Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
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The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Examination of a Patent Application

1. Objective

Definition of the examination process of a patent application and the manner of controlling the process.

2. Definitions

(Not applicable)

3. Applicable Documents

3.1 The Patents Law, 5727-1967 (hereinafter: the "Law").

3.2 The Patents Regulations (Office Practice, Rules of Procedure, Documents and Fees), 5728 - 1968, as amended according to the provisions of Section 194 of the Patents Law, 5727-1967, and updated in public records from time to time (hereinafter: the "Regulations").

3.3 The Commissioner's Circulars concerning examination of patents that are in force on the examination day.

3.4 Quality Manual QM- 7.5.1, Control of Service Provision.

3.5 Quality Manual QM- 8.2.4, Product Monitoring and Measurement.

3.6 Work Instructions WI- 23.4 – Monitoring the Process of Examination of a Patent Application.

4. Methodology

4.1 Examination of patent applications shall be conducted by the patent examiners at the Israel Patent Office.

4.2 An examiner receiving a file for examination shall examine whether the invention described in the application belongs to the field he is authorized to examine. Should the invention described in the application file not belong to the field under the examiner's authority, the file shall be returned for further consultation with the examiner's Team Manager.

4.3 The examiner is required to ensure that all correspondences are documented in the scanned application file in the operating system, examination of the application shall not commence without a response to Section 18 of the Law.

4.4 The examination process

4.4.1 The examiner shall conduct a formalities examination for ensuring the orderliness of the application according to the provisions of Appendix A, Guidelines for Examining a Patent Application.

4.4.2 The examiner shall conduct a substantive examination according to the provisions of the Patents Law, 5727-1967, and the Commissioner's Circulars concerning examination of patents in force on the examination day, according to the provisions of Appendix A, Guidelines for Examining a Patent Application, and the other appendices regarding interpretation of the Patents Law's sections.

4.4.3 Completion of the examination process could be conducted in one of two manners:

4.4.3.1 Acceptance of the application (PC 13) pursuant to that stated in Appendix A, Guidelines for Examining a Patent Application, Chapter IX.

4.4.3.2 Refusal of the application

4.4.3.2.1 Refusal of the application according to the provisions of Section 21B of the Law, upon the applicant's request.

4.4.3.2.2 Refusal of the application according to Regulation 45 and as defined in Appendix A, Guidelines for Examination of a Patent Application, Section 8.

4.5 Issuance of a patent certificate shall be conducted according to Work Instruction WI- 21.4, Issuance of a Patent Certificate.

5. Responsibility

The responsibility for implementation of this guideline shall apply to the Director of the Israel Patents Office, the Superintendent of Patent Examiners, the patent examiners, and the Office employees whose position is related to this guideline.

6. Appendices

Appendix 1 – Guidelines for Examination of a Patent Application

Appendix 2 – Section 3 of the Law – A Patentable Invention

Appendix 3 – Section 7 of the Law – Excluded Subject Matter

Appendix 4 – Section 8 of the Law – Unity of Invention

Appendix 5 – Sections 2, 9, and 19 of the Law – Overlapping Applications

Appendix 6 – Section 4 of the Law – Novelty

Appendix 7 – Section 5 of the Law – Inventive Step

Appendix 8 – Principles for Classifying a Patent Application

Appendix 9 – Guidelines for Searching Prior Art

Appendix 10 – Section 10 of the Law – The Right to Priority

Appendix 11 – Section 13 of the Law – The Claims

Appendix 12 – Section 12 of the Law – Description of the Invention in the Application Specification

Appendix 13 – Section 17(c) of the Law – Examination and Acceptance of an Application Based on a Corresponding Patent

Appendix 14 – List of the Issues to be Considered in the Examination According to Section 17(a) of the Law

Appendix 16 – Negative Limitations / Disclaimers in Patent Application Claims

Appendix 18 – Examination Guidelines in the Field of Polymorphism and Salts of Compounds

Appendix 19 – Amendments in the Specification

Appendix 20 – Emphases in Examination of Applications Concerning Antibodies

7. Forms

From the automated system.

Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
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Appendix 1 - Guidelines for Examining a Patent Application

1. Start of Examination

(References and documents relating to the start of the examination: Section 18 of the Patents Law 1967 (hereinafter "the Law") – regarding the applicant's duty to provide prior-art publications).

1.1. Allocation of applications – the Team Manager shall monthly allocate the applications intended to be examined, according to the classification criteria of the applications, the examiner's goals, and the time frames of the service level agreement.

1.2. The order of examination of applications – the applications shall be examined, considering the classification system in place at the Office and according to the order of filing thereof (subject to receiving a response to Section 18 of the Law). The examiner is required to note the type of application (accelerated, divisional, addition, etc.).

1.3. The examiner shall ensure that all of the documents required for starting the examination are documented in the automated system. Should some of the documents be missing, it is required to contact directly the applicant in writing, through a Notice of Clarification to which he is required to respond within three months, so that he would submit the missing documents through the filing website. No application files are to be received via email. Upon receipt of missing documents, it is required to consider the relevant date the document was submitted (particularly regarding amendments that may be deemed substantial amendments according to Section 23 of the Law). In case of doubt regarding the relevant date of the documents, the Team Manager should be consulted.

1.4. Where prior-art publications were filed in a language that is not an official language or in English, it is required to attempt translating them through machine translation available on the internet. Where the examiner considers that the machine translation is not sufficient, a translation should be requested from the application according to Regulation 36(2).

1.5. The examiner shall examine whether documents were submitted by a third party.

2. Substantive Examination

(References and documents relating to substantive examination: Sections 3, 7(1) and 7(2), 2, 3, 4, 5, 7(1), 7(2), 8, 9, 10, 12, 13, 17(a), 18, 19, 23, and 24(b) of the Law; Regulations 20(a)(3), 21, 22(c), 39(b), 41, and 51; **Commissioner's Circulars 20/2012-Patents** (2012), **034/2017-Patents** (2020), **035/2017-Patents** (2021); and Appendices 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 16).

2.1. It is required to read the specification and claims in-depth to examine and understand the technical problem that the invention is intended to solve and the difference between the claimed invention and the prior art teaching the same problem and/or a corresponding problem according to the applicant's explanations in the application's specification.

2.2. The examiner shall review the applicant's response to Section 18 of the Law and third-party documents (if any were submitted). In the absence of a response to Section 18 or in the case where the correspondence titled "Response to Section 18" does not actually constitute a response to Section 18 of the Law, the Team Manager should be consulted. The examiner shall review at least two examination reports issued by foreign Offices for corresponding applications (including International Authorities), where they are available, while assessing the relevance of the prior art cited to the claimed invention under examination.

2.3. The examiner shall conduct a substantive examination of the application, including the following:

2.3.1. The compliance of the invention with the requirements of Section 3 of the Law regarding utility, industrial applicability, and a field of technology shall be verified according to the criteria specified in Appendix 2 – Section 3 of the Law – A Patentable Invention. Any objection raised under Section 3 of the Law shall be subject to the approval of the Team Manager after consulting him.

2.3.2. The compliance of the claims with the provisions of Sections 7(1) and 7(2) of the Law (see Appendix C – Excluded Subject Matter) shall be verified. Without derogating from the aforementioned, these claims shall be examined also according to the other sections of the Law, including novelty and inventive step.

2.3.3. No request shall be made for the deletion of portions of the description of the invention that describe a method of medical treatment of the human body, since in themselves they do not contravene the provisions of Section 7(1) of the Law.

2.3.4. The compliance of the claims with the requirements of Chapter B in Commissioner's Circular 034/2017-Patents shall be verified while noting the following:

2.3.4.1. Use claims worded as follows are not allowable: "Use of X as a paint".

2.3.4.2. Process claims shall define the steps required for performing the process, which are novel and involve an inventive step. Therefore, claims of the type "Use of X in the manufacture/preparation of Y" that do not define steps, which are novel and involve inventive step, for performing the process would not be accepted. Where the process for manufacturing a product lacks novelty or inventive step, which only exists in the new use, a claim of the type specified in this section would not be accepted.

2.3.4.3. Claims for a new use of a known product may be worded as follows: "Product X for use as a medicament", or: "Product X for use in the treatment of Y".

2.3.4.4. For the avoidance of doubt, the provisions of Chapter B of Commissioner's Circular 034/2017-Patents apply to all fields of technology and are not limited to the medical field.

2.3.5. The compliance of the claim set with the provisions of Section 8 of the Law regarding unity of invention (see Appendix D – "Unity of Invention") shall be verified.

2.3.6. Compliance of claims relating to sequence listings with the requirements of Chapter F of Commissioner's Circular 034/2017-Patents shall be verified.

2.3.7. Entitlement of the application to a right to priority shall be verified according to the provisions of Appendix 10 of the Examination Guidelines – Section 10 of the Law – The Right to Priority.

2.3.8. The compliance of the claim set with the requirements of Section 13 of the Law and Regulation 20(a)(3) shall be verified according to the provisions of Appendix 11 – The Claims.

2.3.9. The patentability of claims referring to drawings or examples, without explicitly reciting all the technical features or aspects of the claimed product or process ("omnibus claims"), shall be verified according to the provisions of Chapter E of Commissioner's Circular 034/2017-Patents. Omnibus claims may not be accepted as part of an examination under Section 17(c) of the Law.

2.3.10. The compliance of the description of the invention with Section 12 of the Law shall be verified regarding clarity and sufficiency of disclosure to enable an average skilled person to perform the invention. Additionally, the compliance of the title of the invention with Section 12(a) of the Law shall be verified to ensure that it is not completely different from the invention or too general (see also Appendix 12 of the Examination Guidelines – Description of the Invention in the Application Specification).

2.3.11. Where the description includes references to documents by using the expression "incorporated by reference", it is required to act according to the provisions of Chapter D of Commissioner's Circular 034/2017-Patents and Appendix 12 of the Examination Guidelines – Section 12 of the Law – Description of the Invention in the Application Specification.

2.3.12. The drawings shall be reviewed and their consistency with the description shall be verified. The compliance of the drawings with Regulation 21 shall be verified for applications that are not international applications entering the national phase in Israel.

2.3.13. Full classification of the application shall be conducted according to the principles set out in Appendix 8 – Principles for Classifying a Patent Application and the automated system shall be updated accordingly. Applications first filed in Israel after 1.9.2016 shall be classified according to the CPC.

2.3.14. A prior-art search shall be conducted while considering the application's date (see Appendix 9 – Guidelines for Searching Prior Art).

2.3.15. Assessment of novelty and inventive step shall be conducted in respect of all the claims according to the provisions of Appendix 6 of the Examination Guidelines – Section 4 of the Law – Novelty and the provisions of Appendix 7 of the Examination Guidelines – Section 5 of the Law – Inventive Step). It should be emphasized the assessment of novelty and inventive step shall be performed regardless of the compliance of the application with other sections of the Law or with the requirements of the Commissioner's Circulars (other than in exceptional cases subject to the approval of the Team Manager).

2.3.16. Examination of whether there are conflicting applications under Sections 2 and 9 of the Law shall be conducted according to the provisions of Appendix 5 of the Examination Guidelines – Overlapping Applications and Appendix 9 of the Examination Guidelines – Guidelines for Searching Prior Art.

2.4. The first Notice of Deficiencies shall include the objections raised along with appropriate explanations while maintaining their order according to the provisions of Regulation 41 and Appendix 14 of the Examination Guidelines – List of the Matters to be Considered in the Examination According to Section 17(a) of the Law.

2.4.1. References to the relevant provisions of the Law, the Regulations, the Commissioner's Circulars, or the Examination Guidelines shall be indicated for each objection raised.

2.4.2. The patentability of all the claims shall be examined. Where, following the examination of the claim set, some of the claims were found non-patentable, the patentable claims shall also be indicated in the Notice of Deficiencies. For the avoidance of doubt, compliance with the

requirements of Sections 4 and 5 of the law, regarding novelty and inventive step, shall be assessed for each claim in the claim set, in view of the cited prior art.

2.5. Examination based on examination report of a corresponding application – for a large part of the applications filed in Israel, search and examination have already been conducted for corresponding applications at other Offices. In order to accelerate and streamline the examination process, the examiner is entitled, in the preparation of a Notice of Deficiencies, to refer to an International Preliminary Report on Patentability or a foreign Examination Report according to the conditions detailed below. In this regard, discretion shall be exercised, and such reference shall only be made after verifying that the reasoning associated with the deficiencies indicated in the other (international/foreign) report is relevant to the claim set under examination and the Patents Law in Israel. For the avoidance of doubt, even where the examination is based on an examination report of a corresponding application, the examiner would not be exempt from substantive examination of the application as set out in Section 2.3 above.

2.5.1. Definitions

2.5.1.1. International report – a Written Opinion issued by an International Searching Authority, or an International Preliminary Report on Patentability (Chapter II of the PCT) issued by an International Preliminary Examining Authority, regarding the novelty, inventive step, and industrial applicability of the claimed invention in an international application for which the application under examination has entered the national phase in Israel.

2.5.1.2. Corresponding application – an international application for which the application under examination is that entering the national phase in Israel, an application sharing the same priority document(s), an application claiming priority from the application under examination, an application from which the application under examination claims priority, and any other application having an identical description as that of the application under examination.

2.5.1.3. Foreign examination report – examination report issued for a corresponding application, except for an international (PCT) application, by an Office other than the Israel Patent Office.

2.5.2. During the examination of an application (subject to the aforesaid in Section 2.5.3) the examiner is entitled to conduct the examination based on an international report or a foreign examination report. The Notice of Deficiencies shall indicate which parts of the other report the examination is based on, by indicating the relevant sections of the other report as well as the relevant prior-

art publications, while referring to the relevant sections of the Israeli Law and addressing the patentability of all the claims.

2.5.3. Discretion should be exercised when conducting the examination based on a foreign examination report, which is only allowable where the Examination Guidelines in Israel are not different from those of the Foreign Office (see examples in the table below in the section titled "Differences in the Examination Guidelines with Foreign Offices"). In this regard, it is emphasized that raising a lack of unity of invention objection based on a foreign examination report is only permissible where this objection in the foreign report is based on PCT Rule 13.1.

2.5.4. Where the claim set under examination is not identical to that of the corresponding application, it shall be verified that the objections raised in the foreign report are relevant to the claim set under examination. If this criterion is met, it should be indicated in the Notice of Deficiencies that the claim sets are not identical and what is the difference between them (examples of the difference in the claim sets that do not lead to different conclusions include: translation, rectification of an obvious mistake or clarification, amendments made to comply with Section 7(1) of the Law, amendments made to comply with Sections 9-11 of Commissioner's Circular 034/2017-Patents regarding use claims, the claimed scope in the application under examination is broader than that of the corresponding application, etc.).

2.5.5. The examination of an Israeli application, from which priority right is claimed by an international application, may be based on the international report of the international application, provided that the report was published before the date of examination.

2.5.6. The same Notice of Deficiencies shall not refer to more than one other (international/foreign) report when the examination is based on the report of a corresponding application.

2.5.7. The Notice of Deficiencies shall explicitly indicate the corresponding application number (the publication number may also be added) for which the other report was issued and the date of the examination report.

2.5.8. The continued examination may be based on an examination report of a corresponding application. However, the applicant's arguments in his response to the previous Notice of Deficiencies shall be comprehensively addressed.

2.5.9. Differences in the Examination Guidelines with foreign Offices – various issues require attention, considering the differences that may exist between the Examination Guidelines in Israel and those in other Offices, as (incomprehensively) listed below:

Issue	Reference in Examination Guidelines
New use of a known product and/or process (as long as not relating to second medical use)	Appendix 6, Section 6.9
Claim for a group of items from a broader group disclosed in the prior art	Appendix 6, Section 6.5
Synergism	Appendix 6, Section 6.1, Sub-section b; Appendix 7, Section 5.3.10
Biological mechanism of action	Appendix 6, Section 6.10
Target population	Appendix 6, Section 6.11
Polymorphs and salts	Appendix 18
Antibodies	Appendix 20
Foreign practice - addressing the technical character of the invention when assessing novelty and inventive step vs. ILPO practice - assessment of novelty and inventive step being independent of assessment of the technical character of the invention	Appendix 2
Foreign practice - lack of support as grounds for inventive step vs. ILPO practice - lack of support cannot constitute a basis for lack of inventive step objection	Appendix 7, Section 5.4.6
Foreign practice – lack of novelty may be based on a national/regional application having a publication date later than the relevant date of the application under examination and a filing date prior to it.	In this case, it should be checked whether there is an overlapping Israeli application
Functional claims and result to be achieved	Appendix 11, Section 3
Publications cited in a Foreign Office whose date is after the priority date of the application under examination	
Publications, relevant to the novelty and inventive step, which were not cited in a Foreign Office due to a grace period	

2.5.10. When the examination is based on an international report, patent publications under category [P,X] or [E] in the International Search Report should be considered for the purposes of Section 2 of the Law (double patenting) and Section 9 of the Law (conflicting applications).

2.6. Where documents were submitted by a third party, the examiner shall indicate in the first Notice of Deficiencies their submission, while noting their particulars and attaching the documents to the Notice. The examiner may refer to the above documents at his discretion.

2.7. Notes are not to be made in respect of the applicant's wording in English. This does not refer to errors in English that lead to lack of clarity, erroneous understanding of the claim's scope, or typographical errors.

2.8. Where, during the drafting of the objections in the Notice of Deficiencies, translation is made from English to Hebrew of a feature whose Hebrew name is uncommon, it is required to write in parenthesis the term in English.

2.9. Should the examiner intend to accept the application and issue a Notice before Acceptance (PC 13) in the first examination or in cases where the examiner intends to issue a Notice of Deficiencies regarding non-substantive deficiencies (PC 27) in the first examination, it is required to obtain the Team Manager's approval prior to issuance of the notice.

In contacting the Team Manager for obtaining approval, the examiner is required to specify that he conducted the following actions (of course the list specified below does not exempt the examiner from the other parts of the examination as specified in Section 2.3 above):

2.9.1. examination of publications stated in the CCD database as prior art that served other authorities in examinations of the application (including citation of other applications belonging to the same family);

2.9.2. if necessary, conducting a supplementary search (especially where no search results were conducted/published in other Offices);

2.9.3. examination of overlap with previous Israeli applications where publications under category [E] or [P] were cited in the International Search Report;

2.9.4. inspecting the claims thoroughly, with emphasis on the existence of claims for medical treatment, omnibus claims, unclear claims, or claims that were added to the claim set that was already examined and an opinion was given in respect of it; and

2.9.5. in requests for modified examination according to Section 17(c) of the Law, examination of the priority link between the application under examination and the corresponding patent (with an emphasis on continuation-in-part (CIP) applications), verifying that the claims of the application

under examination and those of the corresponding patent are identical, checking whether the corresponding patent is under opposition or revocation proceedings; and, optionally, consulting the Information and Database Manager where there is difficulty in checking such information.

2.10. It is required to note whether the Notice of Deficiencies is delivered manually (in cases where the applicant is not registered for the electronic delivery service, a warning would be obtained from the automated system upon completing the Notice). In the case of manual delivery, it is required to generate a printed copy of the Notice from the automated system and place it for delivery to the applicant.

3. Divisional Application

(References and documents relating to a divisional application: Sections 2, 13, 18, 24, and 26 of the Law, Regulation 27, **Commissioner's Circulars 020/2012** (2012) and **034/2017-Patents** (2020) **- Patents**, Section 2 of this Appendix, Appendix 5 – Sections 2, 9, and 19 of the Law - Overlapping Applications).

3.1. A task for examining a divisional application is assigned automatically to an examiner without the involvement of the Team Manager. The examiner is required to examine whether an application that was separated according to Section 24 of the Law (hereinafter: the "divisional application") was submitted prior to the acceptance date (according to Section 26 of the Law) of the application that was divided (hereinafter: the "parent application").

3.2. The examination of a divisional application shall include the following:

3.2.1. verifying, in the automated system, that the application under examination claims the same priority documents as the parent application, otherwise, it is required to request amendment of the erroneous data;

3.2.2. verifying that the parent application was not rejected or abandoned before filing the divisional application, otherwise, it would not be possible to recognize the application under examination as a divisional application;

3.2.3. verifying that the specification (description, drawings, sequences) of the divisional application is identical to that of the parent application, otherwise, the applicant is required to indicate the parts of the parent application providing support for the claims of the divisional application;

3.2.4. verifying that no new subject matter of substantive nature was introduced to the specification, such that it is not possible to distinguish between the amendments in the specification of the

divisional application and that of the parent application, otherwise, it would not be possible to recognize the application under examination as a divisional application;

3.2.5. verifying that there is no overlap, according to the provisions of Appendix 5 – Sections 2, 9, and 19 of the Law – Overlapping Applications, between the claims of the divisional application and those of the parent application (Section 2 of the Law), otherwise, it is required to request the removal of the overlapping claims ;

3.2.6. verifying that the parent application is not under opposition proceedings:

3.2.6.1. where the parent application is under opposition proceedings, it is required to indicate in the Notice of Deficiencies that, according to Section 20 of Commissioner's Circular 035/2017-Patents, no extension shall be granted to the applicant in the examination of the divisional applications;

3.2.6.2. where the parent application is under opposition proceedings, and the divisional application includes a claim set that was already examined in the parent application, the examiner shall act for issuance of a Notice before Refusal;

3.2.7. to the extent possible, it is required to examine the divisional application together or immediately after the examination of the parent application, but the examination shall start no later than four months from the date of receiving the response to Section 18 for the divisional application;

3.2.8. a divisional application shall be examined as any other application, according to Section 2 above.

4. Application for a Patent of Addition

(References and documents relating to a patent of addition application: Article E of the Patents Law, Section 10 of the Law, Section 2 of this Appendix)

4.1. The examination of an application for a patent of addition shall not start as long as the main application is not a patent.

4.1.1. In cases where the examiner was assigned an application for a patent of addition for which there is no main patent, the examiner shall contact the Team Manager to return the application to the allocation list.

4.1.2. Where the patent of addition application was submitted during the examination of the main application, before being a patent, the examiner shall notify the applicant of postponing the examination (in a "clarification letter") until the main patent is granted.

4.1.3. It is the applicant's responsibility to update the examiner on the acceptance of the main application.

4.1.4. The examiner shall contact the Team Manager to add a reminder and an updated due date to the examination task.

4.2. The examination of a patent of addition application shall include verifying the following:

4.2.1. the main patent and the patent of addition application are under the same ownership; so that in cases where the main patent is under the joint ownership of two or more owners, the application would not be approved as a patent of addition application where all owners of the patent were not registered also as the owners of the patent of addition application, unless an agreement for settling the rights approved by the Patents Register Officer is presented;

4.2.2. the patent of addition application was filed after the application date of the main patent application or on the same day;

4.2.3. the patent of addition application constitutes an improvement or modification of the invention in the main patent; and

4.2.4. the invention claimed in the patent of addition application is novel compared to that in the main patent; wherein the examiner is not required to examine whether the invention claimed in the patent of addition application involves an inventive step compared to that in the main patent.

4.3. Examiner's attention is drawn to that Section 44 of the Law relates to the **invention** in the main patent and not to the publication of the main patent, and therefore any deficiency regarding lack of inventive step should not be based on any publication (whether it be a corresponding patent, patent application or other publication that is not a patent, whether it belongs to the applicant or another party) that describes the invention in the main patent.

4.4. A patent of addition application may not claim a right to priority **from the main patent application** by virtue of Section 10(a)(4) of the Law (as the inventions are not essentially the same). Therefore, the specification of the patent of addition application is necessarily not identical to that of the main patent, as the patent of addition application is required to include an improvement or modification.

4.5. A divisional application from the main patent cannot be approved as a patent of addition application. The applicant is entitled to change the status of the application from a divisional application to a patent of addition application only where the applicant adds a new subject matter to the application constituting the improvement or modification of the invention in the main patent.

4.6. Examination of an application whose acceptance was requested as a patent of addition on the date of submitting thereof, shall be prioritized in the order of examinations over other applications, except

for applications approved for advanced examination as specified in EG-23.7 (on-the-spot, PPH, and "green applications").

4.7. Subject to that stated in this section, a patent of addition application shall be examined as any other application, according to the examination guidelines in Section 2 above.

4.8. At the end of the examination of the patent of addition application, upon issuing a Notice before Acceptance, this Notice shall indicate that the application is allowable as an application for a patent of addition while mentioning the main patent number.

5. Continued Examination

(References and documents relating to continued examination: Chapters B and C of the Law; Regulations 22(b) and 42-45).

5.1. Tasks for continued examination are assigned to the examiners automatically by the automated system, according to the order of receiving the applicant's response and subject to the order of priority given to the examination as specified below.

5.2. In the order of the continued examinations, prioritization shall be given to applications whose examination was advanced (see EG-23.7 – Request for Advanced Examination), applications for which Notice before Refusal was issued, and then applications that may be processed quickly (Section 17(c) of the Law, an application for patent of addition, and responses to PC 27).

5.3. After completion of processing the applications aforementioned in Section 2, the examiner is required to prioritize the examination of applications whose examination started over five years ago, applications for which a response to a Notice of Deficiencies was received over 9 months ago, applications for which over three Notices of Deficiencies were issued, divisional applications in which an opposition was filed against one of the family members, and applications whose examination was postponed according to Section 19 of the Law.

5.4. In cases where an amended claim set was filed, including more than 50 claims (in applications filed later than 24/01/2010), the matching between the number of claims and the payment sum should be verified, without which the examiner shall not conduct an examination, but shall issue an action titled "Discrepancy between the number of claims and the amount of payment".

5.5. The order of actions in the continued examination process shall be as follows:

5.5.1. reviewing the correspondences and new documents that were updated in the system and reading them carefully;

5.5.2. reviewing the applicant's response regarding all sections of the last Notice of Deficiencies according to the requirements of Regulation 42; in the absence of reference to substantive deficiencies (deficiencies against Sections 2, 3, 4, 5, 7, 8, 9, 12, and 13 of the Law), **acting for issuance of a Notice before Refusal**, except in cases where the applicant's response includes a request to postpone the examination according to Regulation 39(b); and where an examination under Section 17(c) of the Law is requested as a response to the Notice of Deficiencies, examining the application according to the provisions of Appendix 13 – Section 17(c) of the Law - Examination and Acceptance of an Application Based on a Corresponding Patent;

5.5.3. in cases where amendments were filed,

5.5.3.1. examining the substantive amendments and requesting the indication of the amendment submission date in the margins of the amended specification passages, according to the provisions of Section 23 of the Law and Regulation 22(c);

5.5.3.2. examining the amended pages in the specification and their indication according to Regulation 22, wherein an amendment in a claim introducing a new subject matter will cause the whole claim to receive a new date (see the provisions of Appendix 19 of the Examination Guidelines – Section 23 of the Law – Amendments in the Specification);

5.5.4. where during the examination the applicant adds on his initiative a publication to the specification (or another reference to the prior art), requesting an explanation from the applicant as to why the publication was added at that time and what the differences are between the publication and the claimed invention;

5.5.5. where new and/or amended claims were submitted along with the applicant's response, verifying that the applicant has complied with the requirements of Regulation 22(b) and specified in his response how these additions/amendments meet the requirements of Section 13 of the Law, in the absence of which, **the examiner is entitled to act for issuance of a Notice before Refusal**;

5.5.6. examining whether the new/amended claims overcome the objections that were specified in the previous Notice of Deficiencies while paying attention to the arguments that were raised in the applicant's letter;

5.5.7. where the in previous Notice of Deficiencies an objection due to overlapping applications was raised, examining whether the overlap deficiency still exists while reviewing the updated claim set in the application in respect of which the overlap objection was raised;

5.5.8. where the examiner reached a conclusion that the claimed scope was broadened or that an aspect was added to it that was not claimed before, conducting a supplementary search, if necessary,

provided that the claimed scope complies with Section 13(a) of the Law (see the provisions of Appendix 9 – Guidelines for Searching Prior Art).

5.6. In cases where an interview is requested by the applicant regarding the Notice of Deficiencies, the examiner is required to act according to the provisions of EG-23.3 – Interview with an Examiner During Examination of a Patent Application.

5.7. In cases where an informal communication has been made with the applicant or his authorized for clarification, the examiner is required to document its contents according to the provisions of EG-23.3 – Interview with Examiner During Examination of a Patent Application, or, alternatively, indicate it in the next correspondence.

5.8. The Notice of Deficiencies issued in the continued examination shall address all the provisions of section 5 above. The examiner shall first indicate the objections the applicant overcame, then the objections he had not overcome, and finally specify new objections. Each objection should be reasoned **while addressing the applicant's arguments** concerning the objection, if any were given. The Notice of Deficiencies shall address **all** the claims. Recurring deficiencies (for example those the applicant had not addressed at all) should be indicated in the Notice and it is not sufficient to refer to sections of the previous Notice of Deficiencies. Where the applicant had not addressed deficiencies that were indicated, but the examiner found that these deficiencies were removed or are irrelevant, he shall note this in the Notice.

5.8.1. In cases where the examiner deems it appropriate to issue an additional Notice of Deficiencies in respect of an application for which a Notice of [non-substantive] Deficiencies (PC 27) was sent, he is required to obtain the Team Manager's approval, since the certainty regarding the end of the examination it is of great importance for the applicant.

5.8.2. It is emphasized that the continued examination shall address the patentability of all the claims, including a reference to each claim regarding its compliance with novelty and inventive step.

5.9. It is required to note whether the Notice of Deficiencies is delivered manually (where the applicant is not registered for the electronic delivery service), in which case it is required to generate a printed copy of the Notice from the automated system and place it for delivery to the applicant.

6. Acceptance of the Application

(References and documents relating to the acceptance of the application: Sections 17(a), 17(c) of the Law)

Before issuing a Notice before Acceptance, the examiner shall verify whether there are prior-art publications cited against corresponding applications, whose examination was reviewed at the start of the examination at the ILPO, and which might have bearing on the novelty and inventive step of the current claim set.

6.1. Where the applicant has rectified all the deficiencies or presented persuasive arguments against the objections raised regarding these deficiencies, a "Notice before Acceptance" (PC 13) shall be sent to him, in which he would be requested to pay the publication fees. Prior to sending this Notice, the following actions should be conducted:

6.1.1. verifying that all the application's files – the description, the claims, the drawings, and the sequence listings - are in the latest version and are documented in the automated system under the appropriate name;

6.1.2. verifying that the application's specification is duly drafted and all the changes requested by the applicant during the examination – replacements, additions, or deletions of pages – are documented in the automated system, otherwise, corrective actions need to be taken, as this is important to ensure that the requested changes were indeed performed and obtained the appropriate date since the correctness of the information in the automated system is the basis for the correctness of the information on the Office's website;

6.1.3. verifying that the classification of the application matches the version of the classification in force at the end of the examination, and correcting them, where necessary, according to the up-to-date version of the classification system in the automated system;

6.1.4. verifying that the classifications assigned to the application at the start of the examination are still relevant to the claimed invention and, where necessary, correcting them;

6.1.5. where the examination is conducted under Section 17(c) of the Law, indicating so in the automated system;

6.1.6. due to the need for the applicant's certainty regarding the date of completion of the examination, the "Notice before Acceptance" should not include comments regarding the claims and/or the wording of the application's specification, which would require amendments by the applicant, as in these cases a Notice of Deficiencies should rather be issued;

6.1.7. regarding applications that have not yet been published under Section 16A of the Law, inspecting whether a request was submitted by the applicant to defer the acceptance until the "prescribed date" under Section 16A(c) of the Law and, where such a request was submitted, contacting the Team Manager / Superintendent of Patent Examiners for obtaining instructions concerning the issue, while refraining from issuing a Notice before Acceptance;

6.1.8. verifying the correctness and completeness of the application's documents (description, claims, drawings, sequence listings) and of the application's classification.

6.2. For an applicant who is not registered to the electronic delivery service, a copy of the Notice before Acceptance shall be delivered via regular mail, accompanied by a copy of the application status report and a copy of the specification files.

6.3. Prior to the publication of the acceptance of the application, a Formalities Examiner shall inspect the application as close as possible to the date of the Notice before Acceptance, and, where no deficiencies are found, he shall direct the application for publication under Section 26 of the Law. Where deficiencies are found, the following actions should be conducted:

6.3.1. the Formalities Examiner shall notify the substantive examiner of the deficiencies without cancelling the Notice before Acceptance (PC 13);

6.3.2. the substantive examiner shall contact the applicant or his authorized representative by e-mail or telephone in order to rectify the deficiencies; and

6.3.3. after rectifying the deficiencies, the application shall be published under Section 26 of the Law.

6.4. Requests for amendments after Notice before Acceptance (PC 13) are divided into four types:

a. request for amendments to the application documents;
b. request for returning the application to examination according to Commissioner's Circular 035/2017;
c. request for deferral of publication of the acceptance of "on-the-spot" applications until 18 months after the filing date, per applicant's request; and
d. request for return to examination of an application that was examined under Section 17(c) of the Law, following notification of opposition or revocation proceedings of the corresponding patent.

Upon receiving a request for amendments after a Notice before Acceptance (PC 13), a task is automatically created in the automated system for the examiner with a due date for processing it within 7 days. After completing the task, the examiner is required to contact the Team Manager for closing the task, as specified below.

6.5. Amendments to the application (substantive and non-substantive amendments) – amendments made to the specification after Notice before Acceptance (PC 13) are processed according to the following:

6.5.1. A **non-substantive** amendment – an amendment that usually includes correction of errors or re-numbering pages. In case of non-substantive amendment, the examiner is required to promptly approve it and create an action in the automated system titled "Approval of Amendments after PC 13", after which he should contact the Team Manager for closing the task.

6.5.2. Where the amendment includes the addition of dependent claims only, it can be considered non-substantive and create an action "Approval of Amendments after PC 13", provided that the claims are clear, concise, and supported by the specification.

6.5.3. A **substantive** amendment – an amendment usually including the addition of technical features to the dependent or independent claims, which were not part of the allowable claim set. Such an amendment requires the examiner to examine whether the amended claims are supported by the specification and may even require him to re-examine whether they are novel and involve an inventive step.

6.5.3.1. In case of a **substantive** amendment, the examiner shall consult with the Team Manager, and under his approval (while considering the required scope of work) it would be decided whether the application would be transferred to the regular continued examination queue or to prioritized examination. The examiner shall create an action titled "Cancellation of PC 13 following Amendments" notifying the applicant of the cancellation of the Notice of Acceptance and the return to substantive examination. Special attention is drawn to cases where the request for amendments also lists additional prior-art publications cited against corresponding applications.

6.5.3.2. After sending the cancellation notice, the examiner is required to contact the Team Manager to change the task due date according to the prescribed examination due dates.

6.5.3.3. After the completion of the task (sending to the applicant a "Notice of Deficiencies" or "Notice before Acceptance"), the examiner is required to contact the Team Manager for closing the task. At the same time, the examiner shall deliver an email to the Patents Administration to refund the acceptance fee, insofar as this fee has been paid prior to the cancellation of the Notice before Acceptance.

6.6. Commissioner's Circular 035/2017 – Return of the application to examination after a Notice before Acceptance, following an update to the list of prior-art publications. According to the Circular's provisions, following a request to return the application to examination after a Notice before

Acceptance, the examiner shall cancel the Notice before Acceptance (PC 13) and examine the application considering the change in the list of publications. Where the examiner finds that there are deficiencies, he shall issue a Notice of Deficiencies to which the applicant may respond. Where the applicant's response fails to rectify the deficiencies, a Notice before Refusal shall be issued. Following are the steps for implementing this provision:

6.6.1. The applicant shall file a "Request for amendments after PC 13", in which he is required to indicate when he became aware of the change in the list of publications and his request to return the application for examination.

6.6.2. Where the applicant fails to indicate when he became aware of the change (additional prior-art publication(s)) or that he indicates that he became aware of the change before sending his last response to the Notice of Deficiencies, the examiner shall create an action titled "Approval of Amendments after PC 13" in which he indicates that the applicant's request to return the application to examination does not meet the criteria set out in the Commissioner's Circular. It is emphasized that in case no previous Notice of Deficiencies was sent (i.e., a Notice before Acceptance (PC 13) was issued in the first examination), the prescribed date, in this case, will be the last update of the list of prior-art publications under Section 18 of the Law before issuing the Notice before Acceptance.

6.6.3. Where the request for amendments includes other amendments to the specification (description or claims), it shall be examined as a regular Request for Amendments after PC 13, and not according to the provisions of this section. However, the examiner is required to examine the update in the list of prior-art publications, based on which the return of the application to examination was requested, and to refer to it in the next Notice.

6.6.4. Where the request for returning the application to examination meets the criteria of the Commissioner's Circular, he shall create an action titled "Cancellation of PC 13 due to Amendments".

6.6.5. After sending the cancellation notice to the applicant, the examiner shall notify the Team Manager of the Request for Amendments after PC 13, so that the Team Manager would create a new task with a due date (till three months from the date of the request).

6.6.6. The examination shall be based on the additional prior-art publications without indicating other deficiencies that could have been indicated in the examination which was completed.

6.6.7. Where the examiner does not find deficiencies regarding the change, the examiner shall issue a new Notice before Acceptance (PC 13) in which he indicates that the application was examined

due to a change in the list of prior-art publications, and it is allowable for continuation in the acceptance process.

6.6.8. Where, during the examination, the examiner finds deficiencies considering the change in the list of publications, he shall issue a new Notice of Deficiencies (PC 26), to which the applicant would have one opportunity to respond before issuing a Notice before Refusal.

6.6.9. After issuing a Notice of Deficiencies or Notice before Acceptance, the examiner shall contact the Team Manager to close the task.

6.7. Request for deferred publication of acceptance until 18 months after the filing date (on-the-spot applications)

6.7.1. The applicant shall file a "Request for Amendments after PC 13", in which he indicates that he wishes to defer the publication of the acceptance of the application.

6.7.2. The examiner shall contact the Team Manager for updating the task with a reminder date after the elapse of 18 months from the filing date of the application.

6.7.3. Where confirmation of deferral is requested, the examiner shall issue a "Clarification Letter" in which he indicates that the request was received, and the publication of the acceptance is deferred.

6.7.4. When receiving a reminder, the examiner shall ensure that 18 months have already elapsed from the filing date of the application.

6.7.5. The examiner shall conduct a top-up search (considering the findings of examination of corresponding applications) and indicate this on the "Approval of Amendments after PC 13" form he shall issue. Where new relevant documents are found in the to-up search for the purposes of Sections 4, 5, or 9 of the Law (novelty, inventive step, or conflicting applications), the amendments shall not be approved, and the examiner shall consult with the Team Manager as to the continuation of the examination.

6.7.6. After issuing an "Approval of Amendments after PC 13" or a Notice of Deficiencies, the examiner shall notify the Team Manager to close the task manually.

6.8. Return to examination of an application that was examined according to Section 17(c) of the Law, following a notification of opposition proceedings against a corresponding patent. According to Section 17(e) of the Law, it is the applicant's duty, whose application was examined under Section 17(c) of the Law, to notify of opposition or cancellation proceedings against the corresponding patent. According to the provisions of Section 15 of Commissioner's Circular 035/2017-Patents, following such

notification, the application shall be returned to full examination according to Section 17(a) of the Law.

6.8.1. Notification of opposition or cancellation proceedings against a corresponding patent, delivered to the Office after the issuance of Notice before Acceptance and before the date of acceptance, shall be submitted by a request titled "Request for Amendments after PC 13". The examiner shall act according to the steps specified in Sections 6.12.3.1-6.12.3.3 above. For the avoidance of doubt, the examiner shall conduct a full examination of the application.

6.8.2. Notification of opposition or cancellation proceedings against the corresponding patent, delivered to the Office after acceptance, shall be submitted to the Patents Administration (not to the patent examiner) and shall be processed by the Superintendent of Patent Examiners. A notice regarding the cancellation of acceptance shall be published in the Patents Journal and the application shall be returned to full examination, provided that no opposition to granting a patent was filed in Israel.

6.8.3. The following is a chart summarizing the process of processing a request for amendments after a Notice of Acceptance (PC 13):

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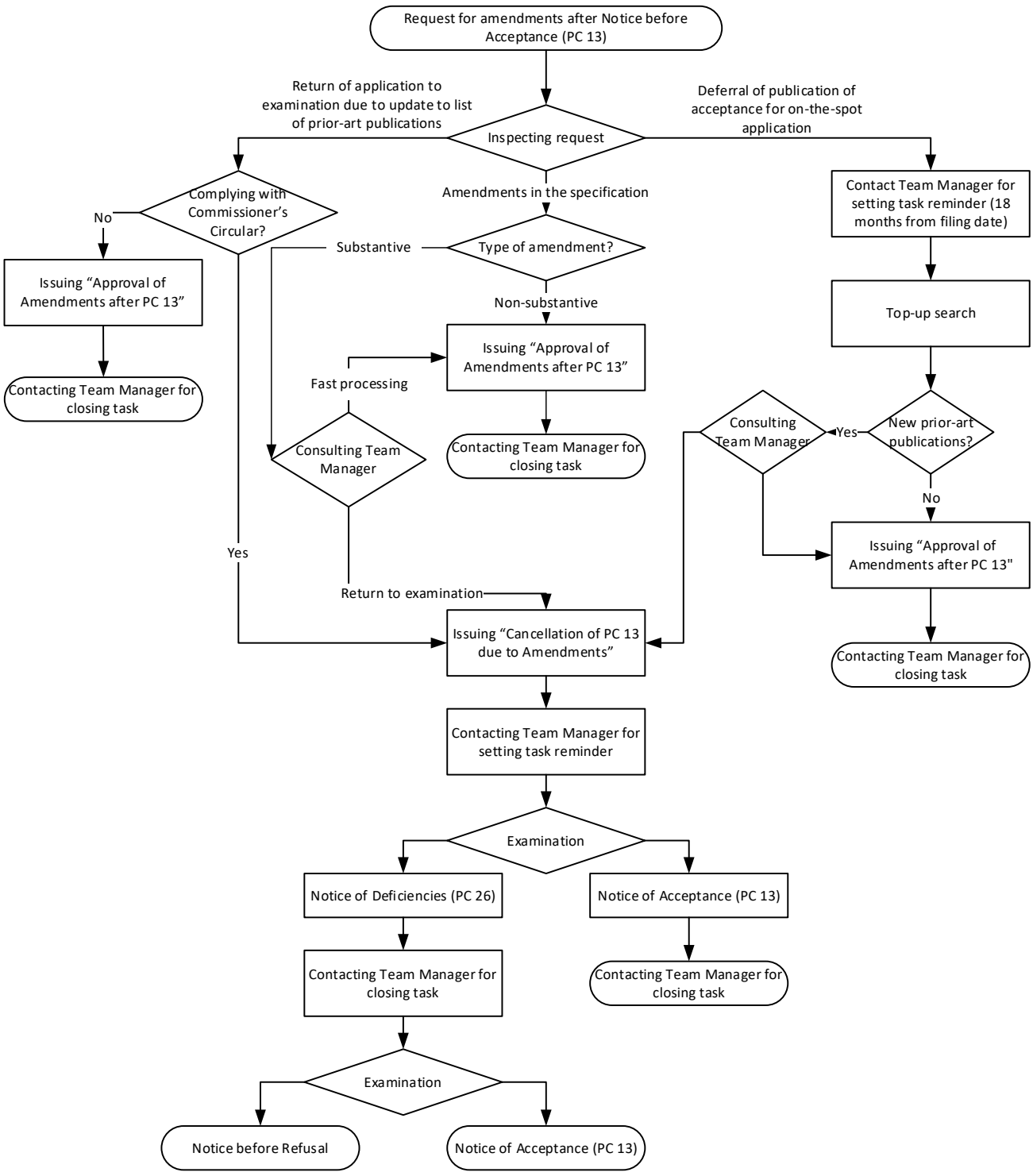

7. Refusal of the Application

(References and documents relating to refusal of an application: Section 161 of the Law; Regulations 45 and 46 of the Regulations; EG-23.3 – Interview with an Examiner During Examination of a Patent Application)

7.1. Should processing the application come to an impasse or after three office actions, the earlier of the two, the examiner is required to act for completing examination of the file. An impasse means, *inter alia*, one of the following:

7.1.1. Return to a claim set that had already been discussed in the past (a) in respect of the application under examination or (b) in respect of the application from which the application under examination was separated and objections against it were raised by the examiner and responded to by the applicant;

7.1.2. In the absence of response to one of the substantive objections in the Notice of Deficiencies;

7.1.3. In the absence of reasoning regarding changing the claim set;

7.1.4. Changing the claim set, in a manner that does not convince the examiner that the new claim set would rectify the deficiencies.

