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Datasheet for the interlocutory decision of 11 October 2021

Case Number: T 0116/18 - 3.3.02

Application Number: 12002626.5

Publication Number: 2484209

IPC: A01N43/56, A01N51/00

Language of the proceedings: EN

Title of invention:
Insecticide compositions

Patent Proprietor:
Sumitomo Chemical Company, Limited

Opponent:
SYNGENTA LIMITED

Headword:

Relevant legal provisions:
EPC Art. 100(b), 54, 56, 112(1)(a)
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:

Grounds for opposition - insufficiency of disclosure
Novelty
Inventive step
Referral to the Enlarged Board of Appeal
Late-filed evidence - submitted with the statement of grounds of appeal - submitted shortly before oral proceedings

Decisions cited:

G 0003/97, G 0001/03, G 0001/12, T 0184/82, T 0101/87, T 0012/90, T 0939/92, T 0609/02, T 1329/04, T 0578/06, T 0536/07, T 1437/07, T 1326/08, T 1397/08, T 0266/10, T 0415/11, T 1791/11, T 0863/12, T 1422/12, T 0895/13, T 2371/13, T 0919/15, T 0184/16, T 0488/16, T 0031/18, T 2015/20

Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the EPC

Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan and anr [2018] UKSC 56

Catchword:

The following questions are referred to the Enlarged Board of Appeal for decision.

If for acknowledgement of inventive step the patent proprietor relies on a technical effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):

1. Should an exception to the principle of free evaluation of evidence (see e.g. G 3/97, Reasons 5, and G 1/12, Reasons 31) be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests **exclusively** on the post-published evidence?

2. If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (ab initio plausibility)?

3. If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (ab initio implausibility)?

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Case Number: T 0116/18 - 3.3.02

I N T E R L O C U T O R Y D E C I S I O N
of Technical Board of Appeal 3.3.02
of 11 October 2021

Appellant: (Opponent)	SYNGENTA LIMITED Syngenta Jealott's Hill International Research Centre Bracknell Berkshire RG42 6EY (GB)
Representative:	HGF Benoordenhoutseweg 46 2596 BC Den Haag (NL)
Respondent: (Patent Proprietor)	Sumitomo Chemical Company, Limited 27-1, Shinkawa 2-chome, Chuo-ku Tokyo 104-8260 (JP)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 December 2017 rejecting the opposition filed against European patent No. 2484209 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	A. Lenzen
	P. de Heij

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the decision of the opposition division (decision under appeal) to reject the opposition against European patent No. 2 484 209 (patent in suit).

The patent in suit originates from European patent application No. 12002626.5, which is a divisional application of European patent application No. 05719327.8.

II. The patent in suit had been opposed pursuant to Article 100(a) EPC for lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), Article 100(b) EPC for insufficiency of disclosure (Article 83 EPC), and Article 100(c) EPC for added matter (Article 123(2) EPC and Article 76(1) EPC).

III. The following documents, submitted before the opposition division, are relevant for the present decision:

D4 WO 03/015519 A1
D8 WO 2005/048711 A1
D8P1 DE 103 53 278.1
(first priority application of D8)
D8P2 DE 10 2004 006 075.4
(second priority application of D8)
D9 Experimental report - field trials (18 pages, filed with the notice of opposition)
D10 Experimental report (2 pages, filed with the notice of opposition)

D21 Additional Test Data (6 pages, filed by the patent proprietor (respondent) with its letter dated 26 October 2016)

D22 Additional Test Data (21 pages, filed with the respondent's letter dated 11 September 2017)

IV. The opposition division's decision can be summarised as follows.

- The grounds for opposition pursuant to Article 100(c) EPC (Article 123(2) and Article 76(1) EPC) did not prejudice the maintenance of the patent in suit as granted.

- The question of the conditions under which synergy was achieved was not relevant for sufficiency of disclosure as this effect was not expressed in the claims. This effect was part of the problem to be solved and had to be dealt with under inventive step. Therefore, the ground for opposition pursuant to Article 100(b) EPC did not prejudice the maintenance of the patent in suit as granted.

- The novelty objections based on D4 and D8 (prior-art documents pursuant to Article 54(2) and Article 54(3) EPC, respectively) were not convincing because at least two selections had to be made from their respective disclosures to arrive at claim 1 of the patent in suit as granted.

- D21 and D22 were admitted into the proceedings. The results in these documents and of test example 2 in the patent in suit proved a synergistic effect from combining thiamethoxam with compounds according to formula Ia of claim 1. The data in D9 and D10 had not been taken into account because, *inter alia*,

the experiments described in them could not be reworked. In view of D4 as the closest prior art, the objective technical problem had to be seen as "*the provision of insecticide compositions comprising anthranilamides out of the group disclosed in D4, together with an insecticidally active mixing partner, showing an advantageous enhanced efficacy.*" (decision under appeal, page 23, penultimate paragraph). The solution to this problem was not obvious because synergism was *per se* unpredictable.

Therefore, the ground for opposition pursuant to Article 100(a) EPC did not prejudice the maintenance of the patent in suit as granted.

V. With its statement of grounds of appeal, the appellant submitted the following document:

D23 Experimental report (8 pages)

The last two pages of the statement of grounds of appeal are headed "Annex 1" and show a calculation of the number of compounds covered by formula Ia in claim 1.

VI. As requested, the parties were summoned to oral proceedings. In preparation for the hearing, the board issued a communication pursuant to Article 15(1) RPBA 2020 with a preliminary opinion on certain issues relevant to the decision to be taken. With regard to the disputed requirement of plausibility, the board indicated that a referral to the Enlarged Board of Appeal might be necessary.

VII. By letter dated 19 April 2021, the appellant withdrew its previously formulated request that the appeal fee be refunded.

VIII. By letter dated 22 April 2021, the appellant submitted a copy of a correspondence between epi and the President of the European Patent Office.

IX. By letter of 22 June 2021, the respondent filed, *inter alia*, sets of claims of a second and a third auxiliary request and the following document:

D24 Selby, T. S., Lahm, G. P., Stevenson, T. M., "A retrospective look at anthranilic diamide insecticides: discovery and lead optimization to chlorantraniliprole and cyantraniliprole", Pest Manag. Sci., 73, 2017, pages 658 to 665

X. Oral proceedings before the board were held as a video conference on 22 July 2021.

At the hearing, the appellant's opening requests were that:

- the decision under appeal be set aside and that the patent in suit be revoked in its entirety
- D21 and D22 not be taken into account to prove the alleged synergy
- D24 not be admitted into the proceedings
- the respondent's pending auxiliary requests not be admitted into the proceedings

It did not maintain the following previously formulated requests that:

- the board order the respondent to file the original data set underpinning the results set out in the patent in suit
- the board order the hearing of witnesses capable of testifying as to the accuracy and completeness of the data set out in the patent in suit

The respondent's initial requests were that:

- the appeal be dismissed, implying that the patent in suit be maintained as granted (main request)
- alternatively, that the patent in suit be maintained in amended form based on the sets of claims of the first auxiliary request, filed with the letter dated 26 October 2016, or the second or third auxiliary requests, filed with the letter dated 22 June 2021
- if the main request was not allowable, that the case be remitted to the opposition division for further prosecution
- figures 1 and 2, shown in the statement of grounds of appeal, as well as the discussion relating to them, not be admitted into the proceedings
- D21 and D22 be taken into account to prove the alleged synergy
- D23 not be admitted into the proceedings
- D24 be admitted into the proceedings

During the oral proceedings, both parties additionally requested that questions be referred to the Enlarged Board of Appeal concerning the disputed requirement of plausibility.

During the oral proceedings, the board decided to:

- admit D23 into the proceedings
- admit figures 1 and 2, shown in the statement of grounds of appeal, as well as the discussion relating to them, into the proceedings
- not admit D24 into the proceedings

At the end of the oral proceedings, the parties confirmed their opening requests and in addition their requests for referring questions to the Enlarged Board of Appeal. The board concluded to continue the proceedings in writing.

XI. An observation by a third party was received on 6 October 2021. As it relates to how the referral questions should be answered, the board did not take it into account for this decision.

XII. The appellant's appeal case, in so far as it is relevant for the present decision, can be summarised as follows.

Admittance of D23

- D23 was filed in view of the surprising course of events before the opposition division, i.e. the change in relevance attributed to D9 and D10, and in response to the respondent's documents D21 and D22. After the opposition division's preliminary opinion, which was in favour of the appellant, the respondent filed D22 and expressed criticism only about two months before the oral proceedings. In view of the complexity of the experiments, the remaining time period would have been too short to provide further experimental evidence. D22 was

intended, *inter alia*, to challenge the appellant's results in D9 and D10. The appellant should be given the possibility to react to the late filing of D22. Hence, D23 should be admitted into the proceedings.

Admittance of figures 1 and 2 shown in the statement of grounds of appeal as well as the discussion relating to them

- Figures 1 and 2 shown in the statement of grounds of appeal merely amounted to a graphic presentation of the data contained in D9. No new information was added, neither in these figures nor in the discussion relating to them. The respondent had also not identified any such new information.

