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Bertoni, Sara

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32 London Bridge Street
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ROYAUME UNI

Date
21.09.2023

Reference	Application No./Patent No.
P43668EP-D3-PCT	20195922.8 - 1113 / 3766408
Applicant/Proprietor Abbott Diabetes Care, Inc.	

EPA/EPO/OEB Formblatt/Form/Formulaire : 2310

Empfangsbescheinigung über den Zugang des vorstehend bezeichneten Schriftstücks
Acknowledgement of receipt of the document specified above
Récépissé du document spécifié ci-dessus

Unter Bezugnahme auf die Mitteilung im ABl EPA 7/2010, 377 wird gebeten, die Empfangsbescheinigung mit Empfangsdatum und Unterschrift zu versehen und **umgehend** an das EPA zurückzusenden:

With reference to the Notice in OJ EPO 7/2010, 377, you are requested to date and sign the acknowledgement of receipt and return it to the EPO **immediately**:

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Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings concerning the above European patent as detailed in the box below. The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings will be public and will take place before the opposition division

from 15.04.24 at 09.00 hrs (CET) to 16.04.24 as a videoconference.

The date of the oral proceedings can only be changed for serious reasons (see OJ EPO 2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC; see also OJ EPO 2008, 471).

Please see Rule 4 EPC as regards the language of the oral proceedings and the decision in Special edition No. 3, OJ EPO 2007, L.1, concerning the filing of authorisations by employees and lawyers acting as representatives before the EPO.

Please provide us with the name and telephone number of a person we can contact about the oral proceedings and an email address to which we can send the details for connecting to the videoconference.

The final date for making written submissions and/or amendments (R. 116 EPC) is 15.02.24

1st Examiner: Kaden, Malte
2nd Examiner: Trattner, Barbara
Chairman: Knüpling, Moritz

For the Opposition Division

Europäisches Patentamt • European Patent Office • Office européen des brevets

Annexes:
Confirmation of receipt (Form 2936)
Rule 4 EPC (EPC Form 2043)
Communication (EPO Form 2906)
Consolidated list of documents

Registered Letter

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Europäisches Patentamt
European Patent Office
Office européen des brevets

21.09.2023

Wichtige Hinweise zur mündlichen Verhandlung

Das Europäische Patentamt verfügt über keine eigenen Dolmetscher. Diese müssen im Bedarfsfall von außerhalb, teilweise sogar aus anderen Ländern, beigezogen werden, was mit einem hohen Aufwand an Kosten und organisatorischen Vorbereitungen verbunden ist. Muss ein Verhandlungstermin kurzfristig abberaumt werden, können Kosten für bestellte Dolmetscher nicht mehr vermieden werden.

Es wird daher gebeten, eine Simultanübersetzung nur bei wirklichem Bedarf in Anspruch zu nehmen. Es wäre wünschenswert, wenn sich die Beteiligten (zweckmäßigerweise gleichzeitig mit der Terminabstimmung) auf die Benutzung einer Amtssprache einigen könnten. Bei Verständigungsschwierigkeiten sind die Mitglíeder der Einspruchsabteilung bereit zu helfen.

Nachstehend führen wir den Zeitpunkt auf, bis zu dem die Verfahrensbeteiligten aus organisatorischen Gründen gebeten werden, ihre bevorzugte (abgestimmte) Verhandlungssprache mitzuteilen. Bis dahin bitten wir auch bei Bedarf eine Simultanübersetzung zu beantragen. Regel 4 (1) EPÜ bleibt hiervon unberührt.

Important information concerning oral proceedings

The European Patent Office has no interpreters of its own. When interpreters are needed they have to be brought in from outside, sometimes even from other countries, which is costly and involves considerable organisation. If oral proceedings have to be cancelled at short notice, the cost of interpreters already engaged still has to be borne.'

Please therefore make use of simultaneous interpreting facilities only where strictly necessary. If possible the parties should agree on an official language for the proceedings, preferably at the time when they arrange a date. The members of the Opposition Division witl be willing to help should any communication problems arise.'

For organisational reasons, we ask parties to inform us by the date specified below of their preferred (agreed) language for the oral proceedings. We also ask them to request any simultaneous interpreting required by the same date. This does not affect application of Rule 4(1) EPC.

Tres important Procédure orale

L'Office européen des brevets ne dispose pas de son propre service d'interprètes. Aussi faut-il appel le cas échéant à des interprètes de l'extérieur, qui viennent même parfois de l'étranger, ce qui occasionne des frais élevés et demande un grand travail d'organisation. Si la date d'une procédure orale doit être annulée au dernier moment, il n'est plus possible d'éviter les frais d'interprètes.

Les parties à une procédure sont donc priées de ne demander une traduction simultanée qu'en cas de réel besoin. Il serait souhaitable qu'elles puissent se mettre d'accord en même temps qu'elles conviennent de la date sur l'utilisation d'une langue officielle comme langue des débats. Si les parties éprouvent des diffícultés de compréhensíon lors des débats, les membres de la división d'opposition sont disposés à leur prêter leur assistance.

Est indiquée ci-dessous la date jusqu'à laquelle, pour des raisons d'organisation, les parties sont priées de communiquer leur langue préférée (sur laquelle elles se sont préalablement mises d'accord). Les parties sont également priées, le cas échéant, de demander une interprétation simultanée avant cette date. La règle 4(1) CBE ne s'en trouve pas affectée.

☐ Verfahrenssprache ist **Deutsch**	☒ Language of the proceedings is **English**	☐ La langue de la procédure est le **français**
Von der/dem/den Einsprechenden wurde	The language used by the opponent/s was	La langue utilisée par l'opposant/les opposants était
☐ Englisch	☐ German ✗ English	☐ l'allemand
☐ Französisch benutzt.	☐ French.	☐ l'anglais.
Es wird um eilige Mitteilung, möglichst per Online Filing (OLF), gebeten.	**Please inform us urgently, where possible by Online Filing (OLF).**	**Prière d'indiquer d'urgence par dépôt en ligne (OLF) si possible.**

möglichst bis	if possible by	si possible jusqu'au
Datum 15.02.24	Date 15.02.24	Date 15.02.24

1. welche Sprache(n) Sie in der mündlichen Verhandlung verwenden (**Sprechen**)
2. aus welcher Sprache Sie eine Simultanübersetzung benötigen (**Hören**).