7.2. The examiner is required to consult the Team Manager, prior to turning to the Superintendent of Patent Examiners or his deputies, to examine whether the applicant's arguments may be accepted.

7.3. Where, following consultation with the Team Manager, it is found that the arguments are not accepted, it is required to refer to the Superintendent of Patent Examiners or his deputy for approval to issue "Notice before refusal of a patent application". The Notice shall draw the applicant's attention to the possibility of conducting an interview prior to refusal in order to voice his arguments. In the Notice it is required to give reasoning for each of the arguments raised in the applicant's last response. Should there be claims that were found to be patentable, these claims shall be indicated in the Notice.

7.4. The options available to the applicant after receiving a Notice before Refusal are as follows:

7.4.1. Submitting a response including reasoned arguments addressing the objections raised in the Notice before Refusal, together with up to two claim sets and any other relevant document supporting the applicant's arguments. The applicant shall state in his response whether he wishes to conduct an interview with the examiner.

7.4.1.1. Should no interview be requested, the examiner shall decide on the acceptance or refusal of the application based on the material that was submitted.

7.4.1.2. Where an interview is requested, it is the responsibility of the applicant or his authorized representative to indicate **in his response** three dates for conducting an interview with the

examiner, which shall be held within two months following the date of submission of the response. The examiner shall contact the applicant for a final determination of the interview date. The interview shall be conducted according to EG-23.3.

7.4.1.3. Where no dates were indicated (or the proposed dates exceed the abovementioned time frame), the examiner shall decide on the acceptance or refusal of the application based on the material that was submitted.

Or

7.4.2. Voicing arguments before the Commissioner according to Section 161 of the Law and WI-90.1.

7.4.3. **It is not possible to take more than one course of action**.

7.5. Where the examiner is convinced of the applicant's arguments, the application shall be returned to examination for rectifying the remaining deficiencies by the applicant or granting Notice before acceptance.

7.6. Where the examiner is not convinced of the applicant's arguments and after consulting the Team Manager and obtaining the approval of the Superintendent/Deputy Superintendent, the examiner shall notify the applicant by a reasoned notice of the refusal of the application via an action titled "Refusal of application according to Regulation 45", and of the possibility to object to the examiner's decision before the Commissioner according to Regulation 46 and WI-90.1 – filing applications for reconsideration and voicing arguments before the Commissioner within one month. Refusal of the application would take effect 14 days following the date of delivery of the Notice.

7.7. As a rule, the notice of refusal shall not indicate new objections and/or prior-art publications that could have been indicated at earlier stages of the examination.

7.8. Where a Notice before Refusal was issued due to failure to comply with the provisions of Regulation 22(b) and/or Regulation 42 and where less than three Notices of Deficiencies were sent, or in case a Notice before Refusal was sent in the first examination, it is possible to return the application to examination (issuance of one or more Notices of Deficiencies) where a reasoned response was received as required from the applicant. However, the Notice before Refusal would be deemed a Notice of Deficiencies for the purposes of the limitation to three Notices.

7.9. The limitation regarding three Notices of Deficiencies (see Sections 7.1 and 7.8 above) shall apply to applications in which no more than one Notice of Deficiencies regarding substantive deficiencies (including applications examination of which had not started yet) before 1.1.2018. Regarding applications in which more than three office actions were delivered prior to 1.1.2018, the examiner

shall act for completing the examination after four Notices of Deficiencies or an impasse (the earlier of the two).

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The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 2 – Section 3 of the Law – A Patentable Invention

1. Section 3 of the Patents Law

1.1. Section 3 of the Law sets out the main essential conditions for the patentability of an invention, as follows:

> "An invention, whether a product or a process in any field of technology, which is new, useful, industrially applicable and involves an inventive step – is a patentable invention."

Meaning, Section 3 instructs the examiner to verify that the invention meets the following cumulative criteria:

1.1.1. the invention's being a **product** or **process**;

1.1.2. the invention's being within **any field of technology**;

1.1.3. the invention's being **novel**;

1.1.4. the invention's being **useful**;

1.1.5. the invention's being **industrially applicable**; and

1.1.6. and the invention's involving **an inventive step**.

1.2. According to Section 2 of the Law, an owner of a patentable invention is entitled to request to be granted a patent for it. As aforementioned, Section 3 of the Law concerns the question of what a patentable invention is. However, there are matters which are excluded from patentability as set out in Section 7 of the Law[1], in which case the examiner is required to act according to the provisions of Appendix 3 of the Examination Guidelines, Section 7 of the Law – Excluded Subject Matter.

[1] Attention is drawn to the fact that the matters listed in Section 7 of the Law do not overlap with the list specified in Article 52(2) of the European Patent Convention regarding inventions excluded from patentability.

2. Novelty of an Invention

The novelty of an invention shall be assessed according to the provisions of Appendix 6 of the Examination Guidelines, Section 4 of the Law – Novelty.

3. Inventive Step of an Invention

The inventive step of an invention shall be assessed according to the provisions of Appendix 7 of the Examination Guidelines, Section 5 of the Law – Inventive Step.

4. Utility of an Invention

4.1. According to case law, "at the time of filing the application it shall provide a promise in respect of the utility."[2] The examiner should not demand the applicant, during the substantive examination stage, to prove the utility in practice. Given this, the examiner is required to take into account the following considerations:

4.1.1. An invention is required to be directed to specific and defined applications, so that it would be possible to examine what are the promised functions or activities of the invention. For example:

- An active/chemical substance described in the application as a substance for treating diseases (in a general manner without specifying at all the types of diseases) is not considered as meeting the promised requirement regarding its utility. However, where the substance is described as a substance for treating a specific disease or list of specific diseases it would be considered as meeting this requirement.
- An invention relating to a genetic/biological sequence without specifying its activity in the application's specification cannot be considered a useful invention.

4.1.2. Inventions that are not directed to specific and defined applications would also be considered as non-useful, for example:

[2] CA 665/84 Sanofi Ltd. v. Unipharm Ltd., IsrSC 41(4), 737

- processes for manufacturing a product (material, composition, device), wherein the product in itself lacks a specific and defined application;
- processes for identification/examination of a product (material, composition, device), where the product in itself lacks a specific and defined application; and
- an intermediate product used for preparing a final product, wherein the final product in itself lacks a specific and defined application.

4.1.3. An invention that cannot be put into practice due to substantial technical limitations (or knowledge gaps) known to a person skilled in the art at the time of filing the application (even where they do not contravene laws of nature) is not useful and therefore not patentable. In this case, an objection is to be raised where there is no doubt as to the non-operability of the invention.

A distinction must be drawn between knowledge gaps related to putting the invention into practice (as specified above) and knowledge gaps related to performing the invention under Section 12 of the Law (in respect of these see Appendix 12 – Section 12 of the Law). For examples of inventions that cannot be put into practice due to substantial technical limitations, please see Appendix 2.1, Examples 1-2.

4.1.4. An invention that includes an unreliable/unreasonable promise regarding its utility is not useful and thus it is not patentable. Inventions belonging to this category are:

- Inventions that contravene known laws of nature and well-established scientific theories (for example, perpetuum mobile, a process for producing gold from lead by a chemical reaction, a universal cure for any disease that would enable eternal life).

  The reasoning required on the examiner's part must rely on scientific references, yet an invention is not to be objected to solely due to its reliance on a new or non-art-recognized theory.
- Inventions that cannot be put into practice (according to the application's specification or according to other reference, even if published after the priority date), see for example, Appendix 2.1, Example 3.

4.2. Rectifying a deficiency regarding the utility of the invention by introducing a new subject matter to the description shall be deemed an amendment of substantive nature in the sense of Section 23 of the Law.

5. Industrial Applicability of an Invention

5.1. The term "industrial applicability" may be read in the context of the field of technology (discussed below) and in light of the invention's being useful. Generally, where the invention can be associated with any field of technology and its utility promised by the applicant can be realized, it is also industrially applicable.

5.2. Where the subject matter claimed concerns an aspect that could be interpreted as relating to a process for "self-use" (i.e., use intended for personal or private purposes), the invention shall be considered as patentable (subject, of course, to compliance with the other sections of the Law), provided that the invention is useful and is within a field of technology, unless it is explicitly stated in the claim that the process is for self-use only.

6. Product or Process

6.1. Examination of an invention whether it relates to a product or process is to be conducted, *inter alia*, in light of the provisions of Chapter B of Commissioner's Circular 034/2017-Patents.

6.2. A process claim shall be defined in terms of stages or steps required for realizing the intended purpose of the claimed process.

7. In any Field of Technology

7.1. In order to identify whether an invention is within any field of technology, it is also possible to refer to specific criteria depending on the nature of the invention described in the application, which would assist in identifying that it is within "any field of technology".

Identification of an invention's being within a field of technology would be determined according to the requirement that in performing the invention, whether it is claimed as a product or whether

it is claimed as a process, a tangible technical process would occur.[3] The technical character of the invention relates to the expression of technical effects on physical entities regarding any matter on which the invention is performed.[4]

Generally, there would be no difficulty in identifying the appropriate field of technology of a claim relating to a product per se (which is not claimed as a process). However, where there is difficulty in identifying the invention's being within a field of technology, the main criterion in this matter would be the presence of a technical character of the claimed product or process providing a tangible result.

7.2. A discovery, a scientific theory, a mathematical formula[5], game instructions, and a mental acts *per se*[6], would be deemed abstract concepts or processes that lack a technical character, whether performed by "manual" means or by computer. Additionally, it was already ruled that methods of doing business per se being within an economic field, would not be considered as inventions within a field of technology.[7]

However, in combining such abstract concepts or processes together with additional technical means, the invention would have a technical character and would be identified with a certain field of technology. In this case, the invention shall be examined, on a case-by-case basis, according to the following:

7.2.1. The invention shall be considered **as a whole** without separating its components and without focusing on one component or group of components.

7.2.2. The invention **as a whole** shall be examined as to whether it brings about a contribution having a concrete result within a field of technology and a technical character providing a tangible result.

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[3] See OA (District Court Jerusalem) 23/94 United Technologies v. The Commissioner of Patents, Isrdc, Volume 26(8) 729.
[4] See the manner in which these were discussed by the Enlarged Board of Appeal of the European Patent Office, case number G0003/08, date of decision dated 12.5.2010.
[5] OA (Tel Aviv) 501/80 **Rosenthal v. the Commissioner of Patents**, IsrDC 5744 (3), 441 (1984).
[6] See OA (District Court Jerusalem) 23/94 **United Technologies v. the Commissioner of Patents**, IsrDC, Volume 26(8) 729, Paragraph E of the judgment; as well as Section 42 of the Commissioner's decision on the matter of **Eli Tamir, Patent Application 131733**, decision dated 21.9.2006.
[7] See the Decision on patent application 131733 (footnote 6 above).

7.2.3. The contribution of the invention **as a whole** shall be examined based on the specification in view of the relevant prior art, without derogating from the requirement of examining the inventive step as required in section 3 above).

8. Technical Character of Inventions Integrating a Computer Software

8.1. To illustrate the manner for identifying a technical character in an invention integrating a computer software, the invention should be examined according to the following criteria:

8.1.1. Whether the performance of the claimed invention results in additional technical effects beyond those resulting from the ordinary operation of an integrated computer system. Should the answer be yes, it is an indication that the invention is within a field of technology.

8.1.2. Whether performance of the claimed invention results in the computer's operation in a new manner, including, but not limited to, improving the computer's performance (such as speed, reliability or more efficient utilization of information storage volume), or whether an interaction has been established between the components of the computer system that did not exist before. Should the answer be yes, it is an indication that the invention is within a field of technology.

8.2. Where an invention is implemented by a computer and there is nothing additional in the computer's operation beyond the 'ordinary' technical effect obtained by running software on a computer, it shall not be considered as having a tangible technical character. This is apart from the question of protection of the code lines by which the software is expressed, which is a form of expression that by its very creation is deemed a literary work under the Copyright Law, 5768-2007. This form of expression is not related to the question of the technical character that could be expressed through it. It should be clarified that a claim for a data carrier including software that is a component of a patentable invention would be acceptable as stated in these guidelines.

8.3. An invention in which the performance by computer of a process that could be performed also without a computer, such as the automation of a manual process and processes for optimization and diagnostics, may have a technical character. For example, a contribution **beyond** the expected and obvious optimization resulting from computerization of an automation process indicates a reasonable basis for the presence of a technical character. Meaning, where performing the invention using the computer differs significantly from the manner of manual performance so that

it is not practical to perform the same process efficiently using "manual" means or that the manner of this implementation has no meaning other than in the context of the computerized process – this indicates the presence of a tangible technical character. All this apart is from the questions of novelty and inventive step that need to be assessed with respect to such processes.

Appendix 2.3 lists examples 1-15 illustrating applying the criteria specified in this section.

Appendix 2.1

Example 1

The claimed invention is a new chemical substance A and the process for manufacturing it (the process of manufacture and characterization of the substance are described in full in the application, meaning the application meets the requirements of Section 12 of the Law). According to the description of the application, by combining substance A with an additional substance having X and Z features, it is possible to manufacture aircraft wings with improved aerodynamic characteristics. A substance having X and Y features and the process for producing it still do not exist (or did not exist at the time of filing the application). Since it is not possible to put the invention into practice, the invention is not useful.

Example 2

A method of remotely controlling an unmanned aerial vehicle within KELT-2Ab's atmosphere environment.

While the invention is applicable and reliable, which was built for all the physical parameters of aviation in KELT-2Ab atmosphere, its intended purpose cannot be realized. Since the planet KELT-2Ab is located in the Andromeda Galaxy 2.5 million light years away from Earth, it cannot be put into practice in today's technological state.

Example 3

The application describes three crystalline configurations of substance A which is used as an antibiotic substance, and its mechanism of action includes a step of its absorption in blood. The results presented in the application indicate that configuration (I) is absorbed at a high level, configuration (II) is absorbed at a low level, and configuration (III) is not absorbed at all. Where the claimed invention relates to configuration (III) it would not be considered as useful.

Appendix 2.2

Example 1

A cosmetic method for treating the hair of a subject comprising the following steps:
(a) applying to the hair composition A of claim 1,
(b) applying to the hair composition B,
wherein step (b) is performed 8 hours after step (a), and further wherein the subject is still in his bed.

The inventive concept relates to a composition (claimed in another claim). Although it appears that the claimed process is intended to be performed as a self-use process, no objection should be raised under Section 3 of the Law.

Appendix 2.3

The following are several examples of applying the criteria set out in Appendix 3 regarding inventions within the software field. These examples were selected solely for the purpose of exemplifying and illustrating the manner of applying the criteria. These examples are not exhaustive, and each case should be examined on a case-by-case basis by the Office's examiners. The examples below do not describe the full invention claimed in each and every case. The claims are presented together with the publication number of the application from which they were cited and in view of which applying the above criteria was made. It is understood that, beyond the question of their being within a field of technology according to the requirements of Section 3 of the Israel Patents Law, the following do not provide any opinion as to the patentability of these applications or patents in other countries, and do not provide any opinion as to the question of novelty or inventive step.

Example No. 1: Improvement of computer operation (GB 2391348)

An optimization compiler in a data processing apparatus, which reacts to signals coming from a trace unit in order to dynamically compile application code during runtime.

The claim:

> A data processing apparatus, comprising:
> A processor;
> A compiler for compiling application code to generate instructions for execution by the processor;
> A non-invasive trace unit coupled to the processor for generating, from input signals received from the processor, trace signals indicative of the instructions being executed by the processor;
> The compiler being arranged to control the compilation of the application code dependent on the trace signals.

The invention's contribution is not the trace unit but rather the ability to modify the compilation according to the processor's features during runtime. Although the invention is defined in terms of software aspects, it is not limited to a computer program *per se*. The invention has an additional contribution affecting the computer's operation. The result of applying the method according to the invention is expressed by improving

the operation of the processor, which is responsible for carrying out the compilation, thereby achieving a technical character with a tangible technical effect.

Example 2: Reciprocal relations between system components (GB 2407655)

This invention concerns access to DLL function libraries that are used simultaneously by several programs running on the computer. The invention relates to execution of functions' library indexation so that the computer would continue to work reliably even where changes were made in the function's library.

The claim:

> A method of operating a computing device having an operating system and a dynamic link library containing a plurality of functions accessible by an executable program, each function in the dynamic link library being associated with an ordinal number, the method comprising:
> Providing the dynamic link library as a first part and an extension part each containing one or more of the plurality of functions;
> Causing the executable program to link to functions in the first part directly by means of the associated ordinal numbers; and
> Causing the executable program to link to functions in the extension part indirectly via a further library containing additional functions.

The invention's contribution is an improvement of the computer's performance and reliability. Although the invention is based on software, the invention has a technical character with a tangible technical effect as expressed in providing an additional contribution beyond that of the ordinary operation of the computer. This is expressed in the interface between internal components in the computer and the operating system, so that the invention presents a technical solution to the disadvantage that existed in the manner of operation of the hardware means managed through it (See Symbian Limited v. Comptroller General of Patents, Symbian Ltd.'s Application [2008] EWCA Civ 1066).

Example 3: Methods of doing business (EP 1301912)

This claim concerns an online transaction between transacting parties to be authorized in a verifiable and non-repudiable manner.

The claim:

A method of operating a transaction processing system enabling users to authorize transactions, said system comprising a central transaction processing system (19) having at least a first data communications interface and a second data communications interface, comprising the following steps carried out by said central transaction processing system (19):

Receiving transaction data from an offering party, relating to a specific transaction to be authorized by a user, and receiving a first transaction reference (TRN) relating to and uniquely identifying said specific transaction, via a first data communication path (16), at said first data communications interface;

Generating a second transaction reference (TRR) which is different than the first transaction reference (TRN) and which uniquely identifies the transaction within the central transaction processing system (19);

Sending said second transaction reference (TRR) to the offering party;

After receiving said transaction data, conducting communications over a second data communication path (22), different than said first data communication path, with said user over said second data communications interface;

Using said second path, conducting a secure access procedure in which authentication data is received and said authentication data is verified;

Using said second path, receiving said first transaction reference (TRN) relating to and uniquely identifying said specific transaction from said user, said transaction reference not being previously transmitted to said user in said second communication path (22);

Using said second path, receiving confirmation from said user; and in response to said confirmation, transmitting an authorization signal to authorize said transaction,

Said authorization signal including said second transaction reference (TRR), wherein said second transaction reference (TRR) is not known to said user.

When considering this invention as a whole, it may be determined that the inventive concept is not based on the business process *per se*, but rather on the means of communication used. Thus, a technical character may be identified in the unique communication architecture between the transacting parties.

Example 4: Presentation of information (GB 2418281)

The invention concerns a computerized process of editing a document having a displayable area, in a manner that provides an efficient solution for the layout of information within sub-areas of the displayable area.

The claim:

> A method of creating a document having a displayable area on which information is placed, the method comprising: a. providing a plurality of content-items which contain information that it is possible to display on the displayable area; b. dividing the displayable area into a set of subareas each capable of receiving one or more of the content-items; c. generating at least one set of proposed arrangements in which the content items have been arranged within the set of subareas; d. selecting at least one of the proposed arrangements, according to predetermine criteria, as the layout of the content-items within the subareas of the displayable area to create the document; and e. causing a printing means to print the created document.

The specification discloses that the main contribution of the invention is in mechanization of the manual design process, where the contribution of that mechanization is limited to the obvious improvement obtained from the automation known within the field. Meaning, the steps defined for the computer program are not substantially different from the performance instructions that were available to the graphic designer.

Additionally, when considering the invention as a whole, no contribution can be identified beyond a computer software *per se*. This is due to the manner in which the software is run and the result of running it, which do not provide a tangible technical effect in addition to that of the ordinary operation of the computer or the system in which it is integrated. Therefore, the claimed method is not considered to have a technical character.

Example 5: Presentation of information (US 2007033615)

This invention concerns visual display of information on broadcasting guide display screen according to the characteristics determined by the user.

The claim:

> 1. A method for transferring programs to a secondary storage device using an interactive television program guide implemented on user television equipment, to cause a first display:
> In a display screen of at least one program listing related to at least one program;

Using the interactive television program guide to enable a user to select a program listing from at least one displayed program listing;
Using the interactive television program guide to cause the program related to the selected program listing to be recorded on a digital storage device;
Using the interactive television program guide to cause a second display in the display screen that includes at least one recorded program listing for at least one program recorded on the digital storage device, wherein at least one recorded program listing includes a recorded program listing for the program recorded on the digital storage device;
Using the interactive television program guide to enable the user to select the recorded program listing to transfer the recorded program from the digital storage device to a secondary storage device; and
Using the interactive television program guide to transfer the recorded program from the digital storage device to the secondary storage device.
2. The method of claim 1 further comprising:
Enabling the user to select a sequence of programs recorded on the digital storage device; and
Transferring the sequence of programs to the secondary storage device.

It may appear that this invention is not within a field of technology. However, the specification of the application teaches that the invention presents additional aspects in which a tangible technical character may be found. For example, the display of information is conducted by combining several storage devices and associating unique displays for each of them; as well as recording from one device to another.

Example 6: Medical supervision (EP 1062615B1)

This invention concerns a system that monitors a plurality of remotely located patients simultaneously.

A method of monitoring, diagnosing and treating medical conditions of a plurality of remotely located patients using a central data processing system configured to communicate with and receive data from a plurality of respective patient monitoring systems, wherein each patient monitoring system is capable of receiving and storing patient data, the method comprising the steps of:
Obtaining patient data from a plurality of patient monitoring systems at the central data processing system;
Analyzing the obtained patient data from each respective patient monitoring system at the central data processing system to identify medical conditions of each respective patient;

Displaying identified patient medical conditions for each respective patient in selectable, prioritized order according to medical severity; and

In response to selecting an identified medical condition for a respective patient, displaying treatment options for treating the medical condition.

In this example, it may be noticed that the computerized diagnosis stage is based, *inter alia*, on collecting data on a patient's condition. The data collection stage of is realized as part of the activity of a technical system, which constitutes the "invention's contribution". When considering the invention as a whole, it can be noticed that the unique and complex technical implementation of that process is in fact the subject matter of the said invention (for example, the interaction between the system that conducts prioritization of medical care and the data collection system from a plurality of remotely located patients simultaneously), thus reflecting the technical character of the invention.

Example 7: Mathematical calculations/image processing (WO 2010128511)

This invention concerns estimating the matching between graphs, each representing an image, using a mathematical calculation conducted on different sets of points.

> A method for determining a matching score between a first set of H1 feature points, and a second set of n2 feature points, the method comprising the procedures of: producing a triple-wise affinity tensor, including the affinity score of assignments of triplets of feature points of said first set of feature points and triplets of feature points of said second set of feature points; determining a leading eigenvector of said triple-wise affinity tensor; iteratively producing a binary optimal assignment vector by discretization of said leading eigenvector; and determining a matching score between said first set of feature points and said second set of feature points according to said triple-wise affinity tensor and according to said optimal assignment vector.

The claimed invention is defined in terms of a computational process conducted on numbers and providing a numerical result, without specifying a practical application beyond the abstract calculation. The claimed invention relates only to a mathematical process that does not have a technical character and does not provide a tangible result, and therefore is not within a field of technology.

Example 8: Mathematical calculations/image processing (WO 2006082590)

This invention concerns de-noising of an image composed of pixels.

> A method for adaptive filtering of at least one pixel having an initial value of an image composed of pixels, the method comprising:
> calculating local expected value for the pixel; calculating local signal to noise ratio; calculating local filtration ratio based at least on said local signal to noise ratio; calculating a weighted average of the initial value and local expected value using said local filtration ratio as weight; and assigning the weighted average as a new value for the pixel.

In this example, the claimed invention relates to a mathematical process of signal processing as part of image processing, which is a clear expression of a technical process having a tangible result. Even if this invention may appear as a numerical presentation for each of the signals (and the mentioned pixels), ultimately it is a process that is adapted to the manner of action of a digit processing system, distinct from a purely mathematical process, and thus it is deemed a process having a technical character with a tangible result.
Additionally, it should be noted in respect of this field (and similar fields of signal coding), that it would be far-reaching to determine that the manner in which a process such as that defined above is performed is analogous to a conceptual process in which apparently a person would have conducted conceptual analysis and processing of an image represented by a plurality of pixels. Such a "manual" operation is impractical, and it cannot be stated that the invention is not patentable for "trivial automation of a manual process" considerations.

Example 9: Classification of images (WO 01/37131)

This invention concerns classification of an image by computerized analysis of the various elements that appear in the image.

> A method of classifying an image, comprising the steps of segmenting the image into a plurality of regions and, for each of at least one of the regions: quantifying each of a plurality of visual properties of the region on a numeric scale for the property; comparing each quantified property with a plurality of bands of the numeric scale for the property, each band being associated with a computer-readable character; and arranging in a predetermined order the characters associated with the bands in which the quantified properties fall to form a region character string.

The claimed method is a method of image processing characterized by quantitative analysis that could be performed only on a computer. The calculative process is part of the invention as a whole. Since the claimed method cannot be conducted other than on a computer and since the processing result is tangible (classification of images), the claimed method is deemed as having a technical character with a tangible result.

Example 10: Data analysis and presentation (EP1184798)

The invention concerns construction of a hierarchical graph for patent documents, with reference to various bibliographical details and citing relations between various patent documents. In addition, the invention concerns the display of dependency relations between claims belonging to the same claim set.

> 1. A method of processing and presenting data, comprising the steps of:
>
> (1) Identifying claim dependencies of claims in a user-selected patent;
>
> (2) Constructing a patent claims hyperbolic tree for said user-selected patent using said identified claim dependencies; and
>
> (3) Displaying said patent claims hyperbolic tree.
>
> 4. A method of processing and presenting data, comprising the steps of:
>
> (1) Retrieving patent citation information pertaining to a user-selected patent, wherein said patent citation information is backward patent citation information or forward patent citation information;
>
> (2) Constructing a patent citation hyperbolic tree using said retrieved patent citation information; and
>
> (3) Emphasizing nodes of said patent citation hyperbolic tree according to time-based criteria, wherein said time-based criteria includes at least one of filing date, priority date, length of pendency, effective filing date, invention date, critical date, on-sale date, public disclosure date, and public use date.

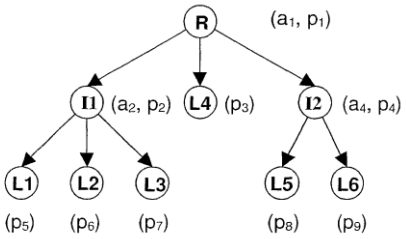
The application presents various aspects related to the manner of use of electronic databases. However, the manner of wording the claim is detached from the mechanization means. Given the nature of the field, it may be considered that a person operating in the patent field would be able to realize the invention through a mental process. Therefore, this invention cannot be deemed within a field of technology.

Example 11: Statistical data analysis (EP 1618498 B1)

This invention proposes construction of a hierarchical graph as part of a computerized process of decoding text.

> A method for managing a tree-like data structure for text-to-phoneme mapping for automatic speech recognition or text-to-speech, each method comprises steps for creating a decision tree comprising a parent node and at least one leaf node, said method comprising also steps for searching data from said nodes, characterized in that the decision tree is created by storing the nodes sequentially in such a manner that nodes follow the parent node in storage order, wherein the nodes refining the context of the searchable data can be reached without a link from their parent node.

To illustrate the components of the invention, following is a drawing from the patent:



The manner of analyzing the data is unique to the manner of computerized analysis performed as part of a voice recognition process or decoding text-to-speech using electronic means. Therefore, this is not a computer program limited to a mere mental act. Even where the electronic means are not explicitly defined in the claim, it is a process implemented in a hardware system adapted to carry it out. Thus, the invention's contribution would be deemed being of a technical character having a tangible result.

Example 12: Machine learning integrated in mechanization means (application PCT/IL2019/050290 - WO2019180698)

This invention concerns a method for detection and selection of a statistical sample from a population of moving objects, which uses a machine learning process.

A method for extracting a statistical sample of population of moving objects, the method comprising: receiving a size of a statistical sample; determining criteria **for machine learning process** to identify objects as relevant objects; projecting *a light source* to a predefined direction for point marking moving objects; facing *an imaging device* to the predefined direction to capture an image by the imaging device; capturing an image to record point marked moving objects; sending said image to a processor; recognizing images that include objects point marked by said light source pointer in a predefined range of angles appropriate for image processing; identifying an object point marked in the captured image as relevant objects according to said determined criteria by said processor; and displaying a list of images of the identified relevant objects having the received size of a statistical sample, wherein the list of relevant objects provides a statistical sample of population of moving objects for statistical measurements.

In this example the method includes steps that are performed by software for machine learning and which are executed on a generic processor; the process integrates steps that are operated by mechanization means (including a light source and imaging means) and the software operates in a manner that is not detached from them. The method executed by the processor is a method of processing an image which is considered to be a technical process (see also Example 8 above). Thus, the invention would be deemed to be of a technical character with a tangible result.

Example 13: Artificial neural network dedicated to designing a nanostructure (WO2018146683 A1)

This invention concerns a process of mechanized calculation and design, which includes an artificial neural network (ANN), intended for designing a nanostructure based on data related to the nanostructure design objectives.

A method of designing a nanostructure, comprising: receiving a synthetic far field optical response and material properties; feeding said synthetic far field optical response and material properties to an artificial neural network having at least three hidden layers; and extracting from said artificial neural network a shape of a nanostructure corresponding to said far field optical response; wherein said artificial neural network comprises at least two parallel sets of layers, wherein said far field optical response and material properties are fed to different sets of layers of said artificial neural network;

wherein said far field optical response comprises a first spectrum describing a response to a horizontally polarized light, and a second spectrum describing a response to a vertically polarized light; wherein said artificial neural network comprises three parallel sets of layers, wherein said first spectrum is fed to a first set of layers, said second spectrum is fed to a second set of layers, and said material properties are fed to third set of layers; wherein all parallel sets of layers have the same number of layers; and wherein each set of said parallel sets of layers comprises three layers.

The invention is based on a computational process (algorithm) that may be conducted on a conventional computer, the product of which is a nanostructure design. However, the claim lists elements related to configuration of the neural network which is specially adapted to the application of the invention (as opposed to incorporating a generic neural network in performing a process). The invention cannot be practically performed by a person, and therefore the invention cannot be deemed mechanization of a manual process or a mental act. This meets the criterion of a technical character with a tangible result.

Example 14: Detection of a medical event by machine learning

The invention concerns detection of a medical event or condition by a model established through machine learning of big data repositories.

A method for detection of medical event or condition, comprising the steps of:

a. constructing a big data repository by:

(i) extracting by a processor a first group of samples of a plurality of biomarkers of a plurality of human subjects from video streams;

(ii) Obtaining from an input device health history records of the of said plurality of human subjects;

b. training a machine learning model according to the big data repository; and

c. determining the probability of a person having a predetermined medical event or condition, using the trained machine learning model with a second group of samples of biomarkers extracted from a video steam capturing said person;

wherein, at least one biomarker of the plurality of biomarkers is associated with at least one sample in said second group;

The first two stages (a, b) of the method are intended for detection of links between biomarkers and a medical condition, and performing the activity of a team of researchers within the medical field combined with

computerized detection of statistical links between various data in medical databases. The third stage (c) relates to direct application of the aforementioned links for detection of the medical condition according to the biomarkers. The method is implemented by a model of machine learning based on big data repositories, including extracting information from a video film in a computerized manner, which cannot be performed manually. Therefore, this method is considered to have a technical character with a tangible result.

Example 15: Determining a surgical plan by artificial intelligence

The invention concerns a method for making a decision on a surgical plan based on expected risk assessment.

> A method for determining a surgical plan for a subject, comprising:
> (i) generating a surgical plan that is to be performed on an operative region;
> (ii) obtaining clinically relevant quantitative data of the subject;
> (iii) obtaining pre-operative three-dimensional images of a region of interest of the subject;
> (iv) accessing a database including data for a plurality of patients, with data for each patient comprising data on any pathology types developed, and additional data on at least one of the associated (a) pre-operative images, (b) post-operative images, (c) clinically relevant quantitative data, and (d) surgical plan;
> (v) obtaining from the database one or more sets of data for patients with similar characteristics as those of at least one of options (a) (b) (c) and (d) of step (vi);
> (vi) determining risks of one or more pathology types for the subject based on correlations of the patients in at least some of said sets, to developed pathology types;
> (vii) using artificial intelligence to combine the previously determined risks, to calculate an overall risk for one or more pathology types for the subject;
> (viii) if said one or more overall risks are above a predetermined risk limit value, selecting an alternative surgical plan and returning to step (v); and
> (ix) if said overall risks are below the predetermined risk limit value, determining that said surgical plan is acceptable.

The invention is based on mechanizing a process that could be manually performed by a physician, which includes reviewing up-to-date relevant data on the patient, and the medical history of various previous patients in a medical database, where the contribution of such mechanization does not go beyond the improvement expected from the automation known in the art.

Notwithstanding the mentioning of the use of AI in this claim, the steps defined for the computerized plan are not necessarily substantially different from those as would have been performed by the physician, and characterization of the artificial intelligence is not specially adapted to the intended use, which could have rendered the claimed method distinct from the physician's actions. Additionally, even when considering the invention as a whole, no contribution can be noticed beyond the computer software *per se*, as the manner of running the software does not provide a tangible result beyond the ordinary operation of the computer or the system in which it is integrated. Therefore, the invention is not considered to have a technical character with a tangible result.

Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
Official Ed. 8 (28.2.2023)	Transl. Ed. 8.1 (10.07.2023)	Page: 1 of: 18	Guideline No.: **EG- 23.1/3**

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 3 - Section 7 of the Law – Excluded Subject Matter

References and documents relating to excluded subject matter: Sections 7, 13 and 17 of the Patents Law, **Commissioner's Circular 034/2017-Patents** (2020), LCA 5768/94 **A.S.I.R. Import Manufacture and Distribution v. Forum Accessories and Consumer Products Ltd.**, 52 (4) 289 (hereinafter: the "A.S.I.R Ruling"), CA 244/72 **Plantex Ltd. v. The Wellcome Foundation Ltd.**, IsrSC 27(2) 29 (hereinafter: the "Plantex Ruling"), the Commissioner's decision on the objection to Patent Application 153109 **Teva Pharmaceutical Industries Ltd. and Unipharm Ltd. v. Merck & Co., Inc.** (hereinafter: the "Decision on 153109").

1. Introduction

1.1. This appendix specifies examination guidelines for examining the compliance of claims of patent applications with the requirements of Section 7 of the Law, according to the wording of the Law, courts' rulings, decisions made at the Patents Office and the customary practice at the Office that are relevant to the provisions of this section.

1.2. Section 7 of the Law sets out restrictions on granting a patent as follows:

> "Notwithstanding the provisions of Section 2, no patent shall be granted for –
>
> (1) A method of therapeutic treatment of the human body;
>
> (2) New varieties of plants or animals, except microbiological organisms not derived from nature."

1.3. These provisions shall apply to all applications under examination, including applications examined according to the provisions of Sections 17(a) and 17(c) of the Law.

2. Background

The legislator found it appropriate to set two restrictions on granting a patent, as noted in the explanatory notes to the Patents Bill:

> "The existing law provides that a patent is not to be granted for an invention the use of which would be, according to the Commissioner's opinion, contrary to law or morality or public order (Section 8(5) of the Ordinance). It is proposed to repeal this provision, as it was proven that the moral examinations vary over time. On the other hand, the proposed law opposes

> granting patents for an invention that is a method of therapeutic treatment of the human body or new varieties of plants or animals – (Section 7)."[1]

Regarding this section the court noted in the A.S.I.R Ruling:

> "It appears that the provision of Section 7(1) of the Patents Law is intended to express a powerful policy: that the Law is not willing to grant a monopoly to anyone in respect of a method of therapeutic treatment of the human body (although the method may remain confidential or commercially used)."

The Court further added in the Plantex Ruling:

> "It seems to me that the approach used as grounds for patentability at the EPO, according to the aforementioned statements, balances the two conflicting interests well, them being the need - on the one hand - to encourage research in the pharmaceutical industry field, and on the other hand - the need for not excessively restricting the activities of those dealing in healing people."

3. Methods of Therapeutic Treatment of the Human Body

3.1. Methods for healing, curing, alleviating, relieving or preventing the aggravation of: symptoms, dysfunction, impairment or disease in the human body (whether physical or mental), as well as methods for preventing a disease would be deemed methods of therapeutic treatment of the human body.

3.2. Claims that, in themselves, concerning cosmetic methods (see section 4.3 below), diagnostic methods or detection methods do not contravene the provisions of Section 7(1) of the Law, since they are not considered claims for a method of therapeutic treatment of the human body (see Appendix 3.1 below, Example 1).

3.3. Notwithstanding the provisions of section 3.2, **surgical** cosmetic methods for the purpose of repairing an injury due to a pathological condition or trauma, would be considered as a method of therapeutic treatment of the human body (for example, a method for breast reconstruction after mastectomy as a result of disease).

3.4. Claims for methods of therapeutic treatment of animals do not contravene the provisions of Section 7(1) of the Law. However, where use is made of terms such as: "animal" or "subject", the generally accepted interpretation is that these terms include humans as well, and therefore it is required to limit

[1] Explanatory notes of the Patents Bill, 1965, Bill 98, Section 2(b).

the method to animals only using appropriate terms such as: "non-human animal" or "non-human mammal". It is required to do so also where the description defines an "animal" or "subject" as "non-human animal" or "non-human mammal", since in such a case it is inconsistent with the generally accepted terminology in the art (in this regard see Appendix 11 – The Claims: Section 4.3.2.2 together with 4.3.2).

3.5. Claims that define a product (composition, device, etc.) that is used in a therapeutic treatment method and claims concerning the production of a product that serves in a therapeutic treatment method do not contravene the provisions of Section 7(1) of the Law (see Appendix 3.1 below, Example 2).

3.6. Subject to the provisions of this appendix above and hereinafter, claims for methods relating to use or operation of a medical device, intended for therapeutic treatment **of the human body**, are not patentable. However, claims for therapeutic methods carried **out outside the human body** do not contravene the provisions of Section 7(1) of the Law.

4. Claims for Hybrid Methods

4.1. A claim for a multi-step process including one or more therapeutic steps shall be examined based on the intended purpose of the process and its essential features. So long as the process is not intended for therapeutic treatment (but rather diagnostic treatment), said one or more therapeutic steps would not prejudice the patentability of the claimed process (see Appendix 3.2, Examples 1-2).

4.2. Notwithstanding the provisions of Section 3.6, a claim for a method where all its essential steps are performed outside the human body does not contravene the provisions of Section 7(1) of the Law, even where it includes trivial steps of interaction with the human body, so long as it is not worded as a claim for a method of therapeutic treatment of the human body or a claim for delivering a therapeutic substance or device into the human body (for example, a method of delivery or a method for administering).

4.3. Method claims that are both therapeutic and non-therapeutic at the same time:

4.3.1. Where a claim for a method **could** be interpreted as a method of therapeutic treatment of the human body, it should be examined in light of the specification, and where the specification does not include any reference to a method of therapeutic treatment of the human body, the claim would not contravene the provisions of Section 7(1) of the Law.

4.3.2. Where the specification makes it clear that the method could also be used for therapeutic treatment it is required to include a disclaimer in the claim that limits it to patentable methods

only. Examples of disclaimers: ***in-vitro***, ***ex-vivo***, **cosmetic** method, treatment in **non-human** animal, **non-therapeutic** method.

Insertion of the disclaimer would usually be requested at the top of the claim (per the examiner's discretion). It should be emphasized that a claim including the disclaimer shall be reasonably supported by the disclosure in the specification according to the provisions of Section 13(a) of the Law (see Appendix 3.2, Examples 3-7).

4.3.3. In cases of claims for a method in which it is not possible to distinguish between the therapeutic effect and the cosmetic effect, since the cosmetic method would necessarily have therapeutic effects, adding a disclaimer to the claim would not make it patentable (see Appendix 3.2 below, Example 8).

4.3.4. Where it is possible to distinguish in a method claim between therapeutic use and non-therapeutic use (for example: dependent on the medical condition of the patient), the existence of a therapeutic effect would not cause the claim to be excluded from patentability. In such cases, as mentioned in section 4.3.2 above, the applicant shall be required to include a disclaimer limiting the method to non-therapeutic uses. For example, a method for suppressing appetite would be deemed therapeutic if performed on a person with pathological obesity, while it would not be considered as therapeutic where the treated person does not suffer from pathological obesity (see Appendix 3.2, Example 9).

5. Use Claims

5.1 Commissioner's Circular 034/2017-Patents (Section 11) prescribes that claims of the type "Product X for use in treatment of Y" or "Compound X for use as a medicament", are patentable.

Accordingly, claims worded: "A device for use in a method for treating…" would be deemed patentable too (see Appendix 3.3 below, Example 1).

5.2 Claims for the use of a product (substance or device) in a therapeutic treatment method such as: "use of X in the treatment of disease Y" are not allowable according to the provisions of Section 7(1) of the Law since they are considered to be a method of therapeutic treatment.

5.3 Commissioner's Circular 034/2017-Patents (Section 10) prescribes that claims of the type:

"Use of X in the manufacture / preparation of Y"

are not allowable where the claims do not define process steps that are new and involving an inventive step. Accordingly, claims worded: "Use of substance X in the manufacture of a medicament to treat Y, the treatment comprising…" are not allowable.

6. Emphases and Special Cases

6.1 A claim for dosage regimen, worded as a claim for a product, constitutes "instructions to the manufacturer" (as distinct from instructions to the attending physician). This type of claim is patentable under Section 7(1) of the Law. The dosage regimen should be defined as a technical feature of the product and addressed accordingly. Therefore, the patentability of a claim set, relating to a dosage regimen as the main technical component, should be examined according to the other sections of the Law.[2]

6.2 Claims for cosmetic treatment methods of skin or hair are patentable. For example, methods for strengthening hair or nails, methods for preventing baldness, etc. A claim for a cosmetic method necessarily having a therapeutic effect, which cannot be distinct from the cosmetic effect, would not be deemed patentable. For example, a claim for a method of acne treatment is not patentable, even if the method has a cosmetic effect.

6.3 Oral treatments – methods for purely cosmetic purposes such as teeth whitening would be considered patentable. Methods for therapeutic purposes such as removal or prevention of plaque, methods of implant implantation, etc., are not patentable.

6.4 Pain management – a process for treating a person's pain would be considered as a therapeutic treatment method and therefore is not patentable.

6.5 Addiction treatment – addiction is considered a disease and is treated by medical professionals, therefore all methods for treating addictions, including smoking cessation, are not patentable.

6.6 Obesity treatment – claims for weight loss processes for cosmetic purposes only including appetite suppression would be considered patentable only where the claim is worded as a cosmetic treatment method.

6.7 Contraception methods are not considered therapeutic treatment, since pregnancy is not considered a disease or a physical disability, and therefore is deemed patentable (see Appendix 3.4 below, Example 2).

6.8 Methods intended for abortion, termination of pregnancy or labor induction are considered methods of therapeutic treatment and therefore are not patentable, since distinction cannot be made between

[2] See the Decision on 153109 – "The fact that a physician would instruct patients to take a medication according to a particular regimen, does not make the invention a therapeutic treatment method. The wording of the claims, as worded in the patent application, ensures that there would not be any impairment of the physicians' discretion, but rather a restriction on the manufacturers only. I believe that the existence of the range does not deprive the invention of patentability under Section 7(1). Thus, the question whether a monopoly may be granted to this application should continue to be discussed according to the criteria of novelty and inventive step").

such methods that are performed on a medical basis and those that are performed on a non-medical basis.

6.9 Claims for methods of infertility treatment on the human body are not patentable. However, claims for methods that are performed outside the human body (see Section 3.6 above), such as *in vitro* fertilization method, would be deemed patentable.

6.10 Claims for methods that affect the function of devices within the body would be deemed therapeutic treatment methods and therefore are not patentable, provided that the function change has a therapeutic effect on the human body.

