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Datasheet for the decision of 23 July 2024

Case Number:	T 0160/22 - 3.3.07
Application Number:	05740127.5
Publication Number:	1747001
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Language of the proceedings:	EN

Title of invention:

MANAGEMENT OF BREAKTHROUGH BLEEDING IN EXTENDED HORMONAL CONTRACEPTIVE REGIMENS

Patent Proprietor:

Bayer Intellectual Property GmbH

Opponents:

Dr. Schön, Neymeyr & Partner Patentanwälte mbB
Ter Meer Steinmeister & Partner Patentanwälte mbB

Headword:

Contraceptive regimen/BAYER

Relevant legal provisions:

EPC Art. 100(a), 56

Keyword:
Inventive step - no (obvious alternative)

Decisions cited:
G 0002/08

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 0160/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 23 July 2024

Appellant: (Opponent 1)	Dr. Schön, Neymeyr & Partner Patentanwälte mbB Bavariaring 26 80336 München (DE)
Representative:	Schön, Christoph Dr. Schön, Neymeyr & Partner mbB Bavariaring 26 80336 München (DE)
Appellant: (Opponent 2)	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Strasse 4 80335 München (DE)
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Respondent: (Patent Proprietor)	Bayer Intellectual Property GmbH Alfred-Nobel-Strasse 10 40789 Monheim (DE)
Representative:	BIP Patents c/o Bayer Intellectual Property GmbH Alfred-Nobel-Straße 50 40789 Monheim am Rhein (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 December 2021 rejecting the oppositions filed against European patent No. 1747001 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairwoman	J. Lécaillon
Members:	J. Molina de Alba
	Y. Podbielski

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision rejecting the two oppositions filed against European patent No. 1 747 001.

II. Claim 1 as granted reads as follows:

"*1. Use of 20 µg of ethinyl estradiol and 3 mg of drospirenone for the manufacture of a medicament for female oral contraception comprising a flexible, extended regimen, the regimen comprising:*

(a) administering to said female said 20 µg of ethinyl estradiol and 3 mg of drospirenone daily for a first administration period of 24 days;
(b) thereafter administering to said female said 20 µg of ethinyl estradiol and 3 mg of drospirenone daily for a second administration period of:
- 96 days, wherein immediately after said 96 days said female initiates a hormone free phase of 4 days, or
- less than 96 days if the female observes during said second administration period three consecutive days of breakthrough bleeding or spotting, wherein immediately after said three consecutive days said female initiates a hormone free phase of 4 days; and
(c) after said hormone free phase, administering said 20 µg of ethinyl estradiol and 3 mg of drospirenone to said female in accordance with (a) and (b) above."

III. The present decision refers to the following documents:

D6 G. Bachmann et al., Contraception, 70, 2004, 191-8

D7 P.J. Sulak et al., Contraception, 70, 2004, 281-7

D19 M. Sillem et al., The European Journal of Contraception and Reproductive Health Care, 8, 2003, 162-9

D20 C. Klipping et al., J. Fam. Plann. Reprod. Health Care, 38, 2012, 73-83

D25 Velmari® Langzyklus, patient information leaflet, December 2014

D32 J.T. Jensen et al., Contraception, 86, 2012, 110-8

IV. In the decision under appeal, the opposition division concluded, among other things, that:

- claim 1 did not add subject-matter,
- the dosage regimen in claim 1 was limiting, and
- the subject-matter of claim 1 was sufficiently disclosed, novel and inventive starting from D7 as the closest prior art.

V. Opponent 1 (appellant 1) and opponent 2 (appellant 2) each filed an appeal against the decision.

VI. The patent proprietor (respondent) replied to the appellants' statements of grounds of appeal.

VII. The Board scheduled oral proceedings, in line with the parties' requests, and set out its preliminary opinion on the case.

VIII. Oral proceedings were held before the Board in the absence of appellant 2, of which it had been previously

notified. At the end of the oral proceedings, the Board announced its decision.

IX. The appellants' arguments, where relevant to the present decision, can be summarised as follows.

The dosage regimen in claim 1 was not limiting because claim 1 was not directed to a method excluded by Article 53(c) EPC. Even if the dosage regimen was considered to be limiting, it lacked inventive step starting from D7 as the closest prior art.

