UPSTAGING NAUTILUS IN IN RE PACKARD: CREATING A NEW EXAMINATION REGIME*

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* This paper represents the views of the writer and does not necessarily reflect the views of any colleague, organization or client thereof.

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I. OVERVIEW

The May 6, 2014, Federal Circuit opinion in *In re Packard*, __ F.3d __ (Fed. Cir. 2014)(per curiam), is most remarkable for a variety of reasons: First and foremost, *Packard* upstages the Supreme Court that is just a month away from its first major exposition of the law in the same area for the first time in more than seventy (70) years. *See* § II, *Paying Lip Service to the Court in Nautilus*

The most serious aspect of *Packard* from the standpoint of consequences to the patent examination system is the proposal for a two-part, piecemeal examination of the issue of indefiniteness under what is now 35 USC § 112(b). If Examiners follow the guidance of the *per curiam* opinion, they can pick any – or every – term in a claim which, in vacuo, may appear to be indefinite and put the burden on the applicant to explain where in the specification – or elsewhere – the term meets the statutory requirements of Section 112(b). *See* § III, *Piecemeal Examination Proposed in Packard*. The Court borrows from the special circumstances of chemical patent nonobviousness to introduce a two part system. *See* § III-A, *A Two Part Indefiniteness Examination*. The Patent Office should resist introduction of this two part system which would only delay patent examination and pit patent applicants and Examiners as adversaries. *See* § III-B, *Proscribed Piecemeal Examination*.

The *per curiam* majority seeks precedent for its two part examination system by focusing upon a practice unique to chemical and biotechnology inventions that makes good sense for such examination and is more efficient in that area, but is distinguishable for areas of the law where the facts are all available to the Examiner. *See* § IV, *The Papesch Two-Part Examination*. 
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To be sure, there are other challenging issues in the *per curiam* opinion of the Court but these issues are of more concern to the litigants – and are left to the litigants to consider in whatever actions they may choose to take. Even more inviting from a standpoint of the budding scholar or patent writer are the provocative and unique perspectives of the concurring opinion: But, as part of a *concurring* opinion they lack precedential value and are not of immediate concern. *See § VI, The Packard Patent Piñata.*

**II. PAYING LIP SERVICE TO THE SUPREME COURT IN NAUTILUS**

A big surprise in *Packard* is that the court totally ducked a merits decision on the issue presented center stage to the Court, the viability of a *sui generis* Patent Office ground of rejection under *Ex parte Miyazaki*, 89 USPQ2d 1207 (PTO Bd.App. & Int. 2008).

A bigger surprise, however, is that more than six (6) months after the December 4, 2014, argument and with only one month left in the Supreme Court to render its merits decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, Supreme Court No. 13-369, the Court issued its panel opinion dealing with the *identical* body of case law as the Supreme Court; the last time the Court gave a thorough review of the law in this area was more than seventy (70) years ago in *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228 (1942).

One would have thought that the panel, having let the case sit for more than six months from argument, could have waited one more month to see what guidance the Supreme Court would offer.
Paying lip service to the Supreme Court, the panel in Packard gave a justification for its premature decision: Citing Nautilus, the panel stated that “we can reach [our] conclusion and decide the present case without regard to the proper formulation of the judicially-applied indefiniteness standard that may be appropriate for post-issuance assessment of indefiniteness, a matter currently under review by the Supreme Court.”

III. PIECEMEAL EXAMINATION PROPOSED IN PACKARD.

The per curiam majority creates an unprecedented two part examination system for compliance with 35 USC § 112(b) which invites an Examiner to pick and choose terms where he “identifies ways in which language … is ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention”, and then put the burden on the patent applicant to rebut his conclusion.

In essence, if the per curiam majority opinion is followed, the Examiner need not consider the specification support and definitions for claim terminology but need merely pick and choose terms in a claim and demand that the patent applicant prove that the terms are in compliance with the statute.
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**A. A Two Part Indefiniteness Examination**

Historically, patent Examiners are required to perform a complete examination on the merits which includes a study of all available evidence – for and against the patent applicant – to determine whether the statutory predicates for grant of a patent under Title 35 are met.

