





The claim game

Interpreting the scope of claims and assessing validity for biotech and pharmaceutical patents

A carefully-worded scope of claims and indepth assessment of validity grounds is necessary to avoid the ugly spectre of any number of “bright eyed and crazy, frightened and lost” possible futures for biotech and pharmaceutical patents, argue Frommer, Lawrence & Haug attorneys, Thomas J Kowalski and Samuel H Megerditchian¹

In summary

-  Inventors and patent counsel should place more emphasis on drafting claims wisely – any amendments or remarks during prosecution will be raised during litigation
-  Minimise amendments as much as possible by thorough study of the state of the art
-  Draft claims that are not only novel and obvious, but also possess the requisite utility
-  Ensure that the specification enables the claims and recites the proper written description. Get it right the first time, because anything subsequently added may be considered new matter

Inventors, inhouse counsel, and the executives to whom they answer, must realise that every action or, indeed, inaction during the course of patent procurement has consequences. In no uncertain terms, patent validity is directly linked to what is done, said or inferred during prosecution. It is understandable, therefore, that no areas of patent law are more prone to controversy than claim construction and claim validity under 35 U.S.C. §§101 and 112. As such, no areas of patent law are more deserving of cooperation between patent lawyers and those they represent, in order to prosecute and enforce claims wisely.

Claim construction

All individuals involved in the procurement and enforcement of patents, lawyers and non-lawyers alike, must appreciate that the scope of a patent is defined by its claims. Indeed, according to the U.S. Court of Appeals for the Federal Circuit, “the name of the game is the claim.”²

Thus, the scope of claims is assessed by a myriad of individuals in a dynamic and strategic manner. For example, inventors/applicants first analyse claims in order to determine whether an invention is patentable and worthy of filing with the United States Patent & Trademark Office (USPTO). The patent examiner in charge of the application also assesses claim scope when determining patentability. Further, third parties, such as competitors, assess claim scope during pre- and post-grant when determining the patentability of their own inventions, for designing around, and for purposes of due diligence when deciding to either purchase, or enter into a licensing agreement on, the subject matter of the claimed invention. Further still, the patent owner, typically the assignee of the inventors, assess claim scope pre- or post-grant for determining whether claims read on third parties’ products or processes and for patentability.

Ultimately, however, it is the province of the courts to construe patent claims in order to establish their meaning and scope for purposes of validity and infringement.³ The court construes the claims of each patent according to the hierarchy of evidence articulated in

Markman v Westview, looking first to the intrinsic evidence of the patent.⁴

The court begins with the language of the disputed claims, which define the scope of the invention and the rights of the patentee.⁵ It is the claims that define the invention.⁶ They are the measure against which validity and infringement are gauged.⁷

Claims should be construed as they would by a person of ordinary skill in the art.⁸ Moreover, the court must construe the words of the claim as of the time of the invention or when the application was first filed.⁹ Thus, the focus in construing disputed claim terms is not the subjective intent of the inventor or examiner; rather, it is the objective test of what one of ordinary skill in the art at the time of the invention would have understood a claim term to mean.¹⁰

Each and every word in a claim must be construed to have meaning.¹¹ The terms of a claim are generally given their ordinary and customary meaning as of the date of the application for the patent.¹² They must also be read in accordance with the precepts of English grammar.¹³ This strong presumption “in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art” may be overcome where: “1) the patentee has chosen to become his or her own lexicographer by clearly and explicitly defining the claim term; or 2) where a claim term would deprives the claim of clarity such that there is no means by which the scope of the claim may be ascertained from the language used.”¹⁴ When a patentee chooses to be his own lexicographer and uses terms in a manner other than their ordinary meaning, the intended definition of the term must be “clearly stated in the patent specification or file history.”¹⁵

In that respect, resort to the specification provides guidance.¹⁶ The court must look to the specification and the file history to see if the inventor varied the ordinary meaning of particular claim terms or if a claim term is unclear.¹⁷ In fact, specifications can be the “single best guide to the meaning of a disputed term” and, therefore, are “always highly relevant to the claim construction analysis.”¹⁸ A patentee, however, need not deliberately or precisely define a term in a lexicographical

manner, but may provide a definition by implication.¹⁹ Thus, the Court of Appeals for the Federal Circuit has “specifically held that the written description of the preferred embodiments can provide guidance as to the meaning of the claims” that are to be construed, “even if the guidance is not provided in explicit definitional format.”²⁰

A court, however, must be careful when turning to the specification for guidance during claim construction. Examples may aid in the proper construction of a claim term; however, the scope of a claim is not necessarily limited by the examples.²¹ Similarly, preferred embodiments like those often present in a specification are not claim limitations.²²

Thus, it is improper either to limit the claim to preferred embodiments or examples in the specification or to broaden the scope of a claim to include embodiments not covered by the claim language.²³ This is not to say, however, that resort to the specification should be avoided. The court can and should use the specification to define claim terms.²⁴

As noted, aside from the claim language and the specification, a proper claim construction analysis requires consideration of the patent prosecution history.²⁵ The specification and prosecution history are both important evidence of “the problem the inventor was attempting to solve,” which is critical to properly construing the scope and meaning of the claims of the patent.²⁶ Like the specification, the prosecution history is intrinsic evidence and is “often of critical significance in determining the meaning of the claims.”²⁷ In addition, prior art considered by the USPTO during prosecution of a patent comprises intrinsic evidence for claim construction.²⁸

A patentee, however, cannot recapture through equivalents that which was surrendered during prosecution, and the doctrine preventing one from doing so is prosecution history estoppel. This arises whenever a patentee makes an amendment to secure the patent and the amendment narrows a claim in scope.²⁹ If a court is unable to determine the purpose underlying a narrowing amendment – and hence a rationale for limiting the estoppel to the surrender of particular equivalents – the court should presume that the patentee surrendered all subject matter between the broader claim and the narrower claim.³⁰ The burden is on the patentee to rebut that presumption and show that the amendment does not surrender the particular equivalent.³¹ To satisfy its burden, the patentee must show that at the time of the amendment one skilled in the art could not reasonably have drafted a

claim that would have literally encompassed the alleged equivalent.³² Note, however, that disclosed but unclaimed subject matter is dedicated to the public.³³

Thus, these three items – the claim

“they flutter behind you your possible pasts some bright eyed and crazy some frightened and lost a warning to anyone still in command of their possible future to take care...”

**Roger Waters, “your possible pasts,”
The Final Cut (Pink Floyd 1983).**

language, the specification, and the prosecution history – are the intrinsic evidence and are the primary evidentiary sources for claim construction. And in most situations, a thorough consideration of the intrinsic evidence will resolve any ambiguity in a disputed claim term.³⁴

When the meaning cannot be determined by intrinsic evidence, however, a court may turn to extrinsic evidence to construe the claims in a patent.³⁵ Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises” and may be useful to show the state of the art at the time of the invention.³⁶

When consideration of extrinsic evidence is necessary to understand the meaning of claim terms, the court may consider testimony on how people skilled in the art would understand technical terms in the claims.³⁷ Where the intrinsic evidence unambiguously describes the scope of the patent, however, it is improper to rely on extrinsic evidence to alter the meaning of the claims.³⁸ Thus, in most instances, a thorough consideration of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term, and the court may not rely on extrinsic evidence to construe the scope of a claim term unless the court first finds that the term is ambiguous even in light of the intrinsic evidence.³⁹

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Claim validity

According to 35 U.S.C. §112, first paragraph, a patent application, to support a claim, must enable the claim and must adequately describe the subject matter of the claim:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Thus, under US law, there are two distinct requirements: the enablement requirement and the written description requirement.

The test for enablement requires a determination of whether any person skilled in the art can make and use the invention without undue experimentation.⁴⁰ The factors involved in determining whether there is sufficient evidence to support a finding of enablement include, among others: the breadth of the claims; the nature of the invention; the state of the prior art;

the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.⁴¹

Analogously, Europe follows the “Sufficiency of Disclosure” rule: that the application must disclose the invention in a manner sufficiently clear to be carried out without undue experimentation by a person skilled in the art.⁴²

There are two independent components of the enablement requirement in the US: how to make the claimed invention over the scope claimed without undue experimentation (eg, “identifying” a compound via a screening method is not the same as teaching how to “make” the compound); and how to use the claimed invention over the scope claimed without undue experimentation. (Note, however, that the presence of specific, substantial and credible utility is not by itself sufficient to meet this criteria.) Similarly, there are two forms of rejections that an examiner may present during prosecution: full scope claimed, but not enabled for how to make and/or use; and a certain identified portion of scope claimed, but not enabled, ie, “scope of enablement.”

Turning to the written description requirement, the United States Patent & Trademark Office provides guidance in its “Written Description Guidelines.”⁴³ These explain:

The first paragraph of 35 U.S.C. 112 requires that the ‘specification shall contain a written description of the invention.’ This requirement is separate and distinct from the enablement requirement. The written

description requirement has several policy objectives. '[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.' Another objective is to put the public in possession of what the applicant claims as the invention. The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis.⁴⁴

According to the Federal Circuit's predecessor court in *In re Edwards*,⁴⁵ the function of the written description requirement is to:

[E]nsure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in ipsiis verbis; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.⁴⁶

Thus, one of the goals of the written description requirement is to convey to a skilled artisan that the patentee invented the claimed subject matter. To this end, the



specification must convey with clarity to one skilled in the art that the patentee had possession of the invention.⁴⁷ Possession may be evidenced, *inter alia*, by actual reduction to practice; by clear depiction in detailed drawings or structural chemical formulas; and through written description describing sufficient relevant identifying characteristics.

Whether there are sufficiently relevant identifying characteristics, in turn, requires weighing a number of factual considerations in view of the level of skill and knowledge in the art. Some factors include:

- complete or partial structure;
- physical and/or chemical properties;
- functional characteristics;
- correlation between structure and function; and
- method of making.

Pharmaceutical and biotech claims raise additional issues. The Federal Circuit has noted that an adequate written description of an invention involving genetic material "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials.⁴⁸ A mere wish or plan, however, is insufficient.⁴⁹

Indeed, the courts warn that merely providing a name of a molecule, knowing how to make it, and knowing what it does, in a general sense, may not put one in possession of the molecule if the art is unpredictable.⁵⁰

Genus claims are also problematic. For example, to support a claim to a genus requires a representative number of species, or sufficiently relevant identifying characteristics of the genus, for there to be acceptable written description. And there is an inverse correlation between the

predictability of the technology and the number of embodiments which must be described; in other words, the less predictable the technology, the more embodiments necessary for compliance with the written description requirement.

Some problems

Let us assume a claim to "An isolated nucleic acid comprising SEQ ID NO: 1 where nucleic acid does not encode an identified protein" [e.g., a "1st generation EST"].

Such a claim would:

- Likely lack an adequate written description for "gene" that falls within the scope of the claim;
- Likely lack enablement with respect to what additional sequences may be added to those specifically disclosed such that the asserted utility would be present; and
- The claim would read on a number of non-enabled embodiments such as: protein coding regions, genes and alleles.

Note, however, that broader claim scope in second generation and third generation DNA claims that would likely be more description and find enabling support in the specification.

In a second scenario, assume general receptor ligand/agonist/antagonist reach-through claims, such as:

- "A receptor [X] agonist"; or
- "A product identified by the screening process of claim 1 (wherein claim 1 screens for agonists of receptor [X])"; or
- "A method of treating disease [Y] by administering a compound which is a receptor [X] agonist" ("Functional use" claim to a method of treating a disease by a compound defined not by its structure but

rather by its ability to bind to a target).

Such a generic claim to “A receptor [X] agonist” would likely not comply with written description requirement when:

- There is no description of structure of representative number of claimed compounds; or
- There is no description of chemical or physical characteristics of representative number of claimed compounds or of function of representative number of claimed compounds (other than binding to identified receptor).
- Such a scenario is analogous to *Regents of the Univ. of Cal. v Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)* (noting that a description of how to obtain compounds is not sufficient without description of what the compounds are.)

A generic claim to “A receptor [X] agonist” is also not likely to comply with enablement requirement when:

- The specification does not teach how to make and use the full scope of agonists or antagonists within that genus without undue experimentation; or
- Specification teaches how to identify compounds, rather than how to make them; specification does not teach how to use the full scope of the compounds within the genus without undue experimentation.

Thus, consider, instead, alternative claim strategies to cover downstream products and for breadth. These might include business method, transmission of data/information, identification and claiming of novel sequences common to various species of genus, disclosure and claiming of % homology + function, filing on second or third generation DNA case rather than first generation, claiming vectors, methods for expressing products, methods for making vectors, etc.

According to 35 U.S.C. §112, second paragraph, a claim must be definite:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

The definiteness requirement forces a patentee to draft claims with clarity and precision.⁵¹ Indeed, Section 112, second paragraph, contains two requirements: First, that the claims be drafted with precision and definiteness, and second, that the claims be directed to the subject matter that the applicant regards as his or her invention.⁵²

The Federal Circuit considers compliance to Section 112, second paragraph, necessary to preserve the notice requirement of a patent.⁵³ The skilled artisan standard is used when analysing claim language for compliance with Section 112, second paragraph.⁵⁴ Further, inconsistency with the specification may make a claim take on an unreasonable degree of

uncertainty.⁵⁵

An invention must be useful, eg it must solve a problem. Indeed, according to the Supreme Court, “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”⁵⁶ Although mechanical and electrical inventions readily satisfy the requirement to demonstrate utility, pharmaceutical and biotechnological inventions may pose difficulties.

The requirements for utility and enablement are closely related. According to *In re Swartz*⁵⁷, where the Federal Circuit held that a claim to cold fusion failed both the utility and enablement requirements, the court explained:

‘The question of whether a specification provides an enabling disclosure under Section 112, paragraph 1, and whether an application satisfies the utility requirement of Section 101 are closely related.’ In order to be enabling, a patent specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Under Section 101, any patentable invention must be useful and, accordingly, the subject matter of the claim must be operable. As a result, if the claims in a patent application fail to meet the utility requirement because they are either not useful or inoperative, they will also fail to meet the enablement requirement.’⁵⁸

The utility requirement finds support in both 35 U.S.C. §§101 and 112:

35 U.S.C. 101: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor[.]”

35 U.S.C. 112: “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”

The USPTO, in an effort to better quantify the utility requirement, published its Utility Examination Guidelines at 66 FR 109 (Jan. 5, 2001); 1242 O.G. 162 (Jan. 30, 2001). According to the USPTO, an invention has a well-established utility if:

- (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (eg, properties or applications of a product or process), and
- (ii) the utility is specific, substantial, and credible.

In other words, specific utility must exist for the claimed invention; substantial utility is utility that has a real-world value, and credible utility asks the questions: would an artisan accept that the disclosed invention is in

currently available form?

A lack of credible utility normally arises where the invention is inoperative or would not be expected to function in the disclosed manner based upon current scientific understanding.

Using a specific example, assume a claim to “An isolated nucleic acid comprising SEQ ID NO: 1” where:

- the nucleic acid does not encode an identified protein, and no particular target of diagnostic relevance is disclosed [“1st generation expressed sequence tag”], or
- the nucleic acid encodes a protein whose function is inferred by homology [“2nd generation EST”], and either
 - assignment of function is rebuttable, or
 - assignment of function lacks sufficient specificity to establish a specific, substantial, credible utility (eg, assignment as “IL receptor” would not be sufficient).

Such a claim may not comply with the Utility Requirement.

Assume further a claim to a receptor where neither the receptor nor its ligand has specific, substantial, and credible utility, and the receptor function cannot be predicted from DNA or protein sequence homology. Where the receptor protein does not meet the utility requirement nor can any of the following meet the screening methods using the receptor; ligands/agonists/antagonists in general identified by the screening methods; methods, uses, or medicaments utilizing the ligands/agonists/antagonists in general; methods, uses, or medicaments utilising specific ligands/agonists/antagonists; and antibodies which recognise the receptor.

Conclusion

It is readily apparent that both inventors and their patent counsel should be aware of the need for the following disciplines when prosecuting pharmaceutical and biotechnology applications.

More emphasis should be placed on drafting claims wisely, with the understanding that any amendments or remarks made during prosecution will likely be held against a patent holder during litigation.

Applicants are advised to avoid amending the claim or, at the very least, minimise amendments as much as possible. To this end, more time should be spent by both clients and their attorneys in studying the state of the art (by way of patentability searches) and drafting claims that are not only novel and unobvious, but which also possess the requisite utility.

Particular care should be taken to ensure that the specification enables the claims and recites the proper written description. The objective is getting the specification right the first time, because anything subsequently added to the specification will likely be considered new matter.

Remarks made during prosecution are admissions which trigger prosecution history

estoppel just as readily as actual claim amendments. This is true even if the remark is not responsive to any of the rejections in the office action. ■

Notes

1 Thomas J. Kowalski, Esq. is a partner and Samuel H. Megerditchian, Esq. is an associate in the New York offices of Frommer Lawrence & Haug LLP. The opinions expressed herein are the personal opinions of the authors, and are not to be considered the opinions of Frommer Lawrence & Haug LLP or any of the firm's clients. Further, nothing in this article is to be construed as legal advice, a substitute for legal advice, or as positions/strategies taken/employed in, or suitable for, any particular case or set of facts.

2 *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998) (citing *Giles Sutherland Rich, Extent of Protection and Interpretation of Claims—American Perspectives*, 21 *Int'l Rev. Indus. Prop. & Copyright L.* 497, 499 (1990)).

3 See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 384 (1996) (determining that claim construction is a matter of law); *Graco, Inc. v. Binks Mfg. Co.*, 60 F.3d 785, 791 (Fed. Cir. 1995).

4 See *Markman*, 52 F.3d at 979 (“To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history”) (internal citations omitted).

5 See *Markman*, 517 U.S. at 373-74; see also *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999); *Bell Comms. Research, Inc. v. Vitalink Comms. Corp.*, 55 F.3d 615, 619 (Fed. Cir. 1995).

6 See *Autogiro Co. v. United States*, 384 F.2d 391, 395-96 (Ct. Cl. 1967).

7 See *SRI International v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121 (Fed. Cir. 1985).

8 See *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1302 (Fed. Cir. 1997).

9 See *Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1357 (Fed. Cir. 2002).

10 See *Markman*, 52 F.3d at 977.

11 See *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995).

12 See *Kopykake Enters. v. The Lucks Co.*, 264 F.3d 1377, 1383 (Fed. Cir. 2001).

13 See *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983).

14 *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) (quotations omitted).

15 *Vitronics*, 90 F.3d at 1582; see also *Novo Nordisk of N. Am. v. Genentech, Inc.*, 77 F.3d 1364, 1368 (Fed. Cir.

1996); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387 (Fed. Cir. 1992).

16 See *Vitronics*, 90 F.3d at 1582.

17 See *Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1466 (Fed. Cir. 1998).

18 *Novo Nordisk A/S v. Becton Dickinson & Co.*, No. 96 Civ. 9506, 2000 WL 294852, at *2 (S.D.N.Y. Mar. 21, 2000); see also *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (using specifications to ascertain the meaning of the claim term as it is used by the inventor in the context of the entirety of his invention); *Amhil Enters. Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1559 (Fed. Cir. 1996) (recognizing that the “entire specification” should be considered in interpreting claim language).

19 See *Vitronics*, 90 F.3d at 1582.

20 *Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268-70 (Fed. Cir. 2001), citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001).

21 See *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303 (Fed. Cir. 1997).

22 See *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988).

23 See *Novo Nordisk of N. Am. v. Genentech*, 77 F.3d 1364, 1369 (Fed. Cir. 1996); *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1278 (Fed. Cir. 1995); compare *Ekchian*, 104 F.3d at 1303, with *Philip v. Mayer Rothkepf Indus., Inc.*, 635 F.2d 1056, 1061 (2d Cir. 1980).

