THE SUPREME COURT OF NORWAY

On 11 December 2017, the Supreme Court gave judgment in

HR-2017-2356-A (case no. 2017/1062), civil case, appeal against judgment

GlaxoSmithKline AS (Counsel Ida Elisabeth Gjessing)

v.

Sandoz A/S
Novartis Norge AS (Counsel Thomas Gaarder-Olsen)

V O T I N G :

(1) Justice **Endresen:** The case concerns issues of trademark infringement. The Supreme Court is to consider whether two specific shades of purple are established by use as a trademark for a pharmaceutical drug.

(2) GlaxoSmithKline AS ("GSK") is the Norwegian subsidiary of the group GlaxoSmithKline, a leading manufacturer of drugs for treatment of asthma and COPD (chronic obstructive pulmonary disease). GlaxoSmithKline manufactures, among others, the inhalation drug *Seretide*.

(3) Sandoz A/S is the Danish subsidiary of the Sandoz group, a major manufacturer of generic drugs worldwide. Generic drugs are legal copies of a drug after the patent on the original drug has expired. Generic drugs are composed by the same active ingredients and have the same pharmaceutical form as the original.

(4) Danish Sandoz A/S is licensed to market the asthma and COPD inhalation drug *Airflusal Forspiro* in Norway, and Novartis Norge AS manages the sale and marketing. This distribution of functions between Sandoz A/S and Novartis Norge AS forms the basis for the action brought against both companies. Hereinafter, "Sandoz" will refer to both Sandoz A/S and Novartis Norge AS, unless the context otherwise requires.

(5) Seretide is an inhalation drug for asthma and COPD patients. It contains two different active ingredients: one *bronchodilating* ingredient extending the respiratory passages, and one *anti-inflammatory* ingredient lessening the inflammation. The patients inhale the medicine through a dry-powder inhaler (a Diskus) or by the help of a spray.

(6) Seretide was launched by GSK in 1999 as the first asthma medicine to combine a bronchodilating ingredient with an anti-inflammatory ingredient. This originated a new class of asthma and COPD medicine called combination drugs.

(7) The drug has had enormous commercial success, both in Norway and worldwide. According to statistics from the Norwegian Pharmaceutical Industry Association, Seretide has, since 2000, been among the most sold drugs in Norway measured in sales value, with a turnover of more than 3 billion Norwegian kroner.

(8) At the introduction of Seretide, GSK spent large sums on the marketing. The marketing costs have continued to be substantial; hundreds of millions have been spent in Norway alone. The marketing has been aimed at physicians and pharmacists through brochures, pamphlets, books and other information material. In addition to the inhaler itself being purple, its packing also has purple elements, and purple has been used on commercial material, stands, gifts etc. Seretide Diskus comes in a dark shade of purple (Pantone 2587C, hereinafter referred to as "GSK dark purple") on the lower part of the inhaler and a lighter shade of purple (Pantone 2567C) on the upper.

(9) The GSK group enjoyed patent protection for Seretide until 2014, after which generic versions of the drug have been launched.

(10) Sandoz's drug Airflusal is such a generic version of Seretide. Airflusal contains the same active ingredients in the same proportions as Seretide. *Forspiro* is the name of Sandoz's dry-powder inhaler. It serves the same purpose as GSK's inhaler Diskus, but there are functional and aesthetic differences between the two inhalers. Airflusal Forspiro is purple with white elements. The shade of purple used (Pantone 2573C, "Sandoz purple") is not identical to any of the two shades GSK uses on Seretide Diskus.

(11) Airflusal was introduced in Norway in March-April 2014. Before that, GSK was alone in Norway to use purple as the main colour on inhalers.

(12) Inhalation drugs can be divided into groups based on various criteria. A main distinction is made between anti-seizure drugs (relievers) and preventive drugs (preventers), and both groups may in turn be divided into subgroups.

(13) Anti-seizure drugs have a quick-acting ingredient that makes the muscles in the respiratory passages relax and extend. Preventive drugs have a more long-term effect, either for extending of the respiratory passages or for lessening inflammations. These drugs are taken regularly to control/prevent asthma and COPD and normally not used as anti-seizure drugs.

(14) Both anti-seizure drugs and preventive drugs come in versions giving a more long-term bronchodilating effect. As mentioned, Seretide combines a bronchodilator (*salmetrol*) and an anti-inflammatory ingredient (*flutikason*). In 2001, AstraZeneca entered the market

with *Symbiocort*, a similar combination drug, but with other active ingredients.

(15) Until 2008, Seretide and Symbicort were the only drugs in this class. The number of providers has increased, but Seretide and Symbicort are still bestsellers by far. In 2013, GSK introduced an alternative combination drug called *Relvar*. Subsequently, several generic versions of Seretide and Symbiocort have been launched, including Airflusal in 2014.

(16) A central issue in the case at hand is whether a colour code system, however informal, exists for inhalers, indicating active ingredients and function. Such a colour code system may have an impact on how we perceive the manufacturer's use of colour, and on how material it is, in this field, that a colour is not reserved for a specific product, the so-called *need for availability*.

(17) GSK does not have any trademark registration for the colour purple in Norway. However, in 2016, GSK applied for trademark registration of "GSK dark purple" for asthma and COPD drugs. On 6 January 2017, the Patent Office issued an explanatory statement expressing that the application clearly cannot be granted. GSK has later opposed the procedure, claiming that the Patent Office was biased. The processing of the application has been suspended pending a ruling in the case at hand.

(18) On 6 July 2017, the European Union Intellectual Property Office (EUIPO, previously OHIM) turned down an application from GSK for registration of GSK dark purple as a joint trademark for the EU countries. The decision has been appealed to the EUIPO Board of Appeal.

(19) GSK has taken legal steps in several other jurisdictions to stop Sandoz from marketing and selling Airflusal Forspiro in purple. I find no reason to present these processes in further detail, as they mainly concern issues that are not relevant to the case at hand.

