the Norwegian Medicines Agency (the NMA) will practice such sanctions concerning pharmaceutical advertising. Chapter 13 of the Medicinal Product Regulation, which governs the rules on pharmaceutical advertising, was subject to several changes which entered into force in July 2020. Prior to January 2022, the NMA's sanctions was limited to order an advertisement in breach of chapter 13 to be stopped, as well as order that the decision of the NMA is published either fully or by a summary, as well as order that violator issues a correction to all recipients. In cases of risk of health, the NMA also has the opportunity to temporarily stop an advertisement if there is reason to believe that there is a breach. If a violator failed to comply with an order by the NMA, there also exists an opportunity to issue fines, either as a one-time fine or as daily fines, although this sanction has never been used by the NMA.

In contrast to the existing sanctions, violation fines are a retroactive sanction, not intended to correct and issue, but with a penal element in mind. The details of when the NMA would use such a sanction has thus been rather unclear. Section 28a allows sanctions towards both individuals and enterprises, although for pharmaceutical advertising, the primary target for such sanctions would be pharmaceutical companies.

Violation fines can be used both against actual individuals (physical persons) and enterprises. In order to use violation fines against enterprises, Section 28a stipulates that violation fines could be issued regardless of whether done intentionally or negligently by anyone working for the enterprise. As such, it would be sufficient that there existed a breach of the rules in chapter 13 in order for the NMA to issue violation fines. However, due to a Supreme Court decision rendered in April 2021 regarding fines for enterprises pursuant to the Norwegian Penal Code, the Supreme Court found that such fines without fulfilling the criterion of guilt would be contrary to the European Convention on Human Rights. This decision has also impacted violation fines, as the Ministry of

Justice has stated that this decision would also impact violation fines. As such, any violation fines on breach of pharmaceutical advertising requires that it be established that the breach was either done with intent or negligence.

In addition to the requirement of establishing intent or negligence, the NMA will also have to consider several factors when deciding if violation fines is an appropriate measure. Pursuant to Section 46 of the Public Administration Act, these are, inter alia:

- the preventive effect of the sanction
- the gravity of the breach, and whether any person acting on behalf of the enterprise is at fault
- whether the enterprise could have prevented the offence through guidelines, instructions, training, controls or other measures
- whether the breach was committed in order to promote the interests of the enterprise
- whether the enterprise has or could have obtained any advantage by the offence
- whether there is any repetition
- the economic capacity of the enterprise
- whether other sanctions have been imposed on the enterprise or any person acting on behalf of the enterprise as a consequence of the breach, including whether an administrative sanction or criminal penalty has been imposed on any natural person
- whether any treaty with a foreign state or international organization presumes the use of administrative corporate sanctions or corporate criminal penalties.

Some guidance can also be found in the NMA's own internal guidelines, which prescribe that violation fines shall be measured out after a specific assessment of the following factors:

- the risk for community, public and animal health
- potential financial gain
- first violation or repeated violation
- other circumstances

Furthermore, the guidelines will also take into consideration whether the self-regulatory Board has previously issued fines for a breach according to the LMI Industry Rules. In addition, the guidelines state that the maximum amount fined is set to 10% of the annual turnover of the company for the previous year. However, the Medicinal Product Regulation sets a "fee cap" on 15 times the Norwegian Social Insurance Scheme's basic amount, i.e. any fine cannot exceed NOK 1,672,155 (per May 2022), regardless of turnover by the company.

Comments

While the criteria of the new rules allow for a wide discretion for the NMA, it seems clear that violation fines for breach of pharmaceutical advertising will primarily be used in cases of more serious breaches, as well as repeated offences. The latter is particularly interesting, as the NMA prior to the overhaul in 2020 had the opportunity to ban all advertising for a particularly medicinal product for a shorter or longer time, and even permanently, in cases of repeated breaches. While this option was initially proposed to be continued in the revised chapter 13 of the Medicinal Product Regulation, the provision was ultimately discontinued. To use violation fines against repeated breaches also makes sense with regard to establishing the necessary guilt – if a violator has previously committed the same breach, intent or

negligence will in most circumstances be considered established. With regard to the size of the fines, both the maximum cap of 15 times the basic amount and the 10% of turnover, opens for fines that exceed by multiple times what has been the self-regulatory Board's practice, which according to the bylaws allow for maximum fines of NOK 300,000. However, actual issued fines are often lower, ranging from 30,000 to 150,000.

Beyond the obvious and significant preventive effect these new rules will have on the industry, the further impact is unclear. In the short term, any violation fines issued by the NMA will attract far more publicity than what has previously been done in past, which also means that pharmaceutical companies may be more likely to challenge any such decisions. This will particularly be the case within topics that are not always clear.

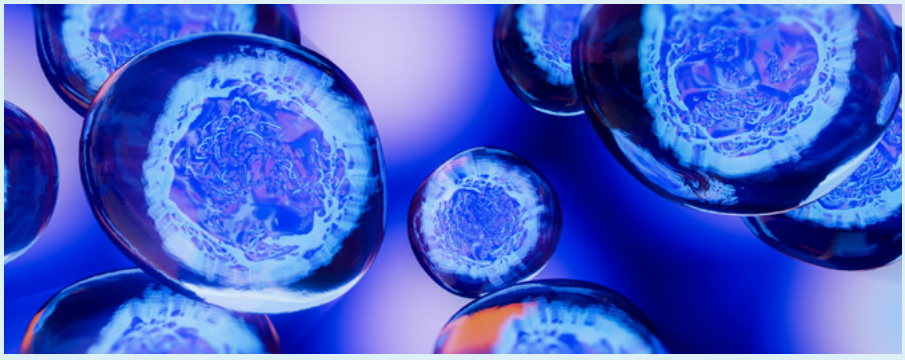
An interesting question is also how the practice of the NMA will affect the Board's practice, and vice-versa. In principle, a pharmaceutical company may now be sanctioned twice with fines from both the Board and the NMA. However, it could also be argued that the Board's self-regulatory regime has delayed the need for a violation fine regime by the public authorities for a long time. One could therefore argue that there will be a shift from a regime with fines issued by the Board to a regime with fines issued by the NMA. But this is unlikely to be the case, at least in the short term. Instead, it may be that the NMA want to focus their attention on areas which are not typically covered by the Board. In addition, the NMA may also want to "test the waters" if they believe that the level of fines issued by the Board is too low.

