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Can a Patent Claim that Refers to Another Claim be Independent?

Pfizer v. Ranbaxy Laboratories Reconsidered

Tony A. Gayoso and Irving N. Felt[1]

Consider the following three hypothetical claims:

> 1. Chemical compound A, chemical compound B, or pharmaceutically acceptable salts thereof.
>
> 2. A chemical compound of claim 1 which is compound A.
>
> 6. A salt of the chemical compound of claim 2.

There can be no doubt that claim 1 is an independent claim and that claim 2 is a dependent claim. But what kind of claim is claim 6?

On the one hand, claim 6 refers to another claim. So, perhaps it should be construed as a dependent claim.

On the other hand, claim 6 is not written in traditional dependent claim format. Could claim 6 be construed as an independent claim that uses a short-hand method of reciting some of its elements? In other words, could claim 6 be construed as a salt of a chemical compound, the structure of which is incorporated by reference from claim 2? Such a construction is consistent with an independent claim.

The claims indicated above are not truly hypothetical, and the questions posed

1 Hoffmann & Baron, LLP. The opinions expressed in this article are solely the current opinions of the authors, and not necessarily those of Hoffmann & Baron, LLP; any of its attorneys or agents; any of its clients; and not necessarily even the future opinions of the authors.

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above are not merely academic. If chemical compound A were atorvastatin acid, chemical compound B were atorvastatin lactone, and the salt in claim 6 were the hemicalcium salt, the claims would essentially be those of Pfizer Inc. in its U.S. patent[2] directed to the low-density cholesterol reducing drug Lipitor®.

The validity of this patent was at issue in a high stakes law suit between Pfizer and the generic drug company Ranbaxy Laboratories. *Pfizer, Inc. v. Ranbaxy Laboratories Ltd*.[3] The apparently unchallenged construction of claim 6 as a dependent claim,[4] and the Federal Circuit's characterization of it as an improper dependent claim, were fatal to Pfizer's attempt to prevent Ranbaxy from selling a generic version of Lipitor®, as we shall see. The authors explain below why they believe the case was wrongly decided.

At trial in the District Court for the District of Delaware, the only claim Pfizer asserted against Ranbaxy was claim 6.[5] Ranbaxy argued that claim 6 was invalid as being an improper dependent claim under 35 U.S.C. § 112, ¶ 4[6], which, in relevant part, states:

> ... a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

The district court starts with the presumption that "[c]laim 6 is a dependent claim..."[7] Moreover, the district court stated that it "...recognizes that there may be a technical problem in the drafting of claim 6 ..."[8]

Nevertheless, the district court ruled against Ranbaxy, and held, *inter alia*, that claim 6 had not been proven invalid under 35 U.S.C. § 112, ¶ 4.[9] The basis of the district court's decision was its inability to find any Federal Circuit precedent applying § 112, ¶ 4 to invalidate a patent.[10] Accordingly, the district court expressed the view that § 112, ¶ 4 is limited to matters of form, to be addressed internally by the United States Patent and Trademark Office (USPTO) through an objection, and not through a rejection.[11]

In support of its decision, the district court noted, with approval, that the USPTO Manual of Patent Examining Procedure (MPEP) is explicit in distinguishing objections to claims, which are directed to formal matters, from rejections of claims, which are directed to substan-

2 U.S. Patent No. 5,273,995.

3 The district court trial is reported at 405 F.Supp.2d 495 (D. Del. 2005). The appeal is reported at 457 F.3d 1284 (Fed. Cir. 2006).

4 The district court declared that "Claim 6 is a dependent claim ..." 405 F.Supp.2d at 507. The Federal Circuit noted that "... Pfizer asserted dependent claim 6 of the ... patent." 457 F.3d at 1291. There is no indication in the report of either decision that these characterizations of claim 6 as a dependent claim were challenged by either party.

5 405 F.Supp.2d at 507.

6 *Id.*

7 *Id.*

8 *Id.* at 508.

9 *Id.* at 510.

10 *Id.* at 508-509.