6.11 Claims for methods of dialysis would be deemed patentable subject to the provisions of Sections 3.6 and 4.2 above.

6.12 Therapeutic methods involving a computer system (computer-implemented treatments) or performed by means of a computer system - a computer-implemented invention involving use of a computer and/or computerized network and/or other computerized device where one or more of the invention's features is performed by computer software. For example, data collection and medical analysis, planning therapeutic treatment, diagnosis, forming prescriptions, programming and operation of medical devices and means, medication injection and surgical robotics, etc. (see Appendix 3.4 below, Examples 2-8 for computer-implemented methods).

The computer's action may be a direct therapeutic action or an action that is preliminary to and/or associated with the therapeutic treatment. To determine whether the claimed method is a method of therapeutic treatment it is required to act according to the aforesaid in the examination guidelines above.

A claim for a method of therapeutic treatment may be modified to a patentable claim by claiming a device for use in a method of therapeutic treatment, subject to the provisions of Commissioner's Circular 034/2017-Patents, Section 11 (see Section 5.1 above).

The method's compliance with the provisions of Section 7(1) of the Law according to the provisions of this appendix, does not exempt it from the requirement of complying with the other sections of the Law and in particular Section 3 of the Law regarding "field of technology".

7. Section 7(2) of the Law

7.1 Section 7(2) of the Law prescribes that a patent shall not be granted to new varieties of plants or animals, except for microbiological organisms not derived from nature. Section 7(2) excludes new varieties of plants and new varieties of animals from patentability, except for new microbiological

varieties of plants of animals that were **not derived from nature**. The expression "not derived from nature" means produced by humans or a man-made environment.

7.2 Section 7(2) does not set out rules in respect of living creatures that are neither animals nor plants, and therefore does not apply to inventions relating to bacteria, fungi, or viruses, etc.

7.3 Claims for new microbiological plant and animal varieties that are not derived from nature do not contravene the provisions of Section 7(2) of the Law.

7.4 Claims for a strain or variety[3] of animals or plants per se shall not be approved.

7.5 Claims that define an invention that is a product (for example: plant, seed, transgenic animal) are not excluded from patentability under Section 7(2) of the Law, even where the claim mentions the term "variety" so long as the claim does not relate to a variety *per se*.

7.6 Claims for processes relating to plants or animals are not excluded from patentability under Section 7(2) of the Law.

Examples of claims that cannot be accepted according to Section 7(2) of the Law are listed in Appendix 3.5 below.

[3]A variety/strain is a term that describes one rank below species and does not have a taxonomic classification. In animal science, according to the ICZN (International Code of Zoological Nomenclature), the term strain no longer exists since 1961 (link 1, link 2). However, the term strain is used in laboratories to differentiate between different groups of experimental animals - mice and rats - as each is different from the other by a unique genetic mutation (Rat strain index, International Mouse Strain Resource (IMSR)). The term strain also has no official status in plant science as part of a taxonomic level. However, in the plant breeding industry a stain is a legal term that enables protection of the development of new varieties of cultivated plants in countries that are subject to the International Union for the Protection of New Varieties of Plants (UPOV) (in Israel, Plant Strains Breeders' Rights Law, 5733-1973).

Appendix 3.1

Example 1

A claim for an aesthetic (cosmetic) surgical method, the claim would be deemed a claim that does not contravene the provisions of Section 7(1) of the Law.

> A method of affecting the projection of a breast, the method comprising:
> (i) Inserting into the breast an internal skeleton comprising
> A base having a first diameter, said base is configured to rest against a subject's chest wall when implanted;
> A dome having a second diameter, said dome is configured to be positioned within breast parenchyma underneath nipple-areola complex when implanted; and an elongated projecting structure extending between said base and said dome; and
> (ii) Adjusting breast projection.

Example No. 2

In a claim for a method of preparation of antibodies and their isolation for preparing a medication, the method does not fall within the scope of "therapeutic treatment", and therefore the claim does not contravene the provisions of Section 7(1) of the Law.

> A method of preparing an immune globulin for use in prevention or treatment of staphylococcal infection comprising the steps of immunizing a recipient with the vaccine of claim 13 and isolating immune globulin from the recipient.

Appendix 3.2

Example 1

A claim for a method for measuring the efficacy of cancer treatment, comprising the administration of an active compound, inherently has also a medical-therapeutic effect and therefore the claim is not patentable.

A method of measuring the efficacy of cancer treatment, comprising administering a compound according to claim 1 to a subject in need, monitoring blood cancer markers and comparing the marker levels after said administration to the marker levels prior to said administration.

Example 2

A claim for a method of monitoring cancer therapy in a subject that includes, *inter alia*, administration of a therapeutic substance, the method is intended for diagnosis and therefore the claim does not contravene the provisions of Section 7(1) of the Law.

A method of monitoring cancer therapy in a subject comprising the steps of (i) administering to a subject in need thereof at least one compound according to claims 1-19 in a diagnostic imaging amount in combination with therapeutically active compound of choice, and (ii) performing diagnostic imaging using PET by detecting a signal from said at least one compound to follow the course of cancer therapy.

Example 3

A claim for a method intended for capture of a corpus disposed in a conduit using a stranded tube. The specification indicates that the method is intended to capture an object in a blood vessel for cleansing the blood and preventing blockage in the blood vessel (therapeutic treatment), and therefore the method would be deemed non-patentable.

A method for anchoring of and into at least one corpus (COR) disposed in a conduit (BV), the method operating a stranded tube (ST) having a plurality of wound coiled threads,
The method being characterized by comprising the steps of:
Engaging the stranded tube with the at least one corpus,
Unwinding at least one wound thread out of the plurality of wound threads, and anchoring the at least one unwound thread into the at least one corpus.

Example 4

A claim for a method for perfusing a beating heart. The specification indicates that there are therapeutic uses for this method, and therefore, since there is no disclaimer limiting the method *ex-vivo*, the method would be deemed a method of therapeutic treatment that is not patentable.

> A method for perfusing a beating heart at a physiological temperature, comprising providing a composition of claim 1 and maintaining the composition at a physiological temperature during perfusion.

Example 5

A claim for a method of assembling a modular valve device, (repairing a heart valve). The specification indicates that the method is essentially intended to be performed inside the body. The claim would be deemed patentable where a disclaimer, such as "*ex-vivo*", is included provided that the possibility of performing the method also outside the body reasonably arises out of the disclosure in the specification.

> A method of assembling a modular valve device comprising: providing a delivery device containing a valve module and a self-assembly member, said valve module in an unassembled form and said self-assembly member in a delivery configuration and attached to said valve module; deploying said unassembled valve module from said delivery device; triggering said self-assembly member to revert to a preset configuration; and assembling said valve module using said self-assembly member.

Example 6

A claim for a method of continuously delivering oxygen to the tissue at a certain rate, could be interpreted also as a method of therapeutic treatment, therefore a disclaimer that the method is carried out outside the body treatment (for example, *in-vitro*) should be included. The disclaimer should be worded according to the provisions of Sections 4.3.1 and 4.3.2 (whether or not the treatment outside the body reasonably is supported by the specification). Where the specification does not provide reasonable support for performing the method inside the human body (but rather only for laboratory use), there is no need to add a disclaimer.

> A method of continuously delivering oxygen to a tissue at a rate of 0.2 cc/hour - 20.0 cc/hour for up to 24 hours by contacting the tissue with the perfluorocarbon gel composition of any one of claims 1-24.

Example 7

A claim for a method of increasing the firmness of the skin or to reduce the appearance of wrinkles or scars in a subject by topically administering a particular composition. Where the description indicates that the method also has therapeutic effects, to comply with the provisions of Section 7(1) of the Law, a disclaimer should be added that such method is a cosmetic treatment method.

> A method of increasing the firmness of the skin or reducing the appearance of fine lines, wrinkles or scars in a subject comprising topically administering to the skin of the subject the perfluorocarbon gel composition of any one of claims 1-24 effective to increase the firmness of the subject's skin or reduce the appearance of fine lines, wrinkles or scars on the subject's skin.

Example 8

A claim for a method of preventing or treating black-line stains on teeth. The claimed method may appear as a method for cosmetic treatment. However, this claim defines using a pharmaceutical substance (antibiotic), so that the claimed method inherently has also a medical-therapeutic effect, therefore the claim is not patentable.

> A method of treating, preventing or treating and preventing black-line stains comprising the step of contacting of a topical oral antibiotic formulation with teeth.

Example 9

A claim for a method of reducing eating and dieting that includes inserting a unique device into the nasal cavity. It is required to include a disclaimer restricting the claim only to uses that are patentable (for example, non-therapeutic method).

> A method for dieting, diet support, and diet complementing method for flattening an eating experience and/or reducing impulse eating, to reduce eating, comprising the steps of:
> Providing an odor preventing nasal insert body for insertion into a nasal cavity, said nasal insert body comprising an inner surface, defining an air passageway, and an outer surface having a first portion and a second portion, said" outer surface adapted to form a seal between said nasal insert body and the nasal cavity;
> Inserting said nasal insert body into the nasal cavity;
> Creating a sealing between said nasal insert and the nasal cavity in the nasal cavity;
> Breathing through the nose, wherein the nasal insert body of said nasal insert is creating a bypass of the olfactory region or directing the air to bypass the olfactory region; and

Preventing or reducing environmental odor from the olfactory region, thereby reducing the sensation of food.

Appendix 3.3

Example 1

A claim for a product characterized, *inter alia*, by the method of its use, does not contravene the provisions of Section 7(1) of the Law.

An implantable material comprising cells and a biocompatible matrix for use in a method of treating an arteriovenous fistula, arteriovenous graft or peripheral bypass graft in a patient comprising the step of locating the implantable material on an exterior surface of the fistula or graft, whereat the implantable material is effective to promote long-term patency of the fistula or graft.

Example 2

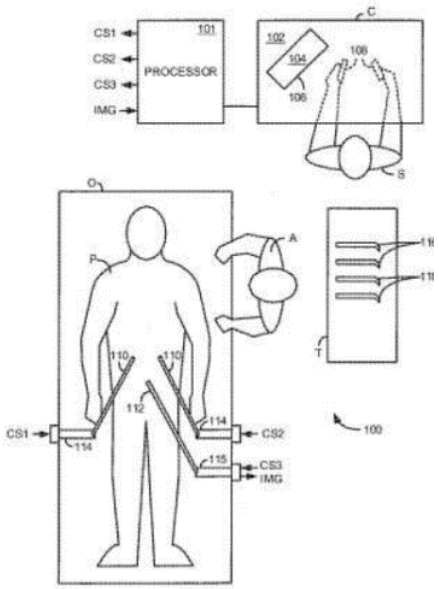
A claim for a method intended for supply of a composition for the prevention of pregnancy as well as treatment or prevention of sexually transmitted diseases is not patentable.

A method of concomitantly providing contraception and treating or preventing a sexually transmitted disease which comprises the steps of (i) positioning the drug delivery system of claims 30-33 within the female vaginal tract and (ii) retaining the system within the vaginal tract for at least about 21 days.

Appendix 3.4

Example 1 (from EP2687184 A1)

A computer implemented tool tracking method comprising: determining a computer model of a tool; receiving a captured image including a view of the tool; determining an estimated position and orientation of the tool from the captured image, and positioning and orienting the computer model at that estimated position and orientation in reference to the captured image; and modifying the estimated position and orientation of the computer model with respect to an image of the tool in the captured image until the computer model approximately overlays the image so as to correct the estimated position and orientation of the tool for the captured image.



The claimed method relates to tracking and navigating a surgical tool during operation on the patient's body. The method enables creating a computer model of the tool, assessing the position of the tool according to an image taken using an endoscope and the positioning of the model according to the assessment, until the computer model overlays the image and the actual tool. The role of the computer in the method is the creation of a computer model of the surgical tool and adjusting its location relative to a photographed image. The method is essentially based on the navigation of the surgical tool during surgery. The method constitutes an integral part of the surgical steps and thus appears to be a method of therapeutic treatment (see section 3.6 above). However, this method is not performed directly on the patient's body but rather outside the human body and it accompanies the therapeutic method. Therefore, the method is not considered a therapeutic method on the human body, and the claim does not contravene the provisions of Section 7(1) of the Law (see section 4.2 above).

Example 2 (from WO03059422 A1)

A method to provide medication to a patient where the medication delivery is triggered by one or more physiological conditions of the patient, comprising the steps of: providing a medication delivery device; providing a local controller having a control algorithm; providing a sensor; providing a remote controller, the remote controller having an input device; and, utilizing the sensor to obtain a signal concerning the physiological condition of the patient, transferring the signal to the controller, entering information contained in the signal in the control algorithm, developing a result based on resulting data from the control algorithm, developing feedback control based on the result from the control algorithm, and manipulating the medication delivery device as appropriate based on the feedback control to deliver the medication to the patient.

The claimed method relates to administering a medication to a patient by remote control of an infusion pump that is implanted in the patient. The role of the computer in the method is to operate the medical device for administrating the medication to the patient in a certain manner according to an algorithm, depending on received feedback. Most of the method steps are performed outside the human body (programming and operation outside the human body of a pump that is implanted in a person). However, an essential part of the method indicates a therapeutic treatment (injection of a therapeutic substance to the patient body). Therefore, since the external operation has an effect on the device implanted in the body and, hence, a direct effect on the patient's medical condition, the method would be interpreted as a method of therapeutic treatment on the human body and is not patentable under Section 7(1) of the Law (See section 4.2 above).

Example 3 (from EP1721282 A2)

A method for remote management of a medication therapy via utilizing a medication containment unit whereby the method comprises the following steps: alerting a patient when it is time to carry out a step of a first therapeutic plan; sensing when the medication containment unit is engaged and recording the same as a medication event; receiving patient physiological data; processing said patient physiological data and said medication event data; and generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data.

The claimed method relates to managing the administration of a medication and compliance with a medication regimen, collecting data, and performing an analysis. The role of the computer in the

method is to provide an alert, collect data and establish a new regimen plan adapted to the patient. The claimed method is not considered a method of therapeutic treatment since it relates to a preliminary action accompanying the therapeutic treatment (administration of a medication).

Example 4 (from US7198630 B2)

A method of controlling a surgical instrument connected to a surgical robot comprising the steps of: locating a controller robot between a handle and a surgical instrument; sensing incident force components present on the handle generated by a surgeon's hand; modulating the incident force components in the controller robot; and outputting through the controller robot a modulated force on the surgical instrument.

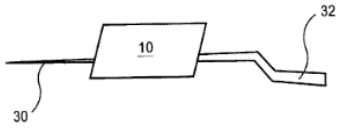


FIG. 4

The claimed method relates to controlling a surgical instrument (for example a knife) that is connected to a robot. The location of the robot is between the surgical instrument and the handle of the instrument. The method is intended for regulating the force exerted by the controller on the surgical instrument based on sensing the force exerted by the user holding the instrument's handle. The role of the computer in the method is regulating the force exerted on the surgical tool. Although the surgical action is performed in a patient, the method is essentially based on controlling the surgical instrument rather than performing the actual surgery, and therefore it is performed outside the human body and would be deemed as one that does not contravene the provisions of Section 7(1) of the Law.

Example 5 (from US8409172 B2)

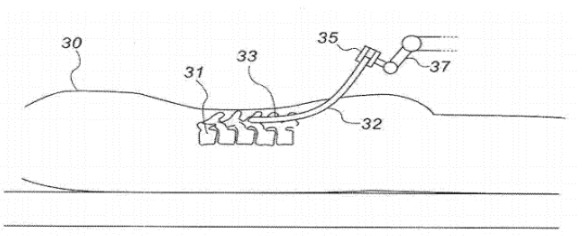
A method for performing a medical procedure on an abnormality of a prostate of a patient using a robotically steerable catheter having a distal catheter portion and a surgical tool carried by the distal catheter portion, comprising: inserting a steerable sheath into the urethra using a robotically controlled system, wherein the distal catheter portion is advanced within the steerable sheath along the urethra until the surgical tool is adjacent to the prostate; manipulating the catheter using the robotically controlled system; imaging an area of the prostate using an imaging device to obtain an image of the area of the prostate; locating an anatomical landmark using the image of the area of the prostate, and storing a position and orientation of the robotically steerable catheter to arrive at the anatomical landmark; creating a restricted zone, based on the image of the area of the prostate, into which the

surgical tool is restricted from entering by a navigation logic of the robotically controlled system; operating the surgical tool using the robotically controlled system to treat an abnormality of the prostate; and wherein the operation of the surgical tool is at least partially automatically controlled based on the image obtained by the imaging device.

The claimed method relates to inserting and operating a catheter inside the prostate by a controlled robotic system for treating a prostate abnormality according to the tissue imaging. The role of the computer in the method is to insert the surgical tool into the patient's body and operate it inside the body for treating the prostate. Operation of the robot activates the catheter inside the prostate for treating the tissue. The essential steps of the claimed method are performed inside the patient's body, and therefore it is considered a method of therapeutic treatment which is not patentable under Section 7(1) of the Law.

Example 6 (from WO2017221257 A1)

A method of planning an intervertebral rod insertion procedure, comprising: using a preoperative surgical plan to define positions for inserting screws into the vertebrae of a subject, calculating the shape of a rod that will connect the heads of said screws; using a path planning algorithm to determine whether the manipulating of a proximal end of said rod having said calculated shape, enables the distal end of said rod to pass sequentially through said heads of said screws; if said distal end of said rod can be passed sequentially through said heads of said screws, providing instructions for the insertion of said screws in said defined positions, providing information for forming said rod having said shape, and providing instructions for the insertion of said rod; if said distal end of said rod cannot be passed through said heads of said screws, adjusting in said plan, at least one of the position and orientation of at least one of said screws in order to moderate bends in a path between said heads of said screws, and recalculating the shape of said rod to match said adjusted positions and orientations of said screws; using said path planning algorithm on said rod having moderated bends to determine whether said rod can be passed through said heads of said screws; and repeating said steps of adjusting said screw positions, and adjusting said rod shape, until said rod acquires a planned shape that enables it to be inserted between said heads of said screws by longitudinal manipulation of said rod from its proximal end.



The claimed method relates to planning the insertion of rod between the spinal vertebrae using a pre-determined surgical plan for defining positions for inserting screws into the patient's vertebrae, planning the insertion path by using an algorithm, and performing the adjustment of the screws' positions and the rod's shape up to suitable insertion through the heads of the screws. The role of the computer in the method is to establish an algorithm for planning the insertion path, providing instructions for the insertion of the rod with adjustments regarding the shape of the rod and positions of the screws. Although the planning step is part of the therapeutic treatment and affects it, the defined method is performed prior to the therapeutic treatment (before the insertion of the rod), and most of the steps of the claimed method are performed outside the human body. Therefore, the claim does not contravene the provisions of Section 7(1) of the Law.

Example 7 (from US2018158538 A1)

A method for facilitating therapy provision to an individual, the method comprising: accessing a log of use corresponding to a mobile application for a mobile computing device associated with the individual; matching the individual to a matched therapeutic entity from a first therapeutic entity and a second therapeutic entity based on the log of use, wherein the first therapeutic entity is configured to be matched based on the log of use indicating a first feature, and wherein the second therapeutic entity is configured to be matched based on the log of use indicating a second feature; determining a health state for the individual based on a health state model and the log of use; transmitting the health state to the matched therapeutic entity; and enabling a communication between the individual and therapeutic entity, wherein the communication facilitates provision of a therapeutic intervention for the individual based on the health state.

The claimed method is a method for providing a patient with treatment by coordinating and matching a patient to the therapeutic treatment that is appropriate for him and the location of treatment, based on the log of use of a mobile application indicating the patient's mental and medical condition. The role of the computer in the method is to determine the medical condition of the patient, coordinate a place of treatment, after processing the data obtained from the mobile application, and deliver the information to the relevant place of treatment. Since the claimed method is a method that accompanies therapeutic treatment, implemented outside the patient's body, and does not constitute the treatment itself, it is not considered a method of therapeutic treatment and therefore does not contravene the provisions of Section 7(1) of the Law.

Appendix 3.5

- An Essentially Derived Variety of NUN 4006 AR having one, two or three physiological and/or morphological characteristics which are different from those of NUN 4006 AR and which otherwise has all the physiological and morphological characteristics of NUN 4006 AR, wherein a representative sample of seed of variety NUN 4006 AR has been deposited under Accession Number PTA 10654.
- A genetically stabilized non-human animal inbred strain made by any one of methods of claims 1, 29 or 43.
- The genetically stabilized non-human animal inbred strain of claim 57 wherein the non-human animal is a rodent.

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 4 – Section 8 of the Law – Unity of Invention

References and documents relating to Unity of Invention: Sections 4, 8, 10, 13 and 15 of the Law, 1967; Regulations 41-43, 51 of the Patent Regulations; PCT Rule 13; Chapter 10 of the PCT International Search and Preliminary Examination Guidelines; Commissioner's Circular 034/2017-Patents (2020).

1. Definitions

1.1. Prior art – as defined in Section 4 of the Law (see the provisions of Appendix 6 of the Examination Guidelines).

1.2. Technical problem – the difficulty existing in the field that the invention would solve. The technical problem can be defined on the basis of the difference between the claimed invention and the prior art known to the examiner at that stage of the examination.

1.3. Technical effect – the result obtained by performing the invention.

1.4. Corresponding technical features – different technical features achieving the same technical effect and providing a solution to the same technical problem. An example for two corresponding technical features: a metallic spring and a rubber block, following compression both of which achieve the same technical effect by demonstrating high resilience to compression, thus providing a solution to the problem of withstanding multiple compressions.

1.5. Common technical features – identical or corresponding technical features contained within a number of claims or within several alternatives of a single claim in a given application.

1.6. Special technical features – technical features defining the claimed invention's contribution over the prior art (justifying novelty and inventive step).

1.7. Corresponding special technical features – different special technical features having the same technical effect and solving the same technical problem.

1.8. Single general inventive concept – an inventive concept (being novel and involving an inventive step) which is common to a number of inventions including identical or corresponding special technical features.

1.9. Applications lacking unity of invention – applications claiming several inventions that do not share a single general inventive concept.

1.10. A priori lack of unity of invention (before factoring in the prior art) – lack of unity of invention occurring when the claim set of a given application contains several inventions lacking a common technical feature or when the common technical feature(s) comprises common general knowledge to a person skilled in the art.

1.11. A posteriori lack of unity of invention (factoring in prior art) – lack of unity of invention occurring when the claim set of a given application contains several inventions, wherein the common technical feature(s) does/do not constitute special technical feature(s) (meaning, they are not novel and/or do not involve an inventive step in view of the prior art).

2. Introduction

2.1. This appendix deals with guidelines for the assessment of unity of invention, based on the provisions of the relevant Sections of the Law, the Regulations, and the Commissioner's Circulars.

2.2. Section 8 of the Law stipulates:

> "A patent shall be granted solely for a single invention".

2.3. All applications shall be examined according to the provisions of PCT Rule 13.

2.4. PCT Rule 13.1 stipulates:

> "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")."

2.5. PCT Rule 13.2 of the PCT Treaty regulations stipulates:

> "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

2.6. Lack of unity of invention can exist between independent claims, between dependent claims, between independent claims and dependent claims, or within the same independent or dependent

claim. The same criteria utilized to assess unity of invention (see Section 3 below) shall also be applied in such cases.

2.7. These provisions apply to applications whose examinations are undertaken according to the provisions of Sections 17(a)(1) and 17(a)(2) of the Law.

3. Methodology

3.1. The procedure for the assessment of unity of invention includes the following:

3.1.1. identification of the technical features in the application claims;

3.1.2. identification of whether one invention is claimed or a group of inventions, in the latter case of which the common (identical or corresponding) technical features shall be identified as far as possible;

3.1.3. determination of lack of unity *a priori* – where no common technical feature can be determined, or where the common technical feature(s) comprises common general knowledge; and

3.1.4. determination of lack of unity *a posteriori* – determination, in view of search results, whether the common technical feature/s is/are novel and involve an inventive step; wherein unity of invention exists in the claim set where a single general inventive concept, meaning all the claims share at least one common (identical or corresponding) special technical feature.

3.2. Implementation

3.2.1. An objection on grounds of lack of unity of invention shall be raised according to the criteria of Section 3.1 above and in light of the emphases detailed herein.

3.2.2. The lack of unity of invention objection may be raised during any stage of the examination (not exclusively in the first office action), for example, based on newly found prior art or owing to amendments made by the applicant in the claim set.

3.2.3. Where it is determined that the claim set lacks unity of invention, whether between different claims or within the same claim, the invention first claimed, based on its order of appearance in the claim set, shall be examined.

3.2.4. In the following cases, **subject to approval by the Team Manager**, only an objection on grounds of lack of unity of invention shall be raised without examining any invention:

a. the first claim comprises a large number of compounds, sequences or various combinations lacking a common structure or said common structure is not novel, and consequently the application would contain unduly large number of inventions;
b. the claim set comprises separate and different inventions from different technical fields necessitating examination by more than one examination team;
c. the invention claimed in the first group of claims does not comply with the provisions of Section 13 of the Law.

3.2.5. A disclaimer excluding certain technical features from the claimed scope might lead to lack of unity of invention, but it does not necessarily constitute grounds for raising an objection of lack of unity of invention. Such objection may be raised where, due to the disclaimer, a single general inventive concept no longer exists.

3.2.6. An objection of lack of unity of invention should not be raised on the basis of a narrow, literal or academic approach, without exercising discretion, while taking into account, among others, the following:
a. the possibility of the existence of overlapping claimed scope between applications, should the application be divided into separate inventions;
b. the scope of the additional search required for the additional inventions; and
c. whether the separate inventions solve the same problem and achieve the same technical effect.

3.2.7. As a rule, an objection of lack of unity of invention should not be raised where the same prior art can be used to deprive all the different inventions/claims of novelty and inventive step. Where the applicant rectifies the deficiencies related to lack of novelty / inventive step, an objection of lack of unity of invention may be raised in the continued examination.

3.2.8. The procedure for the assessment of unity of invention is summarized in the chart of Appendix 4.1 below.

3.3. Independent and dependent claims

3.3.1. Unity of invention shall be assessed initially for the **independent** claims. An objection of lack of unity of invention shall not be raised against dependent claims where their independent claims are novel and involve an inventive step, as well as share a single general inventive concept, even where said dependent claims define additional inventions.

3.3.2. Where the same independent or dependent claim defines a plurality of alternatives, an objection of lack of unity of invention shall be raised where the different alternatives do not share a single general inventive concept. However, where these alternatives are of similar nature, such that it would have been obvious for the skilled person choose them interchangeably, no such objection shall be raised (see also Section 4.2 below regarding Markush claims).

3.3.3. Unity of invention shall be examined between dependent claims where the independent claim is not novel or lacks inventive step. An objection on grounds of lack of unity of invention *a posteriori* may be raised where no single general inventive concept can be identified for the dependent claims (with an emphasis on the provisions of Section 3.2.6-3.2.7).

4. Emphasis and Specific Aspects

4.1. Unity of invention and claim categories

4.1.1. Product and process for its manufacture – unity of invention exists between a claim defining a product and a claim defining a process specially adapted for the manufacture of said product. Said process is specially adapted to directly manufacture the product such that the **special** technical features of the process correspond to (contribute directly to) the **special** technical features of the product. Meaning, unity of invention would be lacking where the product or process lacks novelty and inventive step. However, an objection of lack of unity of invention between a claim relating to a product by a process of its manufacture (product-by-process claim) and another claim relating to a process for the manufacture of said product, even where said product is not novel. The fact that said process is specially adapted for the manufacture of said product does not necessarily mean the product cannot be manufactured by another process.

4.1.2. Apparatus and process – unity of invention exists between a claim defining an apparatus (or means) and a claim defining a process where the apparatus is specifically designed for carrying out the process. Said device is considered specifically designed for carrying out the process when the **special** technical features of the device claim correspond to the **special** technical features of the process claim and it would not be sufficient that the apparatus is merely capable of carrying out the process.

4.1.3. Product and process of use – unity of invention exists between a claim defining a product (for example, product X) and a claim defining the use of said product (for example, method of using product X), provided both the product and the use thereof are novel and involve an inventive step. However, an objection of lack of unity of invention, between a claim defining a method for novel use of the product (for example, method of using product X) and a claim defining the product for the same novel use (for example, product X for use), should not be raised, even where the product itself is already known.

4.1.4. Complementary products – unity of invention exists between two different products claimed in the same claim set where a functional interaction exists between them, such that the function of one of the products is dependent upon the complementary function of the other product, and such that both functions occur simultaneously so as to solve the same technical problem and achieve the same technical effect (for example, a socket and a plug or a transmitter and a receiver). However, examiners should raise an objection of lack of unity of invention where no functional interaction exists between the two different products (i.e., the function of each product is independent of the other) to achieve a given result, such as in the case of a camera and a laptop computer screen.

4.1.5. Different uses of the same product

4.1.5.1. Claims relating to different methods of use for a given product, which lacks novelty or inventive step, to solve the same problem, may be considered as belonging to the same invention, provided the prior art does not teach any solutions to said problem or similar problems using the same product or similar products (i.e., only where the solution using said product is considered novel and involves an inventive step). However, unity of invention would be lacking where similar products are known for solving the same problem, or where the same product is known for solving a similar problem.

4.1.5.2. Where different uses of a given product solving different problems are claimed, unity of invention can only exist if said product is novel and involves an inventive step.

4.1.5.3. Where the prior art teaches one of the different claimed uses (of the same product or similar products) unity of invention would be lacking.

4.1.6. Intermediate and final product

4.1.6.1. An intermediate, which may also be a starting product (i.e., reactants), is defined as a product undergoing chemical or physical changes, to produce, whether directly or indirectly, the final product.

4.1.6.2. Unity of invention between a claim defining an intermediate product and a claim defining a final product exists, provided that the following two conditions are cumulatively met:

a. the intermediate and final products have the same essential structural element in the sense that the basic chemical structure of the intermediate product is identical to that of the final product, or that the chemical structures of the two products are technically closely interrelated, such that the intermediate product incorporates an essential structural element (not disclosed in the prior art) into the final product;

b. the intermediate and final products are technically interrelated in the sense that the final product is manufactured directly from the intermediate product or is separated from it by a small number of intermediates.

4.1.6.3. Where the chemical structure of the intermediate product or that of the final product is not known, there must be sufficient evidence to determine that the criteria set out in Section 4.1.6.2 above are upheld, without such evidence unity of invention between the intermediate and final products would be lacking.

4.1.6.4. Unity of invention may exist between intermediate products yielding the same final product by different processes, as long as they have the same essential structural element that is not disclosed in the prior art.

4.1.6.5. Unity of invention between a claim for an intermediate product and a claim for a final product would be lacking, even where the final product is separated from the intermediate product by a small number of intermediates, when at least one of these intermediates is not novel.

4.1.6.6. Unity of invention between claims for at least two intermediates would be lacking where each of the intermediates meets the criteria of Section 4.1.6.2

above, but for different structural parts of the same final product, such that no common essential structural element exists between said intermediates.

4.1.7. Polymorphs and salts of compounds – regarding emphases and guidelines pertaining to unity of invention for claims relating to polymorphs and salts of compounds see Appendix 18 of the Examination Guidelines, Section 4.

4.2. Markush claims\Markush Practice

4.2.1. Where the invention (for example, a chemical compound, a nucleotide sequence, a protein, etc.) is defined in terms of multiple alternatives (Markush claims\compounds) unity of invention would be present, provided that the following conditions are met:

4.2.1.1. all the alternatives have the same activity, technical effect (result or advantage) or use; and

4.2.1.2. one of the following holds true:

a. all the alternatives share a significant structural element that is essential for said activity, technical effect, or use, wherein said element may constitute a large portion of the compound's structure or alternatively constitute a small portion of the compound's structure where the element has a structurally distinctive portion in view of the prior art; or

b. The alternatives do not share a significant structural element, but all of them belong to the same recognized class of chemical compounds. A recognized class of chemical compounds pertains to substances for which there is a reasonable expectation to behave in the same way within the context of the claimed invention and provide the same result when substituted one for the other.

4.2.2. Unity of invention would be lacking in a Markush claim where a prior-art publication discloses at least one of the Markush compounds, such that its activity, technical effect or use is the same as that of the application under examination; or, alternatively, a prior-art publication discloses the significant structural element shared by the Markush compounds such that its activity, technical effect or use are the same as that of the application under examination.

4.2.3. Where a Markush compound is claimed for a specific use (Compound [Markush] for use), an objection of lack of unity of invention *a posteriori* between alternatives of the same

Markush compound should not be raised, unless said compound for said claimed use is disclosed in the prior art.

4.2.4. Where a Markush claim includes a disclaimer excluding at least one alternative of the Markush compound, and this alternative is not novel in view of the prior art, unity of invention would be lacking, provided that this alternative is disclosed in the prior art as having the same activity, technical effect or use, as claimed in the application under examination.

4.2.5. Where an objection of lack of unity of invention of at least one Markush compound is raised, further to that stated in Section 3 above, the first combination of the alternatives should be examined. According to Section 3.2.4 above, where the application includes an unduly large number of inventions, rendering the choice of which invention to examine impossible, or where the first combination of the alternatives does not comply with Section 13(a) of the Law, only an objection of lack of unity of invention should be raised in the examination report, subject to the approval of the Team Manager.

5. Raising an Objection due to Lack of Unity of Invention

An examination report raising a lack of unity objection shall include the following details:

5.1. a general description of each separate invention, including the numbers of the claims associated to each invention;

5.2. indication of the technical feature(s) common to the separate inventions or the lack of said technical feature(s);

5.3. in case of lack of unity of invention *a posteriori*, reference to the prior art (while indicating the relevant part(s) of each prior-art publication cited), which teaches that the common general concept lacks novelty and/or inventive step;

5.4. indication of the lack of technical effect common to the differing (remaining) features of the separate inventions;

5.5. indication of the (first) invention examined and reference to the provisions of Section 24 of the Law, or, alternatively, indication that no examination has been conducted (in accordance with Section 3.2.4, above); and

5.6. reference to the provisions of Section 6.5 below, regarding the amendment of the specification by replacing the invention which has been examined by another invention, and indication of the possibility that a Notice before Refusal may be issued in such case.

6. Applicant's Arguments and Options

6.1. In response to the lack of unity of invention objection raised, the applicant may act in one or more of the following ways:

a. filing an amended claim set relating to the (first) invention examined;

b. presenting arguments against the objection; and

c. objection to examiner's decision.

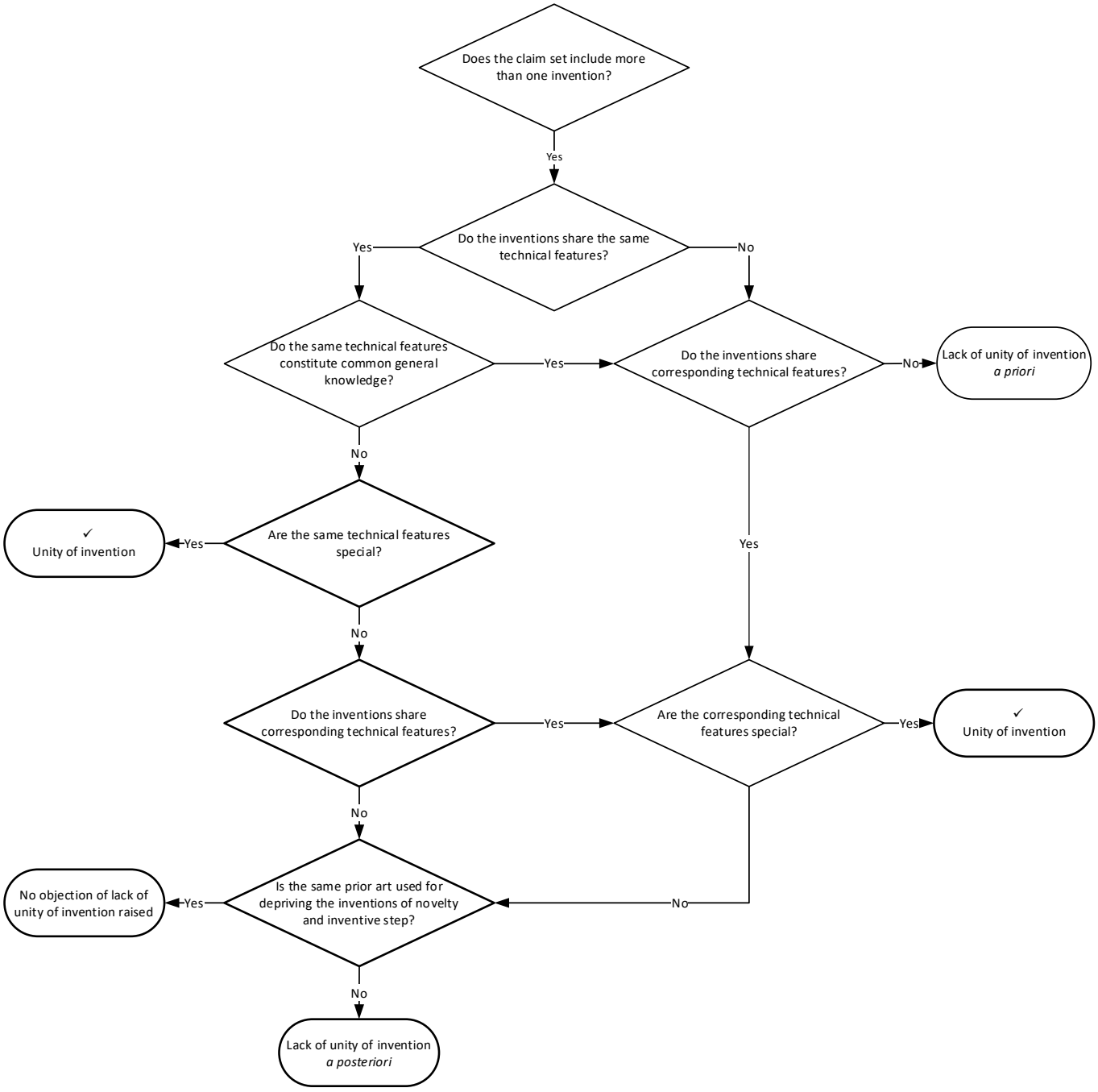
6.2. The applicant is entitled to file divisional applications relating to the other inventions.

6.3. Where the applicant's arguments are found persuasive, the examiner shall notify the applicant of the withdrawal of the objection, and conduct substantive examination to the unexamined claims.

6.4. Resubmitting the same claim set without presenting arguments or with the same arguments presented in a previous examination of the application does not rectify the deficiency regarding lack of unity of invention and may constitute grounds for refusing the application (see the provisions of Appendix 1 of the Examination Guidelines – Guidelines for Examination of a Patent Application, Section 8 – "Refusal of the application").

6.5. Amending the specification by replacing the invention, which was examined and for which an objection was raised regarding a certain deficiency, by another invention, whether it was part of the original claim set or solely described, even if it is supported by the description, does not constitute rectification of the deficiency. In this case, according to Regulation 45, the examiner shall determine that the applicant's reply does not rectify the deficiency, and shall send to the applicant a Notice before Refusal.

Appendix 4.1 – Chart for the Assessment of Unity of Invention



Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
Official Ed. 6 (28.2.2023)	Transl. Ed. 6.1 (10.07.2023)	Page: 1 of 6	Guideline No.: **EG-23.1/5**

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 5 – Sections 2, 9, and 19 of the Patents Law – Overlapping Applications

References and documents relating to overlapping applications: Sections 2, 9, 13, 19, 24 and 50 of the Law, Regulations 38-40, 41-45 of the Patents Regulations, Commissioner's Circular 034/2017-Patents (2020), OA 477/93 (IsrDC) **The Wellcome Foundation v. The Commissioner of Patents, Designs and Trademarks** 1334 (19.8.1993) (hereinafter: the "**Wellcome Ruling**"), Decision regarding the objection to examiner's decision, Patent Application No. 203972 **Novartis AG** (Published on the Israel Patent Office's website 2.12.2014) (hereinafter: "Decision regarding 203972").

1. General

1.1. This appendix specifies examination guidelines for examining overlapping patent applications and the accompanying procedures according to the provisions of Sections 2, 9, 19, and 24(b1) of the Law and the provisions of Regulations 38-40 and 41-45 of the Patent Regulations (and based on the provisions of the Law, regulations, rulings, decisions made at the Israel Patent Office and the Commissioner's Circulars relevant to the provisions of these sections).

1.2. Section 2 of the Law prescribes as follows:

> "The owner of a patentable invention is entitled, under the provisions of this Law, to request that a patent for it be granted to him."

Section 9 of the Law prescribes as follows:

> "Where more than one applicant applied for a patent for the same invention, the patent shall be granted to the first who applied for it according to the law."

Section 19 of the Law prescribes as follows:

> "Where the invention, in whole or in part, is not found patentable, due to a previous application which has not yet been published under Section 16A, then the Commissioner or examiner are entitled to - and where they have been requested to do so by the applicant whose application was not found patentable, they must - instruct that the examination of the later application be postponed until after the publication of the earlier application under Section 16A, or, if the

applicant so requests, until the publication of the previous application under Section 26 or until rejection of the previous application."

1.3. These provisions shall apply to applications whose examination is conducted according to the provisions of Sections 17(a)(1) and 17(a)(2) of the Law, as well as according to Section 17(c) of the Law.

2. Definitions

2.1. An overlap can occur between claims of separate applications bearing different dates, i.e., an earlier and a later application, or between claims of separate applications bearing the same date. Yet, where the earlier application (or its corresponding application) constitutes a prior art document that deprives the later application of novelty and/or inventive step, an objection of lack of novelty and/or inventive step should be raised (rather than an objection on grounds of overlap).

2.2. Insofar as the provisions of this Appendix relate to an overlap between applications, they shall be seen as also applying to an overlap between an application and a patent.

2.3. An overlap between a patent application under examination and another application **exists** when the scope of protection sought in a particular claim/s in the application under examination is identical, includes, or is included in the scope of protection sought in the claim/s of the other application. For applications bearing different dates, **there may likely** be an overlap of substantive nature between them (hereinafter: "substantive overlap") even if there is a difference between the technical features claimed in the two applications. The existence of an overlap in such a case shall be examined in light of the specification of both applications.

A **substantive overlap** exists where the difference between the scope of protection of both applications does not constitute an essential feature of the claimed invention, or where the feature constituting the difference, is described and/or exemplified (although not claimed) in the other application that has not yet been accepted (as in which case the first applicant may still amend the claims such that they include the element that was not claimed previously).

2.4. The terms appearing in the claims should be interpreted in light of the common general knowledge of an average skilled person in the art and in light of the specification of the application/s (including examples or drawings).

2.5. Claims relating to various aspects of the invention may grant the applicant different scopes of protection. However, the two following cases should be noted:

- a use claim (as defined in Chapter B of Commissioner's Circular 034/2017-Patents) should be construed as granting a scope of protection that is identical to that of a claim for the respective process (see the Wellcome Ruling); and
- the scope of protection for a claimed product that is defined in terms of the process by which the product is made ("product by process") should be construed, based on Section 50(a) of the Law, as identical to the scope of protection for the same process.

2.6. The relevant date for the purposes of the assessment of overlap between applications shall be determined according to the earlier date of the following:

- the priority date of the application (so long as the application complies with the requirements of Section 10 of the Law);
- the international filing date (according to Section 48C(3) of the Law);
- the date of filing the first application in Israel (according to Section 15 of the Law); and
- the parent application date in the event of a divisional application (according to Section 24(c) of the Law).

It should be emphasized that where substantive amendments (within the meaning of Section 23 of the Law) have been filed, the application date (or the date of the amendments) shall be the date on which the amendments were filed.

2.7. In the event of an overlap between applications bearing different application dates, the overlap objection shall be raised only in the examination of the later application.

3. Distinguishing between Types of Applications

3.1. Applications bearing the same date

3.1.1. Applications bearing the same date that were filed by different applicants – Section 9 of the Law. Where two applications for the same invention bearing the same application date were filed by different applicants, an overlap objection shall not be raised.

3.1.2. Applications bearing the same date that were filed by the same applicant – Section 2 of the Law. For the purposes of this section, there is no distinction should be made between applications that were filed separately and applications that were separated from parent applications (whether between divisional applications or between a divisional application and a parent application) so long

as the applicant's ownership is the same and the same date was determined for the applications (see Section 2.6 above).

For applications bearing the same date that were filed by the same applicant, an overlap objection should be raised in the following cases:

a. the **same aspect** is claimed in the applications, where the scope of protection sought in the claim of the application under examination is identical (even if the wording of the claim is not identical) to that in the claim of the other application; or
b. **different aspects** are claimed in the applications, where, in fact, the claims define identical scopes of protection (see Section 2.5 above).