24 See *Phonometrics, Inc. v. Northern Telecom, Inc.*, 133 F.3d 1459, 1466 (Fed. Cir. 1998) (“[Patentee] of course argues that additional limitations cannot be imported into a claim from the written description. We may, however, construe a specifically claimed limitation in light of the specification, which is all we do here.”); *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1578 (Fed. Cir. 1996) (“Here, the district court did not import an additional limitation into the claim; instead, it looked to the specification to aid its interpretation of a term already in the claim, an entirely appropriate practice.”).

25 See *Markman*, 52 F.3d at 980 (“The court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims.”).

26 See *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1160 (Fed. Cir. 1997), citing *Applied Materials v. Advanced Semiconductor Material*, 98 F.3d 1563, 1573 (Fed. Cir. 1996).

27 *Vitronics*, 90 F.3d at 1582; see also *Alpex Computer Corp. v. Nintendo Co. Ltd.*, 102 F.3d 1214, 1220 (Fed.

Cir. 1996).

28 See *Vitronics*, 90 F.3d at 1583.

29 See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002).

30 See *id.*

31 See *id.*

32 See *id.*

33 See *Johnson & Johnston Assoc., Inc. v. R.E. Svc Co., Inc.*, 285 F.3d 1046 (Fed. Cir. 2002).

34 See *Vitronics*, 90 F.3d at 1583.

35 See *Vitronics*, 90 F.3d at 1584.

36 *Markman*, 52 F.3d at 980. “The court may, in its discretion, receive extrinsic evidence in order ‘to aid the court in coming to a correct conclusion’ as to the ‘true meaning of the language employed’ in the patent.” *Markman*, 52 F.3d at 980 (internal quotations omitted); see also *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998) (holding that trial court can hear extrinsic evidence to educate itself about patent and relevant technology, but may not use extrinsic evidence to vary or contradict claim terms).

37 See *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1475 (Fed. Cir. 1998) (“The objective of claim interpretation is to discern the meaning of the claim terms to one of ordinary skill in the art at the time of the invention.”).

38 See *Vitronics*, 90 F.3d at 1584.

39 See *Vitronics*, 90 F.3d at 1583-85.

40 See *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

41 See *Wands*, 858 F.2d at 737.

42 See *Art. 83 EPC*.

43 See 66 FR 1099.

44 *Id.* at 1104-05 (internal citations omitted).

45 568 F.2d 1349 (C.C.P.A. 1978).

46 *Id.* at 1351-52.

47 See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

48 *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1983).

49 See *id.*, 984 F.2d at 1169-71.

50 See *id.*; see also *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

51 See *In re Borkowski*, 422 F.2d 904 (C.C.P.A. 1970).

52 See *id.* at 909 (“If the scope of the subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.”).

53 See *Solomon v. Kimberly-Clark Corporation*, 216 F.3d 1372, 1379 (Fed. Cir. 2000) (“As has been noted in the context of definiteness, the inquiry under section 112, paragraph 2, now focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the patentee’s right to exclude.”).

54 See *Atmel Corporation v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1378 (Fed. Cir. 1999) (noting that “as a general matter, it is well-established that the determination whether a claim is invalid as indefinite” is dependent upon whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification).

55 See *In re Cohn*, 438 F.2d 989 (C.C.P.A. 1971).

56 *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966).

57 2002 WL 31497300 (Fed. Cir. Nov. 8, 2002).

58 *Id.* at *1 (internal citations omitted).

The authors

Thomas J Kowalski, left, is a founding partner in Frommer, Lawrence & Haug LLP, a full service US intellectual property firm based in New York City. Mr Kowalski has been in practice for more than 16 years, working across biotech, chemical and medical apparatus patent prosecution, licensing, counseling and litigation.

Samuel H Megerditchian is an associate in the New York office of Frommer Lawrence & Haug LLP. He specialises in patent strategy and procurement (US and international), client counseling, opinion work (infringement and validity) and inter partes proceedings including interferences before the Board of Patent Appeals and Interferences.

