

**Post-KSR Chemical Obviousness in Light of *Pfizer v. Apotex*\***

Harold C. Wegner\*\*

**I. OVERVIEW**

*KSR*<sup>1</sup> and *Pfizer v. Apotex*<sup>2</sup> manifest fundamental misunderstandings of chemical practice case law. These misunderstandings mandate a careful restudy of the fundamental law of chemical compound obviousness, particularly to take into account what has transpired in these two very important cases.

The law of obviousness of a chemical compound evolved from late nineteenth century structural obviousness case law that became highly defined in the 1940's and was modified in the early 1960's to provide a balanced two part analysis: The Examiner has the initial burden to establish *prima facie* or "structural" obviousness, but where this is established, it is up to the patent applicant to present rebuttal evidence demonstrating actual *differences* between the claimed compound and the prior art. See § II, *The Papesch Obviousness Regime*.

Over a period of decades, literally thousands of cases, largely at the Board of the U.S. Patent and Trademark Office (PTO), have established an intricate doctrine of "structural" obviousness. See § II-A, *The Haas-Henze "Structural*

---

\* The views expressed herein are those of the writer and do not necessarily reflect the views of any colleague, organization or client thereof.

Draft dated June 13, 2007.

\*\* Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School. Partner, Foley & Lardner LLP. [[hwegner@foley.com](mailto:hwegner@foley.com)].

<sup>1</sup> *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

<sup>2</sup> *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed.Cir.2007), reh'g en banc denied, \_\_\_ F.3d \_\_\_ (2007), *certiorari petition pending* (discussed *infra* at note 89).

*Obviousness” Predicate.* An equally intricate body of CCPA case law starting in the early 1960’s created a framework for demonstrating the nonobviousness of the invention *as a whole* by proving actual *differences* in properties over the prior art. *See* § II-B, *Papesch-based Nonobviousness Keyed to Properties*. Shortly after *Papesch*, the court focused upon whether a compound which is “obvious to try” – and hence *prima facie* obvious – could nevertheless be demonstrated to be as nonobvious *as a whole* through a *Papesch*-based showing of unexpected differences: Through a footnote within three months of *Papesch*, an affirmative answer was given. *See* § II-C, *Huellmantel Differentiation of a Compound “Obvious to Try”*.

The acceptance of the new doctrine was initially fought by the PTO, but over a period of time, the doctrine became well settled. *See* § III, *The Circuit Courts Adopt Papesch*. The critical battle was fought in the 1960’s at the D.C. Circuit where the CCPA case law was enthusiastically endorsed by the soon to be Chief Justice of the United States. *See* § III-B, *Deutsche Gold* at the D.C. Circuit. Over the next twelve years, a general acceptance of the CCPA view was realized in further appeals to the regional circuits. *See* § III-C, *The Third and Fifth Circuits Follow Papesch*.

By the time of creation of the Federal Circuit in 1982, there was no longer any doubt about the validity of the CCPA line of case law, and indeed there was essentially no controversy at the Federal Circuit until a panel in 1989 drastically restructured the law which, however, was promptly corrected by an *en banc* court that in 1990 reaffirmed CCPA case law. *See* § IV, *Federal Circuit Adoption of Papesch*.

Predating the Supreme Court consideration of obviousness in the mid-1960’s, the CCPA case law on chemical practice was completely consistent with the later evolution of the Supreme Court precedent in that decade. *See* § V, *Focus on Differences, a Primary Graham Inquiry*. Consistent with Supreme Court precedent, a central and primary focus of the chemical compound obviousness inquiry is upon the *differences* in properties of the claimed compound versus the prior art compound. *See* § V-A, *Differences Inherent in the Claimed Invention*.

The fact-finder is not free to select *which* properties are to be considered in the determination of differences, but must consider *all* properties. *See* § V-B, *All Differences Must be Considered*. This is due to the fact that the Supreme Court obviousness inquiry has as a *primary* consideration the *differences* between the claimed invention and the prior art, which necessarily includes the differences in properties of the claimed compound versus the prior art. Hence, the differences are *primary* and not merely “secondary considerations” of lesser importance. *See* § V-C, *Differences are Primary, not “Secondary Considerations”*. Furthermore, a fact-finder must consider *all* differences and cannot, for example, focus exclusively on therapeutic efficacy of a pharmaceutical but consider *all* the properties of the compound. *See* § V-D, *Nonobviousness May be shown by Any Property*.

The question must always be raised whether there is any direct *holding* in a Supreme Court decision that relates to chemical obviousness issues, particularly where case law at the Court deals with the obviousness of a combination of old elements; this is in contrast to organic chemistry entities, *new* structures, totally unlike the invariable combination of old elements of all modern Supreme Court obviousness decisions. *See* § VI, *Supreme Court Dicta from Graham to KSR*.

Because the case law at the Supreme Court has focused upon combination patents, there is an assumption made in some quarters that virtually all patents are to combinations. In fact, there has *never* been a modern Supreme Court grant of *certiorari* to consider the chemical obviousness case law line relating to a new compound nor *any* case in modern times to consider the obviousness of any invention other than a combination patent. *See* § VI-A, *Not All Patents are Combination Inventions*. While the Supreme Court has never at least in modern times reviewed a chemical obviousness case, it has recently relied upon one of the minor CCPA precedents dealing with structural obviousness in support of its rationale for an obviousness determination. *See* § VI-B, *Bergel as the Purported Seminal Case Suggestion Case*.

With an absence of *holdings* on point from the Supreme Court, *dicta* must be sought out from its precedents to flesh out the CCPA line of case law on chemical obviousness. *See* § VI-C, *Lessons from KSR for Papesch Obviousness*. Primary

## Wegner, Post-KSR Chemical Obviousness

---

among the teachings of the Court is the relevance of unexpected results showing a difference between the claimed compound and the prior art. *See* § VI-C-1, *Unexpected Results are Relevant*. Of new importance is a 2006 Federal Circuit panel opinion that mandates an “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”, thanks to its recent quotation with approval by the Court. *See* § VI-C-2, *A Mandatory Explicit Analysis to Suggest the Invention*.

The KSR opinion also contains loose language concerning whether an invention is “obvious to try” which places this arcane maxim center stage, grist for litigation and appellate resolution at the Federal Circuit. *See* § VI-D, KSR “*Obvious to Try*” *Dictum*.

More than forty years after the establishment of the current case law regime and after nearly twenty-five full years of judicial acceptance – throughout the history of the Federal Circuit – CCPA case law on chemical obviousness is under direct attack in a panel opinion. With the support of one additional member of the panel, the Chief Judge of the Federal Circuit has issued what is undoubtedly the single most controversial chemical practice ruling in the history of the Federal Circuit. *See* § VII, *Pfizer v. Apotex Repudiates Papesch*.

Whereas a *difference* between a claimed compound and a prior art compound is one of the *primary* factors to consider under an obviousness inquiry, differences in properties are relegated to the status of “secondary considerations”. *See* § VII-A, *Exclusion of Properties as “Secondary Considerations”*. The panel majority furthermore departs from precedent by *selectively* choosing properties that may be considered in the nonobviousness analysis. *See* § VII-B, *Failure to Consider All Properties*.

Also contrary to established precedent, the majority gives weight to the fact that the prior art is a patent that has a *claim* encompassing the claimed compound, a point relevant to infringement but less relevant to obviousness than the point as to whether there is a relevant teaching to suggest the claimed compound. *See* § VII-C, *The Generic Status of the Prior Art*. A serious misunderstanding of “obvious to try” case law creates new problems particularly for the chemical industry. *See* § VII-D, *Abandoned Huellmantel “Obvious to Try”*.

## Wegner, Post-KSR Chemical Obviousness

---

The panel furthermore relies upon a newly minted and highly controversial panel majority opinion having nothing to do with chemical practice to *sub silentio* repudiate the CCPA case law line. See § VII-E, *Dystar* versus *Papesch*.

Going beyond the arcane world of chemical practice, the recent evolution of panel precedent has emphasized the balkanization of panel precedent, the erosion of the former approach where *en banc* and prior panel opinions created bedrock principles upon which the public can rely. See § VIII, *Dystar Limestone Precedent*. The recent approach is contrary to established precedent. See § VIII-A, *Dystar Repudiation of South Corporation*. It remains an open question whether the *en banc* court will have the resolve to reinforce the correctness of *South Corporation*. See § VIII-B, *Return to South Corporation*.

It is easy to criticize mistakes in judicial opinions, but here a major share of the blame for the problems in both *KSR* and *Pfizer v. Apotex* is due to inadequacies of legal scholarship in the briefing process. See § IX, *A Need for Better Patent Law Scholarship*. All too often legal research consists essentially of electronic Boolean searches for the best “cite bite” and string citation, the great one liner – often without regard to whether the cited or quoted case has a holding that supports the position of the advocate. See § IX-A, *Cite Bites and String Citations*. The embarrassing lack of scholarship in one aspect of *KSR* is directly attributable to the citation of a CCPA “cite bite”, while the *Pfizer v. Apotex* case challenges “obvious to try” based upon cases with holdings directly contrary to the advocate’s position. See § IX-B, *KSR and Pfizer v. Apotex, Case Studies in Boolean Scholarship*. If not widely voiced within the patent arena, the mainstream judiciary has long decried the “string citation” shortcut to legal advocacy. See § IX-C, *Uniform Judicial Criticism of String Citations*.

Because of the crisis in chemical practice created by *Pfizer v. Apotex*, this paper has narrowly focused upon the impact this case together with *KSR* on this one area. Manifestly, there are widespread consequences in all technological fields for *KSR*, alone or together with *Pfizer v. Apotex*. Indeed, it may be expected that at least one major biotechnology panel precedent of the Federal Circuit will be overruled as a consequence of *KSR*. See § X, *The Future*.

## II. THE *PAPESCH* OBVIOUSNESS REGIME

After a generation of uncertainty and then several years of challenges, *Papesch*<sup>3</sup> became the core foundation for modern chemical obviousness practice, seemingly untouched by *KSR*.

Under the *Papesch* regime, obviousness of a new chemical compound proceeds through two stages. First, is there a prior art compound sufficiently close in structure to the claimed compound to *suggest* that the claimed structure would have the same properties? If the answer is negative, then the inquiry is completed: There is no obviousness for such a compound. But, as is particularly the case in a mature field, there is a high degree of predictability of properties of a compound keyed to structure, such that the disclosure of a prior art compound suggests that the claimed compound can and should be synthesized to achieve like results. Here, the claimed compound is *prima facie* obvious based upon the concept of “structural obviousness”. But, the claimed compound is the “thing” that is claimed – the three dimensional structure including all its properties – and it is that “thing” that must be shown to be obvious. Where there is a *prima facie* obviousness case based upon closeness of structure, then it is incumbent upon the patent applicant to demonstrate that there are *actual differences* between the claimed compound and the prior art such that the invention *as a whole* is nonobvious.

### A. The Haas-Henze “Structural Obviousness” Predicate

“The question of ‘structural similarity’ in chemical patent cases has generated a body of patent law unto itself.”<sup>4</sup> Unlike the world of mechanical incremental innovations that focus almost entirely upon the creation of new combinations of old elements, the organic entities are unique structures that may or

---

<sup>3</sup> *In re Papesch*, 315 F.2d 381 (CCPA 1963)(Rich, J.).

<sup>4</sup> *In re Jones*, 958 F.2d 347, 349 (Fed. Cir. 1992)(Rich, J.), citing Helmuth A. Wegner, *Prima Facie Obviousness of Chemical Compounds*, 6 Am.Pat.L.Assoc.Q.J. 271 (1978)(discussing the evolution of the *Haas-Henze* doctrine, named after *In re Haas*, 141 F.2d 122 (CCPA 1944); *In re Henze*, 181 F.2d 196 (CCPA 1950)).

## Wegner, Post-KSR Chemical Obviousness

---

may not have a close *apparent* relationship to prior art compounds. Given a particular organic structure, the skilled chemist can instantly visualize methods to make – quite literally – thousands if not millions of somewhat structurally related compounds that may or may not be expected to behave along the lines of the known prior art compound. But, knowing possible two dimensional structural formulae that *could* be made may or may not include an expectation of similar properties, a fact-intensive inquiry in an ever-changing state of the art.

For example, when the basic prostaglandin structure was isolated from the testicles of sheep, little was known about what variations could be made to achieve compounds with similar properties so that there was a narrow penumbra of structurally related potential derivatives with little known. As the science developed and thousands of prostaglandin derivatives were synthesized and their properties described in the scientific literature, the penumbra of structurally obvious variations broadened.

Yet, merely speculating on the “obvious” two-dimensional structural formula gives no greater picture of the three dimensional thing, the compound itself, than a simple roadmap describes the geographic contours of the landscape traversed by the lines designating the roads. Thus, just as a two dimensional roadmap showing only straight and squiggly lines identified by road names and numbers may lead to the *expectation* that the straight lines identify highways on the plains and convoluted lines may lead to the *expectation* of windy, mountainous roads, only the three dimensional *reality* demonstrates the actual contour of the thoroughfare:

“Indeed, a chemical structure is simply a means of describing a compound; it is not the invention itself.”<sup>5</sup> Particularly in the area of complex organic chemistry, a slight modification – as in the case of a structurally “obvious” homolog – may lead to an expectation of identical properties of compounds in the series, in fact even the smallest structural deviation may so skew the spatial relationship of the compound so that its physiological interaction may mean that one member of a

---

<sup>5</sup> *Regents of University of New Mexico v. Knight*, 321 F.3d 1111, 1122 (Fed. Cir. 2003)(Lourie, J.) (quoting *Papesch*, 315 F.2d at 391)(emphasis added).

homologous series is an effective anticancer agent whereas the structurally related member may have no therapeutic activity.

