Section 39: Contents of complete specification

(1) Every complete specification must—

(a) disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art; and

(b) disclose the best method of performing the invention that is known to the applicant and for which there is an entitlement to claim protection; and

(c) end with a claim or claims defining the scope of the invention claimed; and

(d) include any other prescribed information.

(2) The claim or claims must—

(a) relate to one invention only; and

(b) be clear and concise; and

(c) be supported by the matter disclosed in the complete specification.

(3) A complete specification filed after a provisional specification, or filed with a convention application, may include claims concerning developments of, or additions to, the invention that was described in the provisional specification or the basic application (as the case may be) if those developments or additions are developments or additions for which the nominated person would be entitled to the grant of a separate patent under this Act.

(4) If a complete specification claims a new substance, the claim must not be construed as extending to that substance when found in nature.

~~The complete specification – general~~

~~1. For an invention to be patentable it must be novel over what is already known from the prior art base. Assessment of novelty of a claimed invention is based on whether all of the features of that claim are known from a single prior art document, see for example Ammonia's Application, 49 RPC 409. A mosaic of more than one document to find lack of novelty is not permissible, see for example British Ore Concentration Syndicate v Mineral Separation Ltd, 26 RPC 124 at page 147, and Lowndes' Patent 45 RPC 48 at page 57. Where it appears that a combination of more than one document would anticipate a claimed invention, then it is possible that these documents could be combined to find a lack of inventiveness i.e. the invention is obvious.~~

~~2. The complete specification should be the applicant's most complete attempt at describing and defining the invention to allow the grant of a patent, as adding missing materials after the filing date may lead to a loss of priority date of the amended specification. The complete specification should generally be a self-contained document with respect to the invention. The specification must include a title of the invention, followed by a description of the invention. The complete specification should include a description of the invention, contain~~

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at least one claim and any drawings required to illustrate the invention or other related matters.

3. The claims form part of the specification when filed with the specification at the same time as the application filing date. The subject matter found in the claims but not the description may be used to support the invention. Typically the subject matter which is found only in the claims will be required to be moved into the description to provide support for the claimed subject matter.

4. The purpose of the description is to disclose the invention clearly and completely enough to allow it to be performed by a person skilled in the art, and to provide support for the claimed invention. Where the description includes a consistory clause or other statement (of invention), then the clause or statement should be consistent with the claimed invention. The specification should not be excessively long or contain material which is not required in aiding understanding of the invention (Francis' Application, 27 RPC 87).

Clear enough and complete enough disclosure

5. The complete specification must disclose the invention so that a person skilled in the art would be able to work the invention.

6. The disclosure of the specification must be clear enough and complete enough to enable the person skilled in the art to perform the invention across the entire width of the claimed invention. The disclosure must be an enabling disclosure as in Asahi's Application [1991] RPC 485 HL and Biogen v Medeva [1997] RPC 1 HL.

7. The test for clear enough and complete enough disclosure was set out in Kirin-Amgen v Hoechst Marion Roussel Ltd [2005] RPC 9 as 'first identify the invention and decide what it claims to enable the person skilled in the art to do. Then one can ask whether the specification enables them to do it.'.

8. Claims may be directed to a single product or method, or encompass many separate methods or products. The disclosure should be sufficiently clear enough and complete enough for the person skilled in the art to perform the invention across the entire width of the claimed invention.

9. The specification should normally contain at least one example or method of performing the invention. Enabling disclosure is assessed during examination and is based on the specification at the filing date of the specification (Biogen) and not at a later date.

10. A single example may not be enough to provide an enabling disclosure across the entire width of the claimed invention. A single example of a method of producing a single product may be sufficient only to enable the person skilled in the art to work the invention for that product only. In Generics (UK) Limited and others v H Lundbeck A/S [2009] UKHL 12, [2009] RPC 13, a single product produced by a single method was sufficient to enable the full width of the invention with respect to that product. The specification in other cases may be required to disclose further examples or methods to support the invention across the entire width of the claimed invention.

11. It was noted in Novartis AG v Johnson & Johnson [2010] EWCA Civ 1039 that some non-inventive trial and error by a person skilled in the art is acceptable to determine what would

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~~or would not succeed for the invention to be performed as claimed. However, the specification must disclose all of the essential features of the invention and in enough detail for the person skilled in the art to put the invention into effect. In Edison and Swan Electric Light Co v Holland, 6 RPC at page 282 it was noted that if to work the invention that something new must be added by the person of reasonably competent skill, then the specification was not sufficient (not enabling).~~

~~Best method~~

~~12. The complete specification must include the best method of performing the invention known by the applicant at the time of filing of the application. The assessment of whether or not the applicant has included the best method in the specification can usually only be based upon facts known to the applicant, which are not generally available to the examiner at the time of examination.~~

~~13. There is no requirement for the specification to include the words 'best method' or any other such phrase. It is sufficient that the applicant has included a method of working the invention in the specification.~~

~~End with a claim or claims~~

~~14. Claims form part of the specification and must define the monopoly sought, AMP v Utilux (1974) 48 ALJR 17. The claims should be read with the specification as a whole and there should be consistency between the~~

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Introduction – purpose of Section 39

1. A complete specification is a document that discloses how to perform an invention and defines the scope of patent protection.

2. Section 39 sets out the main requirements for complete specifications. This includes the parts of a specification, how the invention must be disclosed, and specific requirements for the claims. This guideline outlines how IPONZ applies section 39 requirements when examining patent applications.

3. General requirements for applicants preparing complete specifications can be found on the Apply for a patent page of our website.

How to prepare a patent specification

Part 1: Underlying principles

- Construction of the specification and claims
- Form of the claims

Construction of the specification and claims

- Purposive construction

- The role of intention
- Date a which the specification is construed
- Using the specification to construe claims

4. Construction means the exercise of interpreting (construing) the specification and claims. This section covers how a specification is read and understood, and how this informs the purposive construction of claims.

Purposive construction

5. The principle of purposive construction has been described by the New Zealand Supreme Court in *Lucas v Peterson* [2006] NZSC 20:

[26] A patent specification is to be read as a whole and given a purposive construction. It must be construed as it would be understood by the appropriate addressee – a person skilled in the relevant art.

[27] Each part of the specification is to be read objectively in its overall context and in light of the function of that part. The claims are to be interpreted by reference to the object and description in the body of the specification.

[28] The claims define the scope of the monopoly conferred by the patent. They limit what others may do. They must clearly define the protected field so others may fairly know where they cannot go. The description in the body of the specification may assist interpretation, but it cannot modify the monopoly the inventor has clearly marked out.[1]

6. Purposive construction means the patent specification is to be read in light of its purpose, which is to disclose the invention and define the patent monopoly. It is also to be read in light of the common general knowledge in the field of the invention. The person skilled in the relevant art is referred to in this guideline as the "skilled person". More discussion about the characteristics of the skilled person can be found in our inventive step guideline.

Inventive step guidelines

The role of intention

7. Purposive construction is not directly concerned with what the applicant meant to say; it is concerned with what the skilled person would have understood the applicant to be using the words to mean.[2] If the skilled person would understand from the specification that the applicant intended that a term in the claim should be strictly complied with, then any variant that does not strictly comply with that term will fall outside the scope of the claim.[3]

Date at which the specification is construed

8. The complete specification is construed with reference to the common general knowledge at its filing date.

Using the specification to construe claims

9. Claims must always be interpreted in their overall context and by reference to the object and description in the body of the specification.[4] When interpreting terms in a claim, they should be given a meaning consistent with how they would be understood by the skilled person.

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10. If the patent specification gives an explicit dictionary-style definition for a term, the term should be understood by reference to that definition.[5] However, if the specification gives a dictionary-style definition for a term which is in conflict with the meaning as understood by the skilled person, this may result in a lack of clarity. This is discussed further below in the 'Clarity' section.

Clarity of the claims

11. Terms may have a technical meaning to the skilled person in light of their common general knowledge. A technical meaning of a term can be understood by referring to its usage by those working in the art.[6]

12. If a term has no technical meaning to the skilled person, it can be assumed the skilled person will give a meaning to the term which is consistent with its ordinary meaning, and consistent with the way the term is used in context, throughout the specification.

13. The description in the body of the specification cannot modify the monopoly that the inventor has clearly marked out in the claims.[7] This means, the scope of a claim cannot be narrowed or extended by reading into it words which are not in it.

14. The following examples are derived from case law, and illustrate purposive construction of patent claims:

- A claim to a lintel recited one of the support members of the lintel "extending vertically". In context, "extending vertically" did not mean precisely vertical, it meant near enough to vertical to enable the lintel to perform its function of bearing weight over a window or door space.[8]

- A claim to a method of "adjusting the transmission" through an amplifier. The claim's ordinary meaning was a method of adjusting the transmission by using an amplifier. Although the specification described methods of adjusting the amplifier circuit which resulted in changing the transmitted signals, the details of those methods could not be read into the claims to narrow the claim scope.[9]

- A claim to a sawmill included a "moving means whereby the rails can be moved in unison". The ordinary English meaning of this phrase was very broad. "Moving means" was found to mean any mechanism or device which could effect or facilitate movement. However, in the context of the specification, the term "moving means" did not extend to two human operators working together.

- The same claim also required a pair of "separate rails". The word "separate" was given its ordinary English meaning in that the rails were separated from one another. In context, it did not have a narrower meaning of the two rails being completely unconnected.[10]

- A claim to a structure adapted to support a wheel-mounted vehicle included reference to "a bearing". In context, the term "bearing" did not mean a separate physical bearing component was required but was considered to be used in a functional sense.[11]

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15. The features of a dependent claim can give guidance on the true construction of the main claim from which they depend.[12]

16. It should be presumed that redundancy between claims is not intended, so each claim should be construed as being different in scope, where possible.[13]

17. Patent abstracts are not considered part of the complete specification. The content of abstracts should not be referred to when construing the specification or claims.

Form of the claims

- Suitability for use and product claims with functional claim language
- Use claims
- Product "when used" claims
- Product-by-process claims
- Open and closed terms
- Obvious mistakes

18. Although the Act does not set out any form or structure that is required for the claims, most claims follow a common format. The Act categorizes two types of 'invention' which can be the subject of the claims: product and process. Product claims are directed to a physical object, while process claims are directed to an activity.

Section 18: Patents Act 2013 – New Zealand Legislation

19. Usually, the claim begins with an introductory term or phrase that identifies the category of the claim (product or process). Process claims typically use terms like process, method or use, while product claims can use a wide range of terms that refer to a relevant product, such as article, device, apparatus, compound, composition, polypeptide, or vector.

20. The claim will then define one or more features (integers) of the claimed product or process. When the claim is construed, the product or process is interpreted as having all of the features recited in the claim. The claim can also set out any features the product or process does not have. This can be done by stating a proviso, or by using exclusive or closed terms in the claim.

21. While the above is a guide for the form of a claim, there is no set structure for the claims. Providing a claim meets the requirements of the Act and Regulations, the applicant may choose the structure of the claim.

Construction of some common forms of claim

22. Some common forms of claim recite technical features of a product, and also refer to a process, either explicitly or implicitly. These are:

Suitability-for-use claims and product claims with functional claim language

23. These are claims which relate to a product, but also refer to the product's purpose, i.e. how the product is intended to be used. Claims to products as being 'suitable for' a purpose are limited in the sense that subject matter found in the prior art base which is not suitable for that purpose will not anticipate the claim. In other words, depending on the context of the claimed invention, "suitable

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for" in a product claim may confer a limiting feature on the claim. The expression "for" in a claim is considered to have the same meaning as "suitable for".

24. The expressions "adapted to/for", "effective for", "configured to", "arranged to", "capable of", "intended to", "designed to" are also typically used to describe features of a product by reference to its function. Depending on the context of the claimed invention, such expressions in a product claim may confer a limiting feature on the claim. For example, in the context of computer-implemented inventions, claims which recite a computer "configured to" carry out certain processing steps are limited to computers having programming which enables those steps to be performed.