D7 disclosed a flexible, extended regimen for combined oral contraceptives (OCs) which included a shortened hormone-free phase to manage bothersome breakthrough bleeding or spotting that may occur during the extended administration of OCs. The subject-matter of claim 1 differed from the teaching of D7 in the particular combination and amount of OCs, the minimum and maximum length of the phase of daily OC administration, the definition of bothersome breakthrough bleeding and spotting as three consecutive days of breakthrough bleeding and spotting, and the length of the hormone-free phase.

These differences did not produce any technical effect over the regimen disclosed in D7. The patent did not contain any experimental data on the regimen of claim 1 and the post-published data in D20 and D32 did not provide a suitable comparison with the regimen in D7. Therefore, the objective technical problem was to provide an alternative dosage regimen for combined OCs.

The distinguishing features in claim 1 did not interact with each other to produce a combined effect.

Therefore, obviousness could be assessed separately for each distinguishing feature.

The teaching in D7 was presented as being generally applicable to any approved OC, in particular to combined OCs containing 35 µg or less of ethinyl estradiol (EE). This was the case for the OC combination in claim 1, explicitly suggested in D7 with reference to D6. D19 did not prove that there was a prejudice against using that OC combination. The respondent had not demonstrated its allegation that reducing the EE dose from 30 to 20 µg increased bleeding problems. D6 taught that the OC combination in claim 1 was safe, well tolerated and had an acceptable bleeding profile. Furthermore, the regimen in D7 was intended to counter bleeding problems. Therefore, the combination of OCs in claim 1 was obvious.

The choice that the minimum length of the phase of daily OC administration was 24 instead of 21 days was obvious. The application as filed taught that this choice was not critical; the most preferred minimum intake period was from 21 to 24 days (page 7, fourth and fifth paragraphs). Furthermore, D7 and D6 taught that the combination of OCs in claim 1 was administered daily for a minimum period of 24 days that could be extended.

The maximum length of 120 days for the phase of daily OC administration was chosen for regulatory or legal reasons rather than technical reasons. This was taught in the application as filed, page 7, last paragraph to page 8, second paragraph, and Examples 1 to 3. In addition, D19 disclosed the administration of a combination of EE and drospirenone for 42 to 126 days.

Therefore, the choice was arbitrary and did not involve an inventive step.

Four days was the preferred length of the hormone-free phase for most women in D7 (page 283, right-hand column, last full paragraph). Moreover, the definition of the term "bothersome bleeding" as three days of breakthrough bleeding or spotting was arbitrary and could not contribute to inventive step, either.

X. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

The dosage regimen in claim 1 was limiting because it rendered the claimed use therapeutic, excluding it from patentability under Article 53(c) EPC.

D7 could be taken as the closest prior art. It disclosed a flexible, extended OC regimen in which women could initiate a hormone-free phase according to their needs, i.e. whenever they wanted instead of following the occurrence of breakthrough bleeding or spotting. Thus, the subject-matter of claim 1 differed in the OCs used, the minimum and maximum length of the phase of daily OC administration, the length of the hormone-free phase, and the initiation of the hormone-free phase directly after reaching the maximum length of the phase of daily OC administration or following three consecutive days of breakthrough bleeding or spotting. These differences reduced breakthrough bleeding and spotting and menstruation-related disorders, as demonstrated in post-published documents D20 and D32. In particular, D32 compared two flexible, extended regimens: one in accordance with claim 1 ($flexible_{MIB}$), the other representing the teaching of D7 ($flexible_{APC}$). The evidence in D32 supported the

claim that the dosage regimen of claim 1 was advantageous over that in D7. It was not possible to carry out clinical studies comparing the invention with each possible closest piece of prior art.

Based on the technical effect shown in D20 and D32, the objective technical problem was to provide an extended dosage regimen for combined OCs that reduces breakthrough bleeding and spotting and menstruation-related disorders.