(20) In April 2014, almost immediately after the introduction of Airflusal in Norwegian pharmacies, GSK petitioned for a preliminary injunction demanding that the sale of the product be stopped and withdrawn from the market. The basis for the claim was the Marketing Control Act sections 30 and 25. In a ruling of 8 May 2014, Oslo County Court dismissed the petition. GSK appealed the ruling to the court of appeal.

(21) Before the county court, GSK asserted a parallel case between the parties in Germany. The German court had ruled in favour of a preliminary injunction stopping Sandoz from selling Airflusal Forspiro in Germany. GSK argued that the German decision must be regarded as an important source of law in the case in Norway. Following a preliminary statement from the German court of appeal, GSK Germany withdrew its appeal, with the result that the appeal against the ruling of Oslo Probate Court was also withdrawn.

(22) GSK brought an action against Sandoz A/S and Novartis Norge AS by a writ of summons of 28 October 2014 demanding a prohibition against the marketing and sale of purple-coloured Airfusal Forspiro. A claim for damages was also submitted. The action was based on both possible infringement of established trademark rights and breach of the Marketing Control Act section 25.

(23) On 29 October 2015, Oslo District Court gave judgment concluding as follows:

> **"1. Judgment is given in favour of Sandoz A/S and Novartis Norge AS.**
>
> **2. GlaxoSmithKline AS will pay costs to Sandoz A/S and Novartis Norge AS jointly in the amount of NOK 1 439 563 - onemillionfourhundredandthirtyninethousandfivehundredandsixtythree within 2 – two – weeks from the serving of this judgment "**

(24) GSK appealed the district court's judgment to the court of appeal. On 20 April 2017, Borgarting Court of Appeal gave this judgment:

> **"1. The appeal is dismissed.**
>
> **2. GlaxoSmithKline AS will pay costs to Sandoz A/S and Novartis Norge AS jointly in the amount of NOK 2 110 750.10 – twomilliononehundredandtenthousandsevenhundredandfifty 10/100.**
>
> **Time for performance is two weeks from the serving of this judgment."**

(25) GlaxoSmithKline AS has appealed the court of appeal's judgment to the Supreme Court. Before the Supreme Court, the allegations regarding breach of the Marketing Control Act have been abandoned, and it is no longer held that the purple in general is a trademark for Seretide established by use. Instead, it is held that trademark rights have been acquired for GSK dark purple and Sandoz purple.

(26) Leave to appeal was granted by the Supreme Court's Appeals Selection Committee on 14 July 2017. In accordance with the Dispute Act section 30-14 subsection 3, the Committee decided to limit the appeal only to concern the issue of whether a trademark right has been acquired pursuant to the Trademarks Act section 3 subsection 3. Hence, the result must be that the court of appeal's judgment is set aside if the appellant is supported in its claim that such a right exists. A continued hearing of the issue of infringement of a possible trademark right would have to take place before the court of appeal.

(27) The appellant, *GlaxoSmithKline AS*, has mainly contended:

(28) The court of appeal's conclusion is incorrect, as the judgment is based on errors in the findings of facts and error in law.

(29) It must be assumed that GSK, through a long-term, consistent and exclusive use has established the said shades of purple as signs for asthma and COPD inhalers in the relevant circles of trade, see the Trademarks Act section 3 subsection 3.

(30) A trademark is considered to be established by use "when and for as long as it is well known in the circle of trade in Norway for the relevant goods and services as someone's sign", see the Trademarks Act section 3 subsection 3.

(31) It is indisputable that a colour may be someone's sign – i.e. a trademark – that can be registered. Such a trademark can also be established by use. I refer to the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES) and Lassen and Stenvik, *Kjennetegnsrett* [Sign law] (3rd edition) pages 116–117.

(32) The court of appeal has assumed that the patient group is also to be comprised by the circle of trade. This is unfounded. The circle of trade must be identified based on the concerns that justify the possibility of establishing trademarks by use. One must first identify the person making a purchase decision, at whom it would be natural to aim the marketing. Prescription drugs can only be marketed to physicians and pharmacists, as such marketing to the patient group is illegal pursuant to the Pharmaceuticals Regulation sections 13-5 and 13-7. The introduction of e-pharmacies does not change this; it does not give the patients greater influence on the choice of drugs. Moreover, the considerable marketing efforts by the appellant have been exclusively aimed at physicians and pharmacists. In any case, a trademark may be established by use in one specific circle of trade; it is not necessary that establishment has taken place within all circles of trade.

(33) The combination drug Seretide was a novelty when launched in 1999. The absence of other products within the relevant segment using purple for profiling gave GSK an opportunity to establish a trademark for the colour, and GSK took this opportunity. Purple was from day one a central part of the branding. The colour was used because it stood out from other colours used on inhalers for asthma and COPD drugs. Even after the launch of new products, GSK's dominant market position has yielded enough attention to the use of purple for the colour to have been established as a sign.

(34) Sandoz's allegation that a colour code exists for inhalers is disputed. Combination drugs with the same application as Seretide are currently found in various colours, on inhalers, packing etc. Also, the colour use is increasingly versatile for other types of inhalers. Thus, there is no basis for submitting that the colour describes the active ingredient in the drug and thus also its function. Purple used in this context describes neither active ingredient nor function, but constitutes a commercial sign.

(35) GSK's inhaler is fully covered in two shades of purple. Purple is also generally used on the packing and marketing material. When purple is used consistently for this type of drug over a long period of time, and thus become a sign, the requirement for distinctiveness has been met. It has been established that the intensity, duration and extent of the use are important aspects in the assessment. Substantial investments in the branding and the consistent use of purple in all communication to the target groups create an assumption that the circle of trade perceives purple as a trademark for Seretide.

(36) The market surveys carried out strongly support that purple has acquired a distinctiveness by use. An overwhelming share of physicians and pharmacists perceive purple as a sign for one manufacturer. The surveys have applied a well-established method, see the German supreme court's judgment of 21 July 2016 (Sparkassen). This method was also considered in the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES), where the results of the market survey were deemed crucial.