25. It is important to use purposive construction to understand how "suitable for" or any functional language recited in a product claim limits the claim features. In situations where a product such as an article, composition or compound is known in the prior art, discovering a new purpose or suitable use for the same product does not add a technical feature to somehow transform the known product into a new product.

> *Example 1:* A compound X (known compound) for treating a disease D (second medical condition) in a subject.
>
> Commentary: This claim lacks novelty with respect to the prior art which discloses the same compound as claimed. The new purpose of treating disease D does not transform the known compound to a new compound. Since the new purpose is a therapeutic treatment, novelty can be recognized if the claim is amended to a Swiss-type claim. Our Swiss-type claims guideline has more information about these.
>
> **Swiss-type claims guideline**
>
> *Example 2:* A nitrification inhibiting composition comprising an inorganic fertiliser A and an organic fertiliser B.
>
> Commentary: the purposive construction of 'a nitrification inhibiting composition' is a composition for inhibiting nitrification. If a composition comprising A and B is already known in the prior art, the claim lacks novelty.
>
> *Example 3*: A film for carrying out the process of claim 1, which is adhesive when hot and consists of paper or another carrier, and adhesive material incorporated in the carrier and covering its two faces.[14]
>
> *Example 4:* An immunogen derived from a steroidal oestrogen or androgen, for use in a method as claimed in claim 1.[15]
>
> *Commentary*: The words "for carrying out the process of claim 1" or "for use in a method as claimed in claim 1" relate to the process for using the product (the film or immunogen), not the product itself. If a product from the prior art has all of the same features and would be suitable to use in the novel process or method, the product claim lacks novelty.
>
> *Example 5*: A workbench comprising features A, B and C.[16]

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Commentary: The word "workbench" refers to how the claimed product will be used. This in turn implies the product must be suitable for that use. A previously known bookbinder's press had features A, B and C, but was not suitable for use as a workbench because it was too small, so the claim was novel.

Example 6: A hook for a crane comprising features A, B and C.

Example 7: A crane hook comprising features A, B and C.

Commentary: A crane hook needs to be relatively robust and strong and of a size which would allow it to be suitable for the purpose of lifting and moving materials. A prior art fish hook for example may have the same defined features, would not be suitable for the same purpose as a crane hook.

Use claims

Example 8: Use of a disinfectant composition of claim 1 for sanitising a food preparation facility.

Commentary: This type of claim is construed as a process claim and is allowable, even though it may not explicitly recite a step of a process. There is no need for the claim to explicitly recite the process steps, because the skilled person knows what they are from their common general knowledge. For example, sanitising a food preparation facility with the disinfectant composition would require applying the composition to some part of the facility.

Product "when used" claims

Example 9: A fluorescent compound of claim 1, when used to make a security marking label.

Example 10: A compound of claim 1, when used to treat cancer.

Commentary: This type of claim is construed as a process claim. If the process is excluded under section 15 or section 16, an objection will be raised that the claim relates to excluded matter. For example, a compound when used to treat cancer will be objected to as a method of medical treatment.

Product-by-process claims

Example 11: A product obtainable by the process of claim 1.

Example 12: A product made by the process of claim 1.

Commentary: This type of claim is construed as a product claim. More detail on issues which may arise for product-by-process claims is given below in the 'Product-by-process' section.

Product-by-process

Open and closed terms

26. Inclusive or open-ended terms can be used to indicate that the product (or process) could also have additional features (or process steps) that are not recited in the claim. Terms such as "comprising", "including", and "containing" are usually used as open-ended terms. The wording "consisting of" is usually an exclusive or closed term which can be used to indicate that the product

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or process does not have any other features apart from those recited in the claim. The phrase 'consisting essentially of' usually means the scope of a claim is limited to the specified materials, integers or steps, and those that do not materially affect the basic and novel characteristic(s) of the claimed invention.

27. Whether a given term is open-ended or closed can be determined by referring to the context in which it is used, including any definition given for the term in the specification. These terms can also be used in relation the claim as a whole, and/or in relation to specific features recited in the claim. This means that a claim can use both open-ended and closed terms.[17]

28. Optional features can be recited in the claim and are indicated by terms such as “optionally”, "preferably", "with preference", "most preferred", "for example", "such as", "more particularly", or “in particular”. In purposive construction, optional features are disregarded when determining the scope of the claim.

Obvious mistakes

29. Where the disclosure includes an obvious mistake, this will be construed as it would be understood by the skilled person. This will depend on nature of the mistake. If the skilled person knows what the disclosure should be, then the disclosure will be construed as if it contained the correct matter.

Part 2: Requirements of the complete specification

- Enablement
- Best Method
- End with a claim or claims
- Prescribed Information

Enablement

30. The specification must enable the invention to be performed by a person skilled in the art. The requirements for enablement are discussed in more detail in the enablement and support section below.

Enablement and support

Best Method

31. The specification must include the best method of performing the invention known by the applicant at the time of filing of the application.

32. The equivalent requirement from the UK Patents Act 1949 has been interpreted in *E.I. du Pont de Nemours & Co. v. Enka BV*[18] to have three aspects in relation to determining whether a best method had been omitted from the specification. Reworded as they would apply to an application under the Patents Act 2013, these are:

> *(i) that there is matter, omitted from the specification, that would have disclosed a method of performing the invention better than any method disclosed in the specification;*

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(ii) that the method disclosed by the omitted matter was known to the applicant to be better than any disclosed in the specification, and,

(iii) that there was an entitlement to claim protection for the method.

33. This assessment can usually only be based upon information known to the applicant, which is generally not available to the examiner at the time of examination. Where such information is available, the best method requirement is assessed at the specification's filing date. The best method requirement should be assessed with respect to the invention as claimed. There is no requirement to disclose the best method of performing a feature which is not a part of the claimed invention.[19]

34. In the third aspect entitlement relates to the entitlement of the applicant/nominated person to claim protection for the method in the application in question. There is no requirement to disclose methods not invented by the applicant/nominated person, or to which they have not acquired rights. There is also no requirement to disclose methods that are separate inventions to the claimed invention.[20]

35. The specification does not have to include the words 'best method' or any other such phrase. If more than one method is provided there is no need to identify which is the best method. If the specification does not disclose any method of performing the invention the disclosure may not be clear enough and complete enough for the invention to be performed. This will be considered under section 39(1)(a) as discussed in more detail in the enablement and support section below.

Test for enablement

End with a claim or claims

36. A patent application must end with a claim or claims that define the intended scope of monopoly.

37. The claims form part of the specification, however they serve a different purpose to the description. The description has the practical purpose of instructing the skilled person on how to perform the invention, whereas the claims define the monopoly of protection sought, what must not be infringed during the term of the patent if granted.

38. An objection under Section 39(1)(c) will be raised if the specification does not include at least one claim.

39. While section 39(1)(c) requires the complete specification to "end with" a claim or claims, drawings and/or sequence listings may be included after the claims. Prescribed information

40. Other prescribed requirements for the specification are set out in the Patents Regulations 2014. The specification must meet any relevant requirements of Part 1 of the regulations (see regulations 1-45 and 55(a)). The specification is also required to include a title on the first page under regulation 55(b). The title should relate to the invention and correspond to the title provided with the application under regulation 50(1)(b)(iii).

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41. Abstracts, PCT pamphlet summary pages, and translation certificates are not considered part of the complete specification. This is because the inclusion of such pages contravenes the requirement of regulation 55(b) that the first page of the specification is the page containing the title, or the requirement of section 39(1)(c) that the description end with the claims. Inclusion of one or more of these within a complete specification will be objected to and a fresh specification requested under regulation 24(3).

Drawings

42. Drawings form a part of the specification if supplied under section 41. Therefore, the drawings are considered to form part of the disclosure for the purposes of section 39, including for assessing enablement and best method. The drawings pages should follow the claims.

Part 3: Requirements of the claims

- Relate to one invention only
- Clarity of the claims
- Conciseness of the claims
- Enablement and Support
- Enablement
- Support
- Concepts relevant to both enablement and support

Relate to one invention only

- Special technical features
- Unity “a priori” or “a posteriori”
- Markush practice
- International reports
- Assessing prior art
- Restricting examination

43. The Act does not set out any test for determining whether the claims relate to one or more inventions. In general, the approach followed to determine whether there is more than one invention claimed is the same as for ‘Unity of Invention’ under Rule 13 of the PCT Regulations.

Rule 13: Regulations under the PCT - WIPO

44. The examiners should assess unity according to the PCT International Search and Preliminary Examination Guidelines [Part III] Chapter 10 and the PCT Administrative Instructions Annex B.

Chapter 10: PCT International Search and Preliminary Examination Guidelines – WIPO

Annex B: PCT Administrative Instructions - WIPO

45. When raising a non-unity objection, the examiner should clearly identify all separate inventions with corresponding claim numbers and provide a brief summary of each invention in the

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examination report. If it is impractical to list all different inventions, the examiner should advise the applicant accordingly.

- ~~Special technical features~~
- ~~Unity "a priori" or "a posteriori"~~
- ~~Markush practice~~
- ~~International reports~~
- ~~Assessing prior art~~
- ~~Restricting examination~~

Special technical features

46. For there to be unity of invention, claimed inventions need to be linked by a single general inventive concept. Claims are unified when there is a technical relationship among those claimed inventions involving the same or corresponding special technical feature as per PCT Rule 13.2. Special technical features are those features in claims which define a contribution over the prior art.

47. Unity exists between claims of different categories when a special technical feature is shared among the claims. The allowable combinations of claims of different categories are listed in paragraph 10.12 of PCT International Search and Preliminary Examination Guidelines.

Paragraph 10.12: PCT International Search and Preliminary Examination Guidelines - WIPO

48. Unity also exists between claims of related articles in the same category when the special technical features of the claims correspond to each other, such as a transmitter and a receiver in a communication system.

Unity "a priori" or "a posteriori"

49. Unity of invention is assessed "a priori" or "a posteriori".

50. Lack of unity a priori, before the prior art has been examined, can be determined if the subject matter of the claims in question is completely different with no common features. Alternatively, a priori lack of unity can be determined if the common subject matter of the claims in question is clearly known, i.e. common general knowledge.

51. Examples of lack of unity a priori:

Claim 1: Features A+B

Claim 2: Features C+D

Claims 1 and 2 lack unity a priori because they have no common features.

OR

Claim 1: Features A+B

Claim 2: Features A+C

If feature A is common general knowledge, then claims 1 and 2 lack unity a priori.

52. A posteriori lack of unity assessment requires a prior art document (not necessarily the closest prior art document).

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53. If every common feature to all claims is known or obvious from the prior art document, then the claims lack unity a posteriori. A common feature which is not known and not obvious makes a contribution over the prior art, and therefore constitutes a special technical feature for uniting the claims.

54. Example of lack of unity a posteriori in independent claims:

Claim 1: Features A + B

Claim 2: Features A + C

If feature A is known or obvious from a prior art document, then claims 1 and 2 may lack unity a posteriori.

55. If all the features of an independent claim are known or obvious, then lack of unity a posteriori may exist between the dependent claims if there is no same or corresponding special technical feature among them.

56. Example of lack of unity a posteriori in dependent claims:

Claim 1: Feature A

Claim 2: dependant on claim 1 with additional Feature B

Claim 3: dependant on claim 1 with additional Feature C

If the feature A of independent claim 1 is known or obvious from a prior art document, then claims 2 and 3 may lack of unity a posteriori.

57. Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. The examiner should decide the unity of the claims on the balance of probability.

Markush practice

58. A Markush claim is a single claim defining alternatives, which may be chemical or non-chemical.

59. Markush alternatives meet the requirement of a shared special technical feature when the alternatives are “of a similar nature”.

60. When the Markush claim is to chemical compounds, the alternatives are of a similar nature when they all have a common property or activity, and either share a significant structural element or belong to a recognized class of compound.

61. A “significant structural element” is either a large portion of the structure, or a smaller but structurally distinct portion, essential for the common property. If the significant structural element is a large portion of the structure, it does not necessarily have to be novel.

62. A “recognized class of compound” means that each member of the class is expected to behave in the same way in the context of the claimed invention. Each member could be substituted for the other(s) and achieve the same intended result.