Admittance of D24

- The respondent's justification for filing D24 only one month before the oral proceedings before the board was not convincing. In the case at hand, there were no "*exceptional circumstances, which have been justified with cogent reasons*" as required by Article 13(2) RPBA 2020. Hence, D24 should not be admitted into the proceedings.

Sufficiency of disclosure

- The patent in suit did not contain any indication which allowed the skilled person to determine which of the very many claimed combinations, in which ratios, or on which crops and against which pests, might show a synergistic effect. Finding the appropriate conditions amounted to an undue burden for the skilled person. Hence, the invention as

stipulated in the claims of the patent in suit as granted was not sufficiently disclosed.

Novelty

- The subject-matter of claim 1 was not novel over D8; that of claims 1 to 3 was not novel over D4. Novelty could also not be acknowledged because the selections, if there were any, were not purposeful.

Inventive step

- D4 was the closest prior art. Of the examples contained in the patent in suit, only test examples 2 and 5 related to insecticide compositions according to claim 1. The appellant's data in D23 showed that the combination of thiamethoxam with chlorantraniliprole did not act synergistically at certain weight ratios against the same and a very similar insect species as those used in the patent in suit. The data in D23 were reliable and should be taken into account. The board correctly found that the respondent's defence, that the data of D23 were unreliable because similar concentrations of insecticides resulted in very different death rates, was not convincing. Additional untreated food was simply added to avoid the premature death of insects from starvation. Not adding additional untreated food would have falsified the results. It could also not be held against the appellant that it had used a different spreading agent in D23 from that of the patent in suit since claim 1 was not limited in this respect. Furthermore, with test examples 2 and 5, the patent in suit contained only two isolated data points. They could not render the synergistic effect plausible over the entire

breadth of claim 1. Thus, according to established case law of the boards, the post-published evidence, i.e. D21 and D22, had to be disregarded. Even if D21 and its result against *Chilo suppressalis* under point 4 were taken into account, such a single experiment could not render a synergistic effect plausible against this insect species over the entire breadth of claim 1. This was because formula Ia covered more than 10 million compounds. The objective technical problem could only be seen as the provision of an alternative insecticide composition. The solution to this problem was rendered obvious by D4, which suggested the combination of thiamethoxam and compounds according to formula Ia.

XIII. The respondent's appeal case, in so far as it is relevant for the present decision, can be summarised as follows.

Admittance of D23

- The defectiveness of D9 and D10 should have been clear to the appellant upon filing. In any event, the respondent had criticised the data in D9 and D10 in its letter of 11 September 2017, and there was no reason why D23 could and should not have been filed earlier. The opposition division would have acknowledged an inventive step even without D22. The filing of D23 could therefore not be considered a reaction to the filing of D22. Also in view of the reasoning given in decision T 101/87, D23 should not be admitted into the proceedings.

Admittance of figures 1 and 2 shown in the statement of grounds of appeal as well as the discussion relating to them

- Figures 1 and 2 shown in the statement of grounds of appeal as well as the discussion relating to them could and should have been filed before the opposition division. They contained new information which had not been on file. They should not be admitted into the proceedings.

Admittance of D24

- The reason for filing D24 was that the board's preliminary opinion had raised, for the first time in the proceedings, issues concerning inventive step which had only been mentioned in the background section of the statement of grounds of appeal. For the respondent, it was completely unclear what purpose this background section should have. D24 should therefore be admitted into the proceedings.

Sufficiency of disclosure

- The opposition division correctly concluded that the invention set out in the claims of the patent in suit as granted was sufficiently disclosed.

Novelty

- The opposition division correctly acknowledged novelty of the claimed subject-matter of the patent in suit as granted over D8 and D4.

Inventive step

- The subject-matter of claim 1 of the patent in suit as granted differed from the closest prior art D4 in that at least two selections had to be made to arrive at the subject-matter of claim 1. The effect linked to these distinguishing features was the synergistic interaction between thiamethoxam and the compounds of formula Ia. This was evident from test examples 2 and 5 in the patent in suit. There was no scientific reason to doubt this effect. It was therefore up to the appellant to prove that the effect was not achieved over the full breadth of the claim. The appellant's documents D9, D10 and D23 were insufficient to provide such proof. More specifically, the appellant's data in D23 were not reliable and should not be taken into account. In D23, the method of the patent in suit was modified in that additional untreated food was added during the test period. Furthermore, D23 showed that similar concentrations of insecticides resulted in very different death rates. Lastly, D23 used a different spreading agent from the patent in suit.

- There was no legal basis for the concept of "plausibility" relied on by the appellant. Even if an ab-initio plausibility criterion were applied, post-published documents D21 and D22 had to be taken into account because the experimental data in the patent in suit had made the synergistic effect plausible. The data in D21 and D22 showed that the synergistic effect was achieved over the whole breadth of claim 1.

- More specifically, D21 showed that thiamethoxam and a compound according to formula Ia acted

synergistically against *Chilo suppressalis*. The appellant had neither challenged this result nor provided appropriate counter-evidence. There was no scientific reason why this synergistic effect should not also be achieved with other insecticide combinations according to claim 1. After all, formula Ia only covered compounds which were very similar from a chemical point of view.

- Therefore, the objective technical problem had at least to be seen as the provision of an insecticide combination whose insecticides acted synergistically against *Chilo suppressalis*. The solution to this problem was not obvious because synergism *per se* was unpredictable.

- Even if the objective technical problem was the provision of an alternative, the solution of the patent in suit was not obvious.

Reasons for the Decision

The invention

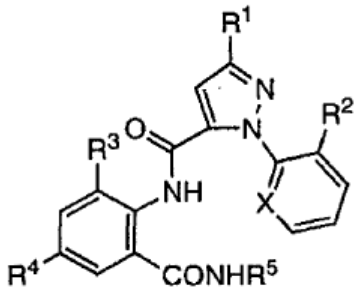
1. The claimed subject-matter

1.1 The patent in suit as granted comprises two sets of claims for different contracting states, i.e.:

- a set of claims for the contracting states IS and LT
- a set of claims for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, MC, NL and SE

1.2 Claim 1 of the set of claims for the contracting states IS and LT reads as follows:

"*An insecticide composition which comprises thiamethoxam and one or not less than two kinds of compounds being selected from a compound represented by the formula [Ia]:*

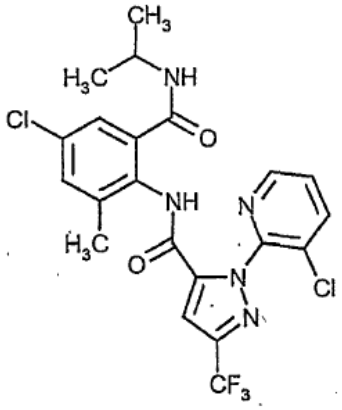


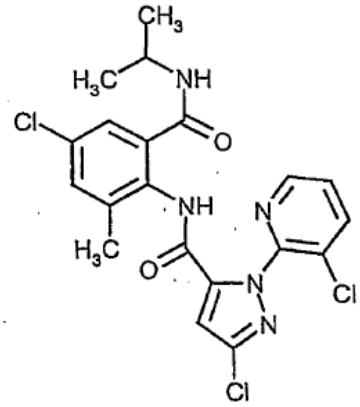
〔Ⅰa〕

wherein R1 is a halogen atom or a C1-6 haloalkyl group, R2 is a halogen atom, R3 and R5 each are a C1-6 alkyl group, R4 is a hydrogen or halogen atom, and X is N, or a salt thereof."

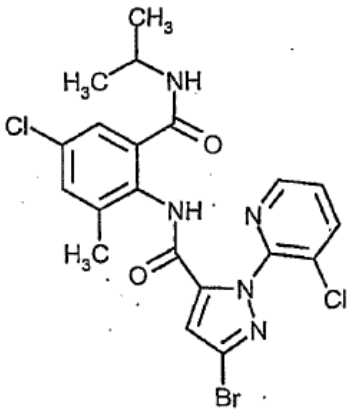
1.3 Claim 1 of the set of claims for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, MC, NL and SE comprises the wording of the above claim 1 and the following proviso:

"*with the provisio* [sic] *that the following compounds are excluded*





and



"

1.4 The respective claims 1 of both sets of claims thus only differ from each other in that claim 1 for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, MC, NL and SE additionally contains a disclaimer. This disclaimer excludes compositions which comprise thiamethoxam and at least one of the three specific compounds mentioned which fall within the general definition of formula Ia.

In the following, reference is made to 'the set of claims' or, for example, to 'claim 1' if the argument applies equally to both sets of claims or to claim 1 of both sets.

2. Background of the invention

2.1 The patent in suit (paragraphs [0002] to [0004]) acknowledges, by reference to previously published patent documents, that both thiamethoxam and the compounds according to formula Ia were known for their insecticidal activity before the priority date of the patent in suit. According to the patent in suit (paragraph [0008]), the inventors have found that mixtures of thiamethoxam and compounds according to formula Ia can produce an insecticidal activity which is greater than that which would have been expected based on their respective individual activities. This means that according to the patent in suit, an insecticide composition according to claim 1 can exhibit an over-additive, i.e. synergistic, effect.

