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Bayer Intellectual Property GmbH intellectual property rights related to rivaroxaban in Estonia

Dear Sirs

We hereby notify you that Bayer Intellectual Property GmbH ("**Bayer**"), with its registered office in Monheim am Rhein, has instructed us to represent its rights and interests in the above-mentioned matter.

1.

Our client's parent company, Bayer AG, based in Leverkusen, Germany, holds a European marketing authorisation No EU/1/08/472 for Xarelto® (active ingredient rivaroxaban), which was granted on 30 September 2008.

Xarelto® is approved in various dosages for the following indications:

- **Xarelto® 1 mg/ml granules for oral suspension**: *Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment.*
- **Xarelto® 2.5 mg film-coated tablets**: (a) *Xarelto, co-administered with acetylsalicylic acid (ASA) alone or with ASA pius clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers*; (b) *Xarelto, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.*

- **Xarelto® 10 mg film-coated tablets**: *(a) Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery; (b) Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.*
- **Xarelto® 15 mg film-coated tablets**: *Adults: (a) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age > 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. (b) Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Paediatric population: Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment.*
- **Xarelto® 20 mg film-coated tablets:** *Adults: (a) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age > 75 years, diabetes mellitus, prior stroke or transient ischaemic attack; (b) Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Paediatric population: Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment.*
- **Xarelto® 15 mg film-coated tablets + Xarelto 20 mg film-coated tablets**: *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.*

2.

Our client is the sole and exclusive owner of the following property rights relating to the drug Xarelto® and its active ingredient rivaroxaban.

- **The Estonian patent No 05169** (hereinafter "EE05169") entitled "Substituted oxazolidinones and their use " protects in particular new oxazolidinone derivatives, methods for their production and their use as active substances in medicinal products. EE05169 was filed on 11 December 2000. The patent was granted on 15 June 2009 with priority date of 24 December 1999. For your Information, we attach the patent specification as **Exhibit 1**.

  Although the original patent term of EE05169 has expired, the supplementary protection certificate No 00025 (hereinafter "the SPC") was granted in Estonia on the basis of EE05169. The SPC was filed on 12 August 2009 and granted on 15 October 2009. **The SPC is valid until 2 April 2024**. For your information, we enclose an extract from the Estonian Patent Office's SPC register as **Exhibit 2**.
- **The European patent EP 1 845 961 B1**, validated in Estonia under the registration No E010728 ("**EP'961**") entitled "Treatment of thromboembolic disorders with rivaroxaban" protects in claim 1 the use of a rapid-release tablet of the compound 5-Chloro-N-({(5S)-2-oxo-3-[4-(3- oxo-4-morpholinyl)phenyl]-1,3- oxazolidin-5-yl}methyl)-2-thiophenecarboxamide for the manufacture of a medicament for the treatment of a thromboembolic disorder administered no more than once daily for at least five consecutive days, wherein said compound has a plasma concentration half-life of 10 hours or less when

orally administered to a human patient. The patent application was filed on 19 January 2006 and the mention of the grant of the patent was published on 22 April 2015. EP'961 was maintained as granted by decision of the Technical Board of Appeal of the European Patent Office dated 27 October 2021 (case number T1732/18). Currently, a revocation action by KRKA d.d., Novo mesto against the EP '961 validated in Estonia has been filed to the Industrial Property Board of Appeal which Bayer considers unfounded. For your information, we enclose the patent specification as **Exhibit 3**. The patent is **valid until 19 January 2026**.