(37) The criticism raised by Sandoz against the surveys is unfounded, at least with respect to the last three surveys asserted in our case. The questions were open and suited for the purpose. There are no facts to substantiate that a colour code has been established to indicate the inhaler's application. There may previously have been indications of that, but today, the use of colour is highly inconsistent. A colour code for combination products does simply not exist.

(38) GlaxoSmithKline AS has submitted this prayer for relief:

> **"1. The judgment of Borgarting Court of Appeal of 20 April 2017 is to be set aside.**
>
> **2. GlaxoSmithKline AS is to be awarded costs before Supreme Court."**

(39) The respondents, *Sandoz A/S and Novartis Norge AS*, refer to the court of appeal's judgment, and have mainly contended the following:

(40) Before the Supreme Court, the case no longer concerns purple in general, but the two shades GSK dark purple and Sandoz purple. GSK has not used Sandoz purple. On the contrary, this is the shade used by Sandoz on its inhaler Airflusal Forspiro. It would be contrary to basic principles in trademark law if a manufacturer were to be allowed to benefit from goodwill earned by someone else. If the Supreme Court should find for the appellant with regard to GSK dark purple, the court of appeal will have to assess whether Sandoz's use of Sandoz purple constitutes a trademark infringement, and the outcome of such an assessment cannot be anticipated.

(41) Hence, this case concerns the shade 2587C, which is one of the colours used by GSK to decorate its inhaler Diskus.

(42) It cannot be excluded that a colour as such can be registered as a trademark, but a colour will normally lack the required distinctiveness, and like for other descriptive trademarks, the threshold for acquiring protection through registration is high. A general need for availability applies for colours.

(43) Although the case concerns the establishment of a trademark by use, the Trademarks Act section 14 subsection 2 a gives valuable guidance. A trademark cannot be registered if it indicates the nature of the product. In this particular case, colour had been used as a description of the type of drug long before Seretide was introduced in the market with the particular shade of purple. Colour codes were already established. Although the colour code system is not publicly regulated or otherwise formally recognised, and although there are variations, there is an extensive use of colour codes to indicate active ingredients in the industry and among the patients. If, nevertheless, it should be possible to obtain trademark protection for a colour, the threshold would be extremely high.

(44) In order to identify potential establishment by use, it must be borne in mind that the circle of trade is not used to perceiving a colour as an indication of commercial origin. On the contrary, the colour applied will normally be regarded as a decorative element, or as an indication of function. This suggests that the colour use will not be perceived as a sign.

(45) The European Court of Justice has several times established that the end users are comprised by the circle of trade. The issue has rather been whether other retail links can. The approach was the same in the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES); the circle of trade is comprised by those who pay for the product or the service. As concerns the relevant type of drugs, it must be assumed that the patients actually have an impact on which drug to take. One of the surveys carried out for the patient group, confirms that this group does not to a sufficient degree associate the colour purple with one manufacturer only.

(46) It is undisputed that market surveys may sometimes be important to clarify whether a trademark is established by use as a sign for a product, but this hardly applies when the trademark is a colour. The surveys in question illustrate this; they reveal the level of knowledge of the colour use, but say nothing about whether the participants have perceived the colour as a trademark. Moreover, several objections have been raised against the structure of the surveys that are now being asserted and how they were carried out.

(47) Sandoz A/S and Novartis Norge AS have submitted this prayer for relief:

> **"1. The appeal is to be dismissed.**
>
> **2. GlaxoSmithKline AS is to cover the costs of Sandoz A/S and Novartis Norge AS before the Supreme Court."**

(48) *I have found* that the appeal must be dismissed.

(49) Before the lower courts, GSK held that purple had been established by use as a trademark for asthma and/or COPD drugs. Before the Supreme Court, this approach has been abandoned, as the only submission now is that trademark rights have been acquired for the two shades GSK dark purple and Sandoz purple.

(50) It has not been held that GSK has used Sandoz purple in the marketing of any product in the relevant group of drugs. Hence, a trademark for this shade cannot be deemed to have been established by use.

(51) If GSK should be supported in its submission that it has acquired trademark rights to GSK dark purple, the question is to which extent this would prevent others from using other shades of purple on alternative products. In its appeal to the Supreme Court, GSK claims that the consequence is that shades which physicians and pharmacists are unable to distinguish from GSK dark purple in a sales situation cannot be used either. Whether the use of Sandoz purple would constitute a trademark infringement, would have to be decided by the court of appeal. Such a decision cannot be anticipated by presenting an independent claim for an exclusive right to use a shade of purple that has actually been used on the competing product.

(52) Hence, the subject matter is whether GSK has acquired trademark rights by the use of GSK dark purple in its marketing of asthma and COPD drugs.

(53) It is clear that this shade of purple is one of two used on the inhaler Diskus since its introduction in 1999. It has also been documented before the Supreme Court that GSK has made extensive use of different shades of purple in its marketing of Seretide/Diskus. This has been well documented before the Supreme Court. However, the documentation lacks information as to *when* the use of GSK dark purple has taken place. While the overall use of purple in the marketing may leave the impression that GSK dark purple is GSK's sign, establishment by use must primarily be by use of GSK dark purple. Special weight must then be placed on the use of this particular shade. The lack of consistency in the colour use may also influence the natural perception of the same. I will revert to this.

