Inside ...

An Opening Statement from the Editor
John Lenahan

I am pleased to introduce on behalf of Crowell & Moring the first edition of our Intellectual Property Law Group newsletter, The Inquisitive Mind. In this and the coming editions of the newsletter, we plan to inform, challenge, and yes, entertain you (IP law can be fun). We invite your comments, suggestions, applause, and criticisms. As the little yellow duck which has become the mascot of our law firm suggests, while we take our clients’ business and our professional responsibilities very seriously, we strive on a personal level for a less serious tone. From time to time, as new and important developments in IP law and litigation present themselves, we will be publishing Inquisitive Mind bulletins. In conclusion, the Intellectual Property Law Group of Crowell & Moring welcomes our readers to The Inquisitive Mind.

Actual Notice of Infringement: 
A Poor Second Choice for Maximizing Damages
Michael I. Coe

Patenting an invention requires a significant investment of time and resources. The patent, however, is just the first step in protecting this hard-earned investment in intellectual property. The patentee’s next step may be to seek license royalties, or perhaps to file suit in order to exclude others from practicing the invention, and to obtain money damages for infringement. In either case, maximizing potential damages is an effective way to strengthen the patentee’s hand during license negotiations and in litigation.

Damages do not begin until the infringer is given “notice” of the infringement. There are two ways to start the clock. The patentee can give “constructive notice” by labeling or “marking” the articles (or their packaging) to identify the patent or patents. The patentee can provide “actual notice” of the infringement by a letter demanding the cessation of infringement or offering to license the patent, or by the ultimate form of actual notice, i.e., a lawsuit for infringement.

The easiest and most effective way to maximize the patent’s value is to “mark” all commercialized embodiments of your invention. Sometimes, however, this is impossible to do. There is, for example, no way to mark a patented process or method. And, sometimes
patentees neglect to mark their products. As a result, it may become necessary to provide “actual notice” of infringement. A properly drafted cease and desist, or offer to license, letter sent to an infringer can serve this purpose.

To provide “actual notice”, the letter must identify: (1) the patent, (2) the activity believed to be an infringement, and (3) a proposal to abate the infringement, whether by license or otherwise. There are no “magic words” to give actual notice of infringement, but court decisions do provide some guidance on what works. For example, giving “mere notice of the patent’s existence or ownership” is not enough. Nor is it sufficient to notify an entire industry of a patentee’s ownership of a patent and generally advise against infringement. This is illustrated by the following, which comes from a letter that the Federal Circuit Court of Appeals found did not provide “actual notice”:

Accordingly, you should acquaint yourself with [our patent] and refrain from supplying or offering to supply component parts that would infringe or contribute to the infringement of our patent. In contrast to the previous letter, a follow-up letter from the same patentee did provide sufficient notice by specifically identifying the infringing device and by charging the same recipient with infringement. The second letter said:

Accordingly, we demand that you immediately cease and desist from any further unauthorized production and sales of such castings that . . . include features covered by our patents.

The Federal Circuit has also confirmed that to provide actual notice of infringement a letter need not demand cessation of the allegedly infringing activity. It is sufficient to offer a patent license for a specific product in wording such as the following:

[the patentee] would be pleased to provide [the accused infringer] with a nonexclusive license under the patent. . . . If you are of the opinion that you do not need a license from [the patentee], it would be helpful if you could give us some insight into your reasons.

Moreover, it is not necessary to expressly threaten a suit for infringement. It is enough to imply that a license is necessary, as demonstrated by the following language from a letter found to provide “actual notice”:

[the infringer] may wish to have its patent counsel examine the . . . patent . . . to determine whether a non-exclusive license under the patent is needed.

Thus a letter may, and sometimes must, substitute for appropriate marking of the invention. However, while it may serve to put the infringer on actual notice of the infringement, the letter may, depending on how it is worded, also create a “reasonable apprehension” of a lawsuit. This reasonable apprehension in turn leads to an “actual controversy” between the parties, which would allow the infringer to preemptively file a lawsuit of its own against the patentee. Such a lawsuit, known as a “declaratory judgment” action, typically seeks a judicial declaration of both patent invalidity and non-infringement, and sometimes patent unenforceability.