11 *Id.* at 509.

tive matters. According to the court, formal objections to claims may be reviewed only by way of petition to the Director of the USPTO. In contrast, the court observed, substantive rejections may be appealed to the USPTO Board of Patent Appeals and Interferences (the Board), whose decisions can, in turn, be appealed to the Federal Circuit.[12]

The district court emphasized that there had been no objection to the form of claim 6 by the examiner during prosecution.[13] Moreover the district court considered claim 6 to be unambiguous.[14] Accordingly, the district court could not find a reason to hold claim 6 invalid.[15]

On appeal, the Federal Circuit reversed the district court, and held that claim 6 was invalid.[16] The sole ground for invalidity was that claim 6 violated § 112, ¶ 4.[17] The Federal Circuit conceded "... that the patentee was attempting to claim what might otherwise have been patentable subject matter."[18] Nevertheless, the Federal Circuit felt compelled to hold claim 6 invalid because it "... fails to specify a further limitation of the subject matter of the claim to which it refers because it is completely outside the scope of claim 2 (inner quotes omitted)."[19]

The only issue addressed by the Federal Circuit in regard to § 112, ¶ 4 was whether it constituted a provision that could invalidate a claim. The court acknowledged that: "... at the time the district court wrote its opinion, there was no applicable Federal Circuit precedent."[20] The Federal Circuit based its decision on a case reported after the district court decision. Referring to its recent decision in *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*,[21] the Federal Circuit stated:

> More recently, however, **we have suggested** that a violation of § 112, ¶ 4 renders a patent invalid just as violations of other paragraphs of § 112 would.[22]

Implicit in the highlighted words "we have suggested" is the recognition by the Federal Circuit that the above statement from the *Curtiss-Wright* case was clearly *dicta*.[23] In the authors' opinion, such *dicta* regarding a technical violation of a purely formal

12 *Id.* at 509 and footnote 6, referring to MPEP 706.01.

13 *Id.* at 509, footnote 7.

14 *Id.* at 507.

15 *Id.* at 510.

16 457 F.3d at 1292.

17 *Id.*

18 *Id.*

19 *Id.*

20 *Id.* at 1291.

21 *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374,1380 (Fed. Cir. 2006).

22 457 F.3d at 1291, 1292 (emphasis added).

23 According to the Federal Circuit in *Pfizer,* the Federal Circuit in *Curtiss-Wright,* in support of the doctrine of claim differentiation, reasoned that: "... reading an additional limitation from a dependent claim into an independent claim would not only make that additional limitation superfluous, it **might render the dependent claim invalid** for failing to add a limitation to those recited in the independent claim, as required by 35 U.S.C. § 112 paragraph 4 (emphasis added, inner quotes omitted)." This statement is *dicta*, since the form of the dependent claim was not at issue in *Curtiss-Wright*.

provision of a statute is an insufficient basis for the Federal Circuit's precedent-setting decision in *Pfizer v. Ranbaxy*.

It is noteworthy that the Federal Circuit in *Pfizer v. Ranbaxy* recognized "...that the patentee was attempting to claim what might otherwise have been patentable subject matter."[24] The court's reliance on *dicta* in *Pfizer v. Ranbaxy* seems especially ill-advised, since its reliance was the sole basis to deprive an inventor of his right to an otherwise valid patent, and his assignee of its considerable investment in developing a major drug.[25]

There were numerous reasons that could have, and, in the authors' opinion, should have, caused the Federal Circuit to uphold the validity of claim 6. For example, the fact remains that the Federal Circuit, like the district court, was unable to point to a single case in which § 112, ¶ 4 had actually been invoked to invalidate a patent. See above.

The authors would like to focus on one possible reason for validity that was not discussed in either the district court decision or the Federal Circuit decision. In particular, the authors propose that claim 6 may properly be read as an independent claim.

The reasoning behind this proposal starts with a well settled principle. As early as 1894, the Supreme Court acknowledged the deference courts owe to an issued patent by stating: "... when the patent office has granted a patent to the successful inventor, the courts should not be ready to adopt a...construction, fatal to the grant.[26] In 1935, the Supreme Court confirmed its earlier admonition to lower courts, ruling that if a claim is "fairly susceptible of two constructions, that [construction] should be adopted which will secure to the patentee his actual invention, rather than to adopt a construction fatal to the grant."[27] The modern formulation of this principle in the Federal Circuit is that "...claims should be so construed, if possible, so as to sustain their validity."[28]

Therefore, claim 6 should have been held valid if it was possible to do so. As discussed below, it was indeed possible to do so.