1. which language(s) you intend to use during the oral proceedings (**Speaking**)
2. from which language you need simultaneous interpretation (**Listening**).

1. quelle(s) langue(s) vous utiliserez au cours de la procédure orale (**pour parler**)
2. à partir de quelle langue vous aurez besoin d'une traduction simultanée (**pour écouter**).

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Sollten Sie Ihren Antrag auf mündliche Verhandlung zurückziehen oder zum anberaumten Verhandlungstermin nicht erscheinen wollen bzw. aus wichtigem Grund daran gehindert sein, werden Sie gebeten,

- **unverzüglich das Amt - möglichst per Online Filing (OLF) - davon zu benachrichtigen, wobei das Schriftstück mit einem deutlichen Vermerk "Dringend, mündliche Verhandlung am..." oder sinngemäß gekennzeichnet sein sollte**
- **in dringenden Fällen**(weniger als 1 Monat vor dem Verhandlungstermin) zusätzlich **auch dem/die anderen Verfahrensbeteiligten**bzw. ihre(n) Vertreter auf schnellstem Weg **direkt zu unterrichten.**

In jedem solchen Fall obliegt der Einspruchsabteilung die Entscheidung, ob die Verhandlung durchgeführt oder abberaumt wird. Es wird jedoch darauf hingewiesen, dass einem Verfahrensbeteiligten, der eine nicht rechtzeitige oder unterbliebene Benachrichtigung zu verantworten hat, die dadurch den anderen Beteiligten verursachten Kosten auferiegt werden können (Art. 104 EPÜ).

Hinweis auf Regel 4 EPÜ

Regel 4
Sprache im mündlichen Verfahren

(1) Jeder an einem mündlichen Verfahren vor dem Europäischen Patentamt Beteiligte kann sich anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen, sofern er dies dem Europäischen Patentamt spätestens einen Monat vor dem angesetzten Termin mitgeteilt hat oder selbst tür die Übersetzung in die Verfahrenssprache sorgt. Jeder Beteiligte kann sich einer Amtssprache eines Vertragsstaats bedienen, sofern er selbst für die Übersetzung in die Verfahrenssprache sorgt. Von diesen Vorschriften kann das Europäische Patentamt Ausnahmen zulassen.

Should you decide to withdraw your request for oral proceedings or not wish to attend on the date set, or if for some special reason you are unable to do so, you are requested

- **to notify the EPO immediately, where possible by Online Filing (OLF), marking the document clearly with the words "Urgent, oral proceedings on ..." or similar**
- **in urgent cases** (less than one month before the date set for the proceedings), additionally to **notify the other party/parties** and/or their representative(s) **direct as rapidly as possible.**

In all such cases the Opposition Division will decide whether the proceedings are to go ahead or be cancelled. You should however note that costs incurred by the other parties may be charged to a party who either fails to notify them or does not do so in good time (Article 104 EPC).

Attention is drawn to Rule 4 EPC

Rule 4
Language in oral proceedings

(1) Any party to oral proceedings before the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings, if such party gives notice to the European Patent Office at least one month before the date of such oral proceedings or provides for interpretation into the language of the proceedings. Any party may use an official language of a Contracting State, if he provides for interpretation into the language of the proceedings. The European Patent Office may permit derogations from these provisions.

Si vous retirez votre requête tendant à recourir à la procédure orale ou si vous ne souhaitez pas vous présenter à la date fixée pour la procédure orale ou ne pouvez vous y présenter pour une raison sérieuse, veuillez

- **en faire avis sans retard à l'Office, par dépôt en ligne (OLF) si possible, en partant sur votre communication clairement la mention "Urgent, procédure orale le..." ou une indication similaire;**
- **dans les cas urgents** (moins d'un mois avant la date fixée pour la procédure orale) **en faire avis également directement** pas la voie la plus rapide à **autre/aux autres partie(s)** ou bien à son/leurs mandataire(s).

Il appartient alors à la division d'opposition de décider si la procédure orale aura lieu ou non. Il est néanmoins souligné que les frais causés aux autres parties par une partie qui est responsable de l'omission d'un tel avis ou de ce que cet avis n'a pas été fait en temps utile peuvent être mis à la charge de cette partie (art. 104 CBE).

Rappel de la Règle 4 CBE

Règle 4
Langues admissibles lors de la procédure orale

(1) Toute partie à une procédure orale devant l'Office européen des brevets peut utiliser une langue - officielle de l'Office européen des brevets autre que la langue de la procédure, à condition soit d'en aviser l'Office européen des brevets un mois au moins avant la date de la procédure orale, soit d'assurer l'interprétation dans la langue de la procédure. Toute partie peut utiliser une langue officielle de l'un des Etats contractants à condition d'assurer l'interprétation dans la langue de la procédure. L'Office européen des brevets peut autoriser des dérogations aux présentes dispositions.

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(2) Die Bediensteten des Europäischen Patentamts können sich im mündlichen Verfahren anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen.

(2) In the course of oral proceedings, employees of the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings

(2) Au cours de la procédure orale, les agents de l'Office européen des brevets peuvent utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure.

(3) In der Beweisaufnahme können sich die zu vernehmenden Beteiligten, Zeugen oder Sachverständigen, die sich in einer Amtssprache des Europäischen Patentamts oder eines Vertragsstaats nicht hinlänglich ausdrücken können, einer anderen Sprache bedienen. Erfolgt die Beweisaufnahme auf Antrag eines Beteiligten, so werden die Beteiligten, Zeugen oder Sachverständigen mit Erklärungen, die sie in einer anderen Sprache als in einer Amtssprache des Europäischen Patentamts abgeben, nur gehört, sofern dieser Beteiligte selbst für die Übersetzung in die Verfahrenssprache sorgt. Das Europäische Patentamt kann jedoch die Übersetzung in eine seiner anderen Amtssprachen zulassen.

(3) Where evidence is taken, any party, witness or expert to be heard who is unable to express himself adequately in an official language of the European Patent Office or of a Contracting State may use another language. Where evidence is taken upon request of a party, parties, witnesses or experts expressing themselves in a language other than an official language of the European Patent Office shall be heard only if that party provides for interpretation into the language of the proceedings. The European Patent Office may, however, permit interpretation into one of its other official languages.