The Patent Examiner is thus more of a “judge” and clearly not an *advocate* against the patent applicant. Yet, the regime proposed in the *per curiam* opinion turns the examination process upside down into what amounts to an adversarial system: The panel determines that the Patent Examiner should look for ways that a claim fails to meet the requirements of 35 USC § 112(b), and then leave it up to the applicant to submit evidence that rebuts the Examiner’s case.

We conclude that, when the USPTO has initially issued a well-grounded rejection that identifies ways in which language in a claim is ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention, and thereafter the applicant fails to provide a satisfactory response, the USPTO can properly reject the claim as failing to meet the statutory requirements of § 112(b). The satisfactory response by the applicant can take the form of a modification of the language identified as unclear, a separate definition of the unclear language, or, in an appropriate case, a persuasive explanation for the record of why the language at issue is not actually unclear.

The Court recognizes that there can be different standards for evaluating indefiniteness of a granted patent in the District Court and examination of a claim before the Patent Office.
[I]ndefiniteness rejections by the USPTO arise in a different posture from that of indefiniteness challenges to an issued patent. See Exxon Research & Eng'g v. United States, 265 F.3d 1370, 1380 (Fed. Cir. 2001). It makes good sense, for definiteness and clarity as for other validity requirements, for the USPTO initially to reject claims based on a well-founded prima facie case of lack of clarity (in its several forms) based on the perspective of one of ordinary skill in the art in view of the entire written description and developing prosecution history. Then, if the applicant does not adequately respond to that prima facie case, to confirm that rejection on the substantive basis of having failed to meet the requirements of 112(b). Furthermore, we can reach that conclusion and decide the present case without regard to the proper formulation of the judicially-applied indefiniteness standard that may be appropriate for post-issuance assessment of definiteness, a matter currently under review by the Supreme Court. See Nautilus, Inc. v. Biosig Instruments, Inc., 715 F.3d 891 (Fed. Cir. 2013), cert. granted, 82 U.S.L.W. 3195 (U.S. Jan. 10, 2014) (No. 13-369).

B. Proscribed Piecemeal Examination

Individual inventors and small and emerging technology companies deserve a complete and fair examination on the merits in the most expeditious manner possible. This means that the Patent Office should look to all available evidence to consider the claimed invention as a whole. The Patent Office should thus look to evidence favorable to the patent applicant that is available and not merely seek out evidence that it can use to deny a patent. After all, the ex parte examination procedure places the examiner more in the position of a “judge” to determine patentability and not as an advocate against granting a patent.

A complete examination on the merits is an essential integer of patent examination. The policy proscribing piecemeal examination is deeply rooted in the Code of Federal Regulations: “The examination shall be complete with respect both to compliance of the application … with the applicable statutes and rules and
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to the patentability of the invention as claimed….” 37 CFR § 1.104(b)(emphasis added).

For more than 100 years the need for a full examination on the merits has been recognized by the Courts. Early on in *Steinmetz v. Allen* at the beginning of the twentieth century the courts recognized “the policy of the law in making full and complete examinations as to the novelty and priority of every claim that is presented for a patent. This is a matter in which the public is greatly interested.” *United States ex rel. Steinmetz v. Allen*, 22 App. D.C. 56 (D.C. Cir. 1903), rev’d, 192 U.S. 543 (1904). Thus, “[t]he examiner's action will be complete as to all matters * * *.” *Watson v. Bruns*, 239 F.2d 948, 951 (D.C. Cir. 1956) (quoting Rule 105); *see also National Rolled Thread Die Co. v. E. W. Ferry Screw Products, Inc.*, 541 F.2d 593, 598 (6th Cir. 1976)(citing 37 C.F.R. § 1.105 (1967)) (“[I]t was the examiner's obligation under the Patent Office rules to make a ‘complete [examination] as to all matters’.”).