The CCPA requirement for a “suggestion” is implicit for established areas of chemistry under the Haas-Henze doctrine<sup>6</sup> that is acknowledged in *Manson*.<sup>7</sup> An essential integer to the Haas-Henze *prima facie* case of obviousness is that a person skilled in the art is *motivated* to make the claimed compound: There is a *suggestion* in the prior art to do so. In well developed arts where literally thousands of closely related structures have been synthesized for a particular utility, a fair degree of predictability arises such that, given a particular structure with a known utility, there is an *implicit* motivation to make homologs, isomers and other structurally similar compounds with the expectation that the same results will be achieved.

Among the many quirks of the *prima facie* obviousness doctrine, it is not of particular relevance that a first patent has a claim that dominates a later claimed species. For example, if the prior patent has a genus encompassing millions of compounds including the claimed improvement compound, the needle in a haystack selection of the claimed compound is generally not *prima facie* obviousness: Whether there is a generic claim in an earlier patent or not does not mean that the later species invention is or is not obvious.<sup>8</sup>

---

<sup>6</sup> H. A. Wegner, *supra* note 4 (citing *In re Hass*, 141 F.2d 122 (CCPA 1944); *In re Henze*, 181 F.2d 196 (CCPA 1950).; *see also* Alvin Guttag, *The Haas-Henze Doctrine*, 43 J. Pat. & Trademark Off. Soc’y 808 (1961).

<sup>7</sup> *Brenner v. Manson*, 383 U.S. 519, 522 n.3 (1966)(quoting *Henze*, 181 F.2d at 200-201 (“Chemists knowing the properties of one member of a series would in general know what to expect in adjacent members.”); also cited are *Hass*, 141 F.2d at 125; *In re Norris*, 179 F.2d 970 (CCPA 1950).

<sup>8</sup> *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994)(Lourie, J.)(citing *In re Jones*, 958 F.2d 347, 350 Fed.Cir.1992)) (“The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.”).

The determination of *prima facie* obviousness is not subject to any rigid formula but represents more of a floating target: In the beginning of exploration focusing upon a completely new ring structure that has been discovered from nature, there is precious little predictability as to what a particular structural variation may bring in terms of expected properties. But, after thousands upon thousands of new compounds have been created and characterized, a higher and higher degree of predictability is established, and a variation which yesterday gave an unpredictable result will today or tomorrow provide greater predictability: As explained in *KSR* in a message relevant to all technologies, the advanced level of knowledge provides “advances, once part of our shared knowledge, define a new threshold from which innovation starts once more.”<sup>9</sup> Related to organic chemistry, “[a]s new discoveries push back the frontiers of the unknown, they also move the boundaries of the unobvious and as areas of research become more highly competitive, teachings of equivalence [between substituent groups] in these areas lead to more frequent findings of obviousness. It is inappropriate to apply simplistic rules which would define precise boundaries of structural change which give rise to the imposition of burdens of persuasion to rebut *prima facie* obviousness, as such determinations require competent consideration of the recognition in identical or closely related art.”<sup>10</sup> Thus, “[t]here must be some logical reason from positive, concrete evidence of record which justifies combination of primary and secondary references.”<sup>11</sup>

Above all, labels such as “homologs” are secondary to the actual chemical realities. For example, even though the Haas-Henze line of cases has established a

---

<sup>9</sup>*KSR*, 127 S.Ct. at 1746 (“We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws.”).

<sup>10</sup> H. A. Wegner, *supra* note 4, 6 APLA Q.J. at 272.

<sup>11</sup> *Id.*, quoting *In re Regel*, 526 F.2d 1399, 1403 n.6 (CCPA 1975).

doctrine of prima facie obviousness for homologs, in some cases the nature of the homology is such that the prediction of similar properties cannot be made, so there is no prima facie obviousness based upon the label of homology.<sup>12</sup>

### **B. Papesch-based Nonobviousness Keyed to Properties**

But, even if one *expects* that a certain structural relationship will yield the same a compound with the same activities – and hence is “structurally obvious” – in fact the real inquiry is whether the actual “thing”, the compound, *per se*, is different. And, if different, whether the invention as a whole is unobviously different from the prior art.

Where there is *prima facie* obviousness, it is then up to the patent applicant to demonstrate that the properties *are* in fact different: Is the invention *as a whole* obvious or not?

The relationship of *prima facie* obviousness based upon structure and establishing nonobviousness of the invention *as a whole* is explained in the *Mayne* case:

First, “[t]he Patent and Trademark Office (PTO) has the burden of showing a prima facie case of obviousness.”<sup>13</sup> The evolution from *Haas-Henze* is explained:

---

<sup>12</sup> H. A. Wegner, *supra* note 4, 6 APLA Q.J. at 273 (quoting *Ex parte Burtner and Brown*, 121 USPA 345 (1951)( “[E]ven in the case of homologs, a rejection on the basis of structural relation may be improper. ... [T]he critical question is not whether the moieties of the molecules under consideration are considered 'homologous' under some available definition but whether they ‘are sufficiently similar from the standpoint of structural similarity so that those now claimed would be suggested to chemists from those disclosed and would be expected to have like properties.’”).

<sup>13</sup> *In re Mayne*, 104 F.3d 1339, 1341-42 (Fed. Cir. 1997)(Rader, J.)(citing *In re Bell*, 991 F.2d 781, 783 (Fed.Cir.1993); see *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988)).

“At one time, the PTO focused only on the ‘structural obviousness’ of the chemical entity. Under this standard, the structural formula of the claimed compound was compared for similarity with the structural formulae of known compounds. This regime did not allow evidence of unexpected results to trump the conclusion of obviousness based on structure. Over thirty years ago [in *Papesch*], courts recognized that unexpected properties can show that a claimed compound that appeared to be obvious on structural grounds was not obvious when looked at as a whole.”<sup>14</sup>

Just shy of twenty years after the genesis of the *Haas-Henze* doctrine of structural obviousness, the three dimensional reality was addressed in the *Papesch* case:

“From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, and the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to *identify* what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it.”<sup>15</sup>

The relationship of *prima facie* obviousness based upon structure and establishing nonobviousness of the invention *as a whole* is explained in the *Mayne* case:

---

<sup>14</sup> *Mayne*, 104 F.3d at 1342 (citing *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)).

<sup>15</sup> *Regents of University of New Mexico v. Knight*, 321 F.3d 1111, 1122 (Fed. Cir. 2003)(Lourie, J.) (quoting *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963))(emphasis added).

First, “[t]he Patent and Trademark Office (PTO) has the burden of showing a prima facie case of obviousness.”<sup>16</sup> The evolution from *Haas-Henze* is explained: “At one time, the PTO focused only on the ‘structural obviousness’ of the chemical entity. Under this standard, the structural formula of the claimed compound was compared for similarity with the structural formulae of known compounds. This regime did not allow evidence of unexpected results to trump the conclusion of obviousness based on structure. Over thirty years ago [in *Papesch*], courts recognized that unexpected properties can show that a claimed compound that appeared to be obvious on structural grounds was not obvious when looked at as a whole.”<sup>17</sup>

### C. *Huellmantel* Differentiation of a Compound “Obvious to Try”

#### 1. The *Papesch* Negation of “Obvious to Try”

The “obvious to try” maxim became important to patent law in 1963 with the *Papesch* clarification of the law of chemical obviousness that it is the invention *as a whole* that must be considered for patentability, and that any unexpected *difference* in properties between the claimed invention and the prior art must be evaluated as part of the obviousness inquiry.

Prior to *Papesch*, “obvious to try” had been an examiner maxim<sup>18</sup> that had been used without critical commentary even by the judge who later became its leading critic.<sup>19</sup>

---

<sup>16</sup> *In re Mayne*, 104 F.3d 1339, 1341-42 (Fed. Cir. 1997)(Rader, J.)(citing *In re Bell*, 991 F.2d 781, 783 (Fed.Cir.1993); see *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988)).

<sup>17</sup> *Mayne*, 104 F.3d at 1342 (citing *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)).

<sup>18</sup> *In re Carpenter*, 151 F.2d 207, 208 (CCPA 1945)(quoting Board)(“It would certainly be obvious to try to azeotropically distill a mixture and to find that it can be done would not be inventive.”); *In re Novak*, 306 F.2d 917, 921 (CCPA 1962)(Martin, J.)(quoting examiner’s statement of “obvious to try”).

## Wegner, Post-KSR Chemical Obviousness

---

In essence, while it may be “obvious to try” a particular solution, given a problem and relevant technology pointing to a solution, this may create *prima facie* obviousness under a post-*Papesch* analysis, but this does not shut the door to the establishment of unexpected *differences* between the claimed invention versus the prior art to rebut such *prima facie* obviousness. Less than three full months after *Papesch*, the author of *Papesch* explained this distinction in what at the time was viewed as footnote of minor importance: “We feel compelled to comment on the Patent Office analysis by which patentability under 35 U.S.C. § 103 is herein determined. The examiner concedes that appellant's composition ‘shows improved results.’ The board accepts this as ‘fact,’ but concludes it is immaterial since ‘it is obvious to at least try’ to substitute one steroid for another in the prior art composition.”<sup>20</sup>

Citing a line of cases leading up to and including *Papesch*, the court states that “the ‘obvious to try’ reasoning, insofar as it negates consideration of properties in determining obviousness under section 103, flies in the face of the plain

---

<sup>19</sup> *In re Ruscetta*, 255 F.2d 687, 692 (CCPA 1958)(Rich, J.)(citing 35 USC § 103)(Certainly it would be obvious to try [the embodiment] and mere proof that it worked would not make it patentable over the [prior art] disclosure[.]). *See also In re Leum*, 158 F.2d 311, 312 (CCPA 1947)(“On the record here we do not see how invention can be involved in carrying out the process of the patent in a closed system. Whether or not the systems were open or closed, it surely would be obvious to try either in a reaction of the character defined by the patent.”); *In re Georgeff*, 291 F.2d 941, 944 (CCPA 1961)(Martin, J.)(stating that one issue is “‘whether it is obvious to try to perform a metal forming operation’ without further discussion of ‘obvious to try’ theory”); *In re Sejournet*, 285 F.2d 823, 825 (CCPA 1961)(A. Smith, J.) (citing *In re Kepler*, 132 F.2d 130 (CCPA 1942); *In re Eisenhut*, 245 F.2d 481 (CCPA 1957))(“The recitation in the appealed claims ... is but the statement of a result of carrying out a method which we hold it would have been obvious to try in view of the teachings of the prior art.”).

<sup>20</sup> *In re Huellmantel*, 324 F.2d 998, 849 n.2 (CCPA 1963)(Rich, J.).

language of the statute as interpreted by this court[.]”<sup>21</sup> Thus, “Section 103 says, inter alia, ‘the subject matter as a whole would have been obvious \* \* \*.’ Nothing is said about ‘obvious to try.’ Consideration of the subject matter ‘as a whole’ in chemical cases requires comparison of properties, pharmaceutical or otherwise, as well as comparison of chemical structures.”<sup>22</sup>

### 2. A Second Meaning for the Maxim

Perhaps due to *dicta* in the *O’Farrell* case<sup>23</sup> it has been increasingly difficult for the patent community to get a grasp on the meaning of “obvious to try” case law. Over the years, the “obvious to try” maxim has simply been repeated as a conclusion<sup>24</sup> but significantly has morphed into a requirement that to establish obviousness there must be “a reasonable expectation of success.”<sup>25</sup> The most

---

<sup>21</sup> *Id.*, citing *In re Lambooy*, 300 F.2d 950 (CCPA 1962); *In re Petering*, 301 F.2d 676 (CCPA 1962); *In re Papesch*, 315 F.2d 381 (CCPA 1963).

<sup>22</sup> *Id.* Of course, this does not necessarily mean that the invention is necessarily nonobvious. “We do not mean to imply that every variance in property of a new compound or composition will tip the balance for patentability where otherwise closely related compounds or compositions are involved. However, all relevant property differences must be considered in the light of the facts of each case in the determination of statutory obviousness.” *Id.*

<sup>23</sup> *In re O’Farrell*, 853 F.2d 894, 903-04 (Fed.Cir.1988).

<sup>24</sup> *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995)(Lourie, J.)(citing *In re O’Farrell*, 853 F.2d 894, 903 (Fed.Cir.1988)) (“‘Obvious to try’ has long been held not to constitute obviousness.”).

<sup>25</sup> *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207-08 (Fed. Cir. 1991)(Lourie, J.)(citing *O’Farrell*, 853 F.2d at 903-04) (“While [the district court] found that [the accused infringers] had shown that these procedures were ‘obvious to try,’ the [prior art] references did not show that there was a reasonable expectation of success.”).

expansive explanation of “obvious to try” occurred in the *O’Farrell* case which hardly supports a finding of nonobviousness, because the *holding* in the case confirmed the *obviousness* of the invention.

This latter meaning goes completely beyond the original intention of its author that the doctrine is only one of *prima facie* obviousness subject to rebuttal through a showing of unexpected differences.<sup>26</sup>

Thus, the “obvious to try” doctrine has been further morphed into two distinct lines of situations: First, there is the issue of “‘obvious to try’ [by] vary[ing] all parameters or try[ing] each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.”<sup>27</sup> Second, there is the issue of “‘obvious to try’ [by] explor[ing] a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”<sup>28</sup> Both situations, however, only lead to a conclusion of *prima facie* obviousness.