(3) Lors de l'instruction, les parties, témoins ou experts appelés à être entendus, qui ne possédent pas une maîtrise suffisante d'une langue officielle de l'Office européen des brevets ou d'un Etat contractant, peuvent utiliser une autre langue. Si la mesure d'instruction est ordonnée sur requête d'une partie, les parties, témoins ou experts qui s'expriment dans une langue autre qu'une langue officielle de l'Office européen des brevets ne sont entendus que si cette partie assure l'interprétation dans la langue de la procédure. L'Office européen des brevets peut toutefois autoriser l'interprétation dans l'une de ses autres langues officielles.

(4) Mit Einverständnis aller Beteiligten und des Europäischen Patentamts kann jede Sprache verwendet werden.

(4) If the parties and the European Patent Office agree, any language may be used.

(4) Sous réserve de l'accord des parties et de l'Office européen des brevets, toute langue peut être utilisée.

(5) Das Europäische Patentamt übernimmt, soweit erforderlich, auf seine Kosten die Übersetzung in die Verfahrenssprache und gegebenenfalls in seine anderen Amtssprachen, sofern ein Beteiligter nicht selbst für die Übersetzung zu sorgen hat.

(5) The European Patent Office shall, if necessary, provide at its own expense interpretation into the language of the proceedings, or, where appropriate, into its other official languages, unless such interpretation is the responsibility of one of the parties.

(5) L'Office européen des brevets assure à ses frais, en tant que de besoin, l'interprétation dans la langue de la procédure, ou, le cas échéant, dans ses autres langues officielles, à moins que cette interpretation ne doive être assurée par l'une des parties.

(6) Erklärungen von Bediensteten des Europäischen Patentamts, Beteiligten, Zeugen und Sachverständigen, die in einer Amtssprache des Europäischen Patentamts abgegeben werden, werden in dieser Sprache in die Niederschrift aufgenommen. Erklärungen in einer anderen Sprache werden in der Amtssprache aufgenommen, in die sie übersetzt worden sind. Änderungen einer europäischen Patentanmeldung oder eines europäischen Patents werden in der Verfahrenssprache in die Niederschrift aufgenommen.

(6) Statements by employees of the European Patent Office, parties, witnesses or experts, made in an official language of the European Patent Office, shall be entered in the minutes in that language. Statements made in any other language shall be entered in the official language into which they are translated. Amendments to a European patent application or European patent shall be entered in the minutes in the language of the proceedings.

(6) Les interventions des agents de l'Office européen des brevets, des parties, témoins et experts faites dans une langue officielle de l'Office européen des brevets sont consignées au procès-verbal dans cette langue. Les interventions faites dans une autre langue sont consignées dans la langue officielle dans laquelle elles sont traduites. Les modifications apportées à une demande de brevet européen ou à un brevet européen sont consignées au procès verbal dans la langue de la procédure.

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State of the procedure

1 European patent No. 3 766 408 is based upon European patent application No. 20 195 922.8 filed on 24-03-2011, which is a third generation divisional application of the ultimate root application EP 11 760 268 (published as WO 2011/119896).

It claims priority of US 61/317,243 filed on 24-03-2010, of US 61/345,562 filed on 17-05-2010, of US 61/361,374 filed on 02-07-2010, and of US 61/411,262 filed on 08-11-2010.

The mention of the grant of the patent has been published in European Patent Bulletin 2022/17 of 27-04-2022.

Proprietor of the patent is:

Abbott Diabetes Care, Inc.
1360 South Loop Road
Alameda, CA 94502
US

2 Notice of opposition has been filed on 26-01-2023 by:

Opponent 1:
Dexcom, Inc.
6340 Sequence Drive
San Diego, CA 92121
US

3 An intervention has been filed on 13-06-2023 by:

Opponent 2:
Dexcom Deutschland GmbH
Haifa-Allee 2
55128 Mainz
DE

4 Documents **D1-D20** have been submitted within the opposition period by Opponent 1; Opponent 2 submitted documents **D21-D24** with the intervention; see the annexed consolidated list.

5 With the notice of opposition, Opponent 1 requests revocation of the patent in its entirety based on Articles 100(a), 100(b) and 100(c) EPC. The Opponent auxiliary requests oral proceedings to be held.

Opponent 1 argues that the subject-matter of all granted claims involves an extension of subject-matter (Article 100(c) and 76(1) EPC) and is insufficiently disclosed (Article 100(b) EPC).

According to Opponent 1, the priority claim of the patent is invalid.

With regard to Articles 100(a) and 56 EPC, Opponent 1 argues that claim 1 lacks an inventive step in view of D1 in combination with any of common general knowledge, D5-D9; in view of D10 in combination with any of common general knowledge, D6, D11, D7-D9; in view of D14 in combination with any of D1, D10, D15-D18; or in view of the prior art acknowledged in the patent, in combination with any of D10, D1, common general knowledge.

6 With letter of 12-04-2023, Opponent 1 requests acceleration of the opposition proceedings due to pending infringement proceedings.

7 With the notice of intervention filed on 13-06-2023, Opponent 2 requests the patent to be revoked in its entirety, and oral proceedings to be held as an auxiliary measure.

Opponent 2 adopts the arguments of Opponent 1 that the patent's priority claim is invalid, and that the claimed subject-matter involves an extension of subject-matter and is not sufficiently disclosed. The inventive step objections of Opponent 1 are likewise endorsed.

Opponent 2 further argues that claim 1 lacks an inventive step in view of D14 in combination with D21.

8 On 19-06-2023 the Proprietor is invited to file within a period of two months their observations on the intervention.

9 With letter of 20-06-2023, the Proprietor requests rejection of the opposition and maintenance of the patent as granted. The Proprietor auxiliary requests maintenance of the patent in amended form based on the 31 auxiliary requests filed with the letter. Furthermore, oral proceedings are auxiliary requested.

The Proprietor additionally requests neither to admit into the proceedings the ground of opposition under Article 100(b) EPC nor the objections against the dependent claims under Article 100(c) and 100(a) EPC; according to the Proprietor, these objections are not sufficiently substantiated.

