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Datasheet for the decision of 4 April 2022

Case Number: T 0752/19 - 3.5.05

Application Number: 12702463.6

Publication Number: 2666113

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
PHARMACEUTICAL PRODUCT AND COMMUNICATION TOOL

Applicant:
Intellectual Property Enabler Stockholm AB

Headword:
Ticagrelor, acetylsalicylic acid and a computer program/ INTELLECTUAL PROPERTY ENABLER STOCKHOLM

Relevant legal provisions:
RPBA 2020 Art. 9
EPC Art. 56
RPBA Art. 12(4)

Keyword:
Inventive step - main request (no)
Late-filed request - submitted with the statement of grounds of appeal - admitted (no) - should have been submitted in first-instance proceedings (yes)

Decisions cited:
T 1670/07, T 0970/12

Catchword:
Improved patient compliance to a pharmaceutical formulation cannot be used to establish an overall technical effect if it is the result of a "broken technical chain", namely an alleged chain of technical effects starting with information provided to a patient which is then broken by the patient's mental activities (see points 2.4 and 2.5).

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Case Number: T 0752/19 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 4 April 2022

Appellant: (Applicant)	Intellectual Property Enabler Stockholm AB Tegnebyvägen 35 168 56 Bromma (SE)
Representative:	Zacco Sweden AB P.O. Box 5581 Löjtnantsgatan 21 114 85 Stockholm (SE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 8 October 2018 refusing European patent application No. 12702463.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	F. Blumer
	J. Molina de Alba
	D. Prietzel-Funk

Summary of Facts and Submissions

I. The appeal is against the examining division's decision to refuse the application. The examining division decided that claim 1 of the main request and of the first auxiliary request then on file did not involve an inventive step (Article 56 EPC).

II. With its statement setting out the grounds of appeal, the appellant re-filed the main request and filed a new first auxiliary request. It requested that the decision under appeal be set aside, that a patent be granted on the basis of one of the requests and, as an auxiliary measure, oral proceedings. It further requested that the board be enlarged to include a member technically qualified in the pharmaceutical art.

III. In a communication pursuant to Article 15(1) RPBA 2020, the board informed the appellant that the board had been enlarged as requested by the appellant, that the board's preliminary opinion was that the main request did not meet the requirements of Article 56 EPC and that the board was minded not to admit the first auxiliary request.

IV. Oral proceedings were held before the board.

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

"Ticagrelor for use in a treatment of Acute Coronary Syndrome or myocardial infarction, in combination with acetyl salicylic acid and a computer program product comprising instructions causing a computer to perform a method comprising the steps

- providing a patient with a set of questions according to a question schedule, wherein said set of questions is specific to ticagrelor;
- collecting answers to said questions from said patient;
- subjecting said answers to a set of functions specific for the set of questions and ticagrelor thereby generating patient-specific feedback information;
- providing said feedback information to the patient;
and optionally extracting clinically relevant information from said answers and providing said clinically relevant information to a database adapted for collecting clinically relevant information during clinical use of ticagrelor,
wherein said computer program product is adapted to be installed on a handheld device."

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that it has the following additional text at the end:

", and wherein said set of questions and said set of functions are related to patient compliance to a preferred or prescribed dosage and/or administration regimen of ticagrelor."

VI. In the present decision, reference is made to the following documents:

D3: Wallentin et al., "Ticagrelor versus Clopidogrel in Patients with Acute Coronary Syndromes", The New England Journal of Medicine, 10 September 2009, vol. 361, no. 11, pages 1045-1057

D4: Johnston et al., "Effects of interactive patient smartphone support app on drug adherence and lifestyle changes in myocardial infarction patients: A randomized study", American Heart Journal, August 2016, vol. 178, pages 85-94

D5: Supplement 1, Description of the e-diary and interactive patient support tool, submitted by the appellant on 11 August 2017

D6: Helms et al., "Textbook of Therapeutics: Drug and Disease Management", 2006, Lippincott Williams & Wilkins, page 480.