2.2 To clarify whether a certain combination of insecticides acts synergistically, the patent in suit first determines the activities of the individual insecticides, where the activity is the death rate, i.e. the percentage of dead insects, observed when a certain number of insects is exposed to a certain amount of insecticide for a certain period of time. From these individual activities, an expected activity for the joint use of both insecticides is calculated using Colby's equation. This expected activity value corresponds to a purely additive effect of both insecticides. If the actually determined activity of the combination of both insecticides is above this expected value, the insecticides act synergistically together. If it is below this value, the insecticides of the combination act antagonistically. The use of this approach to assess the presence/absence of synergism between insecticides was undisputed between the parties.

2.3 The patent in suit (paragraph [0058]) contains a list of examples of insect pests which can be controlled with the above compositions. Among the insect pests mentioned are *Spodoptera litura*, *Plutella xylostella* and *Chilo suppressalis* (for further details, see below under inventive step).

Admittance of D23

3. D23 was filed with the appellant's statement of grounds of appeal to show that thiamethoxam and chlorantraniliprole, i.e. a compound according to formula Ia of claim 1 (R^1 = Br, R^2 = Cl, R^3 = Me, R^4 = Cl, R^5 = Me), do not act synergistically against *Spodoptera littoralis* and *Plutella xylostella* at certain weight ratios. The respondent requested that D23 not be admitted into the proceedings.

4. In respect of the admittance of D23, the history of the case has to be taken into account.

4.1 With its notice of opposition, the appellant filed D9 and D10. These two experimental reports were intended to show that the combination of thiamethoxam and chlorantraniliprole does not or at least does not always act synergistically. D9 reports on field trials, and the insects tested included the two tested in the patent in suit, i.e. *Spodoptera litura* and *Plutella xylostella*.

The respondent criticised the data in D9 in its reply to the notice of opposition and argued that the appellant's data could not be relied upon.

Subsequently, the opposition division in the annex to the summons to oral proceedings accepted the appellant's line of reasoning based on D9 and D10 and concluded "*that the experimental data of reports D9 and D10 show, that the technical effect (synergism) is not achieved over the whole scope of claim 1*" (page 17, penultimate paragraph).

The respondent criticised the content of both D9 and D10 again in its subsequent submissions dated 11 September 2017 and 27 September 2017, and with the first of these submissions filed a set of experimental data as D22. These data were intended to show, *inter alia*, that thiamethoxam acts synergistically with chlorantraniliprole, thus challenging the appellant's findings in D9 and D10.

At the oral hearing, the opposition division admitted D22 into the proceedings and, taking it into account, accepted synergism to be a technical effect of the claimed combinations of insecticides.

4.2 While it is true that, as argued by the respondent before the board, the respondent had criticised the content of both D9 and D10 in its submissions dated 11 September 2017 and 27 September 2017, the board does not see why - in view of the opposition division's preliminary opinion in favour of the appellant - this should have necessarily prompted the appellant to file a new set of experimental data.

Furthermore, the board accepts the appellant's argument that experiments which would be suitable in the current context take a certain period of time. They deal with living insects, have to be repeated a number of times for statistical reasons and require a certain lead

time, adding to the overall complexity of such experiments. Thus, even if the respondent's criticism in its submissions filed after the opposition division's preliminary opinion had been such that the alleged defectiveness of the appellant's data in D9 and D10 had been immediately clear, it would have been unreasonable to expect the appellant to submit a new set of experimental data given that after the respondent's submissions of 11 September 2017 and 27 September 2017 there remained only about two months until the oral proceedings before the opposition division on 28 November 2017.

In addition, the respondent's submission of 11 September 2017 contained new experimental data D22. It was on the basis of, *inter alia,* these late-filed additional experimental data that the opposition division changed its mind compared to its previously issued preliminary opinion. Reference is made in this respect to the first paragraph under the heading "Technical effect:" on page 23 of the decision: "*The result of test example 2 of the patent in suit and the results of the documents D21 and D22 prove synergism as effect from combining thiamethoxam with compounds falling under formula [Ia] of claim 1.*"

4.3 In view of the above, the appellant's filing of D23, which addresses the same combination of insecticides as the appellant's previous submissions D9 and D10, is to be considered a legitimate and timely reaction to the:

- change of the opposition division's assessment of D9 and D10 at the oral hearing and in its written decision compared to that in its preliminary opinion

- respondent's filing of D22 only shortly before the oral proceedings before the opposition division

5. The respondent argued that D23 should not be admitted in view of the reasoning given in decision T 101/87. However, in the case underlying that decision, the appellant relied exclusively on documents newly filed with its statement of grounds of appeal and a prior use based on them. These documents bore little relation to those filed in the original opposition (T 101/87: points IV, 2 and 6). In the board's judgement, this decision relates to an entirely different situation and has no bearing on the case at issue.

6. Due to the reasons given above, the board decided to admit D23 into the appeal proceedings pursuant to Article 12(4) RPBA 2007 (being applicable pursuant to Article 25(1) and (2) RPBA 2020).

Admittance of figures 1 and 2 shown in the statement of grounds of appeal as well as the discussion relating to them

7. As stated above, experimental report D9 relates to field trials and was filed with the appellant's notice of opposition. The table in D9 contains combinations of different amounts of thiamethoxam and chlorantraniliprole and the results obtained when applied against different insect species. In addition to the individual activities of thiamethoxam and chlorantraniliprole, this table also contains the expected activities calculated using Colby's equation and the activities found during the actual application of the combinations.

In figures 1 and 2 in the statement of grounds of appeal, the observed activity for each combination of

thiamethoxam and chlorantraniliprole of D9 is plotted against its expected activity. The respondent requested that these figures and the discussion relating to them not be admitted into the proceedings because they could have been filed in the proceedings before the opposition division and because they contained new information which had not been on file.

In its communication pursuant to Article 15(1) RPBA 2020, the board had set out why it did not find the respondent's arguments convincing, namely because these two figures merely amounted to a graphic presentation of the data in D9 and because, contrary to the respondent's allegation, no new information appeared to have been introduced in and with these figures or the discussion relating to them. When the respondent was asked to comment at the oral proceedings before the board, it merely referred to its written submissions. The board therefore saw no reason to deviate from its preliminary view and decided to admit figures 1 and 2 shown in the statement of grounds of appeal and the discussion relating to them into the proceedings pursuant to Article 12(4) RPBA 2007 (being applicable pursuant to Article 25(1) and (2) RPBA 2020).

Admittance of D24

8. D24 is a document published after the priority and filing dates of the patent in suit describing the discovery of the insecticide class of anthranilic diamides (i.e. the class to which the insecticides of formula Ia in claim 1 belong) and the development of two specific members of this class, namely chlorantraniliprole and cyantraniliprole. The appellant requested that D24 not be admitted.

8.1 The respondent argued that D24 had been filed in response to the board's communication pursuant to Article 15(1) RPBA 2020. In it, the question of whether a technical effect was achieved over the entire breadth of the claims of the patent in suit as granted had been identified as an issue which possibly had to be discussed with regard to inventive step. In the respondent's view, this was a new issue brought up for the first time in the board's communication, and the filing of D24 was a reaction to this. This was not changed by the fact that this issue had been mentioned in the statement of grounds of appeal. More specifically, this issue was addressed only in the background section of the statement of grounds of appeal, without specifying the link to the actual grounds of appeal. The respondent could not have been expected to identify potential issues mentioned only in this background section. D24 should therefore be admitted into the proceedings.

8.2 D24 was filed by the respondent with the letter of 22 June 2021, i.e. after notification of the summons to oral proceedings (the receipt of the notification had been acknowledged by the respondent by fax on 29 September 2020), which took place after the entry into force of the new Rules of Procedure of the Boards of Appeal. Under these circumstances "*[a]ny amendment to a party's appeal case made ... shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.*" (Articles 25(1) and (3) and 13(2) RPBA 2020). The filing of an entirely new document, such as D24, amounts to an amendment of the respondent's appeal case. As explained in the following, the reasons given by the respondent for

submitting D24 only with the letter dated 22 June 2021 are not convincing and for this reason alone cannot satisfy the requirement of Article 13(2) RPBA 2020, in accordance with which there have to be "*exceptional circumstances, which have been justified with cogent reasons*".

As set out above, D24 had been filed to address whether a technical effect was achieved over the entire breadth of the claims of the patent in suit as granted. As correctly noted by the respondent, the breadth of the claims of the patent in suit is addressed in the background section of the statement of grounds of appeal. For instance, under point 9, reference is made to the broad Markush formula Ia and, with reference to Annex 1, it is stated that it comprised at least ten million compounds. However, at the same time, the breadth of this Markush formula is again addressed in subsequent parts of the statement of grounds of appeal. For example, under point 60, reference is made to the number of combinations covered by the Markush claim, and it is explained that because of this the synergistic effect was not plausible for all claimed combinations of insecticides. Contrary to the respondent's assertion, there is thus a clear link between the background section and the subsequent parts in the statement of grounds of appeal, and there can be no doubt that this issue was clearly raised by the appellant. The board's communication reiterating this issue thus does not constitute an exceptional circumstance within the meaning of Article 13(2) RPBA 2020.

