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Datasheet for the decision of 29 January 2026

Case Number: T 1123/24 - 3.3.02

Application Number: 13843426.1

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Language of the proceedings: EN

Title of invention:
RHO KINASE INHIBITORS

Patent Proprietor:
Kadmon Corporation, LLC

Opponents:
Sandoz AG
ELKINGTON AND FIFE LLP

Relevant legal provisions:
EPC Art. 123(2), 56
RPBA 2020 Art. 13(2)

Keyword:
Amendments
Inventive step - reasonable expectation of success (no)
Amendment after summons - exceptional circumstances (no)

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Case Number: T 1123/24 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 29 January 2026

Appellant: (Opponent 1)	Sandoz AG Centralbahnstrasse 4 4051 Basel (CH)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Respondent: (Patent Proprietor)	Kadmon Corporation, LLC 450 East 29th St. New York, NY 10016 (US)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Party as of right: (Opponent 2)	ELKINGTON AND FIFE LLP Prospect House 8 Pembroke Road Sevenoaks Kent TN13 1XR (GB)
Representative:	Kraus & Lederer PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 July 2024 concerning maintenance of the European Patent No. 2903618 in amended form.**

Composition of the Board:

Chairman	S. Bertrand
Members:	A. Lenzen
	L. Bühler

Summary of Facts and Submissions

I. Opponent 1 (appellant) lodged an appeal against the opposition division's decision (decision under appeal) that European patent No. 2 903 618 (patent) in amended form meets the requirements of the EPC.

The patent was granted on the basis of European patent application No. 13843426.1 (application), which had been filed as a PCT application published as WO 2014/055996 A2.

II. Reference is made in the present decision to the following documents filed with the opposition division:

D4 WO 2008/054599 A2
D5 Biswas, P. S., et al., J. Clin. Invest. 2010, 120(9), 3280-3295
D15 WO 2011/062766 A2
D17 Serody, J. S., et al., Biol. Blood Marrow Transplant, 2012, 18 (1 Suppl.), S56-S61
D30 US Office Action dated 23 September 2022 concerning US application No. 16/913,267
D31 US 2021/0147391 A1

III. In preparation for the oral proceedings, which had been arranged at the request of the appellant and the patent proprietor (respondent), the board issued a communication under Article 15(1) RPBA.

IV. Oral proceedings before the board were held by videoconference on 29 January 2026 in the presence of the appellant and the respondent. At the end of the

oral proceedings, the chair announced the order of the present decision.

V. Opponent 2 did not file any submissions or requests on appeal.

The appellant's and the respondent's final requests at the end of the oral proceedings, where relevant to this decision, were as follows:

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

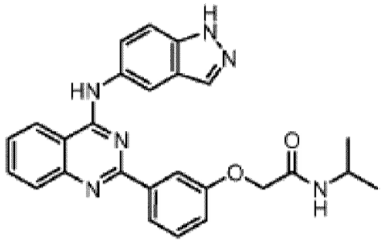
- The respondent requested that the appeal be dismissed, implying that the decision under appeal be confirmed and that the patent be maintained in the form held allowable by the opposition division (main request).

VI. Summaries of the parties' submissions relevant to the present decision and key aspects of the decision under appeal are set out in the reasons for the decision below.

Reasons for the Decision

Main request

1. Claim 1 of the main request reads as follows:

> "*A compound that inhibits ROCK2 for use in treating an autoimmune disorder in a subject, wherein the autoimmune disorder is graft-versus-host disease (GVHD), and wherein the compound that inhibits ROCK2 is a compound of the formula:*
>
> 
>
> *or a pharmaceutically acceptable salt thereof.*"

The compound represented by the structural formula in claim 1 is referred to below by its International Nonproprietary Name (INN), belumosudil. Therefore, claim 1 of the main request essentially relates to belumosudil (or a pharmaceutically acceptable salt thereof) for use in treating graft-versus-host disease (GVHD).

2. Amendments (Article 123(2) EPC)

2.1 The appellant argued that the subject-matter of claim 1 of the main request extended beyond the content of the application as filed.

2.2 In line with the parties' submissions, as far as the application as filed is concerned, the board refers below to the PCT application as published (WO 2014/055996 A2).

2.3 In its decision, the opposition division found that the subject-matter of claim 1 of the main request did not extend beyond the content of the application as filed.

It identified a basis, *inter alia*, in claims 12 and 17 as filed. Although claim 17 did not refer back to claim 12, but instead to a different and unrelated claim, this back-reference was considered to be an obvious error, and it was immediately evident that nothing other than a back-reference in claim 17 to claim 12 had been intended.

