Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 14 April 2026

Case Number: T 0888/24 - 3.3.02

Application Number: 17186150.3

Publication Number: 3309158

IPC: C07D413/14, A61K31/422, A61P7/00

Language of the proceedings: EN

Title of invention:
CRYSTALLINE FORM K OF RIVAROXABAN AND PROCESS FOR ITS PREPARATION

Patent Proprietor:
Krka, tovarna zdravil, d.d.

Opponent:
Bayer Intellectual Property GmbH

Relevant legal provisions:
EPC Art. 83
EPC R. 43(1)

Keyword:
Sufficiency of disclosure - (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0888/24 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 14 April 2026

Appellant: (Opponent)	Bayer Intellectual Property GmbH Alfred-Nobel-Str. 50 40789 Monheim am Rhein (DE)
Representative:	BIP Patents c/o Bayer Intellectual Property GmbH Alfred-Nobel-Straße 50 40789 Monheim am Rhein (DE)
Respondent: (Patent Proprietor)	Krka, tovarna zdravil, d.d. Smarjeska cesta 6 8501 Novo mesto (SI)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 6 May 2024 rejecting the opposition filed against European patent No. 3309158 pursuant to Articl e 101(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	P. O'Sullivan
	R. Romandini

Summary of Facts and Submissions

I. The appeal of the opponent (hereinafter appellant) lies from the decision of the opposition division to reject the opposition against European patent 3 309 158.

II. The patent was opposed under Articles 100(a) EPC (novelty and inventive step) and 100(b) EPC.

III. The following documents, cited in opposition proceedings, are relevant to the present decision:

D11: "Experimental Report on Preparation of Rivaroxaban Form K"

IV. In a communication pursuant to Article 15(1) RPBA, the board provided its preliminary considerations.

V. Oral proceedings by videoconference took place as scheduled on 14 April 2026 in the presence of both parties.

VI. Requests relevant to the present decision

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent (patent proprietor) requested dismissal of the appellant's appeal, implying maintenance of the patent as granted.

Alternatively, the respondent requested maintenance of the patent on the basis of the claims of auxiliary requests 1 to 10, of which auxiliary requests 1 to 7

were submitted during the opposition proceedings and auxiliary requests 8 to 10 with the respondent's reply to the grounds of appeal.

VII. For the relevant party submissions, reference is made to the reasons for the decision set out below.

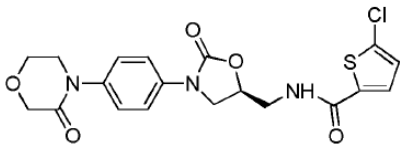
Reasons for the Decision

Main request (patent as granted)

1. Sufficiency of disclosure - Article 100(b) EPC

Claim 1 of the main request reads as follows:

"*Compound (I) of polymorphic form K*



(I),

characterized by the following significant peaks in its X-ray powder diffraction pattern:

No.	Position [°2Theta]	Relative Intensitiy [%]
1	3.6	43
2	7.1	22
3	14.3	22
4	19.9	92
5	20.2	63
6	24.3	100
7	28.9	39

"

1.1 Claim 1 relates to compound (I), hereinafter referred to as rivaroxaban, in polymorphic form K. This form is characterised according to claim 1 by seven XRPD peaks defined not only by the peak position expressed in terms of °2θ values (hereinafter: "peak position"), but also by the relative peak intensity at each peak position (hereinafter "relative intensity"), as set out in the above table.

1.2 The appellant argued that in order for the subject-matter defined in claim 1 to be sufficiently disclosed, the skilled person must be capable of reproducibly obtaining the claimed polymorphic form K having the claimed peak positions and the associated relative intensities. This requirement was however not fulfilled by the opposed patent.

1.3 The board agrees with the appellant for the following reasons. It is acknowledged by both parties that a specific polymorphic form is mainly characterised by the XRPD peak positions rather than by relative intensities, which can vary, even for the same polymorphic form. This was also acknowledged by the opposition division, and indeed forms the basis for the opposition division's conclusion that the respondent's data in D11 demonstrates the preparation of polymorphic form K, and thus that the requirements of sufficiency are fulfilled (decision, page 11, point 15.18). Thus, according to the opposition division, providing a polymorphic form displaying the claimed peak intensities was not needed for the requirement of sufficiency of disclosure to be met.

