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National Prejudice: Alive and Well in the WIPO World

Statistics published by the World Intellectual Property Organization (WIPO) reveal that at least several important U.S. trading partners exhibit a partisan favoritism for their own citizens when deciding whether to grant a patent. The data published on the WIPO website discloses: (i) the number of patent applications filed by residents and non-residents; as well as (ii) the number of patents granted to residents and non-residents, all sorted by country. <<http://www.wipo.org/ipstats/en/publications/a/pdf/patents.pdf>> Statistics published for the years 2000 and 2001 (the latest available published data) show that the Patent Offices in China, France, Germany, Japan and South Korea are far more likely to grant pat-

ents to their own citizens than to citizens of a foreign country. The UK Patent Office, by contrast, demonstrated a fairly balanced result.

Table 1 (below) shows statistics taken from the WIPO data, sorted by country, listing the number of patents applied for by residents and non-residents, as well as the number of patents actually granted to both residents and non-residents in the years 2000 and 2001. The fact that most readily jumps out is that the Japanese Patent Office received substantially more patent applications in 2001 (496,621) than the United States Patent & Trademark

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Festo and the Federal Circuit: The Exception to the Exception to the Exception...

In a recent, highly-anticipated decision, the Court of Appeals for the Federal Circuit established many of the parameters for determining when a patentee will be prohibited from proving infringement under the doctrine of equivalents. In *Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., Ltd.* (known as the *Festo* case), the Court resolved three general issues: first, who should determine whether prosecution history estoppel bars resort to the doctrine of equivalents; second, what factors should be considered in determining whether the estoppel applies; and, third, what evidence should be considered in determining whether the estoppel applies. --- F.3d ---, 2003 WL 22228611 (Fed. Cir. 2003). In resolving those three matters, the Court reached the conclusions urged by three MBHB attorneys in a brief filed on behalf of the Association of Patent Law

Firms – the decision should be made by the judge, not a jury; the factors are complex and best left to case-by-case consideration; and the evidence should generally be limited to the prosecution history (including testimony as to what it means to one of skill in the art) and evidence of the knowledge of one of skill in the relevant art. As one of the Federal Circuit judges noted in a concurrence, however, even those rational decisions are likely to lead to short-term distortions in patent prosecution and litigation. Thus, in the wake of the *Festo* case, it is even more important to plan patent prosecution strategy carefully.

As concurring Judge Rader put it, the *Festo* case relates to “some exceptions to an excep-

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Tools of the Trade: The Section 271(e)(1) Research Exception

On June 6, 2003, a Federal Circuit panel clarified the scope of the exemption afforded by 35 U.S.C. § 271(e)(1) with regard to infringing activities that occur early in the drug development process. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) ("*Integra Lifesciences*"). Section 271(e)(1) provides an exemption for otherwise infringing activities that are "solely for uses reasonably related to the development and submission of information" to the FDA.

Much concern regarding the scope of this exemption arose following a district court opinion in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 U.S. Dist. LEXIS 19361 (S.D.N.Y. 2001) ("*BMS*"), which held that the use of patented intermediates to prepare libraries of taxol derivatives and to identify novel anti-cancer taxol analogs for further development and future FDA submission was exempt under Section 271(e)(1). Thus, the allegedly infringing activity in *BMS* occurred even before identification of a particular compound for which FDA approval would be sought. Until *Integra Lifesciences*, the Federal Circuit did not have the opportunity to opine on how far upstream of FDA approval the scope of the Section 271(e)(1) exemption reaches. In particular, the Court had not opined on whether research activity conducted to identify a drug compound falls with the Section 271(e)(1) exemption.

In *Integra Lifesciences*, Integra sued Merck for infringement of several patents relating to a tri-peptide segment of fibronectin having the sequence Arg-Gly-Asp, which promotes cell adhesion to substrates in culture and *in vivo* by interacting with a specified cell surface receptor. Prior to the suit, Merck partnered with the Scripps Research Institute

("Scripps"), where a scientist had discovered that blocking this receptor inhibited angiogenesis (the process of generating new blood vessels), an effect thought to provide an effective means for eliminating tumor growth and for treating a variety of other diseases. The Merck-Scripps agreement contemplated a research and development program to bring a cyclic peptide receptor inhibitor discovered by Scripps, or a derivative thereof, to clinical trials and through FDA approval. Towards this end, additional Scripps research led to two derivatives of interest,

snippets

[A]s a minimum...a clinical drug candidate must have been identified for the [271(e)(1)] exemption to apply.

and Scripps scientists conducted several *in vivo* and *in vitro* experiments "to evaluate the specificity, efficacy, and toxicity [of the compounds] for various diseases, to explain the mechanism by which these drug candidates work, and to determine which candidates were effective and safe enough to warrant testing in humans." *Integra Lifesciences*, 331 F.3d at 863. These experiments included histopathology, toxicology, circulation, diffusion, and half-life of the peptides in the bloodstream and examined the proper mode of administration for optimum therapeutic effect. Learning of the Merck-Scripps agreement, Integra contacted Merck and offered a license under its patents, which Merck ultimately declined. Integra sued for patent infringement, and Merck asserted Section

271(e)(1) as a defense. The district court held that the Merck-Scripps activity did not fall under the Section 271(e)(1) exemption.