---

<sup>26</sup> Missing from this analysis is the caveat expressed in the cited *O’Farrell* case that “[t]here is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious.” *O’Farrell*, 853 F.2d at 903.

<sup>27</sup> *O’Farrell*, 853 F.2d 894 at 903 (citing *In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278; *Novo Industri A/S v. Travenol Laboratories, Inc.*, 677 F.2d 1202, 1208 (7th Cir.1982); *In re Yates*, 663 F.2d 1054, 1057 (CCPA 1981); *In re Antonie*, 559 F.2d 618, 621 (CCPA 1977)).

<sup>28</sup> *Id.* (citing *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed.Cir.1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed.Cir.1986); *In re Tomlinson*, 363 F.2d 928, 931 (CCPA 1966).). *See also In re Roemer*, 258 F.3d 1303,1309-10 (Fed. Cir. 2001)(Rader, J.) (“[T]he Smith patent

## Wegner, Post-KSR Chemical Obviousness

---

The *O'Farrell* interpretation is the mainstream Federal Circuit interpretation of “obvious to try”: “We wish to emphasize that this is *not* a case where the prior art's lack of definiteness or certainty about the result of using a tertiary amine in a specific reaction system renders the inventive subject matter ‘obvious to try’ but not obvious. While we have made clear that ‘obvious to try’ is not the standard under § 103[,] ... the meaning of this maxim is sometimes lost.”<sup>29</sup>

---

gives ‘only general guidance as to the particular form of the claimed invention or how to achieve it.’ *In re O'Farrell*, 853 F.2d 894, 903 (1988). This ‘obvious to try’ suggestion of the Smith patent does not render claim 1 of the Roemer reissue application obvious, *In re Deuel*, 51 F.3d 1552, 1559 (Fed.Cir.1995)[.]”.

<sup>29</sup> *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1167 (Fed. Cir. 2006)(Gajarsa, J.)(quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed.Cir.1988)). *See also Velandar v. Garner*, 348 F.3d 1359, 1379 (Fed. Cir. 2003)(Gajarsa, J., dissenting)(citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed.Cir.1988)) (“The factual inquiries underlying obviousness include (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art at the time the invention was made, and (4) any objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). ‘The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art.’ *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed.Cir.1988). Obviousness requires one of ordinary skill in the art have a reasonable expectation of success as to the invention – ‘obvious to try’ and ‘absolute predictability’ are incorrect standards. *In re O'Farrell*, 853 F.2d 894, 903 (Fed.Cir.1988). The presence of a reasonable expectation of success is measured from the perspective of a person of ordinary skill in the art at the time the invention was made. *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed.Cir. 2000).”).

From the discussion of “obvious to try” less than three months after *Papesch* in *Huellmantel* through the modern restatement a full quarter century later in *O’Farrell* and through the mainstream interpretation of these cases since then, it has been a cardinal understanding of “obvious to try” that the proper application of this maxim may lead to a *prima facie* case of obviousness which is rebuttable upon proof of unexpected *differences* between the claimed invention *as a whole* and the apparently suggestive prior art.

In hindsight, it would have been far simpler if the post-*Papesch* court had simply indicated that the “obvious to try” maxim *remained* valid but only in terms of the creation of a *prima facie* case of obviousness, instead of the decades-long crusade against this maxim that has injected undue controversy and misunderstanding in the application of the case law, which happened right from the start.<sup>30</sup> A judge some have considered to be the brightest of the patent experts on

---

<sup>30</sup> See, e.g., *In re Tomlinson*, 363 F.2d 928, 935 (CCPA 1966)(Smith, J., joined by Martin, J., dissenting in part)(“The majority's disagreement with th[e] proposition [that it would be obvious for a person skilled in the art to try these salts to stabilize polypropylene] pivots about the phrase ‘obvious \* \* \* to try,’ and appears to support its ultimate conclusion by finding that there was no prior art which taught the use of claimed cobalt salts to stabilize polypropylene compositions. I fully agree that in here considering the invention as a whole, the selection of the particular cobalt salts is a factor to be weighed before reaching the ultimate legal conclusion of obviousness or nonobviousness required by 35 U.S.C. § 103. However, I do not agree with what seems to me to be the majority's rationale that such selection per se supports a finding of unobviousness under the facts here. I do not find that we are here concerned with a problem of the selection of particular materials from a universe which presents many choices. The art here is so developed that the majority finds the use of nickel salts to stabilize polypropylene to be unpatentable. In the composition claims 1, 4, 7, as well as in the process claims 18-20, the rejection of which the majority affirms, the stabilizing salt is selected from the group consisting of nickel and cobalt.”).

the CCPA recognized that it would have been better to have a straight-forward *Papesch*-based analysis than reliance upon the maxim.<sup>31</sup>

### III. THE CIRCUIT COURTS ADOPT *PAPESCH*

*Papesch* was immediately controversial at the Patent Office and ignited a battle through the 1960's to seek Supreme Court review through a split with the Circuit Courts.

#### A. *Deutsche Gold* at the D.C. Circuit

The immediate challenge was to seek a split with the D.C. Circuit which heard many appeals from the Patent Office even in the 1960's.<sup>32</sup> At the trial level in *Deutsche Gold*, the court ostensibly followed *Papesch*, citing that case for the proposition that “[i]t is a well established principle that the pharmacological properties of a chemical compound should be considered in determining the issue of obviousness of the compound.”<sup>33</sup> Yet, the court distinguished *Papesch* and denied patentability.

---

<sup>31</sup> *In re Dien*, 371 F.2d 886, 889 (CCPA 1967)(A. Smith, J., concurring)(“There is, of course, nothing in the statute which permits application of [the ‘obvious to try’] test. *In re Tomlinson*, 363 F.2d 928 (CCPA 1966); *In re Henderson*, 348 F.2d 550 (1965); *In re Huellmantel*, 324 F.2d 998 (1963); see *In re Fay*, 347 F.2d 597 (CCPA 1965). It not only involves an analysis for which there is no authorization but it precludes a consideration of the invention as a whole for which there is an explicit statutory directive.”). See also *In re Henderson*, 348 F.2d 550, 553-54 (CCPA 1965)(A. Smith, J.).

<sup>32</sup>As today, a dissatisfied patent applicant who loses at the PTO Board of Patent Appeals and Interferences has the option to seek a trial *de novo* under 35 USC § 145, a route that was very popular through the 1950's, but less so after the influence of Giles S. Rich and Arthur Smith on the CCPA made that clearly preferable for applicants. Prior to the establishment of the Federal Circuit in 1982, the losing party in a *de novo* trial – including the PTO – had a right of appeal to the D.C. Circuit.

## Wegner, Post-KSR Chemical Obviousness

---

With the patent applicant seeking redress at the D.C. Circuit, there was great expectation at the PTO that it would be affirmed, perhaps with a repudiation of *Papesch*, to thereby create a split that could lead to grant of *certiorari*.<sup>34</sup>

On appeal, it was no less an authority than the soon-to-be Chief Justice of the United States who confirmed the validity of the *Papesch* line of case law in *Deutsche Gold*, shortly before his elevation to the Supreme Court: “The sound reasoning of the *Papesch* case has been unanimously and repeatedly reaffirmed by the Court of Customs and Patent Appeals. Doubtless we must agree with admonitions against deciding questions of chemical obviousness on the basis of structure alone.”<sup>35</sup>

That *Graham* supports and does not undermine *Papesch* was underscored by the Chief Justice: “[I]t would appear that the Commissioner's position [against *Papesch*] is hardly supported, but on the contrary is substantially undermined, by *Graham v. John Deere Co.*, 383 U.S. 1 (1966), although he seems to place great reliance on this case. *Graham* was the first authoritative opinion dealing with the question of obviousness under section 103. It is clear from that unanimous decision that hard and fast rules of general applicability are impossible to achieve under section 103.”<sup>36</sup> Thus, quoting *Graham*, section 103 ““lends itself to several basic

---

<sup>33</sup> *Deutsche Gold-Und Silber-Scheideanstalt Vormals Roessler v. Commissioner of Patents*, 251 F.Supp. 431, 433 (D.D.C. 1966)(Jackson, J.), *subsequent proceedings*, 397 F.2d 656 (D.C. Cir. 1968)(Burger, J.).

<sup>34</sup>It will be recalled that there was a great flurry of activity in patent law at the Supreme Court at the time; the October 1965 Term of the Court had the largest number of patent appeals argued at any time in modern history dating back to at least 1950, a record that still stands today.

<sup>35</sup> *Deutsche Gold*, 397 F.2d at 662 (footnote omitted).

The decision was given on May 08, 1968, while President Nixon nominated the new Chief Justice to that position on May 23, 1969.

<sup>36</sup>*Id.*

factual inquiries,’ enumerated by the Supreme Court: ‘Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.’”<sup>37</sup>

In a subsequent case in the D.C. Circuit, *Deutsche Gold* was distinguished because the patent applicant failed to prove a difference in properties.<sup>38</sup>

### **B. The Third and Fifth Circuits Follow *Papesch***

The Third Circuit was the last regional circuit to consider the *Papesch* doctrine before the establishment of the Federal Circuit in *Lilly v. Premo*.<sup>39</sup> In that case, the court noted both *Deutsche Gold* and the Fifth Circuit in *Lilly v. Generix*<sup>40</sup> had followed *Papesch*, with no dissenting circuits, although one had twice refrained from entering the fray.<sup>41</sup>

---

<sup>37</sup> *Id.* quoting *Graham*, 383 U.S. 1 at 17 (emphasis added).

<sup>38</sup> *Brown v. Gottschalk*, 484 F.2d 813, 817 (D.C. Cir. 1973) (“But in the *Deutsche Gold* case Chief Justice Burger reaffirmed the necessity of comparative testing to prove difference in utility between two compounds.”).

<sup>39</sup> *Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, Inc.*, 630 F.2d 120 (3rd Cir. 1980).

<sup>40</sup> *Lilly v. Premo*, 630 F.3d at 129 (citing *Eli Lilly and Co. v. Generix Drug Sales, Inc.*, 460 F.2d 1096 (5th Cir. 1972)).

<sup>41</sup> *Lilly v. Premo*, 630 F.3d at 130 n.46 (“The Court of Appeals for the Second Circuit has twice been presented with the question regarding structural obviousness and § 103, but has elected both times to dispose of the cases on alternative grounds. See *General Tire & Rubber Co. v. Jefferson Chemical Co.*,

## Wegner, Post-KSR Chemical Obviousness

---

The Third Circuit boiled down the *Deutsche Gold* decision to four factors favoring a finding of patentability:

“The Court of Appeals for the District of Columbia Circuit, speaking through Judge (now Chief Justice) Burger, articulated four reasons for adopting *Papesch*. First, it construed the Supreme Court's admonition in *Graham*, that a determination of obviousness should depend on ‘several basic factual inquiries,’ as directing the courts to look to the relative properties of the new compound and the prior art, as well as to their comparative structures.”<sup>42</sup>

“Second, there exist few compounds whose molecular structure is unknowable prior to their synthesis. The court reasoned that, were it to reject *Papesch*, ‘few pharmaceutical compounds . . . [would] be patent[able], and the incentive aspect of the patent system, which is basic, . . . be lost from an important area.”<sup>43</sup>

“Third, the court observed that the Patent Office traditionally permitted applicants to prove nonobviousness with evidence that the product possessed novel properties.”<sup>44</sup>

“Fourth, the court recognized that another patentability provision, § 101, focuses on ‘what the compound will do, and its properties are of prime consideration’ for this purpose.”<sup>45</sup>

---

*Inc.*, 497 F.2d 1283 (2d Cir.), cert. denied, 419 U.S. 968 (1974); *Carter-Wallace, Inc. v. Otte*, 474 F.2d 529 (2d Cir. 1972), cert. denied, 412 U.S. 929 (1973).”

<sup>42</sup> *Lilly v. Premo*, 630 F.3d at 129 (quoting *Deutsche Gold*, 397 F.2d at 662, (quoting *Graham*, 383 U.S. at 17).

<sup>43</sup> *Id.* (quoting *Deutsche Gold*, 397 F.2d at 663).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* (quoting *Deutsche Gold*, 397 F.2d at 663).

## Wegner, Post-KSR Chemical Obviousness

---

Thus, considering the four factors, “[a]ccordingly, it held that the district court correctly considered all properties of the claimed compound in assessing its obviousness.”<sup>46</sup>

Concerning the Fifth Circuit in *Lilly v. Generix*, the Third Circuit “rejected what it termed a ‘stultifying per se rule of chemical similarity,’ and held that Eli Lilly was permitted to introduce evidence that the patented compound exhibited unexpected, nonobvious differences from the prior art. A rule banning the patentability of structurally obvious chemical compounds, in the court’s view, would be inconsistent with the purpose of the patent laws if applied to the modern drug industry:

“‘In the field of drug patents today therapeutic value, not chemical composition, is the substance of all incentive to invent. Except where the state of the medical art and the state of the chemical art have been advanced and coordinated to the point that it is possible for the mind to conceive or predict with some minimal reliability a correlation between chemical analogues, homologues or isomers and their therapeutic value, reason compels us to agree that novelty, usefulness and non-obviousness inhere in the true discovery that a chemical compound exhibits a new needed medicinal capability, even though it be closely related to structure to a known or patented drug. When such a fresh, efficacious, undisclosed use is identified, its inventor deserves the full ambit of statutory protection.’”<sup>47</sup>

After a review of the *Deutsche Gold* and *Lilly v. Generix* precedents, the court in *Lilly v. Premo* adopted *Papesch* as well:

“We too are persuaded that, in determining whether a new drug meets the nonobviousness requirement of § 103, the district courts should consider all of the properties of the drug—including its structure, uses, and other traits—and compare those properties with their counterparts in the prior art. If the new compound,

---

<sup>46</sup>*Id.*

<sup>47</sup> *Lilly v. Premo*, 630 F.3d at 129-30 (quoting *Lilly v. Generix*, 460 F.2d at 1103).

although structurally obvious, exhibits uses or traits that, at the time of their discovery, were not predictable to chemists or other persons skilled in the prior art, such differences indicate that the new compound is nonobvious for purposes of § 103. Whether the existence of an unexpected use or trait should conclusively establish nonobviousness, we need not decide at this time. If the unexpected property results in a substantial improvement over the prior art in respect to the therapeutic effectiveness or usefulness of the drug, however, it would appear to contravene the purposes of the patent laws to deny patentability on the basis of obviousness.”<sup>48</sup>

#### IV. FEDERAL CIRCUIT ADOPTION OF *PAPESCH*

*Papesch* has been endorsed *en banc* in *Dillon*<sup>49</sup> and until 2007 uniformly supported by other precedent of the court as well.

As stated in *Dillon*:

“This court, in reconsidering this case [*en*] *banc*, reaffirms that structural similarity between claimed and prior art subject matter, 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[.]”<sup>50</sup> Or, rebuttal may be based upon evidence “that the prior art is so deficient that there is no motivation to make what might otherwise

---

<sup>48</sup> *Lilly v. Premo*, 630 F.3d at 130.

<sup>49</sup> *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990)(*en banc*)(Lourie, J.).

<sup>50</sup> *Dillon*, 919 F.2d at 692-93 (citing *In re Albrecht*, 514 F.2d 1389, 1396 (CCPA 1975); *In re Murch*, 464 F.2d 1051, 1056 (CCPA 1972)).

appear to be obvious changes[.]”<sup>51</sup> “[O]r, [rebuttal may be based upon] any other argument or presentation of evidence that is pertinent.”<sup>52</sup>

## V. FOCUS ON *DIFFERENCES*, A PRIMARY *GRAHAM* INQUIRY

### A. Differences Inherent in the Claimed Invention

The focal point of the *Papesch* inquiry is the establishment of an actual *difference* in properties between the claimed compound and the prior art compound. Thus, a *difference in properties* versus the prior art represents one of the “*differences* between the prior art and the claims” which represent one of the *primary* inquiries under *Graham*.<sup>53</sup> It is only “[a]gainst this background [including such differences that] the obviousness or nonobviousness of the subject matter is determined.”<sup>54</sup>

The properties are thus essential attributes that define the invention, “primary” *Graham* factors, as opposed to “secondary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc., [which] might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Id.* 383 U.S. at 17-18.

In *Taborsky*, the court emphasized the mandatory nature to look to all the *differences* between the claimed invention and the prior art:

“Since a compound and its properties are inseparable in patent law [under *Papesch*], ‘\* \* \* the *differences* between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would [not] have been

---

<sup>51</sup> *Dillon*, 919 F.2d at 693 (citing *Albrecht*, 514 F.2d at 1396; *In re Stemniski*, 444 F.2d 581 (CCPA 1971); *In re Ruschig*, 343 F.2d 965 (CCPA 1965)).

<sup>52</sup> *Dillon*, 919 F.2d at 693.

<sup>53</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)(emphasis added).

<sup>54</sup>*Id.*

obvious at the time the invention was made to a person having ordinary skill in the art \* \* \*.”<sup>55</sup>

As stated in *D'Ancicco*: “All th[e] record definitely establishes is that appellants' foams have *different properties* from the reference foams tested. Whether this *difference* was ‘striking’ depends, not alone on the numerical ratio of the quantified value of the property being compared, but on the significance of that difference. In this case, there has been no showing that either of the asserted *differences* between appellants' foams and the prior art foams is of any practical advantage, and appellants' attempt to rebut prima facie obviousness by the method sanctioned in [*Papesch*] therefore fails.”<sup>56</sup>

Citing *Papesch* in the *Lunsford* case, the court faulted the PTO for failure to consider the differences between the claimed product and the prior art: “Appellant was entitled to have *differences* between the claimed invention, the subject matter as a whole, and the prior art references of record evaluated.”<sup>57</sup>

### **B. All Differences *Must* be Considered**

To fail to understand the *differences* in properties as representing a primary *Graham* factor is to fail to understand the essence of the patentability inquiry for a unique compound:

Unlike the world of mechanical and electrical incremental innovations that focus almost entirely upon the creation of new combinations of old elements, the

---

<sup>55</sup> *In re Taborsky*, 502 F.2d 775, 782 (CCPA 1974)(Lane, J.)(quoting 35 USC § 103).

<sup>56</sup> *In re D'Ancicco*, 439 F.2d 1244, 1248 (CCPA 1971)(Rich, J.)(emphasis added).

<sup>57</sup> *In re Lunsford*, 357 F.2d 385, 391 (CCPA 1966)(A. Smith, J.)(emphasis added).

organic entities are unique structures that may or may not have a close *apparent* relationship to prior art compounds. Given a particular organic structure, the skilled chemist can instantly visualize methods to make – quite literally – thousands if not millions of somewhat structurally related compounds that may or may not be expected to behave along the lines of the known prior art compound. But, knowing possible two dimensional structural formulae that *could* be made may or may not include an expectation of similar properties, a fact-intensive inquiry in an ever-changing state of the art.

For example, when the basic prostaglandin structure was isolated from the testicles of sheep, little was known about what variations could be made to achieve compounds with similar properties so that there was a narrow penumbra of structurally related potential derivatives with little known. As the science developed and thousands of prostaglandin derivatives were synthesized and their properties described in the scientific literature, the penumbra of structurally obvious variations broadened.

Yet, merely speculating on the “obvious” two-dimensional structural formula gives no greater picture of the three dimensional thing, the compound itself, than a simple roadmap describes the geographic contours of the landscape traversed by the lines designating the roads. Thus, just as a two dimensional roadmap showing only straight and squiggly lines identified by road names and numbers may lead to the *expectation* that the straight lines identify highways on the plains and convoluted lines may lead to the *expectation* of windy, mountainous roads, only the three dimensional *reality* demonstrates the actual contour of the thoroughfare:

“Indeed, a chemical structure is simply a means of describing a compound; it is not the invention itself.”<sup>58</sup> Particularly in the area of complex organic chemistry, a slight modification – as in the case of a structurally “obvious” homolog – may lead to an expectation of identical properties of compounds in the series, in fact

---

<sup>58</sup> *Regents of University of New Mexico v. Knight*, 321 F.3d 1111, 1122 (Fed. Cir. 2003)(Lourie, J.) (quoting *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963))(emphasis added).

even the smallest structural deviation may so skew the spatial relationship of the compound so that its physiological interaction may mean that one member of a homologous series is an effective anticancer agent whereas the structurally related member may have no therapeutic activity.

Any and all evidence of *differences* should be considered: “Rebuttal [of *prima facie* obviousness] may take the form of ‘a comparison of test data showing that the claimed compositions possess unexpectedly improved properties ... that the prior art does not have, that the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes, or any other argument ... that is pertinent.’”<sup>59</sup> Thus, “a novel chemical compound can be nonobvious to one having ordinary skill in the art notwithstanding that it may possess a known property in common with a known structurally similar compound.”<sup>60</sup> More than a decade after *Papesch*, the court stated that “[i]t has long been our position that a compound and its properties are inseparable and that no property can be ignored in determining patentability over the prior art.”<sup>61</sup> The first Chief Judge of the Federal Circuit reiterated the basic *Papesch* principles early in his tenure as Chief Judge of the predecessor CCPA.<sup>62</sup>

There is no option to selectively determine *which* of the many properties of a compound must be considered: *All* must be weighed in the determination of the

---

<sup>59</sup> *Mayne*, 104 F.3d at 1342 (citing *In re Dillon*, 919 F.2d 688, 692-93 (Fed.Cir.1990) (en banc)(*Dillon* citations omitted in *Mayne*).

<sup>60</sup> *In re May*, 574 F.2d 1082, 1093 (CCPA 1978)(Lane, J.)(quoting *In re Albrecht*, 514 F.2d 1389, 1395-96 (CCPA 1975)).

<sup>61</sup> *In re Wagner*, 371 F.2d 877, 881 (CCPA 1967)).

<sup>62</sup> *In re Cescon*, 474 F.2d 1331, 1334 (CCPA 1973) (citing *Papesch*, 315 F.2d at 391; *Wagner*, 371 F.2d at 881(“It has long been our position that a compound and its properties are inseparable and that no property can be ignored in determining patentability over the prior art.”)).

nonobviousness of the invention as a whole. This is explicitly stated in the *en banc* restatement of *Papesch* nonobviousness in *Dillon*: “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[.]”<sup>63</sup> As explained in *Dillon*, “*Papesch* ... stated that a compound and *all of its properties* are inseparable and must be considered in the determination of obviousness. We heartily agree and intend not to retreat from *Papesch* one inch. *Papesch* [considered] whether the examiner had to consider the properties of an invention at all, when there was a presumption of obviousness.”<sup>64</sup>

### C. Differences are Primary, not “Secondary Considerations”

The court in *Lunsford* pointed out that the comparison of differences in properties is part of the mandatory inquiry under *Graham*: After quoting from *Graham* that the *differences* between the claimed compound and the prior art must be considered, the court differentiated this from the “secondary considerations”.<sup>65</sup>

In a footnote, Judge Smith noted that following this quotation, “[t]he Supreme Court continues in its opinion, recognizing other considerations relevant to the inquiry under section 103[.]”<sup>66</sup>

---

<sup>63</sup> *Dillon*, 919 F.2d at 693. The court adds: “[B]ut it is also clear that the discovery that a claimed composition possesses a property not disclosed for the prior art subject matter, does not by itself defeat a *prima facie* case.” *Id.* citing *In re Shetty*, 566 F.2d 81, 86 (CCPA 1977)

<sup>64</sup> *Dillon*, 919 F.2d at 697 (citing *Papesch*, 315 F.2d at 391)(emphasis added).

<sup>65</sup> *Lunsford*, 357 F.2d at 391.

<sup>66</sup> *Lunsford*, 357 F.2d at 391 n.6 (quoting *Graham*, 383 U.S. at 17-18, citing “secondary considerations...[a]s indicia of nonobviousness [that] may have relevancy.”).

Thus, if a compound has anti-cancer activity whereas the prior art analog does not have this activity, this *difference* between the compounds is to be weighed as a *primary* factor under *Graham*. It is not a “long-felt need” or “commercial success” factor, one of the “secondary considerations” of *Graham*.

### **D. Nonobviousness May be shown by *Any* Property**

While it is true that *all* properties must be considered and while a single, significant difference may be dispositive in favor of patentability, it is also true that the invention *as a whole* may well be considered obvious *because of* comparative testing where the testing demonstrates common properties. In some cases, the invention as a whole may be deemed obvious because there are so many common properties shared by the claimed compound and the prior art compound. For example, within two years of *Papesch* in *Crounse*,<sup>67</sup> the court was faced with the question of whether a claimed compound useful as a dyestuff should be found nonobvious where the evidence demonstrated a “significant difference in shade” versus the prior art. But, the evidence also showed there were ten *other* factors which pointed to a conclusion of obviousness, including several identical properties shared by the claimed compound and the prior art compound.<sup>68</sup> Even for

---

<sup>67</sup> *In re Crounse*, 363 F.2d 881 (CCPA 1965).

<sup>68</sup> *Crounse*, 363 F.2d at 884 (“Against the significant difference in shade is arrayed what we consider to be an overwhelming body of evidence that indicates the invention as a whole is obvious: 1) The compounds are structurally similar, being position isomers; 2, 3) they possess identical ratings as to two properties ‘considered as essential,’ i.e., resistance to fading and to dry-cleaning with perchloroethylene; 4-7) they have identical ratings as to other properties of washing in the presence, and the absence of chlorine bleach, resistance to discharge printing, and to strong alkali; 8) the claimed compound is producible in the same manner as are the monoazo dyestuffs of [the] Fischer [reference], see *In re Lohr*, [317 F.2d 388 (CCPA 1963)]; 9) the intended use as dyestuff for textiles is expected in view of the [Farbwerke] patent; 10) the manner of use is the same;

pharmaceuticals having an identical utility, nonobviousness may be established. Thus, a claimed compound with the *identical* pharmaceutical activity may be patentable by showing a difference in administration timing.<sup>69</sup>

## V. SUPREME COURT DICTA FROM *GRAHAM* TO *KSR*

The entire body of Supreme Court obviousness law interpreting 35 USC § 103(a) of the 1952 Patent Act has been focused upon the obviousness of a combination of old elements: There has never been a modern obviousness case focusing upon whether a unique compound, *per se*, is or is not obvious.

### A. Not All Patents are Combination Inventions

In the entire modern history of the Supreme Court dating back even before the 1952 Patent Act, there has never been a single obviousness inquiry concerning a novel compound. All of the obviousness cases that the Court has handled down have dealt instead with the issue of obviousness of a *combination* of old elements.

