Pharma Report

Retrospective view of legal developments in Norway

Winter Edition 2024

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 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 occurring in 2023, which indeed was an eventful period for the pharmaceutical industry.

In this edition, you can read about the proposed amendments to pharmacy legislation and how these would impact pharmacies in the future. You can also read about recent developments in pharmaceutical advertising, including a rather hefty violation fine issued by regulatory authorities for a blockbuster medicinal product. And if intellectual property is your thing, you can read about both the developments in trademark law as well as recent patent case law.

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

About the authors

Håkon Austdal
Specialist Counsel

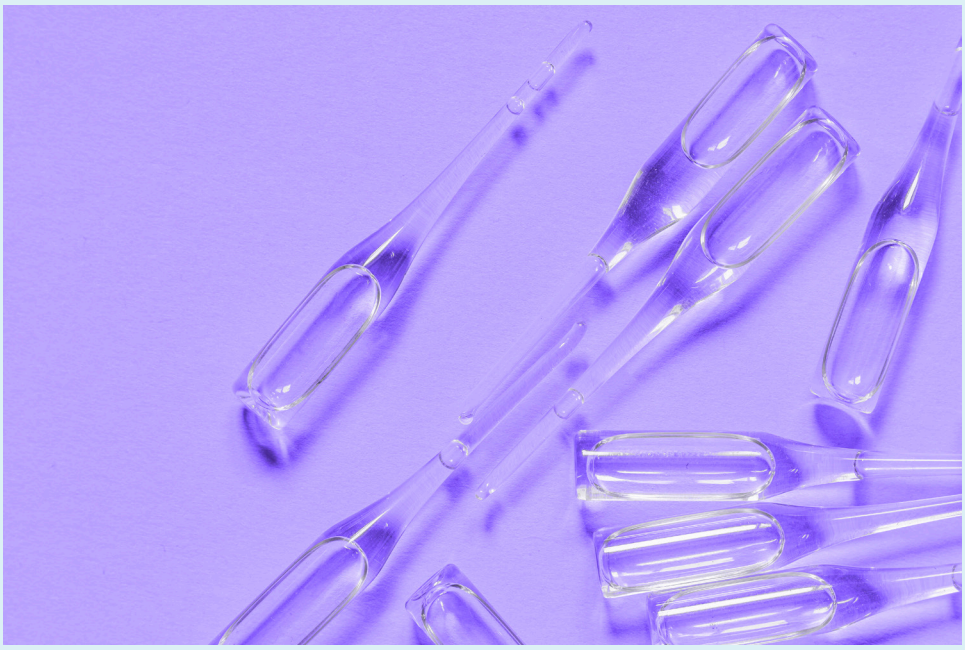
Håkon is the primary author and editor of Haavind's Pharma Report. He specializes in regulatory affairs and intellectual property rights (IP), particularly focusing on the healthcare and life sciences sector. He assists pharmaceutical and biotechnology companies with a variety of services, including 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. 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 Medicines Agency. Håkon is recognized as a Rising Star by Legal500 in the category Intellectual Property and is ranked as a Rising Star by IP STARS.

Vebjørn Krag Iversen
Partner and Head of IP

Vebjørn is a contributing author of Haavind's Pharma Report. He is the Head of Haavind's IP Practice Area and has substantial expertise with advising the pharmaceutical and life sciences sectors with all aspects of IP. His practice includes patent litigation, trademarks and copyright issues, trade secrets, product imitation and strategic IP advice, IP licensing, commercialization and R&D agreements. Vebjørn is recognized as a Next Generation Partner by Legal500 as well as being ranked in Chambers and Partners, both recognitions in the category Intellectual Property. He is also ranked as a Trademark Star in IP STARS as well as being a recommended individual in IAM Patent.

From agency to directorate – more than a name change.

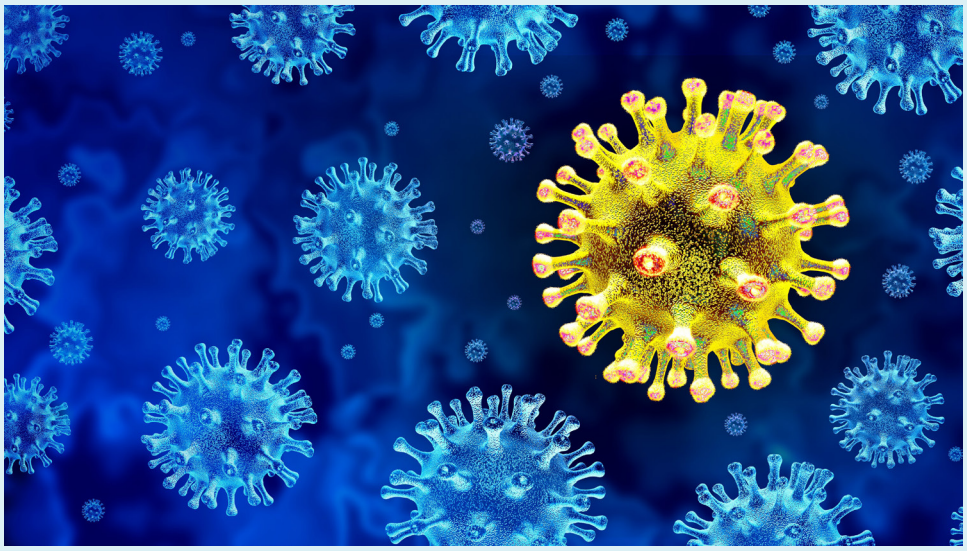
Effective 1 January 2024, the Norwegian Medicines Agency changed its name to the Norwegian Medical Product Agency. However, the amendments are not solely cosmetic.



On 11 May 2023, the Norwegian Government published Norway's Revised National Budget for 2023 (the Report) to the Norwegian Parliament. The Report addresses several topics concerning national health and concerns a reorganization of tasks involving five separate directorates. From a pharma law perspective, the rather eye-catching proposal was a name change for the Norwegian Medicines Agency and extended new assignments.

The Norwegian Medicines Agency (NO: Statens Legemiddelverk) has held its current name since 2001, when it took over assignments from several other directorates. Effective in 2024, the new name will be the Norwegian Medical Products Agency (NO: Direktoratet for medisinske produkter). The short forms will be DMP (Norwegian) and NOMA (English). While the name change came as a surprise, it does make sense based on the agency's responsibilities. Since 2018, the Agency has been in charge of not only medicinal products but also medical devices.

The name change also comes with several new assignments for the newly named agency. Previously, the field of health technology assessments for medicinal products and medical devices was divided between the Norwegian Medicines Agency and the Norwegian Institute of Public Health (NO: Folkehelseinstituttet).



However, the new Directorate is responsible for health technology assessments (HTA) for medical products in its entirety, and the existing working group of the Norwegian Institute of Public Health has been moved to the agency.

The reassignment of HTAs is not the only new task to be assigned. The new Directorate has received two additional responsibilities from other directorates - the responsibility of procurement of vaccines, which previously was held by the Institute, and the responsibility for “blood, cells and tissues”, which was moved from the Norwegian Directorate of Health. The latter means that approvals for facilities handling such biological materials will now have to be applied for at the new Directorate.

According to a press release from the Ministry of Health and Care Services on 11 May 2023, the purpose of the re-shuffling of assignments is to ensure effective use of resources, clarified roles between the different directorates and a more expedient and coordinated management of the various directorates. The changes stem from recommendations in a report ordered by the Norwegian Government last autumn, which was finished in February 2023.

Comments
Prior to the publication of the National Revised Budget, a group of interest organizations for professionals issued a letter to the Norwegian Parliament, which criticized the re-organization. The criticism revolves around the Report being entirely driven by the Ministry itself, without any representatives from the involved directorates, and that the Report was not subject to a consultative hearing. The main argument is thus that it would be unclear if the matter of reorganization had been sufficiently examined from a professional view prior to being presented to the Parliament. The letter culminated in the group requesting that the Parliament did not process the matter and instead instructed the Government to wait until two later expected reports on the public health area were available.

From the perspective of the Norwegian Medicines Agency, the

reorganization by the Ministry does not appear to have caused any major turmoil. The Agency will still be intact as an organization. Still it will receive additional tasks and employees from the other directorates, as was the case in 2018 when the Agency took over the responsibility of medical devices. Nevertheless, there is still a concern that an increase in the field of responsibilities could potentially cause some “clogging” of cases in the short term. Hopefully, increased synergies in the area of HTAs can result in a more efficient and expedient management of HTAs – an area where the Agency has previously been criticized for not being able to process within the stated deadline of 180 days.

One of the areas that could potentially be problematic is the combination of being a supervisory agency while simultaneously being responsible for the procurement of vaccines. There are potential conflicts of interest with those two roles, which must be managed carefully by the new Agency to avoid unfortunate situations.

It remains to be seen if the increased centralization will have the desired effect, but in any event, the long-established name, the “Norwegian Medicines Agency”, is now history.

From a practical perspective, the name change does necessitate some administrative follow-ups for pharmaceutical companies. Educational materials, etc., must be updated with the new name, the new logo and the new weblinks. Furthermore, the Summary of Product Characteristics, which refers to the Norwegian Medicines Agency (e.g. links for reporting side effects) must be updated with new links and the new name, initiating the need for a variation. The Directorate has requested that this be done by 1 January 2025. Finally, the e-mail addresses will be altered from @legemiddelverket.no to @dmp.no, but e-mail addresses using @noma.no will still work. The Directorate has also requested that websites, letters and invoices refer to the new name and logo effective from 1 January 2024.

Regulatory

The future of pharmacies in Norway.

An extensive review of the rules for pharmacies, as well as proposals on amendments to the existing rules, was published in January last year. But will the proposed amendments completely transform the pharmacy market in Norway in the coming years, or is this only a tempest in a teapot?