63. The criteria that alternatives be “of a similar nature” (have a common property or activity, and a shared significant structural element) may also be applied to claims to nucleotides, peptides, and proteins. See the discussion under examples 30 and 35-39 of the PCT Guidelines – Part III Ch 10.

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Examples 30 and 35-39, Part III Chapter 10: PCT International Search and Preliminary Examination Guidelines - WIPO

64. For Markush claims to chemical compounds, the existence of a compound or compounds falling within the scope of a claim will not necessarily result in a unity objection. The Markush alternatives may well still fulfil the requirements for "similar nature" noted above. In such cases, the anticipatory compound(s) may be addressed under novelty.

International reports

65. The examiner should review the international reports when examining a PCT application which has entered national phase in New Zealand. These reports are the International Search Report (ISR) and International Preliminary Report on Patentability (IPRP) Chapter I and/or II. Because IPONZ follows the PCT Guidelines on unity, the examiner will tend to take the same position on unity as the international authority.

66. However, the examiner may raise a unity objection, despite no objection by the international authority, if the claims clearly lack unity in view of the documents available. For example: if there are independent claims to A+B, B+C, and A+C.

67. Similarly, the examiner may not object to unity, despite a unity objection by the international authority, if it is considered that an error has been made and the claims clearly relate to a single invention. For example: if the independent claims are to A+B and A+C, and feature A is novel and inventive over the cited art.

Assessing prior art

68. Unity is assessed in view of the prior art base as defined in section 8(1) only: art published or made available before the priority date of the claims.

Section 8 (1): Patents Act 2013

Restricting examination

69. Where lack of unity has been identified, the examiner will only search the first numbered invention, unless it is possible to search the other inventions without substantial additional time or effort.

70. The examiner should appropriately advise the extent of searching and examination conducted in the examination report.

~~Clear and concise~~

~~43. Section 39(2)(b) requires that the claim or claims must be clear and concise (compare with UK 1977 Act section 14(5)(b)). The claims should be written in such a way that a person skilled in the relevant art would know clearly and unambiguously what the scope of the monopoly is and what to avoid.~~

~~General clarity~~

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~~44. The scope of a claim should be clear when looking at each claim separately and when looking at the claim set as a whole. There should not be any contradictions within a claim or between claims. If a feature is set at a specific value then later on it cannot be said to be a different value.~~

~~45. Sufficiency of the disclosure (section 39(2)(c)) relates to the scope of the disclosure and whether it supports the scope of the claimed invention. This has been referred to as 'Biogen insufficiency', after the case noted above. Whereas enabling disclosure relates to whether or not the disclosure would enable the person skilled in the art to perform the invention.~~

~~46. Terms of a vague, relative or subjective nature should not be used if they create doubt as to the scope of the claim. For example "high", "small", "hot", "pure" can in some cases be unclear. A "high" temperature can vary greatly even within the same art. In these cases, it is better for the applicant to be clear in what they mean by adding measureable features. The term is allowable without further clarification if it has a distinct and accepted meaning in the art such as "high-frequency amplifier". The exact frequency range would not need to be stated in this instance.~~

~~47. Terms that deal with the position of features such as "inside", "end", "above", "upwardly" should be considered as to whether they are clear. Relative terms are allowable if the point of reference is implicitly or explicitly clear and if the scope of the claim is measurable.~~

~~48. The question as to whether such terms as "back", "front", "above", "upwardly", are allowable or whether they introduce uncertainty into the claim, must be decided upon the facts of the case. Particular care is needed when for example the location of a feature of the invention is defined by reference to apparatus not forming part of the invention claimed or even by reference to a person using the invention.~~

~~49. The scope of a claim should not be variable over time. It needs to represent a set monopoly that is being claimed that a reader will be able to ascertain. Claims referring to documents, especially to a claim of another patent document are generally not allowed, as it may be altered, and would not stake out an immovable boundary. Industry standards may also change over time and the scope of a claim should not depend on a standard that has the potential to alter. Similarly, claims to a particular technical standard will be allowed where the substance of that standard is included within the specification.~~

~~50. Claims directed to "any invention as disclosed herein" or similar variations do not clearly define the scope of the invention and should be objected to for lack of clarity.~~

~~51. The term “homology” refers to whether two structures share a common origin, that is they either are homologous or they are not. It is therefore regarded as incorrect to say a polypeptide or nucleic acid sequence has a certain percent homology to another. The more appropriate term “sequence identity” should be used to clarify the scope of the claim.~~

~~52. Where percentages are listed the unit base should be stated where it is appropriate to do so. For example, percent weight, percent volume.~~

~~53. Names that are used exclusively by the applicant and represent a private or internal name given to a material or compound should not be used in the claims. The term should be replaced by an expression known to all skilled persons who may need to determine the monopoly defined by these claims.~~

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54. Terms such as "metabolite", "prodrug" and "derivative" do have a variety of working definitions, for example a metabolite is considered to be a product derived from the metabolic transformation of another compound. However, this definition does not identify what the actual chemical compounds would be in a specific instance. The same point applies to the term 'prodrug'. Unless the specification gives direction to a person skilled in the art what the metabolites and prodrugs are, then these terms will generally be considered to be unclear.

55. With the term "derivative", the allowability may depend on the context it is used. An example of an unallowable use of the term derivative would be "a compound of formula (I) or a derivative thereof" where formula (I) is a Markush structure. In this context the "derivative" would not necessarily fall within the scope of the Markush structure, the Markush structure is a starting point from which the compound is derived. An example of a possibly allowable use of the term "derivative" would be "a compound of formula (I) or an alkyl ester derivative thereof" where formula (I) is a Markush structure with a carboxylic acid group.

Conciseness

56. The claims are required to be concise. The requirement is for each individual claim as well as the claim set as a whole. Each claim should clearly express the intended content without wordiness or undue repetition.

57. The presentation of plural independent claims, each one of which defines a different category of the invention, such as: a product, method of making the product, use (or method) of using the product, and apparatus for making the product, will not in itself draw an objection that the claims are not concise.

58. When plural independent claims of the same category are presented one independent claim should not fall wholly within the scope of another independent claim. A claim that falls wholly within the scope of another claim should not be presented as an independent claim, but instead should be made dependent on a broader claim. This may require re-arranging of claims as claim should not depend on claim later in the claim set. This requirement is based on Bancroft's application 23 RPC 89 which at page 94, lines 23 to 26 states that there may be more than one independent claims "separate in their nature". A claim that falls wholly within the scope of another claim is not considered to be "separate in nature" and so should not be an independent claim.

59. Even where independent claims of the same category and having different and substantial mutually exclusive features, so that one does not fall wholly within the scope of another, are presented, objection that the claims are not concise will be taken if repetition of subject matter from claim to claim is considered excessive.

60. If there is deemed to be such an excessive number of independent claims with excessive repetition, objection will be taken that such a plurality of independent claims makes it difficult, if not impossible, to determine the common novel inventive concept, that is, the claims taken as a whole do not clearly define the invention.

61. The purpose of the claims is to map out the scope of the monopoly sought by the applicant. Each claim should have a different scope. If two claims have the exact same scope

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then one of them is unnecessary and should be deleted in order to fulfil the requirement of conciseness.

Form of the claim

62. There is no set structure for the claims. Providing a claim meets the requirements of the Act and Regulations, the applicant may chose the structure of the claim.

63. The scope of the claim should be defined by technical features of the invention. The claims should not include statements of advantage, or non-technical matters. The technical features should not define the invention by using unusual and non-standard or unreasonable parameters that are unable to be compared with the prior art. Claiming by a result to be achieved should only be used when no other way to define the invention is possible and will need to fulfil the requirements of support over the whole scope of the claim.

64. A claim should consist of a single sentence with a single full stop at the end of the claim. Claims should be numbered consecutively. As the claims are required to be numbered consecutively, this implies an order to the claims. For this reason claims should not be dependent on claims later in the claim set. When amendments to the claim set have taken place, deleted claims should be removed and the remaining claims renumbered. The claims should not include the markings of the amendments such as strikethrough lettering.

Meaning of terms used in the claims

65. In the reading of a claim, the plain dictionary meaning of the terms are used in most cases. If they are terms are known to have a particular meaning to a person skilled in the relevant art then that definition is the one that applies. See Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9. The technical meaning may have to be verified by a regulating body (such as IUPAC for chemistry terms) or those in common use in trade journals.

66. Peterson Portable Sawing Systems v Lucas [2006] NZSC 20 discusses at paragraphs [25] to [28] construing of claims. A specification must be read as a whole with a mind to the function of each part. The purpose of the claims are to confer the monopoly of the patent. The description can help define the claims but it cannot be used to alter the monopoly which is set out in the claims.

67. The specification can be used as a dictionary but cannot be used to change the meaning of what is in the claim. For example, if a claim is directed to a chemical structure and the variable R1 is said to be "lower alkyl", the definition of the specification can be used to define the number of carbons and whether it includes both branched and straight chain alkyls. However, if the specification defines "alkyl" as including cyclic groups, aromatic groups, amines, carboxylic acids ...etc, as this is contrary to what a person skilled in the art would considered be an "alkyl" the definition of "alkyl" may need to be further clarified in the claim.

68. Electrical and Musical Industries Ltd v Lissen Ltd, 56 RPC 23 dealt with a case where the meanings of the claims was trying to be altered by what was in the specification rather than

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what was in the claim itself. The case made it clear that the forbidden field for a third party must be clear from the language of the claim and not found elsewhere in the specification.

69. Objection should be made where the scope of the claims is ambiguous or where the claim is unclear. Terms that in themselves are clear, but their use makes the claims unclear should also be objected to. There are terms that may make the claim unclear in some cases but not in others. Examples of some of these terms are "about", "substantially", "such as", "for example", "approximately", "essentially", "especially", "for instance" and words that appear in brackets. An example of a possible unallowable use would be "wherein the second temperature is substantially higher". If the second temperature being a certain amount higher is an important feature then how much higher should be stated in clearer terms. Another example of an unallowable use would be where there is a contradiction: "a composition that includes an organic acid such as hydrochloric acid" (hydrochloric acid being a mineral acid rather than an organic acid).

70. A claim may include numbers or letters in brackets that reference certain embodiments in the drawings. For example "a rotation means (4)", or "distillation column (7)". These should not be considered as limiting in the construing of the scope of the claims. However, the scope of the claim should be construed as to include the specific embodiment that is being referred to. They should be considered as helping the clarity and there should be no objection to the reference being in the claim except if the reference introduces ambiguity. Examples where a drawing reference may introduce ambiguity is if the same reference number is used for different features, or there is a contradiction between what the claim and the description say the feature is.

71. Terms that give the claim an indeterminate scope such as "likely", "improved", "possibly", "and the like", "not limited to" and "etc." and an objection should be raised to these terms.

72. The terms "novel", "new" and the phrase "the invention" should not be used in the claims. These terms place the onus on the reader to determine what is the novel/new part or what is "the invention" that is being claimed.

73. If a claim recites the invention or features of the invention in broad terms, and then also lists more narrower, more specific terms preceded by "preferably", "with preference", "most preferred", or similar wording, then the claim should be construed in the context of the broader terms. If the claim were granted, the patentee would not have any special protection to the limited options unless they are also the subject of a dependent claim. It may be appropriate to raise to a lack of clarity if the intended scope of the claim is unclear. This may also be the case where the claim is defined by "optional" features. If the intended scope is vague, an objection should be raised.

Open and closed claims

74. Open claims are not restricted to the features that are listed in the claims. The claim has those features and optionally others that may be identified in later dependent claims. Closed claims are ones where the features of the claims are restricted to those that are listed in the claims. The terms used in the claims determines whether it is open or closed. For example "comprising", "including" and "contains" are open terms that mean that the

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claim includes the following features but do not exclude features that are not listed. The term "consisting" is a closed term which means that the claim includes the following features and does not include any other features. A Markush structure claim is a closed claim.

75. Refer to section 40: Amendment of complete specification for introduction of a definition of comprising or consisting.

Purposive construction

76. In construing the claims, the claims should be read with the purpose of the claims in mind. Catnic Components Limited and another v Hill and Smith Limited [1982] RPC 183 said that when reading a claim the purpose of the claim should be taken into consideration. The case was about a window lintel and what the scope of "vertical" was. With a strict definition "vertical" would mean that it is 90 degrees. It was decided that although the vertical portion in the infringers item was a few degrees offset from 90 degrees and so not strictly vertical, the small difference in angle made no practical difference to the invention.

77. The departure of a range could not be considered as variant like in the Catnic case. The reason behind this is that if a patentee uses a descriptive word he may not mean it in a strict literal sense and may have been speaking figuratively. However a specified number does not leave room for interpretation.

Types of claims

78. In general, claims may be directed to either to a physical entity such as a compound, apparatus or a composition; or to an activity such as a method, a use or a process. It should be clear whether the claim is directed to an object or an activity, as it can have some bearing on the interpretation of the language. For example if the claim is directed to an object "for" a particular use then the claim is construed as the object "suitable" for that use and is not considered a restrictive use (L'Air Liquide Societe's Application, 49 RPC 428).

79. However, if the claim was to a method "for" a particular outcome then the method is restricted to that outcome.

80. A claim to an object may be restricted to specific use by using a phrase such as "when used". Where the object is an apparatus which is used for a method, the technical features of the apparatus must be clear from the claim. In cases where the apparatus and the method are both novel then they can usually be claimed independently. Where only one aspect of the claimed subject matter is novel e.g. either the object or the process; then the claim may be required to be limited. For example 'a method... when performed on the apparatus of claim X' or 'an apparatus... when used in the method of claim X. See below for the special case of a product made by a process.

81. A method claim should detail what is expected as the outcome of the method also known as "the promise of the claim". The steps listed should then ultimately result in what the method said would be the outcome of the claim, or fulfil the promise of the claim.

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82. For a process claim to be clear, the starting material, the end product and the means for adopting one to the other should be in the claim. British Celanese Ltd., George Holland Ellis and Frank Brown 51 RPC 192 decided that without identifying the means of converting one to the other, no process has been defined.

83. Claims directed to more than one category "compound, method, process or use according to claims 1-5..." may be of ambiguous scope and therefore unclear.

Product-by-process

84. One of the differences in claim construction from the 1953 Act is the construing of claims to a product made by a process or "product-by-process" claims. Examples of forms of a product-by-process claim are "a product obtained by the process of claim x", "a product obtainable by the method of claim x", or "product made by the steps of...". Under the 1953 Act if a claim to product was restricted to be "obtained" by a novel process then regardless of whether the product was known or not, the claim was considered to be novel. Under the 2013 Act, a claim to the product of a process will only be considered to be novel if there are material differences between the product claimed and what is known in the prior art base, even if it is claimed by being made by a novel process. See Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9.

85. If the product is novel, and a claim is merely to "a product made by process Y" this form would only be allowable if the product could not be described in any other way, such as by its composition, structure or other testable parameters.

Trade marks in claims

86. Trade marks merely indicate the origin of the substance or material. They do not guarantee what the composition or construction of it is. For example, if a food company changed the recipe they would not then have to market the product under a different name, they could continue using the original name. For this reason, technical features should not be defined by a trade mark alone. The features should be defined with the generic version of the trade mark. The trade mark could clarify what is meant by the generic name by being in brackets beside, for example "carbonated beverage (Coca-Cola)".

Claim by results

87. Claims that are defined by a result to be achieved were considered in No-Fume Ltd v Frank Pitchford Co Ltd, 52 RPC 231. In general, claims that define the invention by a result that they wish to achieve should only be allowable in cases where the invention cannot be defined in another way. In the No-Fume case the patent was to an ashtray. The invention was that if you had certain relative sizes of the components then the ashtray would be able to prevent the smoke from coming out of the ashtray. In that patent the claim was formulated so that the physical dimensions of an ashtray were chosen in order to produce the result of collecting the smoke coming off an object. It was decided that claiming by a result was allowable in this case because the area of scope was difficult to define in another

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way and the specification provided the means for achieving the results. Also a person skilled in the art would not have to perform undue experimentation in order to determine if he infringes the claims or not.

88. To allow a claim by result the feature that is defined by the result to be achieved should not be able to be defined in any other, more concrete way. Also, a person skilled in the art, reading the specification should not have to perform undue experiments in order to determine the scope of the claim. The person skilled in the art having to do simple trial and error tests that are laid out in the specification to tell whether the result has been achieved is acceptable. However, if the person would have to perform experiments not laid out in the specification and requiring initiative or inventive ability to determine whether something does or does not fall within the claim then it is not clearly defined.

89. As with all claims, claims by result must be enabled and supported by the disclosure over the entire scope of the claim. If the scope of the claim extends beyond what a person skilled in the art would know to be obvious alternatives of what is explicitly disclosed, then the claim would not be supported or enabled by the disclosure.

90. An example of an objectionable claim by result was discussed in H. Lundbeck A/S V Generics (UK) Ltd [2008] RPC 19 at [60] where is was said that if a man found a new way to make a new substance which is 10 times harder than diamond, he would be able to claim the new method and the new substance but would not be allowed to claim "a substance which is 10 times harder than diamond".

Functional definitions

91. Where an integer of the claim is defined by what it does rather than what it consist of, then this is considered to be a functional definition. For a functional definition to be allowable, a person skilled in the art should either know from the common general knowledge of that art what would or would not be included in the scope, or the specification should contain instructions in the form of testable criteria or experimental tests which would allow a skilled worker to recognize which objects or materials fall within the functional definition and accordingly within the scope of the claimed integer. The skilled worker should not be required to perform inventive measures in order to determine what would fall within the scope of the claims, however, simple trial and error tests to confirm that are laid out in the specification to tell whether the result has been achieved is acceptable, see for example Corvas International Inc [2001] NZIPOPAT 8 (27 March 2001).

Markush claims

92. Markush claims are a special type of claim where a feature is defined by a number of alternatives. The most common form of a Markush claim is a chemical structure claim where variables are indicated on a chemical structure and then they are defined as alternate moieties. Markush claims are closed groups and care should be taken that dependent claims do not introduce new features.

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93. Each variable of the Markush claim should be defined in the claim, or in a claim to which the claim depends. Also there should not be any additional and unnecessary definitions where variables are defined but are not used elsewhere within the claim.

94. The scope of a Markush structure under the 1953 Patents Act was construed to every compound that was within the structure. From Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd [2010] RPC 9 which was decided under the 1977 UK Patents Act, this idea was replaced with the construing of the Markush structure with reference to what the disclosure enabled and supported.

Omnibus claims

95. An omnibus claim is a claim that claims a scope based on a reference to the description, examples or drawings and not on technical features provided in the claim. For example "An apparatus substantially as herein described with reference to the figures and/or examples".

96. Omnibus claims are not prohibited by either the Act or Regulations. It is likely that an omnibus claim would be upheld by a court in keeping with earlier decisions such as Raleigh v Miller (1948) 65 RPC 141 HL and Rotocrop v Genbourne [1982] FSR 241.

97. When examining omnibus claims care should be taken to ensure that prior art examples disclosed in the description, examples or drawings are not also being claimed. Also when other claims are required to be restricted to overcome objections, such as lack of support, anticipation and lack of inventive step, omnibus claims may likewise require restriction.

98. Where the omnibus claim refers to "substantially as herein described" or similar wording where there is no further restriction, there is no restriction to an embodiment and it will be construed as wide as the disclosure of the specification and would include an prior art mentioned in the specification relating to that claim type.

99. Claims that depend on an earlier claim that has features listed are not strictly an omnibus claim as the scope of the claim includes and is limited to the technical features of the claim to which is depends. For example "An apparatus of claim 1 substantially as herein described with reference to the figures and/or examples".

100. Omnibus claims should be carefully worded to ensure that they are clear and not ambiguous.

Reach through claims

101. Reach through claims are generally claims to an object that the invention is worked upon and may be objectionable due to lack of clarity as well as a lack of support. Common forms of reach through claims are where the invention is to a new method of identifying a substance (e.g. compound, antibody, protein) and then claiming the substance identified (e.g. "Antibody X when identified by method Y").

102. Where a method of identifying a substance is novel and inventive the claims to the method are allowable per se. However a known substance is not made new merely due to a new way to identify it. The reach through claims have been likened to an invention of a new

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~~pair of binoculars, and then claiming both known and unknown objects that can be seen through the binoculars e.g. an existing house when seen through the binoculars of claim 1.~~

~~Suitability for use~~

~~103. A claim to an apparatus or object "for" a particular purpose is considered to be "suitable for use" for that purpose (L'Air Liquide Societe's Application, 49 RPC 428). For an apparatus or object to be restricted to a particular use then the claim must specify that it is "when used" or similar wording. Subject matter that is claimed as 'suitable for' a purpose is limited in the sense that subject matter found in the prior art base which is not suitable for that purpose would not be considered as prior art with regard to novelty at least. Additionally, apparatus being suitable for purpose implies certain features of the apparatus for example relating to materials from which is can be made, the size of the apparatus and other features which would be apparent to the person skilled in the art. For example, 'a hook for a crane' or 'crane hook' would necessarily need to be relatively robust and strong and of a size which would allow it to be suitable for the purpose of lifting and moving materials. A 'hook for fishing' or 'fish hook' would not be suitable for the same purpose as a crane hook.~~

~~104. In Hickman v Andrews, [1983] RPC it was decided that although a workbench and a previously known bookbinders press had all the same technical features, the book press did not anticipate the workbench because the dimensions of the book press meant that it was not suitable for the purpose of use as a workbench. Suitability for use is discussed in Adhesive Dry Mounting Co Ltd v Trapp and Co, 27 RPC 341 and G.E.C's Application, 60 RPC 1.~~

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Clarity of the claims

- Inconsistencies
- Antecedent basis
- Implicit features
- Vague, relative, or subjective terms
- Functional terms
- Optional features
- Terms such as "about", "approximately", "essentially" or "substantially"
- Numerical ranges
- Position defining terms
- Terms relating to the merits of the invention
- Reference in the claims to trade marks or other documents
- Reference numerals in the claims
- Claim dependencies, claim numbering, single sentence
- Technology-specific terminology

71. Section 39(2)(b) requires that the claim or claims must be clear and concise. The clarity of the claims is important because it is the claims that define the scope of the invention. This informs the

reader what the scope of the monopoly is so that they can determine what would infringe the claim, and what would not. Section 39(2)(b) was based on the UK 1977 Act section 14(5)(b).

72. Claims are to be given a purposive construction, as discussed in the construction section above. Claims will lack clarity where the skilled person cannot determine their scope using purposive construction. Some common examples of issues that can cause a lack of clarity are discussed below.

Inconsistencies

73. The scope of a claim should be clear when looking at each claim separately and when looking at the claim set as a whole. There should not be any contradictions within a claim, or between claims which refer to one another. If a feature is set at a specific value in a claim, then it cannot be a contradictory value in another claim which refers to that feature.

74. If there is a contradiction between a dictionary meaning of a term given in the specification and its meaning to the person skilled in the art, this may cause a lack of clarity in the claims.

> *Example*: A dictionary style definition in the specification which defines the term "added" as meaning "removed". This is a fundamental inconsistency that cannot be reconciled by any reasonable contextual considerations.

75. Dependent claims which refer to preceding claims directed to differing subject matter are normally clear as long as each of the dependencies are themselves clear and there are no inconsistencies when the claim set is considered as a whole.

> *Example*: Claim 7: An apparatus according to any one of claims 1-5, or a method according to claim 6, wherein the vessel is an anaerobic digester.

76. In this example, the apparatus and method claims both require a vessel, which is specified in claim 7. Claim 7 relates to an apparatus when it depends on claims 1-5, and relates to a method when it depends from claim 6.

Antecedent basis

77. If the claim introduces a feature without clearly indicating what it refers to, the feature is said to lack antecedent basis. To provide antecedent basis for a feature, when the feature is introduced for the first time in the claims, it should be associated with the indefinite article "a" or "an". When it is later mentioned in the same claim or in a dependent claim, it should be referred to as "the", or sometimes "said". This makes it clear that the dependent claim is referring to the same feature, rather than a different feature.

> *Example*: A bicycle comprising *a frame* and *a rear suspension unit*, wherein *said frame* is manufactured from a carbon fibre composite material and *the rear suspension unit* is manufactured from aluminium.

78. If a claim includes a feature that lacks antecedent basis, a clarity objection need not necessarily be raised if the feature is implicit (see below).

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Implicit features

79. If a feature recited in the claims is well-known and the invention lies in modifying it in certain respects, it is sufficient that the claim clearly identifies the feature and specifies what is modified and in what way. For instance, a claim to a "bicycle" does not need to mention the presence of wheels. This is consistent with purposive construction: the skilled person reading the term “bicycle” is familiar with bicycles and knows that the bicycle is required to have wheels.

Vague, relative, or subjective terms

80. Terms of a vague, relative or subjective nature should not be used if they create doubt as to the scope of the claim. For example, "high", "small", "hot", "pure", “resistant”, “increasing”, “reducing”, “improving”, etc. can in some cases be unclear. A "high" temperature can vary greatly even within the same art. In these cases, the term should be clarified by adding measurable parameters so that the scope of the claim is clear. In contrast a “high-frequency (HF) amplifier” has a clear and accepted meaning in the art. The exact frequency range would not need to be stated in this instance.

Functional terms

81. Functional terms in claims are considered with reference to purposive construction. A functional definition or term is clear when the person skilled in the art can determine the scope of the claim. This includes where they know what features or materials can achieve the function, or where they can determine function by performing routine tests. For example, a term such as “elastic material” might indicate a group of materials to the skilled person.

Optional features

82. The claims are required to recite the essential features of the invention but can also recite optional features. Optional features in the claims are usually preceded by expressions like “optionally”, "preferably", "with preference", "most preferred", "for example", "such as", "more particularly", “in particular”, “especially” or "for instance". Optional features do not normally restrict the claim and are normally considered to be clear. Clarity issues may arise where there are contradictions within the claim, or where there is doubt about whether a feature is limiting or not. Similarly, excessive use of optional features may result in a lack of conciseness.

83. A lack of clarity can also result from a contradiction between an essential feature and the optional feature. For example, the wording "the solution is heated up to between 65 and 85°C, particularly to 90°C" is unclear because the temperature after the term "particularly" contradicts the range before it. As another example, "a composition that includes an organic acid such as hydrochloric acid" is unclear, as hydrochloric acid is a mineral acid rather than an organic acid.

84. Terms such as "and the like", "not limited to" and "etc." can result in a lack of clarity as to the scope of the claim. These terms can introduce doubt as to whether the specified feature is essential or what other feature might replace it.

Terms such as “about”, “approximately”, “essentially” or “substantially”

85. Terms such as "about", "approximately", “essentially” and "substantially" are in themselves clear. However, they may cause a lack of clarity depending on how they are used in the claim.

86. By way of example, “a television having a substantially planar screen surface” is interpreted as claiming the same technical feature as “a television having a flat screen surface”. Both expressions

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are considered as claiming a television screen surface which the skilled person in the manufacturing field would consider as being flat or planar. In contrast, the use of the term “substantially” in expressions such as "wherein the second temperature is substantially higher" may be unclear if the difference in temperature is required to determine the scope of the claims.

Numerical ranges

87. A range of values may be defined using terms such as “between” “from/to” “less than” “more than” “up to and including”. The limits of the range should be clear to the skilled person, and this is assessed purposively, on a case-by-case basis.

Position defining terms

88. Terms that deal with the position of features such as “back”, “front”, "inside", "end", "above", "upwardly" should be considered as to whether they are clear. Relative position terms may be used if the point of reference is implicitly or explicitly clear. The question as to whether such terms introduce uncertainty into the claim must be decided upon the facts of the case. Particular care is needed, when for example, the location of a feature of the invention is defined by reference to apparatus not forming part of the invention claimed or even by reference to a person using the invention.

Terms relating to the merits of the invention

89. The purpose of the claims is to define a product or process which is covered by the monopoly. Adding statements about the merits of the invention or statements of commercial advantage can lead to a lack of clarity. This means subjective words such as “improved”, “novel”, “new” or “the invention” can make the scope of the claim unclear. However, statements of purpose are allowed if they assist in defining the invention.

Reference in the claims to trade marks or other documents

90. Claims referring to other documents or web pages generally lack clarity and conciseness. Such claims are onerous for the reader to read and understand.

91. Claims that refer to a technical or industry standard may be clear provided there is no ambiguity. For example, where the standard is reproduced in the specification, where the standard is identified with a specific version or edition number, or where the standard forms part of the common general knowledge.

92. Trade marks merely indicate the origin of a substance or product, rather than their content or composition. This means they generally result in a lack of clarity and should only be used in a claim where their use is unavoidable. For example, the use of the trade mark Velcro is avoidable, as the term hook and loop fasteners can be used instead.[21]

93. Trade marks may be clear when the person skilled in the art would know the content or composition of the substance or product. For example, Tween80 is known to refer to polysorbate 80. Trade marks may also be clear when they relate to industry or technical standards, for example Bluetooth and Wi-Fi. Some judgment may be exercised as to whether an objection is warranted. For example, if the trade mark is used in relation to an optional feature or in a dependent claim, then an objection may not be necessary. An objection to a trade mark in a claim can generally be resolved by

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specifying the generic name of the product in brackets, provided this does not add matter, for example Teflon (polytetrafluoroethylene).

Reference numerals in the claims

94. A claim may include numbers or letters in brackets that reference embodiments in the drawings. For example, "a rotation means (4)", or "distillation column (7)". While these are not limiting on the scope of the claims, the claims should be construed as including these embodiments in their scope.[22] Generally, these references help to clearly explain and define the claims. A clarity objection will generally only arise if there is ambiguity in the references such as a contradiction in reference numbering.

Claim dependencies, claim numbering, single sentence

95. A claim having more than one sentence is not clear in scope. This is because it can be ambiguous whether all the features contained in the separate sentences are to be taken in combination. To avoid this, each claim should consist of a single sentence.

96. Claims should be numbered consecutively. This implies an order to the claims. For this reason, claims should not be dependent on claims later in the claim set.

97. Punctuation is important for interpretation of the claim. Punctuation or the lack of it can sometimes cause a lack of clarity. For example, a claim missing a full stop may indicate that the claim is incomplete.

Technology-specific terminology

98. Amino acid or nucleic acid sequences defined by percent identity have a clear meaning to the person skilled in the art and are clear.

99. Sequences defined by percent similarity should either identify or define the algorithm used to calculate the percent similarity. While various algorithms are known in the art, the calculated percentage will differ depending on the algorithm used.

100. Sequences defined by percent homology require a definition in the specification of how percent homology is calculated. Homology refers to a shared evolutionary origin that does not have a generally understood numerical value.

101. Claims to percent similarity or percent homology that are not limited to a specific algorithm or that do not include a suitable definition will be objected to as the scope of the claims is unclear.

102. Where percentages are listed, the unit base should be stated where it is appropriate to do so. For example, percent weight, percent volume. It will not be necessary to state the unit base in the claim if the unit base will be clear when the claim is construed purposively in light of the specification and examples.

103. Names that are used exclusively by the applicant and represent a private or internal name given to a material or compound should not be used in the claims. The term should be replaced by an expression known to all skilled persons who may need to determine the monopoly defined by these claims.

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104. Terms such as "metabolite", "prodrug" and "derivative" do have a variety of working definitions. For example, a metabolite is considered to be a product derived from the metabolic transformation of another compound. However, this definition does not identify what the actual chemical compounds would be in a specific instance. The same point applies to the term 'prodrug'. Unless the specification gives guidance to a person skilled in the art what the metabolites and prodrugs are, then these terms will generally be considered to be unclear.

105. Regarding the term "derivative", the clarity of the term may depend on the context it is used. An example of where the use of the term derivative would be unclear is "a compound of formula (I) or a derivative thereof" where formula (I) is a Markush structure. In this context the "derivative" would not necessarily fall within the scope of the Markush structure, the Markush structure is a starting point from which the compound is derived. An example of a possibly clear use of the term "derivative" would be "a compound of formula (I) or an alkyl ester derivative thereof" where formula (I) is a Markush structure with a carboxylic acid group.

Conciseness of the claims

- Conciseness of the individual claims
- Conciseness of the claim set

106. Section 39(2)(b) requires that the claim or claims must be both clear and concise. Although there is some overlap between the requirements of clarity and conciseness, the requirement of conciseness should be appropriately assessed in addition to clarity.

107. The requirement for the claims to be concise is for each individual claim as well as the claim set as a whole.

108. An objection to a lack of conciseness should not be made only because the claims could have been presented in a more concise form. In *ChemoCentryx, Inc.* [2025] NZIPOPAT 11, duplicate sets of dependent claims, each dependent on a separate independent claim, was considered concise although only one set of the dependent claims was necessary if rearranged to be dependent on both the independent claims. [23]

Conciseness of individual claims

109. An individual claim may lack conciseness if undue effort is required to determine its scope because of excessive wordiness, repetition, and/or redundancy in the claim. An objection to a lack of conciseness may be appropriate if a skilled person who has read and understood the disclosure would require significant additional effort to determine what would infringe the claim, and what would not.

> *Example:* A lengthy claim with multiple features that are defined by overlapping optional alternatives and preferences so that interpreting the claim requires significant effort to separately construe each of an excessive number of possible combinations, and where the number of combinations is not justified considering the nature of the invention disclosed.

Conciseness of the claim set

110. A claim set does not lack conciseness only because it contains a large number of claims. [24] There is no limit to the number of claims that may be included in a complete specification. However,

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an excess claims fee may apply. Information on fees can be found on the Patent fees section of our website.

111. Each claim in a claim set should have a different scope. If two or more claims are identical, then one of them is unnecessary and an objection should be made that the claims are not concise. If two or more claims are similar, the claims should be interpreted by presuming that redundancy between the claims is not intended. An objection that the claims lack conciseness because they have the same scope should only be made if the claims cannot be reasonably construed to be different in scope.

112. An objection should not be made only because the scope of claims overlap or because the scope of one claim falls wholly within the scope of another.

113. An independent claim that includes all of the same features as another claim, where the claim could instead be presented as a dependent claim, may lack conciseness if it is unnecessarily repetitive. An objection should only be made if the repetition is clearly excessive considering the nature of the invention and how the repetition contributes to the overall length of the claims.

> *Example:* Multiple independent device claims of a page or more in length that repeat all the same features of the broadest claim and only add minor optional features and could more appropriately be expressed in dependent claim form.

114. Many independent claims to similar subject matter may lack conciseness if the scope of protection sought is obscured, or the scope cannot be determined. If the claim set as a whole would present significant difficulty for a skilled person who has read and understood the disclosure, an objection to a lack of conciseness should be made.

> *Example*: An application with 23 independent claims each claiming various combinations of shared features. Due to the intermingled combination of features, it is difficult to determine the scope of each claim and distinguish them from each other. Therefore, a lack of conciseness objection would be appropriate.

Enablement and Support

- Comparison to sufficiency
- General approach during examination

115. The specification must disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art (enablement; section 39(1)(a)); and the claims must be supported by the matter disclosed in the complete specification (support; section 39(2)(c))[25].

Section 39 (2)(c): Patents Act 2013 – New Zealand Legislation

116. In New Zealand, the requirements for support and enablement are closely associated with one another.[26] The two grounds are effectively two sides of the same coin:

- The disclosure needs to enable the claim to be worked across its full range (enablement), and

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- The breadth of the claim must be commensurate with what the disclosure makes available to the skilled person (support).[27]

Comparison to sufficiency

117. In the UK, the questions of support and enablement are addressed together, under the umbrella of "sufficiency". In *Biogen v Medeva* ("*Biogen*"), the two requirements of support and enablement (referred to as support and sufficiency in Biogen) were linked by the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified.[28][29]

118. A complete specification may be objected to as being insufficient under one of the following three types of insufficiency:

- Classical insufficiency. This is where the teaching of the specification does not enable the skilled person to perform the invention. In New Zealand, this type of insufficiency would typically be raised under section 39(1)(a).

- Insufficiency by ambiguity or uncertainty. This is where a skilled person does not know whether they are working the invention. In New Zealand, this type of insufficiency could be raised under either section 39(1)(a) or section 39(2)(c).

- Insufficiency by claim broadness (sometimes referred to as *Biogen insufficiency*). This is where the claims are broader than what is justified by the disclosure. In New Zealand, this type of insufficiency would typically be raised under section 39(2)(c).

General approach during examination

119. As enablement is also a requirement for support, this overlap can lead to uncertainty as to which objection is appropriate in a given situation. The layout of section 39 provides useful guidance to how to approach this overlap:

- Section 39(1) outlines the requirements for the **complete specification**. This indicates that an objection under section 39(1)(a) should be raised where there is a deficiency with the **disclosure**.

- Section 39(2) outlines the requirements for the **claims**. This indicates that an objection under section 39(2)(c) should be raised where there is a deficiency with the **claimed subject matter**.

120. This means that support issues will be raised under s39(2)(c) and will be directed to the claimed subject matter. Enablement issues will be raised under s39(1)(a) and will be directed to the disclosure (which can include the claims). Enablement issues will typically result in corresponding support issues where that matter is also claimed.

121. In some instances, objections under both grounds may be appropriate where there is a deficiency in both the disclosure and the claimed subject matter.

122. The decision of *Pharmalink International Ltd v Pharmazen Ltd* [2025] NZHC 2657 provides guidance on applying support and enablement to a specific application.[30] The decision considers

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various features of the invention and discusses several different aspects of support and enablement which are covered further in this guideline.

Enablement

123. Section 39(1)(a) requires that the complete specification must be clear and complete enough to allow the claimed invention to be performed by the skilled person. To meet this requirement, the complete specification must provide an enabling disclosure so that a person skilled in the art would be able to work the invention across the full extent of the monopoly claimed. [31]

124. *Biogen v Medeva* [1997] RPC 1 at 16 explained enablement as a disclosure such as to enable the invention to be put into practice, i.e. to obtain without undue effort the appropriate range of claimed items. *Biogen* further explained that speculative elements are not automatically bad, but there is a question of degree that comes into it. This will depend on the facts of each case.[32]

Test for enablement

125. The test for enablement is set out in *Kirin-Amgen v Hoechst Marion Roussel Ltd* [2005] RPC 9 ("*Kirin Amgen"*) at paragraph 103 as:

- First identify the invention and decide what it claims to enable the person skilled in the art to do;
- then one can ask whether the specification enables them to do it.[33]

126. In *Eli Lilly v Human Genome Sciences* [2008] RPC 29, at paragraph 239, Kitchin J. gave the following helpful principles when determining whether an application provided an enabling disclosure:

i) the first step is to identify the invention and that is to be done by reading and construing the claims;

ii) in the case of a product claim that means making or otherwise obtaining the product;

iii) in the case of a process claim, it means working the process;

iv) sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and the claims;

v) the disclosure is aimed at the skilled person who may use his common general knowledge to supplement the information contained in the specification;

vi) the specification must be sufficient to allow the invention to be performed over the whole scope of the claim;

vii) the specification must be sufficient to allow the invention to be so performed without undue burden.[34]

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127. What is required to meet the requirements for enabling disclosure will depend on the level of disclosure, the technical field, and the common general knowledge of the skilled person. It is generally expected that the specification should contain at least one example or way of performing the invention. But there is nothing to say that it must disclose more than one way.[35]

128. For example, in *Generics (UK) Limited and others v H Lundbeck A/S* [2009] UKHL 12, [2009] RPC 13 ("*Generics*"), a product claim to a compound was sufficiently enabled by the disclosure of a single method to make the compound.[36]

129. Conversely, in *Schering Biotech's Application* [1993] RPC 249 ("*Schering*"), a single example was not sufficient to enable a wider scope.[37] This was because it was not clear from the specification which vectors falling within this scope would fulfil the purpose of the method and produce the required result. Although some passages provided literal support, the specification did not enable the full scope of the claims.

130. In *Edward Hunia* [2023] NZIPOPAT 14, theoretical analysis alone was not sufficient to teach to skilled person how to put the invention into effect.[38] The specification solely relied on the skilled person to know what is required to perform the invention. However, there were no practical instructions to establish the invention in the real world.

Support

- Requirements for support
- Regeneron Principles

131. S39(2)(c) requires that "the claim or claims must be supported by the matter disclosed in the complete specification". This is intended to ensure that the claims are consistent with the description and to ensure that the claims are not broader than is justified by the applicant's contribution to the art.[39]

132. The claims form part of the complete specification. This means that subject matter found in the description and/or the claims of the original specification may be used to support the claims.

Requirements for support

133. For a claim to be supported by the matter disclosed as required by section 39(2)(c), the following criteria must be satisfied:

i) The disclosure of the specification needs to enable the claimed invention to be worked across its full range, and

ii) The breadth of the claims must be commensurate with what the disclosure makes available.[27]

134. Support is determined from the view of the skilled person. To determine whether these criteria are met, the general approach is to:

- identify the invention by construing the relevant claims;
- compare the claimed invention with the matter disclosed in the complete specification; and

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- determine whether, on the balance of probabilities, the invention defined in the claims is supported by that disclosure, i.e. it satisfies the two criteria above.[40]

135. The word 'support' means more than just a mere mention in the specification. It requires that the disclosure supports the claimed monopoly across its entire width. However, the applicant is not required to restrict the claims to the specific examples disclosed.

136. All essential technical features of the invention must form part of any independent claim. A lack of support may arise if the claim lacks essential features.[41]

Regeneron Principles

137. A useful guide for assessing support is set out in the eight principles in *Regeneron* which was reframed in *Illumina*.[42][43] These principles are summarized below:

i) The requirements of support and enablement ensure that the scope of the claims matches the contribution to the art.

ii) For product claims, the contribution to the art is the skilled person's ability to make the product itself.

iii) Patentees can choose how broadly to frame the scope of their claims. However, they cannot claim broader than what the disclosure enables.

iv) Enablement means that the specification, along with the common general knowledge, must provide enough information to allow the skilled person to perform substantially all embodiments within the scope of the claims.

v) Claims that cover embodiments which cannot be performed by the skilled person exceed the contribution to the art.

vi) The specification does not have to demonstrate that every embodiment within the scope of the claim works. It may rely on a principle of general application if it reasonably enables the scope of the claims.

vii) A claim will not lack support due to irrelevant factors. The requirement of support only applies to relevant ranges within the claim. A relevant range refers to a variable that affects how the invention works.[44][45]

viii) Enablement requires more than just stating that a relevant range will have an intended benefit. Rather, the disclosure must enable the skilled person to perform the invention. How groundbreaking an invention may be does not alter this requirement.

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Concepts relevant to both enablement and support

- Contribution to the art
- Plausibility
- Principle of general application
- Undue Burden
- Relevant date for enablement and support
- External sources
- The role of post-filed information in assessing enablement and support
- Obvious modifications

138. The underlying purpose of support and enablement is the same. Namely to ensure that the disclosure describes how to perform the invention and that the patent monopoly should be commensurate with the contribution to the art.[46] While a claim may correspond to the disclosure, it can still lack support if it encompasses subject matter which is not enabled, as the invention cannot be performed without undue burden.[29]

139. The following sections outline concepts that can relate to both enablement and support.

Contribution to the art

140. The contribution to the art lies in what has been added to the state of the art as a result of the inventive concept. It is not synonymous with the inventive concept. Rather, it is an evaluation of the inventive concept.

141. One way of determining an invention's contribution to the art is to determine what the invention is, based on the disclosure, and then determine how far this has advanced the art.[47]

142. Claims lacking support may exceed the contribution to the art in several ways. The specification may claim results which it does not enable. An example of this is claiming a wide class of products when the specification only enables the making of one product and does not disclose a principle of general application. Another way of exceeding the contribution is when achieving a claimed result makes no use of the invention.

143. For example, if an inventor discovered a way of making a new substance which is 10 times harder than diamond, they cannot generally claim any substance which is 10 times harder than diamond. They could claim the specific new substance and the process for producing it. They cannot claim any substance 10 times harder than diamond since they have not enabled an entire class of substances. Instead, they have only enabled one member of this class.[48]

Plausibility

144. Support and enablement must be apparent from the disclosure, with regard to the common general knowledge of the skilled person. In the context of new therapeutic treatments, the UK Supreme Court has framed this requirement as a plausibility requirement and has set out some useful points for determining whether the plausibility requirement is met[49]. These are summarized below:

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(i) The concept that a product is effective for the treatment of a condition must be plausible.

(ii) It is not made plausible by a bare assertion that it might work.

(iii) A therapeutic effect may become plausible if the specification discloses reasonable scientific grounds why it was worth trying. The disclosure of those grounds marks the difference between a speculation and a contribution to the art.

(iv) While the disclosure does not need to definitively prove an assertion, the skilled person must find reason within the disclosure to believe the assertion true.

(v) This reasonable belief must be based on a direct effect on a metabolic mechanism associated with the disease which is either demonstrated in the specification or known in the art.

(vi) The therapeutic effect does not need to be demonstrated by experimental data. It can be demonstrated by theoretical reasoning. For example, the specification may point to a property of the product or a general principle that would suggest it would work.

(vii) These points can be supplemented by the common general knowledge but still need to be derivable from the specification.

145. The concept of plausibility is often relevant to speculative claiming of new medical uses. However, plausibility applies across all patent applications to ensure that the invention is supported by the disclosure.

Principle of general application

146. A "principle of general application" relates to a broad claim that is enabled by a corresponding broad contribution. Such a claim is enabled if the skilled person can reasonably expect the invention to work with anything which falls within the claim.

147. Most claims are generalisations of the inventive concept set out in the specification. The extent of generalisation allowable is a matter which must be judged in each individual case.

> *Example:* A specification illustrated the use of particular chemical compounds to treat a disease. The claim referred to a broad class of compounds defined only by an agonist function rather than their chemical structural identity. The claim also made further statements about those agonists being active in the gastrointestinal tract to inhibit transport of phosphate ions. This was found not to represent a principle of general application, because the effect in the gastrointestinal tract had not been generally or plausibly shown across the class of agonists.[50]

148. An invention which can be applied practically to open up a new field may be claimed more broadly than one which is concerned with advances in a known technology.

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149. Applicants do not need to demonstrate in the disclosure that every embodiment within the scope of the claim has been tried, tested and proved to have been enabled. Applicants may rely upon a principle of general application if it reasonably enables the whole range within the scope of the claim to be performed.[51]

Undue Burden

150. Undue burden is where a person skilled in the art cannot perform the invention without prolonged research, enquiry or experiment. This will be an issue where further inventiveness or discovery is required to work the invention, such as where there are experimental uncertainties leading to a lack of predictability.

151. Some non-inventive routine trial and error experimentation by a skilled person is acceptable.[52][53][54] However, if to work the invention the skilled person must add something new beyond their common general knowledge, then the specification is not enabling.

152. When considering undue burden, examiners should consider the nature of the invention and the abilities of the skilled person. This includes the degree to which they may normally carry out routine trials and experimentation.

153. The knowledge and abilities of the person skilled in the art will depend on the complexity of the relevant art. The skilled person is not a person of exceptional skill or knowledge. However, they must have a reasonable degree of skill and common knowledge of the art and be able to use this to conduct routine trials.[55][54]

Relevant date for enablement and support

154. The relevant date for assessing enablement and support is the filing date of the complete specification.[56] This is based on the discussion in *Biogen*, where the House of Lords held that sufficiency is based on the specification at its filing date and not a later date, such as the publication date.[57]

155. In *Biogen,* the Court further applied the principles as set out in *Exxon/Fuel oils* [1994] EPOR 149 ("Exxon") stating an insufficient application could not become sufficient because of general developments in the state of the art after the filing date.[29]

External sources

156. The complete specification may rely on external sources by referencing them in the complete specification. This could include methods or materials described in other patent applications, journal articles or other sources, for example proprietary sources of the materials used in the invention. However, if the content of these external sources is not available to the public, then the specification will likely not meet the requirements of enablement and support.

The role of post-filed information in assessing enablement and support

157. Post-filed information can be any information pertaining to the complete specification, such as a declaration, additional experimental data, or external publications provided or dated after the filing date.

158. Post-filed information that does not relate to the state of the art or the teaching of the complete specification at the filing date, cannot be relied upon to overcome an enablement issue.

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This is because the requirement for enablement is assessed at the filing date, and defects in enablement cannot be remedied by a new teaching only available after the filing date. For example, information which teaches something not known from the specification at the filing date cannot remedy a deficiency in enablement. However, information which confirms the teaching of the specification can be used to illustrate that the specification was enabling at the filing date.

Obvious modifications

159. Applicants should be allowed to cover all obvious modifications, equivalents, and uses of what they have described in detail. Thus, applicants should be allowed to draft broader claims when it is reasonable to predict that all the variants covered by the claims have the properties or uses ascribed to them in the body of the specification.

Part 4: Other Matters

- Section 39(3) – Developments or Additions in Complete Specifications
- Section 39(4) – Substances Found in Nature
- Sequence Listings

Section 39(3) - Developments or Additions in Complete Specifications

160. Section 39(3) allows an applicant to file a complete specification, and include claims directed to developments of, or additions to, the original invention disclosed in an earlier provisional or convention application. This includes developments or additions for which the applicant would be entitled to the grant of a separate patent under the Act.

161. This means that an applicant who files a provisional application or basic application may later file a complete specification that expands upon the original disclosure. However, claims including such developments or additions are not entitled to the priority date of the provisional or basic application because the developments or additions would not be supported by the matter disclosed in the provisional or basic application.

Section 39(4) - Substances Found in Nature

162. Section 39(4) requires that any claim directed to a new substance must not be construed as extending to that substance when it is found in nature. This purpose of this provision is so that the monopoly of the invention does not extend to naturally occurring substances. Therefore, even if a substance is newly discovered and claimed in a patent, the scope of the claims does not extend to the substance when found in nature.

> *Examples*: A claim directed to a newly discovered compound that had been isolated from a plant. The scope of such a claim only encompasses the compound when isolated or synthesized and does **not** encompass the compound when naturally occurring in the plant.
>
> *Example:* A claim to a new mutation identified in a human protein. The scope of such a claim only encompasses the mutation when isolated or synthesized and does **not** encompass the mutation when naturally occurring within human beings.

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Sequence listings

163. Sequence listings can either be provided as a 'Sequence listing' document or within the complete specification document (typically after the drawings).

164. A separately filed 'Sequence listing' document is considered part of the complete specification and is relevant for disclosure purposes under support and enablement.

165. While the Patents Act 2013 and Patents Regulations 2014 do not mention sequence listings, IPONZ aligns with standard international practice under the Patent Cooperation Treaty. See rule 5.2 of the Regulation under the PCT, section 208 and Annex C of the administrative instructions under the PCT, which treat sequence listings as being part of the description.

166. Sequence listing filed at WIPO for search purposes only do not form part of the description of the Treaty application and cannot be used for support and enablement for corresponding national phase applications.

Part 5: Common situations

- Claims-by-result
- Product-by-process claims
- Omnibus claims
- Reach-through claims
- Markush chemical structure claims
- Antibodies
- Micro-organisms

Claims-by-result

167. A claim by result is a claim which attempts to define the invention by a result to be achieved, rather than the technical features that produce the result. A claim by result is only allowable if the feature that is defined by the result to be achieved cannot be more precisely defined without unduly restricting the scope of the claims.

168. Claims by result should be clearly defined. Difficulties can arise in determining the full scope of such claims as they are directed to a class of products or processes that possess the specified properties or features. If the skilled person cannot determine whether something does or does not fall within the claim, then it is not clearly defined.

169. As with all claims, claims by result must be enabled and supported by the disclosure over the entire scope of the claim. A claim will not be enabled and supported by the disclosure if it covers a broad range of products, but the specification only explains how to make some products and does not provide a general principle that applies to all. Similarly, a claim is not enabled and supported by the disclosure if it covers every possible way to achieve a result but only teaches some ways, and other ways could achieve the same result without using the invention.[58]

170. If a claim by result is allowable under section 39, the result is considered to be an essential feature of the claim. The claim will not lack novelty unless the result is disclosed in the prior art base or would be inevitably achieved by following the prior art disclosure.

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171. An example of an allowable claim by result was discussed in *No-Fume Ltd v Frank Pitchford Co Ltd*.[59] The patent was to an ashtray. The invention was that if you had certain relative sizes of the components then the ashtray would be able to prevent the smoke from coming out of the ashtray. In that patent the claim was formulated so that the physical dimensions of an ashtray were chosen in order to produce the result of collecting the smoke coming off an object. It was decided that claiming by a result was allowable in this case because the scope of the claim was difficult to define in another way and the specification provided the means for achieving the results. As with all claims a skilled person must be able to determine if they infringe the claims or not without undue burden.

172. An example of an objectionable claim by result was discussed in *Lundbeck A/S v Generics (UK) Ltd* [2008] EWCA Civ 311 ("Lundbeck") at [61] where is was said that if a man found a new way to make a new substance which is 10 times harder than diamond, he would be able to claim the new method and the new substance but would not be allowed to claim "a substance which is 10 times harder than diamond".[48]

Product-by-process claims

173. A product-by-process claim is a claim defined by a process used to make the product, rather than by the material characteristics of the product, such as the structure, composition, physical or chemical properties, or other testable characteristics and/or parameters. Some examples of the form of a product-by-process claim are:

i) "a product obtained by the process of claim x",
ii) "a product obtainable by the method of claim x",
iii) "a product made by the steps of…", or
iv) "a product formed by way of a method according to claim x".

174. A product-by-process claim is construed as a claim directed to the product, having material characteristics imparted to it by the process. The process will only limit the product if it imparts a material difference on the product.

175. This is irrespective of specific terms used to describe the process. For example, whether the process is described in active terms such as "obtained" or inactive terms such as "obtainable". This means that products produced by different processes that have the same material characteristics will anticipate a product-by-process claim.

176. *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9 at paragraphs 89-90 discusses how article 64(2) of the EPC allows a patentee to rely directly on a process claim to allege infringement of products made by a process.[60] Section 18(2)(b) is a similar provision that extends protection of a process claim to products obtained by that process. This means that a product-by-process claim would only be allowed where there is no other practical way of claiming the product.

177. Therefore, examiners will generally object to product-by-process claims under clarity on the basis that it is unclear what features the method imparts onto the resulting product. However, where a new product cannot be satisfactorily defined in terms of its structure, composition, physical or chemical properties, or other testable characteristics or parameters, then the product-by-process claim may be the only way to clearly define the product.

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178. Product-by-process claims can be difficult to identify so care should be taken when assessing claims. For example, a claim directed to “a product comprising features A and B, where feature A is treated in an oven” is a product-by-process claim.

179. Product-by-process claims will lack conciseness when the application has another claim directed to the same product that cannot be reasonably construed to be different in scope. Conciseness is discussed in more detail above.

Conciseness of the claim set

Example:

Claim 1: A compound of formula (I).

Claim 2: A method of producing the compound according to claim 1 comprising a step of reacting intermediates A and B together.

Claim 3: A product produced according to the method of claim 2.

In this scenario, claim 2 is directed to a method of making a compound with the features of formula (I). Claim 3 is directed to a compound produced by the method of claim 2, i.e. a compound with the features of formula (I). This results in claims 1 and 3 being directed to the compound with identical features. Such claims will therefore be objected to since the product can be more clearly defined by explicitly referring to the compound of formula (I), as demonstrated by claim 1.

180. Product-by-process claims may also lack support if the process used to produce the product is not supported.

Omnibus claims

181. An omnibus claim refers to the description, examples or drawings to define its scope, rather than reciting technical features. For example: "A device substantially as described herein with reference to the figures” or “A compound substantially as herein described with reference to the examples". Omnibus claims may also be drafted as dependent claims (see paragraph 186).

182. Omnibus claims are not prohibited by either the Act or Regulations. Therefore, claims of this format should be examined using the same criteria as for any other claims, and as long as they comply with the Act and Regulations, examiners should not object to the presence of these claims. This differs from international practice which generally considers omnibus claims to be unclear, except in rare circumstances where they are the only means of clearly and concisely defining the technical features of an invention.

183. When other claims are required to be restricted to overcome objections, such as lack of support, lack of unity, lack of novelty, and lack of inventive step, omnibus claims may likewise require restriction.[61] For example, an independent omnibus claim may lack unity of invention with other independent claims if it does not necessarily include a common or corresponding special technical feature of the other independent claims.

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184. Where the omnibus claim refers to "substantially as herein described" or similar wording where there is no further restriction, there is no restriction to an embodiment, and it will be construed as wide as the disclosure of the specification and would include any prior art mentioned in the specification relating to that claim category. When examining omnibus claims, care should be taken to ensure that prior art examples disclosed in the description, examples or drawings are not also being claimed. For example, any compound as herein described.

185. Claims directed to "any invention as disclosed herein" or similar variations do not clearly define the scope of the invention and should be objected to for lack of clarity. For example, the invention as disclosed herein.

186. An omnibus claim that depends on an earlier claim is limited to the technical features of the claim on which it depends as well as to the examples or drawings to which it refers. For example, "An apparatus of claim 1 substantially as herein described with reference to the figures and/or examples".

187. Omnibus claims should be carefully worded to ensure that they are clear, unambiguous, and unified with other claims.

Reach-through claims

188. Reach-through claims are where the claims are directed to matter which the invention acts upon but is not produced or changed by the invention. Reach-through claims have been likened to an invention of a new pair of binoculars and then claiming any object that can be seen through the binoculars.

189. A common form of reach-through claims is where the invention is a method of identifying a substance and then claiming the substance identified by the method (e.g. "Compound X when identified by method Y"). A substance (either known or unknown) is not made new merely due to how it was identified.

190. Reach-through claims will lack clarity where a person reading the claim cannot work out what the scope of the claim is.

191. Reach-through claims will lack support and enablement where they extend beyond the applicant's contribution to the art. There is no New Zealand case law that relates specifically to reach-through claims, however, there is a consensus in major jurisdictions that such claims are not allowable as their scope extends beyond what has been disclosed in the description.

192. For example, a reach-through claim may attempt to cover any substance that is identified by a screening method. The description may enable the skilled person to isolate and characterize only a few specific substances. In that case the claim would extend beyond the applicant's contribution to the art.

193. Reach-through claims directed to products identified by a method will lack novelty if any of the products are already known. Where a method of identifying a substance is novel and inventive the claims to the method are allowable *per se*. However, a known substance is not made new merely due to a new way to identify it.

SUPERSEDED

Markush chemical structure claims

- Claim construction – variables and optional features
- Assessment of support
- Functional terms in Markush chemical structure claims

194. Inventions related to a class of chemicals based upon specific experimental data which is later generalised into a chemical structural formula are conveniently represented as a Markush chemical structure in patent claims. Markush chemical structure claims depict a chemical structure in which some positions in the structure can have variable groups. The positions which are variable are denoted with alphanumerical characters. A common notation is to use the letter R (R1, R2, etc.), so the variables are sometimes collectively called "R groups". The characters must be distinct from those normally used to denote chemical elements. For example, the capital letter "N" normally denotes nitrogen so cannot be used to denote a variable. Each variable should then be defined in the claim, or in a preceding claim from which the claim depends.