The statutory framework for claims is provided in the second through fifth paragraphs of § 112. The third paragraph of § 112 delineates three types of claims, namely independent, dependent and multiple dependent. Paragraphs 4 and 5, respectively, define "dependent" and "multiple dependent" claims. There is, however, no definition or statutory framework for independent claims in § 112.

The plain language of § 112, ¶ 4, quoted above, merely states that, for a claim to be a proper dependent claim, it must satisfy three conditions: (i) refer to a previous claim, (ii) incorporate by reference all the limitations of the claim to which it refers, and (iii) specify a further limitation.

Nothing in the language of § 112, ¶ 4 requires the conclusion that every claim that satisfies the first condition, *i.e.*, refers

24 *Id.* at 1292.

25 One sign of the real-world impact of this decision is the report that within a year of the *Pfizer v. Ranbaxy* decision, Pfizer profits fell 48%, in part as a result of the loss of the patent exclusivity on Lipitor. "Pfizer Profit Falls 48 Percent," *Business Week*, McGraw-Hill, July 18, 2007.

26 *Keystone Manufacturing v. Adams*, 151 U.S. 139,145,14 S.Ct 295, 297 (1894).

27 *Smith v. Snow*, 294 U.S. 1, 14, 55 S.Ct. 279, 284 (1935).

28 *ACS Hospital Systems v. Montefiore Hospital*, 732 F.2d 1572 (Fed. Cir. 1984).

to a previous claim, is necessarily a dependent claim. The authors are unaware of any statutory, regulatory, or case law authority that compels such a conclusion.

Nor is such a conclusion compelled by logic. Clearly, there is a qualitative, semantic difference between *referring to* another claim and *depending on* another claim.

For the purpose of this article, the authors will assume the correctness of the Federal Circuit's holding that "... claim 6 fails to 'specify a further limitation of the subject matter' of the claim to which it refers because it is completely outside the scope of claim 2."[29] Even if one accepts this assumption, the most one can say about claim 6 is that it does not satisfy all three conditions required by § 112, ¶ 4 for a proper dependent claim. At least according to the Federal Circuit, claim 6 lacks condition (iii) above.

It does not necessarily follow, however, that claim 6 is an improper dependent claim. As mentioned above, there is no legal or logical reason for considering claim 6 to be a dependent claim at all.[30]

But, if claim 6 is not a dependent claim, we return to the question posed at the beginning of this article. What kind of claim is it? In the authors' opinion, there is no reason that precludes the conclusion that claim 6 is an independent claim. On the contrary.

It is constructive to compare what the Federal Circuit in *Pfizer v. Ranbaxy* considered to be a proper independent claim and the actual language of claim 6 in the Pfizer patent. The Federal Circuit acknowledged that:

> ... claim 6 could have been properly drafted ... as an independent claim – *i.e.*, 'The hemicalcium salt of atorvastatin acid.'[31]

Claim 6 could, in fact, have been so drafted, but was not.

Instead, the applicant chose to formulate claim 6 as it appears in the *Pfizer* patent, namely:

> "The hemicalcium salt of **the compound of claim 2**."

The applicant's formulation of claim 6 is the "unambiguous" equivalent of the Federal Circuit's proposed independent claim, *i.e.*:

> "[T]he hemicalcium salt of **atorvastatin acid**."[32]

29 In fact, the authors do not agree with this assumption. Rather, they find compelling the district court's reasoning that: "As a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form." 405 F.Supp2d at 508. The Federal Circuit gave short, if any, shrift to this interpretation of claim 6 by mentioning it in passing in a footnote. 457 F.3d at 1292, footnote 7.

30 In fact, a strict interpretation of § 112, ¶ 4 precludes claims written in the format of claim 6 from being a dependent claim. Thus, § 112, ¶ 4 states that "... a claim in dependent form shall contain a reference to a claim previously set forth **and then** specify a further limitation of the subject matter claimed. The rule could have simply used the conjunction "and." Instead, the rule states "and then," thereby specifying an order. Taken literally, a dependent claim must first refer to a previous claim, "and then" specify a further limitation. As mentioned above, a claim that uses the format of claim 2 of the Pfizer patent ("A chemical compound of claim 1 which is compound A") has the format required by § 112, ¶ 4. However, claims that first specify a limitation, and then refer to a previous claim, such as claim 6 in the *Pfizer* patent ("The hemicalciurn salt of the compound of claim 2) do not satisfy the literal definition of dependent claims.