8.3 The board therefore decided not to admit D24 into the proceedings.

Main request (patent in suit as granted)

9. Sufficiency of disclosure (Article 100(b) EPC)

The appellant essentially argued that the patent in suit did not contain any indication which allowed the skilled person to determine which of the very many claimed combinations of compounds, in which ratios, or on which crops and against which pests, might show a synergistic effect. Consequently, the skilled person had to carry out random experiments in the dark and to test and re-test different combinations of known ingredients over and over again until they happened to come across a ratio of specific ingredients which showed synergy. Such a research project clearly amounted to an undue burden.

This is not convincing. As correctly set out in the decision under appeal, synergism is not a feature of the claims of the patent in suit. Consequently, whether this effect is achieved over the entire breadth of the claims is not to be assessed under Article 100(b) EPC but Article 56 EPC (G 1/03 (OJ 2004, 413), point 2.5.2 of the Reasons).

10. Novelty (Article 54 EPC)

The appellant maintained its novelty objections from the proceedings before the opposition division based on D8 (against claim 1) and D4 (against claims 1 to 3).

10.1 Novelty objection based on D8

10.1.1 D8 was published on 2 June 2005 and thus after the filing date of the patent in suit (21 February 2005). Compared to the European patent application/the

European patent (published as EP 1 686 857) emanating from D8, the patent in suit additionally designates IS and LT. Therefore, D8 is:

- not prior art for the set of claims for the contracting states IS and LT (see the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000, Article 1, No 1 in connection with Article 54(4) EPC 1973, Article 158(1) and (2) EPC 1973, and Rule 107(1)(d) EPC 1973)
- prior art pursuant to Article 54(3) EPC for the set of claims for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, MC, NL and SE (see, however, point 10.1.4 below)

10.1.2 D8 (claims 1 and 4) discloses an agent containing a synergistically active combination of compounds of formula I and II-1. D8 (page 9, lines 5 to 6) also discloses that six specific compounds according to formula I are particularly preferred. Among these compounds is compound Ig, which is thiamethoxam as referred to in claim 1 of the patent in suit.

The appellant argued that there was a very significant overlap between formula II-1 in D8 and formula Ia in claim 1 of the patent in suit and further that thiamethoxam was a member of a very small group of only six compounds preferably used together with the compounds of formula II-1. The subject-matter of claim 1 of the patent in suit was therefore not novel over D8.

10.1.3 This is not convincing. As regards thiamethoxam, a first selection from a list of six compounds is

necessary to get to claim 1 of the patent in suit. Furthermore, formula II-1 is defined in D8 in claim 4 and on page 13, line 35 to page 14, line 31. However, even in its most preferred and restricted definition (page 14, lines 24 to 31), formula II-1 merely overlaps in scope with formula Ia of claim 1 of the patent in suit so that parts of formula II-1 do not fall under the definition of formula Ia. E.g. formula II-1 allows:

- R^2/R^3 to be CH_3 and C_{1-4}-alkyl
- R^4 to be CF_3, OCF_3, F, Cl, Br or I
- R^5 to be CF_3 or OCF_3
- R^9 to be OCF_2H or OCH_2CF_3

These options are not provided for in formula Ia (see the definitions of NHR^5, R^3, R^4 and R^1, respectively). Thus, a further (i.e. a second) selection is necessary to get to claim 1 of the patent in suit.

It is established case law of the boards that such a double selection from a prior-art document generates novel subject-matter unless a pointer exists in the prior-art document to the double selection. In the case at hand, no such pointer is present. D8 does not disclose that thiamethoxam is preferred among the six compounds mentioned on page 9, lines 5 to 6. Furthermore, there is no indication in D8 that the overlap of formula II-1 and Ia (or an even smaller part of the overlap) would be generally preferred.

Contrary to the appellant's argument, the reasoning of T 12/90 does not contradict the above conclusion as this decision concerns overlapping Markush formulae only. In this case, however, there are not only the overlapping Markush formulae II-1 and Ia, but there is

an additional list of six compounds from which one must be selected.

10.1.4 Furthermore, the filing date of D8 is after the priority dates of the patent in suit. The appellant did not contest the validity of the priority claim of the patent in suit, and the board does not see a reason why it should not be valid. This means that subject-matter disclosed in D8 can only be novelty-destroying if it is also contained in one of its two priority applications D8P1 and/or D8P2 (in the appellant's favour, this was assumed to be the case for the passages of D8 referred to above).

D8 also gives a list of preferred compounds of formula II-1 on pages 15 to 17. Of these, however, only II-1-1 to II-1-16 are disclosed in D8P1 (table on pages 16 and 17) and D8P2 (table on pages 16 and 17), and only six (II-1-1, II-1-3, II-1-4, II-1-9, II-1-11 and II-1-12) are according to formula Ia in claim 1 of the patent in suit, speaking again to the fact that there is no pointer to the (second) selection. D8 (pages 21 to 27) also discloses preferred combinations of compounds of formula I and II-1. However, only very few combinations are combinations of thiamethoxam and a compound of formula Ia in the patent in suit. Of these very few combinations, only three are disclosed in D8P1 (page 17, line 8 to page 18, line 28) and D8P2 (page 17, line 8 to page 18, line 28):

Ig and II-1-9
Ig and II-1-11
Ig and II-1-12

However, these combinations are disclaimed from the subject-matter of claim 1 of the set of claims for the

contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, MC, NL and SE. Furthermore, as set out above (point 10.1.1), D8 is not prior art for the set of claims in the remaining two contracting states IS and LT.

10.2 Novelty objection based on D4 (prior art pursuant to Article 54(2) EPC)

10.2.1 The line of argument put forward by the appellant based on D4 was very similar to that based on D8.

The appellant argued that D4 (claim 1) disclosed a broad Markush formula 1 which overlapped to a great extent with formula Ia in claim 1 of the patent in suit. D4 also disclosed compositions comprising a compound of formula 1 and one additional biologically active compound such as thiamethoxam (page 59, lines 9 to 27). Thus, D4 was novelty-destroying for the subject-matter of claims 1 to 3 of the patent in suit, it argued.

10.2.2 Similar to the arguments relating to D8, this is again not convincing. In D4 (page 59, lines 12 ff., in particular line 27; claim 12), thiamethoxam is only disclosed in a long list of possible additional biologically active compounds. D4 does not disclose that thiamethoxam is preferred. Formula 1 is defined in D4 in claim 1. Similar to D8, formula 1 of D4 merely overlaps in scope with formula Ia of claim 1 of the patent in suit so that parts of formula 1 do not fall under the definition of formula Ia. For instance, formula 1 allows:

- R^1 to be F, Cl or Br
- R^2 to be CF_3

- R^3 to be OCH_2CF_3
- R^{4a}/R^{4b} to be CH_3 and C_{1-4}-alkyl

These options are not provided for in formula Ia (see the definitions of R^3, R^4, R^1 and NHR^5, respectively). There is no indication in D4 that the overlap of formula 1 and Ia (or an even smaller part of the overlap) would be generally preferred. Of the compounds listed in table 1 (pages 37 ff.) and table A (pages 63 ff.) according to formula 1, only a small fraction of them fall under the definition of formula Ia. D4 also discloses more limited lists of 16 preferred compounds according to formula 1 (page 4, line 30 to page 5, line 26; claim 8). However, the last four compounds in these lists do not fall under the definition of formula Ia. Thus, a second selection is again necessary to get to claim 1 of the patent in suit.

10.3 In its letter of 19 April 2021, the appellant further argued that the respective selections from D8 and D4, if there were any, had to be purposeful for the acknowledgement of novelty. The appellant noted that the third criterion of the three-part test for assessing novelty of a numerical sub-range selected from a broader range was no longer applied by the majority of boards. However, in the appellant's view, this was wrong. In this context, the appellant, with its subsequent letter of 22 April 2021, submitted a correspondence between epi and the President of the European Patent Office.

As correctly set out by the appellant, the "purposeful selection" criterion was developed with respect to a selection of a narrower numerical range from a broader range. The case law is therefore not applicable to the case at hand which is not related to numerical ranges

and furthermore concerns a double selection namely (i) from a longer list of compounds and (ii) from a set of compounds defined in the form of a Markush formula. The appellant's argument is thus not convincing.

10.4 Thus, the subject-matter of claim 1 is novel over D8, and furthermore the subject-matter of claim 1 and consequently also of its dependent claims 2 and 3 is novel over D4. The decision under appeal is therefore also confirmed on this point.

11. Referral - Introduction

11.1 After acknowledgement of sufficiency of disclosure and novelty, the next point to be assessed was inventive step. During this assessment, it turned out that questions needed to be referred to the Enlarged Board of Appeal on whether evidence not public before the filing date of the patent in suit and filed after that date ("post-published evidence") can be taken into consideration in view of the plausibility case law of the boards.

11.2 For a referral to be admissible, it is generally considered necessary that the decision on the referral questions be decisive for the outcome of the referral case.

As is clear from the above, the appellant's objections as regards sufficiency and novelty were not successful. Whether an inventive step can be acknowledged will therefore be decisive for the outcome of this case.