The solution proposed in claim 1 was not obvious. It contained a combination of differences over D7 that was not suggested in the prior art. In particular, the skilled person would not use an EE dose lower than 30 µg, since D7 suggested a dose of 35 µg and it was known that reducing the EE dose increased the risk of breakthrough bleeding (D19, page 162, paragraph bridging the columns). The fact that the skilled person could combine the features proposed in claim 1 did not mean that they would do so. Furthermore, the competitors were copying the claimed dosage regimen, as evidenced by D25. This indicated that the invention was superior to the regimens disclosed in the prior art.

XI. The parties' final requests were as follows:

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

- The respondent requested that the appeals be dismissed and the patent be maintained as granted.

Reasons for the Decision

1. Claim construction

Claim 1 is formulated as a Swiss-type claim directed to the use of 20 µg of ethinyl estradiol (EE) and 3 mg of drospirenone for the manufacture of a medicament for female oral contraception characterised by a dosage regimen. The dosage regimen is the core of the invention that the patent is intended to protect and the parties disputed whether it limited the subject-matter of claim 1.

In Swiss-type claims, as in purpose-limited claims in accordance with Article 54(5) EPC, only intended uses excluded by Article 53(c) EPC can be regarded as limiting (see G 2/08, Reasons 7.1.1 and Order). Therefore, the question of whether the dosage regimen in claim 1 is limiting is directly linked to the question of whether the use for which the medicament is intended can be regarded as a method of treatment of the human or animal body by therapy excluded by Article 53(c) EPC. In other words, the question to be answered for determining whether the dosage regimen of claim 1 is limiting is whether the method of female oral contraception comprising the dosage regimen in claim 1 may be regarded as a method of treatment by therapy. This issue was controversial but can be left unanswered since, even if the dosage regimen was limiting, the subject-matter of claim 1 would not involve an inventive step, as outlined in point 2 below.

2. Inventive step (Articles 100(a) and 56 EPC)

As indicated in the paragraph above, the following assessment of inventive step assumes, in favour of the respondent, that the dosage regimen in claim 1 is limiting.

2.1 The invention in the patent belongs to the technical field of low-dose female oral contraception and relates to a particular dosage regimen. The standard regimen for low-dose oral contraceptives (OCs) is based on a 21/7-day cycle, i.e. a cycle of 21 days of daily OC administration followed by a hormone-free phase of seven days. The hormone-free phase allows withdrawal bleeding and mimics the natural menstrual cycle. However, the drop in hormone levels during the hormone-free phase may also cause menstruation-related disorders such as headaches, dysmenorrhoea, pelvic pain, acne, etc. An alternative standard regimen is based on a 24/4-day cycle. The reduction of the hormone-free phase in this regimen to only four days reduces the occurrence of menstruation-related disorders. Nevertheless, these standard regimens are not satisfactory for many women, who prefer extended cycles, i.e. cycles extending daily OC administration beyond 21 or 24 days, to reduce or completely eliminate bleeding and menstruation-related disorders (patent, paragraphs [0001] and [0002]). The problem with extended dosage regimens of low-dose OCs is that they cause bothersome breakthrough bleeding and spotting. The flexible, extended dosage regimen defined in claim 1 is aimed at managing this problem by reducing the occurrence of menstruation-related disorders while minimising breakthrough bleeding and spotting (patent, paragraphs [0020], [0022], [0024], [0026], [0031] and [0047]).

2.2 The parties presented their inventive-step arguments starting from D7 as the closest prior art.

Like the patent, D7 teaches in its introduction that the standard regimen for low-dose OCs is based on a 21/7-day cycle, and that this regimen has the disadvantage that the 7-day hormone-free phase often induces menstrual symptoms, such as bleeding, pain, breast tenderness, etc. In order to minimise the occurrence of these symptoms, a study was conducted in which it was proposed to women using the 21/7-day dosage regimen to extend the daily administration of OCs beyond 21 consecutive days with no maximum number of days. If they experienced bothersome breakthrough bleeding or spotting, they were instructed to initiate a hormone-free phase of no more than seven days, preferably three to four days (page 282, left-hand column, second paragraph). The majority of women took a hormone-free phase of four days (66%) or three days (14%) and reported an improvement in quality of life with the extended, flexible regimen (page 283, right-hand column, last full paragraph; page 285, paragraph bridging the two columns). The conclusion of the study was that, in most women, the bothersome breakthrough bleeding and spotting that occurs in extended OC regimens can be managed by initiating a three- to four-day hormone-free phase when bleeding occurs (page 287, left-hand column, first paragraph).