31 457 F.3d at 1292.

32 *Id.* at footnote 7.

Accordingly, the applicant can be considered to have chosen to incorporate the name of the compound of claim 2 by reference, instead of reciting "atorvastatin acid." Incorporation by reference is a concept well known in patent law.[33] It is, in fact, routine in the case of biotechnology inventions to incorporate amino acid and nucleotide sequences into claims from other parts of the specification.[34]

By choosing to incorporate the name of the compound by reference in claim 6, rather than to state it explicitly, the inventor named in the *Pfizer* patent[35] can be considered simply to have exercised his right to be his own lexicographer. The Federal Circuit has stated "[i]t is a well-established axiom in patent law that a patentee is free to be his or her own lexicographer.[36]

In addition, although the Federal Circuit may have been correct in stating that there was no precedent binding on the district court on the issue whether a violation of 35 U.S.C. § 112, ¶ 4 could invalidate a claim, a 1992 decision of the Board expressly sanctioned the format of a claim similar to claim 6 of the *Pfizer* patent. *Ex parte Porter*.[37]

In *Porter*, an independent apparatus claim, claim 7, defined a nozzle suitable for use in discharging a controlled stream of fluid. The claim in question in *Porter*, coincidentally also claim 6, read: "A method ... which comprises utilizing the nozzle of claim 7."[38]

The Board in *Porter* specifically considered claim 6 in light of § 112, ¶ 4. According to the Board, "...claim 6 could be construed as an independent claim, drafted in a short-hand format to avoid rewriting the particulars of the nozzle recited in claim 7."[39]

As did the district court in *Pfizer v. Ranbaxy*, the Board in *Porter* further expressed the opinion that whether a claim is considered to be an improper dependent claim under § 112, ¶ 4 is a "...formal matter ...solely within the jurisdiction of the Commissioner..." See above.

Even in 1992, according to the Board in *Porter*: "The manner in which claim 6 has been drafted has been an acceptable format for years."[40] It is unfair, and harmful public policy, for the Federal Circuit to deny applicants the right to use a format that (i) had been used for years, (ii) had been specifically sanctioned as possibly independent by the Board in 1992, and (iii) had never been disapproved of by a court.

While future applicants are on notice of the Federal Circuit's decision, what about previous applicants? Were all of the issued claims that were drafted using the format of claim 6 in the justifiable belief they were proper rendered invalid as a result of the Federal Circuit decision in *Pfizer v. Ranbaxy*? Such a result would clearly be unfair, and particularly unwarranted, since the only authority for the decision was *dicta*.

33 37 C.F.R. 1.57 and 37 C.F.R. 1.75.

34 *Hormone Research Foundation v. Genentech*, 904 F.2d 1558,1563 (Fed. Cir. 1990). *See also* MPEP 2422.03 and 37 C.F.R. 1.821(d).

35 Dr. Bruce D. Roth.

36 *Hormone Research Foundation v. Genentech*, *supra* note 34, at 1563.

37 25 U.S.P.Q.2d 1144 (BPAI 1992).

38 *Id.*

39 *Id.* at 1147.

40 *Id.*, citing "claim 11 reproduced in the decision of *In re Kuehl*, 475 F.2d 658, 177 U.S.P.Q. 250 (C.C.P.A. 1973) and claims 11 and 14 reproduced in *Ex parte Blattner*, 2 U.S.P.Q.2d 2047 (BPAI 1987)."

Moreover, courts should, when appropriate, go beyond the literal interpretation of a statute. Courts should at least consider Congress's purpose in passing the statute. In *Pfizer v. Ranbaxy*, however, the Federal Circuit did not address the purpose of 112 ¶ 4, even though it was discussed in the district court decision.[41]

The legislative history of § 112, ¶¶ 3, 4 and 5 is, in fact, instructive. These provisions were, in part, intended to expedite patent prosecution.[41] Patent prosecution is expedited because dependent claims, as defined by § 112, ¶ 4, are typically short and easy to read. Moreover, they are easy for examiners to evaluate for anticipation under § 102 and obviousness under § 103.