Claim construction – variables and optional features

195. Variables are technical features which are common to all compounds which fall within the scope of the claim and are defined using closed lists. Markush chemical structure claims can also recite optional features e.g. optional substituents, counterions, or solvates. Because their presence is optional, they do not need to be defined in a limiting way in the claim. However, if the claim mentions optional features, the skilled person should be able to understand what this means, for example by referring to definitions in the specification. If the specification defines the optional features in a non-limiting way, this does not automatically mean the claim is unclear. If the applicant has set out what types of moieties they contemplate for the optional features for the claim, the skilled person is then able to understand what the applicant means by the words they have used in the claims.[2]

196. While a Markush chemical structure claim defines a class of compounds, it is not considered to represent a disclosure of each and every compound within the class.[62] The specification usually describes how to make a number of example compounds and test their biological activity. The applicant extrapolates to other chemical moieties based on their similarities to groups that have been specifically made and tested. However, if the extrapolation is not based on a reasonable prediction, the claim may be unreasonably broader than the contribution to the art and therefore lack support.

Assessment of support

197. Support is assessed using the same principles as for any other claim type: that is, the disclosure needs to enable the claim to be worked across its full range, and the breadth of the claim must be commensurate with what the disclosure makes available to the skilled person. For the first requirement, the body of the specification must provide sufficient information to enable the person skilled in the art to make substantially all compounds falling within the scope of the claims. For the second requirement, the class of compounds must be such that the person skilled in the art would have a reasonable expectation that all of the class members will behave in the same way in the context of the specification.

SUPERSEDED

198. For a Markush claim to a new class of compounds, support will generally extend to terms such as ‘salts’, ‘stereoisomers’, ‘polymorphs’, and ‘solvates’. These are products that the skilled person, using the new knowledge provided by the specification and the common general knowledge in the art, would be able to prepare by routine methods. Variation in these terms is not generally expected to impact the structure-activity relationship on which the reasonable prediction is based. Therefore, the skilled person can reasonably expect that these products will behave as described in the specification. While the number of these additional products is potentially large that does not detract from the routine nature of such experimentation. Such claims are supported if the additional products are clearly encompassed by the inventive concept and the contribution to the art.

199. If the variation in the claim represented by the variables and/or their optional substituents is too broad, the claim may encompass compounds which do not share the activity of the exemplified compounds, and the claim will lack support. The question of whether the claim scope represents a principle of general application is assessed on a case-by-case basis.

Functional terms in Markush chemical structure claims

200. Functional terms can be used in Markush chemical structure claims, provided the person skilled in the art will clearly understand the meaning and scope of these terms.

201. The terms “protecting group” and “leaving group” have a clearly understood meaning in organic chemistry. These terms will be clear to the person skilled in the art, provided that the specification provides some guidance as to suitable examples of protecting groups or leaving groups.[63]

203. The terms “metabolite", "prodrug" and "derivative" are sometimes used in Markush chemical structure claims. These terms are also discussed in relation to clarity above.

204. The term “linker” is used to denote a multivalent group which can join parts of a Markush chemical structure. Whether the linker needs to be defined in a structural way in the claim will depend on the contribution to the art. In some cases, it may be appropriate for the claim to recite only a “linker” (i.e. a functional term). In that case, the specification should still provide some guidance as to suitable examples of linkers.

Antibodies

- Example 1: Antibodies that bind a known target or epitope
- Example 2: Antibodies that bind a new target or epitope
- Example 3: Antibodies defined by functional features or testable parameters
- Other antibody considerations
- Other binding molecules

205. The binding properties of antibodies are widely understood to be due to the precise structure of the binding region. For a “classic” antibody this will typically require all six complementary-determining regions (CDRs) on the heavy and light chain to be defined.

206. As with all inventions, it is important to consider the contribution of the art, as the scope of the claims must be commensurate with the contribution to the art. See below for some common examples of contributions for antibodies.

SUPERSEDED

Example 1: Antibodies that bind a known target or epitope

207. A common contribution is generating a new antibody to a known target or epitope. This will typically require all six CDRs to be supported by the contribution. Where all six CDRs are not defined in the claim, this will typically be objected to as lacking essential features.

Some examples of claims that do not define all six CDRs include:

- Claims that define less than six CDRs,
- Claims that combine multiple structurally unrelated CDRs; and
- Claims that include structural variation within the CDRs.

208. An exception to this is where a broader scope is enabled by the contribution. For example, by disclosing specific variation that retains the binding properties of the antibody, this may support a claim to that specific variation.

Example 2: Antibodies that bind a new target or epitope

209. If the contribution to the art is in the new target or epitope that the antibody binds, the claims may not require a structural definition of the binding region.

210. This will generally require the new target or epitope to be a principle of general application. Typically, this will require an enabling disclosure of how to create antibodies against the target or epitope and disclosure of what effect binding to that target or epitope will have.

Example 3: Antibodies defined by functional features or testable parameters

211. Antibodies can also have a contribution in a functional feature or testable parameter such as the binding affinity of the antibody.

212. This will generally require the functional feature or testable parameter to be a principle of general application. Typically, this will require an enabling disclosure of how to create antibodies that will plausibly have the functional feature or testable parameter and disclosure of what effect that feature or parameter will result in.

Other antibody considerations

213. Claims directed to multiple antibodies will require consideration under unity as set out elsewhere in this guideline. Markush practice may be applicable to antibody claims. Typically, the binding region will be relevant when assessing the significant structural element.

214. Claims that refer to CDRs within a larger sequence should either define the numbering scheme (e.g. Kabat, Chothia or IMGT) or identify the specific residues within the larger sequence. Claims that lack either definition are not adequately defined and will be objected to as lacking clarity.

Other binding molecules

215. Besides “classic” antibodies, there are numerous other types of binding molecules. These are assessed in a similar way to antibodies. However, consideration should be given to the relevant structure of the binding molecule.

216. Some examples of other binding molecules include antigen binding fragments (Fabs), single-chain antibodies (scFvs), single-domain antibodies (sdAbs), heavy-chain only antibodies (camelid or shark antibodies), T-cell receptors (TCRs) and chimeric antigen receptors (CARs).

SUPERSEDED

Micro-organisms

217. When an invention relates to a micro-organism, or when the invention involves the use, modification or cultivation of a micro-organism, the complete specification needs to meet the deposit requirements under section 43 to comply with enablement and best method requirements.

218. If the deposit requirements are not met, this will typically result in objections under support, enablement and best method. Further information can be found in our guideline on Section 43: Deposit requirements for micro-organisms.

Section 43: Deposit requirements for micro-organisms

SUPERSEDED

Footnotes

1. *Lucas v Peterson Portable Sawing Systems Ltd* [2006] NZSC 20 (*"Lucas"*).
2. *Kirin-Amgen Inc v Hoechst Marion Roussel Limited* [2004] UKHL 46; [2005] RPC 9 ("*Kirin Amgen"*), at [32] and [34].
3. *Catnic Components Limited & Anor v Hill & Smith Limited* [1982] RPC 9 ("*Catnic*"), at page 243.
4. *Hammar Maskin AB v Steelbro New Zealand Ltd* [2010] NZCA 83 ("*Hammar*"), at [48].
5. *Electrical and Musical Industries Ltd v Lissen Ltd*, [1939] RPC 23 ("*EMI v Lissen*"), at page 41, lines 20-23.
6. *Pharmalink International Limited v Pharmazen Limited* [2024] NZIPOPAT 15, at [95]-[99].
7. *Lucas*, above n 1, at [29] and [45].
8. *Catnic*, above n 3, at page 244.
9. *EMI v Lissen*, above n 5, at page 41.
10. *Lucas*, above n 1, at [45].
11. *Hammar*, above n 4, at [56].
12. *Hammar*, above n 4, at [65]-[67] which refers to *Glaverbel SA v British Coal Corporation* [1995] RPC 255 (CA), at page 281.
13. *Lucas v Peterson Portable Sawing Systems Ltd* [2003] NZLR 361 (High Court), at [28].
14. *Adhesive Dry Mounting Co. Ltd. v Trapp* [1910] RPC 341.
15. *Commonwealth Scientific & Research Organisation v The Ministry Of Agriculture & Fisheries* [1993] NZIPOPAT 3.
16. *Hickman v Andrews* [1983] RPC 147.
17. *Sealed Air New Zealand Limited v Machinery Developments Limited* HC Wellington Civ 2003-485-2274
18. *E.I. du Pont de Nemours & Co. v. Enka BV* [1988] FSR 69, at page 88.
19. *C Van Der Lely NV v Ruston's Engineering Co Ltd* [1993] RPC 45, at page 58.
20. *Rediffusion Simulation Ltd v Link-Miles Ltd* [1993] FSR 369, at page 406.
21. *Cardenas Riffo, Nora Cristina* [2021] NZIPOPAT 7 ("*Cardenas*") at [17].
22. *Cardenas*, above n 21, at [15].
23. *ChemoCentryx, Inc.* [2025] NZIPOPAT 11, at [229]-[249].
24. *Bancroft's application*, [1905] RPC 89, at page 94, lines 23-31.
25. Patents Act 2013, s39
26. *Neurim Pharmaceuticals Ltd.* [2022] NZIPOPAT 6 ("*Neurim*"), at [14]-[15].
27. *Ardelyx, Inc.* [2023] NZIPOPAT 17 ("*Ardelyx*"), at [86].
28. Biogen v Medeva Plc [1997] RPC 1 ("Biogen"), at page 49, Exxon/Fuel Oils T 409/91.
29. *Exxon/Fuel Oils* T 109/91 [1993]; [1994] OJ EPO 653; [1994] EPOR 149, at [3.3].
30. *Pharmalink International Ltd v Pharmazen Ltd* [2025] NZHC 2657.
31. *DSM IP Assets B.V.* [2023] NZIPOPAT 11 ("*DSM*"), at [104].
32. *Biogen v Medeva Plc* [1997] RPC 1, at page 16
33. *Kirin Amgen*, above n 2, at [103].
34. *Eli Lilly v Human Genome Sciences* [2008] EWHC 1903 (Pat); [2008] RPC 29, at [239].
35. *DSM*, above n 31, at [106].
36. *Generics (UK) Limited v H Lundbeck A/S* [2009] UKHL 12; [2009] RPC 13 (*"Generics"*).
37. *Schering Biotech's Application* [1993], RPC 249 (*"Schering"*).
38. *Edward Hunia* [2023] NZIPOPAT 14, at [70]-[94].
39. *Charles Caulder Bree* [2017] NZIPOPAT 16, at [10]-[17].
40. *Schering*, above n 37, at page 252.
41. *Neurim*, above n 26, at [15] and [40].

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42. *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27 ("Regeneron"), at [56].
43. *Illumina Cambridge Limited v Latvia MGI Tech SIA and others* [2021] EWHC 57 ("*Illumina v Latvia*"), at [253], [256] and [258].
44. *Illumina v Latvia,* above n 43, at [258].
45. *Neurim,* above n 26, at [40].
46. Neurim, above n 26 at [15], quoting *Exxon/Fuel oils* above n 29.
47. *Generics* above n 36, at [30].
48. *Lundbeck A/S v Generics (UK) Ltd* [2008] EWCA Civ 311; [2008] RPC 19 ("*Lundbeck"),* at [61].
49. *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan and another* [2018] UKSC 56
50. *Ardelyx,* above n 27, at [175]-[176].
51. *Illumina v Latvia*, above n 43, at [253].
52. *Novartis AG v Johnson & Johnson* [2010] EWCA Civ 1039, at [20]-[25], [58] and [63]-[77].
53. *Novartis AG v Johnson & Johnson* [2009] EWHC (Pat) 1671, at [236]-[244].
54. *Biocon Limited* [2018] NZIPOPAT 2, at [29].
55. *Novartis AG v Johnson & Johnson, above n 53,* at [236].
56. *Regeneron,* above n 42, at [48].
57. *Biogen,* above n 32, at page 54.
58. *Biogen,* above n 32, at page 51 and applied in *Neurim,* above n 26, at [37]-[40].
59. *No-Fume Ltd v Frank Pitchford Co Ltd* [1935] RPC 231.
60. *Kirin Amgen*, above n 2, at [89]-[90].
61. *Merial Limited v Bayer New Zealand Limited and Pfizer Inc* [2015] NZIPOPAT 21
62. *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2009] EWCA 1362; [2010] RPC 9, at [30].
63. *Seagen Inc*. [2024] NZIPOPAT 3, at [110].

SUPERSEDED