

**TRANSLATION**

WOLFFLIS  
COPENHAGEN

- AEM

**TRANSCRIPT  
OF  
THE RECORD OF JUDGMENTS OF THE MARITIME AND COMMERCIAL HIGH COURT**

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**RULING**

Given on 8 December 2017

**A-19-17**

- 1) Eli Lilly and Company  
(Attorney Mikkel Vittrup)
  - 2) Eli Lilly Danmark A/S  
(Attorney Mikkel Vittrup)
- v
- 1) Fresenius Kabi AB v/  
Fresenius Kabi  
(Attorney Anders Valentin)
  - 2) Fresenius Kabi Oncology Plc.  
(Attorney Anders Valentin)

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### **The Maritime and Commercial High Court's reasoning and ruling**

It is undisputed that the patent-in-suit is valid. Thus, the Court is only to consider during these proceedings whether the defendants' product "Pemetrexed Fresenius Kabi" containing pemetrexed tromethamine infringes the patent-in-suit.

According to Section 39 of the Danish Patents Act the scope of the protection conferred by a patent is determined by the claims. For the interpretation of the claims the description may serve as a guideline. When determining the scope of the patent protection, it should also be taken into account what can be deemed to be equivalent to the elements of the patent claims. In order to examine whether a patent is infringed by equivalence, the decisive question is whether the essential or significant part of the invention can be found in the alleged infringing product, whether deviations only occur in less significant respects and whether the scope of the claims has been amended during the processing of the case in relation to prior art.

It is stated in claim 1 of the patent-in-suit, among other things, that it relates to the use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein the medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof. It is stated in claim 2, among other things, that it relates to use according to claim 1, wherein the medicament is to be administered in combination with vitamin B12 and a folic binding protein binding agent selected from folic acid or a physiologically available salt or physiological available ester thereof.

Initially, the Court notes that the product "Pemetrexed Fresenius Kabi" does not constitute a literal infringement of the patent, as pemetrexed disodium is not used in this product.

Eli Lilly amended the claims in the patent application in proceedings before the EPO to concern only the disodium salt of pemetrexed. Fresenius Kabi has argued that based on this the patent protection cannot be extended to comprise more than the specific salt form pemetrexed disodium.

The Court notes that the amendment of the patent claims from pemetrexed to pemetrexed disodium was due to the EPO's preliminary objection to added matter for "pemetrexed" in accordance with Article 123(2) EPC. The reason for this preliminary objection and the resulting amendment was not lack of novelty or inventive step. Based on this, the Court finds that Eli Lilly has at least rendered it probable that the amendment of the claims before the EPO cannot in itself entail that the patent protection can only comprise pemetrexed disodium.

Based on both the wording and the description in the patent, the Court takes into account that the invention concerns a new use of a combination of an already known active ingredient pemetrexed. It is new in relation to the use of the known active ingredient that pemetrexed disodium is used in a combination therapy with vitamin B12 and possibly folic acid in order to reduce the toxic effect of

pemetrexed without reducing its therapeutic efficacy. "Pemetrexed Fresenius Kabi" solves the same problem.

The pemetrexed anion, i.e. the diacid, combined with vitamin B12 and possibly folic acid provides the beneficial effect. The counterions to the diacid, i.e. the cations, which form part of the medicinal products are released in connection with dissolution of the medicinal product, and they have neither any therapeutic effect nor any effect against the toxicity of pemetrexed. It is undisputed that the pemetrexed anion, i.e. the diacid, is the active ingredient of the medicinal products and that the counterion is not important to the efficacy of the medicinal product.

Based on the description in the patent, the Court finds that the skilled person to whom the patent is addressed is an oncologist together with a pharmacist. Moreover, the Court finds that based on the information available, it has at least been rendered probable that it was obvious to this skilled person that the invention could be carried out by using other salts than the specific salt pemetrexed disodium. The Court also finds that based on the skilled person's knowledge of potential and commonly used counterions for active ingredients in ion form, the skilled person could expect to find another counterion for the pemetrexed diacid based on the most commonly used salt formations, including tromethamine.

The Court also notes that Fresenius Kabi did not have to submit the trial data usually required in order to obtain approval of "Pemetrexed Fresenius Kabi". Instead, Fresenius Kabi could refer to the data already submitted for "Alimta", stating that the products were therapeutically identical.

Based on this, the Court finds that infringement by equivalence is rendered probable.