3.2. Applications bearing different dates – Sections 2 and 9 of the Law.

3.2.1. In the following cases, an overlap objection should be raised in applications bearing different dates, i.e., between the application under examination and an earlier application:

a. an overlap between claims that claim the same aspect, where the scope of protection sought in the claim of the application under examination is identical, includes, or is included within the scope of protection sought in the claim of the earlier application;
b. an overlap between claims relating to different aspects, where the scope of protection sought in the applications is identical (see Section 2.5 above); or
c. a substantive overlap (as defined in Section 2.3 above) between the claims of the application under examination and the claims of the earlier application (whether the claims relate to the same aspect or different aspects).

4. Postponement of Examination due to Overlap

According to Section 19 of the Law, where an earlier application, which was deemed overlapping with the application under examination, **has not yet been published under Section 16A of the Law**, the examination of the later application may be postponed in its entirety according to the Commissioner's or examiner's decision, until the publication of the earlier application under Section 16A of the Law, or per applicant's request until the publication of the earlier application under Section 16A of the Law, the publication of the earlier application under Section 26 of the Law, or the rejection of the earlier application.

As a rule, the examiners shall raise an objection in the first Notice of Deficiencies regarding an overlap with the earlier application while indicating its number, according to Regulation 38(a) or 39(a).

The examiners shall notify the applicant about the postponement of the examination of the application until the publication of the earlier application under Section 16A of the Law.

A request for postponement of the application may be filed by the applicant within one month from the first Notice of Deficiencies. In the request, he should expressly indicate his wish to postpone the examination of the application in its entirety according to Regulation 39(b).

Where a request for postponing the examination has been filed, the examiners shall carry out the following:

a. Updating the automated system regarding the postponement by entering the number of the earlier application.
b. Issuing an action titled "Notification of Postponement of Examination until Publication of an Earlier Application" for the application under examination.
c. Issuing an action titled "Notification about an Application Delaying Examination of another Application" for the earlier application, notifying the earlier applicant about the existence of a later application, whose examination was postponed. According to Section 18 of Commissioner's Circular 035/2017-Patents, no extensions shall be granted during the examination of the earlier application.
d. Deleting the notice regarding the delay under Regulation 39(b) from the automated system after the completion of the examination of the earlier application. Meaning, the earlier (delaying) application was either published according to Section 16A and/or Section 26 of the Law, refused, or abandoned.
e. Continuing the examination of the postponed application as soon as possible.
f. Reconsidering raising an overlap objection, depending on the scope of protection sought by the earlier application.

Additionally, the applicant may request the postponement of the examination following an objection raised under **Section 9 of the Law** even if the earlier application was published according to Section 16A. In such a case, the examination shall be postponed until the publication of the earlier application under Section 26 of the Law, or until the earlier application is rejected or abandoned.

5. Raising an Overlap Objection

The Notice of Deficiencies shall include at least the following details:

a. where **the earlier application has not yet been published** - the number and filing date of the earlier application, the claims against which the objection is raised in the application under examination, and a notification regarding the postponement of examination until the publication of the earlier application according to Section 16A of the Law;

b. where **the earlier application has been published** – the number of the earlier application, the overlapping claims of the earlier application, and the filing date of these claims, while describing the scope of claims in each of the applications and the reasoning for raising the overlap objection. In the case of a substantive overlap, as defined in Section 2.3 above, the examiner shall also include in the reasoning references to the relevant passages of the specification; and

c. a note regarding the possibility of postponement of the examination.

6. The Applicant's Possibilities to Rectify the Overlap Deficiency

The following examples present several possible cases in which the applicant may be able to rectify the overlap deficiency:

a. deletion of the overlapping claims;

b. removal of the overlapping scope by restricting the claims, for example, exclusion of a narrow scope claimed in one application from the broad scope claimed in a second application, limitation to a specific use, etc.;

c. indicating a substantial and unexpected advantage in selecting a narrow scope in the application under examination vis-à-vis a broad scope in the other application (see Section 6.5 in Appendix 6 of the Examination Guidelines – Section 4 of the Law - Novelty);

d. conversion of one of the applications to a "patent of addition" should it meet the requirements of Sections 44 and 45 of the Law (except in the case of divisional applications).;

e. providing persuasive reasoning that there is no overlap between the applications at hand.

These examples should not be deemed binding and any argument and/or amendment in the claim set should be re-examined in view of the other guidelines set out in this appendix and the general examination guidelines.

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 6 – Section 4 of the Law – Novelty

References and documents relating to novelty: Sections 3, 4 and 6 of the Law, 5727-1967; *Civil Appeal 345/87* ***Hughes Aircraft Company v. State of Israel*** *(1990)* (hereinafter: "the Hughes Ruling"); *Civil Appeal 8802/06* ***Unipharm LTD. v. Smith-Kline Beecham PLC*** (*Nevo* 18.5.2011)(hereinafter: "the Smith-Kline Ruling"); *Civil Appeal 804/89* ***Lanplast (1971) Ltd. v. Eliezer (Lazer) Berkman*** *(1992)* (hereinafter: "the Lanplast Ruling"); Miscellaneous Civil Appeal (Jerusalem) *41362-07-15* ***FMS Enterprises Protection Ltd v. DSM IP Assets BV Knowledge Base*** *(29.12.2016)* (Nevo 22.1.2017) (hereinafter: "the FMS Ruling"); Application for Revocation of Patent 12914, ***Herbert Zilberstein and Migdal David Ltd. v. Uriel Hefetz*** (published in Nevo, hereinafter referred to as "Decision regarding 12914").

1. Introduction

1.1. This appendix specifies Examination Guidelines relating to the assessment of novelty in patent application claims according to the provisions of Section 4 of the Law, as well as relevant rulings and decisions of the Patent Office pertaining to the provisions of this section of the Law.

1.2. Section 3 of the Law prescribes:

> "An invention, be it a product or a process in any field of technology, which is novel and useful, has industrial application and involves an inventive step, is a patentable invention."

1.3. Section 4 of the Law prescribes:

> "An invention is deemed novel if it was not made available to the public, in Israel or abroad, before the application date –
> (1) by written, visual, audible or any other disclosure, in a manner that enables a skilled person to perform it according to the particulars of the disclosure;
> (2) by exploitation or exhibition, in a manner that enables a skilled person to perform it according to the particulars thus made known."

1.4. Section 6 of the Law prescribes:

> "The right of the owner of an invention to be granted a patent shall not be affected by publication said in Section 4 if –

(1) it is proved that the matter made available to the public was obtained from the owner of the invention or his predecessor in title and was made available to the public without his consent, and if the patent application was filed within a reasonable time after the publication became known to the applicant;

(2) (a) the publication was by the owner of the invention or his predecessor in title in one of the following ways:

(I) display at an industrial or agricultural exhibition in Israel or at a recognized exhibition in one of the Member States, of which the Commissioner has received a formal notice prior to their opening.

(II) publication of the disclosure of the invention at the time of the aforesaid exhibition;

(III) use of the invention for the purposes of the exhibition and at the place of the exhibition;

(b) Publication was performed by way of using the invention, even without its owners' consent, at the time and place of the exhibition or outside it;

provided that the patent application was submitted within six months following the opening of the exhibition;

(3) the publication was performed by way of a lecture by the inventor before a scientific society or by publication of the lecture in official transcripts of the society, provided that the Commissioner has received a notice of the lecture prior to its delivery and that the patent application is filed within six months from the aforesaid publication."

1.5. These guidelines apply to applications examined according to the provisions of Sections 17(a)(1) and 17(a)(2) of the Law.

2. Definitions

2.1. Publication: Any disclosure made available to the public (in writing, by audio or visual means) including published patent applications and granted patents, journals or books, as well as disclosures published on the internet or in online or offline databases (excluding the exceptions set out in Section 6 of the Law).

2.2. The publication date of a relevant disclosure will be determined as follows:

- Where the disclosure is a patent application or patent, according to the publication date of this document.
- Where the disclosure is an article, the framework, in which the article was published (e.g., journal, book, etc.), and the publication details, regarding the date (day/month/year) of publication, should

be verified. Where the publication details indicate only a month in a specific year, the publication date for the purposes of Section 4 of the Law shall be the last day of that month in the specific year. Where the publication details indicate only a year, the publication date for the purposes of Section 4 of the Law shall be the last day of that year.

- In case of a disclosure published on the internet, the publication date will be determined in accordance with the specifications set out in Appendix 9.4 of the Examination Guidelines (EG-23.1/9).

2.3. The relevant date of a patent application under examination, for the purposes of Section 4 of the Law, shall be the date of the priority right, where claimed and meets the provisions of Section 10 of the Law, or the date on which said patent application was filed in Israel where no priority right was claimed, or the international filing date of international patent applications entering the national phase in Israel where no priority right was claimed, or the date of amendment of a certain claim (subject to the provisions of Section 23 of the Law) where the amendment is deemed a substantive amendment (by introducing a new subject matter).

3. General

A claim under examination is considered **not** to comply with the provisions of **Section 4(1) of the Law** (i.e. lacking novelty) where there is a prior-art publication disclosing all the elements of the invention defined in said claim, such that a person skilled in the art would know to perform the invention (i.e., elements in a claim for a device or steps in a claim for a process) and said prior-art publication was made available to the public prior to the relevant date of the application under examination.

A prior-art publication deprives a claim of novelty only where its disclosure would have enabled a person skilled in the art to put the invention into practice, while taking into account the common general knowledge of the skilled person in the art.

According to **Section 17(b) of the Law**, the examiner is not required to determine whether an invention lacks novelty under **Section 4(2) of the Law**, owing to the fact that he usually cannot determine whether an invention has already been publicly utilized or presented. However, the examiner should note any possible hints within the application specification which may provide evidence that the invention was utilized or displayed in public.

4. Methodology

For the assessment of novelty, the following steps should be followed:

a. identifying all the elements included within a claim under examination;
b. determining whether a given publication constitutes a prior-art publication, the publication date of which is prior to the relevant date of the application under examination; and
c. assessing whether all elements of the claimed invention as a whole are disclosed in said publication, enabling a person skilled in the art to put the invention into practice.

5. Assessment of Novelty

The **Hughes Ruling** sets forth rules for the assessment of novelty:

> "The first rule is that in order to prove such prior-art publication as would deprive the claimed invention of novelty, it is necessary to indicate a document which contains the invention in entirety, without creating a mosaic of information gathered from different and separate documents in order to form one comprehensive picture (C.A. 314/77 [l], at p. 209; C.A. 75/55 [6], at p. 1992-1993). The logic behind this rule is that the combination of known things into one whole creates a new thing. The novelty might be defeated where "a subsequent publication contains or cites a publication prior to it ..." (C.A. 75/55 [6], ibid.) or where references are made from one publication to another (see for example Cornish, supra, at 123)."

Regarding the cases in which additional publications may be used in support of a single publication disclosing the invention, see Section 6.2 herein as well.

> "A second rule is that the information which was available to the public enabled performing the invention. This requirement is based on Section 4 of the Law and is mentioned in the ruling of the District Court (C.F. (TA) 1290/57 [12], at p. 119). A general description, from which one cannot learn how to perform the invention, is insufficient, and signposts that point in the direction of the patented invention are unsatisfactory."

The invention must be disclosed such that a person skilled in the art can perform it based on the information within a given publication, as required by the Law.

> "A third rule, which is related to the latter rule, is that a patent will not be disqualified owing to lack of novelty merely because the terms or words used in the patent are the same as in the

> disclosure of the prior-art publication. The assessment of novelty is based on the essence of the disclosure, not on its form or wording."

Beyond the identity between the elements disclosed in the prior-art publication and those claimed, it is necessary to ensure that there is identity in the essence as well.

> "A fourth rule is that when assessing the prior-art publication, it is permissible to make use of the common general knowledge, as available at the time, but it is not permissible to add any elements or components which are not mentioned in the prior-art publication."

It is permissible to rely on common general knowledge of a person skilled in the art when verifying his ability to perform the invention according to the disclosure of the prior-art publication, but not to modify it, for example, by adding elements not taught in said publication, whether explicitly or implicitly (see Section 6.2 herein as well).

> "An additional rule, which serves as a standard for this question, links the questions of novelty and infringement to one another: where performing the invention according to the disclosure of the prior-art publication constitutes infringement of the patent, the invention subject matter of the patent is not novel… However, a mere possibility of such an infringement is insufficient as aforementioned; it is necessary to show that following the prior-art publication would lead necessarily to infringement of the patent."

6. Emphases and Specific Aspects in Assessing Novelty

6.1. Implicit/inherent disclosure

A prior-art publication deprives a claim under examination of novelty, where it explicitly discloses all the elements of the claimed invention in said claim. However, a claim may lack novelty in view of a prior-art publication even where a certain element of the invention is not explicitly disclosed in said publication, but inferred implicitly or constitutes an inherent result or feature of the disclosure of the publication.

In the District Court decision on the **FMS Ruling,** it was stated:

> "The very definition of inherency requires that result B would necessarily occur upon the occurrence of phenomenon A, and where phenomenon A does not necessarily lead always to

result B, the definition of inherency is not fulfilled for meeting the prior-art publication requirement, thus depriving the claimed invention of novelty."

An **implicit disclosure** refers to a situation in which a claimed element is not explicitly disclosed in the prior art, but performing the invention according to the disclosure as taught in the prior-art publication would **necessarily** lead to a result falling within the scope of the claim under examination. For example, where a pharmaceutical composition disclosed in the prior art is identical to that claimed in a given application, and where the claimed invention is defined in terms of a specific rate of release, it is considered that the prior-art publication implicitly discloses the same rate of release.

An **inherent feature** is an intrinsic/embedded feature of a given material, such as physical-chemical properties characterizing the material itself like density, boiling temperature, or elasticity are all inherent features. For example, a claim for "elastic material" would lack novelty, where a prior-art publication discloses "rubber", even where such a publication does not explicitly specify that rubber is an elastic material, since rubber is an "elastic material" by definition.

A result or feature is not to be deemed implicit or inherent based on probability or likelihood that said result or feature exists. In cases where there is reasonable doubt, an objection under Section 4 of the Law should not be raised.

Equivalent elements to those disclosed in a prior-art publication shall not be relied on when assessing novelty.

a. Characterization

A claimed product may be deemed not novel where it is characterized by a feature (such as viscosity, conductivity, solubility) or by a value defined by a formula combining several features, and the prior-art publication discloses and exemplifies said product, but said feature or value are not mentioned in the prior art. Said lack of novelty stems from the fact that the claimed **characterizing feature is an inherent feature** of the product, which merely describes an existing state. Characterization of an existing state by different parameters, in itself, does not contribute to novelty. In this case, the burden of proof, for showing that the claimed product differs from that of the prior art, rests upon the applicant.

b. Synergism

A claimed composition, defined by several ingredients and also by a synergistic effect, may be deemed not novel where a prior-art publication discloses the same composition with the same intended purpose, even where it does not disclose said effect. In this case, the latter is to be deemed an inherent effect of the known preparation.

A claimed composition characterized by a synergistic effect may be deemed not novel, where the composition contains two or more ingredients that constitute entire families (such as herbicide, fungicide) or specific families (such as amide herbicide, strobilurin fungicide) and the prior art relates to a composition containing specific ingredients belonging to said families (such as cyprazole that belongs to the amide herbicide family and fluoxastrobin that belongs to the strobilurin fungicide family).

c. Pharmacokinetic parameters

A claimed composition, characterized also by pharmacokinetic parameters, may be deemed not novel where a prior-art publication discloses the same composition with the same intended purpose, even where the publication does not disclose said pharmacokinetic parameters. In this case, the latter are to be deemed inherent features of the known preparation. For example, a prior-art publication discloses a tablet containing the same active compound and the same number of layers containing the same ingredients as those of the claimed invention would deprive the claimed invention of novelty. Since the number of layer and the ingredients in the publication are the same as those of the claimed invention, the resulting effects of the composition, such as maximum concentration of the active compound in the blood, would necessarily be the same as well. Where a claimed composition is defined only in terms of the resulting effects, the claim is to be interpreted according to Section 13(b) of the Law (see Appendix 11 – The Claims).

6.2. Combining publications

In the assessment of novelty, it is not permissible to combine prior-art publications. The claimed invention is deprived of novelty only where it is disclosed in its entirety in a single prior-art publication. In the Decision regarding 12914, the following was stated:

> "Where a given publication explicitly refers to a second prior-art publication, it is permissible to rely on both for depriving the claimed invention of novelty. However, where a publication is merely mentioned in a later publication, it is insufficient to justify grounds for lack of novelty in view of the prior art."

It was further stated in that decision:

> "Where a later publication contains or cites an earlier publication as a reference in which parts that are equivalent to and substitutable for those disclosed in the later publication may be found, this citing does not constitute a "mosaic of several documents", as the author of the later document intended to show that parts of the first publication constitute part of his invention. However, where the later document merely mentions professional knowledge for comparative or analytic purposes, in most cases, such combination of documents or references does not constitute prior art on grounds of which the claimed invention would be unpatentable."

Where a prior-art publication cites a previous (additional) prior-art publication, the information contained in the previous publication may be considered as part of the disclosure of the later publication, subject to the context.

It is permissible to use a second publication to deprive the claimed invention of novelty in the following instances as well:

a. to prove that the first publication includes a disclosure "enabling one skilled in the art to put the invention into practice".
b. to interpret a term appearing in the first publication (for example, by citing a term from a dictionary, encyclopedia or Wikipedia).
c. to prove that a given feature, which is not explicitly disclosed in the first publication is inherent.

6.3. Alternatives

Where a claim contains several alternatives, such as in Markush claims, each of the alternatives disclosed in a prior-art publication, in itself, deprives the claim of novelty.

6.4. Generic (broad) claims versus specific (narrow) disclosure

Where a claim is worded in generic terms, a lack of novelty objection should be raised based on a prior-art publication disclosing specific examples falling within the scope of said generic claim. For example, a prior-art publication disclosing copper deprives the novelty of a claim relating to a metal in the generic sense, while it does not deprive the novelty of a claim relating to a specific metal which is not copper. As another example, a prior-art publication disclosing a nail deprives the novelty of a claim relating to a fastening means, while it does not for a claim relating to fastening means that are not nails.

6.5. Application claiming a group of items from a broader group disclosed in the prior art

6.5.1. In the **Smith-Kline Ruling,** it was ruled that the patentability of an invention claiming "a group of items from a broader group of products or processes" shall be assessed by the same criteria as for any other application. The ruling states:

"thus for example, the novelty requirement as defined in Section 4 of the Patents Law, requires an examination of whether a feature discovered in a component or components from a group described in a previous patent was visible and known; the requirement of inventive step as set out in Section 5 of the Patents Law requires an examination of whether a new feature discovered in a selected component for which a new patent is sought is a feature which embodies a substantial advantage which may constitute an appropriate value in return for granting a monopoly to the inventor."

6.5.2. The examiners should determine whether all the items of the group share the same or corresponding special technical feature (see Appendix 4 – "Section 8 of the Law – Unity of Invention"). If not, an objection on grounds of lack of unity of invention under Section 8 of the Law should be raised.

6.5.3. A claim for a group of items lacks novelty where one of said items is not novel.

6.5.4. Where a publication disclosing a broad group does not include examples disclosing the items of the claimed narrower group and the specification of the application does not disclose a substantial and unexpected advantage for the entire claimed group, an objection under Sections 4 (novelty) and 5 (inventive step) of the Law should be raised, based on the publication disclosing the broad group to which the narrow group belongs.

6.5.5. In lack of a publication that may be cited under Sections 4 and 5 of the Law, while there is an earlier application filed in Israel disclosing a broad group to which the claimed group belongs, an objection should be raised under Sections 2 or 9 of the Law (regarding overlapping claimed scopes between the application under examination and the earlier application).

6.5.6. The applicant should be requested to prove that all items of the claimed narrower group have a substantial and unexpected advantage arising from the same or corresponding technical feature in order to rectify the deficiency against the provisions of Sections 2, 4, 5 and 9 of the Law (see also Section 6 of Annex 5 – Sections 2,9 and 19 of the Law - Overlapping Applications").

6.6. Novelty of an application with respect to ranges (concentrations, quantities, ratios)

In an application claiming specific ranges:

a. Novelty would be lacking where the claimed range is broader than that disclosed in the prior-art publication. For example, a claim defining a concentration range of 0.5%-50% would lack novelty in view of a the prior-art publication disclosing a concentration range of 1%-2.5%.

b. The claimed invention would lack novelty where it defines ranges that are narrower, overlapping or tangential to those disclosed in the prior art; for example, a concentration range of 1%-2.5% in the claimed invention versus a concentration range of 0.5%-50% in a prior-art publication; only if the claimed range is defined arbitrarily (see Section 6.5 above).

c. The claimed invention would lack novelty where a range is defined in words, while the prior art discloses the same range in terms of numerical values (and vice versa). For example, the application claims a solution with a concentration resulting in an acidic pH, whereas the prior-art publication discloses a specific acid concentration of 0.5-0.7 M. In this case, the claimed invention would be lacking novelty where it is clear that said concentration results in an acidic pH.

d. When raising a lack of novelty objection with respect to a claimed range, the units of the claimed range should be identical or comparable to those of the prior-art range, thus enabling comparison between the values of both ranges.

6.7. Novelty assessment of a claim directed to an isolated naturally-occurring material

A claim directed to a naturally occurring material would be deemed novel so long as this material is defined in its isolated state.

6.8. Product by Process claims

Where a claim defines a product in terms of the process by which the product is made, the claim as a whole is directed to the product itself and should be assessed with respect to it. Therefore, where the same product is disclosed in the prior art, the claim would not meet the requirements of novelty according to Section 4 of the Law, even if the claimed product is manufactured by a different process.

6.9. New use of a known product and/or process

A claim directed to a **known** product/process for a certain use would be deemed novel, so long as said use is not disclosed explicitly or implicitly (see Section 6.1 above regarding implicit disclosure) in that prior-art publication disclosing the claimed product/process. In this regard, Section 14 of Lanplast Ruling states:

> "In conclusion, the discovery of a new use of a known product (or process) would be patentable where the following conditions are met: first, protection of the new use in itself shall not be claimed, but must be anchored in a process or product claim (or both) as required by the Law; second, the new use shall involve an inventive step in comparison to the previous use of the same product or process, and it is insufficient for the use to be analogous to its predecessor; third, the required inventive step may relate to the very concept of the new use of the known product or process or to the method of implementing said concept, or to both of them. The assessment of novelty and inventive step shall be carried out according to the rules and criteria developed in the case law relating to these matters, based on the provisions of Sections 4 and 5 of the Law."

6.10. Biological mechanism of action

a. Definitions

- Biological mechanism of action of a pharmaceutical composition relates to biochemical reactions caused by a pharmaceutical compound having therapeutic (chemical or biological) activity. The mechanism of action is defined by the target (such as a receptor, enzyme, cell) on which the pharmaceutical compound acts.
- Biological mechanism of action of a disease relates to the whole range of the biochemical characteristics of the disease.

Claims directed to a new or alternate mechanism of action of a compound or disease may be formulated as: a known pharmaceutical compound defined by its mechanism of action for the treatment of a known disease; or as a known pharmaceutical compound defined as treating a disease, wherein said disease is defined in terms of its biological mechanism of action.

b. Novelty assessment of claims directed to a biological mechanism of action:

In the assessment of novelty of claims relating to a mechanism of action, the components of the pharmaceutical composition and the disease defined in the claim should be identified (in light of the specification in cases of a claimed functional limitation).

Prior art disclosing the same compound for treating the same disease would deprive the claimed invention of novelty, whether the mechanism of action of either the compound or the disease is mentioned or not. The mere discovery of the mechanism of action of a known compound/composition for treating a given disease does not contribute to the novelty to the invention. Examples for claims, relating to a mechanism of actions, which lack novelty are presented in Appendix 6.1.

c. Emphases regarding a biological mechanism of action

- Administering an identical composition to a patient suffering from the same disease would necessarily lead to an identical effect, since the active substance of the identical pharmaceutical preparation cannot have different properties when used for the same purpose.
- The mechanism of action of a compound for the treatment of a given disease is deemed an inherent feature of said compound. For example, if compound X is used to treat disease Y via a mechanism that was unknown, the mere discovery of the new mechanism would not contribute to the novelty of compound X.
- A claim directed to a pharmaceutical composition for the treatment of a certain disease via a certain mechanism of action would not be deemed novel, so long as the prior art discloses the same pharmaceutical composition for the treatment of the same disease, even where the prior art discloses a different mechanism of action. Hence, defining a different mechanism of action in such claim cannot rectify the lack of novelty deficiency. For example, a claim directed to substance X for the treatment of an eye allergy by stabilizing mast cells activity in the eye lacks novelty where the prior art discloses the same substance X for the treatment of an eye allergy through anti-histamine activity.

d. Cases in which the claimed invention, defined in terms of a biological mechanism of action, would be deemed novel

Claims for a **new and different** implementation from that documented in the prior art, based on the discovery of new biological mechanism of action, would be considered novel in the following cases:

- claims relating to compounds, other than those known with respect to a certain disease, which are found as a result of discovering a new biological mechanism of action, such as siRNA that specifically acts on the mechanism;
- claims relating to a pharmaceutical compound for use in the treatment of a specific type of disease that was not previously known to be treated by this compound;
- claims relating to a new method for diagnosing a known disease, based on the newly discovered mechanism.

6.11. Claims directed to a pharmaceutical composition for a certain target population

Examination of a claim directed to a composition for a therapeutic use defining a certain population, for example:

> A pharmaceutical composition for use in treating cancer in a subject with a cancer having a mutation in EGFR (SEQ ID NO: 1), wherein the mutation is substitution of a methionine for a threonine at position 790; and wherein the pharmaceutical composition comprises an irreversible epidermal growth factor receptor (EGFR) inhibitor.

The following must be accounted for during examination:

a) Is the composition recognized for the claimed indication?
b) Is there a difference in one of the composition's components or its relative part in the composition?
c) Is there a difference in the claimed dosage regimen or mode of administration?

The claim would be lacking novelty only where the answer to question (a) is yes and to questions (b) and (c) is no, and the claimed target population is either explicitly disclosed in the prior art or included in the population of the prior art, and there is no teaching-away prior art excluding the claimed target population from that of the prior art. This is due to the fact that the knowledge on treating the claimed target population is part of the prior art regarding the broad population that includes also the target population. In other words, the use of the pharmaceutical composition is known for treating every subject belonging to the broad population, whether or not belonging to the claimed target population.

- A teaching-away prior art may be general with respect to the claimed target population, such as pregnant women, patients with liver failure, patients with kidney failure, etc. On the other hand, teaching-away prior art may be specific to the claimed target population, such as patients suffering from G6P deficiency (G6PD) treated with a sulfonamide-based antibiotic that results in hemolysis.
- Presenting or exemplifying a surprising effect, such as increased efficiency in the target population, is insufficient to qualify for novelty. In other words, it is rather required that the very possibility of treating said target population would be surprising in order for the claimed invention to be deemed novel.
- In some cases, the prior art relates to a specific population while the claimed invention relates to a broader population (including said specific population) or a different specific population. In such cases, the claimed invention would be deemed novel only where there is no overlap between the population of the prior art and that of the claimed invention. Where the prior art relates to a specific population, the latter must be excluded from the claim to meet the requirements of Section 4 of the Law. Examples for claims regarding a pharmaceutical composition for the treatment of a specific target population are presented in Appendix 6.2.

7. Raising an Objection due to Lack of Novelty

7.1. All objections raised by examiners in the Notice of Deficiencies must be thoroughly reasoned.

7.2. In order to cite an Israeli application under Section 4 of the Law, its publication date according to Section 16A of the Law (or Section 26 of the Law where it was not published according to Section 16A) shall be earlier than the relevant date (see Section 2.3 above) of the application under examination.

7.3. In the reasoning of lack of novelty objection under Section 4 of the Law, the elements in the claim that are disclosed in the prior-art publication should be specified, while indicating the relevant references. Where one or more of the claimed technical features are deemed inherently or implicitly disclosed in the prior-art publication (see Section 6.1 above), a reasoned explanation should be provided.

7.4. The lack of novelty objection should be raised against specific claims rather than the entire claim set.

7.5. A number of publications, depriving the claimed invention of novelty, may be cited in the Notice of Deficiencies, where each one of them (in itself) discloses the claimed invention.

8. Options for the Applicant to Rectify Lack of Novelty Deficiency

The following are a number of examples of possible cases in which the applicant may be able to rectify a lack of novelty deficiency.

a. According to **Regulation 42**, the applicant is entitled to indicate why he is not required to rectify the deficiencies and provide a reasoned explanation in support of that.
b. The applicant is entitled to delete the claims lacking novelty.
c. According to **Regulations 22 and 42**, the applicant is entitled to amend the claims, while providing a reasoned explanation of how the amendment renders the claimed invention novel.

These examples are not to be deemed binding guidelines and any response from the applicant and/or change in the claim set should be reexamined in view of the other guidelines set out in this appendix, as well as all other relevant examination guidelines.

Appendix 6.1

Example 1

Compound X for the treatment of disease Y via a new mechanism not disclosed in the prior art is claimed. The claim under examination recites:

> A medicament comprising IGF-1 for use in reducing the loss of glial cells or non-cholinergic neuronal cells suffered after a CNS insult.

The prior art does not relate to the mechanism, for example:

> The use of IGF-1 in the treatment of a CNS insult.

Example 2

A compound acting via mechanism Z for the treatment of a disease defined by mechanism W is claimed. The prior art discloses compound X for the treatment of disease Y. The claim shall be interpreted according to the provisions of Section 13(b) of the Law. Novelty would be lacking where the description of the application discloses (*inter alia*) the use of compound X as an example of a compound acting via mechanism Z for the treatment of disease Y characterized by mechanism W. The claim under examination recites:

> Selective serotonin reuptake inhibitor compounds for the treatment of patients having an imbalance in serotonin levels in the brain.

The prior art discloses compound X for the treatment of disease Y:

> Paroxetine for the treatment of depression.

The application's specification clearly indicates that these mechanisms of action (Z and W) include said compound X (e.g., Paroxetine as in the present example) for the treatment of disease Y (e.g., depression as in the present example).

Example 3

Compound X for the treatment of disease Y via mechanism Z is claimed. The claim under examination recites:

> Leflunomide capable of reducing dihydroorotate dehydrogenase (DHODH) enzyme activity in the central nervous system (CNS) for use in the treatment of Alzheimer's disease.

The prior art discloses the use of the same compound X for the treatment of disease Y by way of a different mechanism T:

> Leflunomide capable of inhibiting the synthesis of IL1-β for use in the treatment of Alzheimer's disease.

Example 4

Compound X characterized by a mechanism is claimed. The claim under examination recites:

> Compound X for use in inhibiting enzyme Y.

The application's specification or common general knowledge in the field links inhibition of enzyme Y to a specific disease (Z) or a group of specific diseases (including Z).
The prior art discloses the same composition (X) for the treatment of disease Z:

> Compound X for use in treatment of disease Z.

Note: the connection between the enzyme's inhibition and the specific disease must be clear to the examiner. Where a clear definition is lacking, an objection should be raised indicating the lack of clarity as to what therapeutic need the medicament is intended.

Appendix 6.2

Example 1

Claim 1: A pharmaceutical preparation for use in treating gastrointestinal disorder in a male subject by administration of a therapeutically effective amount of balsalazide.

Use of the same active ingredient for the same type of treatment for the general population is known in the prior art. In this case, an objection should be raised under Section 4 of the Law, since the population of male subjects is included in the general population and no prior art teaches away from using the same active ingredient for the male subjects.

Example 2

Claim 1: Topical pharmaceutical composition in the form of a hydroalcoholic gel comprising testosterone, for the treatment of hypogonadism in an adolescent boy.

The therapeutic composition is known in the prior art for use in men, and it was clear to a person skilled in the art that said medicament was intended only for a population of adult men, as the absorption mechanism of the medicament in adolescents differs from that in adult men. As the claim relates to a population consisting of adolescent men, and, in light of the prior art, a person skilled in the art would not have included said adolescent men in a population of men for the claimed treatment. Therefore, the claim meets the requirements of Section 4 of the Law.

Example 3

Claim 1: live attenuated Aujeszky-virus vaccine for intranasally protecting maternally immune pigs against Aujeszky's disease.

A composition for vaccinating a non-immune population of pigs (those pigs whose serum test negative for antibodies to the virus) is known in the prior art.
A population of maternally immune pigs is different from the population of unvaccinated pigs, since the serum of the former population is positive for antibodies to a said virus.

Therefore, a person skilled in the art would not have included the claimed population of pigs for the claimed treatment. Thus, the claim meets the requirements of Section 4 of the Law.

Example 4

> Claim 1: Diagnostic agent comprising Adenosine for use as a pharmacological stressor for detecting the presence, or assessing the severity, of vascular disease of coronary arteries by parenteral administration to a human who is unable to exercise adequately in conjunction with radioimaging of the coronary arteries wherein the adenosine is in unit dosage form, comprising from 20 to 200 Fg/kg/min of the compound when formulated for intravenous administration or from 2 to 20 Fg when formulated as a bolus for intracoronary administration.

A composition for use as a pharmacological stressor was known in the prior art without limitation to a specific population. The target population consists of individuals incapable of performing sufficient physical activity. This does not preclude a person skilled in the art from including said population in the general population. Thus, an objection under section 4 of the Law should be raised in this case.

Example 5

> A compound for use in a method of treatment, comprising: Administering Lorcaserin hydrochloride to an individual, wherein said individual has a level of renal sufficiency within a group of renal sufficiency levels consisting of: no renal impairment, mild renal impairment and moderate renal impairment, and wherein said treatment is selected from a group consisting weight management, prevention of obesity or treatment of obesity.

A compound for preventing or treating obesity is known in the prior art without defining a specific population. It is also known in the prior art that the compound has renal clearance. Since a person skilled in the art would have included at least the population with no impaired kidney function within the general population, an objection under Section 4 of the Law should be raised.

Example 6

> A compound for use in a method of treatment, comprising: Administering Lorcaserin hydrochloride to an individual, wherein said individual has moderate renal impairment, and wherein said treatment

is selected from a group consisting weight management, prevention of obesity or treatment of obesity.

A compound for preventing or treating obesity is known in the prior art without defining a specific population. It is also known from the prior art that the compound has renal clearance. In the absence of information in the prior art regarding the safety of the treatment of patients suffering from renal impairment, a person skilled in the art would not have included the subpopulation of individuals having moderate renal impairment in the general population. Therefore, the claim meets the requirements of Section 4 of the Law.

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 7 - Section 5 of the Law - Inventive Step

References and documents relating to inventive step: Sections 3, 4 and 5 of the Patents Law, CA 345/87, **Hughes Aircraft Company v. the State of Israel** IsrSC 44(4) 045 (1990) (hereinafter: "the Hughes Ruling"), CC (Beer Sheva) 21/83 **Gershon Ackerstein et al. v. Alumim** IsrDC 5749 (c) (197) (hereinafter: "the Ackerstein Ruling"), CA 8802/06 **Unipharm v. Smith-Kline** (dated 18.5.11) (hereinafter: "the Unipharm Ruling"), CA 314/77 **L.M. Lipski Ltd. v. Natan Manor** 32(1) 205 (hereinafter: "the Lipski Ruling"), Commissioner's decision on patent application 23921 Arad Ltd. (hereinafter: "the Decision on 23921"), Commissioner's decision on patent application 24862 **The Consultant** (hereinafter: "the Decision on 24862"), Commissioner's decision on patent application 105041 **Vargos** (hereinafter: "the Decision on 105041"), Commissioner's decision on application 136294 **Teva Pharmaceutical Industries Ltd. v. Pharmacia & Upjohn AB** (hereinafter: "the Decision on 136294"), Deputy Commissioner's decision on application 190482 **ECOLAB INC.** (hereinafter: "the Decision on 190482"), Commissioner's decision on the objection to patent application 176831 **Unipharm Ltd. v. NOVARTIS AG** (hereinafter: "the Decision on 176831").

1. Introduction

1.1. This appendix specifies Examination Guidelines relating to the assessment of an inventive step in patent application claims according to the provisions of Section 5 of the Law, as well as court rulings and decisions of the Patent Office pertaining to the provisions of this section of the Law.

1.2. Section 3 of the Law prescribes:

> "An invention, be it a product or a process in any field of technology, which is novel and useful, has industrial application and **involves an inventive step**, is a patentable invention."[1]

Section 5 of the Law prescribes:

> "An inventive step is a step which does not appear obvious, to an average skilled person, in the light of information made available to the public before the application date in ways said in Section 4."

[1] The emphasis (bold text) does not appear in the original text.

1.3. These guidelines apply to applications examined according to the provisions of Sections 17(a)(1) and 17(a)(2) of the Law.

2. General

The requirement of an inventive step is a (cumulative) requirement in addition to the requirement of novelty, meaning, the novelty of the invention is insufficient to justify granting a patent and it is required to show that along with the difference that entitles the invention to novelty, the invention as a whole is not obvious to an average skilled person, in light of the prior art. Similar to the issue of novelty, the issue of an inventive step should be addressed in light of publications made available to the public prior to the relevant date (the priority date or the date of filing of the application if no right to priority is claimed, or the date of amendment of a certain claim where substantive amendment is made under Section 23 (i.e., a new subject matter is introduced))).

In the assessment of inventive step, the definition of "an average skilled person" and "information made available to the public", and the determination whether the claimed invention is obvious based on the relevant tests should be taken into consideration.

3. An Average Skilled Person

An average skilled person is a person crafted by the law.[2] The average skilled person has access to all publications in the technological field that is relevant to the invention and in the fields that are very close to the field of the invention, which were made available to the public up to the relevant date; is familiar with all the practices that are generally accepted within the same field on the relevant date; and is familiar with all prior art in the field, in his capacity as an engineer, technician or worker; and would be ordinarily called to treat the problem the invention is intended to solve, but is unable to invent on his own.[3]

As was interpreted in the Hughes Ruling, a skilled person may also be a team of experts working in different fields and who are used to consulting with one another. In order for a skilled person to be considered a team, it is required to establish that the expert within the main field of the invention is coping with a technical

[2] Regarding an average skilled person, the Supreme Court ruled in its decision in the Hughes Ruling: "The person, to whom the question of inventive step is addressed, is "the average skilled person", meaning an individual (or team of persons, where such is required), who is an expert in the details of the relevant field, however does not exercise inventive thinking skills. This ("reasonable") fictitious figure may be given a different content in a professional or scientific field, these or others, depending on the technical or research nature of these."

[3] In the Decision on 136294 it was stated that "Determining the identity of the average skilled person within the domain shall be made vis-à-vis the technical skills required to carry out the invention."

problem that he cannot solve with his own technical knowledge alone and that he would consider being assisted by an expert from another field.

4. Information Made Available to the Public

The definition of the information that was already made available to the public for the purposes of Section 5 of the Law is identical to its definition for the purposes of Section 4 of the Law (see Appendix 6 - Section 4 of the Law – Novelty).

5. Assessment of Inventive Step

5.1. Methodology

In order to determine whether the claimed invention would have appeared obvious to an average person skilled in the art, the examiner is required to follow four basic steps:

a. identification of the inventive concept of the invention at hand;
b. identification of the prior art relevant to the invention at hand and the level of knowledge of the average skilled person;
c. identification of the differences, if any, between the prior art and the elements of the claimed invention; and
d. determining whether the invention, based on the differences identified in the previous step, would have appeared obvious to the average skilled person without introducing new knowledge from the invention at hand.

It should be noted that this methodology does not replace the requirement of the Law, according to which the invention shall involve inventive step that does not appear obvious to the average skilled person and in appropriate cases other tests may also be used in the assessment of inventive step.

5.2. Combining publications

Generally, the claimed invention may be deprived of inventive step by combining two or more prior-art publications, where the average skilled person would normally and routinely think that they should be combined.[4]

Where more than three prior-art publications need to be combined in order to arrive at the claimed invention, there is a doubt as to whether this combination is obvious, and the doubt increases with the increase in the number of prior-art publications to be combined for depriving the claimed invention of inventive step. However, there may be cases in which it is justified to combine a relatively large number of prior-art publications, especially when it comes to well-known components.

In combining prior-art publications, as well as in the process of analyzing and assessing the inventive step in light of these publications, the following four rules shall be taken into account, all of which are relative and from which there may be deviations in relevant cases:

a. Where one of the publications cites another in a general manner, or includes a hint for an element of the invention that is missing in it while the missing element is disclosed in another publication, the combination of publications is required.

b. It is permissible to combine two publications, one of which describes an element or elements similar to the elements of the claimed invention, and the other publication describes the element(s) (feature(s)) missing in the first publication as part of a product or process in a relevant art identical or close to that of the first publication.

Relevant field of knowledge for combination – all the prior art that an average skilled person in the field of the invention would deem relating to solving a problem, achieving a goal or implementing a particular technical feature in industry. This prior art is usually in the same technological field, but there may be cases where prior art from different technological fields relates to solving a problem or to a well-defined technical feature common to different fields. Therefore, this kind of prior art would also be considered as being within the field of knowledge entitled to combination even if originating from products/processes in different industries.

[4] Regarding combining prior-art documents, see for example Hughes Ruling that states: "In determining on the question of inventive step the whole professional knowledge in the relevant field shall be examined, and for doing so it is permissible to combine prior-art publications together into a whole picture. The aforementioned act of combining should also be obvious to a skilled person on the relevant date. Where an inventive step is required for this purpose - especially where such involves gathering pieces of information from various sources - the whole picture would not be obvious, and it cannot be said that the invention in the patent involves an inventive step."

c. Where there is a contradiction resulting from the combination of prior-art publications, they shall not be combined (and this may even indicate the involvement of an inventive step). Where the prior art teaches the average skilled person away from the invention, the invention may be in contrast to what is generally accepted within the relevant field.

d. It is permissible to combine a publication(s) with common general knowledge within a particular technological field, such as: textbooks, review articles or technical standard specifications.

5.3. Approaches and auxiliary tests for examination

According to the Hughes Ruling:

> In determining on the question of an inventive step it is permissible to be assisted by auxiliary tests, and notwithstanding the fact that they are inconclusive, they may present an indication and assist in this ruling, while cautiously implementing them under the special circumstances of each and every case, and as the issue concerns a more complex and complicated technological field so would the tendency to turn to these tests increase".

Some of the auxiliary tests[5] as well as additional circumstantial approaches may be used by the examiner in examining the question of an inventive step, as detailed below:

5.3.1. Combination/collocation of components or duplicating parts

The question of combining components was discussed in the Hughes Ruling, where it was ruled:

> "The essence of case law within this field concerns the distinction, which is not always easy, between a combination of components that is patentable, and collocation of components that do not interact for achieving the same goal of a novel and inventive invention."

In the Decision on 24862, the Commissioner ruled that mere collocation (aggregation) of elements does not involve an inventive step:

> "This concerns connecting two components which were previously separate and placing them side by side, as each of them performs its ordinary action, with no interaction between them;

[5] Commercial success, which is among these tests, is generally not a question on which an examiner is able to decide.

which is distinct from combination that results from an interaction between the components, thus qualifying for an inventive step."[6]

It should be emphasized that in the case that was deliberated upon in the Commissioner's decision, there was indeed a combination involving an inventive step, but the existence of a combination does not necessarily indicate that the invention is not obvious.

The Ackerstein Ruling also discussed the combination of components, and ruled that:

"The invention subject of the patent concerns a combination of known accessories, in order to form an irrigation and dripping pipe. Where the issue concerns an invention combining known elements, the question becomes more acute as of whether it is obvious, and the difficulty in determining whether the proposed novelty includes an inventive step increases. Indeed, case law in the United States placed more rigid tests regarding the assessment of inventive step for an invention that combines known elements. In order for the combination not to be obvious, it is necessary that its "end result" would be greater than the total contribution of the various elements comprising it [...] As to the practical benefit of this test, doubts were already raised."

An invention based on duplication of known parts would also be deemed lacking an inventive step where there is no indication of an unconventional and/or non-trivial result arising from the duplication.

5.3.2. Equivalent components

An argument regarding the lack of an inventive step may be based on a publication that does not describe certain technical features of the claimed invention, but describes equivalent components that constitute obvious alternatives for an average skilled person. In this case, it is required to refer to an additional publication or common general knowledge to show that these features are equivalent.

