
From: Sarika Patel [/O=FR/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C41998E197374F4286116AB30F0CB9AC-SARIKA N PATEL]
Sent: 7/18/2023 7:42:40 PM
To: cathy.taylor@rws.com
Subject: FW: Fish & Richardson - IPR translation certification opportunity
Attachments: MOM-1007 Harder TR.pdf
Importance: High

Exhibit

9

Hi Cathy,

Please see our correspondence below. Could you please put us in contact with Mr. Sherman as soon as possible to discuss these issues?

Thank you,

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Sarika Patel
Sent: Tuesday, July 18, 2023 2:40 PM
To: 'Andrea Turner' <andrea.turner@rws.com>
Subject: FW: Fish & Richardson - IPR translation certification opportunity
Importance: High

Hi Andrea,

We had some urgent issues come up with the declaration prepared by Mr. Sherman. Are you and Mr. Sherman available for a quick chat to discuss these issues today?

Thank you,

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Sarika Patel
Sent: Wednesday, February 15, 2023 11:54 AM
To: 'Andrea Turner' <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Hi Andrea,

Thank you for reaching out. The reference that we need a declaration of accuracy prepared for is Chapter 15.9 of Wochenbettbetreuung in der Klinik und zu Hause (Childbed care in clinic and at home). David Joshua Sherman at RWS prepared this declaration for us in the past, which I have attached to this email (see attachment at page 1). We were wondering if Mr. Sherman could prepare a similar declaration for us with an updated date and signature, and if so, if you could please provide us with a quote for this service.

Please feel free to contact me if you have any questions. I am available for a call at any time on Friday 2/16 between 9:00a.m. and 7:00p.m. Central Time.

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 817 374 2946

From: Andrea Turner <andrea.turner@rws.com>
Sent: Wednesday, February 15, 2023 8:35 AM
To: Sarika Patel <patel@fr.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

[This email originated outside of F&R.]

Dear Sarika,

Many thanks for your email and enquiry, which has been forwarded to me. My name is Andrea Turner and I am the Key Account Manager for Fish & Richardson at RWS IP Services. I have been working very closely with the Fish & Richardson office in Munich for the last few years.

Could I please ask, do you have a reference/invoice number of the book we translated in 2017, and would you also be able to send a copy of the exhibit that requires translation and certification now? We would also appreciate if you could confirm the required language combination for the exhibit and your preferred deadline.

I will be happy to join you in a call, I have good availability tomorrow and Monday. If you let you know a date and time that is convenient for you, I will be happy to send a MS Teams invitation.

Kind regards,
Andrea

Andrea Turner | Key Account Manager | **RWS Group**
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[Blog](#) | [LinkedIn](#) | [Twitter](#)

From: Sarika Patel <patel@fr.com>
Sent: 14 February 2023 17:21
To: David Sherman <David.Sherman@rws.com>
Subject: Fish & Richardson - IPR translation certification opportunity

Hi David,

I am an attorney at Fish & Richardson P.C.. I am reaching out regarding your availability to certify a translation of a German Book that you translated for us in a prior matter in 2017. We now need a similar certification prepared for an exhibit in an IPR matter.

Please let me know if you are interested and time to briefly speak later this week.

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

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**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Ddrops Company, Reinhold Vieth, and
Elaine Vieth,

Plaintiffs,

v.

iHerb, Inc. and Madre Labs, Inc.
d/b/a California Gold Nutrition,

Defendants.

Civil Action No. 0:16-cv-04278 (JNE-TNL)

DECLARATION OF ACCURACY OF TRANSLATION

I, David Joshua SHERMAN, hereby declare as follows:

1. Rebecca Amy TINWORTH performed the attached translation from German into English of chapter 15.9 of “Wochenbettbetreuung in der Klinik und zu Hause” [Childbed care in clinics and at home] (also attached).

2. Rebecca Amy TINWORTH is competent to perform this translation, because she has a Bachelor of Arts (Honors) degree in German studies.