Based on the above, the Court finds that Eli Lilly has rendered it probable that Fresenius Kabi infringes Patent No. DK/EP 1313508 by manufacturing, offering for sale, putting on the market, marketing, and using the medicinal product "Pemetrexed Fresenius Kabi", see Section 3 of the Danish Patents Act.

Accordingly, and as the other conditions for granting an injunction are deemed to be fulfilled, the Court upholds Eli Lilly's claims as ordered below.

Due to the fact that Eli Lilly has not proved but only rendered it probable that infringement has taken place, the granting of an injunction is to be conditional on the provision of security for the harm and inconvenience that may be imposed on Fresenius Kabi if Eli Lilly is unable to substantiate its claims during a main trial. Based on an estimate the amount of the security is fixed to DKK 30 million.

Due to the outcome of the case, Fresenius Kabi is to pay legal costs to Eli Lilly.

The attorneys' fees are fixed to DKK 1,500,000, having regard to the outcome, the nature and the scope of the case as well as its economic value. The stated expenses for the preparation of the trial bundle and the compilation of case law, literature etc. are included in the above-mentioned amount. DKK 600 covers the court fee.

Based on the statement provided, the expenses for the expert declarations prepared by Jesper Østergaard, Sven Frøkjær and Christian Manegold are fixed to DKK 250,000 in total. The Court notes that Fresenius Kabi has not made any objections to the payment of these expenses, and that in view of the nature of the case the expenses should be considered reasonable and necessary for the adequate conduct of the case.

As for the expenses of DKK 52,500 for the interpreter which the Court takes into account, the simultaneous interpretation during the oral proceedings due to the presence of Eli Lilly's foreign representatives, who were not to give evidence during the proceedings, the Court finds that such expenses were not necessary for the adequate conduct of the case, for which reason it cannot be claimed that the amount be reimbursed, see Section 316 of Administration of Justice Act.

The amount of DKK 963,350 for Zacco Danmark, Ejvind Christiansen, as stated by Eli Lilly, concerns expenses for patent expert assistance. Such expenses for expert assistance other than legal assistance can only be reimbursed under special circumstances. Such circumstances have not been proved in this case. Accordingly, Eli Lilly cannot claim that these expenses be reimbursed.

Based on this, the total amount of legal costs to be paid by Fresenius Kabi to Eli Lilly and Company and Eli Lilly Danmark A/S is fixed to DKK 1,750,600 in total.

#### **IT IS HELD THAT:**

If Eli Lilly and Company and Eli Lilly Danmark A/S provide security of DKK 30 million in total in relation to the defendants, Fresenius Kabi, Fresenius Kabi AB and Fresenius Kabi Oncology Plc., before 20 December 2017, the court will grant the following injunction and order:

The defendants, Fresenius Kabi, Fresenius Kabi AB and Fresenius Kabi Oncology Plc., are enjoined from manufacturing, offering for sale, putting on the market, or using the medicinal product "Pemetrexed Fresenius Kabi", see marketing authorisation numbers EU/1/16/1115/001 and EU/1/16/1115/002, or importing or possessing it for such a purpose as long as Danish Patent DK/EP 1313508 is in force.

The defendants, Fresenius Kabi, Fresenius Kabi AB and Fresenius Kabi Oncology Plc., are ordered to recall all deliveries already made of the medicinal product "Pemetrexed Fresenius Kabi", see marketing authorisation numbers EU/1/16/1115/001 and EU/1/16/1115/002, from all hospitals in Denmark to which deliveries have been made by Fresenius Kabi v/Fresenius Kabi filial af Fresenius Kabi AB and Fresenius Kabi Oncology Plc.

The defendants, Fresenius Kabi, Fresenius Kabi AB and Fresenius Kabi Oncology Plc. are ordered to immediately notify AMGROS I/S and all hospitals to which deliveries of the medicinal product "Pemetrexed Fresenius Kabi", see marketing authorisation numbers EU/1/16/1115/001 and

EU/1/16/1115/002, have been made that it is not possible to purchase the medicinal product "Pemetrexed Fresenius Kabi" as long as the preliminary injunction is in force.

Fresenius Kabi, Fresenius Kabi AB and Fresenius Kabi Oncology Plc. are jointly to pay legal costs of DKK 1,750,600 to Eli Lilly and Company and Eli Lilly Danmark A/S within 14 days.

The amount accrues interest pursuant to Section 8a of the Danish Interest Act.