For inventive step, the respondent relied on, *inter alia*, post-published evidence D21 in support of a synergistic effect. In view of the parties' different

positions on the applicability of the plausibility case law, both formulated opposing requests as to whether post-published evidence D21 should be taken into consideration.

11.3 The board assessed whether D21 is relevant for inventive step because only if it is does the answer to whether post-published evidence such as D21 can be taken into consideration matters for inventive step and thus the outcome of the case.

The board notes that the appellant also relied on post-published evidence for inventive step, namely D23. After the board had decided to admit D23 on procedural grounds (see above), the respondent did not question that D23 could be taken into account. D23 was therefore taken into consideration in the board's assessment of inventive step. However, the board is aware and pointed out during the oral proceedings that D23 is post-published evidence and that it cannot be excluded that after the decision of the Enlarged Board of Appeal, the question of whether D23 can be taken into consideration might have to be re-assessed.

12. Relevance of post-published evidence D21 for inventive step

12.1 As set out above, it was examined whether post-published evidence D21 is relevant for inventive step. The board therefore used the problem-solution approach without (point 12.4) and with D21 (point 12.5) to answer this question.

12.2 Both parties agreed that D4 was the closest prior art. The board saw no reason to deviate from this unanimous view.

12.3 Based on the assessment above with respect to novelty over D4 and in line with the decision under appeal, the subject-matter of claim 1 of the patent in suit is distinguished over D4 in that both thiamethoxam and the compounds according to formula Ia have to be selected from the respective broader teachings of D4.

12.4 Problem-solution approach without D21

With regard to a technical effect linked to the distinguishing features, the respondent relied on a synergistic effect resulting from the claimed combination of compounds and referred to test examples 2 and 5 of the patent in suit.

12.4.1 Test examples 2 and 5 of the patent in suit are the only examples in which insecticide compositions according to claim 1 are tested against different insect species. Test example 2 shows that the combination of thiamethoxam with compound I-1 (in formula Ia: R^1 = CF_3, R^2 = Cl, R^3 = Me, R^4 = H, R^5 = *i*-Pr) acts synergistically against *Spodoptera litura* when both insecticides are used at a weight ratio of 1:1. Similarly, test example 5 shows that the combination of thiamethoxam with compound I-4 (in formula Ia: R^1 = Cl, R^2 = Cl, R^3 = Me, R^4 = Cl, R^5 = *i*-Pr) acts synergistically against *Plutella xylostella* when both insecticides are used at a weight ratio of 1:1.

12.4.2 Thus, the question to be answered is whether test examples 2 and 5 of the patent in suit provide a valid proof that the claimed subject-matter results in a synergistic effect at least against *Spodoptera litura* and *Plutella xylostella*. If this is the case, the

objective technical problem could be formulated as the provision of an insecticide composition which acts synergistically against *Spodoptera litura* and *Plutella xylostella*.

12.4.3 The appellant did not challenge these results of the patent in suit. However, it referred to its tests described in D23. As stated above, D23 serves to show that the combination of thiamethoxam and chlorantraniliprole, i.e. a compound which falls under formula Ia of claim 1 but which is different from those used in test examples 2 and 5, does not act synergistically against *Spodoptera littoralis* and *Plutella xylostella* at certain weight ratios.

12.4.4 The respondent argued that in view of the differences between D23 and the test examples of the patent in suit, the results in D23 had no bearing on the relevance of these test examples. The board does not agree with this argument.

The two relevant examples of D23 are examples 5 and 6. The species used in example 6 of D23 (*Plutella xylostella*) is the same as that used in test example 5 of the patent in suit. The species used in example 5 of D23 (*Spodoptera littoralis*) is different from test example 2 of the patent in suit (*Spodoptera litura*). However, the appellant stated that *Spodoptera littoralis* was closely related to *Spodoptera litura* and that therefore the same results had to be expected when the insecticide combinations of example 5 of D23 were used against *Spodoptera litura*. This was not disputed by the respondent, and the board sees no reason to doubt the appellant's statement.

Furthermore, as argued by the appellant, the general procedure used in D23 was essentially analogous to that described in the patent in suit. The insects were exposed to plant parts treated with an insecticide or a combination of insecticides. After a certain exposure time, the activity of the insecticide(s) (i.e. the death rate) was determined.

This procedure had to be modified in the experiments with *Spodoptera littoralis* in that further untreated plant parts were added after the treated plant parts had been completely consumed by the insects. However, this only served to prevent the premature death of the insects through starvation and thus a falsification of the results, which otherwise would have been due not only to the insecticides but also to a lack of food.

Lastly, in the test compositions of D23, the appellant used a spreading agent different from the ones used in test examples 2 and 5 of the patent in suit. However, the composition of claim 1 is not limited in this respect and essentially allows any spreading agent to be contained in it.

Contrary to the respondent's arguments, the appellant's modifications of the method of the patent in suit cannot therefore call into question the validity of the experiments in D23.

12.4.5 In D23, dose-response experiments were first carried out to determine suitable concentration ranges of thiamethoxam and chlorantraniliprole for the actual synergy experiments. As set out above, the actual synergy experiments are described in examples 5 and 6 of D23. In these synergy experiments, the activities of the two insecticides thiamethoxam and

chlorantraniliprole were initially determined individually again. It may be that, as argued by the respondent, some of the individual activities determined for thiamethoxam or chlorantraniliprole in the dose-response experiments are different from those determined in examples 5 and 6. However, in the board's view, this cannot call into question the validity of the results described in examples 5 and 6 since (i) experiments with living organisms are naturally subject to fluctuations and deviations between different series of experiments are therefore not unusual and (ii) the activities described for the individual insecticides in examples 5 and 6 follow a clear trend, namely towards lower activity with a decreasing amount of insecticide. Because the respondent's defence relating to this alleged lack of reliability was not convincing, there was no need at the oral proceedings to decide on the appellant's request that it not be admitted into the proceedings. In summary, the board considers the results described in examples 5 and 6 of D23 valid.

12.4.6 In example 5 of D23, the effect of the combination of thiamethoxam and chlorantraniliprole against *Spodoptera littoralis* was determined at 25 different weight ratios in a range from 3840:1 to 15:1 (thiamethoxam:chlor-antraniliprole). In example 6, the effect of the same combination was determined against *Plutella xylostella*, at 25 different weight ratios, in a range from 16000:1 to 62.5:1.

As can be seen from the tables in examples 5 and 6 of D23, in both cases thiamethoxam and chlorantraniliprole do not act synergistically at all weight ratios, on the contrary, they even clearly act antagonistically at some weight ratios. For example, while the expected death rate in experiment 6 at a weight ratio of

100:0.0125 (thiamethoxam:chlor-antraniliprole) was 62%, the observed death rate was only 14%. For the two specific species, it is not possible to make out a clear tendency towards synergy over the tested range of weight ratios.

Since claim 1 is not limited to compounds I-1 and I-4 used in test examples 2 and 5 and/or their weight ratios to thiamethoxam, the combinations of insecticides with their weight ratios tested in D23 also fall within the subject matter of claim 1. Therefore, it can be concluded that the synergistic effect described in the patent in suit for *Plutella xylostella* and *Spodoptera litura* is not achieved over the entire breadth of claim 1.

12.4.7 Thus, given only the experimental data in the patent in suit and in light of D23, the objective technical problem would have to be formulated less ambitiously as the provision of an alternative insecticide composition.

12.4.8 D4 discloses the insecticidal activity of both thiamethoxam and compounds according to formula Ia in claim 1. Moreover, the patent in suit itself acknowledges that their insecticidal activities were known before the priority date of the patent in suit (see above). However, arbitrarily combining compounds known to have insecticidal activity to achieve an alternative insecticide composition does not require an inventive step.

12.4.9 Thus, without D21, i.e. solely in view of the experimental data in the patent in suit and in light of D23, the main request would not be allowable.

12.5 Problem-solution approach with D21

Whether this conclusion changes when D21 is taken into consideration is examined below.

12.5.1 The respondent referred to D21, example 4. This example deals with a different species from that used in test examples 2 and 5 of the patent in suit or in D23. Example 4 shows that thiamethoxam and compound I-1, i.e. a compound according to formula Ia of claim 1, at a weight ratio of 1:8, act synergistically against the insect species *Chilo suppressalis*. It was a matter of dispute between the parties whether in view of this the objective technical problem could be formulated as the provision of an insecticide composition that acts synergistically against *Chilo suppressalis.*

The result in example 4 of D21 in itself was not challenged by the appellant, which also did not present any counter-evidence regarding this species in D9, D10 or D23 that could call the result into question.

However, the appellant argued that this isolated example of D21 was not a valid proof of a synergistic effect against *Chilo suppressalis* for all insecticide compositions covered by claim 1. That was because, according to the appellant's conservative calculations in Annex 1, formula Ia covered over 10 million compounds.

The board does not agree. In view of the data in D21 and in the absence of any counter-evidence from the appellant, the board sees no reason not to acknowledge this synergistic effect against *Chilo suppressalis* also for other insecticide compositions covered by claim 1, i.e. insecticide compositions comprising thiamethoxam

and a compound of formula Ia different from compound I-1.