Even at the Federal Circuit there is the misconception that essentially all patents are “combination patents”, as seen from the wisdom of *Straoflex*:

“Virtually *all* patents are ‘combination patents,’ if by that label one intends to describe patents having claims to inventions formed of a combination of elements. It is difficult to visualize, at least in the mechanical-structural arts, a ‘non-combination’ invention, i.e., an invention consisting of a *single* element. Such inventions, if they exist, are rare indeed.”<sup>70</sup>

---

and 11) the shade actually obtained, while not absolutely predictable, is not unexpected.”).

<sup>69</sup> *In re Blondel*, 499 F.2d 1311, 1317-18 (CCPA 1974)(same pharmaceutical utility for both claimed and prior art compounds, but nonobviousness established by demonstrating length of effect).

<sup>70</sup> *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983)(Markey, C.J.)(original emphasis).

A combination of the briefing by parties that have uncritically accepted *Stratoflex* coupled with the lack of cases *other* than combination patents at the Supreme Court has led to the understanding in *KSR* that “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”<sup>71</sup>

### **B. *Bergel* as the Purported Seminal Case Suggestion Case**

*Bergel* has become significant as the purportedly seminal case from the CCPA that established the “suggestion” test for a combination invention:

“When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight.”<sup>72</sup>

But, *Bergel* instead is a case that plays an infinitely small role in the development of the *Haas-Henze* structural obviousness doctrine that warrants only two sentences in a comprehensive treatment of that doctrine.<sup>73</sup> It is hardly seminal in the *Haas-Henze* line,<sup>74</sup> which follows still earlier case law traced to the nineteenth century.<sup>75</sup>

---

<sup>71</sup> *KSR*, 127 S.Ct. at 1741(2007).

<sup>72</sup> *KSR*, 127 S.Ct. at 1741 (citing *In re Bergel*, 292 F.2d 955, 956-957 (CCPA 1961)).

<sup>73</sup> H. A. Wegner, *supra* note 4, 6 APLA Q.J. at 301.

<sup>74</sup> H. A. Wegner, *supra* note 4, 6 APLA Q.J. at 274-75 (1978)(citing *In re Lincoln*, 126 F.2d 477 (CCPA 1942); *Ex parte Clifford*, 63 USPQ 263 (1943); *Ex parte Suter*, 64 USPQ 126 (1943)); *id.* at 303-04, *In re Taub*, 125 F.2d 719 (CCPA 1942)); *id.* at 274-75 (citing *Ex parte Clifford*, 63 USPQ 236 (PO Bd.App. 1943); *Ex parte Suter*, 64 USPQ 126 (PO Bd.App. 1943)); *see also* Guttag, 43 J. Pat. & Trademark Off. Soc’y at 841, *List of Cases Dealing with Homologues and Isomers*

While *Bergel* is totally irrelevant to combination claim obviousness, there is an entirely different, parallel line of cases standing for the proposition that a “suggestion” is needed to render a combination obviousness; this line also predates the 1952 Patent Act,<sup>76</sup> which in turn has even earlier roots.<sup>77</sup>

---

(purportedly tracing cases back to *In re Weitzel*, 39 F.2d 669 (CCPA 1930), but this case has no direct bearing on obviousness of compound inventions).

<sup>75</sup> H. A. Wegner, *supra* note 4, 6 APLA Q.J. at 272 (tracing the concept of *prima facie* obviousness to *Bender v. Hoffmann*, 1898 C.D. 262 (Com’r dec. 1898), where the substitution of a methoxy group (-OCH<sub>3</sub>) for hydroxyl (-OH) was held to be obvious).

<sup>76</sup> *In re Huntzicker*, 90 F.2d 366, 368-69 (CCPA 1937).; *In re Fridolph*, 134 F.2d 414 (CCPA 1943)(“the germinal decision”, Chisum on Patents, § 5.04[1][e][i] (2007)); *In re Goepfrich*, 136 F.2d 918, 920 (CCPA 1943); *In re Gillett*, 133 F.2d 910, 912 (CCPA 1943); *In re Stover*, 146 F.2d 299, 301 (CCPA 1944)(quoting *Fridolph*); *In re Merkle*, 150 F.2d 445, 448 (CCPA 1945); *In re Dalzell*, 152 F.2d 1013, 1014 (CCPA 1946); *In re Udy*, 173 F.2d 230, 233 (CCPA 1949).

<sup>77</sup> *Cimiotti Unhairing Co. v. American Fur Ref. Co.*, 198 U.S. 399, 408 (1905)(quoting *Cimiotti Unhairing Co. v. American Unhairing Mach. Co.*, 115 Fed. 498, 502 (2nd Cir. 1902)(“It will not do to say that the prior art showed such a brush [that could be included in the patented combination]. Every element of the combination in controversy was unquestionably old, but there was nothing in the prior art to suggest a rotary brush working in the environment shown in the Sutton patent.”); *Krell Auto Grand Piano Co. v. Story & Clark Co.*, 207 F. 946, 950 (7th Cir. 1913)(“So the question would be whether the disclosures were so suggestive of the new [claimed] modifications and constructions ... that mechanics skilled in the art of building combination-pianos would, or could when called on, at once adopt the suggestions, or whether there still remained room in the art for the exercise of the inventive faculty in producing the [claimed] device.”)

## C. Lessons from *KSR* for *Papesch* Obviousness

### 1. Unexpected Results are Relevant

Under *KSR*, unexpected results represent one of the indicia of nonobviousness. Citing the *Adams Battery* case, the Court noted that “[t]he fact that the [old] elements [of the claimed combination] worked together in an unexpected and fruitful manner supported the conclusion that Adams's [battery] design was not obvious to those skilled in the art.”<sup>78</sup> Conversely, “[i]f a person of ordinary skill can implement a *predictable variation*, § 103 likely bars its patentability.”<sup>79</sup>

“Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, *all in order to determine whether there was an apparent reason* to combine the known elements in the fashion claimed by the patent at issue.”<sup>80</sup>

### 2. A Mandatory Explicit Analysis to Suggest the Invention

Citing the Federal Circuit *Kahn* opinion as basis, the Court in *KSR* concludes that “[t]o facilitate review [to determine whether there was an apparent reason to combine the known elements], this analysis should be made explicit.”<sup>81</sup> The Court then quotes *Kahn* with approval: “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some

---

<sup>78</sup> *KSR*, 127 S.Ct. at 1740 (citing *United States v. Adams*, 383 U.S. 39, 40 (1966)).

<sup>79</sup> *KSR*, 127 S.Ct. at 1740.

<sup>80</sup> *KSR*, 127 S.Ct. at 1740-41 (emphasis added).

<sup>81</sup> *KSR*, 127 S.Ct. at 1741 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”<sup>82</sup>

### D. KSR “Obvious to Try” Dictum

The *KSR* opinion contains loose language concerning whether an invention is “obvious to try” which places this arcane maxim center stage, grist for litigation and appellate resolution at the Federal Circuit.

The Federal Circuit panel in *KSR* made the mistake of uncritically citing the “obvious to try” maxim, which came back to bite the panel as it is quoted by the Supreme Court: “That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court's view, because [as per *Deuel*] ‘o]bvious to try’ has long been held not to constitute obviousness.”<sup>83</sup>

The Supreme Court scored the panel’s “obvious to try” maxim as part of “[t]he second error” of the panel.<sup>84</sup> This error “lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem.”<sup>85</sup> But, “[c]ommon sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. ...The idea that a designer hoping to make an adjustable electronic pedal would ignore [the]Asano [prior art reference] because Asano was designed to solve [a different] problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an

---

<sup>82</sup> *Id.*

<sup>83</sup> *KSR*, 127 S.Ct. at 1379 (quoting panel opinion, 119 Fed.Appx. at 289, quoting *In re Deuel*, 51 F.3d 1552, 1559 (C.A.Fed.1995)(Lourie, J.)).

<sup>84</sup> *KSR*, 127 S.Ct. at 1742.

<sup>85</sup> *Id.* (citation omitted).

automaton.”<sup>86</sup> Tying this together with “obvious to try”, the Court immediately thereafter explained that “[t]he same constricted analysis led the [Federal Circuit panel] to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was ‘obvious to try.’”<sup>87</sup>

Repudiating this analysis of “obvious to try”, the Supreme Court concluded that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.”<sup>88</sup>

Clearly, the *KSR* repudiation of the panel’s interpretation of the denial of “obvious to try” focused upon the establishment of a *prima facie* case of obviousness as there was no mention of nor contextual basis for *Huellmantel* rebuttal through a showing of a difference in properties.

### **VII. PFIZER v. APOTEX REPUDIATES PAPESCH**

A direct conflict with *Papesch* is found in the panel majority’s rationale to overturn a trial court finding of nonobviousness in *Pfizer v. Apotex*.

(The case is currently at the Supreme Court where an emergency plea for relief has been filed along with a petition for grant of *certiorari*. This paper does not consider the proceedings at the Supreme Court.)

*Sub silentio*, a panel majority in *Pfizer v. Apotex*<sup>89</sup> repudiates the *Papesch* case and its numerous CCPA progeny. The patentee claimed amlodipine besylate<sup>90</sup>

---

<sup>86</sup>*Id.*

<sup>87</sup>*Id.* (citation omitted).

<sup>88</sup>*Id.*

which was prima facie obvious over the prior art amlodipine maleate. The trial court found that the claimed compound “was unexpectedly superior to the amlodipine salts of the prior art.”<sup>91</sup>

### A. Exclusion of Properties as “Secondary Considerations”

---

<sup>89</sup>*Pfizer v. Apotex*, supra note 2. A *certiorari* petition is pending at the Court, No. 06-1582, where Question 1 has been rendered moot by denial of an emergency petition, \_ U.S. \_\_ (June 11, 2007), while Question 2 remains pending:

“1. Whether the Federal Circuit's failure to reconsider its judgment under the *KSR* standard merits summarily granting the petition, vacating the judgment, and remanding for further consideration in view of *KSR*?

“2. Whether, if the petition is [decided after expiration of patent-keyed exclusivity on September 25, 2007,] the Court should instead grant the petition and order the Court of Appeals' judgment vacated under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994).”

As assessed by the patentee, its loss due to the denial of Supreme Court relief cost the company more than a half billion dollars. *Pfizer v. Apotex*, No. 06-1582, Petitioner's *Motion to Expedite Consideration of Pfizer's Petition for Writ of Certiorari Seeking a GVR Order in Light of KSR v. Teleflex*, 550 U.S. \_\_, 127 S.Ct. 1727 (April 30, 2007), p. 4, May 30, 2007 (“Pfizer estimate[d] that the remaining exclusivity period [running through September 25, 2007] is worth over \$ 500 million.”).

<sup>90</sup>*Pfizer v. Apotex*, 480 F.3d at 1356 (Claim 1: “The besylate salt of amlodipine.”).

<sup>91</sup> *Pfizer v. Apotex*, 480 F.3d at 1356 (“The district court ... stated that the besylate salt of amlodipine was unexpectedly superior to the amlodipine salts of the prior art. Specifically, the district court stated that, while amlodipine besylate was not superior to amlodipine maleate ‘in every category,’ it nonetheless ‘clearly and unexpectedly illustrates a superior combination of properties when compared to what was suggested in the preferred preparation’ [versus the prior art amlodipine maleate].”)

Against a trial court's holding that Pfizer's claim to amlodipine besylate has unexpectedly superior non-pharmaceutical properties over the prior art, which were dismissed by the appellate court. The court dismissed any unexpected difference in properties as optional "secondary" considerations: "[E]ven if [the patentee] showed that [the claimed] amlodipine besylate exhibits unexpectedly superior results, this secondary consideration does not overcome the strong showing of obviousness in this case. Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion."<sup>92</sup>

But, the properties of the compound are a part of the claimed invention, the *differences* in properties are *differences* from the prior art that must be considered in every case.

### **B. Failure to Consider All Properties**

The panel majority excludes consideration of some of the properties as they are not therapeutic in nature. This is scored in a dissent:

"The panel ...mistakenly determined that the superior properties of the besylate did not overcome a prima facie case of obviousness because they showed no superior *therapeutic value* – the maleate salt form of amlodipine worked just as well as the besylate form in clinical trials. Therapeutic value, however, is just one property of a pharmaceutical. Other properties, such as solubility, stability, hygroscopicity, and processability, must also play a role in the analysis of advantages. The superior properties of the besylate salt form of amlodipine, overcame the stability and stickiness problems that existed with the maleate salt form and created a superior formulation. Although the maleate salt form was also therapeutically effective, the besylate form was still a significant improvement

---

<sup>92</sup> *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed.Cir.2007) (citing *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed.Cir.1988)).

because it overcame the stability and processing problems that could have prevented successful commercial marketing.”<sup>93</sup>

A dissent from denial of rehearing *en banc* underscored the conflict with *Papesch* that requires consideration of *all* differences between the claimed invention and the prior art:

“[T]he panel improperly placed greater importance on the therapeutic value of a claimed compound over the value of its physical properties. The panel concluded that the improvement of the invention, which related to drug formulation, viz., increased stability and decreased stickiness, was ‘insufficient’ to meet the standards of patentability.”<sup>94</sup>

This second dissent emphasizes the same point, quoting the panel majority’s opinion to make its point:

“[W]e hold that the *optimization of the acid addition salt formulation* for an active pharmaceutical ingredient would have been obvious where as here the acid addition salt formulation *has no effect on the therapeutic effectiveness* of the active ingredient and the prior art heavily suggests the particular anion used to form the salt.”<sup>95</sup> The dissent points out that this “conclusion ... improperly require[es] a compound to possess a specific type of improvement over the prior art – in this case, improved therapeutic properties – to be patentable, negating other important properties, a conclusion that is not compelled by our case law and not sound. Any

---

<sup>93</sup> *Pfizer v. Apotex*, \_\_\_ F.3d at \_\_\_ (Rader, J., dissenting from denial of reh’g en banc)

<sup>94</sup> *Pfizer v. Apotex*, \_\_\_ F.3d at \_\_\_ (Lourie, J., dissenting from denial of reh’g en banc).

<sup>95</sup> *Id.* quoting the panel majority opinion at 1368 (emphasis added in the dissent).

useful and unexpected property should be eligible to overcome a prima facie obviousness determination.”<sup>96</sup>

### C. The Generic Status of the Prior Art

The majority in *Pfizer v. Apotex* places reliance upon the fact that the prior art patent is *generic* to the claimed species:

“We ... note that the [prior art] patent placed no limitations on the acid addition salt whatsoever, except that it be non-toxic and formed from an acid containing a pharmaceutically-acceptable anion. Accordingly, the [prior art] patent contained a strong suggestion that any and all pharmaceutically-acceptable anions would form non-toxic acid addition salts and would work for their intended purpose[.]”<sup>97</sup>

The fact that the prior art had a claim that encompassed the besylate should have been of no moment.<sup>98</sup> But, the relevance, if any, relates to the establishment of a prima facie case of obviousness, whereas *Papesch* is focused upon the *rebuttal* of such a prima face case.

---

<sup>96</sup> *Id.* Continuing, the dissent quotes from *Papesch*, 315 F.2d at 391 (“From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing.... There is no basis in law for ignoring any property in making such a comparison.”).

<sup>97</sup> *Pfizer v. Apotex*, 480 F.3d at 1365.

<sup>98</sup> There is a long line of cases that demonstrates that the scope of a prior art *claim* is not controlling, as explained in the *Baird* and *Jones* cases, supra note 8.

## D. Abandoned *Huellmantel* “Obvious to Try”

### 1. The Panel Majority in *Pfizer v. Apotex*

As the panel majority itself recognized, “[c]ourts should, of course, avoid ‘[u]ndue dependence on mechanical application of a few maxims of law, such as ‘obvious to try.’”<sup>99</sup> The panel focuses upon the *prima facie* obviousness aspect of “obvious to try” to the complete disregard of the primary *Huellmantel* question of rebuttal of such a *prima facie* case of obviousness.<sup>100</sup>

### 2. Post-KSR Differing Views of the *En Banc* Court

In the wake of *KSR* the panel nevertheless hurriedly denied rehearing *en banc*. Among the three dissents from denial of rehearing *en banc* there are several views which flesh out the difficulty the court is having with an understanding of *Papesch* obviousness:

---

<sup>99</sup> *Pfizer v. Apotex*, 480 F.3d at 1366 (Michel, C.J.).

<sup>100</sup> *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d at 1365 (“Parties before this court often complain that holdings of obviousness were based on the impermissible ‘obvious to try’ standard, and this court has accordingly struggled to strike a balance between the seemingly conflicting truisms that, under 35 U.S.C. § 103, ‘obvious to try’ is not the proper standard by which to evaluate obviousness, *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A.1977), but that, under *O’Farrell* and other precedent, absolute predictability of success is not required. 853 F.2d at 903. Reconciling the two is particularly germane to a situation where, as here, a formulation must be tested by routine procedures to verify its expected properties. The question becomes then, when the skilled artisan must test, how far does that need for testing go toward supporting a conclusion of non-obviousness?”).

## Wegner, Post-KSR Chemical Obviousness

---

Insofar as “obvious to try” is concerned, the dean of the court focuses entirely on the issue of *prima facie* obviousness and totally disregards the *Huellmantel* rebuttal of *prima facie* obviousness.<sup>101</sup>

A second dissent notes the unpredictability of pharmaceutical inventions and concludes that “‘obvious to try’ jurisprudence has a very limited application in cases of this nature.”<sup>102</sup> But, this is *precisely* why the author of *Papesch* found it necessary to explain that based upon the unpredictable nature of the differences in

---

<sup>101</sup> *Pfizer v. Apotex*, \_\_\_ F.3d at \_\_\_ (Newman, J., dissenting from denial of reh’g *en banc*) (“Both sides acknowledge that the effects of chemical changes on properties of medicinal products is not predictable; the difference residing in the panel’s acceptance of the long-discredited ‘obvious to try’ standard, on which the panel superimposes the theory that the skill of these inventors guided them to trial of the besylate salt (despite the prior art’s preference for the maleate salt), thereby negating patentability. The panel’s application of the obvious-to-try standard is in direct conflict with precedent; it has long been the law that ‘patentability shall not be negated by the manner in which the invention is made.’ 35 U.S.C. § 103. In *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed.Cir.1990) this court stated that ‘we have consistently held that ‘obvious to try’ is not to be equated with obviousness.’ In *In re Tomlinson*, 363 F.2d 928, 931 (CCPA 1966) the court explained that ‘there is usually an element of ‘obviousness to try’ in any research endeavor, that ... is not undertaken with complete blindness but rather with some semblance of a chance of success.’ The amici curiae representing research pharmaceutical industries in this petition point out that methodical experimentation is fundamental to scientific advance, and particularly for biological and medicinal products, where small change can produce large differences. At the trial there was no contradiction to the testimony of Pfizer’s expert witness Dr. Anderson that ‘one of ordinary skill in the art could neither draw any conclusions nor have any expectations about the properties of amlodipine besylate from the properties of a besylate salt of a different compound.’ Pfizer Br. at 7. Indeed, the parties stipulated this scientific fact.”)

<sup>102</sup> *Pfizer v. Apotex*, \_\_\_ F.3d at \_\_\_ (Rader, J., dissenting from denial of reh’g *en banc*).

properties of chemical compounds that was the basis for *Huellmantel* less than three months from *Papesch* itself.<sup>103</sup>

### 3. The Patentee's *Sub Silentio* Abandonment of *Huellmantel*

The patentee and its supporting *amici* completely lost sight of the genesis of the “obvious to try” line of case law and the sole reason for its institution less than three months after *Papesch*: Even though a claimed compound may be “obvious to try” and in that sense *prima facie* obvious, such an “obvious to try” compound *as a whole* may nevertheless be established to be nonobvious based upon an unexpected *difference* in properties. This is the entire essence of the origins of the “obvious to try” case line of *Huellmantel*.

Instead, the patentee and its supporting *amici* turned to case law at least a quarter century later that had an at best blurred discussion of “obviousness to try” and in the two principal cases that were cited had holdings confirming that the claimed invention was *unpatentable*, i.e., most case citations in support of the patentee’s position represent pure and unadulterated *obiter dictum*.<sup>104</sup>

Appellee in its brief argued to the panel had focused its “obvious to try” argument strictly on *prima facie* obviousness, a meaningless distinction under *Huellmantel*: “Even if besylate were an obvious candidate to try with amlodipine

---

<sup>103</sup> Obviously, the alternative “obvious to try” that is supported by *dicta* in *O’Farrell* also applies in the establishment of *prima facie* obviousness, which is a fundamental aspect of the arcane world of *prima facie* obviousness of chemical compounds discussed in H. A. Wegner, *supra* note 4.

<sup>104</sup> Appellee’s brief, July 5, 2006, p. 31 (citing *In re O’Farrell*, 853 F.2d 894 (Fed. Cir. 1988); *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990)); *see also* PhRMA *amicus* brief in support of rehearing *en banc*, April 13, 2007, p. 6 (citing *O’Farrell*; *Eli Lilly*); BIO *amicus* brief in support of rehearing *en banc*, April 13, 2007, pp. 7-8 (citing *Eli Lilly*). Additionally, BIO cites *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720 (Fed. Cir. 1990), while the SmithKline Beecham-Eli Lilly joint *amicus* brief in support of rehearing *en banc*, April 10, 2007, p. 10 cites *In re Tomlinson*, 363 F.2d 928 (C.C.P.A. 1966).

base, from among the unlimited number of other acids, amlodipine besylate is not thereby rendered *prima facie* obvious. This Court has clearly held that patent claims are not obvious if the prior art suggests that their subject matter is merely ‘obvious-to-try.’”<sup>105</sup> Elaborating on the “obvious to try” *dictum* from the *O’Farrell* case, appellee focused upon the *later*, alternative issue of “obvious to try” which in any event also is limited to *prima facie* obviousness.<sup>106</sup> Appellee states that the *alternative* “obvious to try” doctrine having nothing to do with *Huellmantel* “accurately describes the situation in this case.”<sup>107</sup> A parallel argument is made by PhRMA.<sup>108</sup> BIO, too, argued against *prima facie*

---

<sup>105</sup> Appellee’s brief, July 5, 2006, p. 31 (citing *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988); *In re Eli Lilly & Co.*, 902 F.2d 943, 945 (Fed. Cir. 1990)).

<sup>106</sup> *Id.* at pp. 31-32 (quoting *O’Farrell*, 853 F.2d at 903, and also citing *Pfizer Inc. v. Ranbaxy Labs, Ltd.*, 405 F. Supp. 2d 495, 517 (D.Del. 2005), *appeal argued*, No. 06-1179 (Fed. Cir. May 4, 2006) (citing *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995)) (“Claims are merely ‘obvious-to-try’ where there is a teaching to ‘try each of numerous possible choices until [reaching] a successful result,’ but no teaching ‘as to which of many possible choices is likely to be successful.’”).

<sup>107</sup> *Id.* at p. 32. Thus, “[a]t best, the prior art here identified numerous acids that one could try to combine with amlodipine to make a salt, but there was no teaching of which acid, if any, would be successful, and no direction that amlodipine besylate was the choice that would be successful.” *Id.* This has nothing to do with the nonobviousness of the invention *as a whole* under *Huellmantel* and everything to do with the establishment of a *prima facie* case of obviousness – which, per *Huellmantel* – is rebutted by showing an unexpected *difference* in properties.

<sup>108</sup> PhRMA *amicus* brief in support of rehearing *en banc*, April 13, 2007, p. 6 (citing *Eli Lilly*, 902 F.2d at 945; *O’Farrell*, 853 at 903) (“Whether it might be obvious to try formulations of salts based on known anions, the mere disclosure of a particular compound and a variety of anions that might form salts with that compound is insufficient to render a new salt formulation obvious because that

obviousness.<sup>109</sup> Two leading pharma companies also focused upon the *prima facie* obviousness case: “[T]here is usually an element of ‘obviousness to try’ in any research endeavor, that ... is not undertaken with complete blindness but rather with some semblance of a chance of success .... [To make] patentability determinations based on that as the test would not only be contrary to the statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name ‘research.’”<sup>110</sup>

### ***E. Dystar versus Papesch***

The panel majority relies upon the recent and highly controversial *Dystar* case<sup>111</sup> which does not even *consider* nor is relevant to the *Papesch* line of cases. As the opinion of a bare two member panel majority in conflict with *Papesch* and numerous progeny it bears no consideration, here, beyond its procedural considerations on the erosion of the value of precedent as discussed in the following section.

---

‘disclosure itself does not contain a sufficient teaching of how to obtain the desired result,’ *i.e.*, the salt formulation with superior properties.”).

<sup>109</sup> BIO *amicus* brief in support of rehearing *en banc*, April 13, 2007, p. 8 (“[T]his Court has consistently held that, to establish a *prima facie* case of obviousness, there must be a reasonable expectation of success that the invention will work for its intended purpose. *Eli Lilly and Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1377 (Fed. Cir. 2006). The Panel, however, analyzed the reasonable expectation of success issue by improperly focusing on the inventor's own thought processes.” (citations omitted).

<sup>110</sup> SmithKline Beecham-Eli Lilly joint *amicus* brief in support of rehearing *en banc*, April 10, 2007, p. 10 (quoting *In re Tomlinson*, 363 F.2d 928, 931 (C.C.P.A. 1966)(Rich, J.).

<sup>111</sup> *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (2006).

## VIII. *DYSTAR* LIMESTONE PRECEDENT

When the Federal Circuit *en banc* has an established and unequivocally clear precedent it should be enshrined as “bedrock precedent” and not subject to panel repudiation.

*Papesch* represents the seeded precedent of the Federal Circuit under *South Corporation*,<sup>112</sup> and in any event has the *en banc* endorsement of the Federal Circuit in *Dillon*.<sup>113</sup> Beyond *Papesch*, there are numerous following cases that fleshed out *Papesch* which have the added imprimatur of *en banc* status and which are controlling.<sup>114</sup>

### A. *Dystar* Repudiation of *South Corporation*

Under *South Corporation*, if there is an early panel opinion that has a specific holding, that specific holding remains precedent forever – or until it is overruled *en banc*. So too is the controlling precedent of the CCPA precedent forever – again, unless it is overruled *en banc*.

A cardinal shortcoming of the Federal Circuit has been its failure to police deviations from precedent to the point that an overwhelming body of case law

---

<sup>112</sup> *South Corp. v. U. S.*, 690 F.2d 1368, 1371 (Fed. Cir. 1982)(Markey, C.J.)(*en banc*)(“As a court of nationwide geographic jurisdiction, created and chartered with the hope and intent that stability and uniformity would be achieved in all fields of law within its substantive jurisdiction, we begin by adopting as a basic foundation the jurisprudence of the two national courts which served not only as our predecessors, but as outstanding contributors to the administration of justice for a combined total of 199 years, the Court of Claims and the Court of Customs and Patent Appeals.”).