Reasons for the Decision

1. Request for the enlargement of the board to include a member technically qualified in the pharmaceutical art

1.1 With its statement setting out the grounds of appeal, the appellant requested that the board be enlarged to include a member technically qualified in the pharmaceutical art. The board accepted this request and, in accordance with Article 9 RPBA 2020, decided to enlarge the board so as to include J. Molina de Alba.

2. Main request - Inventive step (Article 56 EPC)

2.1 The appellant did not contest that the second medical use of ticagrelor and acetylsalicylic acid for the treatment of Acute Coronary Syndrome or myocardial infarction was already known at the priority date of the application at hand, e.g. from D3, which the appellant considered to be the closest prior art. The

board agrees that D3 is a suitable starting point to assess inventive step.

2.2 The subject-matter of claim 1 of the main request differs from D3 in that it further includes an interactive computer program. This computer program presents to the patient, according to a question schedule, a set of questions specific to ticagrelor, collects their answers, generates patient-specific feedback based on the answers and provides this feedback to the patient.

2.3 The appellant argued that, according to the established case law of the boards of appeal, in order to answer the question as to whether an intrinsically non-technical distinguishing feature, such as the computer program according to claim 1, contributes to the technical character of the invention, the distinguishing feature was not to be considered in isolation. Instead, it was the overall technical effect brought about by the distinguishing feature which had to be assessed, i.e. if it contributes to the technical character of the claim by interacting with the technical features of the claim to solve a technical problem (see Case Law of the Boards of Appeal of the European Patent Office, Ninth Edition, July 2019, I.D. 9.1.3(c)). It thus has to be assessed whether the computer program according to claim 1 interacts with the technical features of claim 1, namely the combination of ticagrelor and acetylsalicylic acid, to bring about an overall technical effect.

2.4 To answer this question, the board asked the appellant whether the computer program according to claim 1 interacted with any biological target, which the appellant answered in the negative. Thus, it is not

disputed that the computer program according to claim 1 does not interact with the technical features of claim 1 at the level of a biological target. Instead, the appellant argued that the alleged interaction of the computer program with the combination of ticagrelor and acetylsalicylic acid lay in an enhanced likelihood of a patient complying with a prescribed treatment regimen with the combination of ticagrelor and acetylsalicylic acid and consequently in an enhanced therapeutic effect. Referring in particular to T 970/12, the appellant argued that the provision of a new pharmaceutical formulation comprising a known active ingredient but exhibiting good patient compliance was recognised as a technical effect by the boards of appeal. However, the computer program according to claim 1 is neither a pharmaceutical formulation nor an active ingredient in a pharmaceutical formulation, while the pharmaceutical formulation in the case at hand, i.e. the combination of ticagrelor and acetylsalicylic acid, is not new. The appellant did not contest these observations. In T 970/12, the board had defined the objective technical problem as "the provision of alternative inhalation formulations of hypertonic saline solutions exhibiting good patient compliance [emphasis by the board]". In the case at hand, since the pharmaceutical formulation in question, namely the combination of ticagrelor and acetylsalicylic acid, is not new, it cannot be argued that the effect of the distinguishing feature lies in the provision of an alternative formulation exhibiting good patient compliance.

2.5 In this regard, the appellant argued that patient compliance was not an intrinsic property of a pharmaceutical composition, unlike physical properties such as pH, viscosity, solubility, etc., which can be

objectively measured by studying the composition in isolation. Instead, it was an effect which could only be measured after a pharmaceutical composition had been administered to a population of test subjects. Thus, it was obvious that the board in T 970/12 meant by "good patient compliance" an improved compliance when the formulation was administered to a population of subjects, not any objective and intrinsic physical property of the formulation. In the case at hand, the computer program of claim 1 led to improved patient compliance as demonstrated by the clinical studies presented in D4 and D5.