10 On 21-08-2023, Opponent 1 submits further arguments with respect to extension of subject-matter, insufficient disclosure, and lack of inventive step. Document **D25** is filed with the letter, see the annexed consolidated list.

Opponent 1 raises a new inventive step objection in view of D1 in combination with D14.

11 In a letter of 25-08-2023, the Proprietor argues that the submissions by Opponent 1 filed on 21-08-2023 could and should have been made within the opposition period, and asks a period of four months to file their reply, before any preliminary opinion by the Opposition Division. According to the Proprietor, the conduct of Opponent 1 makes the request for accelerated proceedings unjustified. Additionally, the Proprietor requests a period of at least six months between any preliminary opinion and the date for oral proceedings to be observed.

12 On 29-08-2023, the Proprietor files a response to the intervention and argues that claim 1 is inventive in view of D14 in combination with D21.

13 In a letter of 07-09-2023, Opponent 1 provides counter arguments to the the Proprietor's letter of 25-08-2023.

Preliminary opinion

Without the intent to anticipate a decision, this non-binding preliminary opinion is given to help the parties prepare for the oral proceedings.

14 **Admissibility of the opposition and intervention**

The opposition is admissible because it meets all the requirements of Articles 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

The intervention is admissible because it meets the requirements of Article 105 EPC and Rule 89 EPC.

15 **Request for accelerated proceedings**

In the letter of 12-04-2023 Opponent 1 requests accelerated proceedings due to pending infringement proceedings.

In the letter of 25-08-2023, the Proprietor argues that the requirements for acceleration are not met, because Opponent 1 fails to make their submissions promptly and in full (in view of the letter of Opponent 1 dated 21-08-2023). Additionally, the Proprietor asks for a period four months to reply to the letter of Opponent 1 of 21-08-2023 before any preliminary opinion is issued.

15.1 The Opposition Division is of the opinion that the filing of the letter of 21-08-2023 by Opponent 1 does not imply that the requirements for acceleration are not met. In accelerated proceedings the parties should make their submissions promptly and in full, but arguments may be submitted at any stage of opposition proceedings, also in accelerated proceedings. In the letter of 21-08-2023, Opponent 1 mainly replies to the Proprietor's response to the notice of opposition. The letter thus predominately contains further arguments in support of objections raised in the notice of opposition.

The only new facts and evidence appear to be the filing of D25 and the inventive step objection starting from D1 and combining this document with D14.

D25 consists of the original drawings of the original application PCT/US2011/029881; Opponent 1 highlights differences between D25 and the drawings of WO 2011/119896 A1 (in particular, the lack of recesses in some of the figures of D25). D25 thus appears to be prima facie relevant to the question of original disclosure (Articles 100(c) and 76(1) EPC). D25 being part of the original application documents, the Proprietor should be familiar with the submitted document.

The inventive step objection in view of D1 and D14 is a new objection, and as such late filed. The admissibility of this objection will therefore have to be decided. It is nonetheless noted that both documents were used in the notice of opposition to show lack of inventive step in other combinations: D1 was used as closest prior art in one line of attack (see point 9.1 of the notice); another line of attack used D14 in view of D1 (see points 9.19 and 9.22 of the notice). The content of both documents was thus discussed already in the notice of opposition, such that the new objection does not rest on entirely new disclosure.

For the above reasons, the Opposition Division does not consider the behaviour of Opponent 1 to be such that the request for acceleration should be refused.

15.2 The present preliminary opinion is issued without affording the Proprietor a period of four months to reply to the letter of Opponent 1 dated 21-08-2023. The Opposition Division notes that providing a preliminary opinion at this stage of the proceedings does not prevent the Proprietor from filing a response to the Opponent's letter in the further procedure. At the same time, the Proprietor can take the Opposition Division's preliminary opinion into account when filing a reply, which would be in the interest of procedural economy.

The Opposition Division further does not consider the fairness of proceedings or the right to be heard to be violated. There is no general principle that a party has to be given the opportunity to reply to every submission made by another

party. Nor is the Proprietor prevented from making further submissions before the date set under Rule 116 EPC or during the oral proceedings. According to Article 113(1) EPC, the right to be heard entails that decisions may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments. By issuing a preliminary opinion, the Proprietor is not deprived of the opportunity to reply to the letter of Opponent 1 before a decision is taken.

15.3 At the request of Opponent 1 dated 12-04-2023, the opposition proceedings are therefore being accelerated. The EPO expects the parties to file their submissions promptly and in full, and to adhere strictly to the time limits it sets.

As to the period between summons and oral proceedings, the Opposition Division however maintains the standard period of at least six months set out in Guidelines E-III-6. It is unlikely that a reasoned decision could be provided before the oral hearing in the infringement proceedings scheduled for 21-12-2023.

16 Admissibility of the ground of opposition under Article 100(b) EPC

The Proprietor requests the ground of opposition under Article 100(b) EPC not to be admitted into the proceedings, because it is not sufficiently substantiated.

The Opposition Division is, however, of the preliminary opinion that it is clear from the notice of opposition of Opponent 1 (see page 20) what the objection of insufficient disclosure consists in. In essence, Opponent 1 argues that the claimed subject-matter is not sufficiently disclosed over the whole scope of claim 1 due to the broad functional language used in the claim. The argument made by Opponent 1 can thus be understood without difficulty.

As set out in Guidelines F-III-1, an objection of insufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts. This is, however, a matter of substance, not admissibility. The Opposition Division is therefore of the preliminary opinion that the ground of opposition under Article 100(b) EPC is admissible.

17 Admissibility of the objections against the dependent claims

The Proprietor argues that the objections by Opponent 1 against the dependent claims for lack of original disclosure consists of unsubstantiated allegations and in many cases do not provide any reasoning at all.

Similarly for the objections of lack of inventive step, the Proprietor argues that Opponent 1 does not clearly state what attacks are being mounted against the dependent claims.

The Opposition Division is of the preliminary opinion that while the arguments presented to show lack of original disclosure may be brief, they can readily be understood. It is clear from the notice of opposition that Opponent 1 essentially argues that the dependent claims isolate features from the context of the embodiment of inserter 3700 (see the notice of opposition, page 16, last two paragraphs). On Pages 17-19 it is briefly stated what features are lacking. It is thus clear what the objections against the dependent claims consist in.