The appellant contested this finding in its statement of grounds of appeal.

However, the reasoning in the decision under appeal and consequently the appellant's discussion of it in the statement of grounds of appeal are not relevant in the present case, since, as set out below, the subject-matter of claim 1 of the main request is already derivable from the description of the application as filed, without any need to correct an allegedly obvious error in claim 17 as filed.

2.4 The application as filed (paragraph [0001]) relates to inhibitors of the two mammalian isoforms of Rho-associated protein kinase, ROCK1 and ROCK2, and the application of these inhibitors to the treatment of different diseases.

The inhibitors are disclosed in the application as filed with varying degrees of specificity. Paragraphs [0040] to [0076] define various Markush formulas. Paragraphs [0078] and [0079] set out lists of specific compounds by systematic name and by structural formula, respectively. The paragraph in between, i.e. paragraph [0077], depicts the structural formula of just one specific compound, namely belumosudil. Therefore, as set out by the respondent, the general presentation of the inhibitors in the application as filed already indicates a preference for belumosudil.

Moreover, as argued by the respondent, of the inhibitory compounds defined in the application as filed, belumosudil is the only one that was actually used in the biological tests (examples 183 to 191). The application as filed further emphasises that selective inhibition of either ROCK1 or ROCK2 is desirable or may be desirable (see, for example, paragraph [0182] quoted below), and the only specific representative of the Markush formulas in paragraphs [0040] to [0076] to which such selective inhibition is expressly attributed is belumosudil, which is described as a selective ROCK2 inhibitor (again, see examples 183 to 191). It follows that, contrary to the appellant's view, belumosudil is singled out in the application as filed and that its disclosure does not require a selection from a list of compounds.

With regard to the diseases to be treated, paragraph [0182], to which the respondent referred in this context, reads as follows (emphasis added by the board):

> "***According to the invention, targeting Th17 (IL-17-secreting) cells by rhokinase inhibition provides a***

method for treating Th17 cell-mediated diseases, including but not limited to *autoimmune disorders such as rheumatoid arthritis (RA) multiple sclerosis (MS), systemic luypus srythematosus (SLE), psoriasis, Crohn's disease, atopic dermatitis, eczema, and* ***GVHD*** *in humans. In an embodiment of the invention, the Rho-kinase inhibitor is a compound of Formula I. In some embodiments, the rho-kinase inhibitor inhibits ROCK1 and ROCK2.* ***In some embodiments, the rho-kinase inhibitor selectively inhibits ROCK2. Selective inhibition of ROCK2 provides for treatment of Th17 cell-mediated diseases and reduces or prevents toxicities associated with complete inhibition of ROCK activity.***"

This paragraph therefore discloses that the Th17 cell-mediated diseases mentioned in it, including GVHD, are preferably treated with ROCK2-selective inhibitors, since such selectivity reduces or prevents the toxicities associated with complete inhibition of ROCK activity. Against this background, and in particular in view of the fact that belumosudil is the only compound explicitly set out in the application as filed as having a selective inhibitory effect on ROCK2, the board agrees with the respondent that, in the context of the disclosure of paragraph [0182], the skilled person would inevitably understand belumosudil to be the ROCK2-selective inhibitor envisaged for treating Th17 cell-mediated diseases.

Consequently, the treatment of the diseases listed in paragraph [0182], including GVHD, with the ROCK2-selective inhibitor belumosudil is directly and unambiguously disclosed in the application as filed. Contrary to the appellant's argument, only a single

selection from the application as originally filed is therefore required, namely the selection of the specific disease (GVHD), in order to arrive at the subject-matter of claim 1 of the main request. Such a single selection does not result in added subject-matter.

2.5 It follows that the subject-matter of claim 1 of the main request does not extend beyond the content of the application as filed.

3. Inventive step (Article 56 EPC)

3.1 The appellant raised objections of lack of inventive step starting from D15 and D4 as the closest prior art. These objections are addressed below in turn.

D15 as the closest prior art

3.2 D15 (page 7, lines 3 to 6) relates to, *inter alia*, inhibitors of ROCK1 and/or ROCK2 and their therapeutic use.

As is apparent, for example, from claim 1 of D15, each of these inhibitors features a 7-membered cyclic core. The five specific inhibitors tested in example II selectively inhibit ROCK2 over ROCK1.

According to the passage on page 21, line 7 to page 22, line 16, the inhibitors in D15 can be used to treat a variety of disorders related to ROCK activity. Autoimmune disorders such as GVHD are also mentioned within this passage.