5.3.3. Overcoming difficulties

The Supreme Court ruled in the Lipski Ruling that it is possible to acknowledge the inventive step for an invention concerning a new use of a known device where implementation of the

[6] The emphasis (underlined bold text) does not appear in the original text.

new use in respect of the known device involves overcoming new difficulties or adaption thereof to the new implementation.

5.3.4. Obvious to try

The "obvious to try" test is a customary test in Israeli law for the assessment of inventive step.[7] In order to determine whether it would have been obvious to act in an identical manner as outlined in the application, the examiner is required to examine whether the following three conditions were met on the relevant date (see the Decisions on 136294 and 136532):

a. there was a known problem in the field requiring solution;
b. the components of the experimental process for achieving the solution to the problem were known; and
c. an average skilled person in the art would have conducted the experiment for achieving the solution with a reasonable expectation of success, wherein the level of reasonableness of success would be determined according to the other circumstances of the matter.

In the Decision on 136294, it was ruled:

"Determination that an invention lacks an inventive step does not require that the path chosen by the applicant for the discovery of the invention would necessarily ensure him discovery of the invention. It is sufficient that there is some degree of reasonableness of success, the degree of which would be determined in accordance with the other circumstances of the matter, in order to arrive at the conclusion that it would have been obvious to try and reach the invention in the manner the applicant chose."

In order to avoid ex post facto analysis in exercising this test, similarly to the criteria required for examining the sufficiency of disclosure under Section 12 of the Law, it is required to examine the reasonable number of experiments and the reasonable number of paths a person skilled in

[7] See, *inter alia*, Commissioner's decisions (concerning applications 2578, 86979, 101162, 109059, 129097, 133137, 135417, 136532, 136294, 142789 and 153109), District Court rulings (OA 001048/05 Maytronics Ltd. v. Aquaproducts Inc. dated 16.03.2006 on Application 112858, OA 262/09 Beecham Smith-Kline v. Unipharm Ltd. dated 19.05.2011 on application 131392 and COA 35096-09-10 Merck Sharp & Dohme Corp. v. Unipharm Ltd. dated 19/06/2012 on application 153109) and Supreme Court rulings (LCA 6837/12 Merck Sharp & Dohme Corp. v. Unipharm Ltd. dated 28.04.2013 on application 153109).

the art would have been required to perform the invention in view the prior art while taking into account the reasonableness of the expectation of success.

Where an objection is raised on grounds of lack of an inventive step based on the "obvious to try" test, presentation of any general advantage (for example, an improved feature in general) by the applicant would not rectify this deficiency. In these cases, the applicant is required to prove that the manner/path chosen in performing the invention is not obvious. In other words, he is required to indicate the new step which is required to perform that was not customary on the relevant date, and/or present the difficulty he was able to overcome in a manner that is different from what is customary, and/or reveal the improved feature that was not customary to obtain along the process.

5.3.5. Unexpected effect and advantage

In cases where the elements defining the invention are obvious in view of the prior art (for example where there is very close proximity to prior art so that the change is obvious, or for example in the cases listed in Section 6.5. of Appendix 6 of the Examination Guidelines, or for example an invention concerning a dosage regimen, etc.) an inventive step may be acknowledged based on an **unexpected advantage**. In order to establish a basis for an unexpected advantage, the applicant is required to exemplify it, using comparative data and explaining its existence compared to the expected result from the prior art. It is required to establish that the advantage stems from a new feature (or combination of features) that is common to the entire claimed scope, so it may be assumed that this advantage exists in all the components of the claimed group.

Where the prior art **explicitly** directed the average skilled person to take a path that would lead to the claimed invention, the existence of the surprising advantages does not overrule the conclusion on lack of an inventive step.

However, where the exemplified advantage is expected in light of the prior art (for example, an element known for its ability to be combined with other elements and is known to grant the combined products the exemplified advantage) it cannot be established that the invention involves an inventive step. Meaning, this expected advantage is insufficient for determining that the invention is non-obvious.

An **unexpected effect** may also be taken into account in the assessment of inventive step without the need of demonstrating an advantage where there is a prior art, the teaching of

which explicitly leads away from the invention, based on which the skilled person would expect that the claimed invention would be ineffective or have undesirable properties (for example: an element that was expected to lead to a significant decrease in activity). In view of this teaching away prior art, demonstrating that the invention can be put into practice and is effective within the claimed scope is an unexpected result in itself. Therefore, this may qualify for an inventive step even in the absence of an advantage, for example, where the activity obtained is similar to the activity known in the field, but the teaching away prior art indicates that there would be no activity.

An unexpected effect may also be taken into account in the assessment of inventive step without the need to be supported by comparative data where this result cannot be compared with prior art. For example, in the event where a different activity was unexpectedly obtained that allows for different or additional uses. On the other hand, an unexpected effect in light of prior art, which constitutes an undesirable technical effect, cannot in itself qualify for an inventive step. For example: an unexpected decrease in the required activity of the product.

Where an unexpected advantage of the invention is indicated and specified in the specification, but without providing examples supporting it, the examiner is entitled, for the assessment of inventive step, to take into account supporting data that he may receive during the examination. Where the specification does not include an indication to an unexpected advantage, or what that unexpected advantage is, and a skilled person would not conclude the existence of this advantage by reading the application's specification or relate it to the technical problem presented therein, the examiner should not acknowledge supporting data provided by the applicant during the examination (regarding introducing additional data to the application's description, see EG- 23.1/19).

5.3.6. Teaching away

Where the prior art teaches the skilled person to refrain from making the changes required in order to arrive at the claimed invention in the application under examination ("teaching away"), this prior art cannot in itself serve against the application's inventive step, and could even support the invention's non-obviousness.

The following are examples for cases of teaching away:

a. an explicit statement in prior art against making the required change in order to reach the invention claimed in the application under examination, for example, a statement that this change is likely to impair the activity or features of the product or process;
b. data and results in a prior art that constitute an indication for the skilled person that there is no viability in making the change, for example, data relating to similar or close changes to the change that was made in the invention under examination, indicating an impairment of the activity or properties of the product or process;
c. a statement or data in a prior art relating to a substantial technical difficulty in making the change; and
d. a teaching in a publication leading the skilled person to make completely different changes from the change made in the invention under examination, in order to obtain the same result.

However, an objection may be raised against the inventive step of the claimed invention despite the existence of a teaching away publication where there is an additional close publication that explicitly cures the teaching away presented in the former publication, for example, a publication indicating additional data according to which the skilled person would understand that the required change would provide a desirable result despite the indication in the teaching away publication in itself.

5.3.7. Overcoming technical difficulties and previous failures

A technical problem that has been waiting for a long time for a solution may indicate an inventive step where the inventor is the first to solve it and many have failed to solve it before. In this regard, in the Decision on 105041 it was ruled:

"The fact that the development of the device required (according to Mr. Hirsch's affidavit) time, resources and many attempts by a skilled person in order to arrive at the new product indicates, *inter alia*, that the invention before us involves an inventive step, and the development would not have been obvious based on information already available on the filing date of the application. There were restrictions on access to internal screwing in the cylindrical shanks, and this invention overcame and solved the aforementioned access limitations."

Special technical difficulties, the solution to which requires great investment in terms of time, resources and many attempts may indicate the involvement of an inventive step.

Failed attempts by others to achieve the result promised by the invention under examination may also indicate the involvement of an inventive step.

5.3.8. Specific emphases concerning the biotechnology field

5.3.8.1. Cloning and identifying sequences similar to a known sequence by hybridizing nucleotide sequences is a known process. Even where there is difficulty in applying hybridization, it should be taken into account that identifying similar sequencing may be accomplished by computational methods against the background of sequence libraries and even of an entire genome or all sequences published so far and thus there is no inventive step. An inventive step may be acknowledged where it involves a segment that provides unexpected advantages.

5.3.8.2. Preparation of an orthological sequence in itself from another variety, species or genus is considered obvious, since the existing methods enable identifying required sequences that are significantly structurally similar based on hybridization, cloning and isolation thereof.[8] An inventive step may be acknowledged where the origin, meaning the variety, species or genus, was unknown. Additionally, an inventive step may be acknowledged where there is a great difference between the sequences and there is no substantial structural similarity that enables preparation of the orthological sequence.

5.3.8.3. Isolation of additional homologous sequences *per se* in a known protein family is considered obvious, since the methods of doing so are routine (for example, by hybridization).[9] An inventive step may be acknowledged where the degree of identity is significantly lower than that expected of a family member, and the activity is different from that known in that family.

5.3.8.4. Identification of sequences within known sequences and identification of gene activity by homologous comparison to a gene or genes with known activity are considered obvious.

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[8] *Paresh D. Patel, Thomas G. Sherman, Daniel J. Goldman, and Stanley J. Watson, Molecular Cloning of a Mineralocorticoid (Type I) Receptor Complementary DNA from Rat Hippocampus, 3(11) MOL ENDOCRINOl 1877 (1989).*

[9] *Evan S. Deneris, Jim Boulter, Larry W. Swanson, Jim Patrick, and Steve Heinemann, Beta 3: A New Member of Nicotinic Acetylcholine Receptor Gene Family is Expressed in Brain, 264(11) J. BIOL CHEM.*

Usually, the entire tools of bioinformatics enable identification of such sequences (this field is also known as data mining)[10]. Service software available to the public on the NCBI website, for example BLAST with its different variations, enables performing identification of sequences within known sequences. The same is true in respect of identifying gene activity by homologous comparison to a gene or genes with known activity. In genomic banks, such automatic identifications are routinely conducted and presented, and there are many publications within the field[11]. In such cases, an inventive step would be acknowledged only in claims that link the sequence or gene to functionality that is non-obvious.

5.3.8.5. Mutant sequences are considered obvious. Preparation of mutations is a well-known matter, and it is even known to synthetically prepare entire genes. In order for a mutant to be acknowledged as involving an inventive step, it must have an unexpected advantage in view of the prior art. Usually, not only one mutant is claimed, but rather a group or groups of mutant sequences and the aforesaid applies to all. In this regard, it is required to show that all sequences of the group have an unexpected advantage arising from the feature common to the sequences (selection of the group sequences is not arbitrary)[12].

5.3.8.6. For a unique combination of micro-arrays and probes to be acknowledged as involving an inventive step, it is required to have an unexpected advantage. For example, using a combination of probes providing a more accurate detection of a disease in comparison to using each and every probe separately (which is an example of a synergistic effect) is considered to involve an inventive step.

5.3.9. Pharmacokinetic features

[10] *Stephen F. Altschul, Warren Gish, Webb Miller, Eugene W. Myers, and David J. Lipman, Basic Local Alignment Search Tool, 215(3) J. MOL. BIOL. 403 (1990).*

[11] Weidong Tian, Adrian K. Arakaki, and Jeffrey Skolnick, EFICAz: A Comprehensive Approach for Accurate Genome-Scale Enzyme Function Inference. 32(21) NUCLEIC ACIDS RES. 6226 (2004); Chuan-Ching Huang, Chun-Yuan Lin, Cheng-Wen Chang, and Chuan Yi Tang, Enzyme Reaction Annotation Using Cloud Techniques, 2013 BIOMED RES INT; Robert D. Finn, Jody Clements, and Sean R. Eddy, HMMER Web Server: Interactive Sequence Similarity Searching, 39 NUCLEIC ACIDS RES. W29 (2011); Walter C. Dunlap, Antonio Starcevic, Damir Baranasic, Janko Diminic, Jurica Zucko, Ranko Gacesa, Madeleine J H van Oppen, Daslav Hranueli, John Cullum, and Paul F Long, KEGG Orthology-Based Annotation of the Predicted Proteome of Acropora Digitifera: ZoophyteBase - An Open Access and Searchable Database of a Coral Genome, 14 BMC GENOMICS 509 (2013).

[12] Takao Tsuji, Takashi Inoue, Akio Miyama, Keinosuke Okamoto, Takeshi Honda, and Toshio Miwatani, Single Amino Acid Substitution in the A Subunit of Escherichia Coli Enterotoxin Results in a Loss of its Toxic Activity, 265(36) J. BIOL CHEM. 22520 (1990) Dec 25; Andrew F. Worrall and Bernard A. Connolly, The Chemical Synthesis of a Gene Coding for Bovine Pancreatic DNase I and its Cloning and Expression in Escherichia Coli, 265(35) J. BIOL CHEM. 21889 (1990).

Where a claimed composition comprising an active compound is characterized also by its pharmacokinetic features, and there is a prior-art publication disclosing a composition comprising the same active compound and additives similar or alternative (unidentical) to the composition described in the application under examination, without disclosing the pharmacokinetic features, an objection regarding lack of an inventive step shall be raised. This objection can be overcome where the applicant proves that the claimed preparation has an unexpected advantage over that disclosed in the prior art.

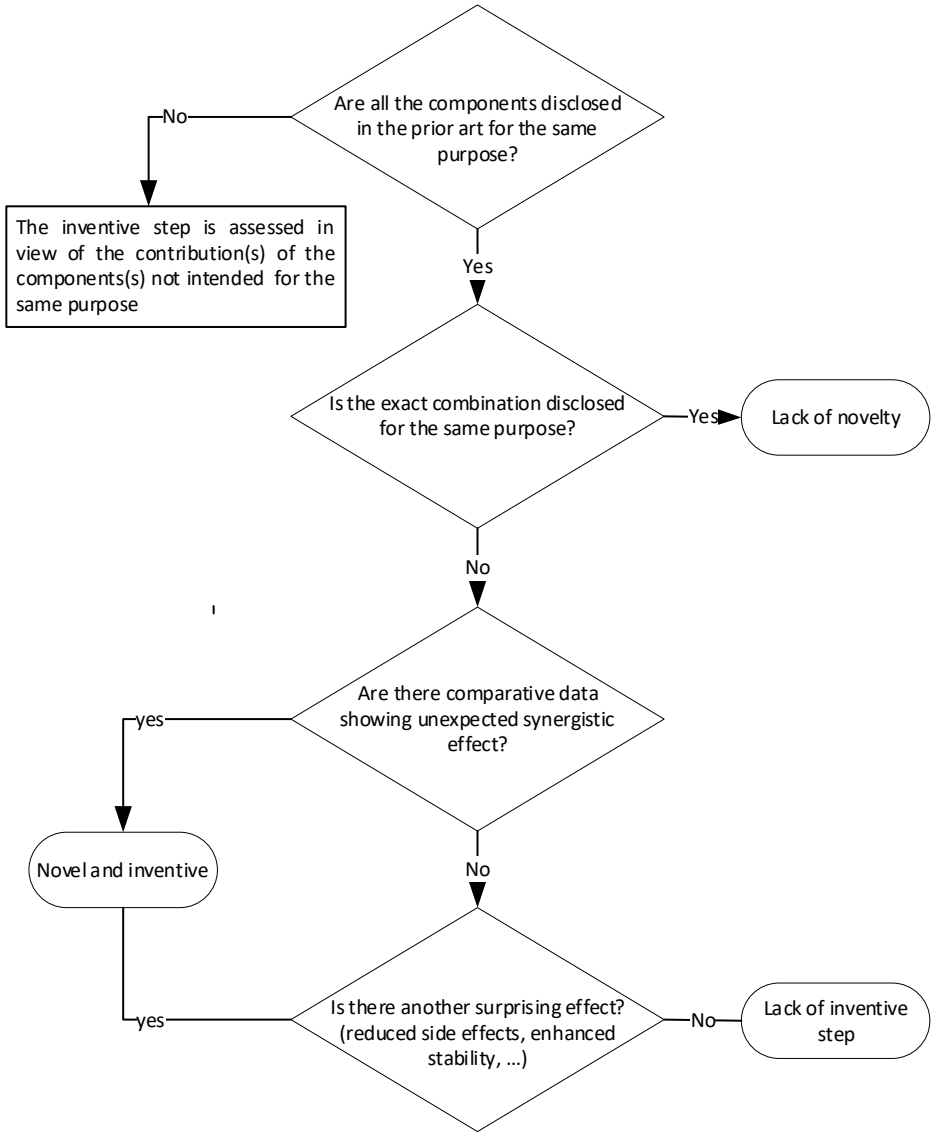
It should be emphasized: where the components of the composition in prior art are identical to those of the claimed composition, even where the pharmacokinetic features are different, the claimed composition would lack novelty. However, where the claim does not define the elements responsible for the claimed pharmacokinetic features, and the application's specification indicates that a difference in the ratio between the claimed components, the dosage form (liquid or solid) or the particle size, leads to the changes in the pharmacokinetic features, the claimed composition shall be examined according to Section 13(b) of the Law, based of which the assessment of inventive steps should be made.

5.3.10. Different effects arising from combining components

5.3.10.1. Stating the effect, such as synergy, in the claims or the specification does not necessarily contribute to novelty (see also Appendix 6 - section 6.1.2) and an inventive step.

5.3.10.2. An inventive step in a claim concerning the combination of several components should not be acknowledged where the prior art does not describe the claimed combination or where the combination of the components is described in different quantitative ratios than those in the claim (or without specifying quantitative ratios at all).

5.3.10.3. Where the components of the combination in the invention are disclosed separately in the prior art in separate products or processes for the same use, without disclosing the combination thereof, and the application's specification does not describe an unexpected effect arising from combining the components, the examiner shall still raise an objection of lack of inventive step.


Are all the components disclosed in the prior art for the same purpose?
No
The inventive step is assessed in view of the contribution(s) of the components(s) not intended for the same purpose
Yes
Is the exact combination disclosed for the same purpose?
Yes
Lack of novelty
No
Are there comparative data showing unexpected synergistic effect?
yes
Novel and inventive
No
Is there another surprising effect? (reduced side effects, enhanced stability, ...)
yes
No
Lack of inventive step

5.3.10.4. Where it is claimed or argued by the applicant that the defined combination includes a synergistic[13], potentiating[14], antagonistic[15] or other[16] effect, it is required to ensure that there is support of the effect in the application's description, such as examples showing a synergistic, antagonistic, potentiating or other effect, including, for example, a comparison between computational data (according to a formula such as Colby, etc.) and experimental data in respect of the combination's activity, as well as a comparison between the activity of each of the components and the activity of the combination of the same claimed components. Regarding the receipt of external data that support the argument of an unexpected effect of a combination, see the guidelines in Section 5.3.5 above.

5.3.10.5. Where the application's examples present data which show that no synergistic effect exists within the entire claimed range, an objection of lack of inventive step against the claim should be raised in light of these data. For example, a lack of inventive step objection should be raised where a claim relates to a mixture with a synergistic effect in the range of ratios of 1:10-10:1, while the specification demonstrates, *inter alia*, that within the range of the ratios of 1:10 - 1:5 there is no synergistic effect.

5.3.10.6. In reasoning the objection of lack of an inventive step, it is possible to be assisted by common general knowledge in the relevant field and in publications 11 through 19 listed in section 9 of this appendix.

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[13] Synergistic effect - an effect that is obtained by a combination of components that is greater (enhanced) effect than the sum of the effects of each of the components separately. This effect may lead to advantages, but also to unexpected over-influence.

[14] Potentiation - where one component, which is ineffective on its own in eliciting an effect, but enhances the effect of the other component(s) of the combination. The difference between potentiation and synergism is the lack of effectiveness of the enhancing component in itself, with respect to the same purpose, compared to the independent activity that all the components participating in synergism have also when being separate. It should be noted that in some cases the term potentiation is used in literature also for describing synergism and in other cases even these terms are used as synonyms. For the purposes of examination, the two terms are not identical nor corresponding and a distinction must be made between the two effects (potentiation vs. synergism). An example of potentiation: use of antibiotics from the penicillin group together with clavulanic acid in order to treat bacteria with beta lactamase resistance mechanism. The clavulanic acid alone is ineffective but it potentiates the antibiotic effect of penicillin. Another example of potentiation: substances with an entourage effect.

[15] An antagonistic effect - where the effect obtained by combination of the components is less than the sum of the effects of each of the components separately. Where one component is active and the other component inactive on its own but inhibits the activity of the active component, it is a particular case of antagonism where the sum of the effects of each of the components individually is equal to the effect of the active (first) component.

[16] There are cases in which a beneficial effect may arise from a combination even though it does not change the effectiveness of the components in achieving the goal for which the combination is claimed (and therefore does not belong to definitions of synergism, potentiation or antagonism). Examples of such beneficial effects: increasing the stability of a compound of substances (extending shelf life), reducing wear and tear of components as a result of their combination, reducing side effects or eliminating undesirable secondary results of a system.

5.4. Additional emphases

5.4.1. The claimed invention should not be deprived of inventive step only since the invention is simple or does not constitute a breakthrough. As ruled in the Hughes Ruling:

> "The required step, in order for it to be non-obvious, does not have to be great: an inventive step is indeed required, but it is sufficient to be modest and small. The simplicity of the invention should not serve as an obstacle to its patentability."

5.4.2. The affidavit of a person skilled in the art filed by the applicant in response to an objection due to lack of an inventive step is equivalent (as administrative evidence) to any other type of response filed by the applicant; should the examiner find that the affidavit does not establish a basis for an inventive step, he shall indicate and provide reasoning for this in a Notice of Deficiencies.

5.4.3. Ex post facto analysis (hindsight vision) - in the assessment of inventive step in view of the prior-art publications, the examiner shall avoid relying on insights, conclusions and/or supplementary knowledge arising from the application under examination.

Case law addressed this impermissible reliance several times in the Hughes Ruling the Court instructed that:

> "One should be cautious in analyzing prior art while using, and not subconsciously, the new knowledge brought along with the patent, meaning use of "ex post facto analysis."

This means that it is required to "forget" the invention and try to think how an average skilled person would solve the technical problem in light of the prior-art publications in order to arrive at the claimed invention. It should be noted that the fact that something has not been tried does not necessarily constitute a teaching away (see in this regard Sections 60 and 61 of the Decision on 176831).

5.4.4. In raising an objection regarding lack of an inventive step, the examiner is required to provide reasoning as to the obviousness of the invention in light of the prior art. Only after presenting well-founded reasoning, the examiner is entitled to request the applicant to provide evidence in support of the inventive step by presenting an unexpected advantage, comparative data or in any other manner).

5.4.5. An objection due to lack of an inventive step cannot be based on the grounds that the claimed invention has no advantage or (surprising or unsurprising) effect without explaining why the invention is in view of the prior art according to the principles set out in this appendix. In this regard, it was ruled in the Decision on 190482:

"It is not necessary that the invention achieves its goal in a manner that is better than the manner prior art revealed, and it is sometimes sufficient that the invention performs it in a different manner, wherein that change is not obvious to the average person skilled in the art".

5.4.6. Lack of support of one or more of the elements of the claimed invention in the specification constitutes a deficiency under Section 13(a) of the Law, and cannot in itself constitute a basis for an objection regarding an inventive step.

6. Raising an Objection due to Lack of an Inventive Step

6.1. In order for an Israeli application to be cited under Section 5 of the Law, it is required that the date of its publication in Israel according to Section 16A of the Law (or Section 26 of the Law where it was not published according to Section 16A) is earlier than the relevant date (see Section 2 above) of the application under examination.

6.2. The dependent claims often define a patentable invention for which no objection need to be raised due to lack of an inventive step. Therefore, this objection shall be raised against specific claims rather than the entire claim set. However, in the relevant cases an objection on grounds of lack of inventive step may be raised against a group of claims based on the same reason, where the group addresses arbitrary technical features, known equivalent alternatives, structural changes and/or processes (including routine experimentation) that an average person skilled in the art routinely conducts, provided the specification does not describe or exemplify a substantial and unexpected advantage with respect to these features.

6.3. Every objection raised by the examiner in the Notice of Deficiencies shall be well-reasoned.

Where an objection is raised based on one prior-art publication combined with common general knowledge, it is required to specify the elements of the claim that are disclosed in the publication, indicate the elements missing in the publication (the gap or difference between the publication and the invention), indicate that the missing elements are deemed common general knowledge in the field, and to specify the motivation for an average skilled person to add the missing elements in implementing the teaching of the publication.

Where an objection is raised based on a combination of prior-art publications, usually, the first publication (the main publication) is the publication that constitutes the best starting point from which an average skilled person would reasonably achieve the invention. It is not necessary that the first publication (the main publication) be the one including a greater number of the invention's elements or features, and it is also not necessary that the first publication would be the closest to the invention.

In raising an objection based on a combination of prior-art publications, it is required to specify the elements of the claim disclosed in the first publication, indicate the missing elements in the publication (the gap or difference between the publication and the claimed invention), how they may be taught from the other publication(s) and specify the motivation for the average skilled person to combine the missing elements in implementing the product or process of the first publication.

The motivation for a combination may be the same as that described in the application under examination or different from it. It should be noted that the motivation for combination should be based on the information that was known to the average skilled person from the main publication and his general knowledge in the relevant field up to the application date rather than from the application itself.

An exceptional case in which it is not required to specify a motivation for the combination is where the examiner determined that the invention relates to a combination or collocation of components between which there is no interaction (see Section 5.3.1 above).

For the avoidance of doubt, an objection due to lack of an inventive step may be raised based on a combination of several publications as well as general knowledge in the relevant field.

Claims depending on an independent claim that is considered to involve an inventive step would too be deemed as involving an inventive step (even where the additional features of the dependent claim lack novelty or an inventive step).

Where an objection is raised under Section 4 of the Law (novelty) against specific claims, no objection under Section 5 of the Law shall be raised where the only reasoning specified is the non-compliance with the requirements of Section 4 of the Law.

7. The Applicant's Options to Rectify a Deficiency of Lack of an Inventive Step

According to the provisions of Regulation 42, the applicant's response as to an objection regarding an inventive step should be well-reasoned, both in the case where amendments were made in the claims as well as in the case such were not made. General statements such as "the examiner's explanations rely on hindsight vision" without specifying what that "hindsight vision" is, or that there is a substantial advantage without describing what it is, or that there is a teaching away without reasoning how the prior art teaches away from the invention, or a difference without explaining why that difference is not obvious from the prior art cited, do not constitute a response as required under this regulation and thus may lead to refusal of the application.

Following are four examples of possible manners in which the applicant may be able to rectify a deficiency due to lack of an inventive step:

a. deletion of the claims lacking an inventive step.

b. narrowing the scope of the claims, accompanied by a reasoned explanation of how the narrowed scope establishes a basis for an inventive step;

c. demonstrating an unexpected advantage and/or effect accompanied by a reasoned explanation and comparative results, if necessary, for example, demonstrating a substantial advantage a narrow claimed scope in the application under examination vis-à-vis a broad scope described in prior art (see also Appendix 6 of the Examination Guidelines – Section 4 of the Law - Novelty);

d. converting the application to a "patent of addition" application, insofar as it meets the requirements of Sections 44 and 45 of the Law, in order to overcome a prior art based on a previous patent owned by the applicant.

These examples are not to be deemed binding provisions and any response and/or change in the claim set should be reexamined in view of the other provisions of this appendix and the examination provisions in general.

8. References Regarding Effects of Combining Components

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Compendium of Pesticide Common Names Fungicides, bcpc (n.d.), http://www.alanwood.net/pesticides/class_fungicides.html

Examination Guidelines			
Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
Official Ed. 10 (28.2.2023)	Transl. Ed. 10.1 (10.07.2023)	Page: 1 of: 9	Guideline No.: **EG- 23.1/10**

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 10 - Section 10 of the Law – The Right to Priority

References and documents relating to the Right to Priority: Sections 10, 24(b1) and 164 of the Patents Law, Patents Regulations 23-28, Implementation Regulation 9, Sections 6B and 22-30 of **Commissioner's Circular 035/2017-Patents** (2021).

1. Definitions

1.1. Previous application – a patent application that was filed by the invention owner (or his predecessor in title) in a member state (per its definition under Section 1 of the Law) prior to the date of filing a patent application in Israel.

1.2. The earliest previous application – the first application that was filed in respect of the invention.

1.3. The invention owner – the inventor himself or persons who derive title under him, being entitled to the invention by operation of law, by transfer or by agreement.

1.4. Priority date – the application date of the previous application.

1.5. Priority document – a copy of the previous application specification of which right to priority is requested.

2. Introduction

2.1. This appendix specifies examination guidelines for the assessment of entitlement to a right to priority according to the provisions of Section 10 of the Law.

2.2. Section 10 of the Law is derived from the provisions of the Paris Convention for the Protection of Industrial Property (Articles 4A(1) and 4C(1)[1]), and is intended to enable the invention owner to file,

[1] Article 4A(1):
Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, **in one of the countries of the Union**, or his successor in title, **shall enjoy, for the purpose of filing in the other countries, a right of priority** during the periods hereinafter fixed.

Article 4C(1):
The periods of priority referred to above **shall be twelve months for patents** and utility models, and six months for industrial designs and trademarks.

within 12 months, in additional countries an application for the invention in respect of which he already filed a previous application and benefit from the date of filing the previous application for the purposes of Sections 2, 4, 5 and 9 of the Law.

2.3. Section 10 of the Law prescribes as follows:

"10. a) Where an invention owner filed a patent application in Israel for an invention for which he or his predecessor in title had already filed a previous patent application in a member state (hereafter – previous application), then he is entitled to request that, for the purposes of Sections 4, 5 and 9, the date of the previous application be deemed the date of the application filed in Israel (hereafter – right to priority), if all the following conditions are met:

(1) the application in Israel was submitted within 12 months from the filing of the previous application; and where more than one previous application have been filed with regards to the same matter – from the date on which the earliest was filed;

(2) the claim of priority right was made no later than two months after the filing of the application in Israel;

(3) a copy of the specification filed along with the previous application, and the accompanying drawings, have been submitted to the Commissioner at the time prescribed in the regulations, and the specification is certified by an accredited authority in the member state to which the previous application was filed;

(4) it appears to the Commissioner that the invention described in the previous application and the invention for which a patent is sought in Israel are essentially the same.

b) Where the claim of a priority right is based on more than one previous application, and a right to priority is claimed on the basis of each of those applications, then the provisions of Subsection (a) shall apply to each and every part of the invention according to the date of the earliest previous application relating to such part.

c) Where the claim of a priority right is based on a part of a previous application, then the provisions of Subsection (a) shall apply as if such part had been claimed overseas in a separate previous application.

d) It is permissible to claim priority right in respect of a part of a patent application, and the provisions of Subsection (a) shall thereupon apply in respect of that part only."

3. Filing a Priority Document

3.1. An application filed under the Paris Convention: the applicant shall submit a copy of the priority document/s within 12 months from the filing date of the application (Section 10(a)(3) of the Law and Regulation 24(a)).

3.2. An application filed under the PCT: the priority document/s is/are available on PATENTSCOPE. According to Implementation Regulation 9, where a priority right is claimed in an international application, based on a previous application that is not in English or Hebrew, a certified translation thereof to Hebrew or English shall be submitted within three months from the date on which the Commissioner required to do so.

3.3. Priority document/s in a foreign language: regarding applications that are not international applications, the examiner is entitled to request the applicant to file with the Office a translation of the document/s according to in the provisions of Regulation **25**.

4. Entitlement to a Right to Priority

4.1. "Essentially the same"

According to the provisions of **Section 10(a)(4)** of the Law, the priority right shall be valid where the invention for which a patent is sought in Israel is **essentially the same** as the invention described in the priority document.

The criterion for the invention's being essentially the same is whether the difference between that claimed in the application under examination and that described in the priority document is **substantial** (regarding a substantial change see the provisions of Appendix 19 of the Examination Guidelines). Meaning, the invention defined in the claim included in the application under examination shall be deemed essentially the same as the invention in the priority document if it was described explicitly, implicitly or inherently in the priority document.

A previous application relating to the same subject matter shall be deemed an application in which the claimed invention was described explicitly, implicitly, or inherently.

4.2. Assessment of validity of right to priority

Examiners are not required to examine the validity of a right to priority, other than in cases where there is a publication or other application that are relevant to Sections 2, 4, 5 and 9 of the Law as detailed below:

4.2.1. There is a publication that is relevant to the novelty and/or inventive step that was published between the priority date and the filing date of the application under examination (P,X or P,Y publication, hereinafter: intermediate publication). In this case, it is required to act according to Chart 2 below.

4.2.1.1. The "essentially the same" criterion relates to the examination of the claims of the application under examination vis-à-vis the priority document as defined in Section 4.1 above. Where this criterion is not met, the application under examination would not be entitled to a priority right and would not comply with the provisions of Section 10(a)(4) of the Law. Consequently, the relevant date for the purposes of Sections 4, 5 and 9 of the Law shall be the date of filing the application in Israel or the international filing date for an international application entering the national phase in Israel.

4.2.1.2. In the event where the application is "essentially the same" as the previous application, it is required to continue and examine whether the provisions of Section 10(a)(1) are met, meaning if there is an earlier previous application by the same applicant on the same matter.

4.2.1.3. Where the right to priority is invalid, it would be possible to cite the intermediate publication. Where the application was found to be entitled to a right to priority, it would be required to examine whether the publication has a corresponding application in Israel, and if yes, then it would be required to examine whether there is overlap between the application and the publication's corresponding application. An objection under Section 4 of the Law (novelty) shall not to be raised along with an overlap objection (see the provisions of Appendix 5 of the Examination Guidelines – Sections 2, 9 and 19 of the Law – Overlapping Applications).

4.2.2. There is a patent application, which is relevant to the novelty or inventive step of the application under examination, which was published after its filing date (publication under category E as defined in the search report). It is required to act according to Chart 3 below.

4.2.3. The application under examination claims priority right from a PCT application. It is required to examine whether the PCT application claims a priority right from an earlier application. If yes, it would be required to act according to Chart 2 or Chart 3 below, as applicable. The investigation

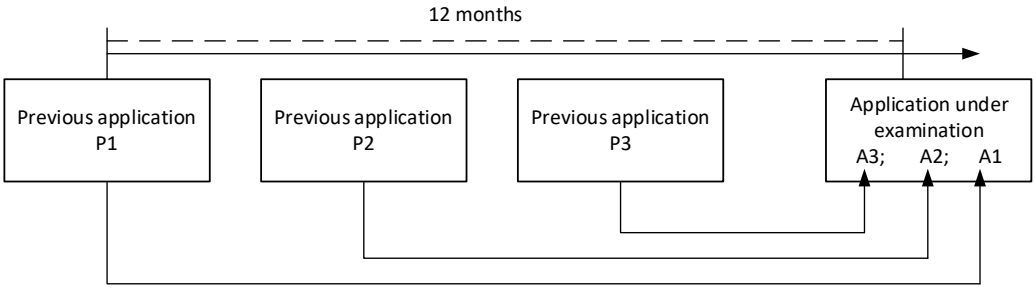
of the existence of priority right for the PCT application may be conducted on the PATENTSCOPE by entering its number.

4.2.4. The previous application is a US continuation or continuation-in-part application. In this case, it is required to act according to Section 4.3.2 below.

4.3. Emphases

4.3.1. Multiple priorities – Section 10(b) of the Law allows the applicant to claim priority rights based on more than one previous application, wherein each part of the invention is accorded the priority date of the earliest relevant previous application.

Chart 1 – Timeline for filing an application



In the event where there is a publication relevant to the novelty or inventive step of the claimed invention in the application under examination, which was published between the priority dates (intervening publication: citation P,X or P,Y), it is required to examine which of the priority documents first described an invention that is essentially the same as the claimed invention. In the event where an essentially the same invention was first described in a priority document dated after the publication date of the intervening publication, the priority claim would not comply with the requirements of Section 10(b) of the Law and the publication may be cited against the relevant claims. Additionally, it is permissible to request the applicant to indicate on the margin of the respective passages of the specification the dates of the foreign applications on which those passages are based, according to Regulation 26(b).

In the event where there is an application of another applicant with multiple priorities, and the priority dates of the application under examination and the other application "intervene each

other" (for example an earlier application with 2 priorities and a later application with 2 priorities, wherein the first priority date of the later application is included within the priority dates of the earlier application) – it is permissible to instruct to divide the applications based on the material that was described in each of the priority documents according to the provisions of Section 24(b1)(2) of the Law.

4.3.2. Claiming a right to priority of a continuation application or a continuation-in-part application – for the purpose of this section, a **continuation application** is a patent application whose description is identical to that of a previous patent application on which it is based, and a **continuation-in-part application** is an application that includes new subject matter added to the description of a previous patent application on which it is based; these types of applications usually exist in the United States and are referred to as continuation and continuation-in-part (CIP) applications.

According to the provisions of Section 6 of Commissioner's Circular 035/2017-Patents, an application that was filed in Israel and claiming a right to priority of a continuation application or a continuation-in-part application shall require to notify the Office regarding the publication dates of the applications in the chain of the continuation applications or continuation-in-part applications and their publication numbers.

All the earlier applications in the CIP chain that were published prior to the priority date of the application under examination constitute prior-art publications.

For previous applications whose priority is claimed, which are continuation-in-part applications, it is required to examine whether there is an earlier application in the chain that was filed over 12 months prior to the filing date of the application under examination. In the event where there is such an application and it discloses an invention that is essentially the same as the claimed invention, the application under examination would not be entitled to a right to priority according to Section 10(a)(1) of the Law, and **any relevant publication** may be cited (including publication of the aforesaid application) where it was published prior to the filing date of the application under examination.

An application under examination shall not be entitled to a right to priority based on a continuation application where an earlier application was filed prior to the filing date of the continuation application and more than 12 months prior to the filing date of the application under examination. In the event where there is a publication disclosing the claimed invention that was published prior to the filing date of the application under examination (including publication of the earlier application) this publication shall be cited as depriving the claimed invention of novelty.

In each case of a priority document being a continuation application or continuation-in-part application, for the purposes of Section 2 of the Law (overlap based on previous application filed by the same applicant), it is required to examine also the existence of Israeli corresponding applications to the applications in the chain.

Chart 2 – Examination of priority right validity in the case of an intermediate publication (P publication)

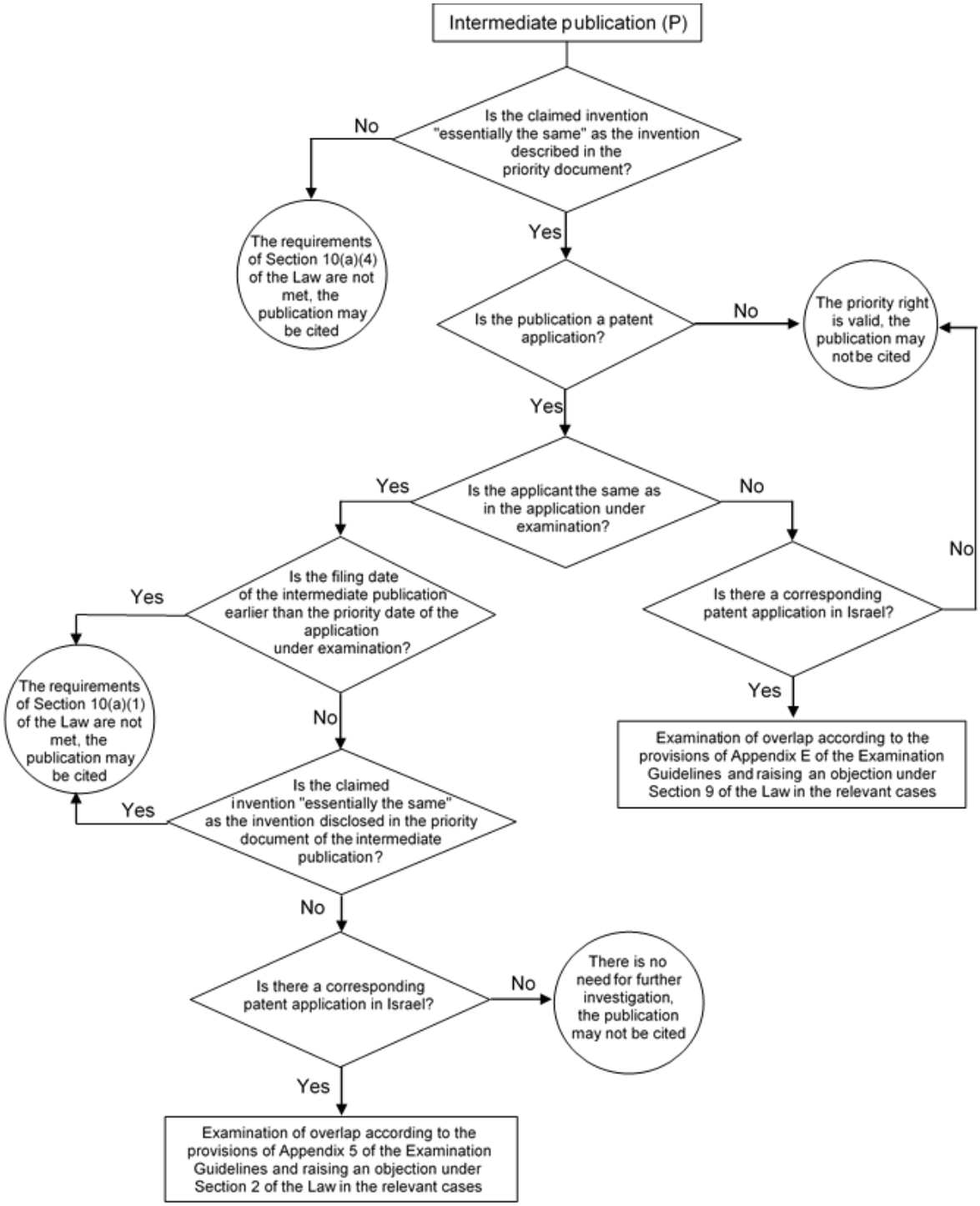
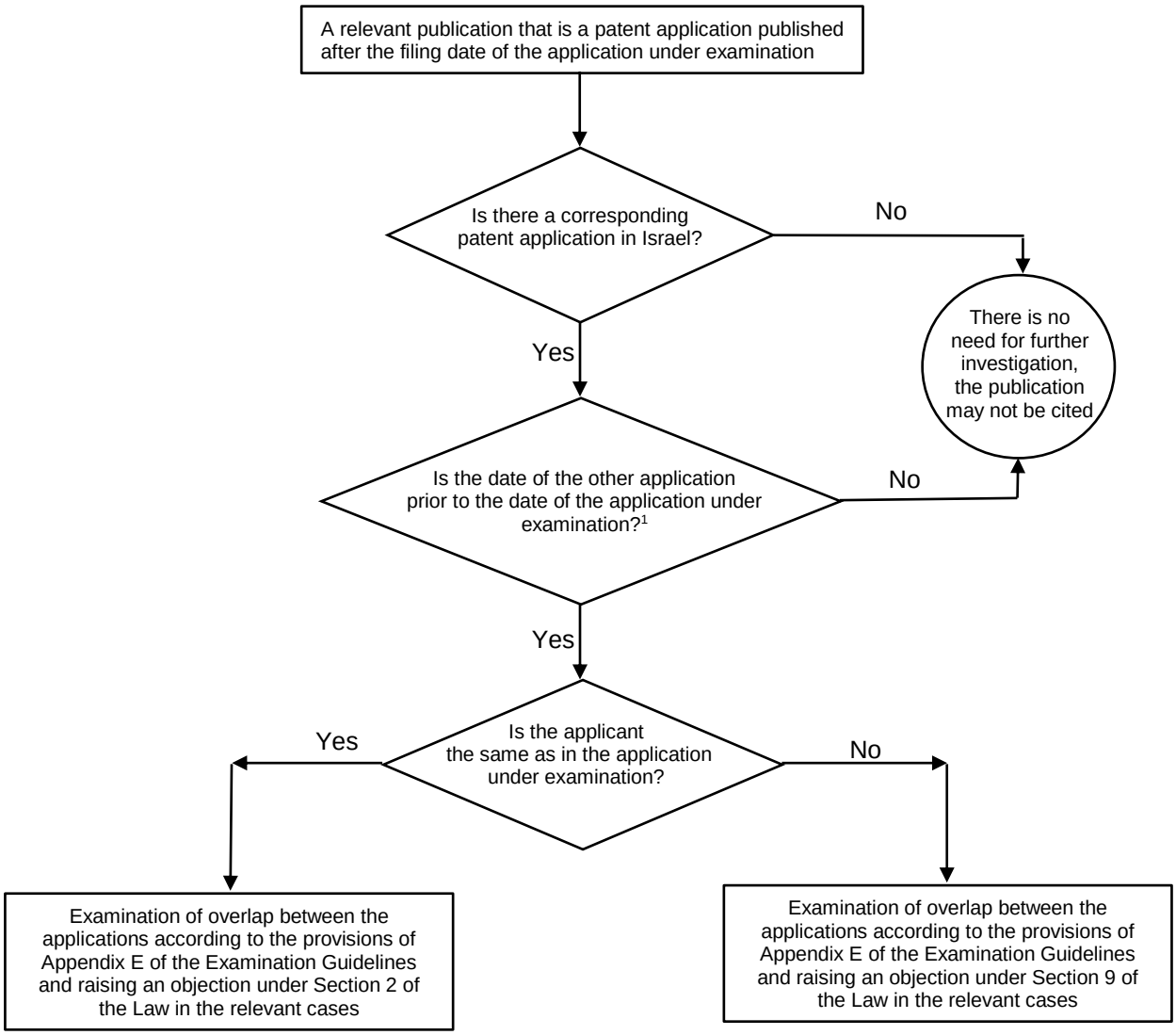


Chart 3 – Examination of priority right validity in the case of a relevant publication that is published after the application date



[1] For each of the applications it is required to determine the application date while examining its entitlement to a right to priority according to Section 10 of the Law (see also section 2.6 of Appendix E of the Examination Guidelines)

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 11 - The Claims

References and documents relating to the claims: Sections 2, 4, 5, 7, 8, 9, 12, 13, 17, 22 and 23 of the Law; Regulations 20(a) and 22(c) of the Patents Regulations; **Commissioner's Circulars 034/2017-Patents** (2020) and **035/2017-Patents** (2021); CA 345/87, **Hughes Aircraft Company v. The State of Israel** IsrSC 44(4) 045 (1990) (hereinafter: "the Hughes Ruling"), OA 1048/05, **Maytronics Ltd. v. Aquaproducts Inc.** (published in Nevo, 16.3.2006) (hereinafter: "the Maytronics Ruling"); OA 598/93 **Shunya Rosenthal v. The Patents Commissioner** (published in Nevo, 21.11.1996) (hereinafter: "the Shunya Rosenthal Ruling"); OM 1008/58 (CC 1290/57), Decision on Patent Application No. 74747 (published in Nevo, 26.6.1989) (hereinafter: the "Decision on 74747"); Decision on the Objection to Patent Application No. 102692 **Rav Bariach Technologies Ltd. v. Mordechai Cohen** (Published on the Patents Office's website, 16.2.2004) (hereinafter: the "Decision on 102692"); Decision on the Objection to Patent Application No. 112858 **Aquaproducts Inc. v. Maytronics Ltd.** (Published on the Patents Office website, 29.11.2004) (hereinafter: the "Decision on 112858"); Decision on Application for Patent Revocation 142049 **Melnick v. Walla! Communications Ltd.** (published on the Patent Office's website, 28.12.2005) (hereinafter: the "Decision on 142049"); Decision on the Objection to Registration of Patent Application 158016 **Pnina Meron v. Shuki Shemer** (Published on the Patents Office's website, 10.11.2010) (hereinafter: the "Decision on 158016"); Decision on the Objection to Registration of Patent application no. 136482, **Albermarle Corporation USA v. Bromine Compounds Ltd.** (Published on the Patents Office's website, 7.11.2010) (hereinafter: the "Decision on 136482").