The arguments presented to show lack of inventive step may be brief, but they do contain references to relevant prior art documents and pertinent passages thereof. That the problem-solution approach is not used is not a reason to hold the objections inadmissible, the problem-solution approach not being mandatory.

The Opposition Division is therefore of the preliminary opinion that the objections against the dependent claims under Article 100(c) and 100(a) EPC are admissible.

18 Extension of subject-matter (Articles 100(c) and 76(1) EPC)

18.1 Claim 1 as granted relates to a glucose monitoring assembly comprising an inserter and an on-body electronics unit. The inserter comprises, inter alia, a carrier having a plurality of gripping arms for detachably engaging recesses of the on-body electronics unit housing. The on-body electronics unit comprises a glucose sensor and wireless communication circuitry

According to the Proprietor, a general basis for claim 1 as granted is provided by claims 1, 3, 13, 14, 19, and 20 of the original application (published as WO 2011/119896). The Opposition Division, however, considers that said claims of the original application alone do not provide a basis for granted claim 1.

The apparatus according to original claims 1 and 13 comprises several features that are not part of the assembly according to granted claim 1, namely:

- a sheath defining a distal surface for placement on the skin of the subject;

- a sharp support extending through a portion of the device support (the device support corresponding to the carrier of granted claim 1);

- the device support comprising a first engagement member for releasably coupling the device support to the sharp support;

- a handle movable between a proximal position and a distal position relative to the sheath, and adapted to urge the device support and the sharp support from a proximal portion to a distal portion; and

- a driver for advancing the sharp support towards the proximal portion when the sharp support reaches the distal position.

Claim 1 as granted, on the other hand, requires features that have no basis in original claims 1, 3, 13, 14, 19, and 20, in particular:

- an on-body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon;

- a glucose sensor;

- on-body electronics coupled with the glucose sensor and disposed within the body-electronics unit housing, wherein the on-body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level.

It is thus necessary to also take into consideration the description and figures of the original application.

18.2 The claimed interaction between the gripping arms of the carrier and the recesses on the on-body electronics unit housing is disclosed in two embodiments: that of fig. 109-134 and that of fig. 135-136.

The Proprietor argues that fig. 30, 45, 79, 80, 98, and 108 also show gripping arms and that fig. 1, 16 and 17 show recesses on the on-body housing (122). The Opposition Division agrees that fig. 30, 45, 79, 80, 98, and 108 may show arms similar to arms 3762 and 3762' in fig. 122 and fig. 135-136, but notes that the claimed engagement of the arms with recesses on the on-body housing is not shown in the figures, nor described in the corresponding description.

The Opposition Division further agrees with Opponent 1 that the original drawings of the PCT application (submitted as D25 in the present proceedings) do not show recesses on the on-body housing in fig. 1, 16, and 17. The recesses shown in fig 1, 16, and 17 of WO 2011/119896 were introduced with replacement sheets filed at a date later than the filing date of the original application.

The claimed engagement of the gripping arms with recesses on the on-body electronics unit housing is thus disclosed only in the context of the embodiments of fig. 109-134 and of fig. 135-136. Paragraph [0258] discloses that the gripping arms serve to hold the on-body housing (322) in place; engagement of the recesses (3766) with the gripping arms (3762) maintains the proper height

location of the on-body housing (322). When the medical device carrier (3730) advances along the sheath (3708) to reach the proximal position during use, the gripping arms (3762) are no longer supported by the sheath (3708) and the force of the adhesive skin patch (318) overcomes the retention force of the gripping arms (3762).

The interaction between sheath and gripping arms is thus functionally linked to the engagement between gripping arms and recesses on the on-body housing as claimed. Omission of the sheath thus appears to involve an extension of subject-matter.

Furthermore, when the original application discloses recesses on the on-body housing, namely in the embodiments of fig. 109-134 and of 135-136, it discloses them in combination with engagement bosses (3764) on the gripping arms (see paragraph [0258]). There does not appear to be any disclosure of recesses on the on-body housing without there being engagement bosses on the gripping arms, nor does there appear to be any suggestion that the engagement bosses may be omitted.

The embodiment of fig. 109-134 further requires an adhesive skin patch (318), a spring (3746), a sharp carrier (3716), and carrier arms (3732). These features serve to retract the sharp to a retracted, proximal position after the sharp and the on-body housing have been advanced to the distal position. As explained in paragraph [0258], when the medical device carrier (3730) advances along the sheath (3708) to reach the proximal position, the gripping arms (3762) are no longer supported by the sheath and the force of the adhesive skin patch (318) overcomes the retention force of the gripping arms. The retraction of the device carrier is explained, for example, in paragraph [0261]: the carrier arms (3732) are not of sufficient rigidity or bias to counteract the bias of the spring (3746) in order to maintain the sharp carrier in the distal position without support from the sheath; accordingly, the spring (3746) urges the sharp carrier (3716) in the proximal direction thereby displacing the carrier arms (3732).

At least the sharp carrier (3716) and the carrier arms (3732) are thus functionally linked to the advancing the medical device carrier and the sharp in a distal direction and to the subsequent retraction of the sharp in a proximal direction. These features are also part of the inserter disclosed in its most general form in paragraphs [0007] and [0013] (corresponding to original claims 1 and 13), the sharp carrier 3716 corresponding to the sharp support, and the carrier arms (3732) corresponding to the first engagement member of the device support.

Omission of the sharp carrier and the carrier arms thus appear to involve an extension of subject-matter.

Spring 3746 serves to retract to sharp from the distal position; it corresponds to the driver required by original claims 1, 13, and 20. Paragraph [0153] further discloses the retracting mechanism in general terms, and gives several possible alternative drive assemblies, not limited to a spring. Claim 1 as granted furthermore includes the feature of the inserter being configured to retract the sharp from the distal position. It thus appears that the omission of a "driver" does not present the skilled person with any new technical information. In view of paragraph [0153], it furthermore seems that claim 1 does not need to specify a spring.