The *Manual of Patent Examining Procedure* emphasizes that piecemeal examination should be avoided: “Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available…Rejections on grounds such as lack of proper disclosure, lack of enablement, indefiniteness and *res judicata* should be applied where appropriate even though there may be a seemingly sufficient rejection on the basis of prior art. Where a non-prior art ground of rejection is proper, it should be stated with a full development of reasons rather than by a mere conclusion coupled with a boiler plate expression.” MPEP §707.07(g).
IV. THE PAPESCH TWO-PART EXAMINATION

D. The Piasecki Justification for the Two-Part Examination

The Court justifies its two-part examination procedure by citing In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1984). To do justice to the per curiam opinion, the relevant portion is quoted, here, in toto:

The USPTO must be able to make the congressionally created examination process work so that it fulfills its purpose of producing patents whose claims meet the statutory standards. We earlier approved a procedural mechanism for the USPTO to use in doing this, which we refer to as the "prima facie case." See In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1984). "In the prosecution of a patent, the initial burden falls on the PTO [examiner] to set forth the basis for any rejection." Hyatt v. Dudas, 492 F.3d 1365, 1369-70 (Fed. Cir. 2007). The USPTO thus meets its obligation to explain adequately the shortcomings it perceives so that the applicant is properly notified and able to respond. "Once the applicant is so notified, the burden shifts to the applicant to rebut the prima facie case with evidence and/or argument." Id.

The "prima facie case" determination is a purely procedural device that operates at the examiner level to clarify how the interaction process proceeds. Thereafter any final rejection by the examiner, and any review of the rejection, whether by the Board or through appeal to the courts, turns on the substantive question of the merits of the rejection. In re Piasecki, 745 F.2d at 1472 (citing In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976) ("When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . . An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability . . . . [A] final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . .")]; see also In re Jung, 637 F.3d 1356, 1362 (Fed. Cir. 2011).
The same approach to making the examination process work is an appropriate one for addressing the question of indefiniteness. We have elsewhere noted that indefiniteness rejections by the USPTO arise in a different posture from that of indefiniteness challenges to an issued patent. See Exxon Research & Eng'g v. United States, 265 F.3d 1370, 1380 (Fed. Cir. 2001). It makes good sense, for definiteness and clarity as for other validity requirements, for the USPTO initially to reject claims based on a well-founded prima facie case of lack of clarity (in its several forms) based on the perspective of one of ordinary skill in the art in view of the entire written description and developing prosecution history. Then, if the applicant does not adequately respond to that prima facie case, to confirm that rejection on the substantive basis of having failed to meet the requirements of § 112(b).

E. Piasecki: Papesch Prima Facie Obviousness

Piasecki is a situation under a long line of cases dating back more than fifty years to In re Papesch, 315 F.2d 381 (CCPA 1963). Under Papesch, there is a two-part examination favors the patent applicant and examiner alike, because only through the two-part procedure is it possible to efficiently conserve patent applicant resources and most efficiently reach a conclusion based upon the evidence as a whole. To be sure, there are now other areas of the law that involve a prima facie showing, but in all areas of practice the Examiner must consider all relevant evidence that he has available.

The reason that there is a “piecemeal” examination of all the factors involved with a chemical compound nonobviousness inquiry is simply because all the evidence is not available to the examiner for his initial consideration of the application. Thus, for the determination of nonobviousness under 35 USC § 103 of chemical compounds (and more recently for larger biotechnology molecules) a two part examination is necessity. The quest of the examination procedure is a determination whether a new chemical compound is or is not obvious: Is the three
dimensional, physical “thing” that is claimed unobviously different from the closest prior art.

It is the “thing” that is under scrutiny, the three dimensional molecule which, with tiny changes in bond angles or other features may lead to a quite different molecule with decidedly different – and unexpected – properties. But, the Patent Office is without its own laboratories to determine such a difference.