1. General

1.1. This appendix specifies Examination Guidelines for examining claims in patent applications according to the provisions of Section 13 of the Law and the provisions of Regulation 20(a)(3) (and referring to the provisions of the Law, Regulations, judgments, decisions made at the Israel Patent Office and the Commissioner's Circulars relevant to the provisions of this Section).

1.2. Section 13 of the Law prescribes as follows:

> "(a) The specifications shall conclude with a claim or claims that define the invention, provided that each of the aforesaid claims reasonably arises out of the disclosure in the specification.
> (b) It shall be permissible to express in the claim any of the elements of the invention as means or step to perform a certain function, and it is unnecessary to specify the structure, material, or acts

required for such function; any claim thus expressed shall be deemed as though the relevant structure, material, or acts are specified in it, as disclosed in the specifications."

Regulation 20(a)(3) prescribes that the specification shall include:

"A claim defining the invention concisely and clearly."

1.3. These provisions shall apply to applications the examination of which is conducted according to the provisions of Sections 17(a)(1) and 17(a)(2) of the Law, except for in examination of Section 17(c) of the Law, unless it was decided not to accept such an examination.

2. The Provisions of Section 13(a) of the Law

2.1. According to the provisions of Section 13(a) of the Law,

"The specifications shall end with a claim or claims that define the invention, provided that each of the aforesaid claims reasonably arises out of the disclosure in the specification."

2.2. Where the claims do not comply with the provisions of Section 13(a) of the Law, relying on the specification to the extent possible, the examiner shall raise an objection, indicating the subject matter of the claim which does not comply with the provisions of Section 13(a) of the Law, while providing reasoning for the objection. The objection should be raised against a specific claim and the claims dependent thereof having such deficiency. The objection should be reasoned by indicating the elements explicitly defined in the claim or those missing from the claim and the scope of their basis in the specification. The application should be examined, to the extent possible, according to the elements recited in the claim without restricting the examination to the examples, unless the terms set out in Section 2.4.7 of this document hold true.

2.3. Defining the invention in the claims

2.3.1. According to Section 13(a) of the Law, the claim or claims shall define the invention, and as stated in the Hughes Ruling:

"It is the claims' role to accurately and cautiously define the scope of monopoly ".

Each of the claims shall define the invention claimed in it. In order to understand the claims, the examiner should read the entire patent application as a complete document and interpret the terms in the claims based on the meaning the applicant gave them.[1]

[1] See the Hughes Ruling: "The patent claims are not to be read in separate from that stated in the description and that described in the drawings."; "Interpretation of the expressions and terms that appear in claims while taking into account the other parts of the specification, in order to grant those expressions and terms the meaning the inventor chose to give them. The meaning may be broad

2.3.2. "What is not included in the claims is not included within the scope of monopoly" (Hughes Ruling). Even if a particular component is indicated and described in the application's description and drawings,

"a claim does not include a component that was not mentioned in it" (Decision on 102692).

Thus, according to Section 2.3.1 above, the scope of the claims should not be construed as including elements of the invention that are not defined in the claim[2].

2.3.3. The claims shall include all the elements of the invention necessary for performing it according to the teaching of the description. Where an essential element, which is necessary for performing the invention, is missing in the claims, the examiner shall request adding it to the claims by virtue of Section 13(a) of the Law.

2.3.4. It is possible to exclude an element from a general definition, so long as such exclusion is clear and concise (see also Sections 3 and 4 in Appendix P). Defining an element solely by way of exclusion (meaning, subject matter that is not present in the claimed invention) does not define the invention but rather what is not included in the invention, and therefore does not comply with the provisions of Section 13(a) of the Law, nor is it clear, hence, also not complying with the provisions of Regulation 20(a)(3).

2.4. The claims reasonably supported by the specification

2.4.1. According to the provisions of Section 13(a) of the Law, every claim "reasonably arises out of the disclosure in the specification". Reference to the definition "the disclosure in the specification", as set out in Section 13(a) of the Law, is made in this appendix subject to Section 12(a) of the Law:

> "The specification shall include a title by which the invention can be identified, its description with drawings as necessary, and also a description of the manner in which the invention can be performed, thus enabling a skilled person to perform it."

and Regulation 20(a):

> "The specification shall include the following subjects, in the order they are here enumerated:

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and may be limited, provided that it would be based in the patent and understood by a person skilled in the art at the time of the patent."

[2] See Maytronics Ruling: "Examination of the claims according to this approach does not mean emptying the claims of content, and are to be interpreted solely according to that stated in the specification."

(1) An introduction, explaining the purpose of the invention, and a concise description of the state of prior art in the professional field within which the invention was made, as far as known to the applicant in view of the invention;
(2) A description of the invention, with reference to drawings, examples or genetic sequences as necessary in order to understand the invention;
(3) A claim defining the invention concisely and clearly."

2.4.2. The subject matter of every claim shall have a support in the description of the application and shall not include anything that is not part of the invention according to the disclosure in the specification.[3]

2.4.3. The scope of the claims shall represent a reasonable generalization of the parts supported by the description.

2.4.4. It is insufficient to provide support for any claimed scope by adding an identical definition in the application's description.

2.4.5. The required degree of reliance on drawings or examples depends on the professional field in which the invention was made, the scope of the prior art relevant to the invention, and the specific features of the invention. As a rule, each of the options defined in the claim shall be supported by the specification, in its full scope, enabling the invention as disclosed in the specification to be carried out[4].

2.4.6. In cases where there is no high level of certainty regarding the support in the specification, the claims should define a group that includes the elements of the invention as set out in examples or their equivalents within the field of the invention. Additionally, attention is given to the following cases:

2.4.6.1. Where a certain element is described in one or a limited number of examples, extending the scope of the claim beyond the scope of the examples, may be deemed not reasonably arising out of the description.

2.4.6.2. Where a certain element (or combination of elements) is known in from the prior art as unsuitable for solving the problem defined in the application, and the specification does not include an example or support for it, the inclusion of the aforesaid element within the scope of the claims is deemed not reasonably arising out of the disclosure in the specification.

2.4.6.3. Where the examples in the specification do not provide support for the claimed selected group, the latter might be deemed as not reasonably arising out of the description.

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[3] See Shunya Rosenthal Ruling:"For understanding the claims and the extent of protection they grant, it is possible (and necessary) to be assisted by that stated in the description, however, this overall interpretation does not lead to the conclusion that the claims may include what is not included in the description."

[4] See the Decision on 142049, Section 81; the Decision on 158016, Sections 52-54.

2.4.6.4. Where the prior art indicates that the alternatives that are claimed, but not exemplified, have the same properties as those exemplified, the scope of the claim would reasonably arise out of the specification. In particular, it is to be expected that replacing element A of the invention, which is exemplified in the application, by element B, which is not exemplified, will lead to the same invention. For example, where within the same field of the invention, one of the elements of the claimed invention is known from the prior art as having several alternatives, all of which are suitable for the exemplified activity or structure, the prior art may serve as a support for the claimed scope in respect of all these alternatives.

2.4.6.5. Where an objection was raised under Section 13(a) of the Law against alternatives that are claimed but not exemplified, as stated in the sections above, the applicant must restrict the claim or provide reasoned explanation why it is expected that also the alternatives, which are not exemplified, are considered equivalent, while referring to the prior art, general knowledge in the field, the properties of the materials, etc.

2.4.6.6. Not all of the claimed categories require the same degree of support in the specification. For example, where there is an appropriate support for a new compound, explicit examples to its related categories, such as a pharmaceutical preparation containing it, a kit that containing it, a combination of this compound with other materials, etc., would mostly not be required, beyond general reference in the description.

2.4.7. Cases in which the claims are not considered to define the invention and to be reasonably supported by the disclosure in the specification include:

2.4.7.1. Omission of an essential element of the invention in the claim may render the claimed scope not reasonably arising out of the disclosure in the specification (see Section 2.3.2 above).

2.4.7.2. Should additional research and development effort be required, such as conducting a significant number of tests and experiments in order to determine the **full scope** of the claimed invention, the claim would be deemed as not reasonably arising out of the disclosure in the specification (regarding research and development, and determination of manners of performance, see Appendix 12 of the Examination Guidelines – Section 12 of the Law – Description of the Invention in the Application Specification, Section 4).

2.4.8. Implementation of sections 2.4.3 and 2.4.4 may likely be different in various technological fields and may likely even be different in various applications within the same technological field.

2.4.9. Amendments in the claims

2.4.9.1. Where the applicant filed amended claims according to his right under Section 22 of the Law, the examiner shall ensure that the applicant has complied with the requirements of Regulation 22(b) and specified in his response how the amendments meet the requirements of Section 13 of the Law.

2.4.9.2. The examiner shall ensure that the amended claims have explicit support in the specification based on the applicant's response. Where no support is found in the specification for the whole scope of the amended claims (except for the amendments defined in section 2.5.3 below), an objection shall be raised against these claims under Section 13(a) of the Law.

2.4.9.3. In the case of an amendment introducing new subject matter that meets the provisions of Section 23 of the Law, the examiner shall request indicating the date of filing the amendment in the margins of the passages including the new subject matter, according to Regulation22(c) (see also the provisions of Regulation 22 and Appendix 19 of the Examination Guidelines – Section 23 of the Law – Amendments in the specification).

2.4.9.4. Where the applicant does not meet the requirements of Regulation 22(b) (detailing how the amendments meet the requirements of Section 13 of the Law), the examiner is not required to examine the support for the amendments and may act for issuing a Notice before Refusal.

2.4.9.5. Where the applicant's response according to Regulation 22(b) has not been found persuasive, the examiner shall request the applicant to provide a reasoned explanation regarding the requested amendments.

2.4.9.6. An amendment is deemed a correction of a clerical error where two cumulative conditions are met:

a. the mere existence of the error is obvious to a person in the field of the invention reading the specification; and
b. the manner of the required correction is also obvious to a person in this field.

Correction of a clerical error may be based on extrinsic sources published prior to the date of the application.

2.4.9.7. Omission of an element (or a combination of elements), which was exemplified or described in the specification as an essential element of the invention, does not comply with the provisions of Section 13 of the Law. Exclusion of this element from the claims changes the scope of the invention compared to the original disclosure of the specification (see Section 2.3.3 above).

2.4.9.8. For a claim (or a certain scope thereof) containing a substantive amendment (i.e., introducing new subject matter) to the application according to Section 23 of the Law after the filing date of the application, the examiner shall request the applicant to indicate the date of the amendment as the date of filing the amendment with the Office according to the provisions of Regulation 22(c).

2.4.10. Restriction of search and examination due to lack of support

2.4.10.1. The search and the examination are not to be restricted insofar as it is possible to conduct a search for the entire scope of the claim.

2.4.10.2. Where one or more of the elements defined in the claim is not reasonably supported by the disclosure in the specification and are too broad to enable search for the full scope of the claim, the search shall be performed for the examples as well as for the claims defining a narrower scope that are reasonably supported by the specification, if any.

2.4.10.3. Where the element lacking support is optional, meaning, is not essential for performing the invention, it is unnecessary to conduct a search and examination in respect of this element.

2.4.10.4. The examiner shall notify the applicant for which part of the invention the search and examination were conducted (see also Appendix 9 of the Examination Guidelines – Guidelines for searching prior art).

2.4.10.5. The scope of the invention for which no search was conducted shall be deemed "lacking support" under Section 13 of the Law so long as the claim has not been amended accordingly.

2.4.10.6. Any case of limiting the search and examination is subject to the approval of the Team Manager.

2.5. Support when restricting a claim

2.5.1. Restricting a claim (by adding an element, omission of alternative elements or exclusion by a disclaimer) constitutes a new definition of the claimed invention. Therefore, it is required to reexamine the restricted claims regarding their compliance with Section 13 of the Law.

2.5.2. The examination of restricted claims, regarding their compliance with Section 13(a) of the Law, is required, whether the restriction was made as an amendment to an existing claim or that the restricted claim is a new claim.

2.5.3. Amendment of claims that is intended to restrict the claimed scope shall not be deemed contravening the provisions of Section 13(a)of the Law, in the following cases:

2.5.3.1. the amendment is intended to exclude prior art from the claimed scope (regardless of whether the restriction could overcome an objection regarding the novelty and inventive step of the claims);

2.5.3.2. the amendment is intended to exclude from the claims a scope overlapping with another Israeli application (Sections 2 or 9 of the Law) (regardless of whether the amendment could rectify the overlap deficiency); or

2.5.3.3. the amendment is an omission of alternative elements only;

provided that essential elements for performing the invention were not excluded from the claimed scope nor substantial parts on which the disclosure of the invention in the specification is based, and which provide enablement to the description for carrying out or for understanding the invention, as well as provided that the claimed scope after the amendment is clear, as stated in Section 4 below and in Sections 3 and 4 of Appendix 16 of the Examination Guidelines - Negative Limitations / Disclaimers in Patent Application Claims.

2.5.4. A later selection or combination of elements lacking a reasonable indication in the specification (such as the examples) to be selected among the other possibilities within the field of the invention as defined in the specification as originally filed, shall be deemed a selection or combination introducing new subject matter compared to the invention disclosed in the original specification. In this case, the amended claimed scope would not be deemed reasonably supported by the original disclosure of the invention.

3. The Provisions of Section 13(b) of the Law

3.1. According to the provisions of Section 13(b) of the Law,

> "It shall be permissible to express in the claim any one of the elements of the invention as means or step to perform a certain function, and it is unnecessary to specify the structure, material or acts required for such function."

3.2. A claim including an element expressed in accordance with the provisions of Section 13(b) of the Law shall be deemed and examined "as though the relevant structure, material or acts are specified in it, as disclosed in the specifications". Thus, an element expressed as aforesaid is considered according to the manner in which it was described and exemplified in the specification rather than in the broad manner defined in the claim.

3.3. The examiner shall indicate in the Notice of Deficiencies and the Notice before Acceptance the numbers of the claims that were examined according to the provisions of Section 13(b) of the Law and

that the search and examination of these claims were restricted according to the structure, material or acts disclosed in the specification.

3.4. Reciting a claim according to the provisions of Section 13(b) of the Law does not obviate the compliance with the requirements of Section 13(a) of the Law in respect of that claim.

3.5. Reciting a claim according to the provisions of Section 13(b) of the Law does not obviate the compliance with the requirements of Regulation 20(a)(3) in respect of that claim, as specified in section 4 of this appendix. Where the application's specification does not include a clear and unambiguous definition of the structure, material, or acts on which a claimed element is based, such that a person skilled in the art would not be able to determine whether this element is within the scope of the invention as disclosed in the specification, the subject matter of this element will be considered unclear.

3.6. A claim that defines part of the invention's elements in terms of a result to be achieved shall be examined according to the provisions of Section 13(b) of the Law, and shall be deemed as though the relevant structure, material or acts are specified in it as disclosed in the specification. The claim would be deemed clear (according to Regulation 20(a)(3)), where the result is clearly defined in the claim, and the application's specification includes a clear and unambiguous definition of the structure, the material and/or the acts that lead to the result.[5]

4. The Provisions of Regulation 20(a)(3)

4.1. According to the provisions of Regulation 20(a)(3), the specification shall include "a claim defining the invention concisely and clearly".

4.1.1. Should the application include one claim, the claim shall define the invention in a concise and clear manner.

4.1.2. Should the application include a number of claims that define the invention, each claim shall be concise and clear, and the claim set as a whole shall be concise and clear.

4.1.3. Each claim shall be defined in only one sentence and end with a period (.).

4.2. Dependent claims and claims referring to preceding claims

4.2.1. Repetition of the scope in a claim as that defined in the preceding claim to which the former refers to or on which it depends, shall be avoided since the repetition is unnecessary and not concise.

4.2.2. The definition of a claim shall not contradict that of a preceding claim to which the former refers to or on which it depends.

[5] See also the Decision on 136532 and the Decision on 136482.

4.2.3. The scope of a claim shall not go beyond that of a preceding claim on which the former depends (out of ambit).

4.2.4. Reference or dependence of a claim on more than one claim simultaneously could render the subject matter of the claim unclear due to the large number of possibilities that this reference or dependence creates. In cases where the examiner believes that there is a lack of clarity as a result, the examiner should request to add a reference to or dependence on one claim or "one of the claims."

The following are some examples of proper dependency:

According to claim 1 or 2

According to claim 1, 2, 3 or 4

According to one of claims 1-4

According to any one of claims 1-4

According to any preceding claim

According to any one of the above claims

The following are some examples of dependency that may be deemed unclear:

According to claims 1-10

According to any of claims 1-10

According to claims 8 and 14

According to the preceding claims

According to any of the above claims

According to one or more of claims 3-9

4.2.5. A claim, referring to or depending on only a schema or formula without indicating the claim in which they are defined (for example "A kit comprising a compound of formula I"), is deemed unclear as their definitions may be different in different parts of the specification (whether in different claims or in the application's description). In this case, the examiner should request to add an explicit reference to a claim in which the schema or formula is defined (for example: "A kit comprising a compound of formula I according to claim 1").

4.2.6. A claim referring to an element in a preceding claim is deemed unclear where this element is not defined as in the preceding claim (for example "said inhibitor" where the word "inhibitor" does not appear in the preceding claim). A claim reciting an element that is defined in the specification using different terms (such as "compound", "agent" or "inhibitor") is also deemed unclear. See also section 4.3.1 of this appendix.

4.3. Meaning of expressions and terms in claims

4.3.3. The terms appearing in the claims set should be used consistently, both in the same claim and in claims among which there is reference or dependency.

4.3.3. The expressions and terms appearing in the claims shall be construed "while taking into account the other parts of the specification, in order to grant those expressions and terms the meaning the inventor chose to give them. The meaning may be broad and may be limited, provided that it would be based in the patent and understood by a person skilled in the art at the time of the patent" (Hughes Ruling). Thus:

4.3.2.1. Expressions and terms appearing in claims should be construed and examined according to their definition in the application's description.

4.3.2.2. Terms or expressions shall be deemed as complying with Regulation 20(a)(3) where the application's specification includes a clear definition of those terms or expressions. However, it is not to be expected from the public to refer to the description for interpreting terms or expressions generally accepted in the art, and therefore they should be given the meaning they normally have in the relevant art.

4.3.2.3. Inconsistency or discrepancy between the claim and the disclosure in the specification is contrary to the provisions of Regulation 20(a)(3) due to lack of clarity (in addition to the need for examining the claim's support in the specification as provided in Sections 2.4 and 2.5 above). Additionally, the existence of such a discrepancy indicates that the claim does not reasonably arise out of the description, which is contrary to the provisions of Section 13(a) of the Law.

4.3.2.4. It is permissible to define within a claim preferred or specific groups from the claimed scope (using expressions such as "optionally", "in particular", "preferably", "especially" "such as" and the like), but for the purpose of examination these definitions do not limit the broader scope defined in that claim. However,

a. definition of an element solely using non-restrictive expressions (such as "A is a group such as") is unclear since it does not enable clear delimiting of the claimed scope and therefore contradicts the provisions of Regulation 20(a)(3); and

b. multiplicity of preferred and/or optional groups may result in a lack of conciseness.

4.3.2.5. In certain cases, the claims may be deemed unclear precisely in light of the definition of expressions or terms in the application's description. Where the definition of the term

contradicts that generally accepted in the art, in a manner that misleads a person having ordinary skill in the art, a lack of clarity objection under Regulation 20(a)(3) should be raised. For example: the definition "between 1 to 5 nmol" in a claim would be deemed unclear where the application's description defines that the digit "1" represents nine (9), the digit "5" represents one hundred (100), and the term "nmol" represents micromolar units (μM). Although each of the terms in the claim relies on a clear definition in the application's description, this claim would be considered misleading and unclear given those definitions, as the public should not be expected to refer to the specification for interpreting common and well-known terms or expressions (in the example above use of the definition "1 to 5 nmol" for claiming "9 to 100 μM"). In such cases, the examiner shall explain the reason for the lack of clarity of the claims. In order to rectify this deficiency, the applicant may adjust the definitions in the specification to their known and generally accepted scope. Alternatively, in cases where it is possible and clear, the applicant may add to the claim the same definition of the term or expression causing lack of clarity as set out in the application's description.

4.3.2.6. Use of the following terms per se blurs the known boundaries of the definitions or terms they address, such as: "about", "approximately", "essentially", "substantially", "equivalent", "thin", "wide", "strong", "weak", "quickly", "rapidly", "slowly", "easily", "stringent", "medium", "mild". As a rule, these terms would be deemed unclear and therefore claims that use these definitions or terms do not comply with the provisions of Regulation 20(a)(3), unless they are clearly defined in the specification as aforesaid in section 4.3.2.2 above. For example, where the claim includes the definition "about 50 kDa" and the term "about" was defined in the application's description such that the claimed lower and upper boundaries are easily identified, this term would not be deemed contravening the provisions of Regulation 20(a)(3).

4.3.2.7. For the purpose of examining the application, the interpretation of transitional terms and phrases should be taken into account, for example:

4.3.2.7.1. The transitional terms "comprising", "including", or "containing" are construed as open-ended terms, including the elements (materials or steps) recited in the claim, without excluding additional elements (materials or steps).

4.3.2.7.2. The transitional term "consisting" limits the scope of the claim only to the elements (materials or steps) defined in the claim.

4.3.2.7.3. The transitional phrase "consisting essentially of" limits the scope of the claim to the elements (materials or steps) defined in the claim and those that do not materially affect the invention.

4.3.3. In the fields of chemistry, biotechnology and pharmaceutics, lack of a clear definition in the application's description for certain terms recited in the claims may render these claims unclear. The following are examples for such terms and cases:

- The term "prodrug" is unclear unless the chemical structure it refers to is defined in the application's description.
- The term "derivative".
- The terms "constitutional isomer" or "structural isomer", including location isomers ("regioisomer" or "positional isomer") and excluding "tautomer", are unclear, unless the chemical structures they refer to are defined in the application's description.
- The term "isostere" is unclear unless the chemical structure it refers to is defined in the application's description.
- The term "complex" is unclear, unless the structure and components it refers to are defined.
- The term "conjugate" is unclear, unless the structure and components it refers to are defined.
- The term "protecting group" of a compound is unclear, unless the chemical groups it refers to are defined in the application's description. Where the claim relates to a preparation process defined using this term, an objection may be raised, at the examiner's discretion, on a case-by-case basis in light of the disclosure in the specification.
- The term "substituted" is unclear unless the substituents it refers to are defined in the application's description.
- The term "homology" is clear, provided that the degree of homology (sequence identity) it refers to is defined in the application's description or in the claim.
- Claiming a product without defining its chemical structure may render the subject matter of the claim unclear, for example, claiming undefined crystalline forms or "small molecule".
- Segments, derivatives, and homologs of a sequence that are claimed without defining their structure or functional activity are considered unclear.[6]

[6] See Commissioner's Circular 034/2017-Patents (2020), Section 28.

4.4. As a general rule, a substance or product should not be defined in a claim using a trademark. A patent application whose claims use a trademark may be incomprehensible since the components of the product defined by a trademark may be the manufacturer's trade secret, and since the trademark may expire and not be in use or change (the Decision on 112858). Thus, claims that make use of a trademark in order to define the claimed invention (with no other mark that is deemed clear) are contrary to the provisions of Regulation 20(a)(3).

4.5. Alternative elements

It is permissible to define in the same claim alternative elements so long as the definition of the claim is clear. The last two alternative elements should be separated by the appropriate conjunction (for example "or").

4.6. Omnibus claims

4.6.1. Subject to the provisions of Chapter E of Commissioner's Circular 034/2017-Patents, a claim that includes reference to the drawings or to the examples in the specification without explicitly stating all the elements of the claimed product or process (an "omnibus claim") is unclear and therefore not allowable.

4.6.2. Where an application includes an omnibus claim, and where its examination has been requested to be performed according to the provisions of Section 17(c) of the Law, the examiner should act according to the provisions of Section 17(d) of the Law. In order to rectify this deficiency, the applicant should omit the omnibus claim from the application and re-request the examination of the application according to the provisions of Section 17(c) of the Law.

4.7. A claim reference to which relies on an extrinsic document

A claim defining the scope of invention that was described in the application only by reference to one or more extrinsic document may be unclear as it is required to be interpreted according to that specified in at least two different documents (the application's specification and the extrinsic document). According to the provisions of Section 18 of Commissioner's Circular 035/2017-Patents, per the examiner's discretion, the applicant shall be requested under Section 22 of the Law to amend the specification such that the specification would include the relevant part of the document to which the reference was made.

4.8. The number of claims

4.8.1. An application that includes more than 50 claims shall be examined after payment of the fee as stated in Item 2 of the Second Schedule to the Regulations for claim 51 onwards.

4.8.2. The number of independent claims – as far as the claims comply with requirements of unity of invention according to the provisions of Section 8 of the Law, there shall be no limit to the number of independent claims, provided that the provisions of Regulation 20(a)(3) are met regarding the clarity and conciseness of the claims. Since each independent claim should be taken into account in order to determine the claimed scope (i.e., to determine whether it adds subject matter to the scope claimed by the other independent claims), there are cases in which multiplicity of independent claims results in non-clarity or non-conciseness of the claimed scope, as in the following:

4.8.2.1. Independent claims having overlapping scopes that repeat many definitions of the same elements of the invention. For example, two independent claims define Markush formulas with a multiplicity of alternative chemical groups and define compounds in overlapping scopes. In order to rectify the non-clarity/non-conciseness deficiency, the common scope of the compounds defined by these claims may be recited in only one independent claim, while the more restricted scopes may be recited in dependent claims. So long as the requirements of unity of invention are met, claiming in additional independent claims Markush formulas relating to compounds that are not included in the scope of another independent claim, would not be considered as contradicting the provisions of Regulation 20(a)(3) regarding the clarity and conciseness of the claimed invention.

4.8.2.2. Independent claims having overlapping scopes, wherein at least one of the claims recites multiple options of preferred features or combinations of features within the overlapping scope. For example, an independent claim defining a compound by a Markush formula and at least one additional independent claim which relates to dozens of specific compounds which belong to said Markush formula. In order to rectify the non-clarity/non-conciseness deficiency, the additional claim, which relates to the preferred features, may be drafted as a dependent claim. So long as the requirements of unity of invention are met, claiming in independent claims compounds that are not included in the scope of the broader independent claim, would not be considered as contradicting the provisions of Regulation 20(a)(3) regarding the clarity and conciseness of the claimed invention.

In such cases, based on the provisions of Regulation 20(a)(3) regarding the conciseness and clarity of the claims set, the examiner should request that claims in which the elements defined

were claimed in a broader claim be worded as dependent claims. In this regard, a product and process are separate from each other (it is permissible that one of them includes a reference to the other, such as "A process for the preparation of the compound of claim 1", and it is permissible to define all the elements separately).

4.9. Medical use

4.9.1. A claim relating to medical use may define a scope including, *inter alia*, the prevention, diagnosis, treatment, or improvement of a medical condition (such as a disease, syndrome, and/or functional disorder), exhibiting symptoms related to any medical condition or the side effects of any treatment.

4.9.2. A claim relating to a medical use (such as the use of a compound or a pharmaceutical composition) shall explicitly specify the relevant diseases included in the claimed scope or define these diseases according to the provisions of Section 13(b) of the Law (please see section 3 of this Appendix).

4.9.3. It should be emphasized that in claims concerning a second use of known compounds, the second use shall be clear and well-distinguished from the known use.

4.9.4. Where the use defined in a claim relates to a non-medical use (such as an enzyme inhibitor for analytical research use or for other laboratory use in vitro), the scope of use defined in such a claim would be deemed clear. Therefore, a distinction should be made between non-medical use and medical use as specified in sections 4.9.1 through 4.9.4 above. For example, a claim of the form "The compound of claim 1 for non-medical use as a tyrosine kinase inhibitor" is not considered unclear.

4.10. Interpretation of claims relating to use

A claimed invention relating to a product or process for a specific use may be deemed novel and/or involving an inventive step even in cases where the product or process themselves are not new (see Appendix 6 of the Examination Guidelines, Section 4 of the Law – Novelty, Section 6.9). However, attention is given to the following:

4.10.1. Use of terms such as "useful," "useful for" and "capable" for defining a product (or process) in a claim is construed as **"suitable for" the recited purpose.** Therefore, for the purpose of examination, these terms should not be considered as limiting the claimed product (or process) to the recited purpose, unless they result in a difference in the structural elements of the claimed product or a difference in the process steps. For example, "A knife comprising a blade characterized by shape X useful for cutting steel." This claim defines a knife with a blade characterized by shape X that is suitable for use in cutting steel. Therefore, a prior art document that describes a knife with a blade

characterized by shape X, which is inherently suitable for steel cutting (even if the prior art does not teach cutting steel), would deprive the claim of novelty.

4.10.2. Use of the term "for use" in a claim defines a product (or process) **for use.** Therefore, for the purpose of examination this term should be deemed as limiting the claimed scope to the defined use. For example, "A knife comprising a blade characterized by shape X for use in cutting steel." This claim defines a knife with a blade characterized by shape X that is for use in cutting steel, therefore, only prior art that describes a knife with an X shape blade as well as the use of that knife for cutting steel would deprive the claim of novelty.

4.10.3. A claim of the form "A PKC inhibitor compound of formula A" is not deemed a claim for use since it defines the substance itself rather than the use thereof. This is distinct from a claim of the form "a compound of formula A for use as PKC inhibitor", which should be examined according to the defined use.

Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
Official Ed. 10 (28.2.2023)	Transl. Ed. 10.1 (10.07.2023)	Page: 1 of: 10	Guideline No.: **EG- 23.1/12**

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 12 - Section 12 of the Law – Description of the Invention in the Application Specification

References and documents: Section 12 of the Patents Law 5727-1967; Patents Regulation 20, **Commissioner's Circular 034/2017-Patents** (2020); Opposition to Granting a Patent for Application No. 33746, **Haim Arazi v. Aluminum Company of America** (Israel Patent Office 25/12/1977) (hereinafter: "the Arazi case"); Opposition to Patent Application 142809, **Teva Pharmaceutical Industries Ltd. v. Pharmacia AB** (Israel Patent Office 26/02/2015) (hereinafter: "the Pharmacia case"); CA 345/87 **Hughes Aicraft Company v. the State of Israel**, IsrLC 44(4) 45 (hereinafter: "the Hughes Ruling"); Opposition to Granting a Patent for Application No. 34520, **Zisner v. Israel Chemicals Ltd.**, Selection of the Commissioner of Patents Decisions, 1975-1978, Volume A, p. 122 (hereinafter: "the Zisner case"); CC (Be'er Sheva) 21/83 **Ackerstein et al. v. Alumim et al.**, IsrDC 5749 (c) 197 (hereinafter: "the Ackerstein case"); CA 804/89 **Lanplast (1974) Ltd. et al. v. Beckman et al.**, IsrSC 46 (2) 295 (hereinafter: "the Lanplast case"); CC 2478/87 **Eli-Lilly v. Abic Ltd.** (hereinafter: "the Eli-Lilly case"); CA 665/84 **Sanofi Ltd. v. Unipharm Ltd.**, IsrSC 41(4) 729, 736 (1987) (hereinafter: "the Sanofi case")).

1. General

The requirements for describing the invention in the specification are set out in Section 12 of the Law as follows:

> "(a) The specification shall include a title by which the invention can be identified, its description with drawings as necessary, and also a description of the manners of performing the invention, thus enabling a skilled person to perform it.
> (b) For purposes of Subsection (a), where the subject of the invention is a biological material or a process for the production of a biological material or an invention that involves the use of a biological material, and where the biological material has been deposited in a depositary institution,

then part of the description of the invention or of the manners of performing it may be provided by referring to such deposit, all in accordance with the terms and conditions set forth by the Minister of Justice with approval by the Knesset Constitution, Law and Justice Committee."

For purposes of this Section –

"Biological Material" – a biological material not readily available to the public, which cannot be described in such a manner as to enable a skilled person to perform the invention, provided that the biological material can be duplicated or reproduced, either independently or in a host animal or plant cell;

"Depositary Institution" – an institution recognized as an international depositary authority under Section 7 of the Budapest Treaty, or an institution which the Commissioner recognized for purposes of this section, notice thereof having been published in the official gazette;

"Budapest Treaty" – the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977, and amended on September 26, 1980; the Treaty is open to public inspection at the Office."

Regulation 20 sets out the requirements of Section 12 of the Law regarding the specification as follows:

"(a) The specification shall include the following subjects, in the order in which they are here enumerated:

(1) An introduction, explaining the purpose of the invention, and a concise description of the state of the art, as far as known to the applicant in view of the invention;

(2) A description of the invention, with reference to drawings, examples or genetic sequences as necessary in order to understand the invention; where the applicant chooses to refer to the deposit of a biological material in a depositary institution under Section 12(b) of the Law, the reference shall be made according to Subregulation (a1);

(3) A claim defining the invention concisely and clearly.

(a1) A reference under Subregulation (a)(2) shall be performed in the following specified manner:

(1) When filing the patent application, the depositary institution and accession number of the deposit as well as the date on which the deposit was made shall be indicated in the description of the invention; in addition, a receipt from the depositary institution attesting to the reception of the biological material shall be attached to the application according to the Regulations under the

Budapest Treaty as published on the website of the World Intellectual Property Organization (WIPO) (in this regulation – receipt);

(2) In the case of a new deposit in the sense of Section 4 of the Budapest Treaty, of a biological material that had already been deposited, the owner of the application or the patent, as applicable, shall notify the Office of the accession number of the new deposit and attach the receipt within three months from the date it was issued; to the amendment of the application or patent, as applicable, the provisions of Sections 22, 29 and 65 of the Law shall apply;"

2. Formal Requirements

2.1. Where the application includes drawings, they should be described briefly before the full description of the invention, in which all the elements of the invention are described and identified in the drawings by reference signs. The drawings shall not include "any explanation [the explanation is in the specification rather than the drawings] other than terms such as "water", "steam", "cross-section along A-B lengthwise", "open", "closed". Where block diagrams are used for describing electrical devices or process flowcharts, explanatory matter sufficient to enable them to be understood may be added as required under Regulation 21(e)(7).

2.2. Where the application includes genetic sequences, they should be submitted as a separate file named "Sequencelisting". This file should be in XML format prepared according to WIPO Standard ST. 26 for applications whose application date is on or after 1/7/2022, or in TXT format prepared according to WIPO Standard ST. 25 for applications whose application date is prior to this date. It is not required to submit the sequences in additional files or as part of other files.

2.3. Attention must be paid to references to prior-art publications in the application's specification using the expression "incorporated by reference" (for this matter, see the provisions of Chapter D of Commissioner's Circular 034/2017-Patents).

2.3.1. Where the reference is for the purpose of describing the state of the art within the field of the invention, the examiner, at his discretion, shall request deletion thereof.

2.3.2. Where the reference concerns the description of the invention or the manners of performing it, the examiner, at his discretion, may request the applicant to amend the specification such that the specification would include the relevant part of the document to which the reference was made.

2.4. Where the specification mentions documents that could assist the person skilled in the art to understand and perform the invention, these documents must be identified clearly, and the public should have access to them.

2.4.1. Where patent applications that were filed in Israel or abroad are mentioned, the applicant shall be required to indicate the relevant publication number or patent number, except for cases where the application was identified in the specification by an identification number that enables easily locating its publication on the internet.

2.4.2. Where an application was cited in the specification prior to its publication, the applicant should remove its citation from the specification or add a concise description of it to the specification.

3. Substantive Requirements

Section 12 and Regulation 20 indicate that there are four main requirements regarding the specification:

a. the title of the invention should identify the invention;

b. the object of the invention should be explained in the introduction of the specification;

c. the introduction should include a concise description of the state of the art within the field of the invention; and

d. the specification should include a description that is sufficiently detailed to enable a person skilled in the art to perform the invention.

3.1. Title of the invention

3.1.1. It is required that the invention bear a title. All the parts of the application are published after 18 months, and the invention's title constitutes a verbal identifier. However, an objection should be raised (requesting changing the title of the invention) where the title is completely different from the invention or when the title is general and does not enable identification of the invention.

3.1.2. The title of the invention shall be indicated on the first page of the specification.

3.2. Object of the invention

The specification is required to describe the technical field of the invention and the purpose of using it.

3.3. Description of the state of the art

3.3.1. The applicant's duty is to concisely describe the state of the art within the professional domain of the invention to the extent known to him in light of the invention. This duty stems from the need to identify the inventor's contribution relative to prior art. Information regarding relevant prior-art publications that were cited during the examination is available for public review in the application file. However, the applicant may refer to these publications in the application's description, and such an addition shall be deemed a non-substantive amendment (i.e., an amendment that does not add new subject matter) (see also the provisions of Section 3.4.1 of Appendix 19).

3.3.2. Following the concise description of the prior art, the application is required to include an explanation as to the nature of the technical problem that the invention is intended to solve, why the prior art does not solve it or what are the disadvantages of the prior art, and describe the solution proposed by the invention. In this part of the description, a person skilled in the art who reads the description should understand from it what is the technical problem solved by the invention.

3.4. Description of the invention

3.4.1. The description of the invention (relying on drawings or examples to the extent required for understanding it) should be sufficiently detailed so that a person skilled in the art would be able to perform the invention.

3.4.2. In describing an invention relating to a product, it is insufficient to provide a random list of the product's components, but it is rather required to describe in detail the product's structure, the interactions among its components and the function of the product. Similarly, in describing an invention relating to a process, steps required in the process should be described in detail. This case was clarified in the ruling of the Ackerstein case:

> "In any case, the inventor must indicate and prove that he has possession of a detailed and complete description of the means necessary for performing the invention. In the absence of guidance or proof regarding the plausibility of performing the invention, the patent would not achieve the main purpose of enabling the public to carry out the invention."

3.4.3. Where performing the invention requires the use of a biological material deposited in a recognized depositary institution, a reference to the deposit should be made according to the provisions of

Section 12(b) of the Law. It should be emphasized that this reference constitutes part of the description of the invention or the manners of performing it according to Section 12(b).

3.4.4. Per the examiner's discretion, where the invention's description is not "at the degree required for understanding it", it is required to note an objection according to Regulation 20(a)(2).

4. Description of the Manners of Performing the Invention – Sufficiency of Disclosure

In addition to describing the invention, it is also required to describe the manners of performing the invention, thus enabling a person skilled in the art to perform it. In this regard, the Commissioner ruled in the **Arazi** case that the criterion is based on whether the skilled person, who follows the instructions in the specification, is able to produce a product as defined in the claims. If the answer is yes, then the description meets the requirements of Section 12 of the Law.

The Commissioner addressed the grounds of the requirement under Section 12 of the Law in his decision on the **Pharmacia** case:

> "This requirement stems from the deal underlying patent laws, according to which in return for granting exclusive right of use of the invention to the inventor, the public obtains the knowledge of that invention upon the expiration of that period (CA 217/86 Mordechai Schechter v. Avmetz Ltd., IsrDC(2) 846, 852)."

The Commissioner further added:

> "Specification with insufficient disclosure in respect of part of the claimed scope of protection violates that deal and its purposes, and as the Supreme Court ruled in the Sanofi case, p. 744: "…The application must include both a promise as to the efficiency of the composition as well as sufficient disclosure enabling a person skilled in the art to prepare the composition. The existence of these two requirements is the value, the quid pro quo, which is required of a person applying for a patent for his invention."

In the **Hughes** Ruling, it was stated as follows:

> "The requirement of sufficiency of disclosure is intended to ensure that on the application date the inventor indeed was in possession of the invention for which he applied for a patent. This requirement is also intended to serve the informative role of patent laws: stakeholders have the right to know the scope of the invention and the manners of performing it, whether in order not to prevent the encouragement of research in the relevant art, in order to allow benefiting from the invention after

> expiration of the monopoly, or even before then, in order to enable, for example, exploitation of the invention under a license granted by the owner of the patent."

This means that sufficiency of disclosure is examined vis-à-vis the whole professional knowledge in the relevant art/s as of the application date, and the applicant is not required to specify what is included in this knowledge. Section 12 of the Law states the words "a skilled person," which is not other than "an average skilled person" in the sense of Section 5 of the Law regarding the requirements of inventive step (see Appendix 7 of the Examination Guidelines – Inventive Step). In this regard, the Supreme Court ruled in the **Sanofi** case that:

> "The skilled person, to whom the required specification is intended under the Patents Law, is not required to be a single expert. This person would often be a team of experts, who together would constitute a pool of knowledge in the relevant art. Then, it is sufficient that the manufacturing process described in the application would enable a team of experts to perform the invention or that the process would be clear to such a team even with no details." […] "(2) In this case, also in lack of details in the application as to the manner of manufacturing the composition, the process is quite simple and clear, so that a person skilled in the art would be able to perform it after a reasonable number of trials. All the more so that the team of experts would be able to perform it even without trial."

From the ruling on **Sanofi** case, it can be concluded that even in the absence of details in the application regarding the manner of manufacturing the composition, if the process is so simple and clear that a skilled person would be able to perform it after a reasonable number of trials, then the disclosure of the invention meets the requirements of Section 12(a) of the Law.