In an opinion written by Judge Rader, the Federal Circuit affirmed the district court. To support its holding, the Federal Circuit referred to the legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984, Publ. L. No. 98-417, 98 Stat. 1585 (1984) ("the 1984 Act"), which implemented the § 271(e)(1) exemption. In particular, the Federal Circuit cited two legislative goals of the 1984 Act. First, the Federal Circuit found that Congress intended for the Act to provide additional patent term to compensate patentees who must endure a protracted regulatory approval period during the term of their patent before they can enjoy market exclusivity. Second, the Federal Circuit found Congressional intent to eliminate the *de facto* patent term extension arising because generic drug companies had to await patent expiry before they could conduct otherwise infringing activities necessary to generate data for regulatory approval, thereby delaying the generic drug's entry into the market. To achieve these goals, the 1984 Act permitted generic competitors to conduct experiments on patented drugs during the lifetime of the patent so that the generic drug could be marketed as soon as the last of the relevant patents expired.

The Federal Circuit also referred to the House Committee's characterization of the activities permitted by the infringement exemption as "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." The Court considered important the Committee's characterization of exempt activity as interfering with the

patentee's rights in a *de minimis*, rather than substantial, way. By the plain language of its terms, the statute limits the exemption to activities conducted "solely for purposes reasonably related to the development and submission of information under Federal law." At issue in *Integra Lifesciences* was the meaning of the term "reasonably related."

The Federal Circuit reasoned that the term "reasonably related" tied the exempt activities to the submission of information to the FDA. The Court opined that while infringing activities need not directly produce data that is submitted to the FDA to enjoy the safe harbor of Section 271(e)(1), such activities "strain[] the relationship to the central purpose of the safe harbor." *Integra Lifesciences*, 331 F.3d at 866. Accordingly, the Court commended the district court for confining the exemption to activity that "would contribute (relatively directly)" to information the FDA considers for drug approval. *Id.* at 867 (citing *Intermedics Inc. v. Ventritex Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993)). To further define the scope of "reasonably related," the Court referred back to a primary purpose of the 1984 Act: to facilitate the immediate entry into the market upon patent expiration of generic versions of patented drugs already in the market.

Viewed in this context, the Federal Circuit held that the term "reasonably related" does not embrace all activity in the research and development chain simply because the activity may lead to an FDA approval process. In particular, and *de facto* overruling the district court's interpretation in *BMS*, the Federal Circuit stated "[t]he FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval."

Integra Lifesciences, 331 F.3d at 866. "The safe harbor does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests." *Id.* at 867. To view it otherwise, the Court held, would ignore the language of Section 271(e)(1) and its context in the 1984 Act. In addition, the Court recognized that to hold otherwise would vitiate the exclusive rights of a whole class of patentees owning biotechnology tool patents, whose value had been put into question by the *BMS* decision. This outcome would be in direct conflict with the legislative intent that the exempt activity have only *de minimis* effect on patent owners' rights: "[t]he 1984 Act was meant to reverse the effects of *Roche* under limited circumstances, not to deprive entire categories of inventions of patent protection." *Id.* at 867 (citing *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), in which the Federal Circuit held that pre-expiration tests infringe the patent on the pioneer drug).

Applying its reasoning to the facts of *Integra Lifesciences*, the Federal Circuit held that the Merck-Scripps activity, which the Court described as pre-clinical research that did not supply information for submission to the FDA but rather identified a drug candidate that would be subject to future clinical testing for FDA approval, was not exempt under Section 271(e)(1). Judge Newman, concurring in part and dissenting in part, agreed with the majority's reasoning and holding with regard to Section 271(e)(1) but opined that the common law research exemption (which neither party raised nor briefed) would apply.

Thus, the reasoning and holding in *Integra Lifesciences* sets a clear limit on how far upstream in the research and devel-

opment process the Section 271(e)(1) exemption reaches. The Federal Circuit has set as a minimum that a clinical drug candidate must have been identified for the exemption to apply. The area of otherwise-infringing activities that lies between drug discovery and activities that directly generate data submitted to the FDA remains somewhat gray, however, particularly as the activities get closer in time and nature to the identification of the lead candidate.

For an expansive analysis of Section 271(e)(1), the reader is referred to Noonan, Greenfield, and Zuhn, *Paradise Lost: The Uncertain Future of Research Tool Patents*, 15 INTELL. PROP. & TECH. L.J. 1 (2003).

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Drafting the Technology Game Plan

Part 3: Proper Inventorship Determinations

The U.S. patent law provides that whoever “invents” patentable subject matter is entitled to a patent. 35 U.S.C. § 101 (2003). Thus, U.S. patent applications must list the “true and only” inventors. *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997), *cert. denied*, 117 S. Ct. 2459 (1997). Although seemingly innocuous, this rule can operate to invalidate a patent even if just one of the true inventors is not named, or if a single inventor is erroneously named. Thus, there is an important but often underemphasized role in correctly determining who should be listed as an inventor for a patent.

Invention disclosures often include people who are somehow connected with the invention but are not really inventors. For example, a disclosure might identify the true inventors along with their supervisors and various co-workers who provided suggestions, as well as technicians who helped complete the invention. There are varying reasons for this. For example, an employer might name more than the true inventors in a patent application to promote teamwork or for corporate political reasons. Employees also are often eager to be named as inventors to build their credentials or to qualify for bonus or royalty payments. Many people fail to realize, however, that the determination of inventorship is substantially different than the determination of authorship for a publication.

Inventorship is a legal, not collegial, matter. Despite the incentives to name more than the true inventors, the consequences can obliterate any benefit, as a court may find a patent invalid for naming more or less than all of the true inventors. See, e.g., *Trovan, Ltd. v.*

Sokymat SA, 299 F.3d 1292, 1301 (Fed. Cir. 2002). Thus, the proper determination of inventorship is of paramount importance when filing a patent application. This article offers guidance in determining who is a true inventor.

Who Are the True and Only Inventors?

In the United States, invention is a two-step process: conception and reduction to practice. A determination of inventorship, however, focuses almost exclusively on conception. *Burroughs Wellcome Co. v. Bar Labs. Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). The determination of proper inventorship requires the identification of each person who conceived the invention of each of the **claims** of the patent. Inventorship is based on the subject matter being **claimed**; the inventor of disclosed but unclaimed subject matter is not an inventor for the purposes of U.S. patent law. Therefore, the first step in determining inventorship is determining the subject matter of the patent claims. *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998), *cert. denied*, 119 S. Ct. 278 (1998).

Once the subject matter of the patent claims has been identified, the next step is to determine who conceived the invention that is represented in each of the claims. *Id.* at 1460. The U.S. Court of Appeals for the Federal Circuit defines conception as “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). An idea is “definite and permanent” when “only

ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.” *Burroughs Wellcome*, 40 F.3d at 1228. Therefore, conception is complete when an idea is sufficiently definite and permanent to permit one with ordinary skill in the art to reduce it to practice without undue experimentation. *Ethicon, Inc.*, 135 F.3d at 1460. Conception of the invention “must include every feature of the subject matter claimed in the patent.” *Id.* at 1461.

Joint Inventors

A patented invention may be the work of one or more inventors. 35 U.S.C. § 116 (2003). Joint inventorship occurs when two or more people collaborate such that each contributes to the conception of the invention. Donald S. Chisum, 1 *Chisum on Patents* § 2.02 (2001). Each inventor is not required to contribute to the entire invention or to every claim of the patent. 35 U.S.C. § 116 (2003). In fact, a significant contribution to even one claim in the patent is enough to make someone a joint inventor. *Ethicon, Inc.*, 135 F.3d at 1461. Moreover, there is no explicit quantitative or qualitative lower limit to the amount of inventive contribution required to qualify one as a joint inventor. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). However, the contribution that is made must be significant and inventive; someone does not become a joint inventor by merely explaining well-known principles or the current state of the art. *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001).

A contribution is significant when that contribution helped make the invention patentable. *Levins v. Septodont, Inc.*, 34 Fed. Appx. 65 (Fed. Cir. 2002). A person

does not qualify as an inventor simply because his or her contributions appear in the claims of the patent, because many claim elements may not be novel or may be obvious. *Id.* at 73. Someone who contributes to the reduction to practice but not the conception of an invention is not an inventor, even if the patent specification discloses an embodiment developed by the contributor to satisfy the best mode requirement. *Ethicon, Inc.*, 135 F.3d at 1461. This is so even if the reduction to practice is the most time consuming, costly, and difficult part of the invention process. However, if the invention as originally conceived does not work as it should, and a technician reducing the invention to practice then devises a way to make it work, the technician becomes an inventor because the invention would not have been complete without the contribution of the technician. *Id.*

Joint Inventors Must Be Collaborators

In addition to conception, another requirement of joint invention is a collaborative effort to produce an invention. *Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co.*, 973 F.2d 911 (Fed. Cir. 1992). In other words, there must be some element of joint behavior, such as collaboration or “working under common direction.” *Id.* at 915. Examples of such behavior include one inventor seeing a relevant report and building upon it, or one inventor hearing another’s suggestion at a meeting. *Id.*

Joint invention requires communication between the inventors. Collaborators do not have to work at the same location or at the same time, but they cannot be joint inventors if they are completely ignorant

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Who Is An Inventor?

- A person who conceives the subject matter of at least one claim of the patent.
- Two or more persons who collaborate to produce the invention through aggregate efforts.

Who Is Not An Inventor ?

- Someone who reduces the invention to practice by exercising ordinary skill in the art.
- A technician who simply performs experiments or assembles the invention.
- The supervisor or department manager of the person who conceived the invention.
- Someone who contributed an obvious element to the invention.
- Someone who participates in consultations about the invention before or after conception of the invention.
- A person who only conceives of the result to be obtained, but not the idea of how to achieve the result.
- A person who only discovers the problem, unless he contributes to the solution.
- A person who merely provides a suggestion or improvement but who does not work to fit the suggestion or improvement into the invention.
- A second inventor of the subject matter of the invention who did not collaborate with a first inventor of the subject matter of the invention.

Drafting the Technology Game Plan

Part 3: Proper Inventorship Determinations

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of what each other is doing until long after their individual independent efforts. *Id.* at 916. To collaborate, joint inventors must be working towards the same end, on the same subject matter, and producing an invention by their aggregate efforts. *Id.* Even if two inventors work at the same company, if they are wholly unaware of each other's work there can be no collaboration and no joint invention. *E.g., Kimberly-Clark*, 973 F.2d at 916 (holding that three inventors who worked at same company and developed very similar products were not joint inventors on same patent because they were not aware of each other's work).

Correction of Errors in Inventorship

Although the rule of naming true inventors may seem stringent, a mistake may not be fatal to the patent. Correction of inventorship is generally allowed when the failure to name the correct inventors occurs without deceptive intent. *Stark v Advanced Magnetics, Inc.*, 119 F.3d 1551, 1553 (Fed. Cir. 1997). In fact, errors in inventorship can be corrected even after a patent issues. *Id.* at 1555.

It is a mistake, however, to rely on the ability to correct inventorship instead of properly performing an inventorship determination before a patent application is filed; the principal reason being that correction of inventorship is easier while a patent application is pending than after it has issued. To correct inventorship, each person being added or deleted must sign a statement that the error in inventorship occurred without deceptive intent. 37 C.F.R. § 1.48 (2002). This can be a problem when one or more of the persons is not available, as they may have left the company, or may now be

hostile to the company and refuse to sign the statement. After a patent issues, correction of inventorship also requires a statement from the inventors named on the issued patent agreeing to the change in inventorship. *Id.* Again, locating inventors, as well as obtaining agreement from everyone potentially several years after a patent has issued, may be difficult. The administrative expense alone is enough reason to avoid this practice. Moreover, a misjoinder of inventors is likely to be a red flag to those seeking to invalidate the patent in litigation. For all these reasons, every reasonable effort should be made to get the inventorship correct before filing an application and thereby avoid the need to correct it later.

Do It Once and Do It Right

While the final inventorship determination cannot be made until the claims have been drafted, the best time to begin the inventorship determination is as soon as the invention disclosure is prepared. Ask the tough questions then, and be prepared to smooth over relations with those persons who believe they are inventors but don't understand the legal aspects and consequences of inventorship. Mistakes happen, but a court is more likely to tolerate improper joinder of inventors when it can be shown that a reasonable effort was made to make the right determination. So if there are close calls, document your decisions. Of course, the inventors themselves should keep accurate records of their inventive contributions.

Changes in Inventorship

Inventorship can change during the prosecution of an application. Because inventorship is based on what is being claimed rather than what is disclosed, claim amendments during prosecution

can result in changes of inventorship. The most common situation is where one or more claims is canceled, whether when responding to a restriction requirement or for reasons related to patentability. Any person who is an inventor or co-inventor of only the subject matter of the canceled claims must then be removed from the list of inventors.

The outline shown on page 5 should help in arriving at a correct inventorship determination.

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National Prejudice: Alive and Well in the WIPO World

| TABLE 1 | | Raw Data for 2000-2001 | | | | | | |
|--------------------------------|-------------|------------------------|---------|---------|---------|-------------------|----------------|---------|
| | | China | France | Germany | Japan | Republic of Korea | United Kingdom | USA |
| 2001 Patent applications filed | Resident | 30 324 | 21 790 | 80 222 | 388 390 | 74 001 | 34 500 | 190 907 |
| | Nonresident | 118 970 | 153 332 | 212 176 | 108 231 | 116 021 | 230 206 | 184 750 |
| | Total | 149 294 | 175 122 | 292 398 | 496 621 | 190 022 | 264 706 | 375 657 |
| 2001 Patents granted | Resident | 5 395 | 11 010 | 19 242 | 109 375 | 21 833 | 3 975 | 87 606 |
| | Nonresident | 10 901 | 31 953 | 28 965 | 12 367 | 12 842 | 35 674 | 78 432 |
| | Total | 16 296 | 42 963 | 48 207 | 121 742 | 34 675 | 39 649 | 166 038 |
| 2000 Patent applications filed | Resident | 25 592 | 21 471 | 78 754 | 388 879 | 73 378 | 33 658 | 175 582 |
| | Nonresident | 96 714 | 138 707 | 183 796 | 97 325 | 98 806 | 199 565 | 156 191 |
| | Total | 122 306 | 160 178 | 262 550 | 486 204 | 172 184 | 233 223 | 331 773 |
| 2000 Patents granted | Resident | 6 475 | 10 303 | 16 901 | 112 269 | 22 943 | 4 170 | 85 071 |
| | Nonresident | 6 881 | 26 101 | 24 684 | 13 611 | 12 013 | 29 586 | 72 425 |
| | Total | 13 356 | 36 404 | 41 585 | 125 880 | 34 956 | 33 756 | 157 496 |

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| TABLE 2 | | Percentages by Residency 2000-2001 | | | | | | |
|--------------------------------|-------------|------------------------------------|--------|---------|--------|-------------------|----------------|--------|
| | | China | France | Germany | Japan | Republic of Korea | United Kingdom | USA |
| 2001 Patent applications filed | Resident | 20.31% | 12.44% | 27.44% | 78.21% | 38.94% | 13.03% | 50.82% |
| | Nonresident | 79.69% | 87.56% | 72.56% | 21.79% | 61.06% | 86.97% | 49.18% |
| 2001 Patents granted | Resident | 33.11% | 25.63% | 39.92% | 89.84% | 62.96% | 10.03% | 52.76% |
| | Nonresident | 66.89% | 74.37% | 60.08% | 10.16% | 37.04% | 89.97% | 47.24% |
| 2000 Patent applications filed | Resident | 20.92% | 13.40% | 30.00% | 79.98% | 42.62% | 14.43% | 52.92% |
| | Nonresident | 79.08% | 86.60% | 70.00% | 20.02% | 57.38% | 85.57% | 47.08% |
| 2000 Patents granted | Resident | 48.48% | 28.30% | 40.64% | 89.19% | 65.63% | 12.35% | 54.01% |
| | Nonresident | 51.52% | 71.70% | 59.36% | 10.81% | 34.37% | 87.65% | 45.99% |

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Office (375,657). Yet despite this fact, the United States PTO issued more patents (166,038) than the Japanese Patent Office (121,742). The same proved true in 2000 when the Japanese Patent Office received 486,204 applications and granted only 125,880 patents, whereas the United States PTO received 331,773 applications and granted 157,496 patents. This anomalous result perhaps can be attributed to the tendency of Japanese companies, according to conventional wisdom, to file patent applications on vir-

tually every nuance and improvement of their research & development, whereas U.S. companies tend to have a higher threshold for distinctiveness before filing an application.

On closer inspection, however, another anomaly jumps out. Namely, the statistics for some countries reflect a curious pattern wherein foreigners file more applications, but local national residents receive more issued patents. One anomaly may be coincidence, but two anomalies warrant further consideration.

One way to inspect the data more closely is to convert the numbers to percentages. Dividing the number of applications filed by the number of patents issued provides an approximation as to the percentage of applications that issued as patents. In order for this approach to be rigidly correct, it assumes that applications filed in the year 2000 also issued in the year 2000. That assumption is, of course, *not* correct. The patents that issued in the year 2000 were probably filed at least several years earlier. However, if we assume that the number of applications filed and patents issued represents an approxi-

| TABLE 3 | | Patents granted as a percentage of applications files 2000-2001 | | | | | | |
|---------|-------------|---|--------|---------|--------|-------------------|----------------|--------|
| | | China | France | Germany | Japan | Republic of Korea | United Kingdom | USA |
| 2001 | Resident | 17.79% | 50.53% | 23.99% | 28.16% | 29.50% | 11.52% | 45.89% |
| | Nonresident | 9.16% | 20.84% | 13.65% | 11.43% | 11.07% | 15.50% | 42.45% |
| 2000 | Resident | 25.30% | 47.99% | 21.46% | 28.87% | 31.27% | 12.39% | 48.45% |
| | Nonresident | 7.11% | 18.82% | 13.43% | 13.99% | 12.16% | 14.83% | 46.37% |

mate steady-state trend, as appears to be true from the 2000 and 2001 data, then we can approximate the percentage of applications that issue as patents by dividing the numbers published for a single year. These percentage numbers are set forth in Table 2 below.

Inspection of the percentages in Table 2 shows that the “anomalies” are, in fact, widespread. Except for the U.S. and the U.K., the other countries listed exhibit a disturbing lack of consistency between the percent of applications filed by foreign citizens and the percent of patents granted to foreign citizens. That is, in every listed country other than the U.S. and the U.K., the percent of issued patents attributable to foreign citizens is significantly less than the percent of applications filed by foreign citizens.

Further refinement of the raw data makes the situation crystal clear. Table 3 below shows the percentage of applications that issued as granted patents, i.e., the number of patents granted divided by the number of applications filed. The left side column for each year provides the relevant number for local citizens of the country in question; the right side column provides the same information for foreigners of the country in question. Table 3 reveals that China, France, Germany, Japan and South Korea all demonstrate a striking disparity in patent issuance.

Benjamin Disraeli once said, “There are three kinds of lies: lies, damned lies, and statistics.” From that perspective, critics will find many ways to dismiss and disparage the information of Tables 2 and 3. By contrast, the wise person will adjust her budget for patent filing outside of the U.S. and the U.K.

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tion to an exception to the standard rule of infringement” – when a patentee can avoid a presumption of prosecution history estoppel from barring the application of the doctrine of equivalents to find infringement. The case does not relate to literal infringement, in which an infringer makes, uses, sells, offers for sale, or imports what is expressly set forth in at least one claim of the asserted patent. Instead, it relates to infringement under the doctrine of equivalents, which involves an infringer being liable for infringement because it makes, uses, sells, offers for sale, or imports something insubstantially different from the claimed product or process. The doctrine of equivalents is limited by more than just the magnitude of the differences between the claims and what the infringer does, however. Prosecution history estoppel, which can arise when a patentee makes changes to the scope of the patent’s claims in prosecution before the Patent and Trademark Office, can prevent a finding of infringement under the doctrine of equivalents altogether. The *Festo* case addresses the circumstances when prosecution history estoppel should not bar such a finding.

In *Festo*, the Court first set forth the decision tree into which its holding would fit. (See Figure on page 11). First, there must have been an amendment to a claim in the prosecution of the patent. If the amendment did not narrow the scope of the claims, there is no estoppel. If the amendment did narrow the scope of the claims, the next question is whether the prosecution history shows the amendment was not for reasons of patentability. If the intrinsic record of the prosecution history shows that the amendment was not for reasons for patentability,

again there is no estoppel; if not (including if the prosecution history is silent on the reason for the amendment), a court will presume that the patentee intended to surrender any protection of the subject matter falling between the original scope of the claim and the granted scope of the claim. It is only then, in determining whether a patentee can rebut that presumption and recapture some of the territory beyond the literal scope of its claims, that the factors enumerated in *Festo* come into play.

snippets

[T]here is a far greater premium on applicants sitting down with counsel before filing any applications to determine strategy for obtaining protection most effectively...In short, the holdings of the *Festo* case are likely to reward patentees who plan carefully with counsel and greatly punish those who fail to do so.

Having established the context for its decision, the Federal Circuit turned to who would make the decision whether a patentee had rebutted the presumption of prosecution history estoppel. It found that the decision was a question of law for the judge, not a question of fact for a jury. As it had in past cases (before the Supreme Court had reversed an earlier *Festo* decision), the Court reasoned that prosecution history estoppel has traditionally

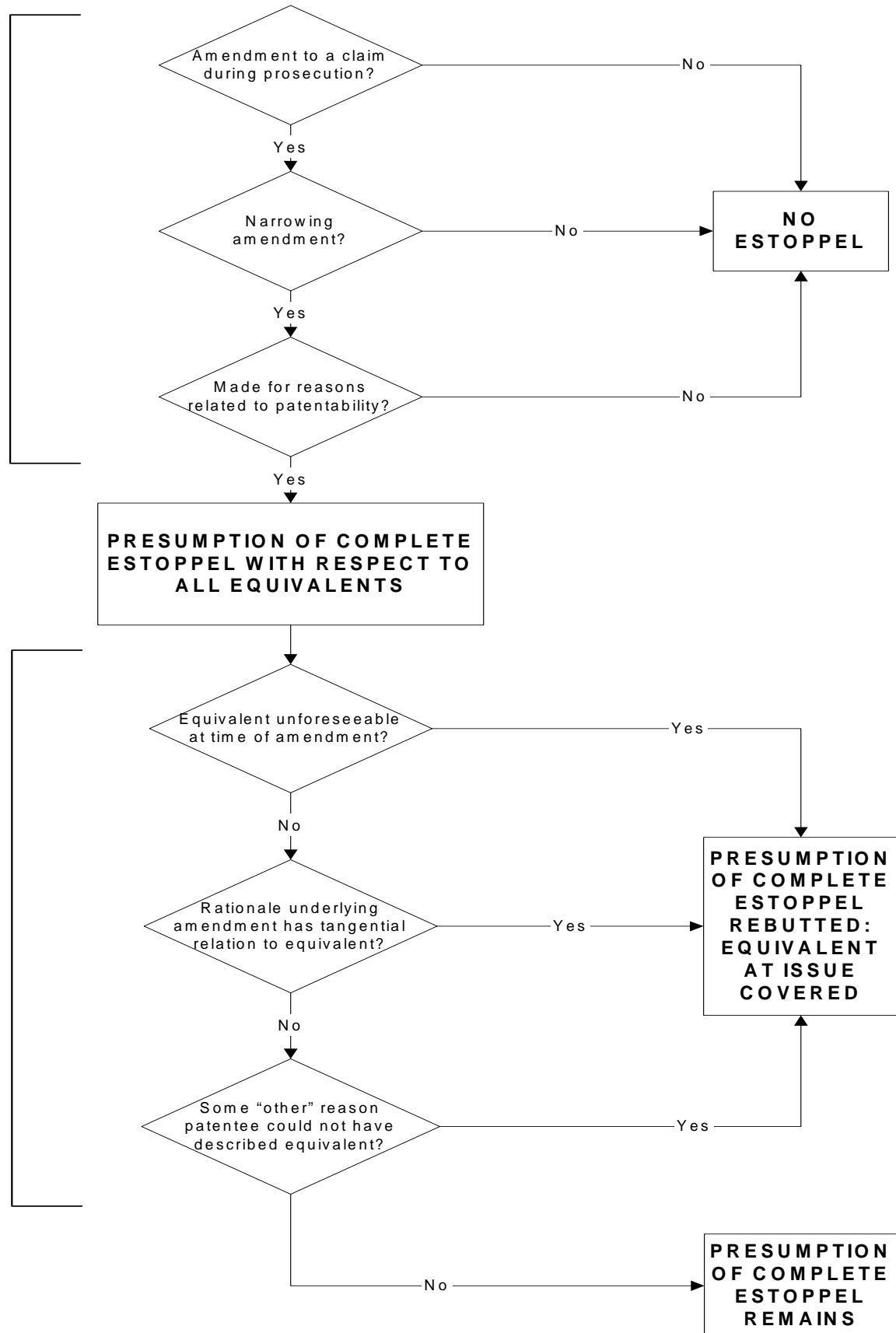
been viewed as an equitable issue which would be better resolved by a judge. Although there may be underlying factual considerations in the decision, the Federal Circuit found the judge should decide those as well. The Court was unconcerned about any factual issues because they would be subsumed within the broader legal decision, just as they would be in relation to a *Markman* hearing on claim construction.

The Supreme Court had found three ways in which a patentee could overcome the presumption of prosecution history estoppel. *Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., Ltd.*, 535 U.S. 722, 740-741 (2002). The Federal Circuit decided it would be best to approach those inquiries flexibly, on a case-by-case basis. However, it gave general guidance on all three of those inquiries, including by identifying the most appropriate evidence for deciding them. Specifically, the Federal Circuit decided that all three should be viewed objectively, not subjectively, and that the evidence should generally come from the intrinsic evidence in the prosecution history, supplemented by evidence of the knowledge and understanding of those of skill in the relevant art.

The first means of rebutting the presumption is showing that a purported equivalent product or process was “unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered.” Sensibly, the Court suggested that a technology developed after the amendment or not known in the relevant art at that time generally would not have been foreseeable. In contrast, as the Court pointed out, old technology

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Establishing the presumption of prosecution history estoppel



Recovery of particular equivalents by rebuttal of presumption

The Festo Decision Tree

***Festo* and the Federal Circuit: The Exception to the Exception to the Exception...**

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(especially known in the prior art of the field of the invention) is far more likely to have been foreseeable. Therefore, a court deciding foreseeability would have to consider evidence of the state of the art and the understanding of one of skill in the relevant art at the time of the amendment. As to those questions, the Federal Circuit indicated that a court could consider expert testimony and other extrinsic evidence.

The second means of rebutting the presumption is showing that “the rationale underlying the narrowing amendment bears no more than a tangential relation to the equivalent in question.” That question should be resolved from the prosecution history alone, except to the extent that testimony is needed to clarify how one of skill in the relevant art would have understood the amendment. The Federal Circuit found that it could ensure that prosecution histories provide fair public notice of the scope of patent claims only through limiting the evidence to their objectively discernable public contents.

The third means of rebutting the presumption is showing “some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.” While that inquiry is quite vague, the Federal Circuit made it clear that it must be narrowly cabined. Again, it suggested that the evidence should generally be limited to the prosecution history and that a patentee should not be able to rely upon this catch-all factor if the purported equivalent was in the relevant prior art.

As Judge Rader pointed out in his concurrence, the *Festo* holding is likely to

cause great short-term displacements in patent prosecution and litigation. Because it applies to not only future patents but also granted patents (including those involved in pending litigation), it holds patentees responsible for past decisions made without the benefit of knowing the rules on how those decisions would be interpreted. In fact, it introduces an additional level of arbitrariness into infringement inquiries. Because patent examiners, like all human beings, differ in how stringently they approach prosecution issues, the need to amend the claims will be subject to the arbitrary determination of the identity of the examiner. Furthermore, it is likely to make both prosecution and litigation of granted patents more expensive because of the need to address the unknowing decisions of the past.

The *Festo* case should also cause a sea change in how inventors approach the patent prosecution process and how litigation proceeds. Most importantly, there is a far greater premium on applicants sitting down with counsel *before* filing any applications to determine strategy for obtaining protection most effectively. The traditional strategy of filing a broad first claim and a series of ever-narrower dependent claims may not be the best approach, as it may prevent the assertion of infringement under the doctrine of equivalents if the examiner requires narrowing amendments to the broadest claim. Then, after filing, applicants must carefully weigh the cost, delay, and difficulty of arguing against rejections or appealing to the Board of Patent Appeals and Interferences instead of amending in order to preserve the greatest scope of protection. Indeed, the Federal Circuit recently raised the ante on amending by holding that the estoppel that applies to a narrowing amendment to a single claim

applies to the same element in all other claims. *Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.*, -- F.3d --, 2003 WL 22358859 at *9 (Fed. Cir. 2003). In litigation after a patent is granted, the tests of the *Festo* case are again likely to increase cost and difficulty. In many situations, expert testimony will be advisable to help determine the scope of the prior art and foreseeability of equivalents. In fact, courts may choose to begin holding pre-trial *Festo* hearings to determine whether the doctrine of equivalents will be an issue for trial, just as they hold pre-trial *Markman* hearings to determine claim construction. In short, the holdings of the *Festo* case are likely to reward patentees who plan carefully with counsel and greatly punish those who fail to do so.

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Doha Revisited: WTO Endorses Parallel Compulsory Licensing

Shortly after the first issue of snippets™ went to press, significant new developments took place that affected my article on the Doha Declaration implementation problems. In a surprising reversal of position, the United States consented to the parallel compulsory licensing scheme for pharmaceuticals discussed in my previous article. After a series of intense discussions, which only days before had been described as a failure, on August 30, 2003, the WTO General Council adopted Decision IP/C/W/405, entitled “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” (the “Decision”). Founded on the principle that “exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceuticals,” the Decision implemented a plan long opposed by the majority of countries of the Western Hemisphere. Specifically, the Decision allows countries to grant compulsory licenses on patents related to pharmaceuticals and other medical products that are useful in treating diseases affecting the public health where the licensee intends to manufacture and export such products to the least developed countries (“LDCs”). Previously, a WTO member’s obligations under Article 31 of TRIPS precluded such licenses unless the products were used primarily for domestic purposes.

Given the potential impact of the Decision it seems appropriate to address several major questions it raises.

Why Was Parallel Compulsory Licensing Selected to Implement the Decision?

The impetus for a parallel licensing scheme arose because of the recognition

that allowing LDC’s alone to benefit from compulsory licenses would not help solve the health problems facing those countries, because of the typical lack of infrastructure and manufacturing facilities available in LDC’s. Although early discussions, as well as the current goals of the Doha Declaration, reflected a desire to help LDC’s build the infrastructure and manufacturing capabilities necessary to meet their own needs, such a process would invariably require a significant commitment of both time and resources by the developed nations, and would fail to resolve immediate health crises.

When Do the Protections of the Decision Terminate?

The Decision envisions a permanent amendment to the TRIPS Agreement that would codify and supercede the Decision. ¶ 11. On the date that a relevant amendment takes effect in a WTO member country, the protections of the Decision cease.

Who Can Avail Themselves of the Decision?

The Decision contains express definitions of eligible importing and exporting countries. ¶¶ 1(b)-(c). Specifically, an “eligible importing member” is either (a) an LDC or (2) any other WTO member that makes a notification under Paragraph 2 of the Decision of its intent to avail itself of the Decision. *Id.* at ¶ 1(b). WTO members are permitted to file statements indicating under what circumstances, if any, they will invoke the decision (e.g. only in cases of “a national emergency”). *Id.* A number of developed nations have indicated that they will either not use the system set forth in the decision or invoke it “in no more than situations of national emergency or other circumstances of extreme urgency.” *Id.*

Any WTO member can qualify as an “exporting member” for the purposes of the Decision. *Id.* at ¶ 1(c). As of the time of this article, Canada has already indicated its intention to take advantage of the implementation decision. Elena Cherney and Christopher J. Chipello, *Canada Looks Set to Export Generic Drugs to Poor Nations*, WALL ST. J., Oct. 2, 2003, at D7.

What is the Procedure for Activating a License?

In order to invoke the Decision, an eligible importing member must prepare a notification, which should include: (1) the names and expected quantities of the products needed; (2) confirmation that the eligible importing member has insufficient or no manufacturing capacity with respect to the products in question; and (3) confirmation that, if the products are patented in the importing member, it intends to grant a compulsory license under Article 31 of TRIPS. ¶ 2(a). The Decision in turn contains an Annex defining (in a rather circular manner) what constitutes “insufficient or no manufacturing capacity.” The countries on the United Nations list of least developed countries are assumed to meet the lack of capacity requirement. A non-LDC member can meet the requirement by either “establish[ing] that it has no manufacturing capacity in the pharmaceutical sector” (hence the circularity of the definition) or examining its capacity excluding that of the patent owner and determining that the capacity is currently insufficient to meet the need.

Exporting members are required to notify the TRIPS Council of the WTO of the grant of a compulsory license, along with the conditions attached to the license. ¶ 2(c). The exporting member notification is substantially more detailed than that for

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the importing member, and must include the name and address of the licensee, the name of the products for which the license is granted, the importing countries for which the licensed products are destined, and the duration of the license. *Id.* The Decision imposes several restrictions on licenses granted by exporting members. Specifically, the license is limited to “only the amount necessary to meet the needs of the eligible importing member,” and the entirety of the production must be sent to the importing member(s). ¶ 2(b)(i). In addition, all products produced under the compulsory license must be labeled or marked as such, and the packaging or coloring or shaping of the product should indicate the special nature of the product. ¶ 2(b)(ii). The licensee must also set up a website detailing the quantities of products being produced, the destination for the products and the special markings and/or labeling of the products. ¶ 2(b)(iii).

How Will the System Ensure Protection of Patent Rights as Well as Protection of the Public Health?

While the Decision provides for “adequate remuneration” of the patentee by an exporting member (an issue which is sure to be problematic), the greater concern to many patentees will be the potential for re-exportation of the products by the importing member and the provisions for policing licenses granted pursuant to the decision. The Decision places much of the policing burden on the members

whose companies will hold the patents that are the subject of the licenses. The Decision requires LDC’s only to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation....” ¶ 4. Effectively, this means that LDC’s will not be held accountable for breaches of the Decision. The Decision then decisively lays the burden on the developed world by noting that when an LDC has difficulty in policing re-exportation, the developed countries should provide technical and financial assistance upon request. *Id.* The Decision also provides that members should set up systems to prevent importation of re-exported goods into their territories. ¶ 5. The sole mechanism for review expressly provided for in the Decision is a complaint by a member to the TRIPS Council. *Id.*

Where do Pharmaceutical and Medical Device Patentees Go From Here?

Pharmaceutical innovators now face an amorphous assault on their patent rights with little chance for developing effective defensive positions. Unfortunately, although the Decision has provided a great deal of power to grant and utilize compulsory licenses, it has done little to provide any decisive scope for those licenses or effective mechanisms for policing the licenses. In fact, the Decision has done little to clarify many of the significant issues raised by the lack of definition in the Doha Declaration. Even patentees who

spend substantial time and effort in obtaining strong patents will be subject to the whims of a given country’s definition of what constitutes a disease affecting the public health. Perhaps worse yet, countries not affected by these diseases will have incentive to use the system to develop their own pharmaceutical industries, as Canada has indicated it will do. The patenting process for pharmaceuticals and medical devices now will require not only planning to ensure that any patents obtained are as strong as possible, but also planning for the potential dangers of compulsory licensing and the requisite enforcement programs that will inevitably follow.

S. Richard Carden has experience in all areas of patent and trademark law practice, with particular emphasis on litigation, client counseling, and patent procurement in the chemical and biotechnological arts. His patent litigation experience spans diverse technologies, including medical devices, diagnostic equipment, pharmaceuticals, injection-molding systems, and automotive refrigerants. He has also assisted in litigating trademark, trade dress, and unfair competition issues on behalf of the firm’s clients.

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Review of Developments in Intellectual Property Law

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