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PATENT HAPPENINGS®

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on judicial, legislative, and administrative developments in patent law.

HIGHLIGHTS

1. *Foreign manufacturer's display of accused product at a U.S. trade show supported exercising personal jurisdiction under Rule 4(k)(2) even though product was not offered for sale in the U.S.* 1
2. *Patent misuse from using a patent to cause another patentee to refuse to license its patent* ... 2
3. *Quanta precludes enforcement of a post-sale use condition, such as a single-use restriction* 3
4. *Claims to artificially reducing a biological activity lacked adequate written description where specification failed to adequately describe how the reduction would be attained* 4
5. *Obviousness-type double patenting for a method of making a product in view of a prior patent claiming the product assessed based on the methods of making known at the time the method application is filed* 6
6. *Canceling independent claim and rewriting dependent claim in independent form creates presumption of surrender even though additional limitations had to be added to overcome prior art* 7
7. *Patentee drug manufacturer did not have a duty to preserve electronic data before receiving its first Paragraph IV certification letter* 8
8. *USPTO announces pilot patent prosecution highway with German patent office and extends pilot program with Australian patent office* 8

JUDICIAL HAPPENINGS

Chilling Foreign Participation in US Trade Shows

A foreign medical device manufacturer, having virtually no jurisdictional contacts with the U.S., sends a representative to a trade show in San Diego, California. The representative brings with him five samples of an accused product; a locking bone plate. The samples are displayed at the trade show, but not used for the purposes for which they were designed. Not having FDA approval to sell the product in the United States, the samples are visibly marked as not being for sale in the U.S., the restriction on sale is printed in the product brochures, the representative tells visitors that the device cannot be purchased for use in the U.S., and does not provide any information about the product's price. The foreign manufacturer admits that it sent its representative to the U.S. trade show to promote international sales of the product to other non-U.S. attendees. At the conclusion of the show, the representative returns to his home country taking all five samples with him. A patentee later sues the foreign manufacturer for patent infringement in the Southern District of California. The patentee alleges that by bringing the samples into the U.S. and showing them at the trade show, the manufacturer infringed the patent under the importation and offer for sale prongs of 35 U.S.C. § 271(a)[1] in an unlawful attempt to generate interest in the accused infringing products to the patentee's commercial detriment. On these facts, a district court holds the foreign manufacturer's contacts with the U.S. are insufficient to support personal jurisdiction.[2] The Federal Circuit reverses in *Synthes (U.S.A.) v. G.M. dos Reis Jr. Ind. Com. de Equip. Medico*, No. 2008-1279, 2009 WL 1025760 (Fed. Cir.

[1] *See generally*, Robert A. Matthews, Jr., Annotated Patent Digest § 10:12 Offering a Product as an Infringing Act; § 10:97 Importing a Patented Product into the United States – § 271(a).

[2] *Synthes (U.S.A.) v. G.M. dos Reis Jr. Ind. Com. de Equip. Medico*, 2008 WL 789925, *4-*5 (S.D. Cal. Mar. 21, 2008).

Apr. 17, 2009).

In finding that displaying the accused product at the trade show permitted exercising personal jurisdiction over the foreign manufacturer, the Federal Circuit relied on Rule 4(k)(2) of the Federal Rules of Civil Procedure. Rule 4(k)(2), entitled "Federal Claim Outside State-Court Jurisdiction," provides that "[f]or a claim that arises under federal law, serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant if: (A) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction; and (B) exercising jurisdiction is consistent with the United States Constitution and laws." As explained by the Federal Circuit, Rule 4(k)(2) "serves as a federal long-arm statute, which allows a district court to exercise personal jurisdiction over a foreign defendant whose contacts with the United States, but not with the forum state, satisfy due process." *Id.* at *9.

Analyzing the application of Rule 4(k)(2),[3] the court instructed that Rule 4(k)(2) imposes three requirements before jurisdiction can be exercised: "(1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) the exercise of jurisdiction comports with due process." *Id.* at *7. Under the facts of the case, factors 1 and 2 were quickly ascertained to be met. The patentee's claim of patent infringement arose under federal law, so factor one was met. The accused infringer argued that it was not subject to the jurisdiction of any state court in the U.S., and the Federal Circuit accepted this concession as showing that factor 2 was met.[4] As to factor three, the Federal Circuit held that the foreign manufacturer's acts showed that it "purposefully availed itself of the United States" by bringing the accused product into the U.S. to demonstrate it at a U.S. trade show to further its international sales. *Id.* at *10. Additionally, the Federal Circuit found that due process would not be offended by exercising specific personal jurisdiction since the acts of displaying the product at the trade show formed the basis of the patentee's claim of infringement. *Id.* It noted that while the foreign manufacturer's sales efforts were not directed to U.S. residents, the manufacturer's travel to the U.S. with the accused products and displaying the products at the U.S. trade show, which was attended by U.S. residents, was activity directed to U.S. residents. *Id.* at *11.

In one of the more surprising aspects of the opinion, the Federal Circuit rejected the foreign manufacturer's argument that specific personal jurisdiction did not exist because the acts of bringing the products into the U.S. to display at the trade show did not constitute *prima facie* acts of patent infringement under § 271(a), i.e., the foreign manufacturer allegedly did not "import" or "offer for sale" the accused products within the meaning of § 271(a).[5] The court held that since Rule 4(k)(2) does not have a "tortious injury" component, as is present in many state long-arm statutes, the patentee did not have to show a *prima facie* case that the acts relied on to establish personal jurisdiction were acts of patent infringement. *Id.* at *11. The Federal Circuit therefore left for another day the question of whether the foreign manufacturer's acts of bringing the product into the U.S. to display, but not sell, at the trade show constituted an infringing importation or offer to sell under § 271(a). *Id.*

Inducing a Refusal to License & Patent Misuse

In general, a patentee misuses its patent if it imposes conditions on licensees "that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect."[6] The law deems some acts to be misuse *per se*, while other acts will be misuse if the

[3] The Federal Circuit further instructed that Federal Circuit law, rather than regional circuit law, governed the analysis since the court applies its own law in analyzing questions of personal jurisdiction for patent-related matters. *Id.* at *6; *see generally*, APD § 36:128 Federal Circuit Law Controls for Patent-Related Claims.

[4] The Federal Circuit noted that since it is often difficult to prove a negative – here, that the defendant is not subject to the jurisdiction of any state court – the regional circuit courts of appeals have applied different procedural mechanisms to evaluate this factor. Relying on the accused infringer's assertion that no state court could exercise jurisdiction over it, the Federal Circuit opted not to decide which procedural mechanism it would endorse. *Id.* at *7-*9.

[5] Before *Synthes* some district courts, in an effort not to chill participation in U.S. trade shows by foreign entities, had held that bringing an accused device into the U.S. to display it at a trade show without the intent to sell the product in the U.S. did not constitute prohibited importation under § 271(a). *Black & Decker, Inc. v. Shanghai Xing Te Hao Industrial Co., Ltd., S.K.*, 2003 WL 21383325, *3 (N.D. Ill. June 12, 2003) (dismissing for lack of personal jurisdiction); *Creo Prods. Inc. v. Presstek, Inc.*, 166 F. Supp. 2d 944, 976 (D. Del. 2001), *aff'd on other grounds*, 305 F.3d 1337 (Fed. Cir. 2002).

[6] *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004); *see generally*, APD § 28:12 Conduct Must Improperly Broaden the Scope of the Patent.

patentee cannot justify them under a "rule of reason" analysis.[7] The Federal Circuit has instructed that "[u]nder the rule of reason, 'the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.'"[8] Additionally, Congress, in enacting 35 U.S.C. § 271(d), expressly exempted some conduct from being classified as patent misuse.[9] One such provision, § 271(d)(4), provides that "No patent owner … shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . *refused to license or use any rights to the patent*[.]" Under the plain language of the statute it appears that a patentee, even one with market power,[10] does not commit patent misuse by refusing to license its patent.[11]

Considering an interesting twist to the "refusal to license" scenario, the Federal Circuit addressed in *Princo Corp. v. Int'l Trade Comm'n.*, No. 2007-1386, 2009 WL 1035222, *11-*16 (Fed. Cir. Apr. 20, 2009), what happens if a first patentee allegedly uses its patents to cause a second patentee to agree not to license a patent owned by the second patentee? Does such conduct constitute misuse of the first patentee's patents? The Federal Circuit concluded that it may.

Princo concerned the licensing of a pool of patents directed to recordable compact discs covering an industry standard, called the "Orange Book" standard.[12] The pool administrator sued an accused infringer on subset of the patents in the pool. These asserted patents were all owned by the pool administrator. A second patentee contributed a patent, the "Lagadec" patent, to the pool that, while being reasonably necessary to practice the Orange Book standard, additionally disclosed an alternative technology that allegedly could compete with the standard. The accused infringer argued that the pool administrator colluded with the second patentee to have the second patentee agree not to license the Lagadec patent in a manner that would permit the public to develop the alternative competing technology disclosed in the second patentee's patent. The Federal Circuit held that the accused infringer's allegations, if proven true, would support a finding of patent misuse of the first patentee's asserted patents under a rule of reason analysis. *Id.* at *13; *see also id.* at *11, n.11. The court stated:

> In contrast to tying arrangements, there are no benefits to be obtained from an agreement between patent holders to forego separate licensing of competing technologies….
>
> Agreements between competitors not to compete are classic antitrust violations. Agreements preventing patent licensing of competing technologies also can constitute such violations. Such agreements are not within the rights granted to a patent holder.

Id. at *13 (citations and footnote omitted).

The Federal Circuit remanded the case back to the ITC for the Commission to make findings as to the viability of developing an alternative competing technology with the Lagadec patent and whether the patentee really did make an agreement with the owner of the Lagadec patent to cause the owner not to license the Lagadec patent for uses that competed with the Orange Book standardized technology.

Enforceability of Post-sale Use Restrictions

Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992), holds that imposing a contractually valid post-sale condition on how a purchaser of a patented product may use that product, e.g., a single-

[7] *See generally*, APD § 28:13 Acts that are *Per Se* Misuse; § 28:15 Two-Part Test for Determining if Conduct Amounts to Misuse.

[8] *Virginia Panel Corp. v. Mac Panel Co*., 133 F.3d 860, 869 (Fed. Cir. 1997) (quoting *State Oil Co. v. Kahn*, 118 S. Ct. 275, 279 (1997))

[9] *See generally*, APD§ 28:14 Statutory Exempt Conduct Under § 271(d).

[10] Other provisions of § 271(d), e.g., § 271(d)(5), limit their applicability to patentees who do not have "market power in the relevant market for the patent or patented product on which the license or sale is conditioned." The notable absence of this condition in § 271(d)(4) suggests that the exemption applies even if a patentee who has market power refuses to license. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

[11] *See generally*, APD § 28:32 Refusal to License Others or Discriminatory Licensing. But, over a decade ago, one district court ruled that despite § 271(d)(4), a patentee's refusal to license can be misuse under a rule of reason analysis. *In re Independent Service Organizations Antitrust Litig.*, 964 F. Supp. 1454, 1460 (D. Kan. 1997).

[12] This standard has nothing to do with the FDA Orange Book for purposes of ANDA litigations.

use restriction, does not constitute patent misuse and that violations of the condition may be remedied by an action for patent infringement.[13] Relying on *Mallinckrodt* in its 2007 opinion, the district court in *Static Control Components, Inc. v. Lexmark Int'l., Inc.*, 487 F. Supp. 2d 830, 846-48 (E.D. Ky. April 24, 2007), ruled that a patentee's "prebate" program, whereby the patentee imposed a single-use restriction requirement on printer cartridges it sold at a discounted price and also required the purchaser to promise to return the spent cartridge only to the patentee and not to reuse the cartridge, was a valid provision enforceable under the patent laws. On a motion for reconsideration, however, the district court reversed itself in view of the intervening Supreme Court opinion of *Quanta Computer, Inc. v. LG Elec. Inc.*, 128 S. Ct. 2109 (2008). The district court held that *Quanta* overruled *Mallinckrodt* such that any authorized sale of a product exhausts the patent rights in that product for all post-sale uses of the product. Consequently, patent law can't be used to enforce an alleged contractual post-sale use restriction. *Static Control Components, Inc. v. Lexmark Intern., Inc*., 2009 WL 891811, *6-*12 (E.D. Ky. Mar. 31, 2009).

Analyzing the Supreme Court's precedent on exhaustion, the district court concluded that the "[Supreme] Court has consistently held that patent holders may not invoke patent law to enforce restrictions on the post-sale use of their patented products. After the first authorized sale to a purchaser who buys for use in the ordinary pursuits of life, a patent holder's patent rights have been exhausted." *Id.* at *6. Agreeing with the accused infringer, Static Control, the district court stated that "[t]he patent exhaustion doctrine articulated in *Quanta* invalidates Lexmark's effort to create patent-based use restriction through its postsale Prebate terms, as well as Lexmark's attempt to enforce the Prebate terms under patent law against Static Control." *Id.* at *8. The district court faulted the patentee for "confus[ing] the distinction made in *Quanta* between conditions restricting the *right to sell*, like the condition in the license agreement between the patent holder and the manufacturer in *General Talking Pictures* which prohibited the manufacturer from making its initial sales of the patented amplifiers to commercial users, and post-sale conditions on *use*." *Id.* (emphasis added).

Addressing the continued validity of *Mallinckrodt*, the district court stated that it "is persuaded that *Quanta* overruled *Mallinckrodt sub silentio.*" *Id.* at *9. The court further explained that "[t]he Supreme Court's broad statement of the law of patent exhaustion simply cannot be squared with the position that the *Quanta* holding is limited to its specific facts." *Id.* It concluded, therefore, that "after *Quanta*, Lexmark may not invoke patent law in order to enforce its Prebate terms." *Id.* at *10.

The district court did note that although patentees may not rely on patent law to enforce post-sale use restriction, they may attempt to invoke state contract law to enforce such provisions. *Id.* While the Supreme Court has not yet expressed a definitive opinion on the use of state contract law to enforce post-sale use restrictions, it has acknowledged the possibility.[14]

Describing Result, but not How to Achieve Result

The Federal Circuit treats 35 U.S.C. § 112, ¶ 1 as imposing a "written description" requirement, separate from an enablement requirement. It does so, in part, as a way of ensuring that the patent applicant possessed the claimed invention as of the application filing date.[15] The court has instructed that "[o]ne shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious."[16] Given that actual possession of the invention is required, the Federal

[13] *Id.* at 708-709. *See generally*, APD § 11:34 —Single-Use Restrictions.

[14] *Quanta*, 128 S. Ct. at 2122 n.7 ("We note that the authorized nature of the sale to Quanta does not necessarily limit LGE's other contract rights. . . . [W]e express no opinion on whether contract damages might be available even though exhaustion operates to eliminate patent damages."); *Keeler v. Standard Folding-Bed Co.*, 157 U.S. 659, 666 (1895) ("[O]ne who buys patented articles of manufacture from one authorized to sell them becomes possessed of an absolute property in such articles, unrestricted in time or place. Whether a patentee may protect himself and his assignees by special contracts brought home to the purchasers is not a question before us, and upon which we express no opinion. It is, however, obvious that such a question would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws.").

[15] *See generally*, APD § 22:25 Show Applicant Possessed Invention. *But see Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) ("A showing of 'possession' is secondary to the *statutory* mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.")

[16] *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)

Circuit has held that merely describing the result the claimed invention will achieve, without describing *how* the claimed invention will achieve the result, fails to show the applicant possessed the invention.[17] The Federal Circuit's recent opinion in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. Apr. 3, 2009), exemplifies this legal principle.

In *Ariad*, the named inventors had discovered that a protein, denoted as NF-κB, helped to regulate activity in the immune system. In essence, NF-κB exerts its biological function in response to external stimuli (*e.g.*, the presence of bacteria, viruses) by acting like a switch to turn on or off the immune system. Through their work, the inventors realized that "if NF-κB activity could be reduced artificially, it could ameliorate the harmful symptoms of diseases that trigger NF-κB activation…" *Id.* at 1370. Seeking to protect their discovery, the inventors obtained claims broadly directed to methods of "reducing NF-κB activity."

In the district court, the patentee succeeded in proving infringement and withstood the accused infringer's invalidity challenges. On appeal, however, the Federal Circuit reversed the denial of the accused infringer's motion for JMOL that the claims were not adequately described in the specification. Specifically, the Federal Circuit found that while the specification described the result of "reducing NF-κB activity," it failed to describe how the reduction was achieved.

The patentee argued that the patent specification described three types of molecules that could be used to achieve the reduction in NF-κB activity: (1) specific inhibitors (molecules that bind to NF-κB and inhibit its activity); (2) dominantly interfering molecules (mutants of NF-κB lacking certain functions); and (3) decoy molecules (nucleic acid molecules that resemble the NF-κB binding site on DNA). Examining each of these molecule types, the Federal Circuit concluded that the specification's description was insufficient.

For the specific inhibitor, the Federal Circuit noted that the specification disclosed a specific inhibitor protein (IκB), known in the art as of the effective filing date. But, apparently because the amino acid sequence of that inhibitor was not provided as of the effective filing date, the court held that there was inadequate description of any specific inhibitor. It stated that "[i]n the context of this invention, a vague functional description and an invitation for further research does not constitute written disclosure of a specific inhibitor." *Id.* at 1374. As to the interfering molecules, the Federal Circuit found that the applicants' failure to provide in the specification specific examples of using "interfering molecules" to reduce the cell activity showed that "the description of the dominantly interfering molecules 'just represents a wish, or arguably a plan' for future research." *Id.* at 1375. For the decoy molecules, the court found that while the specification disclosed some prophetic examples of using "decoy molecules," under the circumstances, the examples failed to provide an adequate written description where the description of the decoy molecules was deemed to just be "not so much an 'example' [but] a mere mention of a desired outcome." *Id.*

Concluding its findings, the Federal Circuit noted that the patent specification "discloses no working or even prophetic examples of methods that reduce NF-κB activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity." *Id.* at 1376. It further noted that "[t]he state of the art at the time of filing was primitive and uncertain, leaving [the patentee] with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure." *Id.* Consequently, the court found there was insufficient evidence to support the jury's verdict that the claims were not proven invalid.

In contrast to *Ariad*, the district court in *Regents of Univ. of Cal. v. Dako N. Am., Inc*., 2009 WL 1083446, *9-*13 (N.D. Cal. Apr. 22, 2009), denied an accused infringer's motion for summary judgment of invalidity for an allegedly inadequate written description of a biological invention. The challenged claims were directed to a generic method for identifying target genes. The method involved staining chromosomes by *in situ* hybridization using "chromosome specific staining reagents." The specification only disclosed one working example directed to one specific human chromosome, but it stated that the method could be applied to a variety of organisms. Rejecting the accused infringer's argument that the specification had to disclose a sufficient number of representative examples to provide an adequate written description, the district court noted that the patentee provided unrefuted expert testimony that "the claimed blocking method 'utilizes DNA hybridization principles that

[17] *See generally*, APD § 22:33 Describing Result But Not Way is Not Sufficient.

apply equally to all types of chromosomal DNA.'" *Id.* at *9 (emphasis added). As a result, the district court concluded that "the 'representative species' requirement is low. To hold otherwise would place improper and undue limitations on the breadth of the claimed invention." *Id.*

The court also rejected the accused infringer's contention that the biological arts are always unpredictable, and therefore a generic disclosure can never satisfy the written description requirement. The district court explained:

> The unpredictability factor only applies when there is unpredictability in the results themselves and even then the law does not preclude genus claims. If the law were to hold all of biology to a higher standard, . . . no seminal biotechnological advancement would be patentable as anything more than a modest development limited in literal scope to its concrete examples. Prophetic examples would be worthless and the doctrine of equivalents would be nullified. Indeed, the value of the patent system itself would be diminished if every slight alteration, substitution or improvement upon a fundamental biotechnology method could escape infringement of a literally-claimed (or invalidate a more broadly-claimed) patent to a pioneer invention. . . . The case law makes clear that, even in unpredictable arts, the written description requirement can be met when a patent specification frames functional descriptions of biologic materials used in related methods if those functional definitions are coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.

Id. at *11 & *13.

Double Patenting of Product/Process Claims

Obviousness-type double patenting[18] may arise in the context of claims directed to a product in a first patent and claims directed to a method of producing that product claimed in a second patent. The Federal Circuit has instructed that where there is only one way to make the claimed product, double patenting bars an applicant from obtaining separate patents with separate terms for both a product and the process for making that product. Double patenting for a process will not necessarily apply if the product can be made by two or more processes that are "patentably distinct" from each other.

In considering whether two or more processes exist to create a product, an issue may arise as to what point in time the two processes must exist. The Federal Circuit addressed this precise issue in *Takeda Pharmaceutical Co., Ltd. v. Doll*, 561 F.3d 1372 (Fed. Cir. April 9, 2009). There it held that the proper temporal reference for assessing the existence of available patentably distinct processes is the filing date of the second application. Rejecting the PTO's attempt to limit the time period to the first application's filing date, and rejecting the patent applicant's contention, which the district court had adopted,[19] that there should be no limit on when a second process can be shown to exist, the Federal Circuit held that the policies' the double patenting doctrine seek to achieve require rejecting both contentions. Instead, the court held that the filing date of the second application acts as a cutoff date for assessing whether more than one patentably distinct process exists to make the product. Explaining its rationale the court stated:

> When filing the secondary application, the applicant essentially avers that the product and process are "patentably distinct." Thus, the relevant time frame for determining whether a product and process are "patentably distinct" should be at the filing date of the secondary application. . . . This approach allows an applicant to rely on some later-developed methods to show that the product and process are "patentably distinct," even though the alternative processes for making that product may not have been known at the filing date of the primary application. This rule gives the applicant the benefit of future developments in the art. At the same time, however, it prevents the inequitable situation that arises when an applicant attempts to rely on developments occurring decades after the filing date of the secondary application.
>
> This approach should encourage the swift development of materially distinct, alternative processes.

Id. at 1377.

Judge Schall dissented. In his view, the original application filing date should be the cutoff date for assessing whether patentably distinct processes of making a claimed product exist. *Id.* at 1379. Summing up his view, he stated: "As far as I can tell, there is no

[18] *See generally*, APD § 19:8 Overview of Obviousness-Type Double Patenting.

[19] *Takeda Pharmaceutical Co., Ltd. v. Dudas*, 511 F. Supp. 2d 81, 91-96 (D.D.C. Sept. 24, 2007).

other doctrine or rule that allows unpatentable material to spring back into patentability based on later developments in the field." *Id.* at 1380.

Clarifying Prosecution History Estoppel

In *Felix v. Am. Honda Motor Co., Inc.*, No. 2008-1367, 2009 WL 962660, *10-*12 (Fed. Cir. Apr. 10, 2009), the Federal Circuit provided additional clarity to five aspects of amendment-based prosecution history estoppel, *i.e*. *Festo*-type estoppel.[20] Specifically, the court addressed: 1) prosecution history estoppel arising from rewriting a dependent claim in independent form; 2) whether an estoppel will apply if the narrowing amendment fails to overcome the examiner's rejection; 3) applying the estoppel to nonamended claims; 4) where multiple limitations are added a presumption of surrender applies individually to each limitation; and 5) evidence necessary to overcome the presumption of surrender based on a contention that the amendment has only a tangential relation to the asserted equivalent.

The prosecution fact pattern in *Felix* involved the following scenario. The applicant submitted to the PTO an independent claim having four limitations. The applicant also submitted a first dependent claim (claim 7 in the application) adding two additional limitations, a "channel" limitation and a "gasket" limitation. The applicant also submitted a second dependent claim (claim 8 in the application) which depended from the first dependent claim and added another limitation. The PTO rejected the independent claim and the first dependent claim, i.e., claims 1 and 7, over prior art. The PTO further objected to the second dependent claim, claim 8, and stated that it would be allowable if the applicant rewrote the claim in independent form. Rather, than rewriting the second dependent claim (claim 8) in independent form, the applicant cancelled the independent claim and rewrote the *first* dependent claim (claim 7) in independent form. The PTO maintained its prior art rejection of claim 7. Thereafter, the applicant cancelled claim 7 and rewrote the second dependent claim (claim 8) in independent form. During litigation, the patentee attempted to assert that an accused product met under the doctrine of equivalents the "gasket" limitation. The district court granted the accused infringer a summary judgment that prosecution history estoppel barred any assertion of equivalents for the gasket limitation, and the Federal Circuit affirmed.

On appeal, the Federal Circuit first held that the applicant's first amendment, whereby it cancelled the independent claim and rewrote the first dependent claim in independent form, "had the effect of adding the channel and gasket limitations of dependent claim 7 to the broader claim that was cancelled." *Id.* at *10. Consequently, "the rewriting of dependent claims into independent form coupled with the cancellation of the original independent claims create[d] a presumption of prosecution history estoppel."[21,22]

Second, the court held that the examiner's repeating its rejection of claim 7 was of "no consequence" to the applicability of the presumption of surrender. *Id.* Explaining that "[i]t is the patentee's response to a rejection—not the examiner's ultimate allowance of a claim—that gives rise to prosecution history estoppel," the court held "that the presumption of prosecution history estoppel attaches when a patentee cancels an independent claim and rewrites a dependent claim in independent form for reasons related to patentability, even if the amendment alone does not succeed in placing the claim in condition for allowance." *Id.*

Third, the court further held that the estoppel to the gasket limitation arising from canceling the independent claim and rewriting claim 7 in independent form "applie[d] to all claims containing the added limitation, regardless of whether the claim was, or was not, amended during prosecution." *Id.* at *11.[23]

Fourth, the court held that while the narrowing amendment added two limitations, "[t]he resulting estoppel attache[d] to each added limitation." *Id.* The court based its ruling on the general principle that "when a patent applicant relinquishes claim scope to secure allowance of a patent claim, an estoppel will apply to the full extent of the relinquished subject matter even if the applicant narrowed the claim more

[20] *See generally*, APD § 14:11 The Four-Part Test for Determining if an Estoppel Arises from a Claim Amendment.

[21] *See generally* APD § 14:17 Rewriting Dependent Claim as an Independent Claim; *see also* APD § 14:18 Canceling Claims may Raise an Estoppel to Remaining Claims.

[22] The Federal Circuit additionally noted that it was not addressing whether the presumption of surrender for the gasket limitation would have applied if the applicant had cancelled both claims 1 and 7, and rewritten the second dependent claim, claim 8 with its one additional limitation, in independent form. *Id.* at *10 n.4.

[23] *See generally*, APD § 14:8 Infectious Estoppel – Applying Estoppel to Claims Not Amended.

than was necessary to avoid the prior art."[24]

Finally, the court addressed the applicant's attempt to rebut the presumption of surrender by showing that the narrowing amendment adding the gasket limitation was only tangentially related to the asserted equivalent.[25] The patentee argued that because the applicant only relied on the "channel" limitation to overcome the prior art rejection, the portion of the amendment adding the gasket limitation was only tangentially related to the asserted equivalent. The Federal Circuit rejected this argument. It found that the prosecution record showed that the applicant relied on the channel limitation and "other structure" to distinguish over the prior art. Hence, it was not "objectively apparent" from the prosecution history that the applicant relied only on the "channel" limitation.[26] *Id.* at *12. The court also noted that the patentee had "identified no explanation in the prosecution history for the addition of the gasket limitation," and therefore it failed to meet its "burden to show that the rationale for adding the gasket limitation was tangential to the presence and position of a gasket." *Id.*

Preserving E-Mails in ANDA Litigations

"The law generally imposes on litigants a duty to preserve discoverable material once the party knows, or should know, that the material is likely to be requested in discovery."[27] Seeking sanctions, including "death knell" sanctions, for spoliation where a party fails to preserve discoverable information appears to be on the rise in patent litigation.[28] The case of *Forest Labs., Inc. v. Caraco Pharmaceutical Labs., Ltd*., 2009 WL 998402, *2-*3 (E.D. Mich. Apr. 14, 2009), addresses a patentee's duty to preserve evidence in the context of ANDA litigation. In *Forest Labs.*, the accused infringer attempted to show that the patentee's destruction of e-mails and back-up tapes amounted to spoliation. To support its contention, the accused infringer argued that the patentee's duty to preserve evidence arose from when the patentee first began developing its drug product, since, given the nature of the Hatch-Waxman litigation framework, the patentee should have known that litigation would ensue. Noting that the accused infringer failed to cite any authority for extending the duty to preserve so far back in time, the district court rejected this argument. It held that "a rule requiring large corporations … to retain backup tapes whenever future litigation is merely *possible* would be crippling." *Id.* at *2 n.2. Instead, the court held that the patentee's duty to preserve relevant evidence related to the patent did not arise until it received the first Paragraph IV certification letter. *Id.* Accordingly, the court held that the accused infringer's spoliation claims based on e-mails and other materials destroyed before the patentee received its first Paragraph IV certification failed as a matter of law. For alleged destruction of back-up tapes occurring after that date, the court held that, while the back-up tapes were deemed "inaccessible," and therefore normally exempt from the preservation duty, the court had to hold a hearing to determine if any exceptions applied that, under the specific circumstances, would make the destruction of the back-up tapes an act of spoliation. *Id.* at *3.

PTO Happenings

PPH Pilot Program Begins in Germany

Effective April 27, 2009, the U.S. Patent and

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[24] § 14:10 Estoppel Not Limited to Relinquishment Necessary to Avoid Prior Art.

[25] A patentee may rebut the presumption of surrender by showing that "the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740(2002); *see generally*, APD § 14:49 General Aspects of Being Tangentially Related to the Equivalent.

[26] A patentee may only rely on intrinsic evidence, i.e., the prosecution history, to show the reasons for its narrowing claim amendment are only tangentially related to the alleged equivalent. APD § 14:50 Extrinsic Evidence Not Permitted.

[27] APD § 41:230 Duty to Preserve Evidence.

[28] *See e.g., Phillip M. Adams & Associates, L.L.C. v. Dell, Inc.*, No. 1:05-CV-64 TS, 2009 WL 910801, *12-*13 (D. Utah Mar. 30, 2009) (finding that one accused infringer spoliated evidence by failing to preserve source code and other material even though the patentee delayed in bringing suit or notifying the accused infringer of its claim of infringement); *Micron Technology, Inc. v. Rambus Inc.*, 255 F.R.D. 135 (D. Del. Jan. 9, 2009) (holding patents unenforceable as a sanction for spoliation after finding that the patentee, after reasonably anticipating litigation, instituted a document retention policy under which it destroyed hundred of boxes of documents relevant to the accused infringer's patent misuse and inequitable conduct defenses, and that the accused infringer proved by clear and convincing evidence the destruction was done in bad faith, and that it was thereby prejudiced). *But cf. Hynix Semiconductor Inc. v. Rambus, Inc*., No. C-00-20905 RMW, 2009 WL 292205 (N.D. Cal. Feb. 3, 2009) (addressing same conduct as issue in *Micron Technology, Inc. v. Rambus Inc.*, 255 F.R.D. 135 (D. Del. Jan. 9, 2009), and refusing to give issue preclusive effect to *Micron* in view of the court's earlier finding, as set forth at 591 F. Supp. 2d 1038 (N.D. Cal. Jan. 5, 2006), that document destruction did not amount to spoliation sufficient to show unclean hands and preclude the patentee from enforcing its patents).

Trademark Office (USPTO) and the German Patent and Trade Mark Office (DPMA) have agreed to implement a two-year trial cooperation initiative called the Patent Prosecution Highway (PPH). Under the PPH, an application containing at least one claim determined to be allowable/patentable in the Office of first filing (OFF) may request accelerated examination of the corresponding application in the Office of second filing (OSF) in view of the search and examination results from the OFF. The procedures and full requirements for filing a request with DMPA to participate in the trial program can be found at http://www.dpma.de/english/patentlfonns/index.html. Provisional applications, plant applications, design applications, reissue applications, reexamination proceedings, and applications subject to a secrecy order are excluded from participation in the PPH.

Currently, the USPTO also has a full-time PPH program with the Japan Patent Office and the Korean Intellectual Property Office and pilot PPH programs with the United Kingdom Intellectual Property Office, the Canadian Intellectual Property Office, IP Australia, the European Patent Office, the Danish Patent and Trademark Office, and the Intellectual Property Office of Singapore.

Extension of PPH Pilot Program in Australia

In a Notice dated April 13, 2009, the USPTO announced that it will extend the PPH pilot program with IP Australia to provide more time to assess the feasibility of the PPH pilot program before making a formal decision about the program.

FIRM HAPPENINGS

At the end of May, Bob Matthews will be speaking at the Intellectual Property Owners Association (IPO) conference in Washington, D.C., entitled "Realities and Myths in Patent Litigation Today: 'Non-Practicing' Patent Owners and Other Issues," on the availably of injunctive relief for patent holding companies. Information about the conference can be found at the IPO website at www.ipo.org.

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