It is hard to see how the Federal Circuit's holding that a violation of § 112, ¶ 4 is sufficient to invalidate claims advances the plainly stated congressional intent. As a more enlightened panel of the Federal Circuit, quoting Learned Hand,[43] noted[44]:

> ... it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

It is also important to remember that the constitutional purpose of the patent act is "to promote the progress of ... useful arts."[45] Consistent with this purpose, courts are mandated by binding precedent to construe claims to be valid, if possible. See above. It is difficult to see how the Federal Circuit's rigid and harsh decision in *Pfizer v. Ranbaxy* promotes this purpose or satisfies this mandate.

In fact, it is difficult to imagine any public policy that is promoted by the Federal Circuit's decision in *Pfizer v. Ranbaxy*. It is equally difficult to imagine any public policy that is harmed by considering claims in the form of claim 6 to be valid independent claims. It should be kept in mind that both the district court[46] and the Federal Circuit[47] agreed that claim 6 is unambiguous as to its meaning. Also, neither the examiner of the *Pfizer* patent nor the Board in *Porter* indicated any problem with this form of claim. See above.

As can be gleaned from the above, the authors believe the *Pfizer v. Ranbaxy* decision was wrongly decided, and should be overruled. At very least, it should be limited to its specific facts.

Thus, claim 6 of the *Pfizer* patent, at least according to the Federal Circuit, "... is completely outside the scope of claim 2." Claims that refer to subject matter in other claims, but that are within the scope of the subject matter of the other claim, should not be subject to invalidity in accordance with *Pfizer v. Ranbaxy*. Such claims satisfy all of the requirements of § 112, ¶ 4, and may be considered to be

41 405 F.Supp.2d 495, 509,

42 See S.Rep. No. 89-301 (1965), *reprinted in 1965 U.S.C.C.A.N. 2315*

43 *Cabell v. Markham*, 148 F.2d 737, 739 (2d Cir.), *aff'd*, 326 U.S. 404, 66 S.Ct. 193, 90 L.Ed. 165 (1945).

44 *Roche Products v. Bolar Pharmaceutical*, 733 F.2d 858, 861 (Fed. Cir. 1984).

45 United States Constitution, Article 111, Section 8.

46 405 F.Supp.2d at 507.

47 457 F.3d at 1292, footnote 7.

proper dependent claims. Alternatively, such claims may be considered to be proper independent claims that merely incorporate subject matter by reference from another claim, as explained above.

For example, the nozzle in claim 6 of the application at issue in *Porter* is completely within the scope of the nozzle in claim 7, and merely adds a use limitation.[48] See above. Accordingly, claim 6 of *Porter* is either a proper dependent claim or a proper independent claim.

It is interesting to note in this regard that, under recently issued USPTO rule 75(b)(2), a claim that either does not incorporate all of the limitations of a claim to which it refers, or that refers to a claim of a different statutory class, will be treated as an independent claim for the purposes of fee calculation and enforcing the 5/25 claim threshold. As mentioned above, claim 6 of the *Pfizer* patent was held not to incorporate all of the limitations of a claim to which it refers. As can be seen from the discussion above, claim 6 of the *Porter* application refers to a claim of a different statutory class. Therefore, the claims at issue in both the *Pfizer* and *Porter* cases would have been treated in the USPTO as independent claims for the limited purposes mentioned in new rule 75(b)(2).

The new rules do not, however, indicate whether, for the purpose of evaluating patentability, the USPTO will consider such claims to be independent claims, or dependent claims to be evaluated under 35 U.S.C. § 112, ¶ 4 in accordance with *Pfizer v. Ranbaxy*. Needless to say, the Federal Circuit is unlikely to be influenced by the new USPTO rules in its determinations of claim validity.

In conclusion, the authors consider the Federal Circuit's decision in *Pfizer v. Ranbaxy* to constitute an unnecessarily limited, and indeed draconian, interpretation of § 112, ¶ 4. They further consider the decision to be an unwarranted extension beyond the stated congressional purpose of § 112, ¶ 4, and, more broadly, of the constitutional mandate "to promote the progress of ... useful arts."

48 Similarly, the chemical compounds in the claims in decisions cited with approval by the Board in *Porter*, namely *In re Kuehl, id.*, and *Ex parte Blattner, id.*, are all within the scope of the chemical compounds in the claims from which they depend.