In the **Hughes** Ruling, it was stated that technical features already known to a person skilled in the art are not required to be detailed. This refers to details that are well-known by a person skilled in the art and that are not essential for the invention. However, where these are details pertaining to the essence of the invention, the applicant is required to describe them clearly, without general and vague expressions, so that a person skilled in the art would be able to perform the invention according to the specification's instructions and per his common general knowledge. In this regard, the Commissioner ruled in the **Zisner** case:

> "It is a rule in patent laws that where there is an abstract invention without disclosing the manner for performing it and there is a need for trials to be carried out by others in order to implement it, then the invention is not qualified for protection under the patent laws. A person is not deemed an inventor where that person only pointed at the desired result or expressed a concept leaving to others the manner

for putting the concept into practice, and the method and means of achieving the desired result. It is not enough to present a concept without providing full details of the manner for implementing it. Meaning, the reader [skilled person] in the field of the invention would be able, according to the instructions in the specification, to produce what is included in the claimed scope without exercising inventive skills of his own, and without struggling in exploring questions whose solution is not in sight."

In the Eli-Lilly case, the Court ruled as follows:

"The description must be correct, and therefore clear and precise. It must be clear of vagueness and unclarity that could be prevented, or of ambiguity, and must be simple to the extent possible. It may not include false or misleading messages that could mislead the people for whom the specification is intended and make it difficult for them to perform the invention without many trials and experiments. For example, it may not propose several manners for performing the invention where only one manner is possible, even where those skilled in the art would choose the same manner. The description must be complete and provide all the information necessary for use or performance of the invention, without rendering the result subject to luck or chance and where it requires special warnings in order to avoid failures, it should so provide. Furthermore, the inventor must act in complete good faith and provide all the necessary information."

In most cases, a detailed description of one example of the invention would meet the requirements of Section 12(a) of the Law. Unlike the existing requirements in several other countries, in Israel there is no obligation to describe an example of the preferred embodiment of the invention, i.e., an embodiment providing the best results. However, it is of course desirable that the preferred embodiment be detailed in the description of the invention. In this regard, the Supreme Court ruled in the **Lanplast** case that there is nothing wrong with the fact that in order to carry out the invention, trial and error are required, while not exceeding what is reasonable on case-by-case basis, and that the skilled person should not be exempted from all calculation operations necessary for producing the product according to the invention.

5. Submission of Additional Documents Supporting Sufficiency of Disclosure

Additional documents submitted during the examination to provide evidence of compliance with Section 12 of the Law (such an affidavit or article), whose publication date is after the application date,

must rely on the knowledge disclosed in the specification and support it. It is required to examine whether it is possible to perform the invention according to the disclosure in the specification, meaning that there are no essential features that are not described in the specification, and whether performance of the invention relied on that known on the application date as described in the specification, as distinct from relying on means that did not exist on the date the application was filed.[1]

6. Practical Aspects in Raising an Objection due to Insufficient Disclosure

6.1. The disclosure of the invention in the specification is deemed insufficient where it does not enable the performance of the invention, as distinct from cases in which the invention is not useful according to the provisions of Section 3 of the Law.

6.2. An objection raised under Section 12 of the Law or Regulation 20(a) must be reasoned, and include references to the relevant parts of the description in the application.

6.3. Where the objection concerns the **description of the invention**, it is required to indicate the steps or technical elements that are described in an unclear or insufficient manner in the description, due to which it is not possible to understand the invention.

6.4. Where the objection concerns **description of the manners of performing the invention**, the examiner is required to indicate the insufficiency of specific steps or technical elements that does not enable performance of the invention while addressing, where appropriate, also the common general knowledge and the skills of the average skilled person in the art.

6.5. Where there is a teaching indicating that the invention cannot be performed as described, a reference to it should be presented. The reference may be in the form of a specific publication, review, professional literature or common general knowledge. In the case of common general knowledge, it is sufficient to mention a general consideration. An example of a general consideration: it is well-known that the activity of a molecule is determined by its structure, therefore, unlimited modifications in the molecule cannot preserve its activity.

6.6. As a rule, for the purposes of the examination procedure, one manner of performance that is within the scope of the invention is sufficient for meeting the requirements of Section 12 of the Law. Where it is determined that the described manner of performance does not constitute sufficient support to the

[1] See the Commissioner's Decision on the Pharmacia case (paragraph 50) where it was ruled that the additional experiments that were filed by the patent owner in support relied on additional knowledge that was not included in the description of the patent application.

entire scope of the invention, as defined in the claim set, an objection under Section 13 of the Law should be raised (see the provisions of Appendix 11 of the Examination Guidelines – The Claims).

6.7. An objection under Sections 4 (novelty) and 5 (inventive step) of the Law should not be raised together with an objection under Section 12 of the Law, where both objections refer to the same step or specific technical element, wherein on the one hand it is claimed that it is known or obvious from the prior art (including common general knowledge) and on the other hand it is claimed that it is insufficient and therefore cannot be completed by the prior art (including common general knowledge).

Examination Guidelines

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The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 13 – Section 17(c) of the Law – Examination and Acceptance of an Application Based on a Corresponding Patent

1. General

1.1. The examiner is required to verify that the request for a modified examination was stated by an explicit reference to Section 17(c) of the Law.

1.2. Where such an examination was not requested, no comment is to be made as to its non-compliance with the terms Section 17(c) of the Law.

1.3. A request for modified examination **with no explicit reference** to Section 17(c) of the Law shall be examined according to the provisions of Section 17(a) of the Law.

2. Definitions

2.1. Corresponding application – a patent application that was filed for the same invention in another country that appears on the list published by the Commissioner in the Official Gazette.

2.2. Corresponding patent – a patent that was granted for the same invention in a country that appears on the list published by the Commissioner in the Official Gazette.

2.3. Application under examination – the Israeli application under examination.

2.4. Member state – the union state or a country that is a member of the World Trade Organization.

2.5. Grace period – the period prior to the priority date, during which the inventor may publish his invention without the publication being considered as prior art. A grace period is practiced in several countries, but not in Israel.

3. Examination of the Application under Sections 17(c)(1)-17(c)(5) of the Law

3.1. The examiner shall verify that the applicant based the request for modified examination of the application under Section 17(c) of the Law on one corresponding patent.

3.1.1. Where the applicant based his request on two patents, the application may be accepted if the claims set in both corresponding patents relate to one invention.

3.1.2. Where there is doubt regarding the unity of invention, in light of the two corresponding patents on which the claim set filed is based, the request for examination under Section 17(c) of the Law may be rejected.

3.1.3. Where the applicant requested modified examination of his application based on more than two patents, his request shall be rejected.

3.2. The examiner shall verify that corresponding patent based on which the applicant requests modified examination was granted in one of the countries that appear on the list published in the Official Gazette according to Section 17(c) of the Law. The list, as of the date of these guidelines, is: Austria, Australia, the United States, Germany, Denmark, the United Kingdom, the Russian Federation, Japan, the European Patent Office, Norway, Canada and Sweden.

3.3. The examiner shall verify that the application meets the provisions of Section 17(c)(1)(a)-(c) of the Law regarding the conformity of priority rights with the corresponding patent.

3.3.1. The Israeli application under examination claims priority from the corresponding application.

3.3.2. The corresponding application claims priority from the Israeli patent application under examination.

3.3.3. The application under examination and the corresponding application legally claim priority from a same application filed in a Member State.

3.4. Multiplicity of priority rights

3.4.1. Where the application under examination claims priority from more than one priority document and the corresponding patent claims priority from one priority document, the application may be examined under Section 17(c) of the Law, provided that claim set is supported by the **common** priority document.

3.4.2. Where the application under examination claims priority from one priority document and the corresponding patent claims priority from more than one priority document, the application may be examined under Section 17(c) of the Law, provided that the claims of the application under

examination are supported by the common priority document. In this case, the examiner shall request to indicate the support of the claims in the common priority document. In this regard, it should be noted that only the claims supported by the common priority document may be examined under Section 17(c) of the Law.

3.5. Divisional application

Where the examination under Section 17(c) is requested for a divisional application, the examiner is shall compare the claim set in the divisional application to that in the parent application. Should there be an overlap between the application under examination and the parent application, an overlap objection shall be raised (see the provisions of Appendix 5 – Sections 2, 9, and 19 of the Law – Overlapping Applications).

3.6. According to the provisions of Sections 17(c)(3)-(4) of the Law, the applicant is required to submit to the Office a translation of the claims of the corresponding patent to the language in which the application was submitted in Israel. It should be noted that these sections of the law do not authorize the examiner to request a certified translation of the claims. Therefore, where there is any doubt regarding the identity of the claims or regarding the accuracy of the translation, the applicant's statement, that the claim set under examination is identical to that of the corresponding patent, is sufficient. Where the examiner is convinced that the claims are not identical, the examiner shall indicate the non-compliance with the requirements of Section 17(c) of the Law.

3.7. The examiner shall verify that number of claims in the application under examination is equal to or smaller than the number of claims in the corresponding patent.

3.7.1. An application with a narrower claimed scope compared to that of the corresponding patent shall not be allowed for examination under Section 17(c) of the Law.

3.7.2. Where number of claims in the application under examination is lower than that in the corresponding patent, it may be allowed for modified examination, provided that the claims' dependency terms did not change as a result of reducing their number. Changing the "claims' dependency terms" following removal of the claim on which the claims set to be examined were dependent, and as a result leads to a change in the dependency, cannot be interpreted as a reduction in the number of claims. On the other hand, a claim set that was filed in Israel may be accepted where the difference between it and the corresponding patent is removal of claims, which

do not lead to a change in dependency, so that the claim set in the Israeli application remains identical to that in the corresponding patent, except for the claims that were removed.

3.7.3. The submitted claims shall be identical to the corresponding patent's claims. However, omnibus claims are not allowable, as they do not meet the requirements of Commissioner's Circular 034/2017-Patents.

3.8. Where the claim set, the examination of which was requested under Section 17(c) of the Law, is not identical to the claim set of the corresponding patent due to the existence of typographical errors, which were corrected by the applicant after granting the patent, the examiner is required to accept the claim set under examination without indicating lack of compliance with the terms of identity of the claims.

3.9. Where the applicant filed a description and drawings that are identical to those of the corresponding patent, it is not required to examine whether the specification complies with the provisions of Section 12 of the Law. Should the specification not be identical to that of the corresponding patent, the examiner shall verify that the description and drawings meet the requirements of Section 12 of the Law. To verify the compliance with Section 12 of the Law, the following should be verified:

a. The title of the invention identifies the invention.
b. Drawings are available if necessary.
c. The manners of performance according to which a person skilled in the art would be able to perform the invention are described.

3.10. In examination under Section 17(c) of the Law, the examiner is not required to verify the compliance of the application to Section 13 of the Law.

3.11. Where the application meets the provisions specified in this section, it is to be deemed as complying with the provisions of Sections 4, 5, 8, 12 and 13 of the Law.

4. Examination according to Section 17(c) of the Law

In an examination according to Section 17(c) of the Law, the examiner is required to examine whether the application meets the requirements of Sections 2, 3, 7(1), 7(2), and 9 of the Law and Chapters B and E of Commissioner's Circular 034/2017-Patents.

4.1. In an examination according to Section 17(c) of the Law, no objection shall be raised regarding Regulation 20(a)(1) and Sections 18 and 19 of Commissioner's Circular 034/2017-Patents.

4.2. Examination according to Section 17(c) of the Law does not exempt the examiner from examining the compliance of the application with the provisions of Section 10 of the Law. For the avoidance of doubt, where the corresponding patent constitutes a continuation application of a US application, from which the application under examination claims priority, the application may be examined according to the provisions of Section 17(c).

4.3. Where the application is examined according to Section 17(c) of the Law, the examiner shall indicate so in the examination report.

4.4. Where the application under examination does not comply with at least one of the requirements of Section 17(c) of the Law, the examiner is required to indicate only the non-compliance with the requirement. Non-compliance with the requirement does not constitute grounds for starting the examination according to Section 17(a) of the Law. An exception to this rule is Section 17(e) of the Law, regarding existence of opposition or cancellation/revocation proceedings against the corresponding patent, according to which, where the application is examined according to the provisions of Section 17(c) of the Law and there are proceedings of opposition or cancellation/revocation of the corresponding patent, the examiner shall examine the application according to the provisions of Section 17(a) of the Law.

4.5. Where the examiner finds that the requirements for examination according to Section 17(c) are not met, yet, *prima facie*, there are no substantive deficiencies in the application, the examiner shall contact (by phone) the applicant/his authorized repetitive and notify him of this. With the applicant's consent, the request for modified examination according to Section 17(c) of the Law shall be removed and the examiner shall issue a Notice of [non-substantive] Deficiencies (PC 27) or a Notice before Acceptance (PC 13).

5. Section 17(d) of the Law

5.1. The Commissioner, the Superintendent of Patent Examiners or her deputies, are entitled to reject the request for modified examination under Section 17(c) of the Law, even where the application meets the requirements of this section, based on the material available to them or provided to them during the examination procedures. For the avoidance of doubt, only deficiencies concerning non-compliance with the requirements of the relevant sections or chapters in Commissioner's Circular 034/2017-Patents may be raised without obtaining the approval of the Superintendent of Patent Examiners or her deputies.

5.2. The following are the cases in which the examiner shall refer to the Superintendent of Patent Examiners or her deputies to decide regarding the rejection of the request for modified examination according to Section 17(c) of the Law:

5.2.1. non-compliance with the provisions of Sections 4, 5, 8, 12 and 13 of the Law or part thereof, based on the material available to the examiner or which he was provided with during examination; and

5.2.2. where the request for modified examination under Section 17(c) of the Law is based on a corresponding patent granted in a country operating a grace period, the existence of prior-art publications, published within the grace period, which are relevant to the novelty or inventive step of the claimed invention.

6. Section 17(e) of the Law

6.1. Although it is the applicant's duty to notify the Office of the existence of proceedings for cancelling/revoking the corresponding patent or proceedings of opposition to granting the corresponding patent, the examiner is required to examine whether no such proceedings are taking place. Where such proceedings are taking place, the application shall be returned for examination according to Section 17(a) of the Law.

6.2. According to Section 15 of Commissioner's Circular 035/2017-Patents, following applicant's notification of proceedings for cancellation/revocation or opposition against the corresponding patent after a Notice before Acceptance (PC 13) and until granting the patent in Israel, the application shall be returned for full examination according to Section 17(a) of the Law. However, a condition for returning the application for examination after acceptance is that no opposition to granting the patent in Israel was filed.

7. Continued Examination

7.1. Pursuant to Regulation 42 of the Regulations, the applicant is required to specify in his response, *inter alia*, how amendment of the claims rectifies the deficiencies indicated in the objections raised or why he should not rectify the deficiencies.

7.2. Where the claim set of the corresponding patent, on which the modified examination is based according to Section 17(c) of the Law, is narrower compared to the claim set against which an objection was raised

regarding the novelty and/or the inventive step, there is no duty imposed on the applicant to address the objections that were raised in the previous Notice of Deficiencies.

Where the claim set of the corresponding patent, on which the modified examination is based according to Section 17(c) of the Law, is identical or not essentially different from the claim set against which an objection was raised regarding the novelty and/or the inventive step, and the applicant failed to address the objections raised in the previous examination report, the examiner shall refer to the Superintendent of Patent Examiners or her deputies in order to exercise the authority set out in Section 17(d) based on the reasoning presented in the Notice of Deficiencies.

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 14 – List of the Issues to be Considered in the Examination According to Section 17(a) of the Law

The examiner shall indicate the deficiencies in the Notice of Deficiencies regarding the following issues according to the following order:

1. Postponement of the examination, according to Section 19 of the Patents Law (hereinafter: the "Law").
2. Patentability of the claimed invention regarding its being a product or a process, in a field of technology, useful and industrially applicable, according to Section 3 of the Law.
3. Excluded subject matter under Section 7 of the Law and Chapter B of Commissioner's Circular 034/2017-Patents (2020).
4. Unity of invention, according to Section 8 of the Law.
5. Conflicting applications, according to Section 9 of the Law.
6. Double patenting, according to Section 2 of the Law.
7. Novelty, according to Section 4 of the Law.
8. Inventive step, according to Section 5 of the Law.
9. Right to priority, according to Section 10 of the Law and Section 10(a)(1) of the Law (in cases of overlapping applications – conflicting applications / double patenting).
10. The description, according to Section 12 of the Law, Regulation 20 and Chapters D-F of Commissioner's Circular 034/2017-Patents (2020).
11. The claims, according to Section 13 of the Law, Regulation 20 and Chapters E-F of Commissioner's Circular 034/2017-Patents (2020).
12. Deficiencies in the form of the application, according to Regulations 11, 20(b) and 21.
13. Amendments in the specification, according to Regulation 22 and Commissioner's Circular 035/2017-Patents (2020).
14. Changes in the list of citations, according to Section 18A of the Law.

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 16 - Negative Limitations / Disclaimers in Patent Application Claims

1. Essence of the Disclaimer

A disclaimer is a provision that defines the scope excluded from the scope claimed in the patent application or a provision that defines in a more limited manner the claimed scope in an explicit manner. The disclaimer enables exclusion from the scope of the invention, which is defined in terms of positive features indicating that certain technical features are present, particular technical features that do not constitute part of the claimed invention.

2. The Manner of Wording Disclaimers

Examples of disclaimers' wording:

- "provided that X is not __"
- "with the proviso that X cannot be __"
- "under the proviso that when Y is __, X is not __"
- "wherein the compound is other than __"
- "wherein __, __ and __ are excluded"
- "wherein __ is disclaimed"
- "provided that when X is __, Y is__"

3. A Disclaimer Exclusively Used for Expressing an Invention Element

It is not permissible to define an element of the invention in a claim solely in terms of a disclaimer. The addition of a disclaimer to a claim is an exception, since the disclaimer excludes the inventions that are not included in the claimed scope. As a rule, addition of a disclaimer to a previously

defined claim adds complexity to the claim. Therefore, in view of the provisions of Regulation 20(a)(3), addition of a disclaimer shall be permissible solely in cases where the scope of the claim cannot be defined in a clear and concise manner when worded only in terms of positive technical features.

4. Multiple Disclaimers

Addition of a large number of disclaimers to a claim, defined in terms of positive technical features, shall be deemed unclear and unconcise since the multiplicity of disclaimers adds complexity to the claim and makes it difficult to determine the scope of protection. Thus, while one or a few disclaimers may assist in wording a clear and concise definition of the claimed scope, a claim that includes a large number of disclaimers would not be deemed clear and concise, and it would contravene the provisions of Regulation 20(a)(3). The examiners are required to request that the claim be worded based on the existing features of the invention so that there would be no need for excluding many features from this scope.

5. Adding a Disclaimer that Modifies the Claimed Scope

In many cases, adding a disclaimer to the claim set is conducted during the examination, and therefore it is required to determine whether the original specification of the application provides support to the amended claims. Although addition of a disclaimer narrows the claimed scope, it is required to verify that the claimed scope in the amended claims is supported by the original specification in a manner that complies with the requirements under Sections 12(a) and 13(a) of the Law. In particular, it is required to examine whether the addition of the disclaimer may add a new technical contribution or new scope to the claims, compared to the invention defined in the original specification. Furthermore, it should be emphasized that:

a. addition of a disclaimer that excludes a scope, **which is not explicitly disclosed** in the application's specification, is deemed an amendment that is not of substantive nature (i.e., does not introduce new subject matter);
b. addition of a disclaimer that excludes a scope, **which is explicitly disclosed** in the application's specification as one of the alternatives of the invention, is deemed an

amendment that is not of substantive nature, so long as the scope of the claim after the addition of the disclaimer is supported by the description of the application.

c. Where adding the disclaimer leads to a change of the claimed scope in a manner that introduces a technical contribution, a new meaning, or new features compared to the original specification, an objection under Section 13(a) of the Law should be raised on grounds of lack of reasonable support in the original specification, for example:

- selection of a particular group that has no explicit support in the specification other than its being generally mentioned in the original specification with many alternatives (such as a Markush formula);
- where a particular feature (or combination of features) is explicitly defined in the application's specification as an essential feature that is described and exemplified in detail, exclusion of this feature from the claims would substantively modify the scope of the invention compared to the description of the original specification.

Therefore, in any event where a claim is amended by addition of a disclaimer that leads to a change in the scope of the invention in a manner that renders the subject matter of the claim not reasonably supported by the original specification, an objection under Sections 12(a) and/or 13(a) of the Law should be considered. An amendment as such shall be examined according to the provisions of Section 23 of the Law and the provisions of Section 4.1.5 of Appendix 19 of the Examination Guidelines (regarding amendments to the specification).

6. Excluding Prior Art by a Disclaimer

Prior art within the field of the invention may be cited under Section 5 of the Law against the inventive step of the claimed invention, even if the scope of this prior art was excluded by a disclaimer. Where the prior art is very close to the claimed invention, for example, relating to the same technical field of the invention or constituting a solution for the same problem addressed by the invention, it may be cited under Section 5 of the Law also in cases where there is a disclaimer as to the scope that was explicitly disclosed in such a publication.

7. Unity of Invention under a Disclaimer

A disclaimer that excludes certain features from the claimed scope may affect the unity of invention. However, not every disclaimer leads to lack of unity of invention, but this rather depends on the scope of the disclaimer relative to the scope of the claimed invention. In the event where the disclaimer leads to exclusion of a special technical feature common to the separate inventions, an objection on grounds of lack of unity of invention under Section 8 of the Law should be considered.

8. The Applicant's Duty under Regulation 20(a)(1)

According to the provisions of Regulation 20(a)(1) the applicant is required to concisely describe the state of the art in the professional field of the invention, to the extent known to the applicant in light of the invention. Prior-art publications, on which a disclaimer is based, are part of the state of the art within the professional field of the invention that was known to the applicant. Therefore, according to the provisions of Regulation 20(a)(1) the applicant is required to indicate these publications in the specification together with appropriate explanations.

9. Adding a Disclaimer for Rectifying an Overlap Deficiency

Subject to the aforementioned, exclusion by means of a disclaimer may be used to rectify a deficiency of overlap with another Israeli application (Sections 2 or 9 of the Law) subject to section 6b of Appendix 5 to the Examination Guidelines.

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The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 18 - Examination Guidelines in the Field of Polymorphism and Salts of Compounds

1. Objective

Due to the complexity of examining applications within the field of polymorphism and salts, and since the scope of the protection is naturally narrower, the application's specification should be carefully considered, particularly the examples and drawings.

The objective of these guidelines is to establish a consistent methodology in examining applications concerning different solid states and different salts of a known compound, which may appear in a variety of states: crystals, hydrates, solvates, co-crystals, and amorphous state.

2. Definitions[1]

2.1. Solid State Characterization: a field dealing with synthesis, structure, and characterization of properties of compounds in a solid state. Compounds may appear in a wide variety of solid states, which include: crystals/polymorphs, hydrates, solvates, salts, co-crystals, and amorphous state.

2.2. Polymorphism: the ability of a compound in a solid state to exist in more than one crystalline form. This feature of crystallization of the compound in various forms is called polymorphism, and each of the crystalline forms is called polymorph. Change of the crystalline form is expressed by the change of the atom arrangement that confers different characteristics on the polymorph, such as solubility, bioavailability, stability, hygroscopicity, melting point, etc.

2.3. Crystal (crystal form, polymorph, form): the form of the compound and its arrangement in the solid state. The main feature of a crystal is the existence of the same long-range internal arrangement in the form of a basic structure, called a unit cell, which repeats itself over the entire space of the solid state. The polymorphs are used in a wide variety of fields, such as medications, materials, food, agrochemicals, paints, and explosives.

[1] See Section 11 for the references of the definitions.

2.4. Pseudo-crystal (pseudo polymorph): a crystalline form containing water or any other solvent, forming a hydrate or solvate.

2.4.1. Hydrate: a crystalline form in which a water molecule constitutes part of the crystalline structure, in any stoichiometric ratio with the compound's molecules, such as hemihydrate, monohydrate, dihydrate, sesquihydrate, pentahydrate, etc., or with a non-stoichiometric ratio.

2.4.2. Solvate: a crystalline form in which a certain solvent molecule constitutes part of the crystalline structure, at any stoichiometric ratio with the compound's molecules, such as methanol solvate, acetone solvate, acetonitrile solvate, etc., or at a non-stoichiometric ratio.

2.5. Salt: a structure (crystalline or amorphous) that combines positively charged ions or negatively charged ions (obtained by use of appropriate acids or bases) and a compound in any stoichiometric ratio.

2.6. Co-crystal: a crystal including two compounds in the solid state (such as two active compounds or a compound and an additive) are arranged together in a unit cell forming crystalline forms, without covalent bonds between them, as the bonding between the compounds is maintained by non-covalent forces, such as hydrogen bonds, Van der Waals bonds, and hydrophobic interactions.

2.7. Amorphous: a state characterizing a compound that is not of a defined form, meaning the compound does not have a crystalline order in space (with zero or close to zero crystallinity) on the molecular level. Examples of amorphous materials include glassy, oily, sticky, and foamy materials.

2.8. Seeding: a process in which crystal nuclei are added, such as a small amount of the desired single crystal or another appropriate additive, creating an appropriate environment for enhancing the formation of desirable crystals. Crystal nuclei serve as a basis for the growth of crystals on them. In this state, the intermolecular interactions between the molecules are formed more easily compared to the intermolecular interactions formed in the random flow that exists in the solution. The use of already-formed crystal nuclei reduces the time required for nucleation in the crystallization process. The customary seeding processes include:

- adding crystal nuclei to a saturated solution;
- adding crystal nuclei to a molten solution and cooling it; and
- transferring vapors of a solution containing the compound onto the crystal nuclei, to enable growth into larger crystals.

2.9. Crystal Habit: the external shape of a crystal. Examples of typical crystal habits of a compound in a crystalline state include needle-like, cubic, acicular, prismatic, etc.

3. General

The examiner is required to carefully review all the examples and drawings that appear in the application's specification and prior art in light of the claimed invention, with an emphasis on the following matters:

3.1. The method/s used for characterizing the crystal (main/supplementary, complete/incomplete characterization).[2]

Crystal characterization methods: for the purpose of characterizing the crystalline form, it is common to use one of the following methods:

- **XRD** - X-Ray Diffraction (XRPD- X-Ray Powder Diffraction)
- **FTIR** - Fourier Transform Infrared Spectroscopy
- **FT-RAMAN** - Fourier Transform Raman Spectroscopy
- **SSNMR** - Solid State Nuclear Magnetic Resonance

Supplementary characterization methods: these methods in themselves are insufficient (independently) for characterizing the crystalline form:

- **DSC** - Differential Scanning Calorimetry[3]
- **TGA** - Thermal Gravimetric Analysis
- **M.P.** - Melting Point

Special attention should be paid to that supplementary characterization methods, such as DSC or TGA or melting point (M.P.), are insufficient (independently) for characterizing the solid state claimed in a complete manner.

3.2. The crystal habit/morphological form of the crystal.

3.3. The preparation processes of the compound (types of solvents, process steps, and data regarding the seeding stage).

3.4. Description of polymorphic transitions.

3.5. The types of compositions (solid/liquid) and the processes for the preparation thereof.

[2] Terence L. Threlfall, Analysis of Organic Polymorph, A Review, 20 ANALYSIS OF ORGANIC POLYMORPHS 2435 (1995); ANGELINE ZAKRZEWSKI & MAREK ZAKRZEWSKI, SOLID STATE CHARACTERIZATION OF PHARMACEUTICALS 134 (1st. ed. 2006).

[3] Since DSC includes several thermal transitions it may be considered as a complete characterizing method.

4. Section 8 of the Law – Unity of Invention[4]

4.1. Where the compound is novel, all of the claimed solid states of the compound shall be deemed one invention. In such a case, the applicant may claim the compound in these states also by the use of general definitions (such as crystals, hydrates, solvates, salts, etc.).

4.2. Where the compound is not novel and more than one solid state is claimed, the examiner normally should not raise an objection of lack of unity of invention under Section 8 of the Law, provided that the same prior-art publication is used for depriving the claimed solid states of novelty or inventive step.

Where the applicant presents an additional common feature(s) (besides the compound) for all the claimed solid states, which is novel and involves an inventive step (common special technical features), the application should be deemed as complying with the requirements of Section 8 of the Law. For example, the presentation of similar solubility or stability levels for the claimed states which are significantly improved relative to the prior art, may be considered as a common special technical feature. Otherwise, an objection of lack of unity of invention should be raised.

5. Section 4 of the Law – Novelty[5]

5.1. Where a compound in a certain crystalline form or a process of preparing the compound is claimed, and the prior art discloses and exemplifies the compound in a specific manner, and one of the following conditions is fulfilled:

5.1.1. the claimed physical properties of the compound are not disclosed in the prior art or that the physical properties disclosed in the prior art are different from those of the claimed invention (for example, the prior art discloses the melting point of the compound while the application under examination discloses XRD or SSNMR data, etc.);

5.1.2. the compound is generally defined in a certain solid state; and

5.1.3. the preparation process described or claimed in the description of the application under examination is entirely or partially identical to the process disclosed in the prior art, so that in view of the disclosure of the prior art and that of the specification, it may be assumed that the compound of the prior art is in the same crystalline form as that of the claimed compound.

In all the above cases, an objection on grounds of lack of novelty in view of the prior art should be raised, since the characterization in itself of a known compound by various parameters does not

[4] See also the provisions of Appendix 4 of the Examination Guidelines – Section 8 of the Law – Unity of Invention.
[5] See also the provisions of Appendix 6 of the Examination Guidelines – Section 4 of the Law – Novelty.

render the claimed invention novel. It should be noted that the use of different characterization methods does not provide a basis for the novelty of the claimed compound, unless the applicant demonstrates, using the same characterization methods and under the same conditions, that the prior art discloses a compound having a different crystalline form than that claimed in the application.

5.2. In comparing the characterization data of the claimed compound vis-à-vis the prior art, attention should be paid as to whether the claimed physical features in the application compared to those disclosed in the prior art are of the same values and measured by identical or comparable characterization methods. In cases where the data are identical (within the accepted deviation range) or non-comparable, an objection on grounds of lack of novelty should be raised in view of the prior art.

Examples of non-comparable data include:

a. different characterization methods, such as XRD data versus FTIR data, XRD data versus DSC data, DSC data versus melting point (performed through capillary method), etc.;
b. use of different values produced by the same technique, such as characterization by angles (2Θ) using the XRD method versus characterization by distances (d-spacing, Å) through the XRD method, and characterization by the FTIR (drift) method versus FTIR (disc) method, etc.; and
c. selection of data from the same characterization method, such as characterization by selecting peaks no. 1, 3, 5, 7, etc. versus characterization by selecting peaks no. 2, 4, 6, 8, etc. in the same XRD pattern.

Examples of data that are considered identical include:

a. deviation of $2\Theta \pm 0.20$ in XRD data is considered an acceptable deviation in the art that could result from several different factors such as the use of equipment from different manufacturers, preferred orientation that results from different grinding of the sample, different crystal habits of the crystalline form, a different degree of cleanliness, etc.;
b. deviation of $\pm 4 cm^{-1}$ in FTIR data is considered an acceptable deviation in the art.

Therefore, when examining the claims, it is important to consider also the drawings that show the full characterization of the claimed compound.

5.3. In cases where a compound or compositions containing the compound in a dissolved state (meaning, the compositions are liquid or not limited to solid compositions) it should be noted that in a

dissolved state the crystalline structure is destroyed[6], and there is no difference between the compound or composition that contains the claimed crystalline structure in a dissolved state and the compound or composition that contains the compound described in prior art. Therefore, claims relating to a compound in a dissolved state, liquid compositions, or compositions that are not limited to solid compositions lack novelty.

5.4. The "disappearing polymorph" phenomenon is a phenomenon in which a compound in a certain crystalline form was known in the prior art, yet the known process for producing the crystalline compound no longer leads to the production of that crystalline form, due to various environmental influences (such as seeding, contamination, change of temperature). Where a claim relates to a "disappearing" polymorph (as a product claim) prepared by a novel method, an objection on grounds of lack of novelty should be raised in view of the prior art although the preparation process is novel and involves an inventive step.[7]

6. Section 5 – Inventive Step[8]

6.1. Where novel crystalline/amorphous forms or novel crystalline/amorphous salts of a known compound and/or methods for preparation thereof are claimed, the degree of proof required for demonstrating an inventive step is high. This is because the compound is not novel and is disclosed in the prior art, and the generally accepted methods for preparing the crystalline/amorphous forms or the methods for preparing the salts are well-known to an average skilled person in the art. In such cases, where the specification does not include comparative results of all the crystalline/amorphous forms compared to the prior art, the applicant is required to submit data indicating a substantial and unexpected advantage compared to that disclosed in prior art. It should be noted that an inventive step cannot be acknowledged solely based on general statements or differences in the characterization methods.

6.2. Where the prior art discloses the compound in an amorphous state, and the application under examination claims a certain crystalline form, indicating the differences between the two states is insufficient for demonstrating the involvement of an inventive step, and a substantial and unexpected advantage should be pointed out, since an average skilled person in the art is aware that there are differences between the data of a compound in a crystalline state compared to a

[6] N. K. Jain & M. N. Mohammedi, Polymorphism in Pharmacy, 23(6) INDIAN DRUGS 316 (1986).
[7] See Deputy Commissioner's decision, Noah Shalev Shlomovitz's decision, 117035, SmithKline Becham plc. & Unipharm (published on the Patent Office's website, 16.4.2009).
[8] – See also Appendix 7 of the Examination Guidelines – Section 5 of the Law – Inventive Step.

compound in an amorphous state. For example, an average skilled person in the art would expect an improvement in the stability, filtration, or drying properties of the crystalline compound compared to the amorphous compound that is known in the prior art which has higher hygroscopic and/or solubility properties and improved availability.[9]

6.3. As stated in Sections 6.1 and 6.2 above, where the compound is known from the prior art and in the lack of data indicating a substantial and unexpected advantage, an objection should be raised regarding lack of an inventive step.

6.4. In cases of claims relating to crystalline forms, the examiner should indicate that polymorphic screening of a known compound is considered routine experimentation that is carried out by trial and error. For example, it is known and generally accepted in the art that most of the pharmaceutical compounds investigated through standard methods in the art would result in obtaining at least one crystal.[10] Different crystalline forms of a compound are expected to have different physical properties, such as melting point, stability, solubility, hygroscopicity, FTIR pattern, XRD pattern, etc. Therefore it would have been obvious to an average skilled person in the art to try crystallizing known compounds, with a reasonable expectation of success (although not guaranteed),[11] without involving inventive skills. Thus, to meet the requirement of inventive step, a substantial and unexpected advantage of the claimed invention should be demonstrated compared to that disclosed in the prior art.

6.5. Where a process for preparing amorphous/crystalline compounds, based on generally accepted methods in the art, is claimed, an objection on grounds of lack of an inventive step should be raised. For example, the use of general process steps, such as:[12]

6.5.1. preparation of crystals by dissolution (change of solvents or solvent mixture), seeding, mixing, rapid or slow evaporation, cooling, obtaining the desired crystal, filtration, drying, etc.; and

6.5.2. preparation of an amorphous substance by rapid evaporation, rapid cooling, lyophilization, addition of an excipient that prevents crystallization of the compound, etc.

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[9] Stephen Byrn, Ralph Pfeiffer, Michael Ganey, Charles Hoiberg & Guirag Poochikian, Pharmaceutical Solids: A strategic Approach to Regulatory Consideration, 12(7) PHARMACEUTICAL RSCH. 945 (1995); Bruno C. Hancock & Michael Parks, What is the True Solubility Advantage for Amorphous Pharmaceuticals?, 17(4) PHARMACEUTICAL RSCH. 397 (2000); Lian Yu, Amorphous Pharmaceutical Solids: Preparation, Characterization and Stabilization, 48(1) ADVANCED DRUG DELIVERY REV. 27 (2001); T 777/08-3.3.01- Decision of technical Board of Appeal 3.3.01 dated 24 may 2011.

[10] Mino R. Caira, Crystalline Polymorphism of Organic Compounds, 198 TOPICS IN CURRENT CHEMISTRY 166 (1998).

[11] See Appendix 7 of the Examination Guidelines – Section 5 of the Law – Inventive Step, Section 5.3.4 – Obvious to try.

[12] Hancock & Parks, What is the True Solubility (see footnote 9 above); Yu, Amorphous Pharmaceutical Solids (see footnote 9 above); BRIAN S. FURNISS, ANTONY J. HANNAFORD, PETER W. G. SMITH & AUSTIN R. TATCHELL, VOGEL'S TEXTBOOK OF PRACTICAL ORGANIC CHEMISTRY 135-139 (5th. ed. 1989); HARRY G. BRITTAIN, POLYMORPHISM IN PHARMACEUTICAL SOLIDS 184-219, 331-358 (1999); HARRY G. BRITTAIN, POLYMORPHISM IN PHARMACEUTICAL SOLIDS 1-2, 76, 78-81, 88, 95-100, 122-123, 186, 233-236, 283-284, 587-588 (2nd ed. 2009).

Where the claimed process includes special conditions or steps that are not obvious to an average skilled person in the art, an inventive step may be acknowledged.

6.6. Salts – standard and generally accepted methods in the art for preparing salts of known compounds include a screening of the salts obtained by using acids and/or bases together with the known compounds. The purpose of the screening is to obtain a salt compound with improved solubility and/or stability. Therefore, a claim for a method of preparing a salt of a known compound would be deemed to involve an inventive step, so long as a substantial and unexpected advantage in the production process is presented. Where a crystalline form of a salt of a known compound is claimed without demonstrating an inventive step of the salt per se, an inventive step may be acknowledged with respect to the crystalline form of the salt, provided that a substantial and unexpected advantage is demonstrated for the crystalline form, except for cases in which the prior art explicitly directs the average skilled person skilled in the art to go through the path for obtaining the same crystalline form or in cases where the crystalline form was obtained spontaneously during the process of preparation of the salt.

6.7. Where the applicant argues that the crystal/s and/or salt/s or the process/es for preparation thereof involve an inventive step, due to overcoming a special technical difficulty, the fact that the application discloses several crystalline forms and/or salts of a known compound that are obtained by known methods, indicates the tendency of the compound to crystallize and the likelihood that an average person skilled in the art would obtain one of the disclosed forms, is contrary to the applicant's argument. Moreover, where there is a large number of processes that include a broad variety of solvents, all of which lead to obtaining one crystalline form, it would be very likely that an average skilled person in the art would obtain the claimed crystalline form based on the general knowledge available to him, without the involvement of inventive skills.

6.8. Where a crystalline compound is known with a certain morphological shape (needles, cubes, etc.), an additional morphological shape does not in itself constitute evidence for a different crystalline state involving an inventive step. A different morphological shape of a known crystal does not constitute a basis for the involvement of an inventive step except in cases where the new morphological shape provides a substantial and unexpected advantage that is not known and generally accepted in the field. Examples of known advantages arising from the morphological shape include using crystalline compounds with morphological shapes that are different from a needle shape, which is known as unsuitable for transportation; and using non-amorphous compounds for filtration or for preparing compositions due to the unsuitability of the sticky nature of the amorphous compounds for filtration

or for preparing compositions as the compounds in an amorphous state adhere to the production or filtration apparatus.

6.9. Spontaneous polymorphic transitions between the different crystalline forms or between the crystalline and amorphous states do not qualify as a basis for the involvement of an inventive step. For example, where the specification states "The form X was found to convert to form Y over the storage of the material" and the polymorphic transition as described in the specification is obtained spontaneously, an inventive step cannot be acknowledged for a crystalline form resulting from this transition.[13]

6.10. Crystalline mixtures containing at least one known crystalline form – where the dominant crystal in the mixture is disclosed in the prior art, or where a claimed crystal can be obtained as a result of a spontaneous polymorphic transition during storage, an inventive step cannot be acknowledged for the mixture without demonstrating a substantial and unexpected advantage with respect to the mixture compared to each individual crystalline form.

7. Section 13 – Claims[14]

7.1. Compositions – where the claims relate to a composition containing a compound in known crystalline form and the specification does not include examples describing compositions, an objection should be raised, indicating that these claims are not reasonably supported by the specification in respect of the compositions containing the compound in a crystalline state combined with any suitable additive. In compositions that include crystalline compounds, it is important that the additives used in preparing the composition would not cause a change in the crystalline form. Additionally, it is unlikely that any known additive would be suitable for performing the invention.

7.2. Processes – where the claims relate to a process for the preparation of a crystalline compound and the process includes general steps (for example, use of any organic solvent) without defining the essential features of the process, an objection should be raised on the grounds that the claims describe general steps for preparing the compound without defining all the features necessary for carrying out the invention, such as the type of solvent, the ratio between solvents, the temperature at which the process is carried out, the cooling/heating rate, etc.

7.3. Claims defining a crystalline compound in terms of the peaks of an XRD pattern, by the use of expressions such as "at least one peak", "at least two peaks", "at least three peaks", "at least four

[13] See the Supreme Court's ruling on CA 2167/16 Sanofi v. Unipharm Ltd. dated 12/07/2021, sections 137-138 regarding application 139790.

[14] See also the provisions of Appendix 11 of the Examination Guidelines – Section 13 of the Law – The Claims.

peaks", "one or more peaks", do not precisely characterize the crystalline form of the compound and are considered unreasonably broad, since they refer to a limited number of peaks that are insufficient for characterizing the crystalline form and distinguish it from other crystalline forms. A precise characterization of the crystalline form of the compound can be done by selecting the peaks with the highest intensities that can clearly and unambiguously characterize the crystalline form (such as by the ten peaks having the highest intensities).[15]

7.4. Claims including a partial definition of the unit cell characterizing the crystalline form are also considered unreasonably broad. In provide a complete and clear definition of the crystalline form, the claims should define all the sides (a, b, c) and all the angles (α, β, γ) of the unit cell.[16]

7.5. Claims defining a crystalline form of a compound by use of a term such as "form B" or "form I", which is described in various manners in the specification, is considered unclear and does not define the invention. Therefore, the claims should unambiguously define the crystalline form, include a reference to a previous claim in which there is a clear definition of the crystalline form, or include a reference to an unambiguous definition in the description and/or drawings.

8. Section 12 – Description of the Invention in the Application Specification[17]

8.1. Where the specification does not disclose **the process for preparing the crystalline form/s**, but only provides a characterization of the crystalline form, the disclosure in the specification is deemed insufficient to enable a person skilled in the art to carry out the claimed invention regarding the preparation of the claimed crystalline form.

8.2. Where the specification describes the preparation of **different crystalline forms by an identical process**, the disclosure in the specification is deemed insufficient to enable a person skilled in the art to carry out the claimed invention regarding the specific process steps that are necessary for obtaining each of the different crystalline forms.

8.3. Where the specification provides an **incomplete characterization** of the crystalline form or does not provide any characterization at all, the disclosure in the specification is deemed insufficient to enable a person skilled in the art to carry out the claimed invention.

[15] BRITTAIN, POLYMORPHISM (1999) (see footnote 12 above, page 236); BRITTAIN, POLYMORPHISM (2009) (see footnote 12 above, page 334).
[16] ALLAN S. MYERSON, HANDBOOK OF INDUSTRIAL CRYSTALLIZATION 33-42 (1993).
[17] See also the provisions of Appendix 12 of the Examination Guidelines – Section 12 of the Law – Description of the Invention in the Application Specification.

8.4. Where a claimed process defines the use of **crystal nuclei** while the specification does not disclose a process for the preparation of the initial crystal nuclei, the disclosure in the specification is deemed insufficient to enable a person skilled in the art to carry out the claimed invention regarding the preparation of the initial crystal nuclei.

9. Regulation 20(a)(3) – Lack of Clarity, Breadth, and Conciseness of the Claims[18]

9.1. Independent claims defining a crystalline form in terms of supplementary characterization methods only, for example, DSC or TGA, are deemed unclear because they do not define the crystalline form unambiguously.

9.2. Claims relating to general compositions that contain a crystalline compound and any appropriate additive (for example, a pharmaceutically acceptable carrier) are deemed lacking the essential components for obtaining the compositions. These compositions are not limited to solid compositions, but may also relate to liquid compositions, in which case the crystalline structure is completely lost.

9.3. Claims that define a crystalline compound by use of general terms, such as "substantially pure", are deemed unclear where the specification does not provide a clear definition of these terms.

9.4. Claims that define a hydrate by use of expressions such as "hydrate content lies between the mono and sesquihydrate" or "multi-hydrate" are deemed unclear, since hydrates having different degrees of hydration do not have the same crystalline structure. Therefore, the degree of hydration should be accurately and clearly defined.