This position is further supported by the fact that the variability of formula Ia is quite limited in chemical terms. All compounds are based on the same characteristic core structure, namely an anthranilic acid amide part acylated with a (pyridin-2-yl)-1H-pyrazole-5-carboxylic acid. Groups R1 to R5 allow for different substituents, in particular alkyl and haloalkyl groups. According to the appellant's calculations in Annex 1, the number of compounds covered by formula Ia is very high precisely because of these alkyl and haloalkyl groups. However, the compounds of formula Ia and in particular the compounds of formula Ia with different alkyl or haloalkyl groups are, at least in the board's view, not so chemically different that a different behaviour would necessarily be expected in combination with thiamethoxam.

Therefore, the synergistic effect observed in example 4 of D21 against the insect species *Chilo suppressalis* can be acknowledged to be achieved over the entire breadth of claim 1 provided D21 can be taken into account.

12.5.2 Given the post-published data in D21 and in line with the respondent's arguments, the objective technical problem would have to be formulated as the provision of an insecticide composition in which the insecticides act synergistically against *Chilo suppressalis*. As explained during the oral proceedings, the board does not take issue with the formulation of this more specific objective technical problem which also includes a specific insect species. This is because it would be technically nonsensical to require synergism

against each and every insect species (for a similar view, albeit with regard to sufficiency, see T 1326/08, point 4.2.2 of the Reasons). The respondent did also not object to the formulation of this objective technical problem.

12.5.3 The appellant only ever argued that the objective technical problem lay in providing an alternative insecticide composition. It never addressed obviousness on the basis of the above more ambitious objective technical problem. In fact, the skilled person confronted with the above more ambitious technical problem would not have found any suggestion in the prior art to arrive at the claimed subject-matter. For that reason alone, an inventive step would have to be acknowledged, provided D21 can be taken into account.

12.6 In summary, the main request would not be allowable if only the data in the patent in suit and D23 could be taken into account. If the post-published data in D21 could also be taken into account, the main request would be allowable. Therefore, the allowability of the main request crucially depends on the question of whether the post-published data in D21, which are the only proof of a synergistic effect against *Chilo suppressalis*, can be taken into account.

13. Need for the referral questions

13.1 As set out below, whether post-published evidence, such as D21, can be taken into account is a fundamental question of law for which diverging lines of case law exist.

13.2 For the assessment of inventive step, the problem-solution approach is regularly applied by the

departments of the EPO (Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019 (CLBA), I.D.2). This approach requires, *inter alia*, that:

- the closest prior art be identified (which may not necessarily be the one mentioned in the patent in suit or envisaged by the patent proprietor)
- a comparison be made between the subject-matter of the claim at issue and the disclosure of the closest prior art and that the difference(s) between both be identified
- the technical effect(s), linked to the difference(s), be determined
- the objective technical problem be formulated, i.e. the problem which can be seen to have actually been solved in light of the closest prior art

In this analysis, it is often necessary, like in this case, to provide post-published evidence (i.e. evidence that was not public before the filing date of the patent in suit and was filed after that date) as proof that the problem has been solved (i.e. that the alleged technical effect is actually achieved). This applies in particular when the objective technical problem has to be reformulated, e.g. with regard to a closest prior-art document previously unknown to the patent proprietor.

Where the proof that a problem has been solved (in this case, the provision of an insecticide composition in which the insecticides act synergistically against *Chilo suppressalis*) rests on such post-published evidence (in this case, D21), there are, in the board's view, three diverging lines of case law from the boards regarding the circumstances under which the evidence

can or cannot be taken into account. The subsequent discussion identifies these different lines of case law.

13.3 Before starting this discussion, the board would like to make the following remarks.

13.3.1 Whether D21 can be taken into account arose in the case at hand in the context of inventive step because the synergistic effect is part of the problem to be solved. In other cases, the same issue, namely whether post-published evidence can be taken into account, arose under the heading of sufficiency of disclosure because the effect was expressed in the claim at issue. While the fact that an effect is part of the problem to be solved or expressed in the claim at issue dictates which provision of the EPC is applicable (G 1/03 (OJ EPO 2004, 413), point 2.5.2 of the Reasons), it does not - at least not in the board's view - have an impact on the considerations applying to the above issue. Therefore, not only decisions dealing with this issue under Article(s) 100(a) and/or 56 EPC but also those dealing with this issue under Article(s) 100(b) and/or 83 EPC are mentioned below.

13.3.2 The following discussion is directed at the question of whether post-published evidence can be taken into account on substantive grounds, depending on the plausibility of the technical effect based on the evidence submitted as proof. This discussion should not be confused with whether post-published evidence can be taken into account on procedural grounds in particular in view of Articles 12 and 13 RPBA. The following discussion is based on the assumption that the post-published evidence in question does form part of the appeal proceedings.

13.4 Ab initio plausibility

In accordance with a first line of case law, post-published evidence can be taken into account only if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved. In this line of case law, experimental data or a scientific explanation in the application as filed commonly serve as reasons which justify this assumption. This line of case law applies a standard which is referred to in the following as the "**ab initio plausibility**" standard. The line of case law applying this standard is denoted in the following as the "ab initio plausibility line of case law".

13.4.1 For example, in T 1329/04, the underlying application as filed related to a new polypeptide (denoted growth differentiation factor-9 (GDF-9)), and stated it to be a new member of the transforming growth factor-β (TGF-β) superfamily. One alternative in the claim at issue related to GDF-9. In view of the closest prior art, the problem to be solved was defined as isolating a further member of the TGF-β superfamily. The board in question noted that GDF-9 did not have the structural features generally accepted for members of the TGF-β superfamily and that the application as filed did not contain any evidence as to whether the mode of action of GDF-9 permitted assignment to the TGF-β superfamily. Thus, although the application as filed explicitly set out GDF-9 to be a member of the TGF-β superfamily, the board concluded (point 11 of the Reasons; emphasis added by the current board):

> "*that the application does not sufficiently identify this factor as a member of this family i.e. that there is not enough evidence in the application* ***to make at least plausible that a solution was found to the problem which was purportedly solved.***"

Post-published evidence establishing that GDF-9 was indeed a growth differentiation factor was not taken into account, and the presence of an inventive step was ultimately denied. The board based its conclusion on the following consideration, which was later on applied in several other decisions applying the ab initio plausibility standard (point 10 of the Reasons; emphases in bold and annotation in squared brackets by the current board):

> "*Hence, it is particularly important* [in a first-to-file system] ***that the application allows to conclude that the invention had been made, i.e. that a problem had indeed been solved, not merely put forward at the filing date of the application.*** *Therefore, the issue here is rather how much weight can be given to* ***speculations*** *in the application in the framework of assessing inventive step ...*"

Thus, it seems to have been of crucial importance for the board in T 1329/04 (and the other decisions applying the ab initio plausibility standard) to be able to ensure that the patent applicant was actually in possession of the invention at the time of filing to prevent purely speculative claiming and thus to safeguard a balance between the actual technical contribution and the patent monopoly defined by the claims.

13.4.2 This decision was in line with the earlier decision T 609/02, in which the board in the context of sufficiency of disclosure reasoned (points 5 to 9 of the Reasons; emphasis added by the current board) that:

> "*The patent specification provides no evidence at all relating to the invention in claim 6 ... The appellant provided post-published evidence showing that steroid hormones such as needed to carry out the use according to claim 6 were later structurally identified and that they, indeed, have an effect on AP-1 stimulated transcription. ... On the basis of the disclosures of these post-published documents, it was argued by the appellant that by carrying out the claimed invention, one would necessarily obtain pharmaceutical compositions since it was by following the teachings of the patent in suit that the post-published results had been obtained. Consequently, in the appellant's opinion, sufficiency of disclosure had to be acknowledged. The board cannot share this opinion. Sufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. Acknowledging sufficiency of disclosure on the basis of relevant technical information produced only after this date would lead to granting a patent for a technical teaching which was achieved, and, thus, for an invention which was made, at a date later than the effective date of the patent. The general principle that the extent of monopoly conferred by a patent should correspond to, and be justified by, the technical contribution to the art, has to be kept in mind ...* ***It is required that***

the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se. *... Once this evidence is available from the patent application, then post-published (so-called) expert evidence (if any) may be taken into account, but only to back-up the findings in the patent application in relation to the use of the ingredient as a pharmaceutical, and not to establish sufficiency of disclosure on their own.*"

13.4.3 The ab initio plausibility standard was adopted for example in T 488/16 that reads (point 4.2, 4.5 and 4.19 of the Reasons; emphases added by the current board):

"*It is established jurisprudence of the boards of appeal that the assessment of inventive step is to be made at the effective date of the patent on the basis of the information in the patent together with the common general knowledge then available to the skilled person. Post-published evidence in support that the claimed subject-matter solves the technical problem the patent in suit purports to solve may be taken into consideration, if it is already plausible from the disclosure of the patent that the problem is indeed solved (see Case Law of the Boards of Appeal, 8th edition, I.D.4.6; T 1329/04, point 12 of the Reasons; T 1043/10, point 12 or* [sic] *the Reasons). Thus, for post-published evidence to be taken into account, it is necessary to establish whether or not the asserted activity has been made sufficiently plausible for dasatinib at the effective date of the patent in*

suit. Basis for this assessment is the application as filed and the common general knowledge of the person skilled in the art at the filing date."