- **The European patent EP 1 720 866 B1**, validated in Estonia under the registration No E005910 (**"EP'866"**) entitled "Production method" protects a process for preparing 5-Chloro-N-({(5S)-2-oxo-3-[4-(3- oxo-4-morpholinyl)phenyl]-1,3- oxazolidin-5-yl}methyl)-2-thiophenecarboxamide of the formula known from claim 2 of 05169 for the active substance rivaroxaban by reacting 4-{4-(5S)-5-(aminomethyl)-2-oxo-1,3-oxazolidin-3-yl]phenyl}morpholin-3-one (VII) hydrochloride with 5-chlorothiophene-2-carbonyl chloride (IV). The patent application was filed on 31 December 2004 and the mention of the grant of the patent was published on 3 August 2011. The patent is in force and **valid until 31 December 2024**. For your information, we enclose the patent specification as **Exhibit 4**.
- **The European patent EP 1 689 370 B2**, validated in Estonia under the registration No E005910 (**EP'370"**) entitled "Method for the production of a solid, orally applicable pharmaceutical composition comprising 5-chlor-N-({(5-2-oxo-3-[4-(3-oxo-4-morpholinyl)-phenyl]-1,3-oxazolidin-5-yl}-methyl)-2-thiophenecarboxamide protects a method for the production of solid, orally an applicable pharmaceutical composition containing 5-chlor-N-({(5-2-oxo-3-[4-(3-oxo-4-morpholinyl)-phenyl]-1,3-oxazolidin-5-yl}-methyl)-2-thiophenecarboxamide in hydrophilized form, the corresponding pharmaceutical composition and its use for the prophylaxis and/or treatment of thromboembolic diseases. The patent was filed on 13 November 2004 and the mention of the grant of the patent was published on 13 February 2008. By decision of the Technical Board of Appeal of 9 June 2015, the patent was maintained in amended form. The mention of maintenance of the patent in amended form was published on 14 September 2016. For your information, we enclose the patent specification in the amended form after the opposition and appeal proceedings as **Exhibit 5**. The patent is in force and **valid until 13 November 2024**.

3.

According to the Estonian Agency of Medicines (Ravimiamet) medicinal product database following marketing authorisations for generic rivaroxaban medicinal products have been granted:

	strength and form	MA holder	MA No
ENKIA	15mg, 20mg tablet	Medochemie Limited	1098323, 1098223
KARDATUXAN	2,5mg, 10mg, 15mg, 20mg tablet	Gedeon Richter Plc.	1069922, 1070822, 1071422, 1072022
RAZARXO	2,5mg, 10mg, 15mg, 20mg tablet	TAD Pharma GmbH	1140424, 1139024, 1139224, 1140524
RIVAROXABAN ACCORD	2,5mg, 10mg, 15mg, 20mg tablet	Accord Healthcare S.L.U.	EU/1/20/1488

RIVAROXABAN ALEMBIC	2,5mg, 10mg, 15mg, 20mg tablet	Alembic Pharmaceuticals Europe Limited	1045921, 1046021, 1046121, 1046221
RIVAROXABAN ALIUD	15mg, 20mg, 15mg/20mg capsule	Stada Arzneimittel AG	1098423, 1098623, 1098523
RIVAROXABAN AUXILIA	2,5mg, 10mg, 15mg, 20mg tablet	Auxilia Pharma OÜ	1032721, 1032521, 1032821, 1032621
RIVAROXABAN G.L. PHARMA	10mg, 15mg, 20mg tablet	G.L. Pharma GmbH	1015120, 1014920, 1015020
RIVAROXABAN ORION	15mg, 20mg tablet	Orion Corporation	1108823, 1108923
RIVAROXABAN STADA	2,5mg, 10mg, 15mg, 20mg, 15mg/20mg tablet	Stada Arzneimittel AG	1076622, 1076822, 1077022, 1076722, 1076922
RIVAROXABAN TEVA	10mg, 15mg, 20mg tablet	Teva B.V.	1020521, 1020421, 1020321
RIVAROXABAN VIATRIS	2,5mg, 10mg, 15mg, 20mg 15mg/20mg tablet	Viatris Limited	EU/1/21/1588
RUNAPLAX	2,5 mg, 10mg, 15mg, 20mg tablet	Sandoz Pharmaceuticals d.d.	1017820, 952617, 952717, 952517
XABOPLAX	2,5mg, 10mg, 15mg, 20mg, 15mg/29mg tablet	Sandoz Pharmaceuticals d.d.	1132323, 1132223, 1131323, 1132123, 1132023
XANIRVA	10mg, 15mg, 20mg capsule	Zentiva k.s.	1006520, 1006620, 1006720
XANIRVA	10mg, 15mg, 20mg tablet	Zentiva k.s.	1000820, 1000720, 1000620
XERDOXO	2,5mg, 10mg, 15mg, 20 mg tablet	KRKA, d.d., Novo mesto	1005220, 1005120, 1005320, 1005020

Listed generic medicinal products have been approved for the indications covered by Xarelto®. Estonian Agency of Medicines decides on the bases of criteria given in the Medicinal Products Act and may refuse granting the marketing authorisation only when any of the conditions provided in § 74 of the Medicinal Products Act exist. Medicinal Products Act § 74 does not allow to take into consideration whether importing, marketing, offering, storing of generic rivaroxaban in Estonia is infringing existing patent rights. Therefore, decision by the Estonian Agency of Medicines does not legitimize or exclude a patent infringement even if the agency grants marketing authorisation for a generic rivaroxaban. Same applies to marketing authorisations granted by the European Medicines Agency.