1.4 However, as stated by the appellant, the fact that relative intensities are less important for characterising a polymorph does not mean that the relative intensities defined in claim 1 are no longer limiting features of the claim. According to the principle of party disposition, it is the patent proprietor who chooses how to define its invention. According to Rule 43(1) EPC, the claims shall define the matter for which protection is sought in terms of the technical features of the invention.

1.5 In the present case, the respondent has chosen to define its invention not solely in terms of peak position, but also in terms of the relative intensity of each individual peak. Peak intensity is therefore a technical feature of the claim, at least to the extent that it is considered meaningful. In this context, the respondent acknowledged that relative intensities are not irrelevant, and merely argued that the peak positions are of higher importance.

1.6 The claimed peak intensities therefore constitute mandatory technical features of claim 1. Hence, claim 1 of the main request is directed not only to a polymorphic form K of rivaroxaban defined by XRPD peak positions, but a specific polymorphic form K with further limitations, namely in a physical form capable of providing the claimed relative intensities in an XRPD pattern.

1.7 Consequently, for the requirements of sufficiency of disclosure for the subject-matter to be fulfilled, the skilled person must be capable of preparing polymorphic form K having **both** the claimed peak positions and the claimed relative intensities.

1.8 Example 4 of the patent discloses the preparation of polymorphic form K, the XRPD pattern of which is shown in figure 1. A list of seven XRPD peaks, No. 1 to 7, and their relative intensities, are provided in paragraph [0038] of the patent and reproduced in the table in claim 1 (above). The respondent's submission that the peak position and relative intensities provided in this table originate in the XRPD pattern of figure 1 related to example 4 of the patent, while not specified in the patent, can be accepted for the purpose of the present decision.

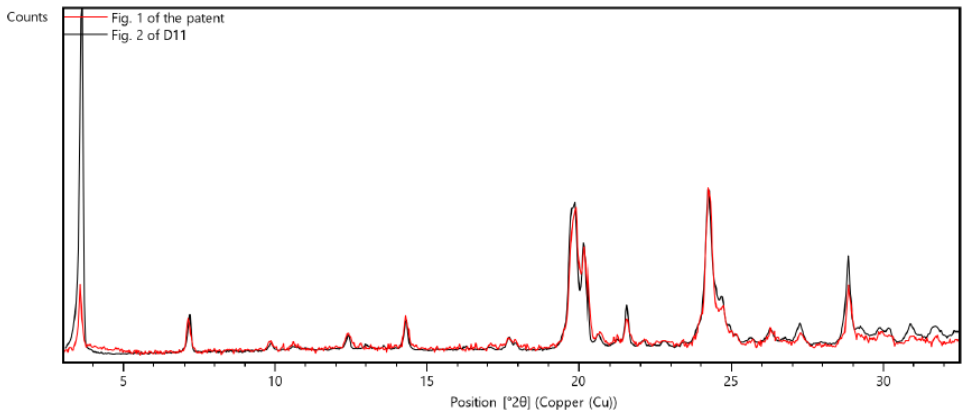
1.9 The appellant argued that the respondent's experimental evidence D11 served as proof that the polymorphic form prepared in example 4 of the patent and characterised according to the table in claim 1 could not be reproduced so as to obtain a polymorphic form K having the claimed relative intensities. Hence, the invention defined in claim 1 was not sufficiently disclosed.

1.10 The board agrees. Experimental report D11 was submitted by the respondent in opposition proceedings. It describes the attempted repetition of example 4 of the patent by an employee of the respondent. XRPD patterns of the wet and dry polymorphic product are depicted in figures 1 and 2, respectively.

1.11 The XRPD patterns of both figures 1 and 2 meet the requirements of claim 1 in terms of peak positions no. 1 to 7 (table in claim 1).

1.12 However, it was not disputed by the respondent that the peak intensities obtained in D11 are not identical to those claimed.

1.13 In this context, the respondent provided an overlay comparison of the XRPD pattern obtained in figure 1 of the patent (an XRPD pattern of the product of example 4) with that of figure 2 of D11, as reproduced below:



1.14 In this overlay, the peak intensities were scaled such that peak no. 6 (at 24.3°; the dominant peak according to claim 1) was of equal intensity in both patterns. On the basis of this comparison, the respondent submitted that the intensity of peaks no. 2 to 6 were "virtually identical" to those in figure 2 of D11. It acknowledged however that peak no. 1 at 3.6° differed significantly in intensity, and that peak no. 7 at 28.9° "fairly corresponded" (but was not identical to) the intensity provided in claim 1.

1.15 A similar comparison between the relative intensities of figure 2 of D11 and those set out in claim 1 of the patent was carried out by the respondent by measuring the heights of the peaks of figure 2 of D11 with a ruler and setting the obtained heights in relation to one another, with peak no. 6 at 24.3° being set to 100% relative intensity as in claim 1, as reproduced below:

Table

Peak No.	Claim 1		Fig. 2 of D11		
	°2Θ	**rel. Intensity [%]**	°2Θ	Intensity [mm]	**rel. Intensity [%]**
1	3.6	**43**	3.6	64.5	**202**
2	7.1	**22**	7.1	9	**28**
3	14.3	**22**	14.3	7.5	**23**
4	19.9	**92**	19.9	29.5	**92**
5	20.2	**63**	20.2	20	**63**
6	24.3	**100**	24.3	32	**100**
7	28.9	**39**	28.9	20	**63**

1.16 According to this table, when peak no. 6 at 24.3° is set to a relative intensity of 100% as required by claim 1, peak no. 1 in figure 2 of D11, at 202% relative intensity, is more than four times as intense as peak no. 1 in claim 1, at 43% relative intensity. Peak no. 7 had 63% relative intensity in figure 2 of D11, and 39% in claim 1.

1.17 The respondent submitted that, although differences arose in the relative intensities as set out above, in particular for peak no. 1, but also for peak no. 7, this was not decisive for sufficiency. The data showed that the intensities of five peaks (Nos. 2 to 6) in figure 2 of D11 were virtually identical to the claimed values.

1.18 According to the respondent, the skilled person would not base the assessment of a polymorphic form on a comparison of intensities only. In a technically sensible interpretation of claim 1, the skilled person would take into account the common general knowledge that deviations in intensities for the same polymorphic form could occur, and indeed would be expected. Such differences occurred in particular due to effects such as non-random orientation of the plate-like particles of polymorphic form K of claim 1 (see e.g. the SEM image in D7), which rendered XRPD intensities more

sensitive to particle orientation. Indeed, that such deviations occur was part of the common general knowledge of the skilled person.

1.19 Accordingly, the skilled person would not interpret claim 1 as strictly requiring the claimed relative intensities, and would hence consider that the product of Figure 2 of D11 corresponded to the polymorphic form K of claim 1. Consequently, D11 was proof that the invention defined in claim 1 could be carried out by the skilled person without undue burden.

1.20 The board disagrees. Claim 1 defines the subject-matter for which protection is sought in terms of the technical features of the invention, including the claimed relative intensities.

1.21 This means that as set out above, to prepare a polymorphic form K as defined by claim 1, **all** of the claimed peak intensities must be obtained. There is no provision in the EPC which permits disregarding claimed technical features by virtue of being less important, or less characteristic of a claimed product than other technical features of the claim.

1.22 In this regard the board accepts the respondent's position that a polymorphic form is normally characterised by peak position and that peak intensity plays a less important role. The common general knowledge that relative peak intensity may vary, even for the same polymorphic form, is also accepted.

1.23 However, this does not justify disregarding features explicitly defined in the claim. Accordingly, **all** of the claimed relative intensities constitute limiting features of the claim.

1.24 It follows that a product lacking any the claimed relative intensities does not fall within the scope of the claim. Consequently, the polymorphic form prepared according to D11 does not correspond to that of claim 1.

1.25 Hence, the respondent's own evidence D11 casts serious doubt on the reproducibility of a polymorphic form K having all claimed relative intensities.

1.26 The respondent's further arguments to the contrary failed to convince the board.

1.27 The respondent argued that the discrepancy between the relative intensity of peak no.1 in claim 1 (43%) and the same peak in figure 2 of D11 (202%) was attributable to non-random orientation of the plate-like particles in the sample tested. Accordingly, despite this difference, the skilled person would consider the product of figure 2 of D11 as identical to that of claim 1, i.e. exhibiting the claimed peak intensities. Such orientation effects were more pronounced at lower angles, which explained why the relative intensity of peak no.1 in figure 2 of D11 differed from the claimed intensity to such an extent, while peaks nos. 2 to 6 were virtually identical. Therefore, the effects of non-random orientation did not affect the relative intensities of the peaks in the spectrum equally. Hence, the respondent contended, the non-random particle orientation did not affect the relative intensities of all peaks equally.

1.28 The board disagrees. The product of D11 cannot be regarded as identical to that of claim 1, as it lacks the mandatory features of the claim, including the

claimed relative peak intensities, as set out above. The relevant question for sufficiency of disclosure is whether the skilled person, starting from the sample of figure 2 of D11 and considering the alleged effect of particle orientation on relative intensities, would know how to prepare a sample that exhibits the claimed intensity values.

1.29 No evidence was presented to substantiate the respondent's argument that particle orientation affects peak intensity differently depending on peak position. Moreover, the respondent's suggestion, proposed during oral proceedings, that lower-angle peak intensities are disproportionately affected, is contradicted by the substantial difference in the relative intensity of the highest angle peak listed in claim 1, namely peak no.7 (39%), compared to figure 2 of D11 (63%), while lower angle peaks no. 2 to 6 display almost identical relative intensities. Hence, the argument that peak intensities are disproportionately affected at lower angles does not account for the deviation in relative intensity at peak no. 7.

1.30 Finally, as stated above, it is the patent proprietor, in the present case the respondent, who defines the matter for which protection is sought. If this subject-matter included a low-angle XRPD peak with a specific relative intensity, then it is for the patent proprietor to ensure that this feature can be reproducibly achieved. In the present case, this has not been demonstrated and is not credible based on the evidence on file.

1.31 The respondent also referred to the differences observed between the XRPD patterns of figures 1 (before drying at 40°C) and 2 (after drying at 40°C) of D11,

and argued that relative intensities were affected by the degree of dryness of the sample. For example, in the wet sample of figure 1, peak no. 1 had a relative intensity of 304% (measured by peak height relative to the peak at 24.3), while after drying this intensity was reduced to 202% (relative to the same peak at 24.3; see table above). The respondent argued that since the sample tested in figure 2 of D11 had only been dried at 40°C rather than the 50°C stipulated in example 4 of the patent, further drying would be expected to provide peak intensities closer to those of claim 1. In particular, since the intensity of peak 1 reduced from 304% to 202% upon drying at 40°C, drying at 50°C would be expected to reduce the relative intensity of peak 1 further towards the claimed value (43%; see table in claim 1).

1.32 This argument is unconvincing. As stated by the appellant, even if it were assumed that drying would have some influence, it is not credible that merely increasing the drying temperature from 40°C to 50°C would yield a reduction of from 202% to 43%, i.e. approximately 80%, while going from not drying at all to drying at 40°C reduces the intensity of peak no.1 from 304% to 202%, i.e. by only approximately 33%. Furthermore, this allegation is contradicted by the patent itself, which teaches drying as an optional step in the preparation of the claimed polymorphic form (patent, paragraph [0039]). Consequently, the allegation that further drying of the sample tested in figure 2 of D11 at 50°C would result in a polymorphic form exhibiting all claimed relative intensities is merely speculative, and therefore cannot be accepted.

1.33 Thus, the ground for opposition under Article 100(b) EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1 to 10

2. Sufficiency of disclosure - Article 83 EPC

2.1 As noted by the board during oral proceedings and acknowledged by the respondent, claim 1 of all auxiliary requests is directed to either rivaroxaban polymorphic form K or a process for its preparation, said form requiring the same peak positions and relative intensities as set out in claim 1 of the main request.

2.2 Consequently, for the same reasons as provided for claim 1 of the main request above, the invention defined in claim 1 of each of auxiliary requests 1 to 10 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, as required by Article 83 EPC.

2.3 Hence, none of the auxiliary requests are allowable, and the patent is to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

U. Bultmann M. O. Müller

Decision electronically authenticated