"*In the board's judgement,* ***a mere verbal statement that "compounds have been found active" in the absence of any verifiable technical evidence is not sufficient to render it credible that the technical problem*** *the application purports to solve, namely providing PTK inhibitors to treat disorders or diseases associated therewith,* ***is indeed solved ...***"

"*... the board concurs with the opposition division and the respondents that the post-published documents (9) and (10) are the first disclosure showing that ... the purported technical problem has actually been solved. In accordance with established case law, these documents are therefore not taken into consideration in the assessment of inventive step.*"

13.4.4 Other decisions in line with the three mentioned above include T 415/11 (points 45 to 55 of the Reasons), T 1791/11 (points 3.2.5 to 3.2.7 of the Reasons) and T 895/13 (points 15 to 17). In the decisions cited in section 13.4, which all apply the ab initio plausibility standard, plausibility was ultimately denied.

13.5 Ab initio implausibility

In accordance with a second line of case law, post-published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have

been achieved on the filing date of the patent in suit. Such doubts may arise, for example, from the fact that either the application as filed or the common general knowledge on the filing date of the patent in suit give an indication that the purported technical effect can in fact not be achieved. In other words, post-published evidence must always be taken into account if the purported technical effect is not **im**plausible. This line of case law applies a standard referred to in the following as the "**ab initio implausibility**" standard. The line of case law applying this standard is denoted in the following as the "ab initio implausibility line of case law".

13.5.1 An example of a decision that applies the ab initio implausibility standard is T 919/15, which concerned the use of herbicide combinations for controlling harmful plants ("weeds") in soybean crops, the combination having an active content of two different herbicides (A) and (B). While the application as filed contained experimental proof of a synergistic interaction for some combinations of herbicides falling under the definitions for (A) and (B), the proof of other combinations was submitted only after the filing date. The opponent argued that the synergistic interaction of herbicides was inherently unpredictable and that the application as filed did not make the synergistic effect plausible for the combinations for which only post-published evidence had been submitted. Therefore, the post-published data had to be disregarded for the assessment of inventive step.

The board in question did not agree. It reasoned (point 5.6 of the Reasons; translation provided and emphasis added by the current board):

"*Thus, in the absence of evidence to the contrary in the common general knowledge for herbicide combinations containing herbicide (A), it cannot simply be assumed that a synergistic interaction would be per se* ***implausible*** *for the combinations not tested in the application as filed. This conclusion is in line with decision T 863/12, in which the plausibility of an effect was also confirmed on the basis of, inter alia, the fact that the common general knowledge did not contain any indications that could question this plausibility ...*"

13.5.2 A further noteworthy example in this context is decision T 578/06. Here, claim 1 of the main request read as follows (emphasis added by the current board):

"*[u]se of somatostatin ... in the formulation of a pharmaceutical ... preparation for the treatment of a human patient in receipt of transplanted isolated pancreatic islet cells, wherein the pharmaceutical composition is administered ...,* ***whereby the functional life of the isolated transplanted pancreatic islet cells is extended relative to untreated transplanted isolated pancreatic islet cells.***"

In the appealed decision, the examining division had come to the conclusion that it was not plausible that the effect of extending the functional life of transplanted pancreatic islet cells could be obtained with the claimed subject-matter. The board, in overturning this decision and acknowledging plausibility of the effect, noted the following (points 13 and 15 of the Reasons; emphases added by the current board):

"*The board notes that the EPC requires no experimental proof for patentability and considers that the disclosure of experimental data or results in the application as filed and/or post-published evidence is not always required to establish that the claimed subject-matter solves the objective technical problem.* ***This is in particular true in the absence of any formulated substantiated doubt as is the case here.***"

"*The board re-emphasises in this context however that this case law considers the establishment of plausibility only relevant when examining inventive step* ***if the case at hand allows the substantiation of doubts about the suitability of the claimed invention to solve the technical problem addressed*** *and when it is thus far from straightforward that the claimed invention solves the formulated problem.*"

After plausibility had been acknowledged, the board took the post-published evidence into account (point 17 of the Reasons).

13.5.3 Further decisions in line with the two above are T 536/07 (point 11 of the Reasons), T 1437/07 (point 38.1 of the Reasons), T 266/10 (point 37 of the Reasons), T 863/12 (point 7.3.3 of the Reasons), T 184/16 (points 2.4 to 2.7 of the Reasons) and T 2015/20 (point 2.7 of the Reasons). In all the decisions cited in section 13.5 applying the ab initio implausibility standard, plausibility was ultimately acknowledged.

13.5.4 The current board acknowledges that some of the decisions discussed above that apply the ab initio implausibility standard contain statements according to which they do not contradict T 1329/04, i.e. a decision considered by the current board to apply the ab initio plausibility standard. This would appear to imply that there is no divergence between the lines of case law applying the ab initio plausibility and the ab initio implausibility standard, respectively. However, close reading reveals that despite these statements, these decisions considered it decisive that there were no indications of doubt or reasons for implausibility on the filing date of the patent in suit (ab initio implausibility standard).

Furthermore, irrespective of whether a divergence is considered to exist, in this board's view at least, it is a fundamental question of law whether the ab initio plausibility or ab initio implausibility standard is to be applied.

13.5.5 The difference between the two lines of case law referred to above cannot be better illustrated than by the judgment of the UK Supreme Court of 14 November 2018, Generics (UK) (trading as Mylan) v. Warner-Lambert Company Ltd ("the UK Supreme Court decision") and the follow-up on this judgment by C. Floyd, "Plausibility: where from and where to", GRUR, 2021, 185. In the case underlying the UK Supreme Court decision, claim 3 at issue referred to the use of pregabalin for the preparation of a pharmaceutical composition for treating neuropathic pain. A central question to be answered was whether it was plausible at the priority date that the therapeutic effect of treating neuropathic pain could be achieved and

whether, in view of this, the post-published evidence could be taken into account.

The majority opinion answered this question in the negative. It was held that the experimental data in the application as filed were predictive of efficacy for the treatment of inflammatory pain. But the application as filed did not claim that the experimental data presented made it plausible that pregabalin was effective for the treatment of any kind of neuropathic pain (point 42 of the decision). According to point 52 of the decision, it could:

> "... *not ... be enough to justify a monopoly that it is "possible" a priori that a drug which was effective for inflammatory pain would also be effective for neuropathic pain, in the absence of any reason to suppose that the possibility had some scientific basis or that it was more than speculative. Everything is possible that is not impossible, but "not impossible" is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that.*"

So the majority in the UK Supreme Court decision seems to have applied what this board has termed the ab initio plausibility standard.

The minority opinion answered the above question in the positive. According to this opinion, the patent proprietor was not required to demonstrate within its patent a *prima facie* case of therapeutic efficacy (point 180 of the decision). Furthermore, according to point 181 of the decision (emphasis added by the board), recent decisions of the boards:

> "... *do not require that the patent discloses experimental evidence to demonstrate that plausibility* ***unless there is an allegation, supported by sufficient evidence, that the invention does not work, ...***"

It was also added (point 195 of the decision, emphasis added by the board) that:

> "***Only if a person skilled in the art would have significant doubts*** *about the workability of the invention would it, in such a case, fail for insufficiency of disclosure.*"

Hence, the minority in the UK Supreme Court decision seems to have applied what the board has termed the ab initio implausibility standard.

13.6 No plausibility

A third line of case law seems to reject the concept of plausibility altogether. This third line of case law is referred to in the following as applying the **"no plausibility"** standard. The line of case law applying this standard is denoted in the following as the "no plausibility line of case law".

13.6.1 In T 31/18, the underlying application as filed related to pharmaceutical tablets comprising imatinib or pharmaceutically acceptable salts of it. The claim at issue was essentially directed to a tablet comprising imatinib and cross-linked polyvinylpyrrolidone in certain amounts. In view of the closest prior art, the patent proprietor formulated the problem essentially as the provision of imatinib tablets having a

disintegration time of 20 minutes or less, and it also filed experimental evidence to prove that this problem had been solved. According to one of the opponents, this experimental evidence was not to be taken into account as it related to an effect which had not been plausibly shown to be achieved by the claimed tablets in the application as filed. The board held (point 2.5.2 of the Reasons) that:

> "*This line of argumentation appears to be incompatible with the assessment of inventive step according to the problem solution approach ... It can indeed not be expected from a patent applicant to include an extensive number of experimental evidences corresponding to all technical features which can possibly be claimed in the application as filed and which can possibly constitute a future distinguishing feature over the closest prior art, since said closest prior art and its technical disclosure may not be known to the applicant at the filing date of the application.*"

The board took the experimental evidence into account but held that it could not support the alleged effect of a low disintegration time vis-à-vis the closest prior art.