Lastly, D15 (page 22, lines 19 to 28) also refers to the results in D5, which are stated to be incorporated

into D15 in their entirety. D5 (page 3292, right-hand column, second paragraph) describes that inhibition of ROCK2 leads to reduced expression of the pro-inflammatory cytokines IL-17 and IL-21 and concludes that this "*supports the idea that development of compounds selectively targeting ROCK2 may represent an important treatment modality for RA, SLE, and possibly other autoimmune disorders characterized by enhanced IL-17 and IL-21 production.*" D15 accordingly explains that, in some embodiments, the disorder to be treated may likewise be associated with pro-inflammatory cytokine expression, for example, IL-17 and/or IL-21.

3.3 Distinguishing features

3.3.1 It was common ground between the parties that belumosudil as referred to in claim 1 of the main request is structurally different from the ROCK inhibitors disclosed in D15.

3.3.2 Although GVHD is listed as an autoimmune disorder, D15 does not provide any technical information linking its inhibitors to efficacy in GVHD. As discussed during the oral proceedings, the mere disclosure of five specific ROCK2-selective inhibitors in example II of D15 does not render it credible that these five specific inhibitors, let alone all the inhibitors encompassed by the broad Markush formulas in D15, are suitable for the treatment of one of the diseases listed in the passage on page 21, line 7 to page 22, line 16 (see Case Law of the Boards of Appeal of the European Patent Office, 11th edition 2025 (CLBA), I.C.4.12). D15 therefore fails to disclose that any of its inhibitors are in fact suitable for the treatment of GVHD.

The appellant's assertion that the level of disclosure of D15 and of the application as filed with regard to the suitability for the treatment of GVHD was the same may be relevant to the assessment of the sufficiency of disclosure of the invention of claim 1 of the main request - an objection which the appellant deliberately did not raise; however, this contention has no bearing on the above assessment of the disclosure of D15.

Contrary to the appellant's argument, the above conclusion, namely that D15 does not disclose the suitability of its ROCK inhibitors for the treatment of GVHD, is not affected by the fact that D15 incorporates the disclosure of D5 by reference. Even if, despite its vagueness, the disclosure of D5 (see the quote in point 3.2) were interpreted in the appellant's favour as teaching that ROCK2 inhibitors are, *per se*, suitable for the treatment of autoimmune disorders characterised by enhanced IL-17 and IL-21 production, it still could not be concluded that ROCK2 inhibitors are likewise suitable for the treatment of the autoimmune disorder GVHD. This is because neither D5 (which does not mention anything whatsoever regarding GVHD) nor D15 discloses that GVHD is associated with enhanced IL-17 and IL-21 production. On the contrary, and as submitted by the respondent, D15 addresses diseases related to IL-17/IL-21 expression separately from the diseases listed in the passage on page 21, line 7 to page 22, line 16 (including GVHD), without establishing any link between them.

3.3.3 Therefore, the subject-matter of claim 1 of the main request is distinguished from D15 in that it relates to a different active pharmaceutical ingredient, namely belumosudil, and in that it relates to the treatment of GVHD.

3.4 Technical effect and objective technical problem

The respondent argued that belumosudil allows for safe and effective treatment of GVHD, and this was not contested by the appellant. Therefore, in line with the respondent, the objective technical problem is to provide safe and effective treatment of GVHD.

3.5 Obviousness

3.5.1 As regards obviousness, the appellant stated at the oral proceedings that, contrary to its previous written submissions, it was no longer relying on D17 as a secondary document in support of its inventive-step objection starting from D15 as the closest prior art. Instead, the appellant referred to D4 alone, which, in its view, rendered the subject-matter of claim 1 of the main request obvious.

3.5.2 Similarly to D15, D4 (paragraph [0003]) relates to inhibitors of ROCK1 and/or ROCK2 and to their therapeutic use. Of the specific inhibitors disclosed, belumosudil, which selectively inhibits ROCK2 over ROCK1, is highlighted (example 82; paragraph [0463]; figures 10 to 14). D4 (paragraph [0209]) states that its inhibitors are suitable for the treatment of e.g. rheumatoid arthritis and multiple sclerosis.

3.5.3 However, when faced with the objective technical problem formulated above, the skilled person would have had no reason to consult D4 as this document does not mention anything whatsoever regarding GVHD.

3.5.4 Even if, for the sake of argument, the skilled person had consulted D4, it is not apparent why, in view of

the fact set out above that D15 does not even demonstrate the suitability of its ROCK inhibitors for the treatment of GVHD, the skilled person would have had a reasonable expectation of success that the structurally different inhibitor belumosudil would have been suitable for that very purpose.