2.3 It was undisputed that the subject-matter of claim 1 differs from the teaching of D7 in the following features:

- the OC is specified as being the combination of 20 µg EE with 3 mg drospirenone,

- the minimum period of daily OC administration is of 24 days instead of 21 days,
- the maximum period of daily OC administration is of 120 days instead of unlimited,
- the hormone-free phase is of exactly four days, and
- the hormone-free phase is initiated either directly after 120 days of daily OC administration or following three consecutive days of breakthrough bleeding or spotting.

2.4 The parties did not agree on the technical effect produced by these differences. On this point, the Board shares the appellants' view that no evidence on file demonstrates that the dosage regimen of claim 1 is advantageous over that in D7.

2.4.1 The only experimental data in the patent are disclosed in the comparative example, which is not in accordance with claim 1. This example presents the results of a study on a flexible, extended OC regimen that reduces menstruation-related symptoms and manages bothersome breakthrough bleeding and spotting. The dosage regimen and the results in the comparative example appear to be those disclosed in D7 (abstract; Table 1; page 283, paragraph bridging the columns, and right-hand column, penultimate paragraph; page 286, right-hand column, penultimate paragraph).

2.4.2 The respondent relied on the results of the clinical studies reported in post-published documents D20 and D32 to demonstrate a technical effect over D7. However, as noted by the appellants, D20 and D32 do not provide conclusive evidence in that respect because the clinical studies therein do not provide a comparison with a regimen as disclosed in D7.

The clinical study in D20 compares three dosage regimens in which the OC is a combination of 20 µg of EE and 3 mg of drospirenone (abstract and page 75). First, a flexible, extended regimen as defined in claim 1, designated as "flexible$_{MIB}$". Second, a fixed, extended regimen based on a 120/4-day cycle, designated as "fixed extended". Third, a regimen based on a 24/4-day cycle, designated as "conventional 28-day". The study concluded that the flexible$_{MIB}$ regimen resulted in statistically significant fewer breakthrough bleeding and spotting days than the fixed extended regimen and the 28-day conventional regimen. However, this result cannot be extrapolated to a comparison with the dosage regimen of D7 which, like flexible$_{MIB}$, is a flexible, extended regimen instead of a fixed extended or a 28-day conventional regimen.

The clinical study in D32 also compares three dosage regimens of the combination of 20 µg of EE with 3 mg of drospirenone (abstract and section 2.3). First, a flexible, extended regimen as defined in claim 1, designated as "flexible$_{MIB}$". Second, a flexible, extended regimen in which women received OC for a minimum of 24 days and initiated a four-day hormone-free phase at any time during days 25 to 120, regardless of the occurrence of bleeding. This regimen was designated as "flexible$_{APC}$". Third, a regimen based on a 24/4-day cycle, designated as "conventional 28-day". The number of breakthrough bleeding or spotting days occurring in the flexible$_{MIB}$ and flexible$_{APC}$ regimens was similar (point 3.1.2.4), although there were some differences in the median length of the bleeding episodes and the number of unscheduled bleeding days (points 3.1.2.2 and 3.1.2.3). These results are nevertheless irrelevant to the case

at hand since, like the regimen of claim 1 and unlike $flexible_{APC}$, the hormone-free phase in the regimen of D7 is initiated when breakthrough bleeding or spotting occurs. Therefore, a comparison of $flexible_{MIB}$ with $flexible_{APC}$ does not allow any conclusion to be drawn on the technical effect of the regimen of claim 1 compared with that of D7.