4.

Our client has become aware that several generic rivaroxaban marketing authorisation holders have filed a request to the Health Insurance Fund (Tervisekassa) for the inclusion of their generic medicinal products in the reimbursement list, including (the list is not exhaustive):

KARDATUXAN	2,5mg, 10mg, 15mg, 20mg tablet	Gedeon Richter Plc.	1069922, 1070822, 1071422, 1072022

RIVAROXABAN ACCORD	2,5mg, 10mg, 15mg, 20mg tablet	Accord Healthcare S.L.U.	EU/1/20/1488
RIVAROXABAN STADA	2,5mg, 10mg, 15mg, 20mg, 15mg/20mg tablet	Stada Arzneimittel AG	1076622, 1076822, 1077022, 1076722, 1076922
RIVAROXABAN TEVA	10mg, 15mg, 20mg tablet	Teva B.V.	1020521, 1020421, 1020321
RUNAPLAX	2,5 mg, 10mg, 15mg, 20mg tablet	Sandoz Pharmaceuticals d.d.	1017820, 952617, 952717, 952517
XANIRVA	10mg, 15mg, 20mg capsule	Zentiva k.s.	1006520, 1006620, 1006720
XERDOXO	2,5mg, 10mg, 15mg, 20 mg tablet	KRKA, d.d., Novo mesto	1005220, 1005120, 1005320, 1005020

The Board of the Health Insurance Fund decides on the bases of criteria given in the Health Insurance Act § 43 (2) that does not allow to take into consideration whether importing, marketing, offering, storing of generic rivaroxaban in Estonia is infringing existing patent rights. Therefore, decision by the Board of the Health Insurance Fund does not legitimize or exclude a patent infringement even if the board decides to satisfy a request to include generic rivaroxaban in the reimbursement list.

5.

According to Estonian Patents Act § 15 (1) the exclusive right of the proprietor of a patent means that during the term of validity of the patent and without the permission of the proprietor of the patent no person shall:

- manufacture, use, distribute, sell or offer for sale products protected by the patent or acquire (incl. by way of importation) such products for the aforesaid purposes;
- use, distribute, sell or offer for sale a product manufactured according to the patented process, or to acquire (including by way of importation) such products for the aforesaid purposes.

Bayer has sent notice letters to all marketing authorisation holders of generic rivaroxaban in Estonia and asked the holders to confirm that they and/or their affiliates will respect Bayer's intellectual property rights and will not interfere with the scope of their protection. In addition, Bayer has sent reminders to marketing authorisation holders that have filed a request to the Health Insurance Fund for the inclusion of their generic rivaroxaban medicinal products in the reimbursement list.

In order to protect its patent rights Bayer is preparing for a request of preliminary injunction against marketing authorisation holders trying to enter the Estonian market with their generic rivaroxaban products that are infringing its patent rights. Bayer will vigorously defend its patent rights including bringing preliminary injunction requests against marketing authorisation holders trying to enter the Estonian market with generic rivaroxaban products that infringe its patent rights. All rivaroxaban products offered or brought to the market prior to 3 April 2024 will infringe SPC No 00025. As of 3 April 2024, every generic rivaroxaban product that is administered once daily will also infringe EP 961, particularly rivaroxaban products with the strengths 10 mg,

15 mg and 20 mg. Bayer currently does not have sufficient information to determine whether also EP 866 and EP 377 are infringed by certain generic products.

Due to the above, we would like to draw your attention to the fact that buying, wholesale, offering for sale and distributing generic rivaroxaban medicinal product in Estonia may lead to unwanted legal consequences for the wholesalers. If you purchase, wholesale, offer for sale or distribute generic rivaroxaban medicinal product in Estonia, you, as a wholesaler, may also become an infringer of Bayer's patent rights.

If you infringe Bayer's patent rights, then Bayer is entitled to use available legal remedies to protect its rights which we would like to avoid. Therefore, we ask you to confirm by

by 23 February 2024 at the latest

that your company respects and observes the property rights of our client listed in this letter and will not purchase, wholesale, offer for sale or otherwise distribute generic rivaroxaban medicinal products in Estonia. Please send the corresponding confirmation by e-mail to mari.must@ellex.legal latest by 21 February 2024.

Yours sincerely

/signed digitally/

Mari Must
Counsel

/signed digitally/

Ants Nõmper
Managing Partner