(54) The condition for acquiring a trademark right is described as follows in the Trademarks Act section 3 subsection 3:

> **"A trademark right is acquired without registration when the trademark is established by use. A trademark is considered to be established by use when and for as long as it is well known in the circle of trade in Norway for the relevant goods and services as someone's sign. …"**

(55) In Proposition to the Odelsting no. 98 (2008–2009) The Trademarks Act, it is emphasised on page 42 that the term "sign" reflects a requirement that the trademark must have sufficient distinctiveness to qualify as a sign for the goods or services it question. It is also emphasised that the conditions for establishment is a continuation of previous law. Attention should thus be paid to the description of the requirement in previous preparatory works. In Proposition to the Odelsting no. 59 (1994–1995) Act relating to amendments to the legislation on industrial legal protection, the following passage of the Patent Law Committee's recommendation with regard to the Trademarks Act 1904 is referred to as clarifying:

> **"The term 'well known' implies that the trademark in the circle of trade must not in itself be known as the owner's product description, but also be generally considered as a trademark, which by virtue of its use evolves on its owner in such a way that its use by others according to the perception within the circle of trade will constitute an impropriety that infringes the trademark right acquired by the owner.**

(56) This is also how the Trademarks Act section 3 subsection 3 is interpreted in practice and in theory.

(57) Hence, the statutory requirement is that the shades of purple asserted as trademarks established by use must not only be well known, but also well known as someone's sign.

(58) The Trademarks Act section 14 subsection 2 a, which governs the registration of a trademark directly, is also significant to determine establishment by use if the trademark consists exclusively of signs indicating the kind, quantity or other features of the product. Nevertheless, such a trademark may still be established by use, but the use will not naturally be perceived as anything other than what the trademark directly expresses. In the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES) para 48 this is described as follows:

> **"Hence, it takes a lot before a descriptive trademark is sufficiently established by use to be eligible for registration. This is because the issue is not only whether or not the trademark is well known, but also whether it has acquired such a distinctiveness that it may function as a sign for someone's goods or services. But establishment by use may be the result if the trademark has been promoted so intensively that it has acquired a different meaning than merely being a generic term. Where that is the case, the need for availability will not prevent registration. This is set out in, among others, the EEC Court of Justice's ruling C-108/109/97 (C-108/97) CHIEMSEE premises 44 and 47."**

(59) In the said ruling para 57, the justice delivering the leading opinion also agrees that a conclusion whether the requirements for distinctiveness are met must be based on an overall assessment. This assessment must include the elements that may determine whether the trademark has been being used to communicate that the product comes from a specific manufacturer. When determining establishment by use, the assumed perception of the trademark within the circle of trade is significant.

(60) Before I turn to the circumstances I believe are crucial in the case at hand, I will make some general remarks on the case law from the EU bodies and on the overall issue of whether it is possible to acquire trademark rights to a colour.

(61) The conditions for establishment by use are not comprised by the Trademarks Directive [Council Directive 89/104/EEC], see recital 5 in the preamble, and the rulings of the European Court of Justice will not have the same application as in issues comprised by the Directive. However, this does not mean that the case law of the European Court of Justice and other EU bodies is irrelevant. The fact that the individual state may regulate the terms for establishment by use does not imply it would be disadvantageous to have coinciding rules also in this field. In the absence of express Norwegian special regulations, the emphasis on EU case law seems justified. In this regard, I refer to the Supreme Court judgments Rt-2005-1601 (YELLOW PAGES) para 57 and HR-2016-1993-A (Pangea) para 46. The first refers to a ruling by the European Court of Justice concerning whether a descriptive trademark had become sufficiently distinctive by use, and the second stresses the relevance of decisions from the European Union Intellectual Property Office.

(62) According to case law from European Court of Justice, it is possible under the circumstances to have a colour registered as a trademark, and such registration may also take in place in Norway. I cannot see that there is a basis for excluding this possibility in connection with establishment by use.

(63) However, based on what I have already said about descriptive marks in general – it takes a lot. I find further guidance in examining the requirements tailor-made for the registration of colours as trademarks.

(64) The following is stated in Lassen and Stenvik *Kjennetegnsrett* [Sign law], third edition page 116:

> **"Colours *are capable* of being represented graphically, and may therefore be trademarks within the meaning of the Trademarks Act (section 14 subsection 1 first sentence, cf. the Trademarks Directive article 2, see details in chapter 1, I, 2). However, not all forms of representation are accepted. Generic colour descriptions such as 'orange' or 'green' are normally deemed too vague; they cover too many shades. And the presentation of a specific shade on a piece of paper is not tenable as it may fade with time. However, an international colour code would be both precise and tenable, and must therefore be generally deemed to mee the requirement for a graphic presentation (see the EU Court of Justice's decisions C-104/01 Libertel […] premises 2 -37 and C-49/02 Heidelberger Bauchemie […] premise 42).**
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> **If the colour or the combination of colours is to be *accepted for registration*, it must also have such distinctiveness as is required in the Trademarks Act section 14 subsection 2, and it must not indicate the product's qualities, see section 14 subsection 2 a. Colours seldom actually meet the requirements set herein. In the same way as for product equipment, the consumers are not in the habit of perceiving a colour as a means of individualisation – as an indication of the product's commercial origin – but rather as an aesthetic choice, as being natural for the material etc. (Libertel, premise 65). When seeing a yellow chewing gum, one may think that it tastes of lemon, and when seeing a green lawn mower, one may think the colour is chosen to make the product look attractive. Moreover, for colours there will be a stronger *need for availability* than for words and figures. Indeed, there are countless shades of colour, but the consumers' ability to distinguish them from each other – when not being able to compare them side by side, but seeing them on separate occasions – is limited. The use of**

> **adjacent shades of colour may entail a risk of confusion, which means that the range of colours available would soon be exhausted, if colours were to be commonly registered. (Libertel, premiss 54)."**

(65) On the next page, the authors conclude that the admission to register a colour as a trademark is extremely limited, but that colours like other trademarks originally lacking distinctiveness, may "strive to obtain the requirement distinctiveness through establishment by use".

(66) In my view, this forms a useful basis for the individual assessment of whether GSK's colour use is consistent with the Trademarks Act section 3.

(67) A central issue in the proceedings also before the Supreme Court is whether there exists a colour code for asthma and COPD drugs. The court of appeal has thoroughly reviewed evidence presented in this respect, and I quote:

> **"… Based on the evidence presented, the court of appeal deems it clear that colours to a large extent have been used to visually support the written information about the purpose/function and the strength of the product. It started in 1970 when Ventolin, an anti-seizure drug, was introduced on the market with a clear blue colour on the inhaler. Later, drugs with the same function and the same colour were introduced by other manufacturers. A couple of years later, GSK entered the market with Becotide, an anti-inflammatory drug. This product was marketed with a brown colour.**
>
> **Subsequent colour use has not been entirely consistent, but the manufacturers of inhalation drugs have since 1970, with no exception, been using a blue colour on the user equipment for anti-seizure drugs. For anti-inflammatory drugs, steroids, the manufacturers have largely used red, orange or brown on the user equipment. Extensive documentation has been submitted showing that colours were used to communicate the purpose of the drugs along with the introduction of new drugs with other active ingredients and other functions. Below are a few examples.**
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> **In *Norsk elektronisk legehåndbok* [Norwegian online physicians' manual] (23 April 2012), it is stated that some inhalers have a colour code that makes it easy to separate them from each other. The examples of colour use are as described above, and in addition, purple is stated to be the colour of combination drugs. *Fagblad for lungesykepleiere* [Journal for pulmonary nurses], no. 1-2013, provides an overview in colour of the main groups of inhalation drugs, active ingredients, effect etc. It is pointed out that the background colours are not randomly picked since 'most drugs, with the exception of some of the new, follow colour codes'. Then a summary is provided of the colour use in line with what is mentioned above.**
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> **In an undated publication from *Privathospitale*t regarding the treatment of asthma for adults, advice of use is given with the same colour references in addition to text.**
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> **The National Competence Network for Pharmaceuticals for Children uses, in its information from July 2013, the term colour codes. Regarding the use of inhalers, it is stated that the plastic containers 'have different colour codes indicating the medicine you are taking. See the colour under the name of your medicine'.**
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> **Several examples from other countries have been presented of information material on asthma inhalers indicating that colour is descriptive for the different types of drug. Mentioned examples are a brochure from the UK National Health Service of December 2016 and a brochure from the Danish Pharmacists Association.**
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> **The witness Nils Ringdal, retired specialist in pulmonary deceases, held that an informal colour code existed in practice for asthma and COPD inhalation drugs that distinguishes between different main types of drug. He himself had used the colour scale**

in his communication with patients because to help them know which drug to take. He stated that the colour codes were highly advantageous from the patients' perspective since they contributed to reducing the risk of confusing drugs with the serious consequences that could have. His experience was also that the choice of inhaler was often made in consultation with the patients based on the individual wishes and preferences within the options present for the relevant type of drug.

GSK uses the same colour scale as mentioned above on its inhalers. Seretide Diskus is currently sold in blue, green, brown/orange and purple. All variants have the same shape, but the colours indicate the function: blue for seizures, orange/brown for anti-inflammation, green for prevention and purple for the combination drug.

When GSK in 2013 launched Relvar, a generic product of Seretide, in blue, this caused reactions. In a report published on 19 February 2014 Lead Respiratory Pharmacist, Leeds Teaching Hospital NHS Trust, the following is set out:

> **For many years, pharmacists and other healthcare professionals have been educating patients on when to use their inhalers for asthma and COPD, and frequently use simple terms such as 'reliever' or 'blue inhaler' to advise patients when to use their salbutamol or terbutaline, and terms such as 'preventer' or 'brown, red or purple inhaler' to advise patients when to use their inhaled corticosteroid inhaler.**
>
> **We are concerned that the new Relvar Ellipta inhaler will be confusing for patients because it has a blue cover and the brand name sounds similar to 'reliever'. This could cause patients mistakenly to use Relvar Ellipta on an 'as needed' basis rather than regularly just once a day.**
>
> **When we have shown pictures of the new Relvar Ellipa inhaler to patients and healthcare professionals, almost all have thought that this looked like a reliever inhaler and that it should be used when necessary for symptomatic relief.**

As a result, GSK changed the colour of the product to yellow. Although GSK contested the basis for the warning, the case illustrates that there was a firm opinion among professionals that the colour used on asthma and COPD inhalers are perceived as describing the medicine's function.

Colour is also used as a visual description of the strength of the drug, since paler/weaker shades are used on the spray aerosol versions to indicate weak strengths and stronger/brighter colours to indicate a higher concentration of active ingredients. This appears to be more rational; colour is used as additional information easily accessible for all, both professionals and patients. The court of appeal cannot see that such a systematic use of a colour scale on the user equipment has any rational purpose other than being an easily recognisable indication of the strength of the drug. The fact alone that colour shades are used to indicate strength suggests that GSK has not established by use certain shades of purple as a trademark.

Based on the evidence presented, the court of appeal finds that manufacturers of asthma and COPD inhalation drugs have systematically used colour to indicate the purpose and function of the relevant types of drug. Whether or not the colour is chosen for aesthetical purposes, or as an eye-catcher, is irrelevant in this assessment.

GSK has held that no colour code system exists, and referred to the varying colour use in most function areas for these drugs. The court of appeal agrees with GSK that no formal – or officially recognised - colour code system exists for asthma and COPD inhalation drugs. It is also correct that the colour use is less consistent than earlier. Nevertheless, the court of appeal deems proved that the industry over time has exercised an increasing use of colour codes for this type of drug. When assuming that colours for years have been extensively used as visual product information in addition to text to

> **distinguish between inhalation drugs with various functions and various active ingredients, the court of appeal finds that it takes a lot before a new colour on a new type of inhalation drug acquires the distinctiveness required to earn trademark protection. This applies in particular when the new colour – in this case purple – was a likely choice for a combination drug consisting of two components, where the blue colour code has been used consistently on one of them and a red colour code, at least partially, for the other. In his witness statement, pharmacist Ekroll Aarvold also expressed that purple was a natural choice of colour based on a colour code system."**

(68) The evidence presented before the Supreme Court gives no basis for reaching a conclusion different from that of the court of appeal. Rather, it is so that more evidence has been presented that support this conclusion. In his written statement to the Supreme Court, physician Nils Ringdal states the following:

> **"Many of the lectures I held arranged by GSK were on Seretide, and in that respect it has been natural to talk about colour codes on inhalers. I never received any response from GSK as to whether purple was not a colour code as opposed to the other colours."**

(69) Professor Leif Bjermer, who has given an expert witness statement before the Supreme Court for GSK, expresses it like this:

> **"In the 1990s, when there were not that many inhalers to choose from, colour was also used to indicate the type of medication. For example, Bricanyl and Ventoline came in different shades of blue while Pulmicort and Becotide came in different shades of brown. This taught the patients to distinguish between the blue anti-seizure drug (beta-2) and the brown preventive drug (inhaled cortisone), thus one may say that a certain colour code did exist."**

(70) Professor Bjermer stresses that in his view this has changed, but the statement is nevertheless relevant, especially since Seretide was introduced in 1999. If purple at that time, based on the use established, was naturally perceived as a continuation of the colour code system, one cannot conclude that this perception of the colour use was changed as a result of a subsequent and less consistent compliance with the colour codes

(71) For the same reason, it is also relevant that GSK itself referred to the established colour code when introducing Seretide in 1999. In the company's brochure "Adult asthma patients", the various drugs were introduced under headlines in different colours. Blue was used for 'relievers', orange was used for 'preventers', green-blue was used for 'symptom controllers' and purple was used for combination drugs, i.e. 'relievers' and 'preventers' in one and the same inhaler. This colour use indicates that GSK, with the introduction of Seretide, did not have as its primary object to include purple as a colour to identify the enterprise, but that it planned to extend the colour code to comprise purple for combination drugs, of which GSK, at the time, was the sole provider.

(72) This use of colour codes is significant irrespective of whether the colour use has not been consistent and of whether the it may not have been generally known in the circle of trade. This was clarified in particular in the European Court of Justice's ruling C-191/01 *Doublemint* of 23 October 2003. In para 44 of the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES) the justice delivering the leading opinion presents the essence of the European Court of Justice's ruling as follows:

> **"… In the DOUBLEMINT ruling, the EC court thus held that it is sufficient for excluding a descriptive trademark from registration that 'at least one of its possible meanings identifies a quality of the relevant products or services' and that it is not a**

requirement, on the date of registration, that it is actually used as a descriptive term in the market."

(73) The fact alone that the use of colour codes *may* serve as important user guidance will thus contribute to strengthen the need for availability on the relevant area.

(74) GSK has not used purple in its marketing of the company and its products in a way that generally links the colour purple to the company. If the circle of trade is meant to perceive purple inhalers as GSK's sign, this alone must derive from the company's use of purple as the colour for asthma and COPD drugs. But also within this limited area, GSK's colour use is inconsistent, and it is clear that the colour found in other asthma and COPD drugs marketing is not used as a sign for these drugs. GSK's reliever Ventoline is blue, yet no objections were raised when other manufacturers also chose blue for their corresponding drug.

(75) GSK has used numerous shades of purple in its marketing. Provided that it cannot be reasonably expected that a trademark has been established by the use such of a broad colour spectre, the lack of consistency implies that any establishment of a sign for Seretide has not been conscious. The inconsistent use also makes it less likely that the colour has been perceived as a sign, see the ruling by an appeal court within Office for Harmonization in the Internal Market of 1 July 2005 in R 799/2004-1 – Blue and Yellow (Colour Mark).

(76) There is nothing unusual about the use of purple on various drugs. Purple is used in a number of settings by a number of companies. Purple is to some extent also used in the profiling of companies. It is significant that GSK's main competitor on asthma and COPD drugs, AstraZeneka, uses purple in its logo, and that the company has added a purple detail to the red and Symbicort inhalers.

(77) Establishment by use of a product's sign may represent material goodwill, and the protection of this value is makes basis for the rule in the Trademarks Act section 3 subsection 3, see the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES) para 64. This concern must then be held up against the opposite concern for the need for availability. The concern for acquired goodwill will naturally have less weight where the signs established by use only have a limited impact on the buyer's decision. In the case at hand, one must assume that physicians will primarily prescribe drugs based on the patient's condition. Moreover, it follows from the Blue Prescription Regulation of 28 June 2007 no. 814 section 7 subsection 3 that the physicians have an obligation to prescribe the least expensive medicine unless weighty reasons suggest otherwise.

(78) My overall view is that the circumstances to which I have referred imply that GSK dark purple is not perceived as a sign for Seretide/Diskus. The issue is whether the market surveys carried out must be deemed to document that establishment by use has nevertheless taken place, so that the conditions in the Trademarks Act section 3 subsection 3 are met.

(79) Whether or not a trademark has been sufficiently used to qualify as a sign is an ordinary evidentiary issue. As in other cases, the evidence must be subject to a free assessment comprising the relevant evidentiary aspects.

(80) To clarify how widely known a sign, or a colour, is as special for a product, it may be appropriate to carry out market surveys, which under the circumstances may be given great weight. This is not controversial. The significance of such surveys must be determined in each case. In the Supreme Court judgment Rt-2005-1601 (YELLOW PAGES), the majority concluded that the sign was sufficiently established by use, and emphasised the market survey carried. The minority came to the opposite conclusion, but that was not due to a different principal view on the significance of the survey, but a deviating individual assessment of the evidence presented.

(81) GSK has commissioned several market surveys aimed at general practitioner physicians, pharmacists and some patients have received questions aiming to establish whether purple has been established by use as a trademark for Seretide. Expert witness for Sandoz, Doctor Anne Niedermann, had numerous objections to the first survey in Norway in 2014. This survey has not been asserted before the Supreme Court. In 2015, a new survey was carried out aimed at physicians and pharmacists concerning GSK dark purple. In 2016, another two were carried out, one of which concerned the same shade and was aimed at asthma patients or their superiors. The second survey was aimed at physicians and pharmacists. This survey concerned Sandoz purple, which is the shade used on the inhaler Airfusal Forspiro. The purpose of the survey was to find out whether this shade also is associated with Seretide and GSK.