On 31 January 2023, the so-called Pharmacy Committee (the Committee) appointed by the Norwegian Government published its long-awaited Official Norwegian Report (the Report) on proposed amendments in legislation regulating pharmacies, foreshadowing what could be some significant changes for the future.

The Report is a rather extensive document, consisting of more than 250 pages, outlining the current rules, the Committee's assessments and its proposals for changes in legislation. In this article, we will highlight some of the most notable proposals.

Removing the requirement for physical premises for patients/ customers

Internet trade with medicinal products has been available for some time in Norway, opening for so-called "online pharmacies". However, due to the definition of a pharmacy in the Norwegian Pharmacy Act, a pharmacy must have a physical premises available for patients/customers. As such, there are pharmacies in Norway which fulfill this requirement, but where the premises has never been visited.

The Committee proposes that the requirement in the Pharmacy Act that the physical premises of a pharmacy must be available for patients/customers is removed. The requirement is highlighted as a barrier to entry and a hinderance to the development of innovation for pharmacies.

At the same time, it is important to stress that pursuant to the proposal, a pharmacy will still be a physical sales premises which offers guidance to end users on medicinal products. As such, it is not possible to e.g. grant a pharmacy license to a virtual online store.

Removing the requirement of physical premises being in close proximity to the main pharmacy.

Under current rules, a pharmacy license is granted for a specific municipality. As such, the main premises of the pharmacy will be in this municipality. This requirement has some implications, mainly that it has been interpreted that the main activities of the

pharmacy must occur on the main premises of the pharmacy, and also that any additional premises (e.g. for manufacturing) must be in geographical proximity to the main premises.

The majority of the Committee suggests that this requirement be altered by allowing the authorities to approve additional premises not in geographic proximity to the main premises, as long as these are in Norway. This could open for significantly more flexibility in the development of new pharmacy solutions and the use of new technologies. In particular, it could open for the expedition of medicines by the pharmacy employees to occur remotely. At the same time, the Committee stresses that the requirement of professional responsibility will still apply, and that the pharmacy manager still will have to ensure that the pharmacy follows all other requirements in the legislation.

Mandatory education for a pharmacy manager
The Committee also proposes an additional requirement in relation to the application for a license to operate as a pharmacy manager, cf. section 3-2 of the Pharmacy Act. In short, the applicant would have to document that he/she has completed a mandatory education in the rules of pharmacies prior to the license being granted. The aim is to provide the applicant with an introduction to the rules and the responsibilities of the pharmacy manager. This is important since the pharmacy manager indeed is responsible for the pharmacy fulfilling all professional requirements stipulated in laws and regulations. Such a requirement may, according to the Committee, also contribute to increased notifications to the authorities where there are disagreements between the owner of the pharmacy and the pharmacy manager on whether an action is in violation of the professional requirements.

Validations of technical solutions
The Committee also points out that the current Act does not contain a legislative basis for determining requirements for validation and verification of technical solutions in pharmacies. The Committee is of the opinion that this should be a requirement, proposing a new legislative basis provided for in the Pharmacy Act. It is briefly stated that this would result in

increased costs for the participants, but that this is necessary to ensure safety and professional conduct when introducing and using available technology. The use of technology also requires that healthcare professionals have the competence and have received the necessary training in the use of the solution.

While anyone can agree in general that solutions should be validated and verified prior to implementation, the proposed revisions raise several questions that are not answered. Unfortunately, it is unclear what the Committee actually foresees as an issue. The report provides no details on the matter, nor elucidates on whether this is a common issue in pharmacies today, nor how this requirement would relate to other requirements related to e-solutions or otherwise.

Furthermore, the proposed provision leaves room for improvement. If the purpose is to allow the authorities a larger role in the process of validation and verification, the more sensible part is to ensure that the provision is drafted as an “anchor provision”, allowing authorities to specify further requirements in a regulation.

Specialty pharmacies – but to what extent?
An interesting and rather controversial topic from the majority of the Committee is a proposal to open for differentiation of the duty for pharmacies to supply various goods. Currently, the Pharmacy Act stipulates that pharmacies must supply all medicinal products and ordinary medical devices used by consumers. The Act allows the authorities to specify this requirement further in regulations, and also either extend or limit the duties by regulations.

The majority of the Committee proposes that the extension or limitation should also be applicable for individual pharmacies, which in practice would open for exceptions for an individual pharmacy in the duty to supply. The rationale of the majority of the Committee is that this would facilitate for "specialty pharmacies", for instance, pharmacies solely selling veterinary medicinal products. However, the majority itself could not agree on how far this principle should extend. Some of the members of the Committee even suggested to allow pharmacies which only supply goods for certain treatment areas, such as, for instance, diabetes.

The minority did not support the proposal since the duty to supply is a critical measure to ensure patient access to medicines regardless of which area they live. In the view of the minority, a differentiation in the duty would potentially weaken the reliability of the supply of medicines and may also contribute to watering down the concept of pharmacies in general. The minority also points out that under today's rules, a pharmacy may specialize in certain areas even if the duty to supply all medicines exist.

Duty to report on "quality indicators"
Pharmacies today already have several reporting requirements, mainly concerning economic aspects of the business. However, pursuant to section 5-5 of the Act, pharmacies may still be required to report on other aspects. However, the Committee found that the authorities had limited possibility to determine the quality of the pharmacy's performance of legal tasks. As such, the Committee proposes an addendum to section 5-5,

clarifying that this could also include quality indicators.

The proposal is a bit vague with regard to details on what such quality indicators are. However, the likely reason for adding quality indicators is to open for reporting on the number of personnel of the pharmacy during its opening hours, as well as report on absence of sickness. In addition, further quality indicators could be on registered discrepancies, number of expeditions and type of services offered.

Outsourcing of tasks

Another controversial topic that the Committee was divided on was whether a pharmacy should be allowed to outsource some of its tasks that are prescribed by law. Today, this is only possible for manufacturing. However, this requirement causes certain restraints on the technological development of pharmacies. As such, the majority of the Committee proposed a new provision that would allow for outsourcing of certain tasks.

The majority was split between those who wanted to open for outsourcing all tasks, provided that the requirements of responsibility were adhered to in such tasks, and those who believed that core tasks such as control by a pharmacist, expedition of prescriptions and guidance on proper medicinal use should not be outsourced, while other tasks could. To achieve a majority on proposing for outsourcing, the latter restrictions applied, proposing a new provision which allows for outsourcing of the pharmacy's task with the exception of the three abovementioned tasks. This would open for more flexibility and increased innovation, opening for new technical solutions. Potentially, this means that certain storage tasks and dispatchments of shipments could be outsourced to wholesalers, which would simplify the requirements for onli3ne pharmacies significantly.

The minority of the Committee did not support an outsourcing of any tasks, stating that this would lead to increased risks in the management of pharmacies which could be severely detrimental to the patients and users. The minority believed that the need for a clear centralized control and responsibility for the entire

process on selling and delivering medicines is necessary.

Exceptions from the wholesaler's duty to supply
Today, a wholesaler who delivers to pharmacies, has a duty to supply to all pharmacies. The majority of the Committee proposes that this requirement should still be the main rule, but that it should be possible to make exceptions for wholesalers established to supply either directly to a customer, to its own pharmacy or to a group of independent pharmacies. To allow for such an exception would increase competition and remove barriers from entry. The minority of the Committee opposes to such an exception, believing that safeguarding this requirement is essential to ensure the supply of medicinal products to all pharmacies in Norway.

Other proposals
The Committee also presents several other minor proposals, which inter alia includes:

- Limitations/exceptions on which medicinal products that shall be dispatched to customers should be based on a specific risk assessment.
- Increased access to advertising for discounts for non-prescription medicinal products.
- Reintroduction of an arrangement of reimbursement of transportation costs to remote customers.
- Mandatory continuous education for pharmacists working in pharmacies.

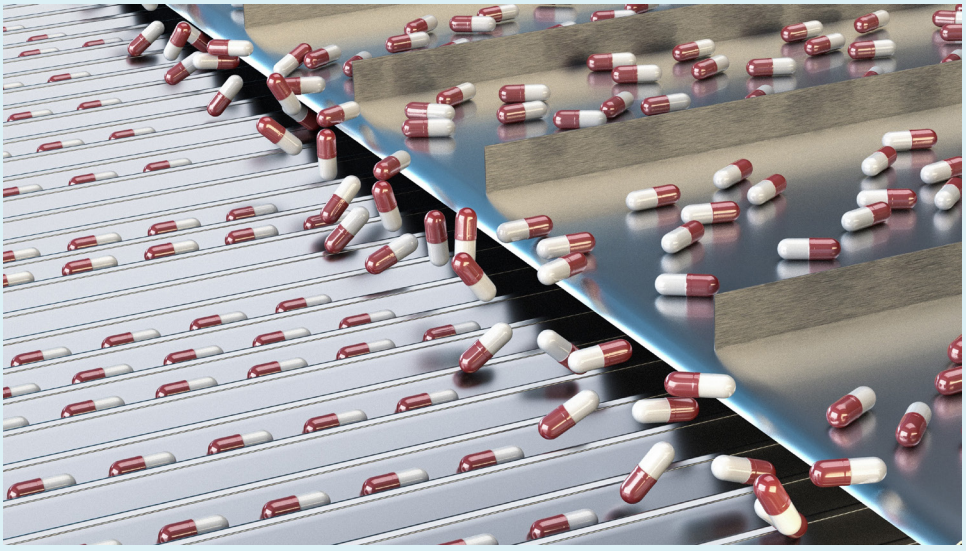
Comments
The Report was sent on a consultation procedure in May 2023, allowing for comments on the Report itself. As expected in a sector which involves many different players with (at least partially) conflicting interests, the reactions to the Committee's report have been mixed.