As explained in paragraph [0094], the on-body housing "includes or is attachable to" an adhesive pad; the on-body housing is thus not necessarily provided with an adhesive pad. Paragraph [0148] further discloses that the medical device "can include" features to maintain the device in position with respect to the skin after insertion, e.g. barbs, tabs, adhesive, etc. Several other options (besides an adhesive pad) for holding the device in place are thus disclosed; these features are furthermore presented as optional. Further considering that the most general disclosure of the inserter in paragraphs [0007] and [0013] does not include an adhesive skin pad, it appears that the omission of this feature from granted claim 1 does not involve an extension of subject-matter.

The embodiment of fig. 109-134 further requires a distal end cap (3704), which serves to maintain a sterile environment for the medical device and sharp (see paragraph [0251]). The distal end cap is, however, described as a removable component (paragraph [0251]), which is removed from the inserter prior to use (see paragraph [0259]; fig. 126). The distal end cap is furthermore not functionally linked with the other features of the inserter; there is in particular no functional link to the engagement between the gripping arms and the recesses on the on-body housing. Finally, there is also no requirement for a distal end cap in the general disclosure in paragraphs [0007] and [0013]. The omission of the distal end cap thus does not appear to involve an extension of subject-matter.

Paragraphs [0007] and [0013] further require a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject. The embodiment of fig. 109-134,

however, does not require a separate handle; rather the housing (3702) is alternatively referred to as handle (see paragraph [0264]), and advancing the device support to a distal position is part of granted claim 1.

18.3 The features of granted claim 1 relating to the on-body electronics unit are disclosed in general form in the beginning of the detailed description (see in particular paragraphs [0094]-[0108]) as well as in the section "Embodiments of in Vivo Monitoring Systems" (see paragraph [0112] onward).

Paragraph [0108] discloses that the on-body electronics may be provided in a housing, together with at least a portion of the sensor; according to paragraph [0112], the analyte monitoring system includes on-body electronics electrically coupled to an in vivo analyte sensor; the on-body electronics include an on-body housing that defines an interior compartment. The sensor may be a glucose sensor (see e.g. paragraph [0094]). Paragraphs [0102] and [0103] disclose that the on-body electronics may comprise a memory, a power supply, and a processor. The sensing system may provide data to another unit, e.g. by a wireless connection (see paragraph [0107]).

It is clear from the whole disclosure that the on-body electronics may be used together with any of the disclosed inserters (see e.g. paragraphs [0094], [0112]). The combination set out in granted claim 1 of an inserter and an on-body electronics unit (referred to as a glucose monitoring assembly) therefore does not appear to involve an extension of subject-matter.

18.4 In summary, the Opposition Division considers that claim 1 as granted involves an extension of subject-matter in that it omits the sheath, the sharp carrier, and the carrier arms.

18.5 Opponent 1 argues that claim 1 as granted omits further features of the inserter 3700. For the following reasons, the Opposition Division preliminarily does not agree.

Paragraph [0007] discloses in general terms in inserter having a sheath, wherein no guide rails on an inserter housing are mentioned. Inserter 300 (see fig. 36-37) comprises a sheath 342 movable within a housing 302, wherein no guide rails are provided; the same applies to inserter 400 (see fig. 48-49) and inserter 2500 (see fig. 81-87). The guide rails mentioned in paragraph [0256] therefore do not seem to be inextricably linked to the function of the invention.

Detent 3724 and snap 3726 are described from paragraph [0262] onwards and serve to lock the sheath in a pre-fire position until a minimum force is overcome when the sheath is moved longitudinally with respect to the housing. These

features are, however, not presented as essential to the invention (see e.g. paragraph [0262]), and inserter 2500, for example, does not appear to comprise corresponding features.

It is clear from the original application as a whole that the electronics unit is provided in an on-body housing, see for example paragraphs [0087]-[0088], [0094], [0112]. Although it is not explicitly mentioned in the context of the disclosure of inserter 3700, it is thus nevertheless evident that the housing 322 houses the electronics unit.

A plurality of recesses disposed circumferentially on the on-body housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, is directly and unambiguously derivable from, for example, fig. 126. The recesses (3766) on housing (322) are circumferentially disposed on the housing in a spaced relation.

The on-body electronics unit comprising a glucose sensor is disclosed throughout the original application, for example in paragraph [0094].

The features of a processor, memory, and power supply as part of the on-body electronics is disclosed, for example, in paragraphs [0102]-[0103]. It appears to be evident from the whole disclose that the on-body electronics may be used together with any of the disclosed inserters (see e.g. paragraphs [0094], [0112]). Wireless communication is disclosed in paragraph [0107] without the need for any display part, data processing module, or remote terminal.

While the features in granted claim 1 relating to advancing the on-body electronics unit and the sharp to a distal position and retracting the sharp from the distal position may be disclosed for the inserter 3700 as a specific sequence of functional steps involving co-operating structural elements (see paragraphs [0262]ff, [0256]-[0258]), the lack thereof in granted claim 1 does not appear to involve an extension of subject-matter.

The general concept of advancing both the device and the sharp to the distal position and retracting only the sharp is present in original claim 1, and other embodiments are disclosed (for example, inserters 200, 400, 2400, 2500, 2700) which fulfill these functions without necessarily requiring the sequence of steps or the structural elements disclosed in connection with inserter 3700.

18.6 With reference to paragraph [0178], the Proprietor argues that the sheath is optional. Paragraph [0178], however, only describes the sheath of inserter 200 as optional. This does not imply that the sheath of inserter 3700 is optional, too; the more so since there is a functional relationship between the sheath and the gripping arms of inserter 3700.

Regarding the sharp support, the Proprietor argues that the inserter is disclosed without limitations to a sharp support and refers to paragraphs [0148], [0152], [0153]. The sharp support is thus neither essential nor indispensable to the function of the invention.

For the inserter 3700, however, the original application discloses the sharp support (3716) as functionally interlinked with other components, e.g. the driver (3746), sheath (3708), and carrier arms (3732). Omission of the sharp support requires modifications to make up for the change.

Regarding the engagement boss, the Proprietor argues that paragraph [0258] describes this feature as optional, and further refers to original claims 3 and 19. Paragraph [0258], however, describes the combination of engagement boss and recesses as optional, not the engagement boss alone ("In some embodiments, gripping arms 3762 are provided with engagement boss 3764 which are configured to engage with corresponding recesses 3766"). When the original application discloses recesses on the on-body housing, there are also engagement bosses on the gripping arms (see inserters 3700, 3700'). Original claims 3 and 19 refer to movable arms engaging the device, not to movable arms engaging recesses on the device.