(82) For a market survey to have significance, it must be aimed at the relevant circle of trade, see the Trademarks Act section 3 subsection 3. I will therefore first consider which relevant circle of trade is relevant in this case.

(83) The appellant has asserted that the circle of trade for prescription drugs must be physicians and pharmacists. The patient does not choose which drug to be prescribed. The correctness of this approach is, according to the appellant, confirmed by the prohibition against aiming the marketing of such drugs at the patient group. The respondent, on the other hand, has mentioned in particular that patients do participate in the decision-making process, and, with reference to Rt-2005-1601 (YELLOW PAGES) para 56, held that decisive weight must be placed on who pays for the products.

(84) To me, the judgment asserted by the respondent does not generally establish that it is decisive who pays for the product. It was clearly relevant in that particular case, but the underlying determining factor was that the service was *the sale of adverts,* thus the relevant circle of trade had to be the buyers of the adverts.

(85) The determination of the circle of trade must be based on the object of the rules governing establishment of trademarks, so the question is who may directly or indirectly influence someone's decision to buy a product. The circle of trade must then be adjusted to the trading pattern of the relevant product. It is far from certain that the circle of trade is identified that way for all prescription drugs. The case at hand concerns drugs that are mainly used by patients with a chronic condition who undoubtedly have a particular interest in the choice of drugs. The patients may experience different effects of the different products, and their feedback is crucial for which drugs to prescribe. Based on the evidence presented before the Supreme Court, it must also be assumed that the patients are actually involved in the decision-making process, and must be considered a natural part of the circle of trade.

(86) Also, for drugs included on the list of products from alternative providers ('swap list'), it is so that although the physician decides which drug to prescribe, the patient may freely choose to buy an alternative with the same function, see the Blue Prescription Regulation section 8 subsection 3. Potential extra costs must be covered by the patient, but the patient has the final word.

(87) My preliminary view is that the patients must be comprised by the circle of trade for the group of drugs involved in the case at hand. Nevertheless, it may be appropriate to examine whether EU case law suggests otherwise.

(88) Of particular interest is the European Court of Justice's rulings C-371/02 *Björnekulla*, judgment 29 April 2004 and C-412/05 *Travatan*, judgment 26 April 2007. Paras 23-25 of the first judgments read as follows:

> **"(23) If the function of the trade trademark as an indication of origin is of primary importance to the consumer or end user, it is also relevant to intermediaries who deal with the product commercially. As with consumers or end users, it will tend to influence their conduct in the market.**
>
> **(24) In general, the perception of consumers or end users will play a decisive role. The whole aim of the commercialisation process is the purchase of the product by those persons and the role of the intermediary consists as much in detecting and anticipating the demand for that product as in increasing or directing it.**
>
> **(25) Accordingly, the relevant classes of persons comprise principally consumers and end users. However, depending on the features of the product market concerned, the influence of intermediaries on decisions to purchase, and thus their perception of the trade trademark, must also be taken into consideration."**

(89) The starting point is clearly that the end users constitute a part of the circle of trade. The Travatan case concerned drugs and has direct relevance to our case. That case also questioned whether physicians etc. were to be comprised by the circle of trade. In para 57 the following is stated, after that being established:

> **"However, contrary to what the applicant claims, the fact that intermediaries such as healthcare professionals are liable to influence or even to determine the choice made by the end-user is not, in itself, capable of excluding all likelihood of confusion on the part of those consumers as regards the origin of the goods at issue."**

(90) No ruling has been presented before the Supreme Court excluding patients from the relevant circle of trade, and there is no reason to do so in a case like ours, where one has every reason to believe that the patients to a large extent interact with the physician in the decision-making process, and thus have an impact on which drug is being prescribed.

(91) On the other hand, the arguments given in the two rulings by the European Court of Justice in favour of including physicians and other health personnel in the circle of trade make one ask whether pharmacists should have been included in the surveys. When it comes to prescription drugs, the pharmacists will primarily deliver the drug prescribed. If the drug is included on the 'swap list', the pharmacist has a duty to inform the patient of the alternative and cheaper drug, and if the patient insists on buying the prescribed product, the patient must be informed of the economic consequences of that choice. Hence, it is not granted that the pharmacists have such influence on the patients' choice in this situation that they constitute a natural part of the circle of trade.

(92) It would not be appropriate to operate with more than one circle of trade in the case at hand, as the circle of trade is not geographically defined. When the various groups comprised by the circle of trade act in the same market, special rights granted to one group will in practice function as special rights for all marketing towards the circle of trade.

(93) To finally determine whether the scope of establishment by use would be sufficient, the level of establishment required should in principle be identified first, subject to the special need for availability for a colour, and not to mention the need to continue, strengthen and/or extend the established colour code. The various groups comprised by the circle of trade would have to be considered next, and it would be necessary to address the various methodical objections raised against the surveys.

(94) If the circle of trade is corrected the way I have described, the knowledge measured by the surveys would hardly be sufficient for acquiring trademark rights, even though it is assumed that the knowledge measured in the circle of trade does demonstrate that GSK dark purple is perceived as a sign for Seretide. However, here, I find that the methodology of the surveys is so unsuited to clarify the extent to which purple is perceived as a sign, that the procedure I have indicated is not necessary.

(95) I take as a starting point the general concern that while it is normally feasible to map the actual knowledge of the use of the trademark, it might be far more difficult to clarify whether the person possessing such knowledge and knowing that the trademark can be associated with a manufacturer, have also perceived the trademark as a sign. As illustrated, the results from the market surveys may just as well be due to knowledge of both the colour use and of the manufacturer of the relevant drug.

(96) The appellant has strongly emphasised that international case law has demonstrated that the method applied in the market surveys is correct. A special reference is made to the so-called three-step method, which is held to be widely applied in Germany, and the appellant finds that it would be unfortunate if other rules should apply under Norwegian law than those in other parts of Europe. In this respect, the German Supreme Court's ruling in the Sparkassen case, see BGH, 21 July 2016, in case I ZB 52/15, has been mentioned in particular.

(97) I find no reason to elaborate on which rules should apply to such market surveys; it is clear that no method exists that may be deemed satisfactory without having to assess specifically whether the method answers the questions that the case raises. The appellant has emphasised that the method used in the relevant surveys coincide with the method used in the survey relied on by the Supreme Court in Rt-2005-1601 (YELLOW PAGES). That may well be the case, but it does not mean that the method is appropriate in the case at hand, and by no means that the results from the survey will have the same impact. The market surveys will have to be included as a part in the overall assessment of evidence.

(98) I will now turn to the market surveys carried out by GSK. Various objections may be raised against them that cannot automatically be discarded. In my view, however, it is not necessary to account for and consider to which extent these aspects of the completion of the surveys may have influenced the results. In any case, I cannot see that it has been identified to which extent the participants have perceived the colour as one manufacturer's

sign. The surveys indicate how many associate purple inhalers with one manufacturer, but this does not, as the case stands, give a basis for concluding that purple is perceived as a *trademark*. It seems far more likely that the answers reflect knowledge regarding both the product and the manufacturer.

(99) There are alternative and reasonable explanations to the answers given, suggesting that the colour in this particular field cannot reasonably be assumed to be perceived as a sign. The colour code applied to indicate active ingredients and function strongly suggests that the colour has not been perceived in that way. It seems more likely that the answers are based on knowledge of the drug Seretide, that the inhaler Diskus comes in two shades of purple and that GSK is the manufacturer. Nothing suggests that the participants in the survey conclude from the fact that the product is purple that GSK is the manufacturer. The knowledge of who the manufacturer is rests primarily on a different basis. Thus, under the circumstances, it cannot be deemed substantiated that the participants who replied that they thought the purple inhaler came from a specific manufacturer did so because they believed that purple was used as a sign for this provider.

(100) In other contexts, the fact alone that the trademark is well known may be a basis for concluding that it is also known as a sign. Based on the overall presentation of evidence in the case at hand, of which the market surveys are a part, there is no reason to believe that this is the case. The differences in result for the three groups participating in the survey indicate the same.

(101) Seretide/Diskus is a mass product. According to the documentation presented, as many as 200,000 units of Diskus are sold in Norway annually, which means that each pharmacy sells an average of one Diskus every day throughout the year. Evidently, most pharmacists know that Seretide/Diskus is purple and that it is sold by GSK; it is a best-selling drug. However, this knowledge is not an indication of purple being perceived as a sign.

(102) The group of physicians is more complex; it also comprises physicians who have prescribed the relevant drugs to a limited extent. Nevertheless, one must assume that most of them will know that there are two main competitors in this field, and that GSK is one of them. Many of them will know Seretide/Diskus and that it is purple. With the established use of colour to indicate active ingredients and function, the physicians will also have had greater reason to note the colour by virtue of their profession. Doctor Ringdal, with special expertise and long experience in the field, is not representative for the group, but his statement is nevertheless illustrating. He emphasises that he has prescribed around 100,000 Seretide inhalers in the course of 15 years, and that he, of course, knows what they look like. He also knows that GSK has manufactured the vast majority of purple inhalers. If he were asked what he associates with a purple inhaler, he would reply Seretide or Diskus, but he does not agree that purple is to be perceived as a sign for this drug.

(103) In the group consisting of users of asthma and COPD drugs and their superiors, the knowledge is significantly poorer, and the figures are so scarce that they are harder to interpret. Generally, one should also expect far less knowledge within this group; it may be assumed, from statistics, that that many of them only take other drugs than Seretide, and it must expected that they have limited knowledge of the use of colour on drugs that they do not take. Such an assumption seems to be confirmed by the fact that only 19

percent reply that they have seen the colour purple in connection with inhalers before, and that such inhalers are manufactured by one company. Only six of the participants in the survey reply that this company is GSK and one replies Seretide.

(104) The surveys show that the knowledge among pharmacists and physicians on the actual colour use is substantial, but in the assessment of whether this also means that the participants perceive the colour as a sign, one must consider the circumstances that create a presumption that the participants cannot be expected to perceive the colour in this way. I refer to my previous discussion in this regard.

(105) Thus, to me it is clear that it cannot be assumed that GSK dark purple is well known in the circle or trade as a specific company's sign. Consequently, GSK has not acquired trademark rights for this shade of purple either, and the appeal must be dismissed.

(106) The respondents Sandoz A/S and Novartis Norge AS have won the case completely and claimed compensation for costs in the Supreme Court. Costs are awarded in accordance with the main rule in the Dispute Act section 20-2 subsection one. The appellant has not asserted any exemption provisions, but objections have been made against the necessity of the time spent on preparations. Considering the efforts by both parties in three instances, and the impact the judgment will have for them, I find that the hours spent are justifiable, and costs are awarded as claimed in the amount of NOK 1,390,830.

(107) I vote for this

J U D G M E N T :

1. The appeal is dismissed.

2. GlaxoSmithKline AS will pay costs in the Supreme Court to Sandoz A/S and Novartis Norge AS jointly in the amount of NOK 1 390 830 – onemillionthreehundredandninetythousandeighthundredandthirty – within 2 – two – weeks from the serving of this judgment.

(108) Justice **Webster:** I agree with the justice delivering the leading opinion in all material aspects and with his conclusion.

(109) Justice **Kallerud:** Likewise.

(110) Justice **Noer:** Likewise.

(111) Chief Justice **Øie:** Likewise.

(112) Following the voting the Supreme Court gave this

J U D G M E N T :

1. The appeal is dismissed.

2. GlaxoSmithKline AS will pay costs in the Supreme Court to Sandoz A/S and Novartis Norge AS jointly in the amount of NOK 1 390 830 – onemillionthreehundredandninetythousandeighthundredandthirty – within 2 – two – weeks from the serving of this judgment.