The board does not agree with the appellant's theory. To the contrary, improved patient compliance could be recognised as the overall technical effect of the distinguishing features of claim 1 only if it were shown to arise objectively in an unbroken technical chain from the intrinsic properties of the claimed pharmaceutical formulation. In general, in a pharmaceutical formulation exhibiting improved patient compliance, the intrinsic properties of the improved pharmaceutical formulation either lead to fewer side effects or make the administration of the pharmaceutical formulation into the patient's body easier, thus objectively lowering the risk of discontinuation or interruption of the therapy regimen. For example in T 970/12, the board traced such an unbroken technical chain starting from "the addition of hyaluronic acid or a salt of ester thereof with a low molecular weight or an intermediate weight at a concentration of between 0.01% and 1%, instead of quinine sulfate" to an inhalation formulation, which led to "better local tolerability, with a reduction in the inflammatory component affecting the mucosa of the airways", which in turn led to "a lower risk of

discontinuance of the treatment", ending thus in "good patient compliance" (see point 2.3.1 of the Reasons).

In the case at hand, the pharmaceutical composition is indeed not new. Since the computer program of claim 1 does not interact with the intrinsic properties of the pharmaceutical composition, it can be ruled out that it leads to an overall technical effect in terms of improved patient compliance. Any improved patient compliance in the case at hand, as apparently demonstrated by D4 or D5, is instead the result of a "broken technical chain" (see T 1670/07, point 11 of the Reasons), namely an alleged chain of technical effects starting with information provided to a patient which is then broken by the patient's mental activities. In the case at hand, the possible final technical effect of improved patient compliance brought about by a computer program generating and presenting patient-specific feedback is conditional on the patient's mental activities and thus cannot be used to establish an overall technical effect. This is analogous to the information provided on a package insert, which would also not produce any technical effect in an unbroken technical chain. In fact, D6, an extract from a textbook on therapeutics, which was cited in the contested decision and also discussed by the appellant, lists several such techniques involving a broken technical chain, such as labelling prescriptions with clear directions, encouraging the use of stickers or calendars to remind patients to take medications, providing feedback to patients, establishing a positive relationship with them or rewarding them for taking medications. While the board does not dispute that such techniques may have the effect of improved patient compliance, such an effect is conditional on the patient's mental activities and

thus does not contribute to the technical character of the invention.

2.6 Another argument brought forward by the appellant was that a CE marking was a secondary indicator of technical character. The interactive support tool of D4, which corresponds to the computer program according to claim 1, was subsequently approved as a medical device (see D4, page 93, "Contributions") in accordance with EU regulations. In order to be registered as a medical device, the computer program had to achieve the performance intended by the manufacturer and solve technical problems. Therefore, a CE marking was in essence the acknowledgement of the achievement of a technical effect. However, regulatory approval of a device has no relevance to the assessment of its patentability in accordance with the EPC.

2.7 Therefore, the distinguishing features of claim 1 of the main request do not have any overall technical effect, thus do not solve any objective technical problem and do not involve an inventive step (Article 56 EPC).

3. Admission of the first auxiliary request (Article 12(4) RPBA 2007)

3.1 In its statement setting out the grounds of appeal, the appellant stated that the subject-matter of this auxiliary request was not submitted before the examining division, as "it was [...] not considered relevant to burden the first instance proceedings with an auxiliary request with this subject-matter". However, refraining from filing a request before the examining division and then filing it before the board

is contrary to the primary object of appeal proceedings, which is to review the contested decision.

3.2 According to Article 12(4) RPBA 2007, the board has discretion not to admit requests which could have been presented in the examination proceedings. The appellant argued that the additional subject-matter of claim 1 of the first auxiliary request was in a dependent claim of the main request but did not seem to be a promising direction to restrict the claimed subject-matter at the proceedings before the examining division. The board was not convinced that these arguments speak in favour of the admission of the first auxiliary request. Instead, they demonstrate that the first auxiliary request could have been filed before the examining division but the appellant decided not to do so.

3.3 Therefore, the board did not admit the first auxiliary request into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated