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Recent Developments

RECENT DEVELOPMENTS IN PATENT LAW: DECISIONS BY THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Table of Contents

***499** The year 2003 was another busy year for the Federal Circuit. The Federal Circuit refined the doctrine of prosecution history estoppel in Festo IX, clarified its holdings with respect to anticipation through inherency, provided more claim construction guidance, and further defined circumstances of inequitable conduct, among other things.

I. Novelty And Loss Of Right To A Patent--§102

A. Anticipation

"Anticipation under 35 U.S.C. § 102 means lack of novelty, and is a question of fact. To anticipate, every element and limitation of the claimed invention must be found [expressly or inherently] in a single prior art reference . . . ."[1]

1. Broad Claims May Be Unintentionally Anticipated By The Prior Art

In Akamai Technologies., Inc. v. Cable & Wireless Internet Services, Inc.,[2] the representative claim of Akamai's patent-in-suit called for, among other things, ***500** an "embedded object identified by the modified embedded object URL [to be] served from a given one of the content servers as identified by the first level and second level name servers."[3] According to the majority, the patent-in-suit disclosed and claimed "web page content delivery systems and methods utilizing separate sets of servers to provide various aspects of a single web page," namely, "a set of content provider servers (origin servers), and a set of alternate servers," as well as use "of a load balancing software package to locate the optimum origin servers and alternate servers for the quickest and most efficient delivery and display" of content.[4]

C&W owned the '598 patent, which was prior art to the patent-in-suit, and sold products embodying that patent under the name FOOTPRINT.[5] According to the panel majority, the relevant difference between the disclosure of the '598 patent and "Akamai's preferred embodiment disclosed in the '703 patent is the location of the load balancing software."[6] That is, the panel majority compared the preferred embodiment of the patent-in-suit to the prior art. The C&W accused software, FOOTPRINT 2.0, installed the load balancing software at the DNS servers rather than the content providers' servers.[7] The jury determined, after a 19-day trial, that, among other things, some of the asserted claims were invalid as anticipated by the '598 patent.[8]

On appeal, the Federal Circuit panel majority focused on one issue - "the placement of the load balancing software at either the DNS servers or the origin server."[9] The majority explained that if the claims at issue required load balancing at the DNS servers, then they were not anticipated; however, if the claims did not require that limitation, then they were anticipated by the '598 patent.[10] The majority concluded that those claims did not include a load balancing limitation, explaining that "although the written description 'unquestionably contemplates' the preferred location of the load balancing software," those claims, according to their ***501** plain meaning, did "not expressly require that location."[11] Accordingly, the majority found those claims to be invalid.[12]

2. Anticipation Shown Through Inherency

Whether one of ordinary skill in the art must recognize an asserted inherency is an issue that appears to be dividing the Federal Circuit. In a first and subsequently vacated opinion by an en banc court, the majority in Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research[13] emphasized that one of ordinary skill in the art would not have recognized the asserted inherency.[14] The dissent strongly urged that "[i]t matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics."[15] In a "replacement" opinion, Elan Pharmaceuticals, Inc. v. Mayo Foundation. for Medical Education & Research,[16] the unanimous majority "clarified" that "invalidity based on anticipation requires that the asserted anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation."[17] This time, the Federal Circuit characterized the district court as having held that the Mullan reference anticipated Elan's claims because the Elan mouse was inherent in Mullan.[18] The court, however, chose to avoid the inherency issue.[19] The district court had not addressed enablement, and thus the panel remanded.[20]

The court in Schering Corp. v. Geneva Pharmaceuticals, Inc.[21] gave a possible preview of how the en banc Elan court could have resolved the "knowledge" issue. The Schering court held, as a matter of first impression, that a prior art reference may anticipate, through inherency, the entirety of a later-claimed compound even though that compound was never mentioned in the prior art.[22]

***502** Schering owned two patents, the '233 and '716 patents, drawn to antihistamines.[23] The '233 patent was prior art to the '716 patent-in-suit, and was drawn to the antihistamine loratadine, the active component of CLARITIN.[24] The '716 patent was granted for a metabolite of loratadine known as descarboethoxyloradadine (DCL).[25] Although there was some dispute, the district court and the Federal Circuit concluded that the evidence showed that the DCL metabolite was formed when a patient ingested loratadine covered by the '233 patent.[26]

The issue arose when the defendants sought to market a generic version of loratadine upon expiration of the '233 patent.[27] The defendants filed an Abbreviated New Drug Applications (ANDA) with the FDA asserting that the '716 patent was invalid.[28] The district court ultimately granted summary judgment of invalidity.[29]

On appeal, the Federal Circuit affirmed.[30] First, the panel rejected "the contention that inherent anticipation requires recognition in the art,"[31] citing vacation of the decision in Elan as well as quoting from In re Cruciferous Sprout Litigation,[32] MEHL/Biophile Int'l Corp. v. Milgraum,[33] and Atlas Powder Co. v. IRECO Inc.[34] Previously, the Federal Circuit held in Continental Can Co. USA v. Monsanto Co.[35] that in order to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."[36] In Schering, however, the panel said that "Continental Can does not stand for the proposition that an inherent feature of a prior art reference must be perceived as ***503** such by a person of ordinary skill in the art before the critical date."[37] Rather, "Continental Can stands for the proposition that inherency, like anticipation itself, requires a determination of the meaning of the prior art. Thus, a court may consult artisans of ordinary skill to ascertain their understanding about subject matter disclosed by the prior art, including features inherent in the prior art."[38]

According to the court, "this court [in Continental Can] did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference."[39] Indeed, the court broadly held that "[i]n sum, this court's precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention."[40] The court further explained that in "prior inherency cases, a single prior art reference contained a partial description of the anticipatory subject matter."[41] Here, however, and, for the first time, the prior art did not contain an "express description of any part of the claimed subject matter," that is, the prior art "did not disclose any compound identifiable as DCL."[42] "This case," the court explained, "asks this court to find anticipation when the entire structure of the claimed subject matter is inherent in the prior art."[43]

Nevertheless, the court reasoned that "a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates."[44] The court stated that
[b]ecause inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect.[45]

As the court suggested, however, anticipation might have been avoided by a skilled patent drafter.[46] The panel suggested that the metabolite could be claimed in its pure and isolated form, or as a pharmaceutical composition (that is, with a carrier) or as a method of administering the metabolite or the corresponding pharmaceutical ***504** composition.[47] According to the court, "[t]he '233 patent [did not] provide an enabling disclosure to anticipate such claims because [] the '233 patent [did] not disclose isolation of DCL.'"[48] That may be so, of course, but recognizing, as an initial matter, what may or may not be inherent in the prior art will almost certainly challenge a skilled patent drafter - particularly if those skilled in the art do not recognize the inherent matter.

In Toro Co. v. Deere & Co.,[49] however, the Federal Circuit stated how Schering clarified the issue.[50] Toro had brought suit against Deere, alleging infringement of three of Toro's patents, one of which was directed to technology for aerating soil to increase turf growth by "using an apparatus with a row of adjacent nozzles that periodically shot concentrated jets of pressurized water or other liquid (that is "slugs") into the turf and top soil."[51] The district court had, among other things, found Toro's patent to be not invalid.[52] In doing so, the district court concluded that a prior art Rogers patent did not inherently "read on" or teach the parameters to produce the aeration pattern claimed in the '168 patent.[53]

On appeal, the Federal Circuit ultimately affirmed that particular finding, reiterating and clarifying its decision in Schering that "the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."[54] The court

emphasized again that for inherent anticipation the Rogers patent "must have sufficiently described and enabled at least one embodiment that necessarily featured or resulted" in the claimed subject matter, but "neither description nor contemporaneous recognition of these necessary features or results [is] required."[55]

***505 B. Whether Activity Amounts to an "Offer for Sale" May Depend on Industry Practice**

Under § 102(b),[56] an inventor loses the right to a patent if the invention was "in public use or on sale in this country, more than one year prior to" the U.S. filing date.[57]

In Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.,[58] the patents-in-suit, all owned by Lacks, concerned a method for providing a decorative surface to automotive wheels.[59] The issues of infringement and validity in relation to one of the patents were referred to a special master, who found that certain claims were infringed but were also invalid.[60] The special master's invalidity finding involved, among other things, the issue of whether Lacks' own pre-critical date promotional activity was sufficient to qualify as "on sale" activity.[61] The special master's report was issued before the decision in Group One, Ltd. v. Hallmark Cards, Inc.,[62] and therefore relied on RCA Corp. v. Data General Corp.[63] The special master found that under Lacks' activity qualified as an "on sale" bar the RCA standard.[64] On appeal, the defendants urged that the special master's decision should be affirmed despite the change in the law because Lacks' activities reflected "how business is done in the automotive industry."[65]

The majority noted that the court held in Group One that "only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)."[66] Here it was clear that the special master had applied the lesser RCA standard.[67] The defendants, though, urged that, under U.C.C. § 1-205, factors bearing on whether there was a contractual offer include ***506** course of dealing and industry practice evidence.[68] The majority accordingly remanded the issue with the suggestion that "the district court (or Special Master) may need to take additional evidence on the practice in the industry to determine if the activities by Lacks rise to an offer for sale under the UCC."[69]

The last comment drew a dissent from Judge Newman. Judge Newman urged that
[s]uch industry-specific, local, and subjective criteria are a regression toward the imprecision of the discredited 'totality of the circumstances,' a standard purposefully rejected by the Supreme Court in Pfaff v. Wells Electronics, Inc. Determination of whether there has been an offer of sale in terms of § 102(b) requires objective application of uniform contract law, not indulgence based on disputed local custom in the automotive tire wheel cladding business.[70]

II. Obviousness/Nonobviousness--§ 103: There Can Be Little Better Evidence Negating An Expectation of Success Than Actual Reports of Failure

So the Federal Circuit held in Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.[71] In the 1980s, Porcine Reproductive Respiratory Syndrome (PRRS) infected pig herds.[72] "Up to thirty percent of the piglets in litters from infected sows were stillborn, and up to eighty percent of piglets in infected herds died before weaning."[73] "Both Boehringer and Schering developed attenuated viruses that [were] effective as vaccines against PRRS."[74] Boehringer alleged that Schering's PRIMEPAC vaccine, which was grown on MA-104 monkey kidney cells, was prepared by an infringing process.[75]

The jury found that that the asserted claims were both valid and infringed under the doctrine of equivalents.[76] "The district court denied Schering's motion for JMOL or a new trial."[77] On appeal, the Federal Circuit affirmed.[78] On the issue of ***507** validity under § 103,[79] the Federal Circuit noted that an ultimate finding "of obviousness [required] a motivation or suggestion to combine or modify [the teachings of] prior art references[, plus] a reasonable expectation of success."[80] According to the court, the secondary references relied on by Schering not only suggested that PRRS viruses could be isolated with monkey kidney cells, but also reported a failure of such attempts.[81] The court reasoned that "[w]hile absolute certainty is not necessary to establish a reasonable expectation of success, there can be little better evidence negating an expectation of success than actual reports of failure."[82] The court then concluded that "[a] reasonable jury could [find] that [an artisan] would not have had a reasonable expectation of success in attempting to isolate the PRRS virus on MA-104 cells at the time the invention was made."[83]

III. Double-Patenting and Restriction Requirements

Under 35 U.S.C. § 101,[84] an applicant may obtain "a patent" for an invention.[85] Double-patenting is intended to preclude one from obtaining a series of patents on the same invention, thus improperly extending the term of exclusivity.[86] "Obviousness-type" or non-statutory double patenting is a judicially created doctrine that extends to claims that would have been obvious over the claims of an earlier patent.[87] Obviousness-type double patenting can be overcome by filing a terminal disclaimer.[88]

In Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC,[89] the district court held several of GSK's patents invalid for obviousness-type double-patenting. On ***508** appeal, the Federal Circuit affirmed.[90] In doing so, the Federal Circuit announced several new "rules" governing restriction requirements.[91]

The patents-at-issue traced their lineage to Patent Application No. 05/569,007.[92] The PTO had issued an 8-way restriction requirement in the '007 application, resulting in subsequent applications falling into two branches - one leading to patents granted in 1985, the other to patents granted in 2000-01.[93] All of the patents refer to the antibiotic clavulanic acid and its related salts.[94] One of those salts, potassium clavulanate, was an active component of a commercially successful antibiotic that GSK marketed as AUGMENTIN.[95]

***509** The plaintiffs (collectively "Geneva") filed an ANDA with the FDA seeking regulatory approval to market generic versions of AUGMENTIN.[96] Geneva filed declaratory judgment lawsuits seeking a declaratory judgment that the patents were invalid.[97]

The district court issued a series of rulings. Overall, the district court granted (1) GSK's motion for partial summary judgment that the '552 patent was not invalid for obviousness-type double patenting over the '352 patent; (2) granted Geneva's motion for partial summary judgment that the '380 patent was invalid for obviousness-type double patenting over the '720 patent; (3) granted Geneva's motion for partial summary judgment that the '093, '977, and '703 patents were invalid for nonstatutory double patenting over the '720 patent; and (4) ruled that the '552 and '352 patents were invalid for nonstatutory double patenting over U.S. Patent No. 4,441,609 (the Crowley patent), and that the '720 patent was invalid for nonstatutory double patenting over U.S. Patent No. 4,367,175 (the Fleming patent).[98] GSK owned the Crowley and Fleming patents as the result of a merger with the original assignees of those patents.[99] The district court's key finding was that a 1979 examiner interview during the prosecution of the '007 application did not constitute a restriction requirement - in addition to the 8-way restriction requirement previously mentioned.[100]

On appeal, GSK argued, among other things, that the district court erred in finding that the 2000-01 patents were invalid because § 121 shielded the patents from obviousness-type double patenting over the '720 patent.[101] During reexamination proceedings for the '093, '977, and '703 patents over the '720 patent, the PTO determined with respect to the [2000-01] patents that there was common ancestry and a restriction requirement, and concluded that § 121 shielded those patents from obviousness-type double-patenting.[102] Nevertheless, the district court disagreed with the PTO,[103] and so did the Federal Circuit.[104]

According to the Federal Circuit, GSK faced two hurdles to reach § 121 protection. First, "the original '007 application (the parent to the [2000-01] patents ***510** and the '720 patent) did not contain the 'method of use claims' that later appeared in the '720 patent." Second, "the examiner did not issue a formal restriction requirement relating to the claims at issue in any document in the record [excepting the 8-way restriction requirement]."[105]

As for the first hurdle, GSK argued that § 121 did not require that the claims actually be present in the application before restriction.[106] The Federal Circuit disagreed, stating:

Section 121 indicates otherwise. The first clause states: 'If two or more independent and distinct inventions are claimed in one application . . . .' This clause notes that the restriction requirement applies to a single application that formally claims two or more distinct inventions. This indicates that the earlier application must contain formally entered claims that are restricted and removed, and that claims to the second invention reappear in a separate divisional application after the restriction. The text of § 121 does not suggest that the original application merely needs to provide some support for claims that are first entered formally in the later divisional application.[107] According to the court, the method of use claims had not been entered in the '007 application, and thus "could not have been subject to a restriction requirement."[108] The court reasoned that if the applicants had desired the benefit of § 121, they "should have requested entry of the claims so that the PTO could issue a formal restriction requirement under [37 C.F.R.] § 1.145."[109]

A practice point - although the court in the remaining portion of the opinion seems to back off from a strict requirement that only those claims actually pending at the time of a restriction are subject to the protection of the § 121, that is not as clear as a practitioner would desire. Given the court's foregoing strong language ("If the applicants sought the benefit of § 121, the applicants should have . . . ."),[110] counsel should consider adding all sets of claims that might reasonably be desired in subsequent divisional applications and ensuring that any restriction requirement specifically addresses such claims.

The opinion becomes somewhat unclear after this point because of some broad statements made by the court. For example, the court states that "[e]ven if non-pending claims could be restricted, the prosecution history in this case does not document a restriction requirement. The examiner issued no document referring ***511** anywhere to 'restriction.'"[111] That, of course, is not literally true. As the court subsequently addressed, the PTO first issued a 4-way restriction requirement during the prosecution of the '007 application, then an 8-way restriction requirement, both in 1976.[112]

In a subsequent 1979 examiner interview, which GSK contended was a further restriction requirement, the examiner interview summary form stated: "Agreed that 'simple [ß]-lactamase inhibition' compositions are proper in this case, but that method of use claims will go in a (Goldberg) Divisional (964035)" .[113] The Federal Circuit criticized the statement, reasoning that it neither explained why the compositions were "proper" and the method of use claims were not, nor described the subject matter of the "method of use claims."[114] That criticism is valid, at least insofar as the interview summary form is concerned. Nevertheless, despite that the interview summary form may not have strictly met the standards set for a restriction requirement, from the viewpoint of a patent practitioner, there seems little doubt that the PTO, through its examiner, was requiring "restriction."[115] Also, even though the interview summary form does not "describe the subject matter of the 'method of use claims,'"[116] that, of course, would be readily apparent from the prosecution history.

The Federal Circuit then reasoned:

> At oral argument, GSK's counsel conceded that the 1979 interview summary does not refer to groups of claims set forth as separate inventions as required by an earlier PTO restriction requirement. . . . No separate groupings correspond to the "simple [ß]-lactamase inhibition compositions" and "method of use" - the subjects referred to in the 1979 interview summary. GSK contends that the 1979 interview summary refers to a restriction requirement made orally at the interview. The record does not support that contention.[117]

Again, through the eyes of a patent practitioner, the 1979 interview summary clearly does support that contention.[118] It appears that after the initial 8-way restriction, ***512** the examiner considered claims to the method of use as being drawn to an "independent and distinct invention" under § 121. The examiner did not issue a written "restriction requirement," but oral restriction requirements were prevalent - and encouraged - in the 1970s.

The Federal Circuit next reasoned:

> Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement. If a restriction requirement does not clearly set forth the line of demarcation, then challenged claims could not satisfy the consonance requirement. Therefore restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121's protections.[119]

In general, of course, restriction requirements were always supposed to do that, that is, provide a line of "demarcation." In practice, sometimes that occurred and sometimes it did not. Does this now mean that claims in a subsequent divisional application may be held invalid because an earlier restriction requirement was unclear? That is a likely outcome. In this case, the court criticized the examiner interview summary form as referring to "method of use claims," (note the plural), when, according to the court, there was only one such claim.[120] However, in a subsequent examination response, the applicants stated the following:

It was agreed that "simple [ß]-lactamase inhibition" composition claims, i.e., new claims 97 through 112, are proper in the present case but that method of use claims, that is a method of effecting [ß]-lactamase inhibition in humans and animals would not be proper in the present case and therefore an appropriate set of method of use claims corresponding to new claims

97 to 112 will be presented in Divisional Application, Serial No. 964,035.[121] The line of "demarcation" was thus a "set of method of use claims corresponding to new claims 97 to 112."[122] It seems reasonably clear that the PTO was simply drawing a line between claims to the compound and to its method of use.

With respect to the reexaminations, the Federal Circuit commented:
[I]n confirming the claims under reexamination, the examiner relied on flawed reasoning expressed in the corresponding Notices of Intent to Issue Reexamination Certificate (NIRC). In each reexamination, the examiner relied on the ambiguous 1979 interview ***513** summary to substantiate the alleged restriction requirement. The reexamination examiner stated that the "present series of application [sic] has been consistent with the patentable distinction of compounds (and simple compositions thereof) and their methods of use." That statement is plainly inaccurate. As explained above, the issued restriction requirements in this case grouped compounds, compositions, and methods of use together."[123]

In this instance, with all respect, the Federal Circuit is simply wrong. To an experienced patent practitioner, the 1979 examiner interview summary form is not "ambiguous" at all. Clearly the examiner was requiring "restriction." The examiner may have been right or wrong in doing so, but the Federal Circuit's opinion is not based on whether that restriction was correct - only whether it occurred at all. And it seems beyond doubt that such restriction did, in fact, occur. The Federal Circuit then disregards that further restriction requirement and holds that the "method of use" claims do not fit within the original categories of the 8-way restriction. As a consequence, those claims did not, according to this opinion, fall within the safeguards of § 121.

The court expressed some antipathy for what occurred here:
GSK took about a quarter-century to prosecute the 1985 and [2000-01] patents to issue. This record does not explain that delay. In any event, the effect of that delay could potentially extend patent protection for the invention in the original '007 application. For that reason as well, this thin and insufficient record simply does not operate to shield these patents under § 121 against double patenting rejections. Section 121 can extend the patent term for inventions that are not patentably distinct, as apparently would be the case here. Given the potential windfall such patent term extension could provide to a patentee, this court applies a strict test for application of § 121. Specifically, § 121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance. The restriction documentation must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions. In other words, § 121 requires a record that shows a discernable consonance.[124]

Objectively, however, the record reflected in the opinion does not show a lack of "discernable consonance." As the examiner on reexamination concluded, the applications, at least as recounted in the opinion, were consistent with the distinction drawn between compounds and their methods of use.[125]

A practice point - to the extent examiners are currently permitted to make oral restriction requirements, counsel may wish to consider insisting on a formal, written requirement that clearly sets out the grounds for the requirement. Secondly, counsel may wish to enter a traverse requiring that the PTO make the restriction requirement ***514** "final," that is, ensure that the record is clear that the restriction requirement is mandatory. And, from the first practice point above, counsel may wish to consider submitting all reasonably foreseeable claims that may be presented in subsequent divisional applications.

IV. Written Description: 35 U.S.C. § 112, P1

A. The Written Description Requirement in Cases Involving Biotechnology

Products of biotechnology face particular hurdles. The Federal Circuit has held in the past, for example, in the context of interference, that failure to disclose a complete DNA sequence may not satisfy the written description requirement.[126] Also, in Regents of the Univ. of California v. Eli Lilly and Co.,[127] the Federal Circuit held that a gene material defined only by a statement of function or result did not adequately describe the claimed invention.[128] In particular, the Federal Circuit held that an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical

name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention."[129] Partly as a result, the PTO issued guidelines to assist practitioners with meting the Federal Circuit's criteria.[130]

Eli Lilly, though, has been increasingly limited to its facts. In Amgen Inc. v. Hoechst Marion Roussel, Inc.,[131] the court noted that in Eli Lilly the court held "that [an] adequate description of claimed DNA required a precise definition of the DNA sequence itself - not merely its function."[132] However, in Enzo Biochem, the court clarified that the written description "requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure."[133] The court held that the claim terms at issue in Amgen were "not new unknown biological materials that ordinarily skilled artisans would easily ***515** miscomprehend" as in Eli Lilly, but rather the claim terms referred to "types of cells that could be used to produce recombinant human [erythropoietin (EPO)]."[134]

Amgen was (and presumably still is) "the owner of a number of patents drawn to the production of [EPO], a naturally occurring hormone that controls the formation of red blood cells in bone marrow."[135] Amgen filed a declaratory judgment action asserting that the defendants (collectively referenced as "TKT" in the opinion) had infringed five of its patents.[136] The district court conducted a three-day Markman hearing, tried the case for 23 days over the course of four months, and issued an exhaustive 244 page opinion.[137] One of the district court's conclusions was that one of the patents-in-suit was invalid under § 112, P 1.[138]

The district court, in rejecting TKT's lack of written description arguments, found that the evidence (principally testimony by expert witnesses) "showed that the descriptions [in Amgen's patents] adequately described to those of ordinary skill in the art [as of the filing date of the applications] the use of a broad class of available mammalian and vertebrate cells to produce the claimed levels of human EPO in culture."[139] The district court had relied in particular on one of Amgen's experts who testified "that there might be 'minor differences' in applying the method of the disclosed examples [using monkey cells to the broader class of vertebrate or mammalian cells], but one of ordinary skill in the art could 'easily' figure out those differences."[140] On appeal, the Federal Circuit agreed.[141] The Federal Circuit concluded that in light of the knowledge of one of ordinary skill in the art, Amgen's patents, as a factual matter, met both the written description and enablement requirements.[142]

***516 B. The "Disclosure-Dedication" Rule: If 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**

In PSC Computer Products, Inc. v. Foxconn International, Inc.,[143] PSC was the assignee of a patent describing an invention for securing a heat sink to a chip using a cam-type retainer clip.[144] PSC manufactured and sold a clip made of metal.[145] Foxconn, on the other hand, sold a competing clip made of plastic.[146]

PSC sued Foxconn for infringement of its patent.[147] "PSC conceded that Foxconn's clip did not literally infringe [its claim covering 'an elongated, resilient metal strap,' . . . but maintained nevertheless that Foxconn's plastic clip [infringed] under the doctrine of equivalents."[148] "Foxconn . . . argued that PSC had dedicated clips with plastic parts to the public, and moved for summary judgment of noninfringement on that ground."[149] The district court agreed with Foxconn, relying on the Federal Circuit's decision in Johnson & Johnson Associates v. R.E. Service Co.,[150] in which the Federal Circuit "held that a patent applicant who discloses but does not claim subject matter has dedicated that matter to the public and cannot reclaim the disclosed matter under the doctrine of equivalents."[151]

On appeal, the Federal Circuit affirmed, further defining the scope of its ruling in Johnson & Johnson. According to the Federal Circuit, "if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, then the alternative matter disclosed is dedicated to the public."[152] The Federal Circuit cautioned, however, that the "'disclosure-dedication' rule [did not] mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public."[153] Rather, "[t]he disclosure ***517** 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."[154]

V. Legal Ethics and Inequitable Conduct

A. Materiality - Which Standard Controls?

The Federal Circuit has not, as yet, formally decided whether the materiality standard of new 37 C.F.R. § 1.56[155] should govern inequitable conduct. However, the court has given a strong indication in two recent cases that it should not.

First, in Hoffmann-La Roche, Inc. v. Promega Corp.,[156] the court stated in a footnote that new Rule 56(a) "was not intended to constitute a significant substantive break in the previous standard."[157] That, of course, gives a strong clue that the Federal Circuit was not inclined to adopt the materiality standard of new Rule 56(a) for deciding whether inequitable conduct had occurred.

The court gave a stronger clue in Dayco Products, Inc. v. Total Containment, Inc.[158] Although expressly finding that "[b]ecause we conclude that the outcome of this appeal would be the same under either materiality standard, we leave for another day a final disposition of this issue,"[159] the court nevertheless devoted over four pages in its opinion to discussing the issue. In doing so, the court quoted the same footnote excerpt from Hoffmann-La Roche and then added several factors. First, "[t]he new rule reiterated the preexisting 'duty of candor and good faith,' but more narrowly defined materiality, providing for disclosure where the information establishes either 'a prima facie case of unpatentability' or 'refutes, or is inconsistent with a position the applicant takes.'"[160] Second,
***518** [i]n promulgating the new regulation, the Patent Office noted that: "Section 1.56 has been amended to present a clearer and more objective definition of what information the Office considers material to patentability. The rules do not define fraud or inequitable conduct which have elements both of materiality and of intent."[161] And, third,

[i]n response to a comment suggesting that courts might interpret the duty of "candor and good faith" to require more than Patent Office rules require, the Patent Office stated that the rule was "modified to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information."[162]

The court concluded by stating: "Thus, the extent, if any, to which the Patent Office rulemaking was intended to provide guidance to the courts concerning the duty of disclosure in the context of inequitable conduct determinations is not clear."[163]

The court also noted in a footnote that "[t]he court's authority to render a patent unenforceable for inequitable conduct is founded in the equitable principle that 'he who comes into equity must come with clean hands.'"[164]

One need not be an oracle or clairvoyant to predict with a reasonable degree of accuracy what likely will occur when the second shoe drops. Even an inept soothsayer would likely have little difficulty predicting the next, if not the final, chapter from the foregoing statements.

Assuming that the court declines to adopt the materiality standard of new Rule 56(a) for judging whether inequitable conduct has occurred, what is the standard then? Is there no definable standard? Unfortunately, the latter seems likely. Once again, the court in Dayco suggested that there were only two sources of a "standard for materiality:" (1) "equitable principles," and (2) "the Patent Office's rules."[165] If the court chooses "equitable principles," which seems likely, then inequitable conduct will presumably be governed generally by the "clean hands" maxim, which in terms of patent preparation and prosecution practice is no standard ***519** at all.[166] Or, perhaps, the court will simply say, as it did in Dayco, that "material" information is "any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent,"[167] which, also, is no "standard," and thus opens up the very real probability of a new "plague" of inequitable conduct accusations.

B. "The New Plague" - Truthful Statements Can Nevertheless Lead to a Finding of Inequitable Conduct

In Hoffmann-La Roche, Judge Newman wrote in dissent:
The New Plague

Of course patent applicants must conduct themselves with honesty and integrity. However, unwarranted charges of inequitable conduct can infect the entire body of invention and inventors. As illustrated in this case, every experiment done and not done, every scientific inference, every judgment or belief, is fair game for opportunistic attack. Such attacks feed upon the complexities of science and technology, and it is rare indeed that some flaw cannot be found. In this case, straightforward scientific and patent activity were distorted until judicial suspicions were raised, despite the absence of any significant error or misstatement. The actions challenged herein, even if viewed in their worst light (whatever that might be)

do not establish material misrepresentation and intent to deceive. The need for attention to the burden of proof and its requirement of clear and convincing evidence of both material misrepresentation and deceptive intent, is forcefully illustrated.[168]

The majority as described by Judge Newman, professed to apply the appropriate standard of review, and found that phrasing an example in the specification in the past tense, even though the example performed as described, constituted inequitable conduct, and that asserting superiority over the prior art, even if true based on available data, may constitute inequitable conduct.[169]

Judge Newman, in a stinging dissent, wrote:
Litigation-induced assaults on the conduct of science and scientists, by aggressive advocates intent on destruction of reputation and property for private gain, produced the past ***520** "plague" of charges of "inequitable conduct." . . . Indeed, the prevalence of accusations of inequitable conduct . . . led judges to suspect that all scientists are knaves and all patent attorneys jackals. Today this court revives that misbegotten era.

. . .

This case illustrates the ease of opportunistic challenge to the conduct of experimental science in patent context. My colleagues have distorted the patent process, and the science it supports, into a game of high stakes hindsight that few patents can survive. This additional risk to those who create valuable advances of science and technology has no countervailing public benefit, for the only beneficiary is the infringer who destroys the patent.[170]

Turning to the subject matter of the patent-in-suit, "the polymerase chain reaction (PCR) . . . permits scientists to generate many copies of [a small sample of DNA] in a short period of time."[171] The high temperatures used, however, destroy the polymerase used in the reaction.[172] Thus, new polymerase is required at the beginning of each cycle - a cumbersome process.[173] "It was [] discovered that the DNA polymerase of Thermus aquaticus, or "Taq," [] found in geysers and hot springs, was stable and active at high temperatures" and needed to be added only once.[174] Scientists at Cetus Corp., predecessor to Hoffman-La Roche, developed a purified, thermostable enzyme that was the subject of the patent-in-suit.[175]

With respect to Example VI in the specification, the inventors used past tense language indicating that the experiment had actually been performed, for example, "[a]ctive fractions . . . were pooled and run . . . . The results show . . . . This specific activity is more than an order of magnitude higher than . . . previously isolated Taq polymerase . . .,"[176] and the "Taq polymerase purified . . . in Example VI was found to be free of any contaminating Taq endonuclease and exonuclease activities."[177] In fact, Example VI had never been performed - at least not in its entirety as written.[178]

***521** Roche argued, among other things, that Example VI was not a misrepresentation because all of the steps were performed as part of two other procedures.[179] There was testimony, though, according to the majority, that the order of the steps and the addition or deletion of a step affected the outcome.[180] Other evidence, the majority said, indicated that the statements made in Example VI concerning the results of that experiment were inaccurate.[181] The Federal Circuit found intent from (1) the inventors' attestation that all statements made in the application were true, (2) one of the co-inventors' admission that in technical publications, the use of past tense meant that an experiment had actually been performed, and (3) the alleged lack of proof as compared with a good faith reason for describing an experiment in the past tense.[182] The majority concluded that the misrepresentation was material because the inventors had argued that their claimed composition was "far more pure" than the prior art, even though that argument was secondary and the examiner did not rely on that argument in allowing the claims.[183] According to the Federal Circuit, "a reasonable examiner would have wanted to know that the patentability argument based on purity was unsupported by the experimental results cited by the inventors."[184]

Judge Newman, in dissent, noted that it was undisputed that Example VI combined the steps of two other purification procedures, both of which had been performed.[185] Judge Newman argued that Example VI was a "faithful representation of the purification columns that were actually run," and that there was "no evidence of suggestion that Example VI did not work as stated."[186] In short, it was not literally true that Example VI had been performed, but it was nonetheless substantively and scientifically accurate.[187] Accordingly, Judge Newman argued, Example VI was not, and could not have been, a material misrepresentation.[188] Further, on the issue of intent, Judge Newman said that the majority misconstrued Dr. Gelfand's testimony.[189] Judge Newman wrote that "[t]elling the truth, even in the past ***522** tense, cannot be a material

misrepresentation or clear and convincing evidence of deceptive intent."[190]

C. Drawing an Application Broadly Can Constitute Inequitable Conduct?

In Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.,[191] the Federal Circuit seems to have taken yet another step toward returning inequitable conduct to the "plague" years preceding 1988. The court also seems to be ignoring its prior precedent requiring a threshold showing of some level of materiality that would justify a finding of inequitable conduct. The asserted materiality here was so low as to border non-existence. In the end, Rhone-Poulenc Rorer's (RPR's) sin appears to have simply been an attempt to obtain broad patent coverage - coverage that it did, in fact, obtain with claims that were found to be fully supported by an enabling disclosure.[192] Yet, RPR's patent was deemed unenforceable.[193]

There were two patents-in-suit, an original patent and a reissue.[194] The patents were drawn to a semi-synthesis of taxol, a drug used in treating cancer,[195] and resulted from work initially done in connection with a scientific article titled "A Highly Efficient, Practical Approach to Natural Taxol," published in the Journal of the American Chemical Society ("the JACS article").[196] Four of the six authors of the JACS article were named inventors of the patents-in-suit.[197] The finding of inequitable conduct stemmed from a failure to cite that JACS article.

The conduct that Bristol was charging as inequitable conduct cannot be fully appreciated without first reviewing the district court's opinion; nevertheless, in essence, the district court believed that attempting to secure broad or generic coverage constituted inequitable conduct.[198] Surprisingly, the Federal Circuit agreed.[199]

***523** The JACS article contained, in footnotes, disclosures allegedly "material" to the question of whether there was an enabling disclosure for the claims in the '011 and '277 patents-in-suit.[200] Nevertheless, the '011 patent also included a lengthy "example" covering more than five columns in the printed patent.[201] The example, coupled with the remainder of the specification, constituted an enabling disclosure supporting the full scope of the claims.[202] The district court denied Bristol's motion for summary judgment based on an alleged lack of an enabling disclosure.[203]

On the whole, however, the disclosure in the footnotes of the JACS article apparently did not have any impact on the overall enabling nature of the specification. Nevertheless, the Federal Circuit, emphasizing that "[m]ateriality is not limited to prior art but embraces any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent,"[204] sustained the district court's finding that the JACS article was material "considering the examiner's obligation to review the application for enablement under 35 U.S.C. § 112."[205]

It is true, of course, that examiners have an obligation to review applications for compliance with statutory requirements, including those imposed by § 112. But claims are not invalid simply because they may cover one or a few embodiments or species that are inoperable or not enabled.[206] Then, even under the "reasonable examiner" standard, the footnote disclosures in the JACS article had, at best, an exceedingly low degree of "materiality" to the examination of the patents-in-suit. Under the court's rationale, however, if one is able to find research among a patentee's records indicating that one, two, or a few compounds are subsequently encompassed ***524** within the scope of later claims and will not work (or would work only marginally), and if such research has not been disclosed to the PTO, the door is opened to charging inequitable conduct. This may occur even if such research could have no bearing on the actual patentability of the claims.

Furthermore, the examiner had independent access to that article by way of a computer search, requested of the PTO's Scientific Library, of chemical abstracts using the chemical structure of claim 1.[207] Whether the examiner actually reviewed the JACS article was unknown, but the point is that the examiner clearly had a citation and ready access to that article - it was, in fact, first on a list of eleven "hits."[208]

In connection with the reissue application, Pilard sent other U.S. counsel a copy of the '011 application and the JACS article with an enquiry about the possibility of filing a reissue application to obtain claims to two intermediate compounds that were disclosed, but not claimed, in the '011 patent.[209] During the prosecution of the reissue application (before the same examiner), the examiner again requested a computer search which again identified the JACS article.[210] Pilard also sent U.S. counsel a letter identifying prior art and references published between the filing dates of the original application and the reissue application, which included the JACS article, but stated "according to our evaluation, these references are irrelevant."[211] Nevertheless, U.S. counsel subsequently disclosed those references, including the JACS article, to the PTO in an information disclosure statement.[212] The examiner indicated that he reviewed the references, and the reissue application subsequently

issued.[213]

As previously noted, the Federal Circuit has held, at least since 1988 (coincidently the time frame in which the patents-in-suit were prosecuted), that evidence of "materiality" must meet a threshold level before that evidence can be weighed against evidence of intent,[214] and even a high degree of materiality cannot alone serve as a basis for presuming intent.[215] Here, neither the district court nor the Federal ***525** Circuit made any findings in relation to the JACS article's level of materiality. In light of the fact that the claims were found to have enabling support, it would seem that the level of materiality could only be characterized as low. Nevertheless, and despite the fact that the examiner never raised any question of enablement even though the JACS article was in the examiner's file, the Federal Circuit ventured that "a reasonable Examiner would have wanted to know whether the unsuccessful use of MOM and TMS discussed in the JACS article affected the ability of a person of ordinary skill in the art to practice the invention, which specifically taught the use of MOM and TMS, without undue experimentation."[216]

Perhaps this is true, but that is almost entirely speculation. What is known is that the enabling portion of the specification largely appears in the 5+ columns of the '011 patent describing in detail an actual example involving several esters and compounds. Claim 1 was broadly drawn in terms of R_2 being a hydroxyl-protecting group and R_3 being a hydroxy-protecting group. The examiner evidently concluded, in allowing the '011 patent, that there was enabling support for that claim. Viewed objectively, even if MOM and TMS chemical groups were inoperable, or generated only low yields, that could not have reasonably affected the examiner's conclusion.

With regard to materiality, the Federal Circuit concluded that (1) the fact that the examiner did not initial the search report and that the file history did contain a copy of the JACS article indicated that the examiner had not considered it;[217] (2) although the examiner's allowance of the reissue after considering the JACS article was probative evidence, a reference is not immaterial simply because the examiner has deemed the claims to be allowable over the reference;[218] (3) the district court did not consider Pilard's statement credible, and, in any event, materiality is judged from the standpoint of a reasonable examiner;[219] and (4) to the extent that there was any inconsistency between the district court's holding on inequitable conduct and its holding on enablement, that inconsistency was due to Bristol's argument that the claims in the '277 patent would have been obvious as well as its argument that the claims did not have enabling support.[220]

On the issue of intent, the Federal Circuit concluded that
***526** [i]n a case such as this, where Mr. Pilard was intimately familiar with the [JACS] article because the inventors with whom he worked wrote it, he approved the article for publication, and the article was in his possession while he was drafting the French patent application, the determination that Mr. Pilard knew of the significance of the JACS article in combination with the finding that he knew of the duty to disclose is sufficient to establish intent.[221] Frankly, the most obvious question is how this train got off of the track. From the foregoing, it seems abundantly clear that there was no inequitable conduct here. Inequitable conduct cases today seem to be largely won or lost at the trial court level due in large part to the Federal Circuit's deference to the district court's credibility findings. Reading the district court's opinion leaves little doubt that the court was miffed by RPR's failure to produce Pilard for trial,[222] and Pilard apparently did not make a credible appearance in his video deposition.[223] The district court's opinion is harshly critical, perhaps unduly so, of Pilard's testimony, as well as most of the other trial testimony that RPR offered. One example:

In light of Mr. Pilard's floundering testimony and inconsistent explanations of his reasons why the patent application and the JACS article are not inconsistent; the consistencies between statements made by the inventors in the JACS article and in the Modes Operatoires; and the expert testimony that a POSA [person of ordinary skill in the art] would not have interpreted footnotes 13 and 16 of the JACS article to mean that the use of TMS or MOM as protecting groups would produce taxol, Mr. Pilard's suggestion that he disregarded the JACS article because it applied only to efficient syntheses of taxol is best characterized as a post-litigation fabrication for the benefit of his long-time employer.[224]

The charge that RPR was only able to secure that coverage because the JACS article was not disclosed is simply not borne out by the facts. The district court's opinion also leaves little doubt that the district court believed, likely at Bristol's prompting, that RPR attempted to obtain broader patent coverage than it was entitled. But, the claims of the patents-in-suit were not deemed invalid on prior art grounds under §§ 102 or 103, or inoperable under § 101, and by the district court's own decision the specification provided enabling support for the full scope of those claims, including claim 1. RPR was thus entitled to broad patent coverage.

Although it is true that the "reasonable examiner" materiality standard is broader than a "but for" standard, nevertheless, the 1977 PTO Rule 56(a) standard that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding to allow the application to ***527** issue as a patent" creates at least some nexus to patentability.[225] Here, the JACS article, as determined by subsequent events given in the case, had no nexus whatsoever to patentability - the actual level of materiality of that article was zero. Nevertheless, viewed prospectively from the filing date of the original U.S. application, the article clearly had the potential for a connection or nexus to the issue of enablement, however slight.

The nexus was amplified when RPR prepared a specification that identified MOM and TMS in the context of "more especially" or "preferably" when existing data suggested otherwise, and then failed to disclose those data to the PTO.[226] Doing so raised a red flag and clearly caused the district court, perhaps unfamiliar with patent practice, to smell a rat. But such misperceptions should be corrected on appeal. Here, the Federal Circuit's rationale that a reasonable examiner would have wanted to know about the unsuccessful use of MOM and TMS is gross speculation, and not justified by the actual claims pending before the examiner, especially claim 1. Furthermore, the Federal Circuit's deference to the district court's credibility determinations is similarly not justified where it is clear that the district court was lead astray.

As noted previously, the underlying rationale of this case could potentially stimulate the bar into raising inequitable conduct whenever actual laboratory data suggested that certain species within a broadly claimed genus would not work or would not work as well as other species, and such data had not been disclosed to the PTO. Whether such a charge should find root obviously depends on factors such as the size of the genus compared to the number of inoperable or minimally operable species, predictability of the art, and so forth; however, none of these were addressed by either the district court or the Federal Circuit. Hopefully, this case will not provide such a stimulus. If it does, patent prosecution will truly become a high-risk profession.

VI. Claim Construction

Deciding patent infringement, of course, requires a two-step analysis.[227] First, a court must determine as a matter of law the correct scope and meaning of a disputed claim term.[228] The Federal Circuit reviews that part of the infringement ***528** analysis de novo.[229] Second, the infringement analysis requires a comparison of the properly construed claims to the accused device, process, or method to determine whether the accused device, process, or method contains all of the limitations, either literally or by equivalents, of the asserted claims.[230]

A. In Determining Whether A Statement By A Patentee Was Intended to be Lexicographic, It Is Important To Determine Whether The Statement Was Designed to Define the Claim Term or to Describe a Preferred Embodiment

Continuing the recent trend of studiously avoiding reading claims too narrowly in light of the specification, in E-Pass Technologies, Inc. v. 3Com Corp.,[231] the Federal Circuit held that "electronic multi-function card" should be given its ordinary meaning, as determined from dictionary sources, despite references in the specification to "[p]articular advantages are provided by the simple form of the electronic multi-function card which has the outer dimensions of usual credit or check cards."[232]

E-Pass was the owner of the patent-in-suit entitled "Method and Device for Simplifying the Use of a Plurality of Credit Cards, or the Like."[233] In essence, the invention was a single electronic multifunction card that could replace multiple credit cards.[234] E-Pass charged that 3Com's Palm Pilot infringed.[235]

The key claim term in dispute was "electronic multi-function card."[236] The district court construed that phrase to mean "[a] device having the width and outer dimensions of a standard credit card with an embedded electronic circuit allowing for the conversion of the card to the form and function of at least two different single-purpose cards."[237] The district court found that "[t]he standard for credit card ***529** dimensions was 'set forth in 1971 by the American National Standards Institute ("ANSI") . . . [which] established the dimensions of credit cards as having a length of 3.375 inches, a height of 2.2125 inches, and a thickness of 0.030 inches (with tolerances of +/-0.003 inches).'"[238] Based on that construction, the district court found that the accused Palm Pilot was significantly larger than a "standard credit card."[239] and granted summary judgment of non-infringement, both literally and under the doctrine of equivalents.[240]

On appeal, the Federal Circuit turned to dictionary definitions of "card," finding that "card" was defined, among other things, as "a flat stiff [usually] small and rectangular piece of material (as paper, paperboard, or plastic)."[241] The court noted that the dictionary definitions provided no specific length, width or depth requirements.[242] Further, the court found nothing in the phrase "electronic multi-function card" that suggested a size limitation.[243] The court thus construed "card" as "a flat, rectangular piece of stiff material."[244]

3Com had relied on statements in the specification, such as "[p]articular advantages are provided by the simple form of the electronic multi-function card which has the outer dimensions of usual credit or check cards" and "[credit] cards . . . normally have standardized dimensions."[245] According to the court,
[i]nterpretation of descriptive statements in a patent's written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims "in view of the specification" without unnecessarily importing limitations from the specification into the claims.[246]

The Federal Circuit observed that "in determining whether a statement by a patentee was intended to be lexicographic, it is important to determine whether the statement was designed to define the claim term or to describe a preferred embodiment."[247] The court reasoned that the patentee had understood and used words such ***530** as "simple form" and "normally" to suggest that the card may deviate from the usual dimensions.[248] Thus, in that context, the patentee's statements suggested "a preferred aspect of the invention subject to variability rather than a precise definition."[249]

B. However, Where the Specification Makes Clear That the Claimed Invention is Narrower Than the Claim Language Might Imply, It is Permissible and Proper to Limit the Claims

So the majority in Alloc, Inc. v. U.S. International Trade Commission[250] held over a strong dissent by Judge Schall. Alloc's three patents-in-suit were drawn to systems and methods for joining floor panels.[251] The ITC's "[ALJ] construed the claims to require "play" or a space between a locking groove on a first panel and the locking element of [an adjacent panel]."[252] Similarly, the ALJ construed the terms "locking means," "locking element," and "locking member" under § 112, P6 as having corresponding structures that required play.[253] Under that construction, the ALJ found no infringement.[254] The Commission issued a Final Determination agreeing that Alloc's claims required a play limitation.[255] On appeal, the Federal Circuit panel majority affirmed.[256]

The majority found that none of the claims used the term "play."[257] Nevertheless, the majority held that the claims recited floor system features, such as "displacement" and "disassembly," "in which play was necessarily present."[258] The majority, relying extensively on the specification and drawings, as well as the prosecution history, concluded that patents-at-issue "describe only flooring systems and [system joining methods] with 'play' between the locking groove and the locking element."[259]

According to the panel majority:

> ***531** In so concluding, this court recognizes that it must interpret the claims in light of the specification, yet avoid impermissibly importing limitations from the specification. That balance turns on how the specification characterizes the claimed invention. In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. For example, it is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.[260]

As previously noted, Judge Schall strongly dissented, stating four ways to limit the ordinary meaning of a claim:
First, a claim term will not receive its ordinary meaning if the patentee acted as his or her own lexicographer and clearly set forth a definition of the disputed term in either the specification or prosecution history. Second, a claim term also will not receive its ordinary meaning if the term "chosen by the patentee so deprives the claim of clarity" as to require resort to other intrinsic evidence for a definite meaning. Third, if the patentee phrased a claim term in means-plus-function format, the term will only cover the corresponding structure disclosed in the specification, as well as equivalents thereto. Finally, and most

relevant to this case, a claim term will not carry its ordinary meaning if the intrinsic evidence shows that the patentee limited the scope of the claims.[261] In Judge Schall's view, the majority's reliance on the specification violated the rule against reading limitations from the specification into the claims.[262]

C. Definition of Term in "Highly Pertinent" Prior Art Patent Discussed During Prosecution May Trump Dictionary Definition of Term

In Kumar v. Ovonic Batter Co.,[263] "Kumar discovered that using certain rare earth-transition metal alloys to store hydrogen in rechargeable nickel metal hydride batteries would overcome [a fracturing problem] associated with repeated recharging," and obtained patents covering that discovery.[264] In an infringement action against Ovonic, Kumar asserted claims calling for, among other things, an "amorphous rare earth-transition metal alloy material."[265] Ovonic urged that the term "amorphous" should be construed as "completely" amorphous relying on a dictionary defining "amorphous" as "without real or apparently crystalline form: uncrystallized." ***532** [266] Kumar, on the other hand, urged that "amorphous" should be construed to cover partially crystalline alloys "with long range order less than 100 nm," relying on two textbooks, an article he had published prior to the filing date of his application, and a prior art patent to define the term.[267] The district court agreed with Ovonic and granted summary judgment of non-infringement.[268] On appeal, the Federal Circuit reversed.[269]

In countering Ovonic's proposed dictionary definition of "amorphous," Kumar principally relied on a patent - the "Polk patent" - referenced during prosecution of his patent, which apparently "defined a 'solid amorphous metal' as one 'in which the constituent atoms are arranged in a spatial pattern that exhibits no long range order, that is, it is non-crystalline.'"[270]

The Federal Circuit noted that
[o]ur cases have recognized that although the dictionary can be an important tool in claim construction by providing a starting point for determining the ordinary meaning of a term to a person of skill in the art, 'the intrinsic record' can resolve ambiguity in claim language or, where clear, trump an inconsistent dictionary definition. Our cases also establish that prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence.[271] Here, the Federal Circuit noted that

the Polk patent was considered by both the applicant and the examiner to be highly pertinent prior art, and there is no indication that the Polk patent's express definition (even if inconsistent with the general dictionary definition) was in any way at variance with the definition that would have been used by those skilled in the art at the time.[272] The Federal Circuit accordingly concluded that the Polk patent definition should be "preferred over the general dictionary definition relied upon by Ovonic" and "should control unless the specification clearly states an alternative meaning or this meaning was disclaimed during prosecution."[273]

*533 D. In Cases Involving Unpredictable Technology, It Seems More Likely That Claims Will Be Restricted By The Specification, Especially If That Construction Is Supported by the Prosecution History

An example is Biogen, Inc. v. Berlex Laboratories, Inc.,[274] in which the issue was whether claims in the patents-in-suit "directed to the production of human interferon in Chinese hamster ovary cells were correctly construed as limited to the use of a single DNA 'construct' to introduce both a selectable marker gene and the human interferon gene into [a] host cell."[275] The district court determined the claims did do so, and the Federal Circuit agreed.[276]

One claim representative of the issue in the context of the method claims was claim 42:

> 42. A method for the production of human interferon in a Chinese hamster ovary cell, comprising growing a Chinese hamster ovary cell having incorporated therein a DNA construct comprising human [*a1*]- or [β]-interferon gene, which construct is effective for expression of said human interferon gene, under conditions whereby the interferon gene in said construct is expressed.[277] The claims were thus not expressly limited to using a single DNA construct, and Berlex argued that the cell and method claims at issue were not limited to any specific method of introducing the human interferon DNA.[278] Rather, pointing to several portions of the specification, Berlex argued that the claims were drawn to the larger invention of using selected Chinese hamster ovary cells to produce human interferon.[279] Both the district

court and the Federal Circuit, though, disagreed.

The court noted that the process of "transformation" or "transfection" involved introducing a DNA "construct" (or "vector" or "vector construct" or "plasmid") carrying foreign ("heterologous") genes into a host cell.[280] When multiple genes were linked in a single DNA construct, the process was known as "linked co-transformation," and when multiple genes were introduced using separate DNA constructs, the process was known as "unlinked co-transformation."[281] "The district ***534** court observed that integration of heterologous genes [was] a 'rare event,' typically successful in less than one cell in 100,000."[282]

According to the Federal Circuit, the specifications of the two patents-in-suit described "linked co-transformation," that is, a single DNA construct, in which a single construct was used to carry both the human interferon and a gene for a marker that was used in detecting and isolating transformed cells.[283] In the accused Biogen process, "the same genes [were] used for the same purpose in the same cells, but the interferon gene and the [marker] gene [were] introduced by separate constructs."[284]

Berlex argued that (1) "the single construct described in the specifications [was] only a preferred embodiment," (2) it was irrelevant under the claim language "whether transformation of the Chinese hamster ovary cells [was] achieved by single or multiple constructs," and (3) the "claims [were] not limited to the use of a selectable marker."[285] Biogen responded that (1) if the claims were construed as Berlex urged, "[the claims] would be invalid for lack of a written description," and (2) "the examiner did not view the [] claims as having the breadth [that Berlex asserts]."[286] Both parties pointed to portions of the specification that allegedly supported their arguments.[287]

The Federal Circuit concluded that although the specification mentioned viral vectors, "it is well recognized that for complex biological processes a reference to known general techniques does not establish whether or how such techniques may be successfully adapted to a particular activity."[288] The Federal Circuit found that the specification described "only linked DNA sequences and transformation procedures using single constructs," and did not describe any other configuration for introducing the human interferon and marker genes.[289] With respect to the prosecution history, the Federal Circuit noted that a parent application (of which the current application/patent was a divisional) was limited to a "single construct of linked interferon and marker genes," and that statements in the prosecution history indicated that the examiner viewed the present claims as also being so limited.[290]

***535 E. If Claim Term Has An Established Meaning That Is The Meaning That Controls: If Claim Term Has No Meaning, Then Term Is Limited By Intrinsic Record**

In Altiris, Inc. v. Symantec Corp.,[291] the patent-in-suit was drawn to "a method for intercepting and controlling the boot process of a [computer], and a [] system programmed to perform that method."[292] In general, "the invention . . . allow[ed] a network administrator working from [a] network server to remotely access individual network computers as [] they [] booted to, for example, update or install software."[293] Two of the disputed terms were "boot selection flag" and "automation code."[294]

The term "boot selection flag" as a whole did not have an established meaning.[295] The district court limited the term to a system ID byte based on the specification.[296] The Federal Circuit held that was error, noting that "simply because a phrase as a whole lacks a common meaning does not compel a court to abandon its quest for common meaning and disregard the established meanings of the individual words."[297] Based on a technical dictionary definition, the court concluded that a "flag" can be "one or more bits of data or information that act as a signal or marker to identify a status, a condition, or an event."[298] A "boot selection flag" was construed as "one or more bits of data or information indicating which boot cycle (automation or normal) has been selected."[299]

However, the Federal Circuit held that the district court correctly construed "automation code" as being limited to the description of the preferred embodiment because that phrase had no definable scope.[300] Looking at the individual words, according to the Federal Circuit, was not helpful.[301] "Automation" was defined in a dictionary as "making an apparatus, a process, or a system operate automatically,[302] ***536** and thus "automation code" meant code that boots the system "automatically."[303] That definition, according to the Federal Circuit was "far from a clear," and was "so broad as to lack significant meaning."[304] The court found the "surrounding claim language" to be "similarly unhelpful," and concluded that "the patentee chose a phrase that 'so deprives the claim of clarity as to require resort to the other intrinsic evidence for a definite meaning.'"[305] The Federal Circuit accordingly looked to the specification and, noting that the patentee had made

"only a limited disclosure," consulted "the description of the preferred embodiment."[306] The court thus limited the term to that embodiment.[307]

F. "Prosecution Disclaimer" Added To The Patent Lexicon

In Omega Engineering, Inc. v. Raytek Corp.,[308] the court added the phrase "doctrine of prosecution disclaimer" to the patent lexicon, that is, a doctrine that precludes patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.

Omega's three patents-in-suit were drawn to "laser sighting systems for [] infrared thermometers . . . also known as radiometers."[309] "[I]nfrared radiation is not visible to the naked eye, [and thus] a radiometer user cannot easily determine the size and position of the surface area encompassed by the 'field of view"' of the radiometer's lens.[310] The patents-in-suit disclosed methods and "devices for using one or more laser beams to visually 'outline' or determine 'the periphery' of the surface area encompassed by the field of view."[311]

The broadest claim in one of the patents called for "means for causing said at least one laser beam to strike the periphery of the energy zone for visibly outlining said entire energy zone."[312] The district court interpreted the phrases directed to "outlining" the energy zone (and equivalent phrases in the other two patents-in-suit) as "projecting a laser towards the surface but not encompassing any 'light striking ***537** the center or interior portion of the energy zone."'[313] It was undisputed that the accused devices had a laser beam directed to the center of the energy zone, and the district court accordingly granted summary judgment of non-infringement.[314] On appeal, the Federal Circuit reversed.[315]

The Federal Circuit concluded that the plain words of the claims, for example, "periphery," literally required that the laser beam strike the periphery of the energy zone.[316] However, the court found no contradiction between that construction and the stated purpose of the claim of "visibly outlining said entire energy zone" because (1) the words of the claim permitted more than one laser beam ("at least one laser beam") and (2) the words of the claim did not require the laser beam to strike inside of the energy zone (but likewise, the claim did not preclude the same).[317] Thus, the court concluded that there was no support for the district court's "negative limitation."[318]

The court then turned to the prosecution history to determine whether the use of a central laser beam had been disclaimed.[319] In response to a rejection based on prior art, the patentee argued that the invention relied "on the use of at least one laser beam that [was] able to outline the energy zone rather than illuminate it entirely."[320] The patentee had further told the examiner that the "clear advantage offered by such a device is that it only directs energy at the edge of the energy zone to be measured to outline same and, as such, has virtually no effect on the temperature measurement to be taken."[321] The Federal Circuit interpreted that statement as meaning that "[t]he invention would not add appreciable heat to the energy zone."[322] Accordingly, the court concluded that the claimed function should be construed as "the causing of at least one laser beam to strike the periphery of the energy zone for visibly outlining the entire energy zone, without adding appreciable heat to the energy zone as to affect the accuracy of the temperature measurement." ***538** [323] In doing so, the court explained that "[a]s a basic principal of claim interpretation, prosecution disclaimer promotes the public function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution."[324] The court also noted that to "vague or ambiguous" statements do "not qualify as a disavowal of claim scope."[325] The court explained that "we have required the alleged disavowing statements to be both so clear as to show reasonable clarity and deliberateness and so unmistakable as to be unambiguous evidence of disclaimer."[326]

The Federal Circuit further concluded that the "prosecution disclaimer" in the earlier patent applied to the other two later patents as well (one was a continuation-in-part and the other was a continuation).[327] The court explained that "an interpretation asserted in the prosecution of a parent application could also affect continuation applications," continuation-in-part applications, and "even related continuation-in-part applications arising from the same parent."[328]

VII. Construction of Means- and Step-Plus-Function Limitations

Section 112, paragraph 6, provides:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be

> construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.[329]

There are essentially two questions underlying the § 112, P 6 analysis: (1) is the claim limitation truly a "means-plus-function" or "step-plus-function" limitation; and (2) what is the relationship between "equivalents" in § 112, P 6 and the doctrine of equivalents? The proper analysis of these questions is still evolving.

However, the Federal Circuit held that once a court determines that a means-plus-function limitation is at issue, the court must construe that limitation by determining (1) the claimed function, and (2) what structures, materials or acts are disclosed in the written description that correspond to the "means" for performing that ***539** function.[330] The Federal Circuit has said that those are questions of law, reviewed on appeal de novo.[331]

A. The Term "Circuit" Coupled With An Identifier Such as "Interface" Conveys A Structural Meaning

In Apex Inc. v. Raritan Computer, Inc.,[332] the three patents-in-suit were drawn to computerized switching systems known as keyboard, video, and mouse (KVM) switches that allowed network administrators to operate multiple server computers.[333] There were a number of claim terms in dispute. The district court held that limitations "first interface circuit" should be construed as means-plus-function limitations under § 112, P6.[334] On appeal, the Federal Circuit disagreed and remanded to the district court with instructions to consider the other terms further.

The court noted that none of the limitations used the term "means," and therefore there was a presumption that § 112, P6 did not apply.[335] In deciding whether that presumption had been rebutted, the court noted that the term "circuit" had been defined as "'the combination of a number of electrical devices and conductors that, when interconnected to form a conducting path, fulfill some desired function.'"[336] The term "interface," according to the court, had been defined as "'[t]he signal connection and associated control circuits that are used to connect devices,'"[337] and that "interface circuit" had been defined as "a circuit that links one type of logic family with another or with analog circuitry."[338] The source for the latter definition, the court noted, provided several examples of an interface circuit.[339] The court concluded that "the ordinary meaning of this term connotes specific structures to one of ordinary skill in the art," and that the written description and prosecution history did not indicate that the inventor had used the term contrary to that ordinary ***540** meaning.[340] In general, the court held that "the term 'circuit' with an appropriate identifier such as 'interface,' 'programming' and 'logic' certainly identifies some structural meaning to one of ordinary skill in the art."[341]

B. Corresponding Structure

1. Mean-Plus-Function - When the Disclosed "Corresponding Structure" For a Means-Plus-Function Limitation is a General Purpose Computer or Microprocessor, The "Structure" is Not The Computer, But Rather the Computer Programmed to Perform the Disclosed Algorithm

In Tehrani v. Hamilton Medical, Inc.,[342] Dr. Tehrani's patent-in-suit related to "an apparatus and method for automatically controlling a respirator used for . . . patient[s] who needs assistance in breathing."[343] One of the independent claims required

> first means for processing data representing at least [an] air viscosity factor in lungs of the patient, barometric pressure, lung elastance factor of the patient and measured levels of carbon dioxide and oxygen levels of the patient, and for providing, based upon said data, digital output data indicative of required ventilation and optimum frequency for a next breath of the patient . . . .[344]

Dr. Tehrani asserted that Hamilton's Galileo ventilators infringed "when operating in Adaptive Support Ventilation mode, a setting that evaluated a patient's breathing efforts."[345] The district court granted summary judgment of infringement and damages were tried to a jury that returned an award of approximately $1,480,000 plus approximately $1,000,000 in attorney's fees and costs.[346] On appeal, the Federal Circuit vacated and remanded.[347]

One of the issues that Hamilton raised on appeal was the district court's construction of the "means for processing" limitation.[348] Hamilton contended that the district court had not identified the "corresponding structure" described in the

specification, and had not explained how the structure of the accused device performing ***541** that function was identical or equivalent to the structure disclosed in the patent-in-suit.[349] The Federal Circuit agreed.[350] The parties, the district court, and the Federal Circuit all agreed that the "corresponding structure" was "a microprocessor that [was] programmed to perform [a particular] algorithm."[351] The district court, however, had not determined the algorithm that was actually performed.[352] On appeal, the Federal Circuit noted that it likewise "[could not] determine whether the algorithm employed by the [accused] Galileo device was identical or equivalent to the algorithm disclosed in the [patent-in-suit]."[353] Noting the rule from WMS Gaming, Inc. v. International Game Technology[354] that "[i]n a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm,"[355] the court concluded that it must remand the case to the district court to determine what algorithm formed part of the structure corresponding to the "means for processing" limitation.[356]

2. The Doctrine of Claim Differentiation May Not Be Used to Expand the Scope of the "Corresponding Structure" When There is Only One Embodiment Described in the Specification

In NOMOS Corp. v. BrainLAB USA, Inc.,[357] NOMOS's patent concerned "a method of fine-tuning the positioning of a patient during radiation treatment [of cancerous lesions] so as to maximize the dose to the lesion while minimizing the exposure of surrounding tissue."[358] NOMOS sued BrainLAB for infringement, claiming that BrainLAB's ExacTrac device, a patient positioning system used in the administration of radiation therapy that utilized a hand-held ultrasound probe, infringed its patent.[359]

***542** The district court held a Markman hearing, and construed the claim term "means for generating at least one ultrasound image of the lesion in the patient's body"[360] under § 112, P 6.[361] The district court apparently identified the recited function as "generating at least one ultrasound image of the lesion in the patient's body," a construction both parties agreed with.[362] The district court further identified the corresponding structure as a "fixed ultrasound probe and a bracket or fixation device that maintains the ultrasound probe perpendicular to the treatment table and constrains it to rotate or move along the axis of the table in order to generate an ultrasonic image, and equivalent structures."[363] The district court thereafter granted BrainLAB's motion for summary judgment for, among other things, non-infringement under the doctrine of equivalents because each performed the recited function in a substantially different manner.[364] On appeal, the Federal Circuit affirmed.[365]

The Federal Circuit relied on the specification in concluding that the corresponding structure should include a fixation device as held by the district court, reasoning that the specification "language indicated that the invention envisioned and claimed by the applicant included a fixation device that secured the probe to the treatment table."[366] According to the Federal Circuit, that was the only embodiment of the invention described in the patent, and, as a result, the corresponding structure was limited to that embodiment and its equivalents.[367] The Federal Circuit also rejected NOMOS's argument that the corresponding structure should not "include a fixation device because dependent claim 3 claimed a 'means for mounting.'"[368] Unpersuaded, the Federal Circuit reiterated that claim differentiation was only a "guide" not a rigid rule, and it did not override the requirements of § 112, P 6 when "the claim will bear only one interpretation."[369]

***543 C. § 112, P 6 Requires That Two Structures be Equivalent, But Not "Structurally Equivalent"**

In Utah Medical Products, Inc. v. Graphic Controls Corp.,[370] Utah Medical's patent-in-suit was drawn to "a medical device for measure pressure within a body cavity [such as within] the uterus of a woman during childbirth."[371] Prior to the invention of the patent-in-suit, "intrauterine pressure was typically measured using fluid-filled intrauterine pressure catheters, or IUPCs."[372] "Rigid guide tubes were necessary to insert . . . the IUPCs."[373] The invention of the patent-in-suit used a pressure transducer on the tip of an electronic cable that measured and transmitted pressure data to an external monitor.[374]

The patent-in-suit also disclosed that the device could be inserted without the use of a separate, rigid guide tube.[375] Claim 1 called for, among other things, a "stiffener means permanently encased in said electrical cable means for imparting a desired degree of rigidity to said electrical cable means to facilitate intracompartmental insertion of said transducer using said electrical cable means."[376] With respect to the "stiffener means" limitation, the accused device used a plastic casing for the electrical cable.[377]

The district court construed the "stiffener means" limitation as
a stylet that imparts sufficient rigidity to the cable means so that the transducer can be inserted without the use of an external

guide tube. The stylet is a separate component of the cable means, but must be permanently encased within the cable means. Therefore, this claim element, and its equivalent structure, do not include a structure that is removable from the cable means.[378] The jury ultimately found infringement, and lost profits damages of $20 million.[379] On appeal, the Federal Circuit affirmed.[380]

***544** First, the court agreed with the district court's construction. On the issue of infringement under § 112, P 6, therefore, the court explained that "[t]o qualify as an equivalent of the structure disclosed in the specification under [§ 112, P 6], the structure of the accused device [that is, hard plastic formed in a dual-lumen geometry] could have no more than insubstantial differences from the steel stylet."[381] The Federal Circuit concluded that there was substantial evidence supporting the jury's finding that the stiffening structure in the accused device was equivalent to the steel stylet disclosed in the specification.[382] The court reasoned that "Section 112, paragraph 6, 'requires two structures to be equivalent, but it does not require them to be "structurally equivalent," i.e., it does not mandate an equivalency comparison that necessarily focuses heavily or exclusively on physical construction.' Rather the equivalents analysis under [§ 112, P 6], proceeds with reference to the context of the invention and the relevant field of art."[383]

VIII. Prosecution History Estoppel, The Warner-Jenkinson Presumption, and Festo VIII & IX

A. Federal Circuit Festo IX

The Federal Circuit's long awaited decision in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,[384] after remand from the Supreme Court (1) construes Festo VIII,[385] (2) restates the portions of Festo VII[386] that remained intact, and (3) offers guidelines of what may be offered to rebut the Festo VIII presumption.

The Federal Circuit construed the Supreme Court's decision in Festo VIII as (1) agreeing with the Federal Circuit's holding that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel,"[387] and (2) rejecting the Federal Circuit's absolute bar, but instead establishing
a presumption that a narrowing amendment made for a reason of patentability surrenders the entire territory between the original claim limitation and the amended claim limitation, and explained that a patentee may overcome that presumption by showing that "at the time of the amendment one skilled in the art could not reasonably be expected ***545** to have drafted a claim that would have literally encompassed the alleged equivalent."[388]

According to the Federal Circuit, the Supreme Court had enumerated three ways in which a patentee may overcome that presumption, that is, (1) forseeability, (2) tangentialness, and (3) "some other reason."[389] The Supreme Court remanded the case to the Federal Circuit or the district court to determine whether Festo could demonstrate that the narrowing amendments at issue did not surrender the particular equivalents in question.[390]

After remand, the Federal Circuit asked the parties to brief.
1. Whether rebuttal of the presumption of surrender, including issues of foreseeability, tangentialness, or reasonable expectations of those skilled in the art, is a question of law or one of fact; and what role a jury should play in determining whether a patent owner can rebut the presumption.

2. What factors are encompassed by the criteria set forth by the Supreme Court.

3. If a rebuttal determination requires factual findings, then whether, in this case, remand to the district court is necessary to determine whether Festo can rebut the presumption that any narrowing amendment surrendered the equivalent now asserted, or whether the record as it now stands is sufficient to make those determinations.

4. If remand to the district court is not necessary, then whether Festo can rebut the presumption that any narrowing amendment surrendered the equivalent now asserted.[391]

Before turning to those questions, however, the Federal Circuit restated the holdings from Festo VII that it believed were

unaffected by Festo VIII, namely:

• "[W]e recognize that the Court expressly endorsed our holding that a narrowing amendment made to comply with any provision of the Patent Act, including § 112, may invoke an estoppel;"[392]

• "We next reinstate our holding that a 'voluntary' amendment may give rise to prosecution history estoppel;"[393]

• "[W]e clarify that the Supreme Court's Warner-Jenkinson[394] presumption, which treats a narrowing amendment as having been made for a 'substantial ***546** reason related to patentability' when the record does not reveal the reason for the amendment, remains intact after the Court's Festo decision, although the consequences of failing to overcome that presumption have been altered;"[395]

• "Although the Supreme Court rejected that 'complete bar' approach, it confirmed that a patentee's failure to overcome the Warner-Jenkinson presumption gives rise to the new Festo presumption of surrender;"[396] and

• "A patentee is now entitled to rebut the presumption that an 'unexplained' narrowing amendment surrendered the entire territory between the original and the amended claim limitations."[397]

The court explained that the Festo and Warner-Jenkinson presumptions operate as follows:

> The first question in a prosecution history estoppel inquiry is whether an amendment filed in the [PTO] has narrowed the literal scope of a claim. If the amendment was not narrowing, then prosecution history estoppel does not apply. But if the accused infringer establishes that the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial one relating to patentability. When the prosecution history record reveals no reason for the narrowing amendment, Warner-Jenkinson presumes that the patentee had a substantial reason relating to patentability; consequently, the patentee must show that the reason for the amendment was not one relating to patentability if it is to rebut that presumption. In this regard, we reinstate our earlier holding that a patentee's rebuttal of the Warner-Jenkinson presumption is restricted to the evidence in the prosecution history record. If the patentee successfully establishes that the amendment was not for a reason of patentability, then prosecution history estoppel does not apply.

If, however, the court determines that a narrowing amendment has been made for a substantial reason relating to patentability--whether based on a reason reflected in the prosecution history record or on the patentee's failure to overcome the Warner-Jenkinson presumption--then the third question in a prosecution history estoppel analysis addresses the scope of the subject matter surrendered by the narrowing amendment. At that point Festo VIII imposes the presumption that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation. The patentee may rebut that presumption of total surrender by demonstrating that it did not surrender the particular equivalent in question according to the criteria discussed below. Finally, if the patentee fails to rebut the Festo presumption, then prosecution history estoppel bars the patentee from relying on the doctrine of equivalents for the accused element. If the patentee successfully rebuts the presumption, then prosecution history estoppel does not apply and the question whether the accused element is in fact equivalent to the limitation at issue is reached on the merits.[398] ***547** With respect to the four questions the Federal Circuit had posed for en banc review, the court answered the first two: (1) "rebuttal of the presumption of surrender is a question of law to be determined by the court, not a jury,"[399] and (2) the Supreme Court identified three ways in which the patentee may overcome the presumption - (a) foreseeability, (b) tangentialness, and (c) "some other reason."[400] On the three ways of rebutting the presumption, the Federal Circuit offered some general guidelines.

With respect to foreseeability, the court said:

> This criterion presents an objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment. Usually, if the alleged equivalent represents later-developed technology (e.g., transistors in relation to vacuum tubes, or [VELCRO] in relation to fasteners) 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, would more likely have been foreseeable. Indeed, if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment. By its very nature,

> objective unforeseeability depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment. Therefore, in determining whether an alleged equivalent would have been unforeseeable, a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries.[401]

In essence: (1) it is an objective enquiry, that is, whether the inventor or the prosecuting attorney was aware of the alleged equivalent is not decisive; (2) later-developed technology will "usually" be deemed not foreseeable; (3) "old" technology will "more likely" be deemed foreseeable, and "certainly should have been foreseeable" if the alleged equivalent was known in the prior art in the field of the invention; and (4) because the issue is factual, the district court may hear expert testimony and may consider extrinsic evidence.[402]

With respect to "the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question," the question is "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent."[403] As guidelines, the Federal Circuit noted that

> an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim. . . . [M]uch like the inquiry into ***548** whether a patentee can rebut the Warner-Jenkinson presumption that a narrowing amendment was made for a reason of patentability, the inquiry into whether a patentee can rebut the Festo presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment. . . . [T]hat reason should be discernible from the prosecution history record, if the public notice function of a patent and its prosecution history is to have significance. . . . [W]hether an amendment was merely tangential to an alleged equivalent necessarily requires focus on the context in which the amendment was made; hence the resort to the prosecution history.[404]

Accordingly, the Federal Circuit concluded that "whether the patentee has established a merely tangential reason for a narrowing amendment is for the court to determine from the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record."[405] Thus, "tangentialness" is determined (1) objectively on the intrinsic record, and (2) if made to avoid prior art, then the amendment almost certainly will not be deemed "tangential."

For "some other reason," the Federal Circuit construed that category as "a narrow one" that "is available in order not to totally foreclose a patentee from relying on reasons, other than unforeseeability and tangentialness, to show that it did not surrender the alleged equivalent."[406] According to the court,

> the third criterion may be satisfied when there was some reason, such as the shortcomings of language, why the patentee was prevented from describing the alleged equivalent when it narrowed the claim. When at all possible, determination of the third rebuttal criterion should also be limited to the prosecution history record.[407] Thus, successful reliance on "some other reason" may be predictably slight, and mostly limited to reasons evident from the intrinsic record.

On the third and fourth en banc questions relating to remand, the Federal Circuit concluded that

> Festo cannot show that the "magnetizable" and "sealing ring" amendments to the Stoll and Carroll patents were "tangential" or were made for "some other reason." However, because there exist factual issues relating to the objective unforeseeability of the two accused equivalents, we remand to the district court to determine whether Festo can rebut the presumption of surrender by demonstrating that the accused device's aluminum sleeve and sealing ring elements would have been unforeseeable to a person of ordinary skill in the art at the time of the amendments.[408]

***549 B. Prosecution History Estoppel Post-Festo IX**

1. Presenting a New Independent Claim Resulting From Rewriting a Dependent Claim as an Independent Claim Results in a Narrowing Amendment Even Though the Scope of the Dependent Claim Was Not Changed, (2) Prosecution History Estoppel and the Festo VIII Presumption Applies, and (3) Unamended Claims Containing The Same Limitation as the Dependent Claim Are Subject to the Same Estoppel and Presumption

In Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.,[409] the court held that (1) presenting a new independent claim that rewrites a dependent claim as an independent claim results in a narrowing amendment even though the scope of the dependent claim was not narrowed at all (!), (2) prosecution history estoppel and the Festo VIII presumption therefore applies, and (3) an unamended claim containing the same limitation as the dependent claim is likewise subject to the same estoppel and presumption per Builder's Concrete.[410]

Deering's patent-in-suit was drawn to a "light-weight, pocket-type scale capable of [] weighing substances up to [10] grams."[411] The device had a balance beam, fulcrum posts, a material holder, and sliding weights.[412] What the Federal Circuit described as an "important aspect" of the invention was one of the sliding weights that was used to "minimize the overall weight of the scale by moving the center of mass of the [] weight to the plane created by the fulcrums."[413] The specification also explained that a metallic insert was offset from a pointer such that it was disposed "substantially in the plane" of the fulcrum when the weight was in its zero position.[414] That feature was also a claim limitation. Independent claim 1 called for, among other things, "said sliding weight when in its zero position having a portion thereof disposed substantially in an imaginary plane containing the fulcrum of the beam" (referred to as the "Zero Position Limitation.").[415]

The accused infringing device had the two slidable weights that were movable along a balance beam, but the metallic insert on slide was positioned directly below ***550** the pointer.[416] Based on construction of the term "substantially," which the district court construed as meaning "at or near the imaginary plane," the district court found no literal infringement which the Federal Circuit affirmed.[417] The district court also found no infringement under the doctrine of equivalents based on the "absolute bar" of the 2000 Federal Circuit en banc Festo case.[418] On appeal, the Federal Circuit vacated and remanded, but also effectively denied the patentee any access to the doctrine of equivalents.[419]

The application maturing into the patent-in-suit was originally filed with independent claims 1 and 9. Original claim 1 did not contain the Zero Position Limitation, but original claim 9 did.[420] Original dependent claim 3 (dependent directly from claim 1) also contained the Zero Position Limitation.[421] During prosecution, claim 1 (and other claims) were rejected under § 103.[422] Claims 3 and 9 (and other claims) were "objected to" but were indicated as being allowable if rewritten in independent form.[423] In response, the applicant noted that claim 9 was already an independent claim, and claim 9 was not amended.[424] Dependent claim 3 was rewritten in independent form (that is, original claim 1 and original dependent claim 3; no other limitations were added), as independent claim 11.[425] Independent claim 11 issued as patent claim 1.

The Federal Circuit concluded that patent claim 1 (application claim 11) was subject to prosecution history estoppel and the Festo VIII presumption:
Deering's addition of independent claim 11, coupled with the clear surrender of the broader subject matter of the deleted original independent claim presumptively bars Deering from arguing infringement under the doctrine of equivalents. . . . Here, the patentees clearly disclaimed the territory between the original claim 1 and new claim 1 as issued.[426] ***551** According to the court, the original claim 1 had called for "a sliding weight movably carried by said beam for movement along said scale."[427] In response to a § 103(a) rejection, "the applicants deleted original claim 1 and 3 and settled for claims containing the narrower requirement that a portion of the sliding weight be disposed substantially in a plane defined by the fulcrums originally present in claim 3."[428]

Deering, of course, argued that the scope of dependent claim 3 was not narrowed - or, indeed, changed in any form.[429] The Federal Circuit rejected that argument without analysis, noting that "there is no question" that the claim had been narrowed, and "[b]ecause the amendment in this case is not 'truly cosmetic,' estoppel presumptively applies."[430]

With respect to application claim 9 (patent claim 4) that had not been amended, the Federal Circuit concluded that
this presumption applies to all claims containing the Zero Position Limitation, regardless of whether the claim was, or was not, amended during prosecution. . . . "To hold 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."[431] The Federal Circuit remanded the issue to the district court to determine whether the Festo VIII presumption could be rebutted.[432]

2. The Inability to Add New Matter By Amendment Does Not Constitute Unforeseeability; (2) "Infectious Estoppel:" Subject Matter Surrendered Via Claim Amendments During Prosecution is Also Relinquished for Other Non-Amended Claims Containing the Same Limitations

In Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.[433], Glaxo owned a patent directed to controlled, sustained release tablets containing bupropion hydrochloride, and marketed its sustained release formulation as WELLBUTRIN SR for treatment of depression and as ZYBAN for smoking cessation.[434] The key ingredient for ***552** achieving sustained release is hydroxypropyl methylcellulose ("HPMC"), which extends drug release by transforming into a gel that swells upon ingestion.[435] Glaxo's patent claimed "a sustained release tablet containing an admixture of bupropion hydrochloride and HPMC."[436] As originally filed, however, many of the claims did not recite HPMC as a limitation.[437] During prosecution, the PTO rejected for lack of enablement the claims that did not recite HPMC because Glaxo's original application did not disclose any sustained release mechanism other than HPMC.[438] Glaxo amended those claims to overcome the rejection.[439]

Impax, a manufacturer of generic pharmaceuticals, filed two ANDAs with the FDA, "one proposing a generic substitute for Glaxo's [WELLBUTRIN] SR, and the other proposing a generic substitute for [ZYBAN]."[440] The sustained release agent in Impax's proposed composition was, apparently, hydroxypropyl cellulose ("HPC"), which, like HPMC, was also a hydrogel-forming compound.[441] Glaxo sued Impax for patent infringement.[442] The district court granted Impax's motion for summary judgment of noninfringement, stating that Glaxo's claim amendments "indisputably narrowed the patents with respect to sustained release."[443] According to the district court, "[a]t the time of the disputed amendments, anyone skilled in the art would have known that HPC and HPMC were substantially equivalent."[444]

On appeal, the Federal Circuit affirmed the district court's decision. According to the Federal Circuit, "the examiner's enablement [rejection]," which the Federal Circuit said that "Glaxo did not rebut, show[ed] that Glaxo surrendered other controlled sustained release agents known to act as equivalents of HPMC."[445]

Glaxo had urged, in attempting to rebut the presumption of surrender, that because it could not have added HPC as an amendment in 1994 without drawing a new matter rejection, it had, on that basis, sufficiently rebutted the Festo VIII presumption. ***553** [446] In particular, Glaxo pointed to the Supreme Court's emphasis on an applicant's ability to claim an alleged equivalent as a "hallmark of unforeseeability."[447] The Federal Circuit rejected Glaxo's argument, explaining that "new matter prohibitions are not directly germane to the doctrine of equivalents or the patentee's proof to overcome the [Festo VIII] presumption."[448] According to the Federal Circuit, "[t]he new matter doctrine prevents an applicant from adding new subject matter to the claims unless the specification shows that the inventor had support for the addition at the time of the original filing[, ensuring] temporal integrity of the amendment process in the Patent Office."[449] The new matter doctrine, the Federal Circuit explained, "does not apply to nontextual infringement."[450] In fact, the Federal Circuit explained, "[t]he quintessential example of an enforceable equivalent, after-arising technology, would always be unclaimable new matter. In that sense, the doctrine of equivalents compensates for the patentee's inability to claim unforeseeable new matter."[451] The Federal Circuit further reasoned that the Supreme Court addresses "the time of amendment" only and "does not address the instance where the applicant would not properly claim a known equivalent because it had purposely left that known substitute out of its disclosure at the time of filing."[452] According to the Federal Circuit, in that situation, the applicant "should have foreseen and included the proposed equivalent in its claims at the time of filing,"[453] as the Supreme Court stated in Festo VIII: "The patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents."[454] Having "scoured the record in vain" for any evidence that Glaxo would not have considered HPC a suitable sustained release agent for bupropion, the Federal Circuit held that Glaxo had "not rebutted the presumption that prosecution history estoppel bar[red] a finding of infringement under the doctrine of equivalents."[455]

As for those of Glaxo's claims that had originally called for HPMC as the sustained release agent, and therefore had not been amended in that regard, the Federal Circuit nevertheless held that the doctrine of equivalents with respect to the ***554** HPMC limitation was barred for those claims as well. Glaxo had urged on appeal that claim 1 would thus be "plagued by 'infectious estoppel;"' however, the Federal Circuit concluded that "Glaxo misdiagnoses the legal situation."[456] According to the Federal Circuit, the Festo VIII bar applied to all of Glaxo's claims containing the "critical" HPMC limitation, that is, "subject matter surrendered via claim amendments during prosecution [was] also relinquished for other claims containing the same limitation."[457] The reason for that rule, the Federal Circuit explained, was to "ensure consistent interpretation of the same claim terms in the same patent."[458]

IX. Relief

A. Punitive Damages

Punitive damages are subject to constitutional restraints. The Supreme Court in BMW of North America, Inc. v. Gore[459] identified three guidelines for determining the constitutionality of punitive damage awards, namely, (1) the degree of reprehensibility of the defendant's misconduct, (2) the disparity between the harm (or potential harm) suffered by the plaintiff and the punitive damages award (the ratio test), and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.[460] In Cooper Industries, Inc. v. Leatherman Tool Group, Inc.,[461] the Supreme Court held that appellate courts must review the constitutionality of punitive damage awards under a de novo standard of review, that is, an independent examination or review.[462]

One of the presently few cases on the issue is the Federal Circuit's opinion in Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.[463] holding that "[i]ndependent examination or review means a searching review, one that hunts for error and gives virtually no weight to the decisional process under review. Each aspect of the appellate review puts each aspect of the decision under review in sharp focus."[464] Additionally, the Federal Circuit construed the Supreme Court's admonition in ***555** Cooper Industries that the Seventh Amendment would not permit a court, in reviewing a punitive damages award, to disregard a jury's fact findings,[465] to mean "that if a punitive damages determination rests on purely factual issues, [the court is] to assume that those factual issues have been resolved adversely to the defendant, absent contrary indication."[466]

The Federal Circuit further viewed Cooper Industries as suggesting that the first BMW "factor [could] be influenced by the demeanor and credibility of witnesses, matters on which an appellate court must defer substantially to the jury."[467] According to the court in Rhone-Poulenc I, it appeared that much of the "reprehensibility" in this case turned on an evaluation of DeKalb's witnesses.[468] Even on appeal, the Federal Circuit noted that the "cold record" revealed "several rather implausible explanations and assertions by DeKalb witnesses."[469] Accordingly, based almost entirely on perceived witness credibility, the Federal Circuit found "that DeKalb's conduct was sufficiently reprehensible to support the award of punitive damages."[470]

The Supreme Court granted certiorari in Rhone-Poulenc I, vacated the Federal Circuit's decision, and remanded the case for reconsideration in light of State Farm Mutual Automobile Insurance Co. v. Campbell.[471] On remand, in Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.,[472] the Federal Circuit reached the same conclusions.[473] The court explained that in Rhone-Poulenc I, the court had considered the Gore factors, and State Farm did not change the result.[474] In Rhone-Poulenc I, the court had concluded that "[i]t is true that the facts alleged herein do not demonstrate any of the criteria enhancing reprehensibility mentioned in Gore, such as an act of violence, disregard for the health and safety of others, a pattern of misconduct, or the exploitation of a financially vulnerable target."[475] The court explained that when it had issued its opinion, "DeKalb's actions did not squarely fit the reprehensibility criteria listed in Gore, and the court did not consider a party's intentional ***556** malice to be one of the Gore factors, since only one member of the Gore Court specifically identified malice as a criterion to be considered in the reprehensibility assessment."[476] In State Farm, however, the Supreme Court expanded the list of criteria that courts must use to determine a defendant's reprehensibility:

"The most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct." We have instructed courts to determine the reprehensibility of a defendant by considering whether: the harm caused was physical as opposed to economic; the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others; the target of the conduct had financial vulnerability; the conduct involved repeated actions or was an isolated incident; and the harm was the result of intentional malice, trickery, or deceit, or mere accident. The existence of any one of these factors weighing in favor of a plaintiff may not be sufficient to sustain a punitive damages award; and the absence of all of them renders any award suspect.[477]

B. Post-Judgment Interest

In Tronzo v. Biomet, Inc.,[478] the issue was whether post-judgment interest on a punitive damage award should run from the date of the initial judgment or from the date of the district court's action in response to the Federal Circuit's most recent mandate. Primarily because of Tronzo's failure to take timely action, the court held that post-judgment interest should run from the date of the Federal Circuit's most recent mandate.[479]

This is a trap for the unwary. A jury, in an infringement action, originally awarded Dr. Tronzo compensatory damages of $3,805,000, which the district court enhanced by $1,902,500 to account for willfulness, and punitive damages of $20 million.[480] On appeal, the Federal Circuit affirmed liability on the tort claims, but found Dr. Tronzo's patent was invalid, and remanded for recomputation of the compensatory damages.[481] The punitive damage claim had not been appealed.[482] On remand, the district court recomputed compensatory damages to $520 and reduced punitive damages to $52,000.[483] Back on

appeal, the Federal Circuit affirmed the reduction in compensatory damages, but reversed the reduction in punitive ***557** damages.[484] Thus, in essence, Dr. Tronzo was entitled to $20 million in punitive damages even though compensatory damages were a mere $520 due to the procedural posture of the case. The Federal Circuit's latest decision had issued in 2001, but the district court's original judgment had issued in 1996; the difference in interest on $20 million dating from 1996 versus 2001 was substantial. The district court held that post-judgment interest should run from its initial judgment in 1996.[485] On appeal, the Federal Circuit vacated and modified the judgment.[486]

Under 28 U.S.C. § 1961,[487] interest in a civil case runs from "the date of the entry of the judgment" in the district court.[488] Under Federal Rule of Appellate Procedure 37(a), if a money judgment is affirmed on appeal, interest runs from the date of the original judgment, but under Federal Rule 37(b), if a money judgment is modified or reversed on appeal, the appellate court is required to decide questions of interest.[489] If the court does not, the district court is powerless to award interest other than as provided in § 1961, that is, from the date the district court enters judgment on return of the appellate court's mandate.[490] In general, appellate courts have discretion under Federal Rule 37(b) in deciding when interest should begin to run.[491] If the appellate court does not address the issue of interest, a party should seek reformation of the court's mandate in a petition for rehearing or a motion to reform the mandate.[492] Here, the Federal Circuit noted that Dr. Tronzo had not asked the court to reform its earlier mandate to address the interest issue.[493] Accordingly, the Federal Circuit concluded that interest should run from the date of the final judgment entered by the district court after the court's mandate in 2001.[494]

X. Conclusion

Patent law developed significantly during 2003 and continues to develop as 2004 unfolds. In what was perhaps its most widely-noted opinion, the Federal Circuit in Festo IX provided an analytical structure for evaluating prosecution history ***558** estoppel. In Schering Corp. and in Toro, the Federal Circuit clarified that an inherent feature of a prior art reference did not need to be perceived as such by a person of ordinary skill in the art at the time of invention. Patent practitioners were given a new phrase to use, namely, "prosecution disclaimer," in Omega Engineering. As always, time will reveal how those and other decisions will define the law of patents.

Footnotes

a1 Cox & Smith Incorporated, San Antonio, Texas

aa1 Cox & Smith Incorporated, San Antonio, Texas

1 Brown v. 3M, 265 F.3d 1349, 1351 (Fed. Cir. 2001) (citing Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 2001)).

2 344 F.3d 1186 (Fed. Cir. 2003).

3 Id. at 1193.

4 Id. at 1190.

5 Id. at 1191.

6 Id. (emphasis added).

7 Id.

[8] Akamai Techs., 344 F.3d at 1191.

[9] Id. at 1193.

[10] Id.

[11] Id.

[12] Id. at 1194.

[13] 304 F.3d 1221 (Fed. Cir. 2002), vacated, 314 F.3d 1299 (Fed. Cir. 2002) (en banc) [hereinafter Elan I].

[14] Id. at 1229.

[15] Id. at 1231 (quoting In re Cruciferous Sprout Litigation, 301 F.3d 1343, 1350 (Fed. Cir. 2002)).

[16] 346 F.3d 1051 (Fed. Cir. 2003) [hereinafter Elan II].

[17] Id. at 1052.

[18] Id. at 1054.

[19] Id. at 1054 ("We conclude that Elan's arguments are more properly characterized as enablement arguments rather than inherency arguments.").

[20] Id. at 1057.

[21] 339 F.3d 1373 (Fed. Cir. 2003).

[22] Id. at 1379.

[23] Id. at 1375.

[24] Id.

[25] Id.

[26] Id.

[27] Schering, 339 F.3d at 1376.

[28] Id.

[29] Id.

[30] Id. at 1382.

[31] Id. at 1377.

[32] 301 F.3d 1343, 1351 (Fed. Cir. 2002).

[33] 192 F.3d 1362, 1366 (Fed. Cir. 1999).

[34] 190 F.3d 1342, 1348-49 (Fed. Cir. 1999).

[35] 948 F.2d 1264 (Fed. Cir. 1991).

[36] Id. at 1269.

[37] Schering, 339 F.3d at 1377.

[38] Id.

[39] Id. at 1378.

[40] Id.

[41] Id.

[42] Id.

[43] Schering, 339 F.3d at 1379.

[44] Id.

[45] Id.

[46] Id. at 1381.

[47] Id.

[48] Id.

[49] 355 F.3d 1313 (Fed. Cir. 2004).

[50] Id. at 1321.

[51] Id. at 1314.

[52] Id.

[53] Id. at 1319.

[54] Id. at 1321.

[55] Toro, 355 F.3d at 1321.

[56] 35 U.S.C. § 102(b) (2000).

[57] As noted above, public use or sale at any time prior to filing an application results in a bar in those countries, for example, the EPO countries, requiring absolute novelty.

[58] 322 F.3d 1335 (Fed. Cir. 2003).

[59] Id. at 1338.

[60] Id. at 1340.

[61] Id. at 1341.

[62] 254 F.3d 1041 (Fed. Cir. 2001).

[63] 887 F.2d 1056 (Fed. Cir. 1989).

[64] Lacks Indus., 322 F.3d at 1347-48.

[65] Id. at 1348.

[66] Id. at 1347 (quoting Group One, 254 F.3d at 1048).

[67] Id. at 1348.

[68] Id.

[69] Id.

[70] Lacks Indus., 322 F.3d at 1352 (Newman, J., dissenting).

[71] 320 F.3d 1339 (Fed. Cir. 2003).

[72] Id. at 1343.

[73] Id.

[74] Id. at 1344.

[75] Id. at 1343.

[76] Id. at 1344.

[77] Boehringer, 320 F.3d at 1344.

[78] Id. at 1354.

[79] 35 U.S.C. § 103 (2000).

[80] Boehringer, 320 F.3d at 1354.

[81] Id.

[82] Id. (internal citation omitted).

[83] Id.

[84] 35 U.S.C. § 101 (2000).

[85] See In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997).

[86] See In re Zickendraht, 319 F.2d 225, 232 (C.C.P.A. 1963)(Rich, J., concurring). Statutory or "same invention" -type double patenting, is precluded by § 101, but is restricted to precluding more than one patent on the same invention. In this context, "same invention" means the same identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186, 198 (1984); In re Ockert, 245 F.2d 467, 468-69 (C.C.P.A. 1957). One test for determining statutory-type double patenting is whether a claim in a later application or patent could be literally infringed without literally infringing a corresponding claim in an earlier patent. See In re Vogel, 422 F.2d 438, 441 (C.C.P.A. 1970).

[87] See In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 892-93 (Fed. Cir. 1985).

[88] Longi, 759 F.2d at 892.

[89] 349 F.3d 1373 (Fed. Cir. 2003).

[90] Id. at 1375.

[91] For example, in a footnote, the court commented, without citation of authority:
The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include:
1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.
Geneva, 349 F.3d at 1378 n.1. Although point # 1 is true, that is, the claims are compared in assessing obviousness-type double patenting, it is not readily apparent where the Federal Circuit finds (or would find) support for points 2 and 3. Recognizing that the MPEP is not "law," those points are nevertheless potentially contrary to instructions given the PTO examining corps:
Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1 [] (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:
(A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;
(B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;
(C) Determine the level of ordinary skill in the pertinent art; and
(D) Evaluate any objective indicia of nonobviousness.
U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 804, at 800-22 (8th ed. 2001) [hereinafter MPEP].

[92] Geneva Pharms., 349 F.3d at 1375; see U.S. Patent Application No. 05/569,007 (filed April 17, 1975).

[93] Geneva Pharms., 349 F.3d at 1375.

[94] Id.

[95] Id.

[96] Id. at 1376.

[97] Id.

[98] Id. at 1376-77.

[99] Geneva Pharms., 349 F.3d at 1377.

[100] Id. at 1376-77.

[101] Id. at 1377.

[102] Id. at 1378.

[103] Id.

[104] Id. at 1382.

[105] Geneva Pharms., 349 F.3d at 1378 (internal citation omitted).

[106] Id. at 1379 (second emphasis added).

[107] Id.; see 37 C.F.R. § 1.145 (2004) (same as version cited).

[108] Id. at 1379.

[109] Id. at 1379-80.

[110] Id. at 1379-80.

[111] Geneva Pharms., 349 F.3d at 1380.

[112] Id.

[113] Id.

[114] Id.

[115] The MPEP defines "restriction" as "a generic term, includes the practice of requiring an election between distinct inventions, for example, election between combination and subcombination inventions, and the practice relating to an election between independent inventions, for example, and election of species." MPEP, supra note 91, § 802.02,at 800-3.

[116] Geneva Pharms., 349 F.3d at 1380.

[117] Id. at 1380-81.

[118] Indeed, both the examiner and the applicant's subsequent response expressly refer to putting the method of use claims in a "divisional." "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.'" MPEP, surpa note 91, § 201.06, at 200-20.

[119] Geneva Pharms., 349 F.3d at 1381 (internal citations omitted, second emphasis added).

[120] Id.

[121] Id.

[122] Id.

[123] Id. at 1382.

[124] Id. (footnote omitted).

[125] Geneva Pharms., 349 F.3d at 1382.

[126] Fires v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

[127] 119 F.3d 1559 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998).

[128] Id. at 1566. But cf. Johns Hopkins University v. CellPro, Inc., 152 F.3d 1342 (Fed. Cir. 1998) (refused to consider an analogous argument based on Hopkins' disclosure of a single antigen and antibody because CellPro had not raised that argument previously).

[129] Id. at 1566 (quoting Fiers, 984 F.2d at 1171).

[130] Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, P 1, 'Written Description' Requirement, 66 Fed. Reg. 1099 (Dep't Commerce Jan. 5, 2001).

[131] 314 F.3d 1313 (Fed. Cir. 2003).

[132] Id. at 1332 (citing Elli Lilly, 119 F.3d at 1566-67).

[133] Id. (citing Enzo Biochem, 296 F.3d at 1324).

[134] Id.

[135] Id. at 1319.

[136] Id.

[137] Amgen, 314 F.3d at 1320.

[138] Id.

[139] Id. at 1330-31.

[140] Id. at 1331.

[141] Id. at 1337.

[142] Id. at 1332, 1337.

[143] 355 F.3d 1353 (Fed. Cir. 2004).

[144] Id. at 1355.

[145] Id.

[146] Id.

[147] Id.

[148] Id. (quoting U.S. Patent No. 6,061,239, col. 6, line 15 (issued May 9, 2000)).

[149] PSC Computer, 355 F.3d at 1355.

[150] 285 F.3d 1046 (Fed. Cir. 2000) (en banc).

[151] PSC Computer, 355 F.3d at 1355-56 (citation omitted).

[152] Id. at 1360.

[153] Id.

[154] Id.

[155] (2004) [hereinafter “Rule 56”].

[156] 323 F.3d 1354 (Fed. Cir. 2003).

[157] Id. at 1366 n.2. That, however, is factually untrue and accounts for none of the countless hours devoted to the issue over several years by concerned members of the bar through the AIPLA and the ABA's IPL section, among others, or the efforts by the PTO itself to correct what had become a very real problem. The PTO, of course, has authority only to change its rules of practice. It does not have authority to overrule court precedent. Statements by the PTO during the rule-making process, accordingly, expressed deference to the court and the overall issue of inequitable conduct. However, the "reasonable examiner" standard did not arise through Divine inspiration or the Supreme Court. That standard was originally fashioned through PTO rule-making which the court subsequently adopted by default. The result was disastrous. In adopting "new" Rule 56, the PTO was obviously attempting to cure a problem essentially of its own making.

[158] 329 F.3d 1358 (Fed. Cir. 2003).

[159] Id. at 1364.

[160] Id. at 1363-64 (quoting 37 C.F.R. § 1.56).

[161] Id. at 1364 (quoting Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Dep't Commerce Jan. 17, 1992)) [hereinafter Duty of Disclosure].

[162] Id. (quoting Duty to Disclosure, 57 Fed. Reg. at 2025).

[163] Id.

[164] Dayco Prods., 329 F.3d at 1364 n.3 (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945)) (citing United States v. Am. Bell Tel. Co., 128 U.S. 315, 364-65 (1888) (describing the genesis of inequitable conduct in the patent context as from the equity jurisprudence in real property law); Winbond Elecs. Corp. v. Int'l Trade Comm'n, 262 F.3d 1363, 1372 (Fed. Cir. 2001)).

[165] Id. at 1364.

[166] The disclosure standards of new Rule 56 and its companion rules would, in that instance, represent only one category of inequitable conduct. Other conduct that might be deemed "inequitable" under particular circumstances would have no boundaries other than the collective, litigation-inspired imagination of skilled teams of lawyers and experts, intent on finding (and perhaps even professionally required to find or attempt to find) some kernel, some lapse, however innocent, opening a door to criticize decisions taken typically years earlier before memories dimmed, and having the benefit of almost unlimited budgets in important cases; far-ranging discovery into documents and files, not to mention general resources, typically beyond the reach of those involved in day-to-day patent prosecution; and 20/20 hindsight.

[167] Dayco Prods., 329 F.3d at 1363.

[168] Hoffmann-La Roche, 323 F.3d at 1381 (Newman, J., dissenting).

[169] Id. at 1373.

[170] Id. at 1372-73.

[171] Id. at 1357-58.

[172] Id. at 1358.

[173] Id.

[174] Hoffmann-La Roche, 323 F.3d at 1358.

[175] Id.

[176] Id. at 1363.

[177] Id.

[178] Id. at 1364.

[179] Id.

[180] Hoffmann-La Roche, 323 F.3d at 1365.

[181] Id.

[182] Id. at 1367.

[183] Id. at 1367-68.

[184] Id. at 1368.

[185] Id. at 1374 (Newman, J. dissenting).

[186] Hoffmann-La Roche, 323 F.3d at 1375 (Newman, J. dissenting).

[187] Id. (Newman, J. dissenting).

[188] Id. (Newman, J. dissenting).

[189] Id. at 1378. (Newman, J. dissenting).

[190] Id. at 1379. (Newman, J. dissenting).

191 326 F.3d 1226 (Fed. Cir. 2003) [hereinafter BMS II].

192 Id. at 1239.

193 Id. at 1242.

194 Id. at 1231-32.

195 Id. at 1229.

196 Id. at 1230.

197 BMS II, 326 F.3d at 1230 n.2.

198 Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 95 Civ. 8833 (RPP), 2002 U.S. Dist. LEXIS 480, at *53 (S.D.N.Y. Jan. 16, 2002) [hereinafter BMS I]. According to the district court,

> Mr. Pilard has never suggested that his failure to disclose the JACS article was a mere oversight or that he forgot about the JACS article when the application was made for the 011 patent. Instead, Mr. Pilard has contended that the JACS article was irrelevant because (1) the article only applies to an efficient synthesis of taxol and is intended for a different audience; (2) footnotes 13 and 16 are not inconsistent with his patent application because they do not state that the process did not work at all with TMS or MOM; and (3) that it is possible that the inventors continued to work with MOM subsequent to drafting the JACS article and achieved better results. None of these proffered explanations are grounds for not submitting the JACS article to the U.S. Patent and Trademark Office nor were the explanations credible.

Id. at *40 (footnote omitted) (internal citation omitted). In actuality, of course, all of those appear to be valid reasons why the JACS article either was not material, or had an exceedingly low level of materiality.

199 BMS II, 326 F.3d at 1235.

200 Id. at 1230.

201 See U.S. Patent No. 4,924,011, col. 4, line 9 to col. 9, line 20 (issued May 8, 1990).

202 BMS II, 326 F.3d at 1238-39.

203 Id. at 1239.

204 Id. at 1234 (citing GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)).

205 Id.

206 See Johns Hopkins University v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1269 (Fed. Cir. 1986).

207 BMS II, 326 F.3d at 1231.

[208] Id.

[209] Id. at 1232.

[210] Id. at 1232. The opinion does not explain what the file history shows in relation to that second computer search, that is, whether the examiner initialed it or not.

[211] Id. at 1232-33.

[212] Id. at 1233.

[213] BMS II, 326 F.3d at 1233.

[214] See, e.g., Specialty Composites v. Cabot Corp., 845 F.2d 981, 993 (Fed. Cir. 1988); Allen Organ Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1557 (Fed. Cir. 1988).

[215] See, e.g., KangaROOS U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1577 (Fed. Cir. 1985).

[216] BMS II, 326 F.3d at 1235.

[217] Id. at 1236. But in Fiskars, Inc. v. Hunt Manuf. Co., 221 F.3d 1318, 1327-28 (Fed. Cir. 2000), the examiner expressly indicated that he had refused to consider a cited highly material reference by lining through the reference on the disclosure form. Nevertheless, the Federal Circuit concluded that the applicant's duty of disclosure was satisfied. Judge Schall was on both the Fiskars and this case.

[218] Id. at 1237 (citation omitted).

[219] Id. (citation omitted).

[220] Id. at 1239. Although that makes little sense, that was the court's conclusion.

[221] Id. at 1240.

[222] BMS I, 2002 U.S. Dist. LEXIS 480, at *23.

[223] See, e.g., id. at *40, 53.

[224] Id. at *46.

[225] See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1179 & n.8 (Fed. Cir. 1995) (discussion regarding original 1977 Rule 56 and revised 1992 Rule 56).

[226] BMS I, 2002 U.S. Dist. LEXIS 480, at *11.

[227] See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1999); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc).

[228] Johnson Worldwide, 175 F.3d at 988; Cybor, 138 F.3d at 1454; see also Tegal Corp. v. Tokyo Electron America, Inc., 257 F.3d 1331 (Fed. Cir. 2001) ("We need not address each of the parties' claim construction arguments directly. Rather, we construe the term ['electrode' and 'plasma'] according to the normal rules of claim construction," and proceeded to do so independently of the parties' arguments.).

[229] See, e.g., Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1338 (Fed. Cir. 1999); Cybor, 138 F.3d at 1456.

[230] Johnson Worldwide, 175 F.3d at 988; Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1247-48 (Fed. Cir. 1998).

[231] 343 F.3d 1364 (Fed. Cir. 2003) [hereinafter E-Pass II].

[232] Id. at 1369.

[233] Id. at 1365; see U.S. Patent No. 5,276,311 (issued Jan. 4, 1994).

[234] E-Pass II, 343 F.3d at 1365.

[235] Id. at 1365-66.

[236] Id. at 1366.

[237] Id. (quoting E-Pass Techs. v. 3Com. Corp., 177 F. Supp. 2d 1033, 1043 (N.D. Cal. 2001)) [hereinafter E-Pass I].

[238] Id. (quoting E-Pass I, 177 F. Supp. 2d at 1042).

[239] Id.

[240] E-Pass II, 343 F.3d at 1366-67.

[241] Id. at 1367 (quoting Merriam-Webster's Collegiate Dictionary 172 (10th ed. 1999)).

[242] Id.

[243] Id. at 1368.

[244] Id.

[245] Id. at 1369.

[246] E-Pass II, 343 F.3d at 1369 (quoting Texas Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1204-05 (Fed. Cir. 2002)).

[247] Id.

[248] Id.

[249] Id.

[250] 342 F.3d 1361 (Fed. Cir. 2003).

[251] Id. at 1365.

[252] Id. at 1367.

[253] Id.

[254] Id.

[255] Id.

[256] Alloc, 342 F.3d at 1365.

[257] Id. at 1368.

[258] Id.

[259] Id. at 1370.

[260] Id. (internal citations omitted).

[261] Id. at 1377 (internal citations omitted).

[262] Alloc, 342 F.3d at 1377.

[263] 351 F.3d 1364 (Fed. Cir. 2003).

[264] Id. at 1366.

[265] Id. (quoting U.S. Patent No. 4,565,686, col. 6, line 13 (issued Jan. 21, 1986)).

[266] Id. at 1367 (quoting Webster's Third New Int'l Dictionary Of The English Language 72 (1981)).

[267] Id. at 1367, 1372.

[268] Id. at 1367.

[269] Kumar, 351 F.3d at 1366.

[270] Id. at 1367 (quoting U.S. Patent No. 4,116,682, col. 1, lines 13-15 (issued Sept. 26, 1978)).

[271] Id. at 1367-68.

[272] Id. at 1368.

[273] Id.

[274] 318 F.3d 1132 (Fed. Cir. 2003).

[275] Id. at 1133-34.

[276] Id. at 1135, 1140.

[277] Id. at 1134 (quoting U.S. Patent No. 5,376,567, col. 29, lines 18-24 (issued Dec. 27, 1994)).

[278] Id. at 1135.

[279] Id.

[280] Biogen, 318 F.3d at 1133-34.

[281] Id. at 1134.

[282] Id.

[283] Id.

[284] Id.

[285] Id. at 1135.

[286] Biogen, 318 F.3d at 1135.

[287] Id. at 1136.

[288] Id. at 1137.

[289] Id. at 1136-37.

[290] Id. at 1137.

[291] 318 F.3d, 1363 (Fed. Cir. 2003).

[292] Id. at 1366.

[293] Id.

[294] Id. at 1368.

[295] Id. at 1372.

[296] See id. at 1367, 1372.

[297] Altiris, 318 F.3d at 1372.

[298] Id. at 1373.

[299] Id.

[300] Id. at 1375.

[301] Id. at 1374.

[302] Id. (quoting Webster's Ninth New Collegiate Dictionary (1988)).

[303] Altiris, 318 F.3d at 1374.

[304] Id.

[305] Id. at 1374-75 (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2001)).

[306] Id. at 1375.

[307] Id.

[308] 334 F.3d 1314 (Fed. Cir. 2003).

[309] Id. at 1318.

[310] Id.

[311] Id.

[312] Id. at 1318-19 (quoting U.S. Patent No. 5,727,880, col. 9, lines 34-41 (issued Mar. 17, 1998)). .

[313] Id. at 1319-20.

[314] Omega Eng., 334 F.3d at 1320.

[315] Id. at 1334.

[316] Id. at 1322 (citing Webster's Third New Int'l Dictionary Of The English Language 1681 (1993)).

[317] Id. at 1322-23.

[318] Id. at 1323.

[319] Id.

[320] Omega Eng., 334 F.3d at 1326.

[321] Id.

[322] Id.

[323] Id. at 1328.

[324] Id. at 1324 (citation omitted).

[325] Id. at 1325.

[326] Omega Eng., 334 F.3d at 1325 (citation omitted).

[327] Id. at 1332, 1335.

[328] Id. at 1333 (citation omitted).

[329] 35 U.S.C. § 112, P 6 (2000).

[330] Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1307-08 (Fed. Cir. 1998).

[331] Id. at 1308; see also Overhead Door Corp. v. Chamberlain Group, Inc., 194 F.3d 1261 (Fed. Cir. 1999); Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352 (Fed. Cir. 2000).

[332] 325 F.3d 1364 (Fed. Cir. 2003).

[333] Id. at 1367-68.

[334] Id. at 1370.

[335] Id. at 1371.

[336] Id. at 1373 (quoting Dictionary of Computing 75 (4th ed. 1996)).

[337] Id. at 1374 (quoting Dictionary of Computing, supra note 336, 250).

[338] Apex, 325 F.3d at 1374 (quoting Rudolf F. Graf, Modern Dictionary of Electronics 385 (7th ed. 1999)).

[339] Id.

[340] Id.

[341] Id. at 1373.

[342] 331 F.3d 1355 (Fed. Cir. 2003).

[343] Id. at 1356.

[344] Id. at 1357 (quoted U.S. Patent No. 4,986,268, col. 11, lines 21-28 (issued Jan. 22, 1991)).

[345] Id. at 1358.

[346] Id. at 1360.

[347] Id. at 1356.

[348] See Tehrani, 331 F.3d at 1360.

[349] Id. at 1361-62.

[350] Id. at 1362.

[351] Id.

[352] Id.

[353] Id.

[354] 184 F.3d 1339 (Fed. Cir. 1999).

[355] Tehrani, 331 F.3d at 1362 (quoting WMS Gaming, 184 F.3d at 1348-49).

[356] Id. at 1362.

[357] 357 F.3d 1364 (Fed. Cir. 2004).

[358] Id. at 1366.

[359] Id.

[360] U.S. Patent No. 5,411,026, col. 12, lines 11-12 (issued May 2, 1995).

[361] NOMOS, 357 F.3d at 1366-67.

[362] Id. at 1367.

[363] Id. at 1366.

[364] Id. at 1367.

[365] Id. at 1369.

[366] Id. at 1368.

[367] NOMOS, 357 F.3d at 1368.

[368] Id.

[369] Id. (citations omitted).

[370] 350 F.3d 1376 (Fed. Cir. 2003).

[371] Id. at 1378.

[372] Id.

[373] Id.

[374] Id.

[375] Id.

[376] Utah Med., 350 F.3d at 1379 (quoting U.S. Patent No. 4,785,822, col. 10, lines 37-42 (issued Nov. 22, 1988)).

[377] Id.

[378] Id. at 1380.

[379] Id.

[380] Id. at 1386.

[381] Id. at 1383.

[382] Utah Med., 350 F.3d at 1383-84.

[383] Id. at 1384 (quoting IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1436 (Fed. Cir. 2000)).

[384] 344 F.3d 1359 (Fed. Cir. 2003) (en banc) [hereinafter Festo IX].

[385] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002) [hereinafter Festo VIII].

[386] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 533 U.S. 915 (2001) [hereinafter Festo VII].

[387] Festo VIII, 535 U.S. at 736.

[388] Festo IX, 344 F.3d at 1365 (quoting Festo VIII, 535 U.S. at 741).

[389] Id. (quoting Festo VIII, 535 U.S. at 740-41).

[390] Id.

[391] Id. at 1365-66 (citing Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 304 F.3d 1289 (Fed. Cir. 2002) (order)).

[392] Id. at 1366 (citation omitted).

[393] Id. (citation omitted).

[394] Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997).

[395] Festo IX, 344 F.3d at 1366 (internal citation omitted).

[396] Id. (citation omitted).

[397] Id.

[398] Id. at 1366-67 (internal citations omitted).

[399] Id. at 1367.

[400] Id. at 1369-70.

[401] Festo IX, 344 F.3d at 1369 (internal citation omitted).

[402] See id.

[403] Id.

[404] Id. at 1369-70.

[405] Id. at 1370.

[406] Id.

[407] Festo IX, 344 F.3d at 1370.

[408] Id. at 1370-71.

[409] 347 F.3d 1314 (Fed. Cir. 2003).

[410] Id. at 1325-26 (citing Festo VIII, 535 U.S. at 736-37; Builder's Concrete, Inc. v. Bremerton Concrete Products, Co., 757 F.2d 255, 260 (Fed. Cir. 1985) (holding that prosecution history estoppel applies to a claim containing a limitation that was allowed as originally filed because of the addition of the same limitation in another claim)).

[411] Id. at 1317.

[412] Id. (citing U.S. Patent No. 4,744,428, col. 6, lines 12-30 (issued May 17, 1988)).

[413] Id. at 1318.

[414] Id. (quoting Patent '428, col. 5, lines 12-29).

[415] Deering Precision, 347 F.3d at 1317 (quoting Patent '428, col. 6, lines 24-27).

[416] Id. at 1320.

[417] Id. at 1324.

[418] Id. (citing Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (en banc), vacated by Festo VIII).

[419] Id. at 1326.

[420] Id. at 1318-19.

[421] Deering Precision, 347 F.3d at 1319.

[422] Id.

[423] Id.

[424] Id.

[425] Id.

[426] Id. at 1325.

[427] Deering Precision, 347 F.3d. at 1325.

[428] Id.

[429] Id. at 1326.

[430] Id.

[431] Id. (quoting Builder's Concrete, 757 F.2d at 260).

[432] Id.

[433] 356 F.3d 1348 (Fed. Cir. 2004) [hereinafter Glaxo II].

[434] Id. at 1349-50.

[435] Id. at 1350.

[436] Id.

[437] Id.

[438] Id.

[439] Glaxo II, 356 F.3d at 1350.

[440] Id. at 1351.

[441] Id.

[442] Id.

[443] Id. (quoting Glaxo Wellcome, Inc. v. Impax Laboratories, Inc., 220 F. Supp. 2d 1089, 1094 (N.D. Cal. 2002)) [hereinafter Glaxo I].

[444] Id. (quoting Glaxo I, 220 F. Supp. 2d at 1094).

[445] Glaxo II, 356 F.3d at 1352 (citing Festo VIII, 535 U.S. at 734).

[446] Id. at 1354.

[447] Id. (citing Festo VIII, 353 U.S. at 741).

[448] Id.

[449] Id. (citation omitted).

[450] Id.

[451] Glaxo II, 356 F.3d at 1354.

[452] Id.

[453] Id.

[454] Festo VIII, 535 U.S. at 740, quoted in Glaxo II, 356 F.3d at 1354..

[455] Glaxo II, 356 F.3d at 1356.

[456] Id.

[457] Id. (citing Builders Concrete, 757 F.2d at 260).

[458] Id. The Federal Circuit further explained that "the quest for consistency in patent claims also has its limits. Claims that do not recite the amended term are not subject to an estoppel." Id. (citation omitted).

[459] 517 U.S. 559 (1996).

[460] Id. at 574-75.

[461] 532 U.S. 424 (2001).

462 Id. at 436.

463 272 F.3d 1335 (Fed. Cir. 2001), cert. granted, vacated, and remanded sub. nom, DeKalb Genetics Corp. v. Bayer CropScience, S.A., 538 U.S. 974 (2003) [hereinafter Rhone-Poulenc I].

464 Id. at 1347.

465 Cooper Indus., 532 U.S. at 437.

466 Rhone-Poulenc I, 272 F.3d at 1347.

467 Id. at 1349 (citing Cooper Indus., 532 U.S. at 440).

468 Id.

469 Id.

470 Id.

471 538 U.S. 408 (2003).

472 345 F.3d 1366 (Fed. Cir. 2003) [hereinafter Rhone-Poulenc III].

473 Id. at 1368.

474 Id. at 1370.

475 Rhone-Poulenc I, 272 F.3d at 1349, quoted in Rhone-Poulenc III, 345 F.3d at 1370.

476 Rhone-Poulenc III, 345 F.3d at 1370.

477 State Farm, 538 U.S. at 119, quoted in Rhone-Poulenc III, 345 F.3d at 1370-71 (original internal citations omitted).

478 318 F.3d 1378 (Fed. Cir. 2003).

479 Id. at 1379.

480 Id.

[481] Id.

[482] Id.

[483] Id.

[484] Tronzo, 318 F.3d at 1379.

[485] Id.

[486] Id. at 1382.

[487] (2000).

[488] See 28 U.S.C. § 1967(a), quoted in Toronzo, 318 F.3d at 1379.

[489] See Fed. R. App. P. 37, quoted in Toronzo, 318 F.3d at 1379-80.

[490] Toronzo, 318 F.3d at 1380.

[491] Id. at 1381.

[492] Id.

[493] Id. at 1382.

[494] Id.