The main target of the new regime is of course the pharmaceutical industry. The consultative letter of 2017 states that the estimate for 2006 (sic) for the industry annual spending on advertising and other marketing activities were MNOK 500, although the letter also admits that this estimate is uncertain, but indicative of the scope and economic potential in violating the rules. However, while the focus area will be pharmaceutical companies, the rules are not limited to the industry. In recent years, the NMA has targeted both pharmacies and clinics that have used various marketing activities for medicinal products, and in the future these may also be subjected to violation fines.

New regulation on prescribing and dispensing of medicinal products

A new regulation on prescribing and dispensing of medicinal products was approved 2 June 2022. The regulation will enter into force on 1 January 2023. But are there any material differences, and is the update a bit premature?

In essence, the regulation provides details on which rules apply when physicians, dentists and other healthcare personnel prescribe medicinal products, as well as the rules applying when pharmacies dispense them. As such, the regulation is one of



the most important pieces of legislations in Norway regarding medicinal products, as its content is practiced by physicians, pharmacists and others several thousand times every day. The detailed rules in the regulation are therefore well known to practitioners in the field.

The old regulation on prescribing and dispensing was from 1998 and even outdates the Norwegian Pharmacy Act. It has been subject to numerous amendments during the last 24 years. The consultative letter states that the new regulation to a larger degree will be adjusted to a digitalized workday, contribute to the rules being more transparent and thus make it easier for requisitioners and healthcare personnel in pharmacies to inform themselves.

A first assumption would therefore be that the new regulation would be more extensive than the old. However, this is not the case. The new regulation actually has fewer words and fewer provisions than the old regulation, although it has three additional chapters, which is largely an attempt of restructuring the provisions in a manner that is more accessible and maneuverable.

As expected, there are few material changes in the regulation. The majority of amendments in the new regulation compared to the old are rewording and removal of redundant or outdated wording. Furthermore, an update of certain words has also been done. Circumstances that were previously considered as practice have been included in the wording of the provisions.

Change in practice has also ensured that certain options that previously were regulated have been removed. For instance, the old regulation explicitly stated that prescriptions could be transferred by telefax, provided that the prescriber had sufficient routines in place for safe transfer. However, despite its previous widespread use, the Directorate of Health have concluded that use of telefax is not a sufficiently safe medium for transfer of patent information. As such, the new regulation does not include any specific rules on the use of telefax.

A material change introduced with the new regulation is the provision concerning the control by the pharmacist. The old regulation simply states that a pharmacist must control any prescription and any requisition. The new regulation is more extensive, and actually describes the steps which must be made, including that a pharmacist shall approve prescription and

requisition for expedition, provide a professional assessment of the prescription/requisition and approve the pharmacy's documentation for the expedition. The pharmacy staff shall evaluate whether there is any need for special guidance and make sure such guidance is given.

An interesting aspect concerning pharmacist control is the opening for use of IT systems to replace this feature. A pharmacist control of requisitions (i.e. orders for medicinal products to be stored at an institution etc.) has a different purpose than for prescriptions, where the purpose might be e.g. to discover suspiciously large withdrawals of medicinal products attractive on the illegal market or withdrawals of medicinal products that are obviously not used at the institution. The new regulation states that the pharmacist's control of requisitions can be ensured by validated electronic systems if this is deemed as responsible, and that such assessment must be documented. This opens for extensive use of IT systems that use automatic filtering based on pre-approved parameters. The use of such IT-systems should be of particular interest to pharmacies which must handle large quantities of requisitions (e.g. hospital pharmacies).

The Norwegian Health Directorate has also recently issued a consultation procedure on the proposal of guidelines for the new regulation, with a submission deadline on 14 August 2022.

Comments
An overhaul of the rules for prescribing and dispensing medicinal products has been expected for some time. The Ministry of Health and Care Services issued its proposal already in October 2020. From that perspective, the entry into force of the regulation in January 2023 is long overdue. Nevertheless, the timing seems somewhat strange since a committee was appointed in September 2021 to evaluate how pharmacies in the future should be arranged. One of the tasks of the committee was to evaluate the rules related to pharmacies. While there are other aspects of legislation involving pharmacies, including the Pharmacy Act and the Pharmacy Regulation, the Regulation on prescribing and dispensing medicinal products is a key part of the rules affecting pharmacies. Since the committee's report shall be published within the end of 2022, it seems somewhat peculiar that the entry into force of these rules could not wait until the report has been evaluated.

Notwithstanding the timing, the updated regulation and the proposed guidelines should be greatly appreciated by prescribers, institutions and pharmacies.

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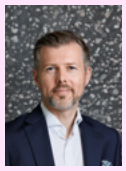

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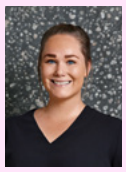

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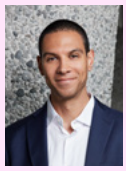

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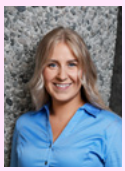

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