3. I have reviewed the translation and confirm that the addition of “to be licked off” (for the German “zum Ablecken”) on page 4 of the translation in the fifth line of the second paragraph under Option 3 makes the translation a more accurate reflection of the German text.

4. I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct; and further declare that I am aware that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code.

Dated: June 8, 2017



D. J. SHERMAN
Senior Translator – UK Translation Division
For and on behalf of RWS Group Ltd
Europa House, Chiltern Park,
Chiltern Hill, Chalfont St Peter,
Buckinghamshire,
United Kingdom

15.9 Prophylaxis of bleeding, rickets and tooth decay

?	Why are babies given vitamin K drops?	p. 256
?	Do all babies need vitamin D tablets?	p. 257
?	Do newborn babies need to take daily fluoride tablets?	p. 260

? Why are babies given vitamin K drops?

Vitamin K is needed to help the blood to clot. Almost all newborn babies have sufficient stores of vitamin K in their bodies at birth to ensure that the blood will clot in the next few weeks of their life (breastmilk contains hardly any vitamin K, and intestinal bacteria in babies are not capable of synthesizing it themselves for the first few weeks after birth).

Vitamin K deficiency in babies aged between 1 and 12 weeks can lead to increased tendency to bleed.

This manifests itself in continued bleeding at the site of injection following the taking of a blood sample, in bleeding of the mucous membranes in the event of intubation or the insertion of a feeding tube, as well as in blood in the stools, bleeding of the umbilical cord or cerebral bleeding.

If a newborn baby is spitting-up blood in the first few days after birth, questions should be asked to clarify the most common causes of this phenomenon: in most cases, the baby will have swallowed blood from its mother, either during the birth (e.g. amniotic fluid containing blood, large episiotomy, Caesarean section) or through feeding from a bleeding nipple.

The connection between vitamin K deficiency and bleeding in infants was established 60 years ago and can occur in around 1% of children (Tönz 1990). As there is no way of knowing whether newborn babies have sufficient stores of vitamin K in their liver, prophylactic increase of vitamin K stores for at-risk children (e.g. following surgical delivery, premature birth or bleeding in children) has been recommended since the 1960s.

Dosage:

Since 1986, the German Association for Pediatrics' Committee on Nutrition advised that all neonates should be given a prophylactic dose of vitamin K following birth. Initially, a single intramuscular or subcutaneous injection of 1 mg of vitamin K was recommended prophylactically after birth. Following the establishment by a British study (Golding et al. 1992) of a connection between the intramuscular administration of vitamin K and an increase in the number of cases of childhood cancers, in 1992 the Committee amended its recommendation to three oral administrations, each containing a 1 mg dose of vitamin K. In

1994, the Committee on Nutrition doubled the oral dose, due to more cases of bleeding as a result of vitamin K deficiency being observed once again.

Nowadays, nearly all neonates receive three doses of 2 mg of vitamin K orally.

Parents must be consulted beforehand and must agree to the prophylaxis. Babies will receive either 2 drops of **Kanavit®** drops or a 0.2 ml ampoule of **Konakion®** 2 mg directly into their mouths. The first dose is given by the midwife following birth (check-up 1), followed by two further doses by a pediatrician at medical check-ups 2 and 3. Each administration of vitamin K must be documented in the child's yellow medical check-up booklet.

Babies should not receive **the first dose of vitamin K** until they have had a lengthy feed at the breast. This is because, firstly, vitamin K is liposoluble and is better absorbed with colostrum, and secondly it gives neonates the chance to familiarize themselves with the taste of breastmilk before being confronted with the foreign taste of the drops (Konakion® tastes like the adhesive coating on a postage stamp).