The Opposition Division does not agree with the Proprietor that the carrier arms are not required by any independent claim as filed. Original claim 1 requires a first engagement member for coupling the device support to the sharp support, and original claim 20 requires the device support to include a feature adapted to engage the sharp support. Independent claim 13 may not explicitly require such engagement features, but the claim is directed at a method instead of an insertion apparatus or system. It can therefore not be concluded from claim 13 that the carrier arms of the inserter 3700 are optional or not functionally linked with other components of the inserter.

18.7 With regard to the dependent claims, the Opposition Division considers that the features of claims 2-20 and 22 find a basis in the orignal application as follows.

claim 2: paragraphs [0258], [0267];

claim 3: paragraphs [0266], [0267];

claim 4: paragraphs [0266], [0267];

claim 5: paragraphs [0258], [0266], [0267];

claim 6: paragraphs [0258], [0266], [0267];

claim 7: paragraphs [0258], [0266], [0267];

claim 8: fig. 122, 135, 136;

claim 9: fig. 122;

claim 10: fig. 126, 135;

claim 11: paragraphs [0258], [0266] fig. 126, 135;

claim 12: paragraph [0264]; fig. 133;

claim 13: paragraph [0251]; paragraph [0095] describes sterility as optional;

claim 14: paragraph [0251];

claim 15: fig. 109-112;

claim 16: fig. 109-112;

claim 17: fig. 130-133;

claim 18: paragraphs [0271]-[0273], [0276]-[0281];

claim 19: fig. 109-112, 127, 135;

claim 20: fig. 109-112;

claim 22: paragraphs [0264], [0265] (adhesive pad may be on the on-body housing, or attached to the sheath prior to use).

18.8 Dependent claim 21 does not appear to find a basis in paragraphs [0101]-[0102] as argued by the Proprietor. According to the claim, at least a portion of the on-body electronics is in a low power state when the on-body electronics unit is in the proximal position. The claim leaves open whether the power state changes when the on-body unit moves to the distal position, or how the power state is changed. Paragraphs [0101]-[0102] only disclose that the power state is changed based on a command received from a display device or via manual activation of a switch on the on-body electronics unit.

Claim 21 thus appears to involve an extension of subject-matter.

19 Sufficiency of disclosure (Article 100(b) EPC)

Opponent 1 argues that claim 1 is not enabled over its whole scope as several functional features are used in the claim, without defining any relevant structure of the invention.

The Opposition Division, however, notes that the patent discloses several embodiments of an inserter configured to insert a portion of a glucose sensor into a subject, for advancing the on-body unit and the sharp to a distal position, and for retracting the sharp from the distal position. At least one way of engaging the gripping arms with recesses on the on-body unit is disclosed

(inserter 3700). Whether a broad field is sufficiently exemplified by a limited number of examples depends on the case (Guidelines F-III, 1). In the present case, the Opposition Division sees no reason to doubt that the embodiments disclosed in the patent enable the skilled person to put the invention as claimed into practice over the whole scope of the claim. No reasons are provided why the skilled person would be unable to implement alternative means for implementing the claimed assembly, beyond the concrete example given in the patent. An objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts (Guidelines F-III, 1); the Opposition Division is of the preliminary opinion that no such doubts have been substantiated. The use of functional features is not in itself a reason to conclude that there is insufficient disclosure (see also Guidelines F-IV, 6.5).

The ground of opposition of Article 100(b) EPC thus does not appear to prejudice maintenance of the patent as granted.

20 **Priority**

The contested patent claims priority of the following four applications:

P1: US 61/317,243;
P2: US 61/345,562;
P3: US 61/361,374; and
P4: US 61/411,262.

The Opposition Division concurs with Opponent 1 that while the patent and the original application are in the name of Abbot Diabetes Care Inc., the four priority applications were filed in the name of one or more natural persons (S. Curry et al. for P1; S. Curry et al. or P2; M. Donnay and P. Robinson for P3; M. Donnay for P4). There is no evidence on file that Abbot Diabetes Care Inc. is the successor in title for the priority applications.

The priority claim of the contested patent thus appears to be invalid.

Furthermore, P1 does not appear to disclose recesses on the on-body housing. P2 and P3 disclose a spring hook (2542) on the gripping arms (see fig. 73G and paragraph [0299] of P2; and fig. 73G and paragraph [0244] of P3), but there is no disclosure of the spring hooks engaging recesses on the on-body housing, nor are there any recesses shown in the figures. P4 appears to show in fig. 96 on the right side of the device carrier (3730) an engagement boss on a gripping arm; fig. 97C-103 furthermore appear to show recesses on the on-body unit housing. However, there seems to be no disclosure of gripping arms engaging the recesses on the on-body unit, see paragraphs [0301]-[0308].

The priority claim thus appears to be invalid also for this reason.

D14 is therefore prior art under Article 54(2) EPC.

21 **Inventive step (Articles 100(a) and 56 EPC)**

The Opponents raise inventive step objections starting from D1, D10, D14 or the prior art acknowledged in the patent. For the following reasons, the Opposition Division is not convinced by the Opponents' argumentation.

21.1 D1 does not appear to disclose a plurality of recesses on an on-body unit housing, comprising a first recess in a spaced relationship to a second recess.

Opponent 1 refers to element 101 in fig. 7 of D1 as recesses. What is referred to as recess 101 in D1 is, however, merely a single spacing between hub 18 and housing 20, compare fig. 4.

Furthermore, D1 does not appear to disclose that the inserter is configured to retract the sharp from the distal position. Rather, the sharp is removed manually, see fig. 16, 34; paragraph [0133]. Opponent 1 refers to paragraph [0115]; this passage, however, discloses bringing the inserter into a position ready for insertion.

None of D5-D9 and D14 appear to disclose recesses on an on-body housing for engagement with gripping arms of an inserter. It therefore appears that the combination of D1 with any of these documents would not lead to the subject-matter of claim 1.