13.6.2 A similar decision was taken in T 2371/13. The claim at issue essentially concerned the use of a combination of two particular cationic direct dyes. In view of the closest prior art, the patent proprietor formulated the problem essentially as the provision of dye compositions having improved colour homogeneity. It also filed experimental evidence showing that this effect was achieved for the compositions tested. One of the opponents argued that the effect of an improved

homogeneity had not been rendered plausible by the application as filed because the latter did not contain any experimental data in this respect. The effect was speculative and at the date of filing, no invention had been made. The board held (point 6.1.2 of the Reasons and catchword of the decision; translation provided by the current board) that:

> "*This line of argument is incompatible with the assessment of inventive step according to the problem-solution approach which requires that the state of the art closest to the invention be identified and that a technical problem in relation to that state of the art be formulated which problem is solved by the claimed subject matter. It is usual to invoke a technical effect for inventive step which is not explicitly mentioned in the application as filed.*"
>
> "*A lack of plausibility of an effect based on the absence of evidence in the patent application is not a sufficient reason to disregard comparative tests filed later to prove that effect. Dismissing them for this reason is inconsistent with the problem-solution approach which requires defining a technical problem from the closest prior art document, which is not necessarily the one cited in the patent application - see point 6.1 of the reasons.*"

The board took the patent proprietor's post-published data into account but considered it as not supportive of the effect over the entire breadth of the claim at issue.

13.7 Further considerations

13.7.1 The three lines of case law discussed above contain two extreme positions, one being a strict application of the ab initio plausibility standard and the other one applying the no plausibility standard. These two extremes illustrate that different results are obtained depending on which plausibility standard is applied. On the one hand, by applying the ab initio plausibility standard strictly, the ultimate result would be that patent applicants receive a patent only for embodiments for which experimental data or other substantiation is contained in the application as filed that makes the effect invoked for inventive step plausible for these embodiments. Hence, any extension of the claimed scope over what has been experimentally shown or otherwise substantiated in the application as filed would lead to refusal of the application. If, on the other hand, no plausibility standard were applied at all, a patent applicant could claim whatever it thinks might possibly be proven later to bring about a purported technical effect. This would give rise to what is often referred to in the case law as "speculative patenting" or "armchair inventions" where a monopoly is conferred to a patent applicant for mere speculation rather than a true invention. The ab initio implausibility standard in terms of its results appears to lie somewhere between these two extreme lines of case law.

13.7.2 On the other hand, requiring plausibility or at least the absence of implausibility to access post-published evidence can be particularly problematic in cases where an effect needs to be established vis-à-vis a prior-art document that has not been, and perhaps could not have been, considered by the patent proprietor/applicant. For instance, if a patent proprietor is confronted with

a new closest prior document which makes a reformulation of the objective technical problem necessary, in particular under the ab initio plausibility line of case law, the patent proprietor would be barred from providing any evidence in support of the reformulated technical problem. This would mean a basically insurmountable hurdle for patentability once an opponent invokes a new closest prior-art document in opposition proceedings. Furthermore, such an approach would go against decades of case law which has allowed the reformulation of the technical problem in view of new closest prior-art documents and the reliance on post-published evidence in support of the newly formulated problem. In fact, the only hurdle applied in this case law has been that the newly formulated problem must be within the spirit of the invention as originally disclosed. See, for instance, T 1397/08, where it is stated in the catchword (translation provided and emphasis added by the current board; see also T 184/82 (point 5 of the Reasons)) that:

> "*According to the problem-solution approach for assessing inventive step in the field of chemistry, the technical problem can be reformulated, and in certain circumstances must even be reformulated, since for the objective determination of the problem, only the result actually achieved in relation to the closest state of the art counts.* ***Nothing prevents, even at the appeal stage, the modification of the problem initially posed, provided that the spirit of the original statement of the invention is preserved ...***"

The same follows from decision T 1422/12. In the case underlying that decision, a certain compound, namely

crystalline tigecycline, was claimed. The effect relied upon was based on an improved stability with respect to epimerisation. This effect was not even mentioned in the application as filed. The board stated (point 2.3.2 of the Reasons, insertion in squared brackets by the current board) that:

> *"In this connection* [i.e. well-established case law]*, any effects may be taken into account, so long as they concern the same field of use and do not change the character of the invention."*

On this basis, the board took post-published evidence into account, concluded that the effect of improved stability was credibly shown and acknowledged inventive step.

13.7.3 An additional tension exists between the ab initio plausibility and ab initio implausibility standards on the one hand and the principle of free evaluation of evidence on the other hand (see G 3/97 (OJ EPO 1999, 245), point 5 of the Reasons and G 1/12 (OJ EPO 2014, A114), point 31 of the Reasons). It is not immediately clear what could be the legal basis for preventing the patent proprietor from relying on a particular type of evidence of a fact relevant to the outcome of the proceedings. Likewise, it is not clear on what basis a board would be prohibited from taking into account evidence it finds convincing and decisive.

13.7.4 In this respect, it should be stressed that, in accordance with Article 56 EPC, an invention must be considered as involving an inventive step if, **having regard to the state of the art**, it is not obvious to a person skilled in the art. There can thus be no doubt that inventive step can only be judged in relation to

the prior art. The rationale developed in the ab initio plausibility line of case law is, however, that the invention had not been made on the filing date. This finding has been, and can only be, arrived at without considering any prior art. So it may be questionable whether Article 56 EPC is a proper legal basis for plausibility. Indeed, the legal basis for the requirement of plausibility has also been questioned elsewhere. In this respect, the current board would like to refer to the opinion expressed in the UK Supreme Court decision that plausibility "*is a court-invented pre-condition to validity*" (point 192 of the decision). In R. Jacob, "Plausibility and Policy", Bio-Science Law Review 17(6), 223, the author goes even a step further and states (page 223, first paragraph under "The Statutory Language") that:

> "*If one actually looks at the words of the EPC a purist would say it is straining the meaning of words beyond breaking point to get plausibility out of them - positively Humpty Dumpty-ish. I suppose it is for that reason that none of the judicial reasoning for getting the notion of plausibility out of either the definition of inventive step (obviousness) or sufficiency has much, or indeed anything, to do with the actual words in the statute. And the word plausibility itself is not in the statute – indeed is not, and never has been, in any patent statute anywhere.*"

Also in A. Slade, "Plausibility: a conditio sine qua non of patent law?", I.P.Q. 2020, 3, 180-203, the author considers Articles 56 and 83 EPC not to be a proper legal basis for the application of any plausibility standard. She advocates for Article 52(1) EPC as a legal basis since a speculative use of a known

compound must fail the initial requirement of this article of being an invention. In this author's view, only if the requirement of Article 52(1) EPC is met can secondary requirements such as lack of inventive step be examined.

14. Conclusion

From the above, it is evident that a referral of questions to the Enlarged Board of Appeal is needed, both to ensure uniform application of the law and because points of law of fundamental importance have arisen. The three referral questions made in the order of the present decision relate to the three lines of case law discussed above, namely whether any plausibility standard can be applied at all (first referral question) and, if so, whether an ab initio plausibility standard (second referral question) or an ab initio implausibility standard (third referral question) is to be applied. The outcome of the referral is decisive for the case at issue since whether post-published evidence D21 can be taken into account depends on this outcome, and since, furthermore, as has been set out above, if taken into account, D21 is relevant to a final decision on inventive step.

15. During the oral proceedings, the board put on screen three preliminary referral questions (for details, see the minutes of the oral proceedings), to which the parties raised the following comments.

The appellant suggested that the questions should define the effective date more clearly. For example, in case of a patent claiming priority, it should be indicated whether the relevant date was the priority or the filing date.

The appellant also argued that it had to be made clear that the effect on which the respondent relied concerned the full ambit of the claim.

The respondent suggested that an additional question should address the burden of proof for (not) achieving the technical effect.

To address the appellant's first comment, the board has replaced "effective date" (which covers priority and filing dates) in the referral questions with "filing date". In the case at hand, evidence D21 was filed after the filing date of the patent in suit. Hence, the question whether evidence can be taken into account that the patent proprietor files after the priority date and before the filing date of the patent in suit does not arise in this case.

As regards the appellant's second comment, the board notes that a clarification that the effect concerns the full ambit of the claim is not deemed necessary. It is clear to the board that the respondent cannot successfully rely on an effect that only relates to a part of the claimed subject-matter (see e.g. T 939/92, points 2.4 to 2.6 of the Reasons).

The issue of the burden of proof for (not) achieving the technical effect raised by the respondent is important but is already encompassed by the current questions. Under the ab initio plausibility line of case law to which the second referral question refers, it is the patent proprietor that has to prove plausibility while in the ab initio implausibility line of case law, to which the third referral question

refers, it is the opponent that has to show implausibility.

Order

For these reasons it is decided that:

The following questions are referred to the Enlarged Board of Appeal for decision.

If for acknowledgement of inventive step the patent proprietor relies on a technical effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):

1. Should an exception to the principle of free evaluation of evidence (see e.g. G 3/97, Reasons 5, and G 1/12, Reasons 31) be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests **exclusively** on the post-published evidence?

2. If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (ab initio plausibility)?

3. If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (ab initio implausibility)?

The Registrar: The Chairman:

M. Schalow M. O. Müller

Decision electronically authenticated