Although no side effects have been described for the oral prophylaxis of vitamin K, the possibility that early contact with the ingredients contained in the solution may increase a child's disposition to allergies cannot be ruled out (Konakion® 2 mg contains: lccithin and glycocholic acid from soya beans, sodium hydroxide, hydrochloric acid, water, vitamin K1. Kanavit® drops contain: polysorbate, sorbic acid, water, vitamin K1). Where parents do not give their consent to the prophylaxis for this reason or for other reasons, all caregivers must accept this; in Germany, there is no obligation to take part in prophylaxes.

? Do all children need vitamin D tablets?

Many parents are uncomfortable with the idea of giving a healthy infant a tablet each day. This is understandable, given that tablets are usually prescribed to treat illnesses. The daily vitamin D tablet, by contrast, does not treat an illness, but is designed to prevent the possible occurrence of rickets. Parents need to be given accurate information on vitamin D and rickets by pediatricians, midwives and pediatric nurses so that they can make an informed decision with regard to a form of **rickets prophylaxis** (see below).

Children need **vitamin D** to store calcium, which in turn is needed to strengthen bones. Vitamin D also promotes the absorption of calcium and phosphate from the intestine. Infants produce their own vitamin D by converting provitamins in the skin to vitamin D under the effect of ultraviolet light (daylight 280-310 nm). Provitamins are precursors to vitamins. They are present in food and are also supplied by the liver (where they are synthesized from cholesterol). Just like plant-based and animal-based foods, breastmilk also contains several provitamins, but only small amounts of vitamin D. Since the only food with a high natural

content of vitamin D is fish liver oil, consumption of cod-liver oil used to be recommended in order to prevent rickets.

In order to make enough vitamin D, children need to be exposed to bright daylight without being covered up. This means that they need to spend at least 2 hours in the open air in the middle of the day; they do not need to be exposed to direct sunlight (Illing 1998).

Vitamin D deficiency, which can lead to rickets, often occurs in winter and spring due to a lack of light.

Rickets is defined as the defective mineralization of growing bones. It peaks in infants between the ages of 3 and 8 months. Typical symptoms are: weakening of the cranial bones (compressible points, flattening at the back of the head), large fontanelles with soft edges, distension of the ends of the bones and later on a permanent distortion of the bones (funnel chest, knock-knees or bandy legs). These are accompanied by general symptoms such as rapid fatigue, anxiety, perspiration on the head, muscular flaccidity and ligament flaccidity, susceptibility to infection and delayed emergence of the teeth.

Rickets is **treated** with high-dose administration of vitamin D (Vigantol®), e.g. a daily oral dose of 3000-5000 international units (I.U.) over the course of 4-6 weeks. In addition, children are also given oral doses of calcium and phosphate (Niessen 1996). In the event of higher doses, particularly in the case of parenteral high-dose therapy of acute rickets, the risk of vitamin D hypervitaminosis must be taken into account. Symptoms of hypervitaminosis often only occur after several weeks: increased phosphorus and calcium in the serum, calcium deposits in the blood vessels and kidneys, irritability, loss of appetite, constipation, vomiting, muscle hypotonia and impairment of intellectual abilities (Niessen 1996, Goebel 1987).

An infant's **minimum daily requirement** of vitamin D is 400 I.U., corresponding to 10 µg or 0.01 mg of crystalline vitamin D (one I.U. of vitamin D corresponds to 0.025 µg of pure crystalline vitamin D₃).

Premature babies have a higher requirement.

Four options for the prophylaxis of rickets:

Option 1:

Year-round substitution with a daily vitamin D tablet containing 500 I.U. (1000 I.U. for premature babies) is the most reliable method of preventing rickets. The vitamin D is given over the course of a year. Should the child's first birthday fall in the winter, then treatment should be continued until the spring. Babies will be given one Vigantoletten® 500 tablet every day from the start of the second week following their birth, preferably before a breastfeed or bottle feed (combination preparations such as D-Fluorelletten®, Fluor-Vigantoletten® or Zymafluor DR®, see p. 260). The tablets disperse quickly in a spoonful of

water and can be drunk easily from the spoon. Since vitamin D deficiency scarcely features in the first few weeks of life, some pediatricians recommend only starting treatment in the 4th week of life in order to allow the baby's digestive system to develop.

Option 2:

Children are given a daily dose of 500 I.U. of vitamin D in the winter only (October-March). Where babies spend two hours a day in natural daylight in the summer period, either no vitamin D is given or a reduced dose, for example half a tablet (250 I.U.) each day or a whole tablet every other day.

Option 3

In the case of children who are susceptible to allergies, or where increased bloating is experienced after taking the tablets, **Vigantol® oil** (1 drop contains 500 I.U.) can also be recommended instead of tablets in both of the options outlined above. The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil). The customary Vigantoletten® contain eleven excipients, namely silicon dioxide, cornstarch, sodium carboxy methyl starch, talc, glycerol tristearate, cellulose, D-mannitol, gelatin, sucrose, partially-hydrated soybean oil and α -tocopherol. Unfortunately, there are no recommended tablets containing fewer excipients. Virgosan® 500 contains lactose (milk sugar), Vitamin D₃-Hevert® is only available in a strength of 1000 I.U. per tablet ('Rote Liste' drug compendium 2001). I consider the long list of additives in the tablets to be worrying for familial allergies and would recommend vitamin D oil instead.

Vigantol® oil is a prescription-only medicine, as there is a risk of an overdose if it is not used properly. Before asking their pediatrician for a prescription, parents must be given full details of the benefits and drawbacks of the oil, and also of its use; if this is not done, their pediatrician will refuse to prescribe the oil for fear of incorrect dosage.

Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be put directly in the baby's mouth! Should 2 drops fall onto the spoon, the spoon should be washed and the process started again. In my experience, skeptical parents are more likely to be accepting of administering drops on a daily basis than a daily dose of tablets. I have also now been able to convince some pediatricians of the advantages of the oil.

Option 4:

In anthroposophic medicine, prophylactic administration of synthetically produced vitamin D is regarded as problematic, owing, inter alia, to the potential impact on the child's mental development "in the sense of early intellectualization and failing to develop thoughts independently" (Goebel 1987). For this reason, **endogenous synthesis of vitamin D** should be primarily promoted; a general, artificial substitute is opposed. With the appropriate lifestyle (the child needs to sit by an open window, on the balcony or outside with his/her

head uncovered for 2 hours each day), there is no need to administer vitamin D, provided that the child is checked every four weeks for symptoms of rickets. Where daylight is in short supply, daily sunlamp treatment can be used to increase the child's vitamin D synthesis. The naked child is held in its mother's arm or on her lap and is exposed to UV light for 30 seconds on his/her abdomen and back, slowly increasing to a maximum of 2 minutes on each side. Caution: babies and mothers must always wear eye protection! In the event of erythema, reduce the time! (Goebel 1987).

Maternal vitamin D intake: Many mothers ask whether they can take vitamin D themselves and pass it onto their babies via breastmilk. Although where mothers take Vigantol® vitamin D and its by-products pass into breastmilk ("Rote Liste" 2001), unfortunately no recommendation exists in this respect, because research has not been carried out into the exact quantity.

Industrially produced infant nutrition almost always contains a vitamin D supplement, meaning that the minimum daily requirement of 400 I.U. (10 µg of crystalline vitamin D₃) is met in part by supplementing infant food. Although some authors (Gahr 1994, Illing 1998) consider double administration to be harmless, when parents ask me about this I recommend calculating the daily vitamin D amount in infant food based on the package label and amount of daily drink and reducing the prophylaxis accordingly, so that their child receives a maximum dose of 500 I.U. of vitamin D each day, because "more doesn't always mean better", and it is better to avoid an overdose.

? Do newborn babies need to take daily fluoride tablets?

No, since from a dental perspective no fluoridization measures to prevent tooth decay are required before the age of six months.

Tooth decay is not caused by a fluoride deficiency, and so taking fluoride tablets before the first milk teeth have erupted is not effective (German Society for Dental and Oral Medicine, DGZMK March 2000).

The combination preparations containing vitamin D and fluoride (D-Fluorctten®, Fluor-Vigantolekten® or Zymafluor DR®) for the prophylaxis of rickets and tooth decay which have been recommended by dentists and pediatricians for years now can no longer be recommended on the basis of current scientific knowledge.

Several studies have shown that fluoride primarily works to inhibit tooth decay through direct contact with the surface of the tooth. For this reason, when using fluorides, local application (toothpaste) takes precedence over the systemic route (tablets). In recent years, in the Scandinavian countries and in the USA and Canada, for example, fluoride tablets have only

been recommended for children who are at risk of tooth decay (children with severe dental caries) and in most cases only starting from the age of three.

The cornerstone of effective prophylaxis of tooth decay:

- A balanced diet (preferably no sugar or white flour products, or only small quantities thereof)
- Daily brushing of teeth (twice a day from the age of three)
- Use of fluorides (primarily through increasing the fluoride concentration in the region of the surface of the teeth).

It is only once the milk teeth have erupted (at 6-7 months) that the hardness of the tooth enamel can be improved by a local increase in fluoride ion concentration on the enamel. Dentists therefore recommend brushing children's teeth daily using a small, soft-bristled toothbrush and no bigger than a pea-sized amount of fluoride-containing children's toothpaste. In order to discourage children from swallowing any toothpaste, children's toothpastes should not be fruit or candy flavored.

Different recommendations: Unfortunately, many pediatricians do not agree with the DGZMK's dental recommendation, continuing to prescribe a daily dose of 0.25 mg of fluoride combined with 500 I.U. of vitamin D to infants from the age of ten days. Although they acknowledge that the proven lack of benefit of the administration of fluoride in the first year of life is scientifically correct, they continue to adhere to the old recommendation. According to the German Society for Pediatrics, the use of vitamin D preparations is an unnecessary complication for prophylactic prescriptions. This behavior is difficult to explain, as the tablets for the prophylaxis of rickets and tooth decay are prescribed by pediatricians, and vitamin D can be prescribed without fluoride substitution without any problems (see above).

It is absurd to prescribe unnecessary fluoride to infants for six months! The halogen fluoride is a highly effective cytotoxin, which is lethal in amounts of 5-15 g (Dauderer 1995, Lewin 1992). A **fluoride overdose** can lead to dental fluorosis, which manifests itself as whitish or brown marks on the enamel of the permanent teeth. Some of the regularly ingested fluoride is stored in the bones. As it suppresses calcium phosphate, particularly in the growth core, daily fluoride intake can be the cause of a constricted jaw and premature aging of the bones in the second half of life. Other side effects can be: poor concentration, forgetfulness, parathyroid hypofunction, porosity of the bones resulting in extreme bone damage (Dauderer 1995, Barmer Lexikon Gesundheit und Medizin).

When providing advice to parents, midwives and pediatricians are caught in the middle of the different recommendations. In light of the evidence-based guidelines of the DGZMK, I am no longer able to recommend fluoride tablets to prevent tooth decay. When it comes to

post-partum care, I will inform parents of the current scientific knowledge and the disagreement among dental and pediatric associations; it will then be up to parents to make the decision.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that Patent Owners Exhibits 2023-2066 are being served on February 8, 2024, by filing Patent Owners Exhibits 2023-2066 through the Patent Trial and Appeal Case Tracking System (P-TACTS) and by electronic mail as directed by Petitioner upon the following counsel of record for Petitioners:

David B. Conrad
Lance E. Wyatt
Sarika Patel
Casey Kraning
Fish and Richardson P.C.
To: IPR53953-0001IP1@fr.com

/Mark E Ungerman/
Mark E. Ungerman
(Reg. No. 32,070)