One of the topics that has raised criticism is that while the Report acknowledges that pharmacies could play a larger role as part of the "front line" in primary care, it lacks specific proposals on how pharmacies could optimize resources in other parts of the

healthcare and thus provide better healthcare for the general public, by supplementing or optimizing existing primary care services. While dispensing of medicinal products will always be the key area for pharmacies, the key debate for the sector is going to be whether pharmacies in an ever-increasing digital world will have to shift from a product-focused view to a more patient-centric and service-focused view. While the Committee can be criticized for the lost opportunity to address this debate, the problem is also with the mandate provided to the Committee, which did not sufficiently address this topic.

Among the criticisms raised by several comments in the consultative procedure is the lack of addressing the vertical integration model between the pharmacies and the wholesalers (in essence, that a wholesaler owns its own retail chain), and whether this model should be prohibited. Again, this was not a part of the mandate of the Committee, but the fact that this topic still raises questions more than 20 years after the Pharmacy Act allowed for that model is interesting. Is it a general concern for dominating players restricting competition or just nostalgia from the “good old days”?

In summary, the proposed amendments in the Report will not likely be a game changer that completely transform the pharmacy market in Norway in the foreseeable future. That being said, the proposed amendments facilitate for a potential increase of online players in the pharmacy market, which may result in several newcomers. As such, the pharmacy market takes one step closer to the situation in the retail market, where “brick and mortar” shops are forced to innovate to keep up with the stiff competition from online stores benefitting from lower costs. Whether the tactics used in the retail market are suitable for this particular market, remains to be seen.



Amendments in trademark law – implications for pharmaceutical trademarks?

On 1 March 2023, several amendments in the Norwegian Trademark Act entered into force. The amendments are a result of the implementation of Directive 2015/2436/EC (the Directive), and thus aim to harmonize Norwegian trademark law with the requirements of the Directive.

Reader's well versed in trademark law will recall that the deadline for Member States implementing the Directive was 14 January 2019. Norway is, however, not a part of the European Union, but a member of the European Economic Area (EEA). While the amendments facilitated by the Directive were approved by the Norwegian Parliament in 2020, the late implementation in Norway was due to the decision by the EEA Committee to implement the Directive in the EEA Agreement being delayed.

In this article, we will take a look at some of the most important amendments:

Repairing lack of distinctiveness with use
Previously, it was possible to request a trademark registration invalid if the trademark did not fulfill the requirement of distinctiveness at the date of the application and the date of registration. Under the new regime, a request for invalidity will not succeed if the trademark has established distinctiveness by use of the trademark prior to the claim of invalidity. In other words, a lack of distinctiveness can be repaired. However, in the assessment on whether distinctiveness has been established by use, any use that occurred after the claim of invalidity was filed shall not be taken into consideration.

Bad faith
Previously, it was possible to object to an application for a trademark which could be confused with (inter alia) a trademark which another party had used and still used prior to the applicant, and the applicant knew of this use before the application was submitted. Such an action constituted a violation of good business practice.

Under the new regime, an application for a trademark registration made in bad faith is now an absolute ground for refusal. An action as described above will still be objectionable, but the new concept of "bad faith" extends beyond such actions. For instance, repeated trademark applications motivated by postponing the deadline for non-use could potentially be considered as bad faith.

None use in opposition proceedings
The new regime simplifies the process of non-use as a defense against opposition proceedings. Previously, if a trademark holder opposed a registration based on priority from an earlier trademark, and a five-year period has passed between the registration of the older mark and the filing of the new application, the new applicant would have to proceed with a separate case if he wanted to claim that the former holder's trademark was invalid due to non-use. The newly implemented amendment now states that in the case of such as opposition, the new applicant may request that the holder of the earlier trademark produces proof of genuine use of the earlier trademark. In the absence of such evidence, the new application shall not be cancelled due to infringement of the right of the earlier trademark. As such, a separate case for non-use is no longer necessary in such instances.

Security in trademark
Amendments in both the Trademark Act and the Norwegian Mortgage Act now make it possible for trademarks and trademark applications to be given as security independent of the undertaking. This has previously not been the case for trademarks but has been available for patents. Since trademarks can be very valuable, this possibility is welcomed. However, the challenges in determining the value of each individual trademark still remain.

It should be emphasized that legal protection for such rights against conflicting rights can be established by recording the security in the Trademark Register, and that recorded rights prevail over rights for which recording has not been received on the same date or earlier. Recorded rights on the same date have equal rights.

Protective scope applies for the colors registered
Under the old regime, trademarks which was registered in black and white would automatically receive protection for other color combinations. With the implementation of the amendments, this practice is no longer continued. This means that all applications submitted after 1 March 2023 will be subject to the new practice, meaning that their protective scope will be more limited. Trademark applicants, thus, need to be conscious with regard to the specific colors they apply for.

Key takeaways for pharmaceutical companies
One of the most important aspects of pharmaceutical trademarks is the interplay between the trademark approval and the approval of the name of the product (invented name), where the first is assessed by trademark offices and the latter by medicines agencies. Pharmaceutical trademarks are thus subject to a "double control" by two different sets of criteria, and any amendments in either would have to be assessed in light of this fact. Fortunately, the amendments implemented in the Trademark Act as of 1 March 2023 are unlikely to upset this balance.

The most important takeaway for pharmaceutical companies is the fact that there is an amendment in practice on combination and figure marks concerning colors. While the word mark of invented names remains the most important aspect of trademark protection, figure marks place an increasingly important role also for the pharmaceutical industry, in particular, in the OTC-segment, where companies may use combination and figure marks to protect, e.g. packaging.

Pharmaceutical companies should also be conscious regarding the fact that bad faith is now an absolute ground for refusal.

It is a well-known fact that the pharmaceutical industry, due to the long regulatory process, often files repeated applications for the same trademark to avoid revocation due to non-use, a practice that potentially can be classified as “bad faith” according to OHIM guidelines.

Pharmaceutical company fined NOK 1,5 million for misleading advertisements.

A new decision provides rare insights into the practice of violation fines for breaches of pharmaceutical advertising.

Background
The Danish-based pharmaceutical company Novo Nordisk has grown exponentially in the last years, and much of the financial growth is based on its three blockbuster drugs Saxenda (liraglutide), Wegovy (semaglutide) and Ozempic (semaglutide), which are all so-called GLP-1 analogs. Saxenda and Wegovy are approved as adjuncts to a reduced calorie diet and increased physical activity for weight management in adult patients with either obesity (BMI ≥ 30) or overweight (BMI ≥ 27) in the presence of at least one weight-related comorbidity (e.g. diabetes type 2 or hypertension), whereas Ozempic is approved for the treatment of insufficiently controlled diabetes type 2 as an adjunct to diet and exercise in certain conditions.

In a letter sent 15 May 2023, The Norwegian Medicines Agency (NOMA) issued a warning letter to Novo Nordisk Norwegian affiliate (Novo Nordisk Norway) concerning a breach of the rules of pharmaceutical advertising for various ads for the three products, forecasting both an order to stop the wrongful advertisements and issue corrections on the matters, daily fines of NOK 5000 if the advertisements are not stopped, as well as a violation fine of NOK 1,5 million. The alleged breaches were, in summary, that the advertisements either violated the requirements of the Norwegian Regulation on Medicinal Products section 13-3 third paragraph a and b (cf. Article 87(3) of Directive 2001/83/EC) that advertisements should encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its property, and not be misleading. Some of the advertisements was also found to be in violation of the requirement stipulated in the Regulation section 13-8 (cf. Article 92(2) of Directive 2001/83/EC), which states that documentation relating to a medicinal product which is transmitted as part of the promotion has to be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

Novo Nordisk replied to the warning letter on 31 May 2023. With one exception, Novo Nordisk rejected the allegations of NOMA. As

part of the argumentation, Novo Nordisk also rejected that there were grounds for a violation fine.

On 11 October 2023, NOMA issued its decision, issuing an order in line with the previous warning letter, ordering Novo Nordisk to stop the wrongful advertisements, issue corrections on the matters, imposing daily fines of NOK if the advertisements are not stopped within a given deadline, as well as a violation fine of NOK 1,5 million for the alleged breaches. The decision, which is 26 pages long, provides several insights which are of interest to pharmaceutical advertisement practitioners.

Marketing of indications
NOMA reacted to three advertisements with regard to the marketing of indications.

The first was a “roll up” poster used for Saxenda. This stated: “Saxenda GLP-1 analog – for the treatment of overweight and obesity”. NOMA argued that the poster was suited to give the impression that Saxenda alone could be used for the treatment of overweight and obesity, which is not in line with the approved indications in the summary of products of characteristics of Saxenda. As stated above, Saxenda is approved as an adjunct to a reduced calorie diet and increased physical activity for weight

management in adult patients with either obesity (BMI ≥ 30) or overweight (BMI ≥ 27) in the presence of at least one weight-related comorbidity (e.g. diabetes type 2 or hypertension).

Consequently, this advertisement was deemed to be misleading. Novo Nordisk had agreed in its reply that the statement could be perceived as misleading, and also that the poster had previously been withdrawn from any further use earlier this year.

The second advertisement for this topic, which also concerned Saxenda, was presented in a professional journal for physicians, concerned a nearly identical statement. NOMA reacted on that the statement "Saxenda (liraglutide) – GLP-1-analog for the treatment of overweight and obesity" was presented in bold font, serving as an eye-catcher in the advertisement. This was also deemed as misleading by NOMA, which also pointed out that Saxenda is approved as a supplement to diet restrictions and exercise. Novo Nordisk had argued that this fact was mentioned in three other places in the advertisement, and that NOMA had not assessed the advertisement as a whole. However, NOMA stated that when a medicinal product is emphasized in a headline in the advertisement, the indications must be clear from the same sentence/headline, and it is not sufficient that such information is presented in smaller font and several other places in the advertisement. In other words, the fact that Saxenda is a supplement treatment to exercise and diet restrictions was not presented sufficiently in the statement in questions.

The third advertisement for this topic concerned and advertisement for Wegovy, presented in a professional journal for pharmacists. In the advertisement, the statement "Wegowy (semaglutide) – for weight control – novelty" was used as a headline and eye-catcher. Similarly as the previous advertisement for Saxenda, NOMA reacted that the word "weight control" was accentuated when the indication for Wegovy (as described above) is approved as a supplement to exercise and diet restrictions. NOMA also pointed out that the approved indication for overweight is for particular patient populations (namely having at least one weight-related comorbidity, e.g. diabetes), and not overweight alone.

Presenting data from studies in the advertisements
NOMA also reacted towards two advertisements with regard to the presentation of data from studies. Both advertisements were presented in professional journals for healthcare professionals.

In the first advertisement, which was for Saxenda, NOMA reacted to a factual claim in the advertisement, namely that "1 out of 3 patients lose >10% of the body weight". NOMA pointed out that neither the summary of product characteristics nor the study referred to demonstrate this result. According to NOMA, the study in question stated that ¼ of the patients with obesity and a comorbidity factor reduced > 10% of their body weight in an expanded route of treatment, and that after separation of the treatment the patients gained weight. The studies in the summary of product characteristics showed that between 1/3 and 1/5 of the patients lost >10% of the body weight. NOMA thus considered the statement to be misleading. NOMA also emphasized that the results of the placebo group and weight gain after separation should be stated, so that the reader is able to form a view of the real effect of the medicinal product over time.

The second advertisement was for Wegovy used the claim "Wegowy 2,4 mg, given as a supplement to diet with reduced caloric intake and increased physical activity, has in studies shown and average weight reduction of 14,9% vs. 2,4% for placebo."

NOMA alleged that this was misleading, since the advertisement did not provide an objective view of what the study in question (STEP 1 study) and the other studies referred to in the summary of product characteristics described. The statement gives the impression that the effect of Wegovy vs placebo is better than what the summary of product characteristics combined described. NOMA referred to that a study for patient populations with a comorbidity factor showed lower weight reduction, and that while the STEP 1 study was the largest study, Wegovy is reimbursable for patients with diabetes, where many patients are overweight, and it is relevant information for this patient group

and the prescribing physicians that the effect will not necessarily be as good for them. Furthermore, the STEP 1 study also demonstrated a lower end result in the follow up period after the medicinal product was separated. In other words, NOMA alleged that Novo Nordisk had chosen the best result in total and presented it as an average, giving the reader an incomplete and misleading impression of the effect. NOMA also emphasized that weight gain after separation of the medicinal product should be clearly communicated.

Advertisement for the treatment of children

An additional point addressed by NOMA was information in an advertisement which highlighted that Saxenda now also could be used for the treatment of children above 12 years. NOMA referred to that the underlying study concerning children showed an immediate weight gain after separation of Saxenda, resulting in the total weight loss being reversed, and that this was a clinically important information which, according to NOMA, should have been clearly communicated in the advertisement. Having failed to do this, NOMA considered the advertisement in violation of section 13-8 second paragraph, since the information was insufficient to allow the recipient to form his/her own opinion of the therapeutic value.

In its reply to the warning letter, Novo Nordisk argued that the advertisement only was to inform about the new change in indication, and that the advertisement did not promote any specific effect. Novo Nordisk also argued that NOMA had just focused on a specific part of the advertisement, whereas the advertisement had to be assessed as a whole. An additional argument was also that the loss of effect was not mentioned in Felleskatalogen (a physician's desk reference). NOMA was not convinced.

Marketing a "side effect" for a medicinal product

In an advertisement for Ozempic, which is approved for the treatment of type 2 diabetes, NOMA reacted on an illustration which indicated that Ozempic could give "Greater weight reduction". The statement was placed next to the reduction in HbA1c and reduction in cardiovascular incidents. NOMA stated that weight reduction is one of the most common side effects of treatment with Ozempic, and not a part of the approved indication, and that promoting a side effect on equal footing with the approved indication was misleading and a violation of section 13-3.

In its argument, Novo Nordisk referred to the weight reducing effect being mentioned in the SmPC. Novo Nordisk also referred to several studies which referred to weight loss as an effect, and an end point in one of the studies, as well as the national guidelines on type 2 diabetes. In fact, Novo Nordisk argued that it would be a violation of section 13-3 not to include information that Ozempic has a weight reducing effect. However, the problematic aspect of the advertisement for NOMA was that weight reduction claim was visually emphasized on par with the effect on blood glucose and cardiovascular incidents. This was the case even if the advertisement included a statement (in a smaller font) that Ozempic was not approved for weight reduction. NOMA also referred to that it was a high probability that this advertisement had contributed to off-label use of Ozempic, referring to that there is extensive prescription of Ozempic on pre-approved reimbursement outside the approved conditions for reimbursement, and that off-label use in weight

reduction has contributed to significant additional costs of the National Insurance Scheme.

Under-communication of weight gain after separation
The last aspect referred to by NOMA was the undercommunication of the results of the studies showing that the separation of Wegovy and Saxenda results in that the weight loss is reversed within 1 year. According to NOMA, this was clinically significant and not present in the advertisements. The advertisements could, therefore, give the impression that the weight loss persisted after separation, which was misleading.

Novo Nordisk argued that they have never communicated that the pharmacological effect persisted after separation. Furthermore, they also referred to that upon separation of any medicinal product, it is obvious that the pharmacological effect will not persists, which health care personnel would understand on their own.

However, NOMA referred to that the use of GLP-1 analogues was a relatively new treatment principle. While it is obvious that the pharmacological effect would not persist, it was not clear to neither therapists nor patients that the weight loss is reversed, and that, in most cases, the treatment must, therefore, be very long or for life. NOMA also referred to that due to a lot of “advertisements” from private persons, especially on TikTok, a misconception had been formed in the general public that these medicinal products could be used as a short-term diet. In such a scenario, NOMA referred to that it was in particular important that Novo Nordisk informed about this reversal upon separation.

Sanctions
With regard to sanctions on the abovementioned infringements, NOMA brought the heavy artillery.

NOMA ordered not only that the illegal advertisements had to cease, but also issued an order for Novo Nordisk to provide corrective statements where the advertisements had been published, and that the corrective statements should clarify that

Saxenda and Wegovy are supplemental treatment options, demonstrate that the effect on weight reduction is different in various studies, that the weight reduction is reversed after separation and clearly inform that Ozempic is not approved for treatment of obesity and overweight.

Furthermore, to ensure the cessation of the illegal advertisements, NOMA issued a daily penalty of NOK 5000 if the order was not followed within 1 November 2023.

The most interesting part of the decision is, nevertheless, the violation fine issued by NOMA, which amounts to NOK 1 500 000. In this regard, NOMA emphasized both the severity of the breaches, as well as repeated breaches.

On the severity, NOMA argued that the unbalanced advertising had made therapists less able to be given a correct understanding of the clinical aspects of the drugs. This was also evidenced by physicians having prescribed Ozempic outside pre-approved reimbursement for the treatment of overweight. The combination of advertising for one of the best results in an underlying study and not stating that weight reduction would be reversed after separation, would according to NOMA be suited to ensure that patients are treated with Saxenda and Wegovy with an erroneous expectation both to the scale and the duration of the weight reduction, and that therapist had initiated treatment with a wrongful expectation that the treatment would be relatively short.

NOMA also referred to that this likely had resulted in Ozempic being used off-label for the treatment of obesity/overweight, which was evidenced by the fact that Ozempic had been prescribed for 22 000 patients on prescription without reimbursement, which had resulted in shortages for diabetic patients.

Furthermore, NOMA also emphasized that weight and appearance is a sensitive area, and that it is especially important that this patient population receives correct information on the treatment options.

An additional argument on severity emphasized was advertising on treatment towards children. NOMA made it clear that their argument is not that the advertisement was directed towards children, which Novo Nordisk had argued that was not the case.

As stated above, NOMA also referred to repeated breaches by Novo Nordisk. The first point of interest in this regard is that NOMA not only referred to breaches for the three medicinal products in question, but also a separate brand name (Victoza) with the same active substance as Saxenda (liraglutide). The second point is that NOMA referred to breaches occurring as far back as 2015. The latter is of particular interest, since violation fines according to the Medicinal Product Act section 28a are subject to a statute of limitations of two years, which Novo Nordisk had also pointed out. However, NOMA argued that while the statute of limitations concerns the breaches in questions, it did not preclude that NOMA could emphasize earlier repeated breaches as a relevant factor.

Finally, NOMA also concluded that Novo Nordisk had achieved a significant financial benefit due to the off-label sales of the three products, which also necessitated a violation fine.

On the amount of the fine, NOMA referred to the total sales of Novo Nordisk in Norway, as well as the sales for the individual products. The maximum amount for violation fines is 15 times the basic amount of the National Insurance Scheme, equivalent to approximately NOK 1 780 000 in 2023. In the decision, NOMA refers to the total sales of Novo Nordisk in 2021 (which exceeded NOK 1 billion), as well as the need for violation fines to be effective, proportionate and of a penal character, also taking into account the financial situation of the violator.

Comments
While NOMA is known for a rather strict practice regarding the interpretation of the rules of pharmaceutical advertising, and thus leaving little room for errors for pharmaceutical companies seeking compliance with these rules, violation fines for breaches of pharmaceutical advertising has thus far been an uncommon practice. The legal basis for such violation fines was introduced in 2022. As such, this case thus serves as an interesting example of NOMAs practice concerning the use of violation fines.

Furthermore, the case also illustrates that the risks for pharmaceutical companies when it comes to pharmaceutical advertising have increased significantly. While the fee might be small in comparison to Novo Nordisk sales of the products involved, it is rather large from an objective viewpoint. As such, the case has received much attention in the media directed towards the healthcare sector.