A further complicating factor in the present case is that D15 merely associates the diseases mentioned in the relevant passage (page 21, line 7 to page 22, line 16), such as GVHD, in general terms with ROCK inhibitors, without distinguishing between selective inhibition of ROCK1 and/or ROCK2; however, as pointed out by the respondent with reference to D15 (page 3, last paragraph), the selective inhibition of ROCK1 alone or of ROCK2 alone may have different effects on cellular functions and downstream targets. Against this background, it is not apparent why the skilled person would have assumed, with a reasonable expectation of success, that an inhibitor selective for only one isoform, such as belumosudil, would have been suitable for the treatment of GVHD.

D4 as the closest prior art

3.6 The disclosure of D4 has been summarised above in point 3.5.2. Therefore, the same compound as that in claim 1 of the main request (belumosudil) is disclosed in D4, but for treating a different disorder (e.g. rheumatoid arthritis and multiple sclerosis).

3.7 Distinguishing feature

It was common ground between the parties that the subject-matter of claim 1 of the main request differs

from D4 only in that it relates to a different disorder to be treated, namely GVHD.

3.8 Technical effect and objective technical problem

The parties agreed that the fact that claim 1 of the main request and D4 tackle different diseases is not associated with an additional technical effect. Therefore, as set out by the respondent at the oral proceedings, the objective technical problem is to provide a specific therapeutic use for belumosudil.

The objective technical problem formulated by the appellant at the oral proceedings (to provide effective treatment of GVHD as a specific therapeutic use of belumosudil) contains a clear pointer to the solution and is therefore not appropriate (see CLBA, I.D.4.2.1).

3.9 Obviousness

3.9.1 At the oral proceedings, the appellant referred to documents D5 and D17, which, in combination with D4, were considered by the appellant to render the subject-matter of claim 1 of the main request obvious.

Upon the respondent's request, the board decided not to admit this objection for the following reasons. As submitted by the respondent, and not disputed by the appellant, the inventive-step objection starting from D4 and including D5 was raised only during the oral proceedings and not in the appellant's previous written submissions. This new objection therefore constituted an amendment to the appellant's appeal case. Under Article 13(2) RPBA, such an amendment should not be taken into account unless there are exceptional circumstances, which have been justified with cogent

reasons by the party concerned. In this context, the appellant argued that it had raised an inventive-step objection starting from D4 in combination with D5 in its written submissions before the opposition division; however, contrary to the appellant's view, and irrespective of the fact that this objection did not include D17, this does not constitute an exceptional circumstance, not least because nothing would have prevented the appellant from already raising such an objection in its statement of grounds of appeal.

3.9.2 As an alternative, at the oral proceedings the appellant referred to its inventive-step objection starting from D4 in combination with D17 only, which had been put forward in its statement of grounds of appeal.

However, this objection from the written proceedings is not persuasive even if the appellant's submissions regarding D17 are assumed to be correct, namely that D17 discloses the possibility of treating GVHD (be it acute or chronic) by reducing the expression of IL-17 and IL-21. The reason is that, as set out by the respondent, neither D4 (which does not mention anything whatsoever regarding IL-17 and IL-21) nor D17 (which does not mention anything whatsoever regarding ROCK and its isoforms) establishes a link between the inhibition of ROCK, let alone ROCK2, on the one hand and a change in the production of IL-17 and/or IL-21 on the other hand. Therefore, even if the skilled person had consulted D17, in the absence of teaching that ROCK2 inhibition leads to IL-17/IL-21 reduction in GVHD, they would not have had any reasonable expectation of success in considering belumosudil suitable for the treatment of GVHD.

In support of the correctness of its understanding of the disclosure of D17, the appellant also referred to D30 and D31, which the opposition division had not admitted into the proceedings. Since, as set out above, the appellant's objection does not succeed even if its understanding of the disclosure of D17 is assumed to be correct, the correctness of the opposition division's decision not to admit D30 and D31 does not need to be discussed.

3.9.3 Lastly, the appellant also argued that the skilled person would have realised that the mechanism underlying at least some of the diseases addressed in D4 (namely rheumatoid arthritis and multiple sclerosis) was identical to that underlying GVHD; however, since this argument was presented without any supporting evidence, it merely amounts to an unsubstantiated allegation and is therefore not convincing. In the absence of any evidence that GVHD shares the same underlying mechanism as at least some of the diseases addressed in D4, the skilled person would have had no reason to extrapolate the therapeutic use disclosed in D4 to GVHD.

Summary of the inventive-step objections

3.10 It follows from the assessments of the inventive-step objections starting from D15 and D4 as the closest prior art that the subject-matter of claim 1 of the main request involves an inventive step.

4. In view of the above, the main request is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Vottner S. Bertrand

Decision electronically authenticated