Significantly, a declaratory judgment action allows the accused infringer to

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1 SRI International Inc. v. Advanced Technological Laboratories Inc., 27 F.3d 1462, 44 U.S.P.Q.2d 1422 (Fed. Cir. 1997)
bring the suit at a time and place of the infringer’s choosing. This first-strike lawsuit by the alleged infringer can greatly disadvantage the patent owner, who is compelled by U.S. procedural rules to countersue for patent infringement. An absence of advance preparation for litigation of the patent, and the loss of choice of the forum in which to litigate, may be a significant setback to the patentee.

Consequently, in the absence of the patentee marking the product, or initiating a lawsuit for infringement, a carefully drafted letter to a patent infringer is required for the patentee to give actual notice of infringement but avoid the adverse consequences of creating a reasonable apprehension of a lawsuit. Despite efforts by some infringers to use notice of infringement letters that are not a threat to sue (e.g., offering a patent license), as a predicate for commencing a declaratory judgment lawsuit, the Federal Circuit has held that not all such letters create a “reasonable apprehension” of suit. In the absence of a “reasonable apprehension”, and therefore an “actual controversy”, the trial court has no jurisdiction over the declaratory judgment action initiated by the infringer. In this case, the patentee is free to pick the time and place of his choosing (according to the statute of limitations and the rules on proper venue) to sue for infringement. The infringer may countersue for declaratory judgment, but without the advantage of being the first to file the suit.

Thus, the preferred course of action for the patent owner to maximize potential damages for infringement of a patent, and to preserve the right to be the first to file a lawsuit for infringement, is to mark patented articles or packaging in accordance with the patent statute. However, if for any reason this is not done a letter from your patent counsel to the infringer can serve to achieve the same goals.

Copyright Protection for Data Collections in a Digital Environment

John I. Stewart, Jr.

The commercialization of the Internet and the continuing expansion of digital media have produced ever greater challenges for the creators of databases and factual compilations. Proprietary data collections, sometimes developed through the expenditure of substantial resources, can be important business assets, with a value far exceeding their cost. The creators and owners of these collections have looked to a variety of sources for legal protection that allows them to maintain and exploit their works. For example, depending on whether a database has value as an internal business asset or as an integral part of services provided to outsiders, its owner may rely on trade secret law or on contractual restrictions imposed on third party users to protect the work.

One traditional source of protection has been copyright law. Although copyright protection does not extend to facts, a limited form of protection can attach to collections of facts or data as “collective works” or “compilations” under the copyright statute. The protectible components of such a work arise from the creator’s selection, arrangement, and organization of the component fact or data elements, and the creator of the compilation acquires no independent rights in the individual elements he or she has compiled. The compiler’s rights in the overall compilation are also contingent on the requirement that the inclusion of any elements that are themselves copyrighted works owned by others must have been lawful. If the inclusion of a preexisting work is authorized, the compiler will have enforceable rights in the use of that work, but only as part of the compilation.

The Supreme Court confirmed that a discernible degree of creativity must be found before a compilation can be held copyrightable at all, in the 1991 Feist case rejecting copyright protection for a white pages telephone directory. The Court held that a listing of every available name, number, and address, arrayed in alphabetical order, did not reflect even the minimal creativity in selection, arrangement, or organization necessary for protection.
under the copyright law. Subsequent cases have found various trade directories and market data collections as falling on one side or the other of the copyrightability line, but all acknowledge that the creativity threshold for a protectible compilation is low.