Novo Nordisk has appealed the decision to the Ministry of Health and Care Services.

The difficult differentiation between information and advertising of medicinal products.

Can you advertise a medicinal product without mentioning its trade name or the active ingredient?

Introduction
Dr. Dropin is a private healthcare provider consisting of clinics providing services from physicians to the general public. On 8 November 2022, the Norwegian Medicines Agency (NOMA) issued a warning letter to "Dr. Dropin". The warning concerned breaches of the legislation on pharmaceutical advertising. NOMA pointed out that on the webpage of Dr. Dropin, there was information about the medicinal product Isotretinoin available, which the agency considered as qualifying as pharmaceutical advertising. Isotretinoin is an active substance in oral drugs primarily used for the treatment of severe acne. The active substance is also a known teratogenic substance, with significant risk for congenital defects in infants exposed to the drug in the uterus. Due to this risk, there is a strict control when prescribing the treatment to women of fertile age.

In its reply to the warning letter later in November 2022, Dr. Dropin pointed out that they had no intention of advertising for medicinal products, but rather wished to share general information on treatment options for acne. The reply also stated that the webpage had been amended after having received the warning.

NOMA's decision
On 15 December 2022, NOMA issued an administrative decision against Dr. Dropin for being in violation of the legislation on pharmaceutical advertising. The administrative decision referred to the amendments done by Dr. Dropin, and that the name Isotretinoin was not present. However, NOMA pointed out that there was still present information about a medicinal product, referring to statements such as a "strong tablet cure", "prescribed by a dermatologist", that it is necessary to take blood samples, that pregnancy cannot occur during the cure, and that women have to use birth control during and after the treatment. The information also referred to several known side effects.

In the administrative decision, NOMA referred to Dr. Dropin as a commercial actor which provides treatment with Isotretinoin to customers, and thus has a financial interest in promoting the use of the medicinal product. Furthermore, the website of Dr. Dropin constitutes information directed to the general public.

NOMA further stated that there is no condition in the legislation on advertising for medicinal products that the name of a medicinal product must be mentioned in order for information about a medicinal product can be considered within the scope of these rules. NOMA thus concluded that the information on Isotretinoin (albeit not explicitly mentioning the name) was considered advertising.

With reference to the prohibition on advertising for prescription medicinal products to the general public, the advertisement was thus considered a breach. The administrative decision also came with a warning of fines of NOK 5000 per day if the advertisements were not stopped within the set deadline.

In its' reasoning, NOMA also referred to decision C-421/07 (Frede Damgaard), where the CJEU concluded that dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, could be regarded as advertising, even though the third party in question was acting on his own initiative and completely independently of the manufacturer and the seller of such a medicinal product. However, whether that is the case would have to be determined by the national courts.

Dr. Dropin filed a complaint on the administrative decision, and also requested that the effect of the decision be suspended until the complaint had been processed. This was later refused by NOMA, which also pointed out that they had observed unlawful advertisements on TikTok and Facebook after the appointed deadline. A meeting between Dr. Dropin and NOMA was held in January 2023, whereafter Dr. Dropin removed all information concerning a "strong tablet cure" pending the appeal of the decision.

The Ministry's decision

The Ministry of Health and Care Services rendered its decision on 20 February 2023. In the decision, the Ministry discusses NOMAs role as supervisory agency on pharmaceutical advertising and its duty to provide guidance on the rules on pharmaceutical

advertising, pointing out that there is no pre-approval of advertising for medicinal products in Norway. NOMA must thus be particularly aware of its role as supervisor and not provide specific advice on how advertising should be designed in practice. These statements are likely addressed to the complainant's statements that they desired which parts of the information disseminated which was not lawful.

On the key point of the case in hand, which is whether the information provided on the website about a "strong tablet cure" is indeed an advertisement of a medicinal product or not, the decision provides little details. The Ministry states that it shares NOMAs view that this information is suited to promote the use of isotretinoin in cases of acne, thus supporting that the information provided was indeed pharmaceutical advertising.

The Ministry also points out several issues addressed by NOMA. In particular, that the advertisement was shown on TikTok, which is a popular social media platform for children and young people, was considered as "extremely unfortunate". Even though the advertisement was not directed towards children, it was easily accessible for children. Furthermore, the fact that the advertisement referred to the "strong tablet cure" for the

treatment of moderate to severe acne, when isotretinoin is approved for severe acne, this was misleading since it fell outside the approved indication.

Consequently, the Ministry upheld NOMAs decision.

Comments
Differentiating between information on medicinal products in the strictest sense and information that is considered advertising can be a challenging exercise. In this particular scenario, it was clear that Dr. Dropin's intent was to promote their healthcare services, and not medicinal products. However, due to how the advertisements were designed, the medicinal product did indeed become the focus of the message, and as such, it is not difficult to understand why NOMA decided to react.

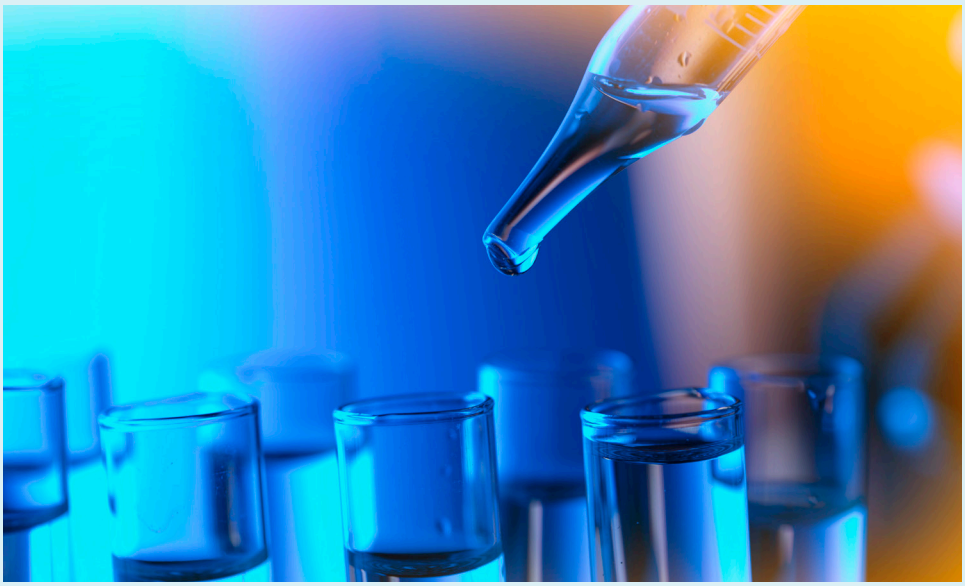
However, the more interesting aspect is the fact that the product in question was not named nor identified. This is the key issue of the case - can it be considered as advertising of a medicinal product when the product is not specifically identified, neither by trade name, by the active ingredient or even by a specific ATC-category? While healthcare professionals would surely understand which medicinal product "a strong tablet cure" refers to, this would not be the case for the general public without further investigations. And can such advertising really be considered misleading for the general public based on promotion outside the approved indication of the product, when the same product cannot be identified by the same general public?

Both the Ministry and NOMA take this position but fail to provide any specific arguments on why this is indeed must be the case from a legal perspective. Despite this lost opportunity for further clarity, there are two important takeaways:

- References to non-specific medicinal products could potentially be considered as advertising of medicinal products, even if neither the trade name, the active ingredient, a specific ATC-category or another identifier is made.

- When advertising for other products or services, businesses should avoid referring to medicinal products in any form, even on a broad level, which can be considered as an inducement to use or sell medicinal products.

Healthcare service providers typically use their website as an information hub on various diseases and conditions. In light of this recent decision, such businesses should review information that refers to treatment options to assess whether this information can be considered as promotional in nature, and if so, ensure compliance with the rules on pharmaceutical advertising.



New tender regime approved – now what?

A recently approved controversial new tender regime for pre-approved reimbursement medicines may be a game-changer for market access. CRGP-inhibitors and SLGT2-inhibitors are the first affected.

Introduction
Somewhat simplified, reimbursement of medicinal products in Norway can be described into two main categories. Products used in hospitals (as well as certain products initiated by hospitals but used in outpatient care) are subject to tender bids by a centralized purchasing entity, whereas reimbursement of product used by patients in primary care (typically initiated by a general practitioners) are for the most part pre-approved for reimbursement and covered by the National Insurance Scheme. The latter is typically referred to as the "blue prescription", which reimburses the maximum prices set by the Norwegian Medical Product Agency (previously the Norwegian Medicines Agency). However, if the expected annual cost of such a drug exceeds NOK 100 million within the first 5 years after the approval, a parliamentary approval is required before pre-approved authorization can be granted.

The two systems have co-existed for a long time. However, in 2022, a pilot tender was initiated for a specific group of medicinal products used for the treatment of high LDL-cholesterol, so-called PCSK9-inhibitors. The rationale of the pilot was two-folded. Firstly, new and costly medicinal products would emerge within several large treatment areas, thus increasing the number of medicinal products that would require parliamentary approval. Secondly, the experiences of tenders in the hospital sector could initiate further price reductions, which in turn could ensure that more patients could receive access to treatment options that would otherwise be deemed too costly.

Proposal for tendering blue prescription medicines
In June 2023, the Norwegian Medical Product Agency (NOMA) published a redacted report on its experiences with the pilot, expressing that the results were good, and with a recommendation to implement a tender bid also for other candidate drugs. However, which exact candidates were redacted in the publicly available report.

In October 2023, the Norwegian Government presented its proposal for the National Budget, where it was suggested that the tender procedure should be permanent. It was stated that

approximately 5% of the active ingredients in the “blue prescription regime” could be candidates for the procedure. A month later, a less redacted report was published, showing the candidates that NOMA had actually considered.