<sup>113</sup> *Dillon*, 919 F.2d at 692-93.

<sup>114</sup> *In re Gosteli*, 872 F.2d 1008, 1011 (Fed. Cir. 1989)(Bissell, J.)(“The CCPA's later decisions control because that court always sat *en banc*.”).

evolves comprising fragmented panel opinions that cannot be reconciled with the bedrock principles established by controlling precedent, further encouraging even further balkanization.

In this balkanized world of panel opinions with conflicting rulings, an attempt is made in *Dystar* case to establish a principle that *all* of the cases in an area should be reconciled to create a fabric of case law, which is quoted with approval by the author of the *Dystar* panel majority in *Pfizer v. Apotex*:

“Obviousness is a complicated subject requiring sophisticated analysis, and no single case lays out all facets of the legal test. [There is] danger inherent in focusing on isolated dicta rather than gleaning the law of a particular area from careful reading of the full text of a group of related precedents for all they say that is dispositive and for what they hold. When parties ... do not engage in such careful, candid, and complete legal analysis, much confusion about the law arises and, through time, can be compounded.”<sup>115</sup>

The *Dystar* panel opinion represents a unique “amicus” argument, speaking for the two member majority, that the Supreme Court itself refused to dignify by any consideration, which it bluntly explained in its opinion.<sup>116</sup>

Clearly, however, unless *South Corporation* is repudiated, the careful parsing of the full text of a group of related precedents should not trump controlling precedent. The panel majority in *Pfizer v. Apotex* dismisses *Papesch sub silentio* as “isolated dicta”.<sup>117</sup>

---

<sup>115</sup>*Pfizer v. Apotex*, 480 F.3d at 1366 (quoting *Dystar*, 464 F.3d at 1367).

<sup>116</sup>*KSR*, 127 S.Ct. at 1743 (“[*Dystar*,] of course, [is] not now before us and do[es] not correct the errors of law made by the Court of Appeals in this case. The extent to which [it] may describe an analysis more consistent with our earlier precedents and our decision here *is a matter for the Court of Appeals to consider in its future cases.*”)(emphasis added).

<sup>117</sup>*Id.*

## Wegner, Post-KSR Chemical Obviousness

---

For more than seventy-five years, the Supreme Court has warned about the importance of avoiding intra-circuit conflicts. Thus, “[i]n *Textile Mills*, the Supreme Court emphasized the importance of avoiding intra-circuit conflicts and promoting finality of decisions.”<sup>118</sup> The *en banc* court stands in the place of the Supreme Court for most practical purposes and is a reason for the establishment of the practice of *en banc* review: “The Supreme Court attached special importance to the capacity of the en banc hearing to promote finality of decision and to resolve or avoid conflict within a circuit, because the courts of appeals ‘are the courts of last resort in the run of ordinary cases.’”<sup>119</sup>

The *Dystar* approach dishonors the value of *en banc* precedent and encourages panel encroachment on existing case law: If *Dystar* is the law, then an activist judge pushing one particular cause can choose to make every decision even remotely related to an issue within the scope of his decision and to choose to issue precedential opinions to do so, adding to the body of “the full text of a group of related precedents for all they say that is dispositive and for what they hold.”<sup>120</sup>

The *Dystar* approach proliferates opinions and gives undue weight to the activist’s approach and is antithetical to the bedrock principles of law established through *en banc* precedent. A contrary insider’s view from within the D.C. Circuit explains that “[t]he conception of the [three member] panel as the agent of the full court [which] works to increase collegiality on the court. The court, like any team, functions best when each member feels responsible to each of the others, and responsible for the performance of the whole. The possibility of en banc rehearing brings home to each panel its responsibility to solicit the views of its nonpanelist

---

<sup>118</sup> Martha Dragich Pearson, *Citation of Unpublished Opinions As Precedent*, 55 Hastings L.J. 1235, 1263 (2004)(citing *Textile Mills Sec. Corp. v. Comm'r*, 314 U.S. 326, 335 (1949))(footnotes omitted).

<sup>119</sup> Douglas H. Ginsburg & Donald Falk, *The Court En Banc: 1981-1990*, 59 Geo. Wash. L. Rev. 1008, 1011 (1991)(quoting *Textile Mills*, 314 U.S. at 335).

<sup>120</sup> *Pfizer v. Apotex*, 480 F.3d at 1366 (quoting *Dystar*, 464 F.3d at 1367.)

colleagues before releasing a decision, and to respect their estimation of whether the panel has erred. Each time the court denies a suggestion for rehearing en banc... it reaffirms its confidence in the panel notwithstanding the inherent uncertainty under which the nonpanelists must cast their votes. That the court rehears en banc only [several] cases per year suggests that the court as principal is overwhelmingly satisfied with the work of its panels as agents.”<sup>121</sup>

### **B. Return to *South Corporation***

*Dystar* creates a public policy conflict with the rationale of *South Corporation*: “To proceed without precedent, deciding each legal principle anew, would for too long deprive the bar and the public of the stability and predictability essential to the effort of a free society to live under a rule of law.”<sup>122</sup>

Thus, “[v]ery weighty considerations underlie the principle that courts should not lightly overrule past decisions. Among these are the desirability that the law furnish a clear guide for the conduct of individuals, to enable them to plan their affairs with assurance against untoward surprise; the importance of furthering fair and expeditious adjudication by eliminating the need to relitigate every relevant proposition in every case; and the necessity of maintaining public faith in the judiciary as a source of impersonal and reasoned judgments.”<sup>123</sup>

## **IX. A NEED FOR BETTER PATENT LAW SCHOLARSHIP**

If there is to be a significant improvement in the quality of decisional law in patents there must be a more responsible patent community that presents more complete and better researched positions to the judiciary.

Two of the most high profile patent cases manifest the serious lack of thorough scholarship that goes into the work product that comprises the appellate briefing before the Federal Circuit. *KSR* is widely acknowledged as perhaps the

---

<sup>121</sup> Ginsburg *et al.*, 59 Geo. Wash. L. Rev. at 1013 (footnotes omitted).

<sup>122</sup> *South Corp.*, 690 F.2d at 1370.

<sup>123</sup> *Id.*, quoting *Moragne v. States Marine Lines, Inc.*, 398 U.S. 375, 403 (1970).

single most important patent case at the Supreme Court in more than forty years while the patentee assesses its loss in *Pfizer v. Apotex* at more than a half billion dollars for the remaining three months of its patent-based exclusivity.<sup>124</sup>

Both manifest legal research that is more and more focused upon a Boolean quest for quick Westlaw or Lexis string cites or quotations, now often referred to by one member of the Federal Circuit as “cite bites”.<sup>125</sup> Cite bites make good one liners in support of an advocate’s position, but all too often are uncritically electronically cut and pasted from Westlaw or Lexis and inserted into advocacy pieces, sometimes without regard to whether the case even had a *holding* in support of the advocates position.

### A. Cite Bites and String Citations

The Federal Circuit practice of “cite bites” and “string citations” is an epidemic. A search for the perfect quotation – the best “cite bite” – is made often without even considering the *holding* of the case. No better example is possible than the various cases cited in support of a “suggestion” requirement in *KSR* where in fact the *holding* in most of the cases ran the opposite way.

All too often, a patent law brief at the Federal Circuit recites a general principle without detailed analysis of the principle or *any* leading case, but there *is* a smothering set of back citations to previous Federal Circuit cases that all have *quotations* or “cite bites” that generally support the proposition that the party is advocating. Yet, the *holdings* of the case may well go in a different direction. Above all, the argument must put a court to sleep, if not simply frustrate an

---

<sup>124</sup>Supra, note 89.

<sup>125</sup> Harold C. Wegner, *Supreme Court Review of Federal Circuit Patent Jurisprudence*, p. 6, Federal Circuit Judges Come to California, Intellectual Property Law Section of the State Bar of California, The Ritz-Carlton Marina del Rey, February 20, 2007 (discussing “cite bites”, a term previously introduced by Circuit Judge Linn).

appellate body that must for itself wade through a mountain of thinly reasoned authorities.

Cite bites to “string citations” represent the current rage amongst too many lawyers. In the overall scheme of more than two full centuries of domestic legal history, the string citation is relatively new. Although plural authorities have been cited in earlier times, a judicial reference to “string citations” crept into the judicial literature not later than 1960.<sup>126</sup> Although there is widespread reference to “string citations”, the Federal Circuit has never acknowledged or even made reference to string citations in a precedential opinion,<sup>127</sup> although the court itself on occasion has had an internal battle of citations to supporting literature for divergent opinions within the court, effectively including one string citation in tabular form of fifty-four (54) authorities.<sup>128</sup>

With just a few minutes on Westlaw, it is possible to take a leading case and find ten or more cases that quote from and may amplify the case. A *polished* brief with numerous cases can be generated from this work with a string of citations to the work product. Indeed, “[s]tring citations to great gobs of cases are typical[.]”<sup>129</sup>

---

<sup>126</sup> *U. S. v. New York, N. H. & H. R. Co.*, 276 F.2d 525, 554 n.3 (2nd Cir. 1960)(“Morgenstern was included in a string citation...”).

<sup>127</sup>The sole reference is found in *Randolph v. Department of Navy*, 250 F.3d 757 (Table), 2000 WL 772720 (Fed. Cir. 2000)(per curiam).

<sup>128</sup>*University of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303,1314-24 (1994)(Rader, J., joined by Gajarsa, Linn, JJ., dissenting from denial of reh’g en banc)(citing fifty-four (54) journal articles analyzing the case law doctrine in controversy).

<sup>129</sup>Robert C. Berring, *Collapse of the Structure of the Legal Research Universe: The Imperative of Digital Information*, 69 Wash. L. Rev. 9, 28 (1994)(“String citations in part are the result of the ease with which it is possible to search through electronic means to come up with large numbers of cases. The judiciary points to computer research as the culprit for string citations.”<sup>129</sup> The sheer volume of cases, coupled with the electronic search tools, geometrically multiples

But, while a brief can be construction quite simply by cutting and pasting the string citations and block quotes, this is all too often done as a shortcut without deep analysis of the cases which all too often have holdings that don't back up the advocate's position: How embarrassing – and costly in terms of outcome – when an opponent is able to *rely upon the very case(s) given credibility in the pleadings*.

### B. *KSR* and *Pfizer v. Apotex*, Case Studies in Boolean Scholarship

In *KSR*, there is a favorable discussion of *Bergel* and the CCPA “suggestion” case law.<sup>130</sup> This should neither be credited to nor blamed on Respondent who did not focus upon *Bergel*.<sup>131</sup> Neither should blame be placed on

---

the challenge of case law selection: “[T]he volume of published cases is breaking down the intellectual structure of the system, weakening what we have called the gestalt of legal thought. No order can be brought to such chaos. Where the [legal] research enterprise once consisted of finding a relevant precedent or two and exploring the universe of cases around them, now each side in any dispute can find bunches of relevant cases. String citations to great gobs of cases are typical, and briefs continue to expand, each page packed with ‘relevant’ authority. Whatever linear nature precedent could once claim is now gone. It is not surprising; no system could survive so much data and stay in the rigid control that was typical of the [pre-electronic search era of the] West digest system.”).

<sup>130</sup> *KSR*, 127 S.Ct. at 1741 (citing *In re Bergel*, 292 F.2d 955, 956-957 (CCPA 1961)) (“When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight.”). See the discussion at § V-B, *Bergel as the Purported Seminal Case Suggestion Case*.

<sup>131</sup> Respondent's merits brief at pp. 25-26: “*Expanded Metal Co. v. Bradford*, 214 U.S. 366, 381 (1909) (explaining that “he who first makes the discovery has done more than make the obvious improvement which would suggest itself to a mechanic skilled in the art”); *id.* (upholding patentability because “[t]here is nothing in the prior art that suggests the combined operation of the Golding patent in suit”); *Mast, Foos, & Co. v. Stover Mfg. Co.*, 177 U.S. 485, 494 (1900) (examining whether claimed invention was “anything more than would

the numerous law professors as *amici* who did not even *cite* to the *Bergel* case, although one brief on behalf of scientists did so.<sup>132</sup> It is the several bar associations who *do* cite to *Bergel* who should be credited with its citation. The American Bar Association cites to *Bergel* as the origin of the suggestion test,<sup>133</sup> while the 1943 *Fridolph* case *is* cited by the Federal Circuit Bar Association,<sup>134</sup> the New York Intellectual Property Law Association<sup>135</sup> and the American Intellectual

---

have been suggested to an intelligent mechanic”); *Day v. Fair Haven & Westville Ry. Co.*, 132 U.S. 98, 102 (1889) (invalidating an invention because it ‘would naturally suggest itself to any mechanic, and that its use in that way is within the range of common knowledge and experience’”).

<sup>132</sup> Cf. “Chemistry and Bioengineering Professors” *KSR* merits amicus brief, p. 5 (citing *In re Bergel*, 292 F.2d 955, 956 (CCPA 1961)) (“[The CCPA] implemented a suggestion test to assist with the determination of what subject matter one of ordinary skill in the art would consider obvious.”).

<sup>133</sup> American Bar Association *KSR* Merits Amicus Brief, p. 3 (citing *In re Hill*, 284 F.2d 955 (CCPA 1960); *In re Bergel*, 292 F.2d 955, 956-57 (CCPA 1961); *In re Imperato*, 486 F.2d 585, 587 (CCPA 1973); *In re Regel*, 526 F.2d 1399, 1403 n.6 (CCPA 1975)) (“Numerous ... decisions of th[e CCPA], both before and after *Graham*, firmly established the requirement for a suggestion to combine prior art disclosures.”).