2.4.3 The respondent argued that the clinical studies in D32 demonstrated an improvement over D7. It submitted that D7 merely proposed an extension of the standard OC regimen in which women could initiate a hormone-free phase "to meet their needs". This meant that women could initiate the hormone-free phase whenever they wanted, independently of the occurrence of breakthrough bleeding and spotting. Therefore, the teaching of D7 was represented by the regimen $flexible_{APC}$ and the comparative data in D32 demonstrated an improvement over D7. The respondent also argued that the teaching of D7 was very broad and that comparative clinical studies could not be conducted for every possible piece of closest prior art. Therefore, D32 should be accepted as evidence of an improvement.

The respondent's arguments are not convincing. D7 is directed to the management of breakthrough bleeding in extended OC regimens and proposes initiating a hormone-free phase of three to four days when breakthrough bleeding occurs. This is apparent from the title: "*Outcomes of extended oral contraceptive regimens with a shortened hormone-free interval to manage breakthrough bleeding*", and is consistently taught throughout the document. For instance, the last sentence of the introduction states: "*This report specifically looks at acceptability, variability and continuation rates of patients extending the active*

pill component with introduction of a HFI of 3-4 days when bothersome breakthrough bleeding and/or spotting occurs" (HFI means hormone-free interval). Also, the first paragraph on page 287 states: "*A 3-4 day HFI interspersed in a continuous regimen when this bleeding occurs was successful in managing the bleeding in most patients*". Thus, contrary to the regimen flexible$_{APC}$ in D32, the initiation of a hormone-free phase in D7 is directly linked to the occurrence of breakthrough bleeding or spotting.

With regard to the argument that comparative clinical studies cannot be conducted for every possible piece of closest prior art, the Board agrees. However, this cannot be a reason for acknowledging a technical effect over the closest prior art when there is no evidence of one.

2.5 In view of the lack of evidence of a technical effect over the dosage regimen of D7, the objective technical problem is to provide an alternative flexible, extended OC regimen.

2.6 The solution proposed in claim 1 consists of several modifications of the dosage regimen disclosed in D7 (see point 2.3 above): (i) the limitation of the OC to the combination of 20 µg EE with 3 mg drospirenone, (ii) a minimum period of daily OC administration of 24 days, (iii) a maximum period of daily OC administration of 120 days, (iv) a hormone-free phase of exactly four days, and (v) the initiation of the hormone-free phase either after the 120 days of daily OC administration or following three consecutive days of breakthrough bleeding or spotting.

The respondent argued that, even if the skilled person could combine the features in claim 1, they had no motivation do so. However, as noted by the appellants, the modifications over D7 proposed in claim 1 do not interact with each other to produce a combined effect. They are juxtaposed independent modifications with independent effects and the obviousness of each modification can be assessed separately. In this context, the respondent's arguments were primarily directed to the inventiveness of the choice of the OC, i.e. the combination of 20 µg EE with 3 mg drospirenone.

2.6.1 The limitation of the OC to the combination of 20 µg EE with 3 mg drospirenone was obvious. The dosage regimen proposed in D7 was generally applicable for managing bothersome breakthrough bleeding and spotting in any extended regimen of OCs approved and marketed (page 287, first paragraph). This is also clear from the fact that the women who participated in the study of D7 took different OCs based on an EE dose of 35 µg or less. Therefore, the results presented in D7 were not limited to any particular OC or, at most, were limited to OCs containing EE as the oestrogen component (page 282, left-hand column, last paragraph; page 283, right-hand column, last sentence of last full paragraph). D7 stated that a 24/4-day regimen of 20 µg EE with 3 mg drospirenone had been submitted to the FDA for approval (page 286, left-hand column, last sentence of last full paragraph). Therefore, it was obvious that the flexible, extended OC regimen of D7 was applicable to the available combination of 20 µg EE with 3 mg drospirenone.

The respondent contended that the skilled person would not apply the teaching of D7 to the combination of

20 µg EE with 3 mg drospirenone. This was because the dose of EE suggested in D7 was of 35 µg, and it was common general knowledge that reducing the EE dose below 30 µg increased breakthrough bleeding. In that respect, the respondent cited the paragraph bridging the columns on page 162 of D19.