21.2 D10 does not appear to disclose any on-body electronics. Contrary to Opponent 1's position, however, it also seems not to disclose recesses on an on-body unit housing.

Opponent 1 refers to fig. 26 and 29 as showing recesses; however, feet 1227 of arms 1226 do not appear to engage base 122 at a plurality of recesses. Paragraph [0123] merely discloses that the feet clamp, grasp or otherwise engage the base, and the base is not shown to have recesses (see also fig. 18). Rather, it appears that the feet grasp a rim on the base.

None of D6-D9 and D11 appear to disclose recesses on an on-body housing for engagement with gripping arms of an inserter. It therefore appears that the combination of D10 with any of these documents would not lead to the subject-matter of claim 1.

21.3 The parties seem to agree that D14 does not disclose an on-body unit housing with a plurality of recesses in a spaced relation for engagement with gripping arms of the inserter.

As argued above, neither D1 nor D10 appear to disclose such recesses.

Opponent 1 refers to fig. 15a and paragraph [0126] of D15, which however disclose recesses (22, 23, 24, 28) on a skin-securable cradle (20) for engagement with corresponding latches in a mounting housing (30). D15 thus does not seem to suggest to provide recesses on an on-body unit housing for engagement with gripping arms of an inserter.

As argued by Opponent 1, D16 discloses in fig. 7 gripping means (345, 346) for engaging the housing of an infusion device. Even with the assumption that the gripping means can be considered gripping arms, fig. 7 appears to show only a single arm (345), and there appears to be only one recess on the housing (350). In any case, it is not obvious how the teaching of D16 should be applied to the inserter of D14, due to the different structure of the two devices.

D17 discloses in fig. 8 and paragraph [0042], [0044] a plurality of projections (112a, 112b) of an inserter (110) for engaging apertures (60a, 60b) in an analyte monitoring assembly (10). The inserter has a cavity within which the monitoring assembly is received, whereas in D14 a needle hub (136) is provided on top of the on-body housing (122), see fig. 28 for example. It is therefore not obvious how the teaching of D17 should be applied to D14.

D18 discloses according to Opponent 1 in fig. 41 and 45 and paragraph [0121] that barbs (1023) of a housing (1022) engage apertures in the side wall of the infuser base. There is, however, no disclosure that the infuser base has a plurality of recesses; it rather appears that the barbs (1023) grasp a single rim on the infuser base (compare fig. 3-4).

It therefore appears that the combination of D14 with any of D1, D10, D16-D18 would not lead to the subject-matter of claim 1 in an obvious way.

Opponent 2 argues that D21 discloses in fig. 2A and paragraph [0069] protrusions (71) on the insertion device (70) that extend to engage recesses (77) in the cap element (24) of body (20). According to D21 however, the protrusions and recesses serve to prevent rotation of the insertion device (70) relative to the body (20). In contrast, the gripping arms and recesses according to granted claim 1 serve to hold the on-body housing (322) in place and to maintain the proper height location of the on-body housing (322), see paragraph [0258] of the original application and granted claim 1: "... gripping arms configured to be engaged with a corresponding recess ... <u>when the on body electronics unit is in the proximal position</u>"). It thus appears that the skilled person would not consult D21 when seeking means for holding the on-body unit housing of D14 in place.

21.4 Opponent 1 raises an inventive step objection starting from the prior art acknowledged in the patent (see paragraph [0003]). It appears that Opponent 1 mixes the acknowledged prior art and common general knowledge as evidenced by D19 and D20: for example, it appears that paragraph [0003] of the patent does not directly and unambiguously disclose on-body electronics including a processor, memory, a power supply, and wireless communication circuitry.

In any case, the acknowledged prior art does not comprise any structural features of the inserter, whereas granted claim 1 lists several such features. The other prior art documents used as starting points in the raised inventive step attacks (D1, D10, D14) disclose at least some of the required structural features of the inserter.

The Opposition Division is therefore of the preliminary opinion that, compared to D1, D10 or D14, the prior art acknowledged in the patent is not an equally valid springboard for an inventive step attack. Following Guidelines G-VII-5.1, the Opposition Division intends to disregard the inventive step objection starting from the acknowledged prior art.

21.5 For the above reasons, claim 1 as granted appears to involve an inventive step.

22 Auxiliary Requests

While some of the auxiliary requests include some of the features identified above as leading to an extension of subject-matter (see point 18.4), none of the requests includes all the features in combination.

It therefore appears that Auxiliary Requests 1-31 are not allowable under Article 76(1) EPC.

Oral proceedings

The grounds of opposition, and any issues that may arise in relation to the grounds of opposition, will be discussed during the oral proceedings.

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CONSOLIDATED LIST - KONSOLIDIERTE LISTE - LISTE RÉCAPITULATIVE

P: Abbott Diabetes Care, Inc.
1: Dexcom, Inc.
2: Dexcom Deutschland GmbH

	CITATIONS – ENTGEGENHALTUNGEN - CITATIONS	P	1	2
D1	US 2004/0002682 A1		D1	
D2	US 5,390,671		D2	
D3	US 5,568,806		D3	
D4	US 5,586,553		D4	
D5	US 2009/0292185 A1		D5	
D6	US 2006/0020189 A1		D6	
D7	US 2007/0203407 A1		D7	
D8	US 2008/0097246 A1		D8	
D9	US 7,344,500 B2		D9	
D10	US 2009/0124979 A1		D10	
D11	US 2008/0269683 A1		D11	
D12	US 7,585,287		D12	
D13	US 6,602,268		D13	
D14	WO 2010/091005 A1		D14	
D15	WO 2009/016638 A1		D15	
D16	WO 2004/098684 A2		D16	
D17	WO 2008/115409 A1		D17	
D18	US 2008/0243051 A1		D18	
D19	Review article Klonoff D, Diabetes Techn. & Therap. Vol. 7, No. 5, 2005		D19	
D20	Review article De Block et al. Current Diabetes Reviews, 2008,4,159-168		D20	
D21	US 2007/0135774 A1			D21
D22	Copy of complaint from German infringement proceedings;			D22
D23	English translation of complaint from German infringement proceedings			D23
D24	Copy of official confirmation of service of German proceedings			D24
D25	Original drawings of PCT/US2011/029881 obtained from PATENTSCOPE		D25	