<sup>134</sup> Federal Circuit Bar Association *KSR* Merits Amicus Brief, p. 14 (“The [TSM] test has a long history, pre-dating *Graham*. Before the creation of the Federal Circuit, the requirement of a teaching, suggestion or motivation (then generally referred to as a ‘suggestion’) was well established in [the CCPA].”) ((citing *In re Leonor*, 395 F.2d 801, 802 (CCPA 1968); *In re Bergel*, 292 F.2d 955, 956-57 (CCPA 1961); *In re Shaffer*, 229 F.2d 476, 479 (CCPA 1956); *In re Fridolph*, 134 F.2d 414, 416 (CCPA 1943)).

<sup>135</sup> New York Intellectual Property Law Association *KSR* Merits Amicus Brief, p. 16 n.6 (citing *In re Imperato*, 486 F.2d 585, 587 (CCPA 1973); *In re Bergel*, 292 F.2d 955, 956-57 (CCPA 1961); *In re Fridolph*, 30 CCPA 939, 942 (1943)) (“There is no single case in which the Federal Circuit announced the teaching-suggestion-motivation test. Rather the test has developed from a long line

## Wegner, Post-KSR Chemical Obviousness

---

Property Law Association.<sup>136</sup> Other *amici* WARF *et al.*<sup>137</sup> and Tessera *et al.*<sup>138</sup> cite to *Fridolph* as well, although the latter exaggerates by stating that the CCPA of the 1940's "regularly applied" the suggestion test – which obviously is untrue as the *holdings* of *Fridolph* and other 1940's cases *denied* patentability.<sup>139</sup> *Fridolph* was cited in several *amici curiae* filings as the earliest CCPA case establishing the requirement for a suggestion in the prior art to sustain a prior art rejection.<sup>140</sup>

---

of cases, some of which even pre-date the enactment of Section 103, which recognize the importance of protecting the patent evaluation process from the scourge of hindsight analysis.”).

<sup>136</sup> American Intellectual Property Law Association *KSR* merits amicus brief, p. 12 (citing *In re Bergel*, 292 F.2d 955, 956-57 (CCPA 1961)) (“Even before *Graham*, in keeping with this Court's decisions the CCPA required a reason to combine prior art disclosures.”).

<sup>137</sup> Brief of Wisconsin Alumni Research Foundation, Regents of the University of California, Board of Regents of the University of Texas System, Washington Research Foundation, Science and Technology Corporation @ UNM, Rensselaer Polytechnic Institute, and Research Corporation Technologies, Inc.

<sup>138</sup> Tessera, Inc., Qualcomm Inc., and AmberWave Systems Corp., p. 5.

<sup>139</sup> *Id.* (“During the 1940s, the [CCPA] *regularly applied* a variation of that standard to determine whether references were properly combined. *See, e.g., In re Fridolph*, 134 F.2d 414, 416 (C.C.P.A. 1943) (“[I]n considering more than one reference, or a reference alleged not to be in the art involved, the question always is: does such art suggest doing the thing which the appellant has done? We think the art of record clearly suggests doing what appellant has done.”))(emphasis added).

<sup>140</sup> *KSR* merits *amici curiae* briefs supporting Respondent by Tessera, Inc., Qualcomm Inc., and AmberWave Systems Corporation; and the Federal Circuit Bar Association.

In terms of citations to and quotations from cases that have *holdings* which are directly against the position of the advocate, *Pfizer v. Apotex* is a classic example, with various briefs of both the patentee party and supporting *amici* citing *O'Farrell* and *Eli Lilly* against an “obvious to try” invalidity theory – where the holding in each case was invalidity of the patent in question.

### C. Uniform Judicial Criticism of String Citations

Judge Aldisert is quoted as saying that string citations are “generally irritating and useless.”<sup>141</sup> The Sixth Circuit Chief Judge as one of his major criticisms of briefing at his court notes the use of “excessive string cites[.]”<sup>142</sup> A Fifth Circuit judge notes that she and her colleagues “are unimpressed by string cites.”<sup>143</sup> One of her colleagues advises counsel to “[a]void long ‘string cites’: We

---

<sup>141</sup> Alex Glashausser, *Citation and Representation*, 55 Vand. L. Rev. 59, 112 n. 483 (2002), citing “*Lopez v. Constantine*, 76 Fair Empl. Prac. Cas. 95, 96 (S.D.N.Y. Dec. 22, 1997)(denigrating party's citation of certain cases as ‘only in ‘string citation’ form’); Ruggero J. Aldisert, *Winning on Appeal* § 13.3.1, 243 (rev. 1st ed., NITA 1996) (‘Don't use string citations. They are generally irritating and useless.’).”

<sup>142</sup>Bryan A. Garner, *Judges on Briefing: A National Survey*, 8 Scribes J. Legal Writing 1, 19 (2001-2002)(quoting Hon. Boyce F. Martin, Jr.)(“[M]ore than half the briefs that are filed are incomprehensible; they contain either excessive string cites or not enough factual information to understand why they are objecting to the lower court's decision.”).

<sup>143</sup>Garner, 8 Scribes J. Legal Writing at 30 (quoting Hon. Edith H. Jones)(“Appellate judges read the briefs; we are familiar with basic legal principles and are unimpressed by string cites and hornbook generalities.”)

do not count the number of cases and statutes cited any more than we weigh the briefs (except subconsciously to favor the shorter, lighter ones).”<sup>144</sup>

“Briefs that resort to string citations may show off research skills, but they do not accomplish much more.”<sup>145</sup> DuVivier explains that string citations “can so seriously interrupt an argument that they cause readers to lose the thread entirely.”<sup>146</sup> The gist of an argument is lost “if it is shrouded in a forest of citations and squirreled away” amidst string citations.<sup>147</sup>

The Supreme Court has pejoratively referred to arguments that rely upon string citations: “The battle of the string citations can have no winner.”<sup>148</sup> “The ... majority followed its ... dictum with a string citation of three cases, none of which

---

<sup>144</sup>Jacques L. Wiener, Jr., *Ruminations from the Bench: Brief Writing and Oral Argument in the Fifth Circuit*, 70 Tul. L. Rev. 187, 197 (1995).

<sup>145</sup>Andrew H. Baida, *Writing a Better Brief: The Civil Appeals Style Manual of the Office of the Maryland Attorney General*, 3 J. App. Prac. & Process 685, 685 (2001).

<sup>146</sup>K.K. DuVivier, *The Scrivener: Modern Legal Writing: String Citations – Part II*, 29-SEP Colo. Law. 67 (September 2000) (citing DuVivier, *String Citations–Part I*, 29 The Colorado Lawyer 83, at 83-84 (July 2000)) (“[S]trings of citations generally are not effective in briefs: they do not give readers enough specific information about each authority, and they can so seriously interrupt an argument that they cause readers to lose the thread entirely. Consequently, in most briefs, it is better to eliminate string citations and replace them with a more in-depth explanation of the one or two most relevant authorities.”).

<sup>147</sup>*Id.* at 68. (“In persuasive writing, readers need to be convinced that the authorities support the result. ... Readers may miss key information if it is shrouded in a forest of citations and squirreled away in what appears to be a parenthetical aside.”).

<sup>148</sup>*Smith v. Wade*, 461 U.S. 30, 93 (1983)(O’Connor, J., dissenting).

sustains its point.”<sup>149</sup> “The majority ... offers an impressive-looking string citation in support of the claim.”<sup>150</sup> “[I]f a court can find an undue burden simply by selectively string-citing the right social science articles, I do not see the point of emphasizing or requiring ‘detailed factual findings’ in the District Court.”<sup>151</sup> “The Court’s string citations to our prior cases, many of which yielded only plurality opinions ... simply highlight the lack of authority for the path that the Court now takes.”<sup>152</sup>

### X. THE FUTURE

Taken alone or together, *KSR* and *Pfizer v. Apotex* present challenges to the patent community both within the specialized field of organic chemistry but also in other fields as well.

Considering first the field of obviousness of new chemical compounds, it is imperative that the Federal Circuit maintain a predictable body of law, particularly where, as here, the entire field of organic chemistry research into new chemical entities for pharmaceutical and agricultural and other product are at stake. The procedural approach of *Dystar* that is carried forward in *Pfizer v. Apotex* represents yet another area of major concern that the court must address. Whether the panel opinion in *Pfizer v. Apotex* will be rendered a nullity by the Supreme Court remains to be seen.<sup>153</sup> If not, it remains to be seen whether panels will follow the controlling precedent under *South Corporation* or follow a balkanized approach

---

<sup>149</sup>*U.S. v. Mead Corp.*, 533 U.S. 218, 254 (2001)(Scalia, J, dissenting).

<sup>150</sup> *Carmell v. Texas*, 529 U.S. 513, 568 (2000)(Ginsburg, J., joined by Rehnquist, C.J., O’Connor, Kennedy, JJ., dissenting).

<sup>151</sup> *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 991 n.6 (1992) (Scalia, J., joined by Rehnquist, C.J, White, J., Thomas, J., concurring in the judgment in part and dissenting in part).

<sup>152</sup> *Caldwell v. Mississippi*, 472 U.S. 320, 350 (1985)(Rehnquist, J., joined by Burger, C.J., White, J., dissenting).

<sup>153</sup> A petition for vacatur is pending, *supra* note 89.

under the rationale of *Dystar* that states a “danger inherent in focusing on isolated dicta rather than gleaning the law of a particular area from careful reading of the full text of a group of related precedents for all they say that is dispositive and for what they hold. When parties ... do not engage in such careful, candid, and complete legal analysis, much confusion about the law arises and, through time, can be compounded.”<sup>154</sup>

Beyond organic chemistry, there is bound to be at least some degree of uncertainty as to the precise meaning of the “obvious to try” line of case law which, even before *KSR*, had been completely misunderstood by a fair percentage of the patent community, and completely misunderstood in *Pfizer v. Apotex*. How the “obvious to try” case law sorts itself out remains to be seen. In technologies other than organic chemistry there is bound to be fallout from the two cases as well. In the field of biotechnology, a virtually *per se* of patentability for new biotechnology entities had been crafted in *Deuel*.<sup>155</sup> *Deuel* has been the subject of heavy criticism from the scholarly community and is cynically discussed in a dissent in the *Fisher* case.<sup>156</sup> It may be expected that in the wake of *KSR* there will be a renewed challenge to the viability of *Deuel*.

---

<sup>154</sup>*Dystar*, *supra* note 111.

<sup>155</sup> *In re Deuel*, 51 F.3d 1552 (Fed.Cir.1995).

<sup>156</sup> *In re Fisher*, 421 F.3d 1365, 1381-82 (Fed. Cir. 2005)(Rader, J., dissenting) (“Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions. See *In re Deuel*, 51 F.3d 1552 (Fed.Cir.1995); Martin J. Adelman et al., *Patent Law*, 517 (West Group 1998) (commenting that scholars have been critical of *Deuel*, which ‘overly favored patent applicants in biotech by adopting an overly lax nonobviousness standard.’ (citing Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 Harv. J.L. & Tech. 53 (1996))); Philippe Ducor, *The Federal Circuit and In re Deuel: Does § 103 apply to Naturally Occurring DNA?*, 77 J. Pat. & Trademark Off. Soc’y 871, 883 (Nov.1995) (‘The Court of Appeals for the Federal Circuit could have formulated its opinion in only one sentence: ‘ 35 U.S.C. § 103 does not apply to newly

## Wegner, Post-KSR Chemical Obviousness

---

It is unlikely that the Supreme Court will revisit *Graham* and *KSR* for several years, if not – as in the past – decades. It is incumbent upon the Federal Circuit to move cautiously forward, panel by panel, and, where necessary, to convene *en banc* where necessary to provide the uniform body of patent jurisprudence to vitally needed by the high technology communities.

A positive sign from the Court and hopefully an emerging trend is the *sua sponte* grant of *en banc* consideration to cases even before a panel has issued a decision. This has taken place within the past year both through an addendum to a panel opinion in *DSU*<sup>157</sup> and through a full blown *en banc* hearing in *Seagate*.<sup>158</sup> No matter the *modus operandi*, a more fundamental understanding of the *holdings* of the case law and the older but still precedential leading cases must be undertaken by the parties and *amici* seeking a sound evolution of the body of patent law.

---

retrieved natural DNA sequences.’ ’); Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 Santa Clara Computer and High Tech. L.J. 1, 44-45 (Feb.1997) (‘This amounts to a practical elimination of the requirement for nonobviousness for these products, even when all the information necessary to discover them is previously available.’); *see also* over fifty additional articles critical of *Deuel* in the ‘Citing References’ tab for *Deuel* on Westlaw. Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used world wide for such assessments (other than in the United States), namely inventive step or obviousness.”).

<sup>157</sup> *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006)(*en banc* in part)(Rader, J.) (“Opinion for the court [as to this part only] filed by Circuit Judge RADER, with NEWMAN, LOURIE, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges, join. Concurring opinion filed by MICHEL, Chief Judge, and MAYER, Circuit Judge.”).

<sup>158</sup> *In re Seagate Technology, LLC*, 214 Fed.Appx. 997 (Fed. Cir. 2007)(*en banc*)(order). The *en banc* hearing was held June 7, 2007; the case is pending awaiting decision.