The proposal for a tender procedure for blue prescription medicines has been rather controversial, and not well met by the pharmaceutical industry. A joint statement by six large pharmaceutical companies called the pilot for “an ordered success story”, referring to that the pilot concerned medicines that patients already had poor access to, and to make such a medicinal product more available naturally would produce favorable results. The pilot’s value for other treatment areas was thus limited. The companies pointed out the challenges of not only reducing the toolbox of physicians by placing restrictions on which medicinal products that could be prescribed for pre-approved reimbursement, but also compliance issues. Should the patient receive a new medicinal product each time a new company wins a tender for the relevant category/ substances? In addition, the proposed tender competition could result in social differences – wealthy individuals with the possibility to pay for medicinal products themselves could receive more options, whereas this was not the case for individuals with less financial resources available.

Patient organizations and the Norwegian Medical Association have also expressed concerns, stating that several of the areas affected are complex treatment areas with the need for tailored individual solutions, that various medicinal product has different side effect profiles. A major criticism is also that the consequences of a tender procedure for these medicines have not been sufficiently studied.

Since the proposal was part of the proposed National Budget and thus had to be approved by the Norwegian Parliament, there was some uncertainty whether the proposal would actually be approved. The Norwegian government does not have a majority of the Parliament and has to rely on support of other parties to actually get to budget approved, which necessitates compromises in order to get it approved. And the relevant partners for the Government expressed a negative opinion of the proposed tender process.

However, in December 2023, it became clear that the tender process would be implemented.

Affected medicinal products and the consequences
In its report, several candidates are mentioned. Among them are CGRP-inhibitors (used for the treatment of migraine) and SGLT2-inhibitors (for the treatment of diabetes). Other candidates are also mentioned and could possibly be subjected to tendering but would, according to NOMAs report, require further clinical investigations. As such, it is highly likely that the two abovementioned categories would be the two first subjects of the new tender procedure. This means that medicinal products that are in the same therapeutical class may now have to compete against each other in order to be subject to pre-approved reimbursement.

Several aspects of how the tender will actually work, are still unclear. With regard to patients who are currently on a medicinal product that is affected, the Ministry of Health and Care services has in the press indicate that patients who currently use a medicinal product shall not have to switch, and thus can continue with the same treatment option. Other statements

indicate that reimbursement will be available for the alternatives if the winning tender product cannot be used. However, it is unclear whether this would mean that patients would have to apply for individual approvals of reimbursement, or if the pre-approval regime will still be available. It is also unclear how the procedure will work in cases of shortages of a medicinal product, where physicians previously could easily switch to a comparative product.

Comments

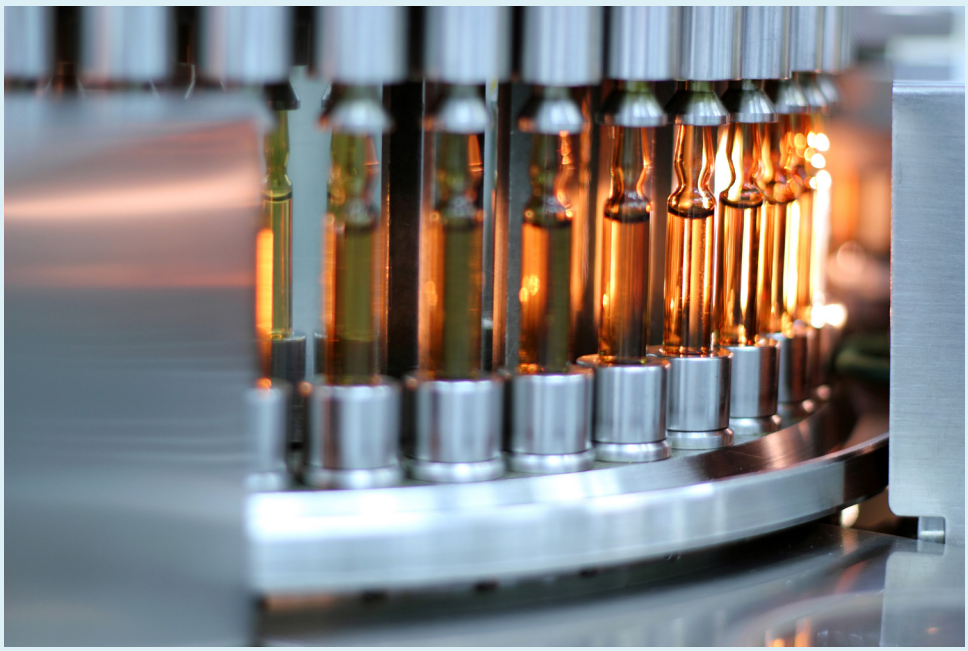
The introduction of tenders for "blue prescription" medicines is a potential game-changer in Norway concerning patient access to innovative medicinal products that are not yet subject to generic competition. The new regime will result in restrictions for physicians with regard to the choice of treatment options. How bureaucratic and cumbersome this regime will be for physicians and patients, remains to be seen. What is clear is that when the door has now been opened for two categories, these will not be the last.

For the pharmaceutical industry, increased competition opens up both further risks and rewards in the form of either increased or decreased market positions. A topic that has not been considered in particular is whether this procedure would affect how companies choose to advertise the medicinal products in questions. A possible outcome could be an increase in comparative advertising for the affected products. Furthermore, it may also result in attempts to increase awareness of the arrangements of individual reimbursement.

It is also unclear how this will affect the generic market in Norway. The signal from the Ministry is that there will not be tenders for candidates that are subjected to generic competition. However, when generic competition does become an option, a possible situation is that the established market position for the tender winner is much higher than that of the other candidates, which could lead to less interest among firms in launching generic medicines of other candidates than the winner.

PI request on dosage patent – the dimethyl fumarate case.

Biogen International GmbH vs. Laboratorios Lesvi S. L., Neuraxpharm Sweden AB and Sandoz A/S - Oslo District Court – 17 February 2023



Introduction
Biogen International GmbH (Biogen) markets the product Tecfidera in Norway, a medicinal product containing the active substance dimethyl fumarate, which is used for the treatment of relapsing-remitting multiple sclerosis (RRMS).

The parent company of Biogen (Biogen MA Inc.) is the holder of European patent EP 2,653,873 (EP'873), which is licensed to Biogen. EP'873 is basically a dosage formulation patent for a pharmaceutical composition containing the active ingredient for the treatment of multiple sclerosis (MS), wherein the dosage to be administered is 480 mg per day.

EP'873 is a divisional of another European patent EP 2,137,537 (EP'537), which was held to be invalid by the Technical Board of Appeal in January 2022. In the EPO-proceedings for EP'873, third party observations had been submitted pointing out that the invention in EP'873 was basically the same as that of the parent patent EP'537. Despite this fact, the patent was granted by EPO's Examining Division in June 2022, and validated in Norway 2022.

At approximately the same time, the tender purchasing entity for the public hospitals in Norway (Sykehusinnkjøp) announced a tender for supply of dimethyl fumarate to Norwegian hospitals, with start from 1 January 2023. In October 2022, it was announced that the pharmaceutical company Neuraxpharm Sweden AB (Neuraxpharm) was ranked as the winner of this tender, whereas the pharmaceutical company Sandoz A/S (Sandoz) was ranked as the runner up. Third place in the tender was Viatris AS (a representative for Mylan Ireland Ltd), which also had initiated an ordinary invalidity action against the patent (which later in 2023 was stayed).

With basis in EP'873, Biogen launched three separate requests for preliminary injunctions against three generic competitors – Viatris/ Mylan), Neuraxpharm (which acts as a representative for Laboratorios Lesvi S.L in Norway) and Sandoz. The matter between Biogen and Viatris/Mylan was subsequently dismissed by a joint pleading between the parties on dismissing the case.

The two remaining matters were decided to be held jointly in January 2023.

The Parties' arguments
There was an agreement between the parties that the products of Neuraxpharm and Sandoz fell under the scope of the granted patent. However, the defendants Neuraxpharm and Sandoz argued that the patent was invalid.

The defendants argued that EP'873 had been amended in such a way that it contains subject-matter that extends beyond the content of the application as filed (i.e. added matter). The defendants also argued lack of novelty, that the patent application was insufficiently described (a plausibility argument – albeit made prior to the Enlarged Board of Appeals decision in G-2/21), and lack of inventive step based on two separate pieces of prior art.

Biogen dismissed all these claims, also stating that there is a presumption for validity for the patent, and also referred to the Examining Division having assessed the invalidity arguments via the third-party notices submitted in the examination proceedings at EPO. Biogen also referred to that the courts should be cautious in deferring from patent authorities' assessments and the impact of EPO case law, which is a well-known doctrine established by the Norwegian Supreme Court (the Swingball-doctrine).

The court's assessment
The court first assessed the allegations concerning whether EP'873 had been amended in such a way that it contains subject-matter which extends beyond the content of the application as filed and found that the crucial question was whether the independent claims of the patent (claim 1 and 5) could be inferred directly and unambiguously so that they thus "appear" in the original patent application as filed.

In this regard, the court referred to the court-appointed experts' assessment, which had stated the skilled person would

not “readily understand that the original application described a pharmaceutical composition for use in the treatment of MS, in which the composition includes DMF, and one or more pharmaceutically acceptable excipients, wherein the composition is to be administered orally, and wherein the dose of DMF is 480 mg per day. The reason for this was according to the court-appointed expert that this was not reflected in the title, and that there are so many embodiments that mentioned other aspects, that what is essential in the patent regarding MS treatment becomes unclear. The court appointed experts also stated that it is possible that the patent will be perceived differently by experts with good experience in reading patents.