The digitization of an otherwise protectible compilation can effectively destroy its protection. In a case decided in the Federal District Court for the Southern District of New York, an on-line B2B (business-to-business) service was found not to have infringed the copyright in a competitor’s 650-page directory, even though it had directly copied into its own database some 92% of the listings in the relevant portions of the CD-ROM version of the book. The court held that copyright protection for the directory, as a fact compilation, covered the selection, arrangement, and organization of the copied listings. But the court concluded that the arrangement and organization of the entries in the print publication were not reproduced in the on-line database, because the listings were now electronically searchable as individual data entries. And the defendant also had selected thousands of additional entries from other sources for inclusion in its database, and thus did not infringe the original selection of data represented in the hard-copy directory. Thus, because of the disaggregative effect of copying the directory into a searchable database, the defendant was able to copy substantially all of the relevant contents of its competitor’s work without infringing its copyright. Parenthetically, the court suggested that the plaintiff might instead have a potential claim to enforce contractual restrictions it sought to impose on purchasers of the CD-ROM version of the directory under a “shrinkwrap license.”

Another example of the same phenomenon, but with a different outcome, was found in the Supreme Court’s decision in the *Tasini* case, issued in mid-2001. In that case, freelance writers had sued newspaper and magazine publishers over the growing practice of making copies of the periodicals available through searchable electronic databases. The writers had clearly consented to the use of their articles in the original newspapers or magazines, which were collective works under the copyright law. And the copyright statute permits publishers of such compilations to use the same material in “revisions” of the originally published collective work or in later issues in the same series. This statutory extension of the original right of use, for example, allows publishers to sell archival microfiche and microfilm versions of the original newspaper or magazine. The Court found, however, that once articles were stored in digitized electronic form, they could be retrieved individually, stripped of the context within which they had appeared in the original publication. As a result, they could not be considered to be part of a revision or subsequent issue of the collective work, and the publishers could therefore not create or authorize such electronic versions of their periodicals without additional permissions from (and presumably payment to) the authors.

Partly because of the limitations on the protection available for commercially valuable data collections under the current copyright laws, legislation that would provide a new kind of protection for databases has been proposed in the two most recent Congresses. The new statutory provisions would generally protect against misappropriations of all or substantial portions of proprietary collections of information to the extent the extraction or use of the data would have a commercially harmful impact on the owner of the collection. Progress towards enacting these new protections has been halting. Initially,

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a virtually final piece of legislation was thrown off track in late 1998 by libraries and other research institutions that feared that the new protection would unduly impede research and other “fair uses” of factual databases. In subsequent years, as the bills were debated further and their implications became more widely known, a variety of industry groups with different approaches to and needs for access to databases (from financial services companies to genealogical researchers) have entered the fray. Computer programs and online communications have also been the subject of specific carve-outs in various versions of the bill.

It is likely that some form of database protection bill will be reintroduced and actively considered in the 107th Congress in 2002, but whether such a bill passes and what its ultimate scope will be, given the wide variety of proposed exceptions and limitations that have emerged, remains unclear. In the meantime, valuable databases remain best protected in the digital environment through a careful program of limiting access, imposing enforceable contractual restrictions on their use, and general vigilance against potential infringements.

Product-By-Process Patent Claims – Valuable to Seek But Difficult to Obtain

Warren A. Zitlau

A product-by-process claim is a patent claim that defines a product in terms of the process by which it is manufactured. Such claims are proper under U.S. patent practice and may be useful in allowing applicants to claim products that resist definition by other than the process by which they are manufactured. The following is an example of a claim for a catalyst as defined by the process which produces it:

A catalyst made by a process comprising: forming an aqueous solution; immersing porous particles in said aqueous solution; impregnating the porous particles with said aqueous solution; separating the impregnated particles; and drying the separated particles.

Some product-by-process claims have an even simpler format, as for example, “A product produced according to the process of Claim 2.”

Applicants are often uncertain as to how the U.S. Patent and Trademark Office examines product-by-process claims, as the examination of such claims is not specifically addressed in the patent statute. According to common practice and governing case law, even though product-by-process claims are limited by and defined by specific process steps, the determination of patentability is based upon the product itself. Patentability does not