SELECTED ASPECTS OF THE IMPACT OF PATENT APPLICATION DRAFTING AND PROSECUTION ON PATENT LITIGATION ISSUES

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I. INTRODUCTION

Issues often arise during patent prosecution which impact the course of subsequent patent litigation. This paper discusses several specific areas in which decisions made during prosecution may particularly impact subsequent litigation.

II. CLAIM CONSTRUCTION ISSUES

A. Background

Claim construction is a matter of law.¹ Proper claim construction entails an analysis of the intrinsic evidence: *i.e.*, the claim language, the written description in the specification, and the prosecution history.² The prior art cited during the examination of the patent is also part of the intrinsic evidence.³ If the meaning of a claim term is unambiguous from the intrinsic evidence, then a court may not rely on extrinsic evidence for purposes of claim construction.⁴ However, extrinsic evidence may be used in claim construction to: (1) resolve any ambiguity in the

intrinsic record; and (2) "ensure that [the judge's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art."⁵

With respect to the claim language itself, the words of the claims govern and are generally given their ordinary and customary meaning.⁶ The focus of this analysis is "what one of ordinary skill in the art at the time of the invention would have understood the term to mean."

However, there are situations in which a claim term may be given a definition other than what one of ordinary skill in the art would give it.⁸ An inventor is entitled to be his or her own lexicographer; thus, where it is apparent from the patent and prosecution history that the inventor intended a meaning different from that understood by one ordinarily skilled in the art, the inventor's meaning governs.⁹

Other claims in a patent can also be a valuable source of enlightenment as to the meaning of a claim term. ¹⁰

Thus, for example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent This is because, under the doctrine of claim claim. 11 differentiation, claims of a patent are presumed to have different scopes, particularly as between independent and dependent claims. 12 While the doctrine of claim differentiation provides a presumption that the claims in a patent have different scopes, it is "not a hard and fast rule of In particular, "the doctrine of claim construction."13 differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence."¹⁴

Although it is impermissible to import limitations from the preferred embodiments described in the specifications into a claim, a claim term should not normally be interpreted in such a manner as to exclude a preferred embodiment.¹⁵

The patent specification is always relevant to claim construction, because pursuant to 35 U.S.C. § 112, ¶ 1, it is the specification that must provide a written description of the invention in such full, clear and exact terms as to allow a person of ordinary skill in the art to make and use the invention. Thus, "a claim must be read in view of the specification of which it is part." Usually, the patent specification is the single best guide to the meaning of a disputed term. However, it is impermissible to read a limitation from the specification into a claim, except in the case of claims reciting means-plus-function or step-plus-function limitations governed by 35 U.S.C. § 112, \P 6. ¹⁸

The prosecution history of a patent is also important for claim construction, because "it may contain contemporaneous exchanges between the patent applicant and the PTO about what the claims mean." Arguments and amendments made during the prosecution of a patent application ... as well as the specification and other claims must be examined to determine the meaning of terms in a

claim."²⁰ Moreover, statements made in the prosecution history may modify the ordinary meaning of a claim term.²¹ A court may also consider the prior art cited in the prosecution history, which may contain clues as to what the claims do not cover.²²

If the claim language remains genuinely ambiguous after consideration of the intrinsic evidence, reliance upon extrinsic evidence to construe the claims is appropriate, but only to the extent that such reliance does not "contradict the claim construction unambiguously apparent from the intrinsic evidence." In addition, extrinsic sources which may be used include dictionaries, treatises and encyclopedias. However, the use of such extrinsic sources to interpret claims must be done with caution, because "the resulting definitions ... do not necessarily reflect the inventor's goal of distinctly setting forth his invention as a person of ordinary skill in that particular art would understand it." In addition, opinion testimony, "whether by an attorney or artisan in the field of technology to which the

patent is directed ... should be treated with utmost caution, for it is no better than opinion testimony on the meaning of statutory terms."²⁶

B. Some Examples of Claim Construction Issues Arising During Prosecution

In *Microsoft Corp. v. Multi-Tech Systems*, *Inc.*, ²⁷ the claims at issue were directed to a communication system. The invention summary in the specification expressly stated that the disclosed communication system operated over a standard telephone line, although it did not rule out the possibility of the use of a standard telephone line and the Internet. However, the Federal Circuit held that the summary of the invention was a definitive, unambiguous limitation of the invention to the transmission of data packets over a telephone line, not the Internet; thus applicant had disclaimed use of the invention with the Internet. ²⁸

In Laryngeal Mask Co. v. Ambu A/S, ²⁹ the patent at issue claimed a laryngeal mask airway device used to deliver anesthetic gas during surgery. The claim at issue

was construed by the district court to <u>not</u> require that the reinforced area of the "cuff" element be connected to the "backplate" element of the device; however, under this construction the district court found the claim invalid for lack of written description because the patent specification only described a thicker and stiffer cuff portion connected to the backplate. However, the Federal Circuit reversed, holding that the summary section of the patent described a reinforcement incorporated into the cuff and did not require the cuff to be connected to the backplate. Thus, the summary section provided a written description of the cuff not requiring connection to the backplate.

In *Chef America, Inc. v. Lamb-Weston, Inc.*, ³⁰ the claim at issue, as originally drafted, was directed to a process for making dough products which required "heating...batter-coated dough to first set said batter and then subsequently melt said shortening flakes...." In response to a nonenablement rejection, Applicant amended the claim to require "heating the resulting batter-coated dough *to* a

temperature in the range of about 400° F - 850° F for a period of time ranging from about 10 seconds – 5 minutes to first set the batter...." (Emphasis added). Although examples in the specification described heating the dough in an oven *at* temperatures of 680° F - 850° F, the Federal Circuit held the claim to require that the dough itself, not the oven temperature, must be heated to 400° F - 850° F, even though the dough would be burned to a crisp (*i.e.*, the claim would be inoperable) under this claim construction. "[W]e construe the claim as written, not as the patentees wish they had written it. As written, the claim unambiguously requires that the dough be heated to a temperature range of 400° F - 850° F."³¹

In *Haemonetics Corp. v. Baxter Healthcare Corp.*, ³² the claim at issue was directed to a centrifugal unit for separating red blood cells from human blood by aphaeresis. More specifically, the claim read in relevant part as follows:

A centrifugal unit comprising a

centrifugal component and a plurality of tubes...wherein said unit includes:

. . .

a plurality of channels extending radially in the base of the centrifugal unit...with the centrifugal unit having a radius between 20-50 mm and a height between 75-125% of the radius.

Defendants argued that "centrifugal unit" must mean the combination of centrifugal component (*i.e.*, vessel) plus tubing throughout claim. Patentee argued that "centrifugal unit" in the context of the dimensional limitations of the claim referred to the vessel alone. To support this argument, patentee further argued that: (i) the claim preamble definition of "centrifugal unit" as including the vessel and tubing was merely a statement of the invention's intended field of use; (ii) the specification clearly stated that the dimensional limitations referred to the vessel alone; and (iii) construing "centrifugal unit" to include the vessel plus tubing would exclude every embodiment described in the specification and ignore the invention's

goals (i.e., small size, light weight and economic disposability).

The Federal Circuit held that "centrifugal unit" must mean the combination of the vessel and tubes, because:

- (i) the claim unambiguously defined "centrifugal unit" as "comprising" a centrifugal component and a plurality of tubes;
- (ii) the body of the claim further recites "the centrifugal unit," not "the centrifugal component" and not "a centrifugal unit;"
- (iii) the specification described a first embodiment where the "centrifugal unit" has a radius of 25-50 mm and a height of 75-125% of the radius, and a second embodiment in which a centrifugal unit "includes a centrifugal component and a plurality of tubes" where the centrifugal unit has a radius between 25-50 mm and a height between 75-125% of the radius. This inconsistent language means that "the centrifugal unit" must have different meanings in different claims;
- (iv) even if this construction yields an absurd result, "we do not redraft claims to contradict their plain language to avoid a nonsensical result";

(v) even if "error" occurred in drafting of the claim, it is what the patentee claimed and what the public is entitled to rely on.

In *Rhodia Chemie v. PPG Indus, Inc.*, ³³ the claims at issue were directed to spheroidal precipitated silica particulates and their process of manufacture. The claims used the terms "dust-free and nondusting." The Federal Circuit held that these terms should be defined by the level of dust created by reference to a particular test described in the written description.

In Conoco Inc. v. Energy & Envtl. Int'l LC,³⁴ the claim at issue was to a process for preparing a friction reducing agent for oil and gas pipelines. The claim stated that the process comprised, inter alia, combining coated polymer particles with a thickening agent selected from the group consisting of water and water-alcohol mixtures (i.e., a Markush group). The accused process used a thickening agent which was a mixture of 8-15% water, 80-82% ethanol and the remainder MIBK (not an alcohol). The MIBK was added to avoid paying liquor taxes and to avoid human

consumption. The Federal Circuit held that the MIBK was an impurity, and because the "consisting of" language does not exclude impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the "consisting of" list, the accused process was within the scope of the claim, despite the presence of MIBK.

In Dippin' Dots v. Mosey, 35 the claimed process comprised the steps of freezing an alimentary composition into "beads" which were then served. specification described the beads as having a "smooth, spherical appearance." The accused process formed both spheres and irregular or odd shaped particles such as popcorn-shaped particles. The Federal Circuit construed "beads" to be limited to only spherical particles, and held that the accused process did not infringe, despite "comprising" transitional language of the claim. "The presumption (that the list of claim elements is nonexclusive) raised by the term "comprising" does not reach into each of the six steps to render every word and phrase thereon open13

ended — especially where, as here, the patentee has narrowly defined the claim term it now seeks to have broadened."³⁶

In *Primos, Inc. v. Hunter's Specialties, Inc.*, ³⁷ the claim at issue was directed to "a game call for use in a person's mouth, comprising ...a first roof-of-mouth engaging yieldable sealing portion" In construing the claim, the Federal Circuit observed that because the terms "engaging" and "sealing" are both expressly recited in the same claim, they cannot mean the same thing, because otherwise one of the terms would be superfluous. ³⁸ In addition, if "engaging" were construed to mean "sealing," a preferred embodiment in the patent would be excluded because the figures in the patent show the membrane as not sealing with the roof of the mouth. Claims should not normally be interpreted to exclude a preferred embodiment. ³⁹

In *Cohesive Technologies Inc. v. Water Corp.*, ⁴⁰ the claim at issue required a HPLC column containing particles having average diameters "greater than about 30 microns." The specification of the patent disclosed,

in the examples, that the desired turbulent flow could not be attained with particles having a nominal diameter of less than 20 microns. Elsewhere in the specification, it was disclosed that particles having a nominal diameter of 50 microns had an actual mean diameter of 42.39 microns (i.e., a 15.22% variance). Based on this information, the Federal Circuit found that "about 30 microns" meant 30 microns +/- 15.22% (i.e., 25.434 - 34.566 microns). In addition, because nominal diameters of less than 20 microns failed to achieve turbulent flow, "about 30 microns" could not include 20 microns + 15.22% (*i.e.*, 23.044 microns). Moreover, in the range between 23.044 – 25.434 microns, the Federal Circuit applied a functional limitation: in that range, "about 30 microns" means a particle of sufficiently large size to assure that a HPLC column containing the particles is "capable of achieving turbulence."⁴¹

C. Section 120 Issues

In Encyclopedia Britannica Inc. v. Alpine

Elecs. Of America, Inc., 42 the Federal Circuit strictly

construed 35 U.S.C. § 120 and held that, because an intermediate patent application in the chain of continuity failed to claim priority to an earlier U.S. application (which in turn claimed priority to a foreign patent application), the patents in suit based upon a later filed U.S. patent application in the chain could not properly claim priority to the earliest application in the chain (which pre-dated the anticipatory foreign patent application published by Britannica). Accordingly, the patents were held invalid as anticipated by Britannica's own published foreign patent application.

D. Divisional Applications and Section 121

Pfizer Inc. v. Teva Pharmaceuticals USA, Inc. 43 presents the issue of the scope of regarding the "safe-harbor" provision of 35 U.S.C. § 121. The third sentence of Section 121 provides a safe harbor to patents that issue on applications filed as a result of a restriction requirement:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

Pfizer first filed the '594 application, which included claims directed to the pharmaceutical compound celecoxib itself, as well as claims directed to a pharmaceutical composition containing celecoxib and methods of using celecoxib. After a restriction requirement was issued by the Examiner, Pfizer elected the claims to celecoxib itself for prosecution in the '594 application, which eventually issued as the '823 patent.

In addition, after the restriction requirement but before the '823 patent issued, Pfizer filed a series of other applications claiming priority to the '594 application and covering the non-elected subject matter, including: (i) a divisional application which included the restricted-out composition claims, which issued as the '165 patent; and

(ii) a continuation-in-part ("CIP") application which included the restricted-out method of use claims. The CIP application eventually issued as the '068 patent.

In subsequent litigation against Teva, Pfizer asserted certain patents, including the '823 patent and the '068 patent, and Pfizer prevailed in the district court. On appeal, Teva argued, inter alia, that the asserted method of treatment '068 patent (which issued from the CIP application) was invalid for obviousness-type double patenting in view of the pharmaceutical composition claims of the '165 patent (which issued from the divisional application). Pfizer countered that, although the '068 patent issued from a CIP application, it was in effect a divisional application for purposes of Section 121, and therefore the safe-harbor provision of Section 121 precluded the use of the '165 patent as a reference against the '068 patent in an obviousness-type double patenting analysis. The Federal Circuit disagreed, finding that because the safe-harbor provision of Section 121 refers only to "divisional applications," the '165 patent could be used as a reference against the '068 patent for obviousness-type double patenting, and that the asserted claims of the '068 patent (which was based upon a CIP application) were invalid for obviousness-type double patenting in view of the claims of the '165 patent.⁴⁴

Additional issues regarding Section 121 were addressed in Amgen, Inc. v. Hoffman-LaRoche Ltd., 45 In Amgen, the claims of the original patent application (the '298 application) were directed to polypeptides (Group I), DNA (Group II), plasmids (Group III), cells (Group IV), pharmaceutical compositions (Group V) and assays (Group VI). After a restriction requirement was issued by the Examiner, Amgen elected to prosecute the Group II claims in the '298 application, which eventually issued as the '008 patent.

In addition, after the restriction requirement but before the '008 patent issued, Amgen filed two continuation applications (the '178 and '179 applications) containing the non-elected groups. The '178 application eventually issued as the '933 patent, and the '422, '349, '868 and '698 patents eventually issued from the '179 application.

In the subsequent litigation against Hoffman-LaRoche ("H-L") Amgen asserted the '933, '422, '868, '698 and '349 patents against H-L, and Amgen prevailed in the district court. On appeal, H-L asserted, inter alia, that the '349, '933 and '422 patents were invalid for obviousnesstype double patenting in view of the '008, '868 and '698 patents, because Section 121 does not insulate the '349, '933 and '422 patents from obviousness-type double patenting, as the '349, '933 and '422 patents issued from continuation applications, not divisional applications. Amgen countered that patents which issue directly from continuation applications (e.g., the '349, '933 and '422 patents) are eligible for Section 121 protection as long as the other requirements of a divisional application are met, and relied on the MPEP Section 201.06 definition of "divisional application:"

A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division."

In other words, Amgen contended that although the '349, '933 and '422 patents issued from continuation applications, they were "divisional applications" as defined by the PTO, and therefore the safe-harbor provision of Section 121 precluded the use of the '008, '868 and '698 patents as references against the '349, '933 and '422 patents in an obviousness-type double patenting analysis. The Federal Circuit disagreed, holding that the safe-harbor provision of Section 121 is limited to divisional applications, continuation and does not apply applications.46

In Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc., 47 the parent '947 application was subject to a restriction requirement in which the Examiner split the

claims into Groups I through X. The Applicant elected Groups II and IX for prosecution, and later filed a divisional application (the "197 application) claiming Groups VIII and X. Subsequently, Applicants also filed another divisional application (the '671 application) which claimed Groups I and III through V. The parent '947 application issued as the '374 patent, the divisional '197 application issued as the '086 patent and the divisional '671 application issued as the '812 patent.

In subsequent litigation, Boehringer Ingelheim ("BI") asserted the '812 patent against Barr. The district court held that the claims of the '812 patent were invalid for obviousness-type double patenting in view of the claims of the '086 patent.

On appeal, the Federal Circuit held that the safe-harbor provision of Section 121 applied to the '812 patent. More specifically, the Federal Circuit held that:

(i) Section 121 applies to a divisional application filed from a divisional application filed from a parent application in

which a restriction requirement was entered; and (ii) the "as a result of" clause of Section 121 applied to both the '086 patent and the '812 patent, because none of the inventions claimed between the '374 patent, the '086 patent and the '812 patent crossed the Examiner's lines of demarcation of inventions identified in the restriction requirement. Thus, consonance was met and the '086 patent could not be used as a reference against the '812 patent under Section 121.⁴⁸

E. Product-By-Process Claims

In *Abbott Labs v. Sandoz Inc.*,⁴⁹ the Federal Circuit finally clarified the conflicting prior case law involving infringement of product-by-process claims, and explicitly held *(en banc)* that process terms in product-by-process claims serve as limitations in determining infringement, thus specifically overruling the Federal Circuit's prior decision in *Scripps Clinic & Res. Found v. Genentech, Inc.*⁵⁰ to the extent *Scripps Clinic* was inconsistent with this rule.

However, it should be noted that the validity of a product-by-process claim involves a different analysis. In *SmithKline Beecham Corp. v. Apotex Corp.*⁵¹ (which was not addressed in the *Abbott* decision), the Federal Circuit held that a product-by-process claim was invalid as anticipated by a prior art patent claiming the product, irrespective of the process limitations of the claim at issue. More particularly, the Federal Circuit held that "anticipation by an earlier product patent cannot be avoided by claiming the same product more narrowly in a product [by] process claim."⁵²

Even more recently, in *Amgen Inc. v*. *Hoffman-LaRoche Ltd.*, ⁵³ the Federal Circuit attempted to further explain the law with respect to the validity of product-by-process claims as follows:

In determining validity of a product-by-process claim, the focus is on the product and not on the process of making it.... That is because of the already described, long-standing rule that an old product is not

patentable even if it is made by a new process. As a result, a product-by-process claim can be anticipated by a prior art product that does not adhere to the claim's process limitation. In determining infringement of product-by-process claim, however, the focus is on the process of making the product as much as it is on the product itself. See Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1293 [90 USPQ2d 1769] (Fed. Cir. 2009) (en banc). In other "process terms words, product-by-process claims serve as limitations in determining infringement." Id. (quotation marks omitted). As a result, a product-by-process claim is not infringed by a product made by a process other than the one recited in the claim. Id.

The impact of these different analyses is significant. For product-by-process claims, that which anticipates if earlier does not necessarily infringe if later. That is because a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot

infringe a product-by-process claim. Similarly, that which infringes if later does not necessarily anticipate if earlier. That is because an accused product may meet each limitation in a claim, but not possess features imparted by a process limitation that might distinguish the claimed invention from the prior art. 54

F. Multiple Joint Infringement of Process Claim

In *Muniauction, Inc. v. Thomson Corp.*, 55 the patent at issue involved a process for electronic auctioning for fixed income financial instruments, in which the bidder performed at least one step of the claimed process, and the accused infringer (Thomson) performed the remaining steps in the process. Thus, although neither the bidder nor Thomson individually performed all the claimed process steps, the bidder and Thomson together performed all the claimed process steps. In analyzing whether the combined actions of the bidder and Thomson could be found to be direct infringement of the process claim, the Federal Circuit stated:

[W]here the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises "control or direction" over the entire process such that every step is attributable to the controlling party, i.e., the "mastermind." ... At the other end this multi-party of spectrum, mere "arm's-length cooperation" will not give rise to direct infringement by any party.⁵⁶

In view of the foregoing legal principle, the Federal Circuit stated that "the issue of infringement in this case turns on whether Thomson sufficiently controls or directs other parties (e.g., the bidder) such that Thomson itself can be said to have performed every step of the asserted claims."

Furthermore, the Federal Circuit stated that "the control or direction standard is satisfied in situations where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed

method."⁵⁷ The Federal Circuit held that "Thomson neither performed every step of the claimed methods nor had another party perform steps on its behalf, and Muniauction has identified no legal theory under which Thomson might be vicariously liable for the actions of the bidders. Therefore, Thomson does not infringe the asserted claims as a matter of law."⁵⁸

Note that that *Muniauction* rationale appears to apply only to method or process claims. For example, in *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, ⁵⁹ Claim 1 was directed to a computerized integrated data management system for tracking a patient incident comprising "a first module capable of dispatching an emergency transport crew . . ." and "a second module capable of receiving information from the first module and billing the patient appropriately . . .," as well as method claims directed to a method for using the system. Defendant emsCharts provided a program that charts patient information and provides integrated billing. Defendant Softtech program provides flight dispatch

software. The two defendants formed a strategic partnership, enabled their two programs to work together and collaborated to sell the two programs as a unit.

The Federal Circuit affirmed (following *Muniauction*) that, because there was insufficient evidence of "control" or "direction" by emsCharts or Softtech, there could be no joint infringement of the method claims. However, with respect to the system claims, the Federal Circuit suggested that emsCharts could have liability for sale of the joint software product due to emsCharts's sale of the joint software.

III. THE DOCTRINE OF EQUIVALENTS

The judicially created doctrine of equivalents ("DOE") exists to prevent the practice of "a fraud on a patent." However, the application of this somewhat metaphysical concept poses a formidable challenge to attorneys seeking to provide meaningful guidance to their clients regarding: (1) the potential liability for patent infringement; and (2) the likelihood of success if patent

litigation occurs. Fortunately, the modern case law provides us with a number of analytical tools which enable us to at least frame the DOE issue in a given instance, as discussed below.⁶¹

A. The Modern Doctrine of Equivalents: *Graver Tank*

In the 1950 landmark Supreme Court case *Graver Tank & Manufacturing Co. v. Linde Air Prods. Co.*, 62 the patent claimed an electric welding flux which was a combination of alkaline earth metal silicate (*e.g.*, magnesium silicate in the patented product) and calcium fluoride. In contrast, the accused flux contained manganese silicate, which is not an alkaline earth metal silicate because manganese is not an alkaline earth metal. 63 Thus, the issue squarely presented was whether manganese was an equivalent of the alkaline earth metal required by the claims. 64

The Supreme Court affirmed the finding of infringement under the DOE. In particular, the Court reviewed the trial record, which showed that:

- (1) Chemists familiar with the patented flux and the accused product testified that magnesium and manganese were similar in many of their reactions.
- (2) A metallurgist testified that alkaline earth metals are often found in manganese ores in their natural state and that they serve the same purpose in the patented and accused fluxes.
- (3) A chemist testified that "in the sense of the patent" manganese could be included as an alkaline earth metal.
- (4) The above testimony was corroborated by reference to recognized inorganic chemistry texts.
- (5) The use of manganese silicate as a flux material was disclosed in the prior art.
- (6) No evidence was shown that the accused infringer independently did research or experiments to obtain the flux, thus permitting the trial court to properly infer that the accused flux was the result of imitation rather than experimentation or invention. 65

Graver Tank foreshadowed many of the issues that continue to influence application of the DOE, such as:

- (1) the appropriate use of technical expert testimony to establish or refute the DOE;
- (2) claim construction of technical terms, and the interplay between such claim construction and the DOE analysis;
- (3) the impact of the disclosure of unclaimed alternative embodiments in the specification on the DOE analysis; and
- (4) the role of the prior art in establishing the claim's boundaries under the DOE.

B. The "All-Elements" Rule

In *Pennwalt Corp. v. Durand – Wayland, Inc.*,⁶⁶ the claims were directed to a fruit sorter using circuitry to provide feedback regarding fruit weight, fruit color and fruit position along the conveyer. The accused device used computer technology to sort fruit weight and color, but did not include any means to track fruit position.

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The Federal Circuit held there was no infringement under the doctrine of equivalents, because "the term 'equivalents' in the 'doctrine of equivalents' refers to 'equivalents' of the <u>elements</u> of the claim, not 'equivalents' of the claimed invention."

In Corning Glass Works v. Sumitomo Electric USA, Inc., 68 the claims were directed to composite optical fiber consisting of an inner core and an outer cladding layer, in which the core was positively doped and the outer layer was either doped or undoped, so that the refractive index ("RI") of the core was greater that the RI of the outer layer. The accused device achieved the same RI differential using an undoped core and a negatively doped outer layer.

The Federal Circuit held that the negatively doped outer layer in the accused device was equivalent to the positively doped core of the claim. For a finding of infringement under the doctrine of equivalents, "[a]n equivalent must be found for every limitation of the claim somewhere in an accused device, but not necessarily in a

corresponding component, although that is generally the case."69

C. The Hypothetical Claim Approach: Wilson Sporting Goods

Wilson Sporting Goods Co. v. David Geoffrey & Associates⁷⁰ represents a further significant development of the DOE analytical framework. In Wilson, the claimed invention was a dimpled golf ball. The issue before the Federal Circuit was whether the district court had properly found infringement under the DOE, given the existence of prior art disclosing dimpled golf balls. The Federal Circuit articulated a new alternative approach to the DOE analysis vís-a-vís the prior art:

Whether prior art restricts the range of equivalents of what is literally claimed can be a difficult question to answer. To simplify analysis and bring the issue onto familiar turf, it may be helpful to conceptualize the limitation the on scope of visualizing equivalents by hypothetical patent claim, sufficient in scope to literally cover the accused product. The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art. If not, then it would be improper to permit the patentee to obtain that coverage in an infringement suit under the doctrine of equivalents. If the hypothetical claim could have been allowed, then prior art is not a bar to infringement under the doctrine of equivalents. ⁷¹

The hypothetical claim approach is not mandatory. However, if employed, in addition to considering the patentability of the hypothetical claim in view of a single reference (*i.e.*, for anticipation under 35 U.S.C. § 102), references may be combined to prove that the hypothetical claim would have been obvious to one of ordinary skill in the art under 35 U.S.C. § 103 and thus would not have been allowed, thereby precluding application of the DOE. The *Wilson* hypothetical claim analysis does not envision application of a full-blown patentability analysis to a hypothetical claim. *Wilson* simply acknowledges that prior art limits the coverage available under the [DOE]."

traditional factors used in the obviousness determination, such as whether the prior art "teaches away" from the subject matter of the hypothetical claim and "secondary considerations" such as "failure by others" and "copying" in evaluation the obviousness of a hypothetical claim.⁷⁵

In addition, "[h]ypothetical claim analysiscannot be used to redraft granted claims in litigation by narrowing and broadening a claim at the same time." Moreover, the use of the hypothetical claim approach still requires that the patentee satisfy the requisite burden of proof of infringement. Thus, once the patentee establishes a *prima facie* case of infringement under the DOE using the hypothetical claim approach, the accused infringer must come forward with some evidence that the hypothetical claim reads on the prior art. However, "the ultimate burden of persuasion rests with the patentee to show that the hypothetical claim does not read on the prior art."

D. *Hilton Davis:* Back to the Basics

In *Hilton Davis Chemical Co. v. Warner- Jenkinson Co., Inc.*, ⁷⁸ both the Federal Circuit and the Supreme Court revisited some of the fundamental aspects of the DOE. The claimed invention was a process for purifying commercial dyes, which required that an aqueous solution was passed through a membrane under a hydrostatic pressure of approximately 200-400 psig, at a pH from approximately 6.0 to 9.0. The accused infringer's process operated at pressures of 200-500 psig and a pH of 5.

Evidence presented at trial also supported the jury's finding that the accused process sometimes operated in the 200-400 psig range, although some evidence was presented that pressure was as high as 500 psig. The Federal Circuit found that the record contained substantial evidence that the pressure element was satisfied both literally and under the DOE using the function-way-result ("FWR") test. 79

At trial, one of the inventors presented evidence that operating the claimed process at a pH of 5

would have the same effect as a pH of 6, and the defendant's expert agreed that the patented process would operate at a pH of 5. 80 During prosecution, the patentee had amended the claim to avoid prior art disclosing an ultra filtration process operating at a pH above 9. No explanation was given in the file history as to why the lower pH limit of "approximately 6.0" was specifically introduced into the claim, although Judge Nies, in her dissent, noted that the Examiner required the specific pH range of 6-9 to be added to the claim to overcome prior art. 81 The Federal Circuit held that substantial evidence existed that a pH of 5 was an equivalent of the claimed pH of 6–9. 82

On appeal, the Supreme Court reviewed several different aspects of the DOE, and held:

- The DOE must be applied to individual claim elements, not the invention as a whole.⁸³
- The intent of the accused infringer is irrelevant to application of the DOE.⁸⁴

- a claimed element is objective evidence in determining whether there is infringement under the DOE, and independent experimentation by the accused infringer is probative of knowledge of such interchangeability. However, the Court found the Federal Circuit's explanation of the relevance of "copying" and "designing around" to the insubstantial differences inquiry as "leav[ing] much to be desired."
- The determination of equivalency is made at the time of infringement, not the issue date of the patent. 86
- Equivalents may include, but are not limited to,
 those disclosed in the patent but not claimed.⁸⁷
- Prosecution history estoppel limits the extent to which the DOE may be applied. A rebuttable presumption exists that a claim amendment was made for a substantial reason relating to

patentability (thus invoking prosecution history estoppel). This presumption may be overcome if the patentee gave an appropriate reason for the amendment during prosecution demonstrating that the amendment was not made for patentability reasons.⁸⁸

• Either the FWR or the "insubstantial differences" test may be used in the DOE analysis. 89

The Supreme Court reversed and remanded the case back to the Federal Circuit, for further proceedings consistent with the above, especially with respect to determination of the reasons the lower pH limitation was added to the claims in the context of prosecution history estoppel, and to insure that meaning for each element of the claims was preserved. The Federal Circuit, in turn, remanded the case back to the district court for an inquiry to ascertain whether the patentee could rebut the presumption that the lower pH limitation of 6.0 was added to the claim for

a purpose relating to patentability. If the presumption remained, prosecution history estoppel would preclude application of the DOE to the accused process. 91

D. Prosecution History Estoppel: The Festo Analysis

The doctrine of equivalents is also limited by the doctrine of prosecution history estoppel. The entire record of proceedings in the PTO, including representations made to the Examiner that the invention is patentable, are included in a patent's prosecution history. 92 "Prosecution history estoppel... preclud[es] a patentee from regaining, through litigation, coverage of subject matter relinquished during prosecution of the application for the patent."93 Thus, "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel."94 Accordingly, prosecution history estoppel is not limited to amendments intended to narrow the patented invention's subject matter, e.g., to avoid prior art, but may apply to a narrowing amendment made to satisfy any requirement of patent law, including the utility, novelty and nonobviousness

requirements of 35 U.S.C. §§ 101-103, respectively, and the written description, enablement and best mode requirements of 35 U.S.C. § 112. 95

However, prosecution history estoppel is not a per se complete bar to the assertion of infringement against all equivalents of the amended claim element. Instead, the reasons for the narrowing amendment must be examined to determine if the particular equivalent in question has been surrendered. The patentee bears the burden of proving that an amendment did not surrender the particular equivalent in question. Thus, a patentee's decision to narrow the claims by amendment is presumed to be a general disclaimer of the territory between the original claim and the amended claim. If the patentee is unable to rebut this presumption by explaining the reason for amendment, prosecution history estoppel applies and bars the application of the doctrine of equivalents as to that claim element. ⁹⁶

The presumption that prosecution history estoppel bars application of the doctrine of equivalents may

met: (1) the patentee demonstrates that the alleged equivalent would have been unforeseeable at the time the narrowing amendment was made;⁹⁷ (2) the patentee demonstrates that the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) another reason exists that the patentee could not reasonably have been expected to have described the insubstantial substitute in question.⁹⁸

With respect to the first criterion, an objective inquiry is presented as to the forseeability of the alleged equivalent to one of ordinary skill in the art at the time the amendment was made. Accordingly, if the alleged equivalent represents later-developed technology, or technology that was not known in the relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, is more likely to have been foreseeable. More particularly, if the alleged equivalent was known in the prior art in the field of the

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invention when the amendment was made, it should have been foreseeable at the time of the amendment. 99

With respect to the second criterion, the relevant inquiry as to "tangentialness" is whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent. This is also an objective inquiry, and is for the court to determine from the prosecution history without the introduction of additional evidence, unless necessary to interpret the prosecution history. ¹⁰⁰

With respect to the third criterion, it is narrow in scope. Thus, this criterion may be satisfied when there was some reason, such as the shortcomings of language that prevented the patentee from describing the alleged equivalent when narrowing the claim. If at all possible, analysis of this criterion should be limited to the prosecution history record. Thus, where the alleged equivalent was in the prior art at the time of amendment, this criterion cannot be relied upon to

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overcome the presumption that prosecution history estoppel applies. 101

In *Talbert Fuel Systems Patents Co. v. Unocal Corp.*, ¹⁰² the claim at issue was directed to liquid gasoline. During prosecution, prior art was cited which disclosed gasoline having an upper boiling limit in the range of 390°–420°F. Applicant argued that its claimed gasoline was distinguishable from the prior art, but also amended the claim at issue to recite a boiling point range of 121°–345°F. The Federal Circuit found that the amendment was a presumptive surrender of gasoline boiling in the range between 345°F and the prior art's lower range of 390°F, and that the patentee had not overcome the presumption. ¹⁰³

Ericsson, Inc. v. Harris Corp. 104 highlights the difficulties which can arise in trying to determine if the Festo analysis is required. In Ericsson, the claim was directed to an apparatus for supplying power to a telephone set. During prosecution, the portion of the claim at issue was amended as follows:

...which, by the control signals, [effectively disconnects] disables the speech signal amplifiers and [actively connects] enables the auxiliary amplifiers so that the speech signal amplifiers, which require power, only supply power to the telephone set when the receiver is off its cradle and a call can be made.

The majority held that *Festo* was not invoked because the equivalence question was limited to whether the speech signal amplifiers only supply power to the telephone set when the receiver is off its cradle, and this claim limitation was never amended. However, in dissent, Judge Newman argued that the claim clause that states the conditions under which power is supplied to the telephone set when the receiver is on its cradle was amended for reasons of patentability (*i.e.*, to respond to § 112 and anticipation rejections), and therefore the *Festo* analysis should have been invoked. In Judge Newman's view, the amendment narrowed the conditions under which power is supplied to the

telephone set, and therefore the *Festo* rebuttable presumption applied.

It should also be noted that the Festo presumption applies to all claims containing a narrowed limitation, even if other claims containing that limitation were not amended during prosecution. This is the so-called "infectious estoppel" doctrine. 105 For example, in Deering Precision Instruments LLC v. Vector Distrib. Sys., Inc., original Claim 1 (directed to a portable scale) claimed "a sliding weight manually carried by [a] beam for movement along [a] scale." In response to an obviousness rejection, the original claim was deleted and an independent claim was inserted requiring that the sliding weight "be disposed in a plane defined by fulcrums" (this limitation was in dependent original Claim 3). The Federal Circuit held that the Festo presumption applied "to all claims containing the Zero Position Limitation, regardless of whether the claim was, or was not, amended during prosecution." "To do otherwise would be to exalt form over substance and distort the logic of this jurisprudence, which serves as an effective and useful guide to the understanding of patent claims." ¹⁰⁶

In Glaxo Wellcome, Inc. v. Impax Labs, *Inc.*, ¹⁰⁷ the claim at issue as originally filed was directed to a controlled release tablet. In response to a lack of enablement rejection, applicant amended the claims to recite that the tablet included hydroxypropyl methylcellulose ("HPMC"). The accused product was a controlled-release tablet which contained hydroxypropyl cellulose ("HPC"). The Federal Circuit conducted a Festo analysis and held that HPC was foreseeable, and therefore the Festo presumption was not rebutted. The Federal Circuit also noted that although the patent application did not disclose HPC, and therefore Glaxo could not have added HPC to the claims without drawing a new matter rejection, the use of HPC was nevertheless foreseeable, based upon prior art submitted by the patentee in an Information Disclosure Statement. The Federal Circuit also found Glaxo's tangentialness argument unpersuasive.

In *Glaxo*, the Federal Circuit also reaffirmed the "infectious estoppel" doctrine. Claim 1 of the patent as filed contained the HPMC limitation, and therefore was not amended during prosecution. However, the court held that the *Festo* bar applied to all claims containing the HPMC limitation, including those claims not amended.

In addition, the patentee may be estopped from relying upon the DOE not only when an amendment was made to overcome the patentability rejections, but also when an argument was made during prosecution that relinquishes coverage of particular subject matter. To invoke argument-based estoppel, the prosecution history must show a "clear and unmistakable" surrender of subject matter. *See, e.g., Cordis Corp. v. Medtronic Ave, Inc.*, 109 (affidavit submitted during prosecution which stated that wall thickness of prior art stent varied by 0.0001 inches was not a clear and unmistakable disclaimer excluding stents which varied in wall thickness by 0.0001 inches or more).

In Bayer AG v. Elan Pharm. Research Corp., 110 the claimed invention was a pharmaceutical composition containing nifedipine crystals of a defined specific surface area (SSA) of 1.0 to 4 m²/g. The defendant Elan's intended product had a SSA of greater than 5 m²/g, and in no event less than 4.7 m²/g. The relevant claims as originally filed claimed nifedipine crystals having a SSA of 0.5 to 6 m²/g. During prosecution, Bayer amended the claims to nifedipine crystals having a SSA of 1.0 to 4 m²/g, and stated in the amendment that this limitation was only being made in response to a rejection made under 35 U.S.C. §112 ¶ 1. However, Bayer also made affirmative statements during prosecution regarding the superiority of the SSA range of 1.0 to 4.0 m²/g, including statements made in various affidavits as to the superiority of the 1.0 to 4 m²/g The Federal Circuit held that "through its SSA range. statements to the PTO and the declarations it filed, Bayer made statements of clear and unmistakable surrender of subject matter outside" its claimed range. 111 The Federal

Circuit held that it was unnecessary to resolve the question of why Bayer amended its claims and whether its reasons were related to patentability because "regardless of why it amended its claims, when it did so it unmistakably surrendered coverage to SSAs above 4 m²/g."¹¹²

In *Honeywell International, Inc. v. Hamilton*Sundstrand Corp., 113 the Federal Circuit made it clear that an amendment adding a new claim limitation also constitutes a narrowing amendment that may give rise to prosecution history estoppel. The court used Warner-Jenkinson as an example: the addition of the term "at a pH from approximately 6.0 to 9.0" narrowed the scope of the claimed invention from processes conducted at any pH to those conducted between pH 6 and pH 9. The court further reasoned that to hold otherwise could lead to "clever claim drafting" where "astute practitioners could... elect to treat most, if not all, amendments as merely adding new claim limitations rather than narrowing preexisting ones." 114

Honeywell further held that rewriting a dependent claim into

independent form, coupled with the cancellation of the original independent claim, could also give rise to prosecution history estoppel. Honeywell presumptively surrendered all equivalents to an "inlet guide vane" limitation because it cancelled independent claims without this limitation and rewrote claims depending from these original independent claims in dependent format.

However, a patentee will not be precluded from claiming equivalence if a claim is amended to expressly include a term that was implicit in the original claim. In *Business Objects, S.A. v. Microstrategy, Inc.*, ¹¹⁶ the original claim (directed to an improvement for searching relational databases) claimed the step of "translating said user query into a structured query language equivalent language (SQL) equivalent statement." The new claim instead claimed the step of "generating queries in the predetermined query language." Because the "predetermined' limitation was implicitly contained in the original term, the amendment did not narrow the scope of the query engine means by expressly

stating that the query language must be 'predetermined' in the amended term." Accordingly, the patentee was not precluded from claiming equivalents of the "query engine" means in accused products.

E. The Interplay of Claim Construction and DOE: The "Claim Vitiation" Doctrine

In Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 118 the claimed invention was a process for the continuous production of high molecular weight polyethylene terephthalate ("PET"), which is used to make containers such as soft drink bottles. The claim required, in relevant part, that the PET granulate be crystallized under an "inert gas atmosphere." The accused product used heated air in the crystallization.

The Federal Circuit's claim construction analysis led to the finding that there was no literal infringement, because the specification required that the "inert gas atmosphere" have limited amounts of water and oxygen, and the claimed process required transfer of the

crystallized granulate while avoiding the addition of air. 119

In its DOE analysis, the court simply stated that "the claim language specifically excludes reactive gases — such as 'heated air' — from the scope of the claims," therefore there could be no infringement under the DOE. 120

In Phillips Petroleum Co. v. Huntsman Polymers Corp., 121 the claimed invention was "a block copolymer comprising" polymeric blocks of homopolymer and copolymer. The accused products were a mixture of polypropylene homopolymer molecules and random ethylene and propylene copolymer molecules, but the amount of block copolymer in the accused product was less than 0.01%. In its claim construction analysis, the Federal Circuit found that the "block copolymer" preamble was a meaningful claim limitation, and that the polymer blocks must be a significant portion of the molecules making up the block copolymer, based upon statements made in the prosecution history. Accordingly, the Federal Circuit found literal infringement. 122

The patentee also asserted that the accused product infringed under the DOE, and that the "block copolymer" limitation was added during prosecution to more clearly define the invention, and therefore prosecution history estoppel did not apply. However, the Federal Circuit sidestepped the estoppel issue, stating more broadly that it would be impermissible to apply the DOE in this case, because it "would effectively read the 'block copolymers' limitation out of the claims" Again, it appears the claim construction issue dominated the DOE analysis.

In *Tegal Corp. v. Tokyo Electron Co., Ltd.*, ¹²⁴ the claimed invention was an etcher device. Claim 1 recited but did not define a term "lower frequency," whereas Claim 7 and the specification provided an indication that it corresponds to frequencies "below about 1 MHz." The accused product was an A-IEM etcher, which was not designed to operate below 2 MHz. The Federal Circuit considered the specification, which did not assign any particular value to the expression "low frequency" except to

describe low frequency as "any frequency less than about 1 MHz," and construed this term to exclude frequencies above about 1 MHz. In light of this construction of "low frequency," the Federal Circuit found that A-IEM etcher did not literally infringe Claims 1 and 7. Moreover the Federal Circuit pointed out that the "A-IEM etcher cannot be found to infringe under the doctrine of equivalents because 2 MHz is twice what we have interpreted low frequency to mean, and a finding of equivalence would therefore vitiate that limitation." 125

In Lockheed Martin Corp. v. Space Systems/Loral, Inc., 126 the claim was directed to a satellite control system, comprising "means for rotating [a transverse] wheel in accordance with a predetermined rate schedule which varies sinusoidally over the orbit at the orbital frequency of the satellite...." The term "varies sinusoidally" was construed as a "variation in a sine-shaped curve that passes through zero." In other words, the wheel must slow to or pass through zero, and then rotate in the opposite

direction. The accused satellite had a rotating wheel which rotated about a non-zero speed bias, and therefore did not literally infringe, because it did not pass through zero, stop, and reverse direction. The Federal Circuit held that there was no infringement under the DOE, because such a finding would vitiate the claim limitation, as no feature of the accused satellite performed this function.

Similarly, in *Novartis Pharm Corp. v. Eon Labs Mfg., Inc.*, ¹²⁷ the Federal Circuit first held that "a hydrosol" was limited to a medicinal preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside of the body. The accused product did not literally infringe because it only formed a dispersion after ingestion. The Federal Circuit also found no infringement under the DOE, because permitting the scope of the claims at issue to encompass a dispersion formed inside the stomach would necessarily read the "hydrosol" limitation out of these claims, and therefore impermissibly vitiate the claim element "hydrosol." ¹²⁸

In Searfoss v. Pioneer Consolidated Corp., ¹²⁹ an "indirect connection" found in the accused product could not be an equivalent of the claimed "direct connection function." To hold otherwise would ignore the Court's construction of the claimed phrase as requiring a "direct, physical, rigid connection" and would effectively eliminate the claimed element in its entirety. ¹³⁰

In *Bicon, Inc. v. Straumann Co.*, ¹³¹ the Federal Circuit held that a concave, frusto-conical abutment was not equivalent to the convex, frusto-spherical basal abutment required by the claim at issue, because the claim recites a particular shape for the basal portion of the abutment that "clearly excludes distinctly different and even opposite shapes." ¹³²

In *Hoffer v. Microsoft Corp.*, ¹³³ the claim at issue was directed to a method by which remote users of computer terminals obtain data concerning economic activity from an index, and interactively post and receive messages concerning economic topics. More particularly, the claim

included a "whereby" clause which stated that "users ... are collectively able to concurrently engage in interactive data messaging on said topic boards." The accused Microsoft method did not permit interactive data messaging. The Federal Circuit first held that there was no literal infringement, because the whereby clause was a claim limitation requiring interactive data messaging. In addition, the court held that there was no infringement under the DOE, because "interactive capability is a material element of the claimed invention ..."

F. Disclosed But Unclaimed Embodiments Cannot be Equivalents

In *Johnson & Johnston Assoc's Inc. v. R.E.*Service Co., Inc., 136 the Federal Circuit held that unclaimed subject matter disclosed in the specification is dedicated to the public and cannot properly be within the scope of equivalents. In *Johnson*, the patent claimed a method for fabrication of printed circuit boards which included "a laminate constructed of a sheet of copper foil... and a sheet

of aluminum." The defendant's product used a steel rather than an aluminum substrate. The specification stated that "other metals, such as stainless steel or nickel alloys may be used," but steel substrates were not claimed. The Federal Circuit noted that a patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after issuance of the patent, employ the DOE to capture the unclaimed but disclosed subject matter. The Federal Circuit also noted that the patentee has remedies: (1) file a reissue application to enlarge the patent scope to include the disclosed subject matter; or (2) file a continuation application under 35 U.S.C. § 120 to claim the additional unclaimed subject matter disclosed in the specification.

In *PSC Computer Prods., Inc. v. Foxconn*Int'l, Inc., 137 Claim 1 was directed to a heat sink assembly for a semiconductor device, in which the heat sink assembly retainer clip has an "elongated, resilient metal strap." The specification disclosed that "other prior art devices use molded plastic and/or metal parts that must be cast or forged

which again are more expensive metal forming operations." The accused product had a plastic clip. The Federal Circuit held that there was no infringement under the DOE, because the applicant had dedicated plastic clips to the public by disclosing them in the specification. "[I]f one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. This "disclosure-dedication" rule does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public. The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." 138

In *The Toro Co. v. White Consolidated Industries*, ¹³⁹ the Federal Circuit emphasized that intent is not a factor in a disclosure-dedication analysis. Whether or not intentional, Toro's disclosure of a "cover with a replaceable ring" in the specification without claiming that

embodiment dedicated "covers with replaceable rings" to the public and precluded a finding of infringement under the DOE. The Federal Circuit further clarified that the level of disclosure needed to trigger the disclosure-dedication rule is different from the level of disclosure required under § 112 to support a claim: one of ordinary skill need only understand and identify the unclaimed disclosed teaching upon reading the written description. ¹⁴⁰

In *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, ¹⁴¹ the claim at issue was to a pharmaceutical composition containing "a saccharide to inhibit hydrolysis."

An example of a prior art composition disclosed in the patent specification disclosed the use of microcrystalline cellulose.

The accused infringer asserted that microcrystalline cellulose could not properly be deemed equivalent to a saccharide under the disclosure-dedication rule. However, the Federal Circuit held that the use of microcrystalline cellulose as a "saccharide" to inhibit hydrolysis was not dedicated to the public, because it was not identified in the patent

specification as an alternative to the "saccharide" claim limitation. 142

G. The Impact of Comments in the Specification on the DOE Analysis

Embodiments that are specifically identified in the specification but excluded from the claims by either express or implied statements are also outside the reach of the doctrine of equivalents. In Gaus v. Conair Corp., 143 the claim at issue (describing a protective circuitry for an electrical device, so that the device shut down upon contact with water) claimed "a pair of spaced-apart electrically exposed conductive probe networks, said pair being responsive to the entry of a conductive fluid." In the specification, Gaus, the patentee, criticized prior art in which the protective device relied on fluid coming in contact with the voltage-carrying portions of the device in order to trigger the protective circuitry. 144 Gaus further described his invention as unique because the probe networks were completely separate from the voltage-carrying portions of the device. The Federal Circuit held that the doctrine of equivalents could not be used to recapture subject matter specifically identified, criticized and effectively disclaimed.¹⁴⁵

H. The Impact of the Patenting of the Accused Product or Process on the DOE Analysis

It is axiomatic that the fact that an accused product or process is patented is irrelevant to the literal infringement analysis. However, the patenting of an accused product or process is relevant to the DOE analysis. In *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 147 Dupont's blasting agent was accused of infringement. Dupont asserted that it could not infringe the patent in suit, because the accused product was itself patented, and therefore constituted a "prima facie determination of nonequivalence" The Federal Circuit disagreed, but noted that if the accused product was patented due to unexpected results, "those unexpected results might prompt a finding of no equivalence ... because, under the *Graver Tank* tripartite

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[FWR] test, the 'results' achieved by the claimed and accused products would be substantially different." 149

Subsequently, in *Hoganas AB v. Dresser Industries, Inc.*, ¹⁵⁰ the Federal Circuit affirmed the district court's finding that a patent directed to a composition of materials for refractory linings was not infringed by Dresser's "Adtech" product. In reaching this result, the Federal Circuit specifically noted that Dresser had obtained a patent covering the Adtech product, and that the patent in suit was listed as art of record for the Adtech patent. "Thus, the PTO must have considered the accused product to be nonobvious with respect to the patented composition. Accordingly, the issuance of that patent is relevant to the equivalence issue." ¹⁵¹

Judge Nies further explained the relevance of the patentability of the accused product or process in *Roton*Barrier, Inc. v. Stanley Works: 152

It is a truism that the fact that an accused device is itself patented does not preclude a finding that such

device infringes an earlier patent of However, the fact of a another. second patent, depending on its subject matter, may be relevant to the issue of whether the changes are substantial. National Presto Indus., Inc. v. West Bend Co., 76 F.3d 1185, 1191 (Fed. Cir. 1996) ("The fact of separate patentability is relevant, and is entitled to due weight."). If the second patent requires practice of the first i.e., the second merely adds an element "D" to a patented combination A + B + C, the combination A + B + C + D clearly infringes. Conversely, if the second patent is granted for A + B + D over one claiming A + B + C, the change from C to D must not have been obvious to be validly patented. Evidence of a patent covering the change, in my view, is clearly relevant unless the patent is invalid. substitution in a patented invention cannot be both nonobvious and insubstantial. I would apply nonobviousness as the test for the "insubstantial change" requirement of Hilton Davis. 153

In view of the foregoing, it is clear that the patenting (or lack thereof) of an accused composition, apparatus or process is relevant to the DOE analysis, whether to bolster or refute the assertion that only insubstantial

differences exist between the claim element or elements at issue and the accused product or process. Careful thought should be given as to how this issue is presented to the fact finder. For example, in *National Presto*, only the first page of the patent covering the accused product was on record at trial, and no evidence was presented at trial concerning the subject matter of the patent. Accordingly, the Federal Circuit found that the patenting of the accused product provided no basis for challenging the jury's verdict of infringement under the DOE. ¹⁵⁴

I. The Impact of Markush Groups On Equivalency

Established chemical patent practice permits that "a specified group of materials which do not belong to an otherwise definable class can be claimed together using 'Markush' language." However, the impact of Markush claiming on subsequent DOE analysis is often not considered by chemical practitioners.

In Tanabe Seiyaku Co., Ltd. v. United States

Int'l Trade Comm'n, 156 the claimed invention was a method

of preparing a benzothiazepine derivative used to treat cardiovascular disease. The claim required that the derivative be prepared by performing a condensation (nalkylation) reaction in the presence of potassium carbonate in a solvent "selected from acetone, lower alkyl acetate, a mixture of acetone and water and a mixture of lower alkyl acetate and water" (*i.e.*, in Markush format). However, the accused product was prepared by conducting the condensation reaction in the presence of potassium carbonate and butanone (or methyl ethyl ketone). Thus, the issue presented was whether butanone was a permissible equivalent solvent for acetone in the claimed method. The structures of acetone and butanone are:

CH₃-CO-CH₃ CH₃-CH₂-CO-CH₃
Acetone Butanone

The Federal Circuit initially observed that acetone and butanone are both homologs. However, it was held that acetone and butanone were not equivalent solvents in the process, because:

- specific base-solvent pairs (*i.e.*, potassium carbonate-acetone, not potassium carbonate-lower alkyl ketone) for the ketone solvent, whereas the base-solvent pairs for the acetate solvent were defined generically (*i.e.*, potassium carbonate-lower alkyl acetate). This demonstrated that substituting butanone for acetone was not an insubstantial change.
- (2) The prosecution history supported a finding of a substantial change, because a prior art statement submitted to the PTO defined the invention in terms of the exact base-solvent pairs in the claim (*i.e.*, only acetone, not lower alkyl ketones), and because the prosecution history suggests that other ketone solvents may result in lower yields than the claimed solvents.
- (3) Pre-application experiments by the patentee using butanone which were unsuccessful indicated that the

- inventors did not consider butanone and acetone to be interchangeable solvents in the claimed process.
- (4) Statements made in corresponding foreign prosecution suggested that other solvents, including butanone, may not be interchangeable with acetone.
- (5) Most experiments conducted by technical experts showed that substitution of butanone for acetone generally gave worse results. Although one experiment showed a better result, it could not be duplicated in larger scale plants.
- (6) The defendant's extensive experimentation to achieve consistent high yields suggested "designing around" and showed that butanone was not readily interchangeable for acetone.
- (7) Using the FWR test, the patentee failed to offer evidence that the accused process operated by way of a "surface solvent phase," which was the way the patented process operated.¹⁵⁹

In Merck & Co. v. Mylan Pharmaceuticals Inc., 160 the claimed invention was a controlled release formulation of drugs used to treat Parkinson's disease, in which the drugs were delivered in a polymeric vehicle which controlled drug release. The parent patent application claimed that the polymer vehicle comprised specified amounts of a "water soluble polymer" and a "less water soluble polymer." The claims were initially rejected as obvious in view of the prior art, and an election of species for examination was additionally required. A continuation-inpart application was then filed, in which the broadest claim recited, in Markush form, the water soluble polymer and less water soluble components. The claims were again rejected as obvious, and an election of species for examination was again required. Merck then filed a second continuation-inpart application, and limited the broadest claim to a specific water soluble polymer Markush species (HPC) and a single less water soluble polymer Markush species (PVACA). In the divisional application, Merck distinguished the prior art as not suggesting the combination of HPC and PVACA. In the divisional application, Merck did not pursue the other polymer species of the original Markush grouping. Both the parent and divisional applications issued and were asserted against Mylan. Merck's patents required 5–25 mg HPC and 2–50 mg PVACA.

Merck asserted that Mylan's product, which contained 29.3 mg HPC and 12.8 mg HPMC, infringed Merck's patents under the DOE. More particularly, Merck asserted that the differences between HPMC and PVACA were insubstantial, in that the compounds were interchangeable in this specific use. The district court granted summary judgment of non-infringement under the DOE, finding that both the prior art and prosecution history estoppel precluded a finding of equivalency. ¹⁶²

On appeal, the Federal Circuit first concluded that prosecution history estoppel had occurred because of Merck's actions in limiting the originally claimed Markush groups to a single species (*i.e.*, HPC and PVACA) in each

group. Although Merck argued that its amendment of the claims was merely in response to the Examiner's election of species requirement, the Federal Circuit concluded that "the controlling fact is that Merck no longer sought to claim any of the several other polymer vehicles." ¹⁶³

However, because "estoppel is not automatic as to everything beyond the literal scope of the claim; its extent must be determined from what was relinquished, in light of the prior art," the Federal Circuit further reviewed the prosecution history *vís-a-vís* the prior art cited against Merck. The Federal Circuit found that the prior art disclosed a HPC/HPMC polymer vehicle, and that the original Markush claims were rejected in view of that prior art disclosure. Accordingly, the Federal Circuit affirmed the district court's holding that Merck was estopped from claiming prior art HPC/HPMC polymer vehicles after Merck limited its claims to HPC/PVACA polymer vehicles. ¹⁶⁴

Tanabe and Merck make clear that a Markush group must be both initially drafted and amended during

prosecution with care. As illustrated in *Tanabe*, the patentee's DOE argument appears to have been significantly undercut by its use of a Markush group which mixed both genus embodiments (*i.e.*, lower alkyl acetate) and species components (*i.e.*, acetone). As made clear in *Merck*, any ambiguities as to why a Markush group was narrowed in prosecution will be construed against the patentee's assertion of infringement under the DOE.

IV. CONCLUSION

Due consideration of the impact of claim construction and the doctrine of equivalents should be made at the outset of the patent application drafting process, and continue throughout prosecution.

Markman v. Westview Instruments Inc., 52 F.3d 967, 979, aff'd, 517 U.S. 370 (1996).

² Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582–83 (Fed. Cir. 1996).

See, e.g., Phillips, 415 F.3d at 1317; see also Vitronics, 90 F.3d at 1583; accord V-Formation Inc. v. Benetton Group SpA, 401 F.3d 1307, 1311-12 (Fed. Cir. 2005) ("prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence" (citations omitted)).

- Key Pharms. v. Herron Labs. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998).
- ⁵ *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).
- Vitronics, 90 F.3d at 1582; see also Renishaw PLC v. Marposs Societa per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998).
- ⁷ *Markman*, 52 F.3d at 986.
- ⁸ Renishaw, 158 F.3d at 1248.
- 9 *Markman*, 52 F.3d at 979–80.
- ¹⁰ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citation omitted).
- *Id.* at 1314 (citation omitted).
- See, e.g., Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1234 (Fed. Cir. 2001)
- ¹³ Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000) (citation omitted)
- Multiform Desiccants, Inc. v. Medzam Ltd., 133 F.3d 1473, 1480
 (Fed. Cir. 1998)
- Primos, Inc. v. Hunter's Specialties, Inc., 451 F.3d 841, 848 (Fed. Cir. 2006) (citation omitted).
- Renishaw, 158 F.3d at 1248.
- ¹⁷ *Vitronics*, 90 F.3d at 1582.
- ¹⁸ Renishaw, 158 F.3d at 1248.
- Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998).
- Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995).
- See, e.g., Hockerson-Halberstadt, Inc. v. Avia Group Int'l Inc., 55 U.S.P.Q.2d 1487, 1491 (Fed. Cir. 2000).
- ²² *Vitronics*, 90 F.3d at 1583.
- Pitney Bowes, 182 F.3d at 1308–09 (quoting Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997)).
- See Phillips, 415 F.3d at 1318.
- 25 *Id.* at 1322.
- ²⁶ *Vitronics*, 90 F.3d at 1585.
- ²⁷ 357 F.3d 1340 (Fed. Cir. 2004).
- Id. at 1349. For a more detailed discussion of the doctrine of "prosecution disclaimer," see, e.g., Miller, "The 'Doctrine of Prosecution Disclaimer' in Construing Patent Claims," 86 JPTOS 931 (2004).
- ²⁹ 96 U.S.P.Q.2d 1757 (Fed. Cir. 2010).

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30
         358 F.3d 1371 (Fed. Cir. 2004).
31
         Id. at 1374.
32
         95 U.S.P.Q.2d 1556 (Fed. Cir. 2010).
33
         74 U.S.P.Q.2d 1321 (Fed. Cir. 2005).
34
         460 F.3d 1349 (Fed. Cir. 2006).
35
         81 U.S.P.Q.2d 1633 (2007).
36
         Id. at 1637.
37
         451 F.3d 841 (Fed. Cir. 2006).
38
         Id. at 848.
39
         Id. at 847-48.
40
         88 U.S.P.Q.2d 1903 (Fed. Cir. 2008).
41
         Id. at 1912-1915.
42
         95 U.S.P.Q.2d 1660 (Fed. Cir. 2010).
43
         86 U.S.P.Q. 2d 1001 (Fed. Cir. 2008).
44
         Id. at 1005-08.
45
         92 U.S.P.Q.2d 1289.
46
         Id. at 1296-1300.
47
         93 U.S.P.Q.2d 1417 (Fed. Cir. 2010).
48
         Id. at 1425-1428.
49
         90 U.S.P.Q.2d 1769 (Fed. Cir. 2009).
50
         927 F.2d 1565 (Fed. Cir. 1991).
51
         439 F.3d 1312 (Fed. Cir. 2006).
52
         Id. at 1318.
53
         92 U.S.P.Q.2d 1289 (Fed. Cir. 2009).
54
         Id. at 1312 (footnote and some citations omitted).
55
         87 U.S.P.Q.2d 1350 (Fed. Cir. 2008).
56
         Id. at 1358 (citing BMC Resources, Inc. v. Paymentech L.P.,
         498 F.3d 1373 (Fed. Cir. 2007)).
57
         Id. at 1358 (citations omitted).
58
59
         96 U.S.P.Q.2d 1065.
60
         Graver Tank & Mfg. Co. v. Linde Air Prods., 339 U.S. 605, 608
61
         For comprehensive discussions of the DOE, the reader is
         referred, for example, to Wegner, Kaminski and Agarwal, "The
         Future of the Doctrine of Equivalents," 26 AIPLA Q.J. 277
         (1998); Wyatt, "Limitations to the Doctrine of Equivalents and
         Recent Cases Since Warner-Jenkinson," 39 IDEA 81 (1998);
         Patel, "Doctrine of Equivalents as Applied to Biotechnology
         Patent Claims," 18 Biotech. L. Rep. 221 (1999); Sirilla, Feddo
         and Antone, "The Doctrine of Equivalents: Both a Sword and a
         Shield," 13 Fed. Cir. B.J. 75 (2003); Harting, "The Doctrine of
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- Equivalents," 86 JPTOS 645 (2004).
- ⁶² 339 U.S. 605 (1950).
- Id. at 610. This is because an alkaline earth metal is an element that is contained in Group IIA of the Periodic Table of the Elements (which includes magnesium), whereas manganese is located in Group VIIB.
- ⁶⁴ *Id*.
- 65 *Id.* at 610–12.
- ⁶⁶ 833 F.2d 931 (Fed. Cir. 1987).
- 67 *Id.* at 953 (emphasis in original).
- ⁶⁸ 868 F.2d 1251 (Fed. Cir. 1989).
- 69 *Id.* at 1259 (emphasis added).
- ⁷⁰ 904 F.2d 677 (Fed. Cir. 1990).
- ⁷¹ *Id.* at 684.
- See, e.g., Conroy v. Reebok Int'l Ltd., 14 F.3d 1570, 1576-77 (Fed. Cir. 1994) (nothing in Wilson mandates its use as the only means for determining the extent to which the prior art restricts the scope of equivalency that the party alleging infringement under the doctrine of equivalents can assert).
- ⁷³ See Key Mfg. Group v. Microdot, Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991).
- ⁷⁴ *Id.*
- See DePuy Spine Inc. v. Medtronic Sofamer Danek,
 90 U.S.P.Q.2d 1865, 1871-75 (Fed. Cir. 2009).
- Streamfeeder LLC v. Sure-Feed Inc., 175 F.3d 974, 983 (Fed. Cir. 1999).
- ⁷⁷ Ultra-Tex Surfaces Inc. v. Hill Bros. Chem. Co., 53 U.S.P.Q.2d 1892, 1896 (Fed. Cir. 2000) (citing Streamfeeder, 175 F.3d at 982-83).
- ⁷⁸ 62 F.3d 1512 (Fed. Cir. 1995), rev'd and remanded, 520 U.S. 17 (1997), remanded, 114 F.3d 1161 (Fed. Cir. 1997).
- Hilton Davis, 62 F.3d at 1524–25. The FWR test states that an accused device or process is equivalent to a claimed device or process if the accused device or process performs substantially the same function in substantially the same way to obtain substantially the same result. See, e.g., Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216 (Fed. Cir. 1996).
- 80 *Hilton-Davis*, 62 F.3d at 1524.
- 81 *Id.* at 1581.
- 82 *Id.* at 1524.
- 83 *Hilton Davis*, 520 U.S. at 29.
- 84 *Id.* at 35–36.

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85
         Id.
86
         Id. at 37.
87
         Id.
88
         Id. at 31-35.
89
         Id. at 39-40.
90
         Id. at 41.
91
         Hilton Davis, 114 F.3d at 1163.
92
         Jonsson v. Stanley Works, 903 F.2d 812, 821 (Fed. Cir. 1990).
93
         Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 122 S.
         Ct. 1831, 1839 (2002) (quoting Wang Labs, Inc. v. Mitsubishi
         Electronics America, Inc., 103 F.3d 1571, 1577-78 (Fed. Cir.
         1997)), on remand, 344 F.3d 1359 (Fed. Cir. 2003).
94
         Festo, 122 S. Ct. at 1839.
95
         Id.
96
         Id. at 1840-42.
97
         The Supreme Court's decision in Festo states that the relevant
         time for this inquiry is "at the time of the [patent] application."
         Festo, 122 S. Ct. at 1842 (emphasis added). However, after
         remand, the Federal Circuit has stated that the relevant time
         period is "at the time of the narrowing amendment ...." Festo,
         344 F.3d at 1365 n.2 (emphasis added).
98
         Festo, 122 S. Ct. at 1842.
         See Festo, 344 F.3d at 1369.
100
         See id.; see also Insituform Techs., Inc. v. CAT Contracting,
         Inc., 385 F.3d 1360, 1367-68 (Fed. Cir. 2004) (finding the
         presumption rebutted because the rationale underlying the
         amendment narrowing the scope of literal claim coverage from
         multiple cups to a single cup bears "no more than a tangential
         relation to the equivalent in question"); Primos, 451 F.3d at 848-
         50 (finding the presumption rebutted because the rationale
         underlying the amendment narrowing the term "plate" to a plate
         "differentially spaced" above the membrane was merely
         tangential to the equivalent in question).
101
         See Festo, 344 F.3d at 1370.
102
         68 U.S.P.Q.2d 1691 (Fed. Cir. 2003).
103
         Id. at 1693–95.
104
         352 F.3d 1369 (Fed. Cir. 2003).
105
         See Glaxo, 356 F.3d at 1356-57.
106
         347 F.3d 1314 (Fed. Cir. 2003)
107
         356 F.3d 1348 (Fed. Cir. 2004).
108
         See Festo, 234 F.3d at 568 ("arguments made voluntarily during
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prosecution may give rise to prosecution history estoppel if they

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evidence a surrender of subject matter").
109
         339 F.3d 1352 (Fed. Cir. 2003).
110
         212 F.3d 1241 (Fed. Cir. 2000).
111
         Id. at 1253.
112
         Id. at 1252.
113
         370 F.3d 1131 (Fed. Cir. 2004).
114
         Id. at 1141.
115
         See id. at 1144.
116
         393 F.3d 1366 (Fed. Cir. 2005).
117
         Id. at 1375.
118
         114 F.3d 1547 (Fed. Cir. 1997), disavowed on other grounds,
         Cybor Corp. v. FAS Tech., Inc., 183 F.3d 1448, 1456 (Fed. Cir.
         1998).
119
         Id. at 1560. Claim construction is a matter of law. Markman v.
         Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995),
         aff'd, 517 U.S. 370 (1996).
120
         Eastman Kodak, 114 F.3d at 1561.
121
         157 F.3d 866 (Fed. Cir. 1998).
122
         Id. at 876–77.
123
         Id. at 877 (citation omitted).
124
         2002 U.S. App. LEXIS 1992 (Fed. Cir. February 1, 2002).
125
         Id. at *13-14. See also Moore USA, 229 F.3d 1091, 1106 (Fed.
         Cir. 2000) (product having longitudinal adhesive strips
         extending 47.8% of length of mailer held not equivalent to
         claimed mailer requiring longitudinal strips extending "the
         majority" of the length of the mailer).
126
         324 F.3d 1308 (Fed. Cir. 2003).
127
         363 F.3d 1306 (Fed. Cir. 2004).
128
         Id. at 312.
129
         374 F.3d 1142 (Fed. Cir. 2004).
130
         Id. at 1151.
131
         441 F.3d 945 (Fed. Cir. 2006).
132
         Id. at 955–56.
133
         405 F.3d 1326 (Fed. Cir. 2005).
134
         Id. at 1330.
135
         Id.
136
         285 F.3d 1046 (Fed. Cir. 2002).
137
         353 F.3d 1353 (Fed. Cir. 2004).
138
         Id. at 1360.
139
         383 F.3d 1326 (Fed. Cir. 2004).
140
         See id. at 1334.
141
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429 U.S. 1364 (Fed. Cir. 2005).

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142
         Id. at 1378-79.
143
         363 F.3d 1284 (Fed. Cir. 2004).
144
         See id. at 1291.
145
146
         See, e.g., Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d
         1575, 1582 (Fed. Cir. 1996) ("[t]he fact of separate patentability
         presents no legal or evidentiary presumption of
         noninfringement").
147
         750 F.2d 1569 (Fed. Cir. 1984).
148
         Id. at 1580.
149
         Id. at 1580 n.3.
150
         9 F.3d 948 (Fed. Cir. 1993).
151
         Id. at 954 (footnote omitted).
152
         79 F.3d 1112 (Fed. Cir. 1996).
153
         Id. at 1128 (Nies, J., additional views).
154
         See National Presto, 76 F.3d at 1191-92.
155
         J. White, Chemical Patent Practice 68 (11<sup>th</sup> ed. 1988) (citing Ex
         parte Markush, 1925 C.D. 126, 340 O.G. 839).
156
         109 F.3d 726 (Fed. Cir. 1997).
157
         Id. at 729 (emphasis omitted).
158
         Id. at 792.
159
         Id. at 732–34.
160
         51 U.S.P.Q.2d 1954 (Fed. Cir. 1999).
161
         See id. at 1956-57.
162
         Id. at 1956.
163
         Id. at 1958 (citing Loral Fairchild Corp. v. Sony Corp., 181 F.3d
         1313, 1326 (Fed. Cir. 1999) for the proposition that "applicant
         may not avoid the conclusion that an amendment was made in
         response to prior art by discussing the amendment under the
         rubric of a clarification due to a §112 indefiniteness rejection").
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Merck, 51 U.S.P.Q.2d at 1958-59.

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