The court agreed with this assessment, and, in particular, referred to the broad description in the patent, which described a number of alternative methods of the intended treatment. The fact that dimethyl fumarate and monomethyl fumarate was stated as one of several active substances was, in the view of the court, not conclusive since the independent claims appeared more as a random composite of various features from the application.

Biogen had argued that it was evident from the patent application that the purpose of the invention was to treat neurological diseases. The court agreed with Biogen, but also stated that it is not clear from the application that the invention specifically targets MS – on the contrary, the application appeared to be one of several neurological diseases to which the invention was directed at the time of the application. The court also pointed out that the dose of 480 mg was mentioned in only one place in the application, and the dose of 720 mg was highlighted.

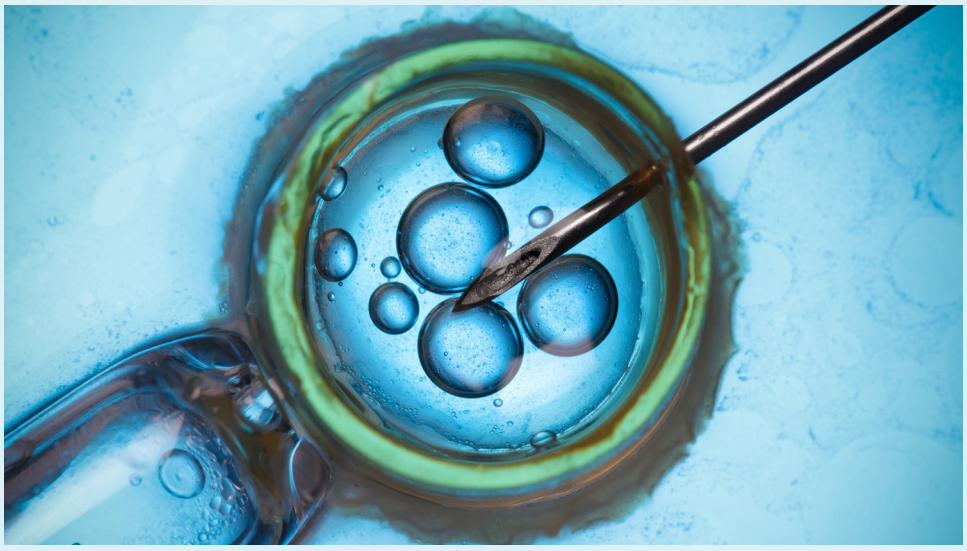
While it was not conclusive for the court, the court also referred to the previous decision of the Technical Board of Appeal on the parent application. The court agreed with the statements in the decision that a dose of 480 mg does not appear to be the preferred one in the application, that the examples in the application do not relate to the treatment of MS and that several dose intervals are described without any of them being designated as preferred.

The court also referred to the fact that EPO's Examining Division had considered the unlawful amendment objection prior to the grant of the patent in July 2022, but gave little consideration to this, which, in the view of the court, was rather brief and not well-founded. The court did not find sufficient grounds for speculating further as to the justification for the result reached by the Examining Division.

Consequently, the court concluded that a skilled person could not directly and unequivocally derive from the patent application the features set out in the independent claims of EP'873, and that the amendment had been unlawful. Thus, the patent was invalid, and the claim of Biogen to request preliminary injunctions against Neuraxpharm and Sandoz was not substantiated.

As the court had concluded on invalidity based on one of the allegations, it was not necessary to comment on the further claims of invalidity presented by the defendants. Somewhat surprisingly, the court nevertheless made an obiter dictum on whether the patent fulfilled the requirement of inventive step.

The court considered that the closest prior art was an article that showed that a dose of 720 mg per day had a statistically



significant effect, while doses of 120 mg and 360 mg did not have a corresponding effect. The court agreed with Biogen claim that what it considered as the closest prior art described a 720 mg dose as safe and well tolerated. These factors indicated that the patent's solution had inventive step. However, in the view of the court, there were several factors that indicated that a skilled person equipped with common general knowledge would choose a daily dosage of 480 mg per day with reasonable expectations of success.

In particular, the court referred to the court-appointed experts stating that the article constituting the closest prior art demonstrated a trend for effect on the primary target when using 360 mg per day, that there are signs of a flattening of the effect between 360 mg and 720 mg. The court also pointed to the experts' statements that a treatment effect against RRMS with a lower dose than 720 mg is plausible, but that the data did not provide a good indication of whether the optimal dosage was equal to or below 720 mg. A higher frequency of non-severe but significant side effects provides an incitement to try a lower dose than 720 mg per day.

In the view of the court, the court appointed experts found that the article constituting the closest prior art meant that it was appropriate for the skilled person to attempt a dosing regimen between 360 mg and 720 mg per day in order to achieve optimized treatment effect, pointing out that the dosage was established in intervals of 120 mg, so that nearby intermediate dosages would be 480 mg or 600 mg per day. As such, it would not have been surprising for a skilled person that a dose of 480 mg per day could be close to an optimal dosage.

As such, the court concluded that invention lacked inventive step, and thus that the patent in its entirety was invalid. Injunctions against the defendants were, therefore, not granted.

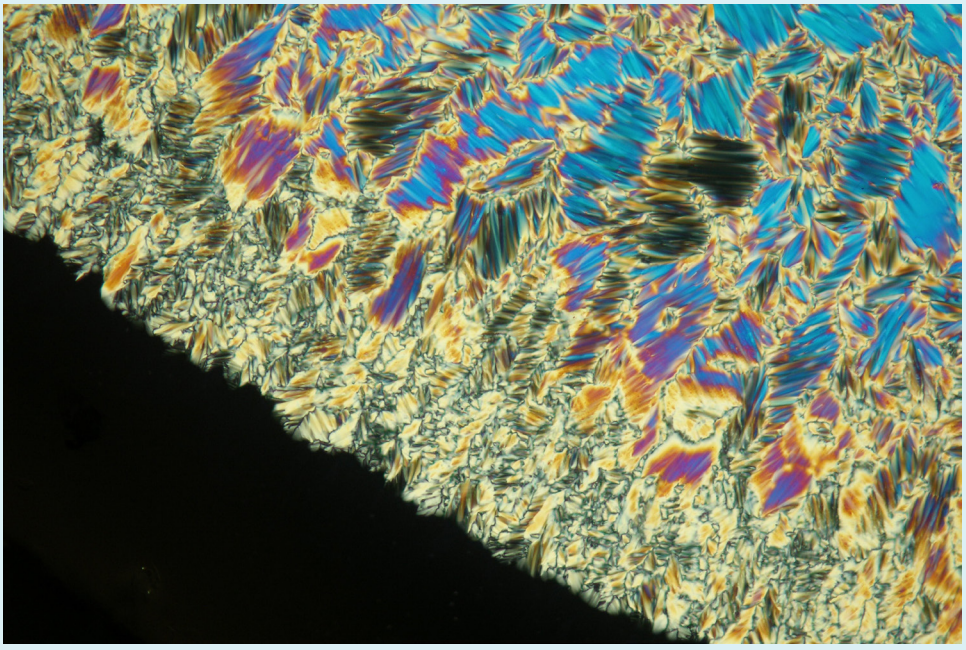
Comments
In many countries, there exists a "threshold test" for the presumption of validity of a patent in an interim injunction case

which the alleged infringer has to overcome, and as such, relying on invalidity as the sole defense can be considered as a somewhat risky strategy. This decision is an example that such a view has less impact amongst Norwegian courts compared to the actual merits of the case. While the “Swingball” doctrine set out in two Norwegian Supreme Court decisions still apply, it also shows that this principle has less impact when the decision to grant is made by the earlier instances of a patent office (in this case EPO) and that the reasoning for a conclusion (or lack thereof) could also affect the courts assessment.

A team of Haavind’s lawyers assisted Sandoz in this particular matter.

Plausibility – a summary of the Norwegian apixaban-case.

Teva Norway AS and Teva Pharmaceutical Industries Ltd vs. Bristol-Myers Squibb Holdings Ireland Unlimited Company - Oslo District Court - 22 May 2023



Introduction
The pharmaceutical company Bristol Myers-Squibb (BMS) is the holder of Norwegian Patent 328 558 (NO'558), which concerns the active ingredient apixaban. Apixaban is an anticoagulant drug primarily used to treat and prevent blood clots and to prevent stroke in people with nonvalvular atrial fibrillation through directly inhibiting factor Xa. BMS markets apixaban under the brand name Eliquis.

In addition to NO'558, BMS also holds a supplementary protection certificate (SPC 2011021) for apixaban. BMS has also applied for a pediatric extension of this SPC.

In June 2022, the pharmaceutical company Teva initiated a legal action against BMS at Oslo District Court, claiming that NO'558 and the SPC were invalid. In addition, Teva requested that the court issued a declaratory judgement that Teva's generic medicinal product containing apixaban did not infringe the patent and the SPC, with reference to the invalidity of the patent and the SPC.

The parties' arguments
Teva's main argument for invalidity of the patent was that the requirement of inventive step was not fulfilled. This was based on an allegation that it was not plausible that the technical problem of what the application of the patent attempted to solve had actually been solved, since neither the activity nor the selectivity of factor Xa was plausibly substantiated in the application of the patent. Teva thus argued that the technical problem in the "problem solution approach" had to be reformulated to obtain alternative chemical formulations without any technical effect being plausible, and that it is not inventive to draw up new chemical formulations without substantiating that the technical effect is plausible.

As an alternative approach, Teva also argued that the requirement that the invention must have an industrial application was not fulfilled. Teva emphasized that these two invalidity reasons were coincidental and could be considered as the requirement of plausibility.

Teva further argued that NO'558 did not fulfill the requirement of inventive step since there was no technical contribution over the closest prior art, and that the patent had made an arbitrary selection of the formulations in the closest prior art without in a plausible manner showing any technical contribution or improved effect over prior art.