The Board cannot agree with the respondent's argument. Firstly, the EE dose tested in D7 was not 35 µg but 35 µg or less (page 282, left-hand column, last paragraph). Secondly, the dosage regimen of D7 reduces breakthrough bleeding and spotting. Therefore, the skilled person would use it for OCs likely to produce breakthrough bleeding and spotting. In addition, when D7 refers to the combination of 20 µg EE with 3 mg drospirenone, it cites D6 (reference [11]). D6 discloses the results of a clinical study on the 24/4-day regimen of the combination of 20 µg EE with 3 mg drospirenone. It concluded that the regimen was effective, acceptable, had a convenient bleeding pattern and was well tolerated (page 197, last paragraph). Therefore, the skilled person was prompted to apply the flexible, extended regimen of D7 to the combination of 20 µg EE with 3 mg drospirenone.

With respect to D19, it is an isolated scientific publication which does not represent common general knowledge and cannot demonstrate the presence of a general prejudice in the prior art. Furthermore, the passage on page 162 of D19 cited by the respondent merely states that EE doses lower than 30 µg can result in breakthrough bleeding. This does not mean that they necessarily cause breakthrough bleeding or that a dose of 20 µg EE causes significantly more breakthrough bleeding than a dose of 30 µg. Therefore, there is no reason why the skilled person would not apply the

teaching of D7 to reduce breakthrough bleeding and spotting in an extended regimen based on the known combination of 20 µg EE with 3 mg drospirenone.

2.6.2 With regard to the minimum period of daily OC administration of 24 days instead of 21 days, the respondent has not put forward any particular argument. The Board agrees with the appellants that this distinguishing feature is a customary modification with no demonstrated technical effect. As noted by the appellants, the application as filed teaches that the most preferred minimum intake period is 21 to 24 days (page 7, fourth and fifth paragraphs). No technical effect is associated with the selection of 24 days. In addition, as explained in point 2.6.1 above, D7 proposes the extension of the 24/4-day regimen of 20 µg EE with 3 mg drospirenone. Therefore, the choice of a minimum period of daily OC administration of 24 days was obvious.

2.6.3 The respondent has not provided any particular argument directed to the choice of 120 days as the maximum period of daily administration, either. The Board again agrees with the appellants that this choice is customary and is not based on technical reasons. The application as filed acknowledges that, if no bleeding problems occur, the maximum cycle length can be extended for as long as desired by the woman (page 7, last paragraph). This can usually be up to two years but due to legal or regulatory requirements it may be limited to a fixed maximum. The application gives several illustrative ranges, such as 77 to 91, 112 to 126, 175 to 189 or 336 to 364 days (page 8, lines 3 to 7). For instance, in Example 1 of the application, the maximum cycle length is fixed on the basis of the study duration to 112 to 140 days, e.g. 120 days. Similarly,

in Example 3 the maximum length is fixed according to the length of the proposed study to 77 to 126 days, e.g. 84 days. Furthermore, D19 discloses an extended method for administering 30 µg EE and 3 mg drospirenone with a cycle length of 42 to 126 days (page 163, paragraph bridging the columns). Therefore, the maximum length of daily OC administration of 120 days was obvious.

2.6.4 The length of the hormone-free phase of four days was by far the most preferred option in D7 and was adopted by 66% of the women. Therefore, this feature cannot provide an inventive step, either.

2.6.5 Lastly, the requirement that the hormone-free phase be initiated following three consecutive days of breakthrough bleeding or spotting is also obvious in view of the teaching in D7 that the hormone-free phase is initiated following bothersome breakthrough bleeding or spotting. The respondent has not shown that the requirement that the hormone-free phase be initiated after three consecutive days of breakthrough bleeding or spotting is critical or has any particular technical effect.

2.6.6 In an additional argument to support its case, the respondent referred to D25 to show that competitors were copying the dosage regimen of claim 1. This would indicate that the claimed dosage regimen was superior to those of the prior art.

This argument fails simply because such a consideration cannot override the outcome of the inventive-step assessment based on the problem and solution approach.

2.7 Therefore, the subject-matter of claim 1 does not involve an inventive step and the ground for opposition of Article 100(a) EPC in combination with Article 56 EPC prejudices maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

B. Atienza Vivancos J. Lécaillon

Decision electronically authenticated