What the Patent Office does have is the ability to search the literature to see whether there is a structurally close compound, so close as to suggest that the claimed product would share the same properties. If in fact there are only shared properties, then the claimed compound is “structurally obvious” – and, until 1963, the Patent Office considered the case closed to the exclusion of any showing of nonobvious (different) properties. The law of “structural obviousness” is explained by the late Giles Sutherland Rich:

“The question of ‘structural similarity’ in chemical patent cases has generated a body of patent law unto itself. [See generally Helmuth A. Wegner, Prima Facie Obviousness of Chemical Compounds, 6 Am. Pat. L. Assoc. Q. J. 271 (1978).] Particular types or categories of structural similarity without more have, in past cases, given rise to prima facie obviousness, see, e.g., In re Dillon, 919 F.2d 688, 692-94 (Fed. Cir. 1990) (en banc)(tri-orthoesters and tetra-orthoesters)[ ]; In re May, 574 F.2d 1082 (CCPA 1978) (stereoisomers); In re Wilder, 563 F.2d 457 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341 (CCPA 1970) (acid and ethyl ester).”

considerations and rebuttal by a showing of a difference in properties can be traced to early cases[.]”). As explained by Circuit Judge Lourie:

“[I]f an examiner considers that he has found prior art close enough to the claimed invention to give one skilled in the relevant chemical art the motivation to make close relatives (homologs, analogs, isomers, etc.) of the prior art compound(s), then there arises what has been called a presumption of obviousness or a prima facie case of obviousness. In re Henze, 181 F.2d 196 (CCPA 1950); In re Hass, 141 F.2d 122, 127, 130 (CCPA 1944). The burden then shifts to the applicant, who then can present arguments and/or data to show that what appears to be obvious, is not in fact that, when the invention is looked at as a whole. In re Papesch, 315 F.2d 381 (CCPA 1963).”

In re Dillon, 919 F.2d 688, 696 (Fed. Cir. 1990)(en banc)(Lourie, J.)

More than fifty years ago in In re Papesch, 315 F.2d 381 (CCPA 1963)(Rich, J.), it was recognized that although the Patent Office could not do its own testing to determine the obviousness of a compound as to its three dimensional real life properties, it must consider the properties where evidence of such properties were presented by the applicant. Out of Papesch was born the two-part examination where in the first instance the Examiner would determine whether there was “structural obviousness” – or, in better terminology – prima facie obviousness. If there is such a finding under Papesch, then the patent applicant can come forward with test evidence establishing that what at first blush appears to be obvious is not obvious because of the properties of the claimed invention as a whole.

While piecemeal examination is to be avoided particularly due to the undue burden on a patent applicant, in the case of a Papesch nonobviousness inquiry, the resources of the patent applicant are actually conserved by such a piecemeal approach: “If the Examiner does not establish prima facie obviousness then “there
is no need [for the applicant] to resort to onerous comparative testing, which may impose serious burdens on research budgets and time and which may waste scarce testing resources, such as experimental animals, needed for productive research.”


Early Federal Circuit precedent recognized the Papesch approach:

“The problem of obviousness considered by the Patent and Trademark Office, and to which we address ourselves here, arises under section 103 of the Patent Act. It is a problem of patent law and not of chemistry. In re Papesch, 315 F.2d 381, 386 (CCPA 1963). Thus, the requirement of unobviousness in the case of chemical inventions is the same as for other types of inventions. A patent will not be granted where the invention, when compared to the prior art, is considered to have been obvious to a person having ordinary skill in the art at the time the invention was made. 35 U.S.C. § 103. This is the mandate to which the examiner, the board, and this court must look.

The procedural devices of the examiner's prima facie case and the applicant's rebuttal were formed to clearly allocate the burdens of going forward and of persuasion as between the examiner and applicant. In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1984). Rebuttal is merely a showing of facts supporting a conclusion of unobviousness. In re Heldt, 433 F.2d 808, 811 (CCPA 1970). When evidence is submitted on rebuttal, the decision maker must consider all the evidence anew, still judging the invention under the § 103 criteria. In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976). *** [W]hether rebuttal evidence is sufficient to persuade the examiner that unexpected results exist is an evidentiary matter left for the trier of fact.