A further argument was that the limitation of the application during the application process constituted "added matter", since the selection made could not be directly and unambiguously derived from the application as filed.

With regard to the SPC, Teva argued that this was invalid since the basic patent (i.e NO'558) was invalid. It was also argued that the SPC was invalid since apixaban was not protected by a basic patent in force, cf. the SPC-regulation article 3a.

BMS maintained that the patent was valid, and that the requirement of industrial applicability was satisfied. BMS referred to that the use of apixaban as an active ingredient in medicines for the prevention and treatment of thrombi was described in the application and had subsequently been documented through preclinical trials and clinical trials.

BMS also alleged that it was not required that efficacy and safety must be documented in the patent application in the form of biological data, and that the patent authorities accept the applicant's information about the therapeutic effect of the drug, unless there are special reasons to doubt the information. If there are special reasons to doubt the information in the application, the patent applicant can substantiate the effect with subsequent documentation. Furthermore, BMS alleged that the efficacy was supported by preclinical data and results from clinical trials available in the case.

BMS alleged that in this case, the problem consisted in producing an effective factor Xa inhibitor for the treatment of thromboembolic disorders, with improved properties. BMS referred to that this was evident from the patent description, and

that it had subsequently been documented through comparative data and was further supported by preclinical data and results from clinical trials. BMS thus refused that there was basis for disregarding this data, as claimed by Teva, and that it is possible to substantiate the effect with subsequent documentation.

BMS also argued that apixaban was not a random selection that did not represent a technical contribution beyond the closest prior art, but an advance compared to the structurally most similar compounds found in this prior art.

Furthermore, BMS refused that the application and been amended so that subject matter had been added. BMS argued that the subject matter of the application had been limited, in that the general formula of the original patent claim 1 was replaced by a formula comprising only the compound apixaban, or a pharmaceutically acceptable salt thereof. Apixaban could be directly and unequivocally inferred from the application filed by the substance being explicitly stated in example 18 and another patent claim.

With regard to the SPC, BMS argued that it could not be invalidated since there was no basis for NO'558 being invalid, and furthermore, that article 3a of the SPC-regulation was satisfied,

since at the time of the application of the SPC, apixaban was protected by the basic patent in force.

Enlarged Board of Appeals' decision in G-2/21 and the UK Court of Appeals case

Patent law aficionados will perhaps remember that on 23 March 2023, the Enlarged Board of Appeal rendered its decision on plausibility in G-2/21, where the Enlarged Board of Appeal concluded that evidence submitted by a patent applicant/proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject matter may not be disregarded solely on the ground that such evidence had not been public before the filing date of the patent-in-suit and was filed after that date.

Incidentally, the decision of the Enlarged Board of Appeal became available after the oral hearing at Oslo District Court, but before court had rendered its decision. The court thus allowed for supplementary pleadings, which were taken into account after the oral hearing was concluded. Both Teva and BMS submitted such pleadings.

The UK Court of Appeal rendered its decision in a parallel case on invalidity of the similar apixaban-patent on 4 May 2023, where the Court of Appeal confirmed the invalidity of the patent. The court allowed the parties to submit brief pleadings commenting on this fact, which both parties also did.

The court's reasoning

The court rendered its decision on 22 May 2023.

In its reasoning, the court first referred to that the basis in Norwegian law is that there are no particularly strict requirements with regard to documenting an effect, and that it is not necessary that the patent application contains experimental data unless it can be raised doubts about the technical effect of the invention. The court found support for this view in both the preparatory works of the Norwegian Patent Act as well as in judicial literature.

With regard to G-2/21, the court referred to the fact that the Enlarged Board of Appeal in this decision moved away from plausibility as an individual requirement or particular legal concept under the European Patent Convention, and that the determinative factor was what the skilled person, based on the patent application at the priority date, and in light of common general knowledge, would understand from the application as the technical teachings of the claimed invention. The court acknowledged that it was unclear from the decision what it means that an effect is " based on the application as originally filed" and "embodied by the same originally disclosed invention", as referenced by the Enlarged Board of Appeal, and that the decision did not provide any guidance on this matter.

The court was nevertheless of the opinion that the claimed technical effect was encompassed by the technical teachings and implemented in the originally published patent application, that apixaban was a plausible invention, and that the skilled person had no reasons to doubt the effect, even without biological data. The court thus found that subsequent evidence could be used to substantiate inventive step. The court thus found no reason to elaborate further on what can be deduced from the Enlarged Board of Appeals decision.

The court also briefly referred to the UK decision but stated that this would not have any impact on the court's conclusion in this case.

The court then performed a specific assessment using the well-known problem solution approach. Having elaborated on what could be determined from the closest prior art, the court found that based on the description of the patent application, the technical problem of the invention was to produce an effective factor Xa-inhibitor with improved properties for the treatment of thromboembolic diseases.

In the view of the court, the main question of the case was whether the patent application had provided an inventive contribution. The court referred to Teva's argumentation that the application stated a general Markush-formula, which referred to a

very high number of possible chemical entities, where only a few had been synthesized and 140 specific entities had been included in the example. Without any additional data substantiating the effect, it would not be plausible for the skilled person that these entities, including apixaban, would potentially be useful Xa-inhibitors.

The court disagreed with this approach and referred to the Board of Appeals decision T 488/ 17 (Dasatinib). In its interpretation of its decision, the court found that the question on inventive step should only be for apixaban, and not for all the other entities in the patent application.

The court proceeded with how the skilled person would interpret the patent application. In the view of the court, the skilled person would understand that the application concerns factor Xa-inhibitors, and that the goal was to identify effective and specific factor Xa-inhibitors with improved pharmacokinetic conditions. The skilled person would note the detailed description of the synthesis and characteristics of the entities which had been produced in a laboratory. The skilled person would further understand that the similar entities were a result of a long optimalization work where the most promising candidates from the closest prior art was furthered. Based on

the structure of the substances, it would be clear for the skilled person that the patent application was a continuation of previous work.

In the view of the court, the skilled person would also see the similarities between apixaban and a previous chemical structure on Xa-inibitors disclosed in a prior art scientific journal. The skilled person would thus conclude that the structure of apixaban was consistent with the skilled person's knowledge of Structure–activity relationship (SAR) concerning factor Xa-inhibitors at the time of the priority date. SAR is a theoretical model that can be used to predict the properties of substances.

The skilled person would also understand that the substances had been tested via ordinary methods and had been shown to be effective Xa-inhibitors, and that apixaban had been chosen due to promising results in introductory tests. The skilled person would also note that apixaban was the only compound to be tested in a large quantity and a cleansing process that was demanding. The skilled person would assume that this was intentional, and that apixaban, therefore, was the most promising candidate intended for animal studies in vivo, and as such, that apixaban had sufficient selectivity to study the antithrombotic activities in vivo. As such, apixaban would be considered a plausible factor Xa-inbitor.

When this was the case, the court concluded that subsequent evidence which substantiates the effect is permitted, and that it was agreed that subsequent evidence indeed demonstrated such an effect.

On the other alternative claim presented by Teva that the invention in NO'588 constituted an arbitrary selection of the formulations over the closest prior art and thus no technical contribution, the court referred to Teva's argument that apixaban had to demonstrate positive attributes over the compounds which was generally included by the Markush-formula in the closest prior art. The court, on the

other hand, highlighted that the comparison should be over the structurally most similar compounds, not the broader group of compounds of the Markush-formula. In the view of the court, the skilled person would have emphasized other attributes than just potency of the drug, such as lower molecular weight and pharmacokinetic properties, etc., which showed improved properties. The court thus found that NO'558 did constitute a technical contribution over the closest prior art.

On Teva's alternative claim that the application had been amended so that it constituted added matter, the decision is rather short. The court simply states that, in its opinion, apixaban was explicitly mentioned in an example of the patent as well as in one of the claims of the application. The court found that the amendment was within what the skilled person could conclude based on the original patent application and in light of the common general knowledge, and the amendment was not arbitrary. In the view of the court, apixaban could thus directly and unambiguously be disclosed by the application, and the amendment had thus a clear basis in the application as filed.

With regard to the claims on the invalidity of the SPC, the court first referred to that since the patent was held to be valid, this attack on validity of the SPC could not succeed. With regard to the claim that apixaban was not "protected by the basic patent", cf. article 3a of the SPC-regulation, the court found that apixaban was protected at the time of the application date for the SPC, and that apixaban was structurally individualized and not only covered by functional indications. Apixaban was found to be specifically identifiable, with a specific structure, and also identifiable based on the information in the patent application.

The court thus upheld the patent and the SPC to be valid, and acquitted BMS with regard to the declaratory statement requested by Teva.

Comments
Plausibility has been a hot topic this year, and like in Norway, there have been several patent cases concerning apixaban in

many European jurisdictions (including UK, France and the Netherlands). Since this is the first decision in Norway on plausibility after the Enlarged Board of Appeals decision in G-2/21, this decision is significant. Unlike the case in UK, the Norwegian court seems to have taken what could be perceived as a rather "patent holder friendly" stance on this topic.

Unfortunately, the Norwegian decision is rather scarce with regard to what can be derived from G-2/21, which is rather unfortunate. That the decision of the UK Court of Appeal, which was available prior to the District Court's decision, and which came to the opposite conclusion, is scarcely mentioned by the court, is also somewhat disappointing, in particular since the assessments by the UK court on several parts diverge from the assessments made by the Norwegian court. Given that the UK decision was made available after the conclusion of the oral hearing, the scarce mentioning of the UK decision is nevertheless understandable.

Since the case has been appealed, it is likely that both parties will refer to both the results and the assessments of the various decisions from foreign jurisdictions more extensively in the next round. This case may thus yet provide us further insight into the Norwegian perspective on a topic that is highly debated among patent practitioners in Europe at the moment.

Finding solutions

Haavind