10. Sections 2 and 9 of the Law – Overlapping Applications[19]

An overlap between a claimed invention relating to crystalline compounds or Salts and a previous claimed invention relating to the same compound is examined according to the provisions of Appendix 5 of the Examination Guidelines. The following includes examples of such cases:

10.1. Where the application under examination claims a specific crystalline compound or salt, while the previous application claims the compound as well as salts or crystalline forms thereof in a general manner (for example: "a compound… or a salt/polymorph thereof"), the claimed scope of the application under examination is included in that of the previous application.

[18] See also the provisions of Appendix 11 of the Examination Guidelines – Regulation 20(a)(3) – Lack of Clarity, Breadth and Conciseness of the Claims.
[19] See also the provisions of Appendix 5 of the Examination Guidelines – Sections 2, 9, and 19 of the Law – Overlapping Applications.

10.2. Where the previous application claims a compound without defining any crystalline forms or salts thereof, but the specification of the previous application includes examples of a process for the preparation of the compound that is identical to that for the preparation of the crystalline form claimed in the application under examination, the latter is considered included in / identical to that of the previous application.

10.3. Where the previous application claims a compound without defining any crystalline forms or salts thereof, but the specification of the previous application includes physical properties for crystalline forms that are identical to the properties of the crystalline forms claimed in the application under examination, the claimed scope of the application under examination is considered included in that of the previous application.

10.4. Where the application under examination claims a composition that is not limited to a solid state containing a crystalline form of a compound/salt, and the previous application claims a composition that contains the same compound and/or a salt thereof, the claimed scope of the application under examination is considered overlapping with that of the previous application.

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Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a Patent Application	
Official Ed. 2 (28.2.2023)	Transl. Ed. 2.1 (10.07.2023)	Page 1 of 6	Guideline No.: **EG-23.1/19**

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 19 - Section 23 of the Law - Amendments in the Specification

References and documents relating to amendments to the specification: Sections 22, 23 of the Patents Law, Regulations 22(b), 22(c), and 43(a)(3) of the Patent Regulations, **Commissioner's Circular 034/2017-Patents** (2020), Commissioner's Decision re: Patent Application 64449 **Lavoratorio Vita** (1989) (hereinafter: the "Decision on 64449").

1. Introduction

1.1. This Annex specifies the guidelines for the examination of amendments made to the application specification during the substantive examination according to the relevant provisions of the Law, Regulations, Commissioner's Circulars, and decisions made at the Israel Patent Office Court regarding this matter.

1.2. Section 22 of the Law defines the Applicant's right to amend the application's specification:

> "The applicant may, at any time before the application is accepted, amend the specification in his application, either in consequence of a notice under Section 20 of the Law or at his own initiative."

Section 23 of the Law prescribes that the application date for the purposes of Sections 4, 5, and 9 of the Law will be determined according to the nature of the amendments:

> "Where amendments of a substantive nature have been added to the specification, then the Commissioner may determine, for the purposes of Sections 4, 5, and 9 of the Law – (1) where it is possible to distinguish between those amendments and the existing specification – that the date of the amendments is the date they were submitted to the Office; (2) Where it is not possible to distinguish between the amendments and the existing specification – that the date of the entire application shall be the date the amendments were submitted to the Office."

Regulation 22(b) determines the responsibility of the applicant to specify the reason for the amendments with respect to the objections raised:

> "Where the amendment is made in response to a Notice of Deficiencies under Section 20 of the Law, the applicant shall specify the deficiencies which were indicated as aforesaid and which the

amendments are intended to remove; where the requested amendment is in the patent claims, the applicant shall specify how the amendment complies with the provisions of Section 13 of the Law."

Regulation 22(c) determines the way in which amendment date should be indicated in the application specification:

"Where the Commissioner, under Section 23 of the Law, determined a date for the amendments submitted, such date shall be indicated in the specification in the margin of the passage containing the amendment."

Regulation 43(a)(3) obligates examiners to determine whether the amendments are of a substantive nature:

"Where the applicant has rectified the deficiencies according to Regulation 42, the Commissioner shall examine the application and specification, as amended, as if they had been so originally filed, and shall examine each amendment as to the following matters: [...] (3) whether it is of a substantive nature."

Section 20 of Registrar's Circular 034/2017-Patents refers to the conditions for incorporation by reference of the priority document into the application specification:

"In the event where the applicant wishes to amend the specification in a manner such that the specification would include the relevant part of the priority document to which reference was made using the phrase "incorporated by reference", he should have done so within a period of 14 months from the priority date (similar to PCT Rules 4.18 and 20). Therefore, following this period, it is no longer possible to add to the patent application's specification anything from the priority document and the applicant would not be able to rely on the disclosure in the priority document, for the purposes of Sections 12 and 13 of the Law."

1.3. These guidelines apply to applications examined under the provisions of Sections 17(a)(1) and 17(a)(2) of the Law.

2. Definitions Relating to the Provisions of this Appendix

2.1. Application specification – all application parts as submitted, including the description, claims, drawings, and sequence listings. The term "Description" shall be used henceforth to refer to all parts of the application that are not claims.

2.2. Substantive amendment – an amendment causing a change in the content of the application as originally filed. The amendment, which may be made in the form of addition, change, or omission, is considered causing a change in the content of the application if it discloses new information that did not explicitly,

implicitly, or inherently exist in the application as originally filed (regarding the definition of implicitly or inherently, see the provisions of Appendix 6 of the Examination Guidelines – Section 4 of the Law – Novelty).

2.3. Non-substantive amendments - amendments that do not change the content of the application as originally filed.

3. Non-Substantive Amendments

3.1. Amendment of an obvious error (erratum) – examples

a. translation errors, such as errors originating from an erroneous translation of the application from the original language to the language in which the application was submitted in Israel;

b. in case of contradiction between a molecule's structure and its name, amendment of one of those to conform with the other is not considered a substantive amendment if it was obvious to a person skilled in the art from the application specification which compound is the subject of the application;

c. when full support for the amendment can already be found in the original specification.

3.2. Obvious clarifications due to lack of clarity of inconsistency – examples

a. addition of a drawing for clarification purposes provided it has a basis in the original specification;

b. new material added to the specification that is known to a person skilled in the art and is considered common general knowledge in the field of the invention;

c. when a technical feature was clearly described in the original application, but the effect was not described or not fully described, while a person skilled in the art is able to deduce the effect from the technical properties detailed in the original application, further clarification of the effect would not constitute a substantive amendment.

3.3. Amendment of definitions based on the generally accepted practice in the field of the invention - example

In the field of organic chemistry, there are cases in which the application description includes definitions of chemical groups that contradict or are broader than the standard terms of IUPAC. Amendments made to the definitions in the application description to match the generally accepted definitions in the field of chemistry according to IUPAC shall be considered non-substantive amendments, provided they do not expand the scope of the original description.

3.4. References to prior-art publications

3.4.1. According to the provisions of Regulation 20(a)(1), prior art published before the application date may be added to the specification for the purpose of describing the state of the art within the field of the invention. Such an addition is not considered a substantive amendment under Section 23 of the Law. However, prior art as such does not provide support for an invention (or part thereof) that was not already described in the original application specification.

3.4.2. Adding relevant passages from prior-art publications when the application as originally filed referred to these publications as "incorporated by reference" to **describe the invention or the manners of performing it** following an examiner objection under Section 18 of Commissioner's Circular 034/2017-Patents, will predominantly be considered a non-substantive amendment.

4. Substantive Amendments in the Claims

4.1. The applicant is entitled to submit an amended claim set according to the provisions of Section 22 of the Law. In this case, the compliance of the claims with Section 13(a) of the Law shall be verified according to the provisions of Appendix 11 of the Examination Guidelines – The Claims, objections shall be raised in case of non-compliance with the requirements of Section 13(a) of the Law.

4.1.1. Where the applicant introduces amendments to the description of substantive nature (adding a new subject matter) to provide support for the claim(s), the amended claim(s) and the relevant passages of the description shall receive the date of submission of said amendments according to the provisions of Section 23(1) or Section 23(2) of the Law (at the examiner's discretion).

4.1.2. The compliance with Regulation 22(c) with respect to indicating the amendment submission date in the margins of the amended specification passages(s), shall be verified where substantive amendments are made (both in the description and claims).

4.2. Adding a disclaimer to the claim

In case a disclaimer is added to the claim, it should be verified that it does not add a technical contribution or a new meaning to the claims, compared to the invention as disclosed in the original specification. For example, excluding an element described or exemplified in the application specification as an essential element to the invention changes its scope when compared to the original specification (for emphases and guidelines regarding adding disclaimers to claims see also the provisions of Appendix 16 of the Examination Guidelines - Negative Limitations / Disclaimers in Patent Application Claims).

4.3. A later selection of a combination of elements not constituting an obvious choice to the average skilled person skilled, being exposed to the specification as originally filed, to reasonably select (such as by way

of examples) compared to other options falling within the field defined in the application specification as originally filed, is considered as selection possibly adding technical contribution or new meaning compared to the invention described in the original application specification. In such cases, the claimed amended scope will not be considered reasonably supported by the original application specification.

4.4. In cases where the amendment requires an additional prior-art search, it might be considered a substantive amendment.

4.5. Adding a specific aspect to the application specification constitutes a substantive amendment in cases where, if not for said addition, a claim based on that specific aspect and/or broader aspect would have been considered unsupported. For example, in the field of organic chemistry, adding a new compound to the application specification shall be considered a substantive amendment. Therefore, a specific claim based on that new compound shall bear the amendment submission date, which should be indicated according to the provisions of Regulation 22(c). However, claims based on a broad aspect (such as Markush claims on which the specific aspect depends) will not bear the amendment date if the examiner finds that said claim has a basis in the application specification, regardless of the new compound. In this regard, see the Decision on 64449:

> "Where an application's specification was amended and the amendment added subject matter to provide support for a general or specific claim, the date of such claims shall be postponed, should they be based on the added subject matter, to the date the amendment was filed with the office. In other words, if there is a claim in the original specification that defines the invention by way of a "MARKUSH FORMULA" and examples were added to the specification, which were not previously mentioned in the specification, to add a basis to the general formula, the claim date with respect to the new examples shall be postponed to the date of their addition."

4.6. When a claim receives a new date - every dependent claim also receives said new date.

5. Amendments to the Application Description

5.1. Adding a new manner of performing the invention, which was not originally mentioned in the application, is considered a substantive amendment.

5.2. In cases where an aspect of an invention is defined in an originally submitted claim but is not supported by the specification, the description may be amended to include this aspect as described in the claim, since the claims are part of the specification. However, if the applicant adds new explanations to the description, the amendment shall receive a new date.

5.3. Overcoming an objection regarding the utility of the invention (see also Appendix 2 of the Examination Guidelines – Section 3 of the Law – A Patentable Invention) but introducing a new subject matter to the specification is considered a substantive amendment of the application, in accordance with the provisions of Section 23 of the Law.

6. Implementation and Additional Emphases

6.1. In cases where a substantive amendment was added to the specification **after the application's publication date** and there are claims based on this amendment - the application itself and all additional material in the application file will be considered prior art with regards to Sections 4 and 5 of the Law. The application publication date in this regard is as follows:

- For an international application entering the national phase in Israel, the publication date will be 18 months from the priority date;
- For an application first filed in Israel, the publication date under Section 16A of the Law will be 18 months from the filing date of the application.

6.2. The date of substantive amendments made in the description should be indicated in the margins of the amended passages, according to Regulation 22(c), even where the claims are not based on these amendments, due to possible ramifications (see Section 5.3 below).

6.3. A divisional application (or parts thereof) submitted after amendments have been made (compared to the parent application from which it was divided) will not benefit from the parent application's date where said amendments are substantive in the sense of Section 24(c) of the Law.

6.4. Where substantive amendments are made to claims, an additional search shall be conducted only for such claims meeting the requirements of Section 13 of the Law.

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Appendix 20 – Emphases in Examination of Applications Concerning Antibodies

1. Objective

1.1. Establishing uniform guidelines for examining applications concerning antibodies as to their compliance with the provisions of Sections 4, 5, 12, 13, of the Law.

1.2. The emphases and guidelines set forth in this appendix do not supersede or exempt from the guidelines prescribed in the previous appendices to the work instruction for examining an application for a patent.

2. Definitions

2.1. Antibody: a protein from the immunoglobulin superfamily, with at least one basic structural unit comprised of two polypeptide chains, at least one light and one heavy that form several defined regions (see below). An antibody has the ability to bind specifically to a target site (epitope).

2.2. Antigen: a substance that is identified as "foreign" to the immune system.

2.3. Immunogen: an antigen which, in addition to its detection by the immune system, triggers an immune response and produces antibodies.

2.4. Epitope: the site on the antigen to which the antibody binds.

2.5. Constant Region: the antibody region that does not participate in the binding to and detection of an epitope (and is, therefore, common to all antibodies generated in a particular animal).

2.6. Variable Region: the antibody region participating in the binding to and detection of an epitope (and therefore varying among different antibodies), comprised of framework regions having less variability in its amino acid sequences and CDR regions having more variability (see below).

2.7. Complementarity-Determining Regions (CDRs): the most important regions of the antibody for binding to the epitope (used for detecting antigens), also referred to as hypervariable regions due to the large variability in the amino acid sequences of these regions between different antibodies.

2.8. Monoclonal Antibodies: antibodies originating from a single cell clone (and therefore include one type of antibody population).

2.9. Polyclonal Antibodies: antibodies originating from different cell clones (and therefore include various types of antibody populations).

2.10. Fragment: a part of an antibody that is formed by translation of a part of a DNA sequence encoding an antibody or by fragmentation of the antibody protein.

2.11. Human Antibody: an antibody encoded by human DNA (even if produced in non-human cells).

2.12. Chimeric Antibody: an antibody obtained by a DNA sequence that is encoded by DNA sequences from more than one species, for example, an antibody whose constant regions are of human origin and variable regions are of animal origin.

2.13. Humanized Antibody: an antibody with partly or wholly non-human variable region sequences, which was modified by replacing at least part of the non-human origin sequences with matching sequences found in human antibodies.

3. Section 12 – Disclosure of the Invention in the Specification[1]

3.1. To comply with the provisions of Section 12, the description shall include disclosure of the manners of performing the invention that enable a person skilled in the art to produce the claimed antibodies. There are several options to provide manners of performance:

a. A sequence of amino acids of the entire protein constituting the antibody, or a DNA fragment that encodes the protein.

b. A sequence of amino acids of all the variable regions or only the CDR of the Antibody, or a sequence of DNA fragments encoding these regions.

c. Reference to the deposited cell that produces an antibody (reference to the deposit number of the cell).

d. Description of a specific process for preparing the antibody or reference to a standard process based on the description of the antigen.

3.2. Disclosure of an antibody based on measurable properties only (for example, binding kinetics – affinity constant or its biological activity) does not meet the requirements of disclosing the manners of performance since a person skilled in the art cannot produce the specific antibody based on these properties without undue experimentation.

[1] See also the provisions of Appendix 12 of the Examination Guidelines – Section 12 of the Law – Description of the Invention in the Application Specification.

4. Section 13 of the Law – The Claims[2]

4.1. A claim that defines an antibody in terms of its properties rather than in terms of its structure shall be deemed a functional claim and shall be examined according to the provisions of Section 13(b) of the Law.

4.1.1. A claim for an antibody defined based on an antigen (or epitope) shall be deemed limited to antibodies that are obtained by routine production methods or production methods that are disclosed in the specification, or by the antibodies' structure disclosed in the specification (for example, according to a sequence).

4.1.2. A claim for an antibody defined in terms of binding kinetics, physical properties or special properties of the antibody (such as the degree of immunogenicity) shall be deemed limited to the antibodies' structure and/or the antibodies obtained by the production methods described in the specification (or by routine production methods), provided that a skilled person would be able to expect reasonably and consistently that these methods would lead to obtaining antibodies with the claimed properties without the need for further effort of research and development. For the avoidance of doubt, the claim shall not be deemed as including all the possible antibodies that meet the conditions set out in the claim, but rather only those that are reasonably and consistently obtained from the methods described in the specification or that are structurally described in the specification.

4.1.3. Where the description of the application does not include a structural definition of the antibody or a description of the methods that enable a skilled person to obtain antibodies reasonably and consistently with the claimed properties, the scope of the claim is not clearly defined and the examiner is required to note that the claim does not meet the requirements under Regulation 20(a)(3).[3]

4.2. In cases where the claim further defines additional properties (in addition to the functional limitation), the claim shall be deemed as meeting the requirements of Section 13(a) of the Law only where the specification describes at least the sequence parts that lead to the additional properties. For example, a claim further defining the affinity constant of the antibody to the antigen shall be deemed as reasonably supported by the specification only where the description discloses at least the whole sequences of the variable regions of the antibody. As another example, a claim further defining an antibody or a fragment thereof in terms of physical, chemical, or biological properties that are not within the realm of antibody-

[2] See also the provisions of Appendix 11 of the Examination Guidelines – Section 13 of the Law – The Claims.
[3] See also the provisions of Appendix 11 of the Examination Guidelines – Section 13 of the Law – The Claims, Section 4.

antigen binding (such as solubility or potential to establish an immune reaction against the antibody) shall be deemed as reasonably supported by the specification only where the specification discloses the sequence of the antibody or the fragment (rather than only the variable regions or the CDR) which leads to the claimed property.

5. Section 4 of the Law – Novelty[4]

5.1. An Antibody is **not novel** where the prior art describes an identical sequence of an antibody or a longer DNA sequence fragment (which was isolated) that encodes the antibody, and where this fragment is described specifically and separately from the remaining DNA sequence.

5.2. A claim that defines an antibody only by a particular region (such as CDR) is **not novel** where the prior art describes a sequence of an antibody that includes the aforementioned region.

5.3. A claim that defines an antibody in terms of its properties rather than in terms of its structure is **not novel** where prior art describes an antibody with the same properties.

6. Section 5 – Inventive Step[5]

6.1. A claim for a new antibody that is structurally defined in terms of an encoded DNA sequence/amino acids sequence **does not involve an inventive step** where one of the following is true:

6.1.1. the prior art discloses the preparation of an antibody that binds to an antigen identical to that described in the application under examination, while the application does not indicate a substantial and unexpected advantage in binding to the antigen (or an advantage due to other properties: physical/chemical/biological);

6.1.2. the prior art discloses antibodies with sequences of the variable regions (VR) that are identical to those of the claimed antibody, while the application also does not indicate a substantial and unexpected advantage with respect to the physical/chemical/biological properties.

6.2. Where the monoclonal antibody is known, preparation of a humanized antibody therefrom is deemed obvious. Exceptions for that include cases where there was technical difficulty in its preparation or use thereof.

6.3. Claims for a second medical use of a known antibody would be deemed involving an inventive step where the second use would not have been obvious for the average skilled person.

[4] See also the provisions of Appendix 6 of the Examination Guidelines – Section 4 of the Law – Novelty.
[5] See also the provisions of Appendix 7 of the Examination Guidelines – Section 5 of the Law – Inventive Step.

Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Interview with Examiner during Examination of a Patent Application	
Official Ed. 11 (28.2.2023)	Transl. Ed. 11.1 (10.07.2023)	Page 1 of 4	Guideline No.: **EG- 23.3**

Drafted by: Simona Aharonovich Superintendent of Patent Examiners	Reviewed by: Jacqueline Bracha Deputy Director of the Israel Patent Office	Approved by: Ofir Alon Director of the Israel Patent Office

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Interview with Examiner during Examination of a Patent Application

1. Objective

Setting forth the process of conducting an interview with an examiner during the examination of a patent application.

2. Definitions

(Not applicable).

3. Applicable Documents

The Patents Law, 5727-1967.

4. Methodology

4.1 An interview between an applicant or his authorized representative (patent attorney or an attorney handling the application) and an examiner, shall be requested by the applicant or his representative, or by the examiner.

4.2 A request for conducting an interview by the applicant shall be submitted on the electronic filing website or to the Patents Administration via an action titled "Request for an interview with the examiner during examination". The request shall include the list of participants intending to participate in the meeting.

4.3 The interview date shall be set under the examiner's responsibility in direct coordination with the applicant or his authorized representative.

4.4 The interview may be conducted through a meeting at the Office, via a phone call or video conference.

4.5 The requester shall provide in writing, prior to the interview, the subjects to be discussed during the interview and the main arguments relating to them.

4.6 The examiner shall notify the Team Manager of the intention to conduct an interview, its purpose, and the subjects to be raised for discussion. Upon the applicant's request, the Team Manager shall participate in the interview.

4.7 Close to the interview, it is possible to send to the examiner no more than two claim sets that would be deliberated upon during the interview.

4.8 In addition to the claim sets, as stated in Section 4.7, the applicant shall deliver to the examiner any document he wishes to present during the interview. All the material to be deliberated upon (including the claim sets) shall be delivered along with the request for conducting the interview. The examiner is entitled to refuse discussing documents at the meeting that would be sent to him later or otherwise act for postponing the meeting date if necessary.

4.9 A summary of the interview shall be prepared and documented by the examiner on a form titled "Meeting with Inventor".

4.10 In cases of informal communication with the applicant (brief clarifications or clarifying non-substantive issues), there is no need to issue a "Meeting with Inventor" action, yet it is required to indicate that communication on the next notice that would be issued during the examination of the application.

4.11 The examiner is entitled, for facilitating documentation of the interview, to electronically record the course of the interview, in which case he shall notify the participants prior to the interview. An electronic file of the recording shall be sent to the applicant or his authorized representative upon his request. It is not required to transcribe the recording, but it is required to document the main matters on the interview summary form.

4.12 The interview summary shall include the following points:

4.12.1 the names of the participants in the interview;

4.12.2 the details of the matters that were and/or are still in dispute and/or the matters that require clarification;

4.12.3 a concise summary of the agreement reached by the parties regarding the continuation of the examination process, the summary shall not specify a detailed protocol for the interview;

4.12.4 where the purpose of the interview was to clarify the invention to the examiner, the examiner shall summarize these clarifications, which shall be taken into account in the examination of the invention;

4.12.5 where the examiner and the applicant have reached an agreement regarding a patentable claim set, this should be indicated, and the examiner shall act according to the Examination Guidelines regarding the acceptance of the application (EG 23.1/1, Chapter 6); and

4.12.6 where the examiner is willing to accept the claim set with certain changes, the required changes shall be indicated in the summary of the interview.

4.13 On the interview summary form, one of the following options shall be indicated:

1. "The date for sending a response to the Notice of Deficiencies dated ____ remains unchanged";
2. "This summary is deemed a Notice of Deficiencies under Regulation 43, for which a response should be sent within 4 months from today";
3. "A Notice of Deficiencies will be soon sent to the applicant";
4. "A Notice of Refusal of the application will be soon sent to the applicant";
5. "A Notice before Acceptance will be soon sent to the applicant".

4.14 The interview summary shall be documented in the automated system.

4.15 The applicant is entitled to submit his comments in respect of the interview summary (via the electronic filing website or by submission on paper), and these shall be documented in the system alongside the interview summary.

4.16 Where holding an interview is requested **prior to** sending a first Notice of Deficiencies, reference to the interview shall be indicated on the Notice of Deficiencies without sending a separate notice of interview summary.

4.17 Interview after a "Notice before Refusal":

4.17.1 Where the interview is requested within the framework of a response to a "Notice before Refusal", it is the responsibility of the applicant or his authorized representative to indicate **as part of his response** three dates on which the interview would be held within two months from the date of submitting the response.

4.17.2 Where, during the interview, the examiner is willing to accept the claim set with certain changes, the examiner shall indicate that the application will be refused in case these changes are not made. In this case, the applicant/his representative shall submit the claim set with the required changes within a period of four months. Where this claim set,

including the required changes, is not submitted in due time the application will be refused. In the interview summary, the examiner shall indicate that the interview summary is deemed a notice under Regulation 43.

4.17.3 Where, during the interview, the examiner and the applicant failed to reach an agreement regarding a patentable claim set, this shall be indicated in the interview summary, and the examiner shall act for issuance of a Notice of Refusal of the application according to the Examination Guidelines concerning the refusal of the application (EG 23.1/1, Chapter 7).

4.18 Where the interview **is not** within the framework of a response to a "Notice before Refusal", and where the examiner and the applicant failed to reach an agreement regarding a patentable claim set, this shall be indicated in the interview summary and the examiner shall decide whether it is required to issue a new Notice of Deficiencies or that the applicant is required to respond to the previous Notice of Deficiencies. Where new objections are raised during the interview, it is required to specify these objections in a new Notice of Deficiencies to which the applicant would be able to respond.

5. Responsibility

The responsibility for implementation of this Examination Guideline shall apply to the Director of the Israel Patent Office, the Superintendent of Patent Examiners or her deputies, the Team Managers, and the patent examiners.

6. Appendices

(Not applicable)

7. Forms

"Meeting with Inventor" form in the automated system.

Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Request for Advanced Examination	
Official Ed. 8 (28.02.2023)	Transl. Ed. 8.1 (10.07.2023)	Page 1 of 8	Guideline No. **EG- 23.7**

Drafted by: Itai Katz, Patent Examiner; Hamutal Sivan, Senior Patent Examiner	Reviewed by: Jacqueline Bracha Deputy Commissioner of Patents	Approved by: Ofir Alon Commissioner of Patents

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Request for Advanced Examination

1. Objective

Setting forth the procedure for processing requests for advanced examination of a patent application.

2. Definitions

2.1. "On-the-spot" Examination – examination of a patent application that is advanced out of turn, where there is a justifiable reason for doing so under the Law.

2.2. "Preliminary Examiner" – the patent examiner who is responsible for the examination of requests for on-the-spot examination.

2.3. Patent Prosecution Highway (PPH) Arrangement – as specified on the Office website:

2.4. https://www.gov.il/en/Departments/Guides/patents-guides?chapterIndex=3

3. Applicable Documents

3.1. Section 19A of the Patents Law, 5727-1967 (hereinafter: the "Law");

3.2. Regulation 35 of the Patents Regulations (Office Practice, Rules of Procedure, Documents and Fees), 5728-1968 (hereinafter: the "Regulations");

3.3. Commissioner's Notice dated 3.11.2019 (hereinafter: the "Commissioner's Notice");

3.4. The PPH arrangements as specified on the Office website at the address noted above.

4. Methodology

4.1 Section 19A of the Law sets out the entitlement of an applicant and a third party to request advanced examination of a patent application according to the provisions prescribed in this section.

4.2 The request for advanced examination submitted by an applicant shall be accompanied by:

4.2.1 an affidavit providing reasoning for the request, which is based on one or more of the grounds for accelerating the examination that are set out under the Law, and

4.2.2 where fees need to be paid, a confirmation of payment of the fees prescribed in the Second Schedule of the Regulations.

The request along with the affidavit are received by the Preliminary Examiner, who shall decide whether the application meets the terms for advancing examination thereof.

4.3 A request for advanced examination that is based on Sections 19A(a)(1) (the applicant's advanced age or medical condition) and 19A(a)(2) (Commissioner's Notices regarding advanced examination under the PPH) is free of charge. For the purposes of Section 19A(a)(1), an "advanced age" is the age of over 70 years (see Section 11 of the Deputy Commissioner's decision on application 216870).

4.4 A request that is based on one of the grounds set out in Sections 19A(a)(1) through 19A(a)(4) shall be decided upon by the Preliminary Examiner.

4.4.1 An application for advanced examination, under the PPH arrangement and according to Section 19A(a)(2), shall be approved by the Preliminary Examiner where the following cumulative requirements are met:

4.4.1.1 A corresponding application, to the patent application in Israel, obtained a positive national/international examination report, according to which at least one claim is patentable/allowable. This application is considered a corresponding application in one of the following cases: the applicant has shown that the patent application in Israel complies with one of the relevant scenarios that are part of the PPH arrangement; or the applicant has shown that the patent application in Israel is explicitly derived from a corresponding application (for example, a divisional application or continuation application), subject to the relevant scenario.

4.4.1.2 The application form for advanced examination under the PPH arrangement was submitted and duly filled out.[1]

4.4.1.3 The "Claims Correspondence Table" (see Appendix B below) indicates that the claims that were filed in Israel sufficiently correspond, meaning have an identical or similar scope as the claims that obtained a positive national/international examination report. Claims with a "similar scope" are claims in which the differences are due to one of the following reasons:

[1] The application form for advanced examination under the PPH can be accessed on the following website: https://www.gov.il/he/service/expedited_application_for_patent_registration

- Translation, correction of an obvious mistake, or clarification.
- Amendments made to comply with the requirements of Israeli law (Section 17(1) of the Law).
- Amendments made to comply with the requirements of Commissioner's Circular 034/2017-Patents.
- Narrowing the scope of claims (adding an element or feature without introducing a new category of claims).

4.4.1.4 All the following required documents were attached:

- all work products of the Office of Earlier Examination (OEE) and translation thereof to an acceptable language where necessary;
- a copy of the claim set in respect of which a positive national/international examination report was obtained, including a translation where necessary; and
- a copy of all the documents cited in the work products of the OEE.

However, there is no need to attach these documents where they can be obtained via available internet search engines.

4.4.1.5 The examination of the application in Israel has not yet started.

4.4.2 According to Section 19A(e) of the Law, an international patent application that has entered the national phase, for which a request for advanced examination was submitted and approved according to Section 19A of the Law, shall be examined only after 30 months from the filing date of the application or from the filing date of the previous application, where a right to priority was claimed, the earlier of the two.

4.5 Where the application does not meet the requirements of sections 4.2-4.4 above, the Preliminary Examiner shall send to the applicant a reasoned notice of the deficiencies in the request for advanced examination. The applicant shall be entitled to rectify the deficiencies once. According to Regulation 41(8) of the Regulations, the applicant is entitled to rectify the deficiencies within four months from the date a notice was sent to him regarding the matter. Where the applicant fails to rectify said deficiencies or fails to respond to the notice, the request for advanced examination shall be rejected and the application shall be returned to the regular examination order.

4.6 Where the request for advanced examination is rejected, the Preliminary Examiner shall provide reasoning for his decision.

4.7 Requests for advanced examination that are based on Sections 19A(a)(5) of the Law (public interest) or 19A(a)(6) of the Law (special circumstances justifying so) shall be brought by the Preliminary Examiner to be decided upon by the Commissioner, except for those that are based on Section 19A(a)(6) according to Commissioner's Notice, for which the Preliminary Examiner shall decide upon and send a notice regarding his decision.

4.8 A request for advanced examination that is filed by a third party according to Section 19A(c) of the Law shall be brought by the Preliminary Examiner to be decided upon by the Commissioner. The Commissioner's decision shall be sent to the Preliminary Examiner, the applicant, and the third party, as applicable, by the Court Administration.

4.9 Where the Commissioner or the Preliminary Examiner finds that the request for advanced examination meets the requirements for this, the Preliminary Examiner shall change the status of the advanced examination of the application in the automated system.

4.10 Where a request for advanced examination was approved, the patent application shall be passed to the responsibility of the Classification Team for preclassication so that the application would be allocated to the relevant Team Manager. The Team Manager shall assign the application to the relevant examiner.

4.11 Where the application is approved by the Commissioner or the Preliminary Examiner, the Preliminary Examiner shall notify the applicant of the name of the examiner who will examine the application.

4.12 The Preliminary Examiner shall attach a request for relevant prior art under Section 18 of the Law to the decision of approval of the advanced examination.

4.13 Upon receipt of the applicant's response to the request under Section 18 of the Law, the application shall be transferred to the assigned examiner.

4.14 A Notice of Deficiencies shall be sent to the applicant within three months from the date of receipt of the response to the request under Section 18 of the Law or the date of approval of the request for advanced examination, the later of the two. The Notice of Deficiencies shall include:

4.14.1 a reasoned statement regarding the patentability of each claim of the claim set in the application, according to Chapters B and C of the Law and the Examination Guidelines.

4.14.2 For applications first filed in Israel or other applications for which no previous search was conducted at other offices, the Notice of Deficiencies shall be accompanied with a search report indicating the prior-art publications depriving the claimed invention of novelty or inventive step; and the search strategy used by the examiner.

4.15 Where the request for advanced examination is based on the Commissioner's Notice, the Notice of Deficiencies shall be issued in English, upon applicant's request.

4.16 For on-the-spot applications and "green applications", the first Notice, whether a Notice of Deficiencies or Notice before Acceptance, shall be approved by the Team Manager prior to its transmission.

4.17 For PPH applications, the first Notice, whether a Notice of Acceptance (PC 13) or a Notice of Deficiencies (PC 27) indicating only non-substantive deficiencies (i.e., those deficiencies that are not against Sections 2, 4, 5, 9, 12 and 13 of the Law), shall be approved by the Team Manager prior to its transmission.

4.18 In applications whose examination was advanced according to Section 19A of the Law (except for PPH applications). As part of the Notice of Deficiencies - PC 27 (regarding non-substantive deficiencies) or as part of the Notice before Acceptance - PC 13, the examiner is required to attach a detailed and reasoned explanation regarding the reasons for accepting the application, while addressing, to the extent possible, the definition of the invention, the relevant prior art, and the difference between them.

4.19 Continued examination of an application whose examination was advanced shall be conducted within 3 months from the date of the applicant's response.

4.20 Where the examination of an application was advanced upon applicant's request, and an extension or postponement was requested, the application shall be returned to the regular examination order, unless the Superintendent of Patent Examiners or her deputies is convinced, based on a submitted affidavit, that the extension is required for circumstances that the applicant or his authorized representative has no control over or the ability to prevent.

4.21 Where the examination of an application was advanced upon the request of a third party, the applicant shall not be granted an extension or postponement, unless it is required for circumstances that the applicant or his authorized representative have no control over or the ability to prevent. In this case, requests for extension shall be decided upon by the Commissioner.

4.22 Where the examination of an application was advanced under the PPH, and during the examination (after a Notice of Deficiencies was sent to the applicant) amendments were made in the claim set so that the claims do not sufficiently correspond to those based on which the examination was advanced, the application shall be returned to the regular examination order, and the applicant shall be notified of so.

4.23 The examiners should receive a monthly report listing the applications whose examination was advanced, for which the applicant's response according to Section 18 of the Law was received, and

whose examination has not yet started. Where a Notice of Deficiencies has not been sent to the applicant by the end of two and a half months, the Preliminary Examiner shall deliver a reminder to the assigned examiner to start the examination.

4.24 A team that receives an application, for which an on-the-spot examination is to be conducted, shall not transfer it to another team, unless given approval by the Superintendent of Patent Examiners or her deputy. Prior to transferring the application from one team to another, the workload of both teams should be taken into consideration.

4.25 Where the applicant wishes that acceptance of an application, which was examined on-the-spot, not be published before the expiration of 18 months from the filing date of the application or the priority date, he is required to notify the examiner of so.

4.26 In addition to the applications noted above, the examination shall be prioritized also for "green applications" (see EG 23.8); patent applications for which an extension order was requested; and divisional applications where the parent application (and/or another divisional application that is derived from the same parent application) are under opposition proceedings.

5. Responsibility

The responsibility for implementation of this examination guideline shall apply to the Director of the Israel Patents Office, the Superintendent of Patent Examiners and her deputies, the Preliminary Examiner, and all Office employees whose position is related to this guideline.

6. Appendices

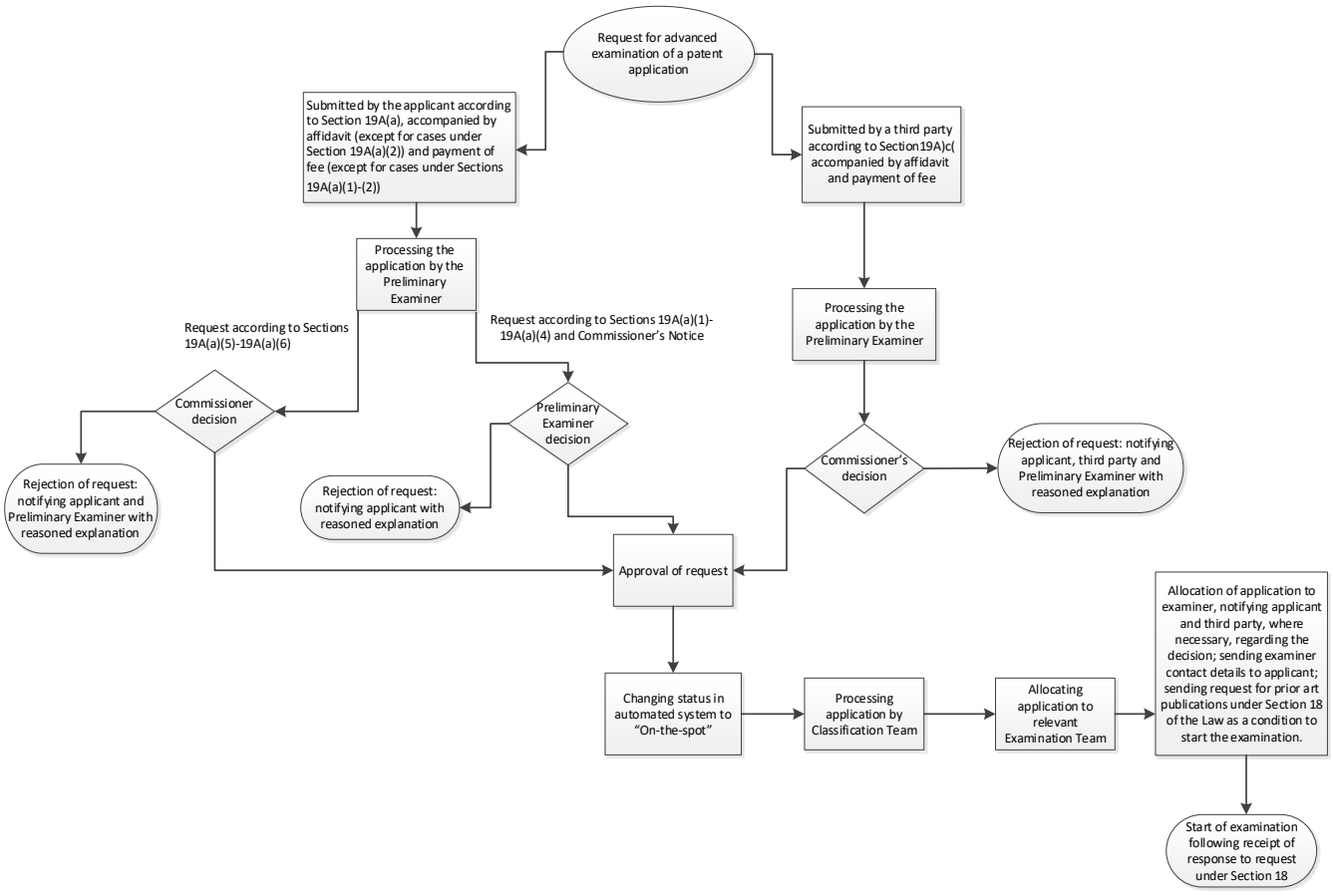
Appendix A – A flowchart describing the process of examining a request for advanced examination.

Appendix B – Claims Correspondence Table (example for filling out) for the purposes of a request for accelerated examination under the PPH.

7. Forms

Forms from the automated system.

Appendix A - Flowchart – Process for Examining a Request for Advanced Examination



Appendix B - Claims Correspondence Table (Example for Filling Out) for the Purposes of a Request for Advanced Examination under the PPH

Claim number in IL application	Claim number in patentable corresponding application at the OEE	Explanation regarding the correspondence
1-10	*1-10*	*The claim sets are identical*
1.	*2*	*The specific claims are identical*
2. A device comprising elements A and B.	*15. A device comprising elements B and A.*	*The order of the elements in the claims is different, but the claims sufficiently correspond to each other*
3. A device comprising elements A, B and C.	*none*	*The ILPO claim has an additional element to independent claim 34 that has been allowed at the OEE, where "C" is supported by the description (see page X, line Y) but is not claimed at the OEE*
4. A device according to claim 1 further comprising an element D.	*none*	*The ILPO claim is dependent on a claim that has been allowed at the OFF, where "D" is supported by the description (see page X, line Y) but is not claimed in the OEE*

Examination Guidelines

Chapter: 23. Patents Dept. – Patent Examiners		Subject: Examination of a "Green Application"	
Official Ed. 3 (28.2.2023)	Transl. Ed. 3.1 (10.07.2023)	Page 1 of 3	Guideline No.: **EG-23.8**

Drafted by:	Reviewed by:	Approved by:
Hamutal Sivan Patent Examiner	Simona Aharonovich Superintendent of Patent Examiners	Simona Aharonovich Superintendent of Patent Examiners

The following guidelines are translated from the official Hebrew Edition of the Examination Guidelines of the Israel Patent Office. In any case of ambiguity, discrepancy, or difference created in the translation, the Hebrew Edition shall prevail.

Request for Examination of a "Green Application"

1. Objective

Setting forth the process for processing a request for examination of a "green application" (advanced examination).

2. Definitions

2.1. Green application – a patent application in which the described invention assists in improving environmental quality, *inter alia*, by delaying the causes of global warming; reducing air, soil, or water pollution; and promoting non-polluting agriculture, etc.

2.2. Preliminary Examiner – a patent examiner who is responsible for the examination of a "Green Application".

3. Applicable Documents

3.1. Regulation 34 of the Patents Regulations (Office Practice, Rules of Procedure, Documents and Fees, 5728-1968 (hereinafter: the "Regulations").

3.2. Commissioner's Circular 034/2017-Patents (2020).

4. Methodology

4.1. Chapter C of Commissioner's Circular 034/2017-Patents specifies the manner of classification of patent applications as "green applications" and prioritizing examination thereof according to the provisions of Regulation 34 of the Regulations.

4.2. The application for advanced examination, submitted by the applicant shall be accompanied by a reasoned letter explaining how the invention assists in improving environmental quality.

4.3. For the avoidance of doubt, an application for classification as a Green Application shall not be considered an on-the-spot application, and thus shall not require additional fees.

4.4. A request for classifying the application according to Chapter C of Commissioner's Circular 034/2017-Patents shall be decided upon by the Preliminary Examiner.

4.5. A request for examination of a "green application" that was approved as aforementioned shall be directed to the Classification Team. This team takes charge of assigning an initial classification for the application and passing it to the responsibility of the relevant Team Manager or, in the absence of a Team Manager, to the one responsible for the allocation of the applications among the team. The Team Manager or the one who is responsible for allocation shall assign the application to an examiner of his team.

4.6. The Preliminary Examiner's decision on the request for examination of a "Green Application" shall be sent to the applicant. Should the application be approved, the Preliminary Examiner shall notify the applicant of the name of the examiner who would examine the application.

4.7. A Notice under Section 18 of the Law (request for providing relevant prior-art publications) shall be attached to the Preliminary Examiner's decision regarding the approval of advancing the examination.

4.8. A Notice of Deficiencies shall be sent to the applicant within three months from the date of receiving the response to Section 18 of the Law and shall include:

a. addressing the patentability of each of the claims in the application, according to Chapters B and C of the Law and the Examination Guidelines;

b. a search report indicating previous publications that deprive the claimed invention of novelty or inventive step;

c. Search Strategy Report for the search conducted by the examiner.

4.9. The continued examination of a "green application" shall be prioritized by the examiner.

4.10. Where the examination of a "green application" was advanced at the request of the applicant, and an extension or postponement was requested, examination of the application shall be returned to the regular order, unless the Preliminary Examiner is convinced, based on an affidavit filed, that the extension is requested due to circumstances over which the applicant or his representative has no control or which they cannot prevent.

4.11. The examiners shall receive a monthly report including the "green applications" whose examination was advanced, for which the applicant has sent a response to Section 18 of the Law, and whose examination has not started. Where a Notice of Deficiencies has not been sent to the

applicant by the end of two and a half months, the Preliminary Examiner shall send a reminder to the assigned examiner to start the examination.

4.12. A team entrusted with the examination of a "green application" shall refrain from directing it to another team, unless given approval by the Superintendent of Patent Examiners or her Deputies, who before directing it to another team, would consider the workload of the assigned team.

5. Responsibility

The responsibility for implementation of this guideline shall apply to the Director of the Israel Patents Office, the Superintendent of Patent Examiners or her Deputies, the Preliminary Examiner, and all Office employees whose position is related to this guideline.

6. Appendices

(Not applicable)

7. Forms

Forms from the automated system.