In re Johnson, 747 F.2d 1456, 1460 (Fed. Cir. 1984)(Nichols, J.). Several years later Judge Lourie considered the Papesch line of case law in the Court’s en banc review in the Dillon case:
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[S]tructural similarity between claimed and prior art [compositions], proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case. Such rebuttal or argument can consist of a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have (*In re Albrecht*, 514 F.2d 1389, 1396 (CCPA 1975); *Murch*, 464 F.2d at 1056), that the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes (*Albrecht*, 514 F.2d at 1396; *In re Stemniski*, 444 F.2d 581 (CCPA 1971); *In re Ruschig*, 343 F.2d 965 (CCPA 1965)), or any other argument or presentation of evidence that is pertinent. There is no question that all evidence of the properties of the claimed compositions and the prior art must be considered in determining the ultimate question of patentability…

*Dillon*, 919 F.2d at 692-93

The Chief Judge has drawn attention to perceived difficulties patentees have had upholding their intellectual property rights before panels of the Patent Trial and Appeal Board. If the procedures of *Packard* are implemented by the Patent Office, this would only create more extreme situations of unfairness to patent applicants. *See § V, Federal Circuit Patent “Death Squads”*

**F. Prima Facie Obviousness Today**

To be sure, the law of *prima facie* obviousness has spread beyond its chemical roots in *Papesch* to embrace all technologies in the context of nonobviousness inquiries.

A modern statement of the *Papesch* principles is found in the *Jung* case:
"[T]he prima facie case is merely a procedural device that enables an appropriate shift of the burden of production." *Hyatt v. Dudas*, 492 F.3d 1365, 1369 (Fed. Cir. 2007) (citing *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). *See also In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). The Patent and Trademark Office ("PTO") satisfies its initial burden of production by "adequately explain[ing] the shortcomings it perceives so that the applicant is properly notified and able to respond." *Hyatt*, 492 F.3d at 1370. In other words, the PTO carries its procedural burden of establishing a prima facie case when its rejection satisfies 35 U.S.C. § 132, in "notify[ing] the applicant . . . [by] stating the reasons for [its] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application." 35 U.S.C. § 132. That section "is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990)."

*In re Jung*, 637 F.3d 1356, 1362 (Fed. Cir. 2011)

The Patent Office also explains the *prima facie* case:

“...The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048 (CCPA 1976); *In re Linter*, 458 F.2d 1013 (CCPA 1972); *In re Saunders*, 444 F.2d 599 (CCPA 1971); *In re Tiffin*, 443 F.2d 394 (CCPA 1971), amended, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit secondary evidence to show nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. ...The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to render obvious the claimed invention.

MPEP § 2142, *Legal Concept of Prima Facie Obviousness* [R-11(2013)]

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The Patent Office has expressly stated that the Examiner cannot simply make a rejection based upon a piece of prior art as being *prima facie* obvious without a clear articulation of reasons:

“The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

MPEP § 2142, *Legal Concept of Prima Facie Obviousness* [R-11(2013)](quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

V. FEDERAL CIRCUIT PATENT “DEATH SQUADS”


If anything, the Administrative Patent Judges populating the PTAB are good “home plate umpires” of the patent system, calling the balls and strikes as they see them. If there are problems for patentees one need look no further than the body of conflicting and unclear case law that the Supreme Court and the Federal Circuit have created. The creation of an adversarial, two-part examination system for indefiniteness only complicates and makes matters more difficult for patentees to
sustain their intellectual property: Patents granted based upon applications filed since March 16, 2013, are now open for attack under the Packard test for indefiniteness under 35 USC § 112(b).

VI. THE **PACKARD PATENT PIÑATA**

This paper has been limited to issues of public policy that should be of great concern to the patent community that seeks a functioning patent examination system with due process for all patent applicants, particularly individual inventors and small and medium sized enterprises. Other issues in the *per curiam* opinion may be of greater importance to the parties, but such issues are their concern and outside the scope of this paper. Perhaps the biggest academic prize of the patent piñata is the *concurring* opinion which raises a variety of issues that would be, indeed, of great importance for consideration *if they had precedential value*. Given that the third opinion is just that – a concurring opinion – there is no urgency to deal with unique treatments of the law and practice.

VII. CONCLUSION

The *Packard per curium* majority and concurring opinions, if judged in the perspective of Federal Circuit decisions of just a few years ago, would be considered quite exceptional. Given the patent jurisprudence of the Federal Circuit of the past three years, *Packard* is hardly exceptional.