Lars Pallisgaard Olsen

Peter Juul Agergaard

Marianne Johansen

**(Sign.)**

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**This is certified to be a true copy**

**The Maritime and Commercial High Court, 8 December 2017**

**Per Jensen**

**Head of department**

**UDSKRIFT  
AF  
SØ- & HANDELSRETTENS DOMBOG**

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**KENDELSE**

Afsagt den 8. december 2017

**A-19-17**

1) Eli Lilly and Company  
(advokat Mikkel Vittrup)

2) Eli Lilly Danmark A/S  
(advokat Mikkel Vittrup)

mod

1) Fresenius Kabi AB v/  
Fresenius Kabi  
(advokat Anders Valentin)

2) Fresenius Kabi Oncology Plc.  
(advokat Anders Valentin)

~~Sagens baggrund og parternes påstande~~

ten thaver i dag skulle kunne genindvinde et bestemt beskyttelsesomfang under en krænkelsessag, når det selv samme beskyttelsesomfang ubestrideligt var blevet opgivet af Lilly under sagsbehandlingen af den patentansøgning, der førte til stridspatentet (pkt. 5.7.1).

Den italienske domstol slog også fast, at Pemetrexed Fresenius Kabi ikke var nærliggende i forhold til den kendte teknik og ikke kunne være blevet opnået alene ved rutinemæssig afprøvning (salt screening) (pkt. 5.9)."

Fresenius har begæret sig tillagt følgende sagsomkostninger:

Advokatsalær:	1.600.000 kr.
Salær til Claus Selch Larsen:	342.000 kr.
Udgifter til Budde Schou A/S:	825.000 kr.
I alt:	2.767.000 kr.

### Sø- og Handelsrettens begrundelse og resultat

Det er ubestridt, at stridspatentet er gyldigt. Der skal således under denne sag alene tages stilling til, om sagsøgtets produkt "Pemetrexed Fresenius Kabi", der indeholder pemetrexed tromethamin, krænker stridspatentet.

Efter patentlovens § 39 bestemmes patentbeskyttelsens omfang af patentkravene. Til forståelse af kravene kan vejledning hentes fra patentbeskrivelsen. Ved fastlæggelsen af patentbeskyttelsens omfang skal der tillige tages hensyn til, hvad der må anses for ækvivalent med elementer i patentkravene. For at efterprøve, om der foreligger krænkelse ved ækvivalens, er det afgørende spørgsmål, om det centrale eller væsentligste ved opfindelsen genfindes i det påståede krænkende middel, om afvigelser kun forekommer på mindre væsentlige punkter, og om der er sket en begrænsning af kravomfanget under sagsbehandlingen over for kendt teknik.

Det fremgår af krav 1 i stridspatentet bl.a., at det vedrører anvendelse af pemetrexeddinatrium til fremstilling af et medikament til anvendelse i kombinationsterapi til inhibering af tumorvækst i pattedyr, hvorved medikamentet skal indgives sammen med vitamin B12 eller et



farmaceutisk derivat heraf. Det følger af krav 2 bl.a., at der er tale om anvendelse ifølge krav 1, hvorved medikamentet skal indgives sammen med vitamin B12 og et folatbindende proteinbindende middel, der er udvalgt blandt folsyre eller et fysiologisk tilgængeligt salt eller en fysiologisk tilgængelig ester heraf.

Retten bemærker indledningsvist, at der ikke ved produktet "Pemetrexed Fresenius Kabi" foreligger en ordret krænkelse af patentet, idet der ikke i dette produkt anvendes pemetrexeddinatrium.

Eli Lilly begrænsede kravene i patentansøgningen ved EPO til alene at vedrøre dinatriumsaltet af pemetrexed. Fresenius Kabi har gjort gældende, at patentbeskyttelsen på den baggrund ikke kan udstrækkes til at omfatte andet og mere end den specifikke saltform pemetrexeddinatrium.

Retten bemærker, at begrænsningen af patentkravene fra pemetrexed til pemetrexeddinatrium skyldtes EPOs formalitetsindsigelse mod manglende basis for "pemetrexed" i overensstemmelse med EPC art. 123, stk. 2. Denne formalitetsindsigelse og den resulterede begrænsning på baggrund heraf var ikke begrundet i manglende nyhed eller opfindelseshøjde. Retten finder på den baggrund, at Eli Lilly i hvert fald har sandsynliggjort, at begrænsningen af kravene ved EPO ikke i sig selv kan medføre, at patentbeskyttelsen alene kan omfatte pemetrexeddinatrium.

Retten lægger efter ordlyden såvel som beskrivelsen i patentet til grund, at opfindelsen angår en ny kombinationsanvendelse af et allerede kendt aktivstof pemetrexed. Det nye ved anvendelsen af det kendte aktivstof består i, at pemetrexeddinatrium anvendes i en behandlingsmåde i kombination sammen med vitamin B12 og evt. folsyre med henblik på at reducere den toksiske virkning af pemetrexed uden samtidig at reducere dets helbredende virkning. "Pemetrexed Fresenius Kabi" løser samme problem.

Det er pemetrexed anionen, dvs. disyren, som sammen med B12 og evt. folsyre giver den gavnlige effekt. Modionerne til disyren, dvs. kationerne, som indgår i lægemidlerne, frigøres

i forbindelse med opløsning af lægemidlet, og disse har hverken nogen terapeutisk effekt eller nogen virkning mod den toksiske effekt af pemetrexed. Det er ubestridt, at pemetrexed anionen, dvs. disyren, er den aktive bestanddel af lægemidlerne, og at modionen ingen betydning har for lægemidlets virkning.

Retten finder på baggrund af beskrivelsen i patentet, at den fagmand, som patentet retter sig imod, er en onkolog sammen med en farmaceut. Retten finder endvidere på baggrund af de foreliggende oplysninger, at det i hvert fald er sandsynliggjort, at det var nærliggende for denne fagmand, at opfindelsen ville kunne udøves under anvendelse af andre salte end det specifikke salt pemetrexednatrium. Retten finder ligeledes, at det på grundlag af fagmandens kendskab til mulige og ofte anvendte modioner til aktivstoffer i ionform var forventeligt for fagmanden at finde en anden kation til pemetrexed disyren med udgangspunkt i de hyppigst anvendte saltdannere, herunder tromethamin.

Retten bemærker tillige, at Fresenius Kabi ikke behøvede at indlevere de ellers påkrævede forsøgsdata i forbindelse med opnåelse af godkendelse af "Pemetrexed Fresenius Kabi". Der kunne i stedet henvises til de data, der allerede var indgivet for "Alimta", under henvisning til, at produkterne var terapeutisk identiske.

Retten finder det på den baggrund sandsynliggjort, at der foreligger krænkelse via ækvivalens.

På baggrund af ovenstående finder retten således, at Eli Lilly har sandsynliggjort, at Fresenius Kabi krænker patent nr. DK/EP 1313508 ved at fremstille, udbyde, bringe i omsætning, markedsføre og anvende lægemidlet "Pemetrexed Fresenius Kabi", jf. patentlovens § 3.

Herefter, og da de øvrige forbudsbetingelser må anses for at være opfyldt, tager retten Eli Lillys påstande til følge, som det er bestemt nedenfor.

Som følge af, at Eli Lilly ikke har godtgjort, men alene sandsynliggjort, at der sker en krænkelse, skal et forbud betinges af en sikkerhed for den skade og ulempe, som kan påføres Fre-

senius Kabi, hvis ikke Eli Lilly kan godtgøre sine påstande under en hovedsag. Sikkerheden fastsættes skønsmæssigt til 30 mio. kr.

Som følge af sagens resultat skal Fresenius Kabi betale sagsomkostninger til Eli Lilly.

Udgifterne til advokatbistand fastsættes til 1.500.000 kr. under henvisning til sagens resultat, karakter og omfang, samt dens økonomiske værdi. De anførte udgifter til fremstilling af ekstrakt og materialesamling er indregnet i ovennævnte beløb. 600 kr. dækker udgiften til retsavgift.

Udgifterne til de ensidigt indhentede eksperterklæringer fra Jesper Østergaard, Sven Frøkjær og Christian Manegold fastsættes i overensstemmelse med den fremlagte opgørelse til samlet 250.000 kr. Retten bemærker, at Fresenius Kabi ikke har gjort indsigelse mod dækning af disse udgifter, og at udgifterne under henvisning til sagens karakter må anses for at have været rimelige og påkrævede for sagens forsvarlige førelse.

Vedrørende udgiften til tolkebistand på 52.200 kr., som retten lægger til grund, er den simultantolkning, der foregik under sagen til brug for de under hovedforhandlingen mødte udenlandske repræsentanter for Eli Lilly, der ikke skulle afgive forklaring under sagen, finder retten, at der ikke er tale om udgifter, der har været fornødne til sagernes forsvarlige førelse, hvorfor beløbet ikke kan kræves godtgjort, jf. retsplejelovens § 316.

Det af Eli Lilly anførte beløb på 963.350 kr. til Zacco Danmark, Ejvind Christiansen, vedrører udgift til patentsagkyndig bistand. Sådanne udgifter til anden sagkyndig bistand end advokatbistand kan kun kræves godtgjort, hvis særlige forhold gør sig gældende. Der er ikke påvist sådanne særlige forhold i denne sag. Eli Lilly kan således ikke kræve denne udgiftspost erstattet.

Sagsomkostningsbeløbet, som Fresenius Kabi samlet skal betale til Eli Lilly and Company og Eli Lilly Danmark A/S, fastsættes på den baggrund til i alt 1.750.600 kr.

**Thi bestemmes:**

Såfremt Eli Lilly and Company og Eli Lilly Danmark A/S inden den 20. december 2017 stiller sikkerhed på samlet 30 mio. kr. over for de sagsøgte Fresenius Kabi, Fresenius Kabi AB og Fresenius Kabi Oncology Plc., vil der blive nedlagt følgende forbud og påbud:

Det forbydes de sagsøgte, Fresenius Kabi, Fresenius Kabi AB og Fresenius Kabi Oncology Plc., at fremstille, udbyde, bringe i omsætning eller anvende lægemidlet "Pemetrexed Fresenius Kabi", jf. markedsføringstilladelsesnumre EU/1/16/1115/001 og EU/1/16/1115/002, eller importere eller besidde det med et sådant formål, så længe dansk patent nr. DK/EP 1313508 er i kraft.

Det påbydes de sagsøgte, Fresenius Kabi, Fresenius Kabi AB og Fresenius Kabi Oncology Plc., at tilbagekalde allerede skete leverancer af lægemidlet "Pemetrexed Fresenius Kabi", jf. markedsføringstilladelsesnumre EU/1/16/1115/001 og EU/1/16/1115/002 fra samtlige sygehuse, hvortil levering er foretaget af Fresenius Kabi AB v/ Fresenius Kabi filial af Fresenius Kabi AB i Danmark og Fresenius Kabi Oncology Plc.

Det påbydes de sagsøgte, Fresenius Kabi, Fresenius Kabi AB og Fresenius Kabi Oncology Plc., omgående at meddele over for Amgros I/S og alle hospitaler, hvortil leverancer af lægemidlet "Pemetrexed Fresenius Kabi", jf. markedsføringstilladelsesnumre EU/1/16/1115/001 og EU/1/16/1115/002, er sket, at det ikke er muligt at indkøbe lægemidlet "Pemetrexed Fresenius Kabi", så længe der er nedlagt midlertidigt forbud.

Fresenius Kabi, Fresenius Kabi AB og Fresenius Kabi Oncology Plc., skal i forening inden 14 dage betale sagsomkostninger på 1.750.600 kr. til Eli Lilly and Company og Eli Lilly Danmark A/S.

Beløbet forrentes efter rentelovens § 8 a.

Lars Pallisgaard Olsen

Peter Juul Agergaard

Marianne Johansen

(Sign.)

—————  
**Udskriftens rigtighed bekræftes**  
**Sø- og Handelsretten, den 08-12-2017**

**Per Jensen**  
**afdelingsleder**

I, the undersigned Carina Ellegaard, certify that the preceding text in the English language is to the best of my knowledge and belief a true and faithful translation of the attached pages 1 and 216-221 of the ruling of the Danish Maritime and Commercial High Court of 8 December 2017.

Witness my hand.

Copenhagen, 20 December 2017



Carina Ellegaard

Translator, MA in Translation and Interpretation (English)



I the undersigned, **John Spøhr**, Notary Public of Copenhagen, Denmark hereby certify that

**Ms. Carina Ellegaard**

has approved and signed this document in my presence.

The identity was proved to me by passport.

There were no obvious amendments or additions to the document, with the exception of those denoted by my signature (initials).



In witness whereof I have hereunto set my hand and notarial seal.

**The City Court of Copenhagen, Notarial Acts Division, 20.12.2017.**

  
**John Spøhr**

Notary Public of Copenhagen, Denmark



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<b>7. by</b> af	<b>Ministry of Foreign Affairs of Denmark</b> Udenrigsministeriet		
<b>8. No</b> nr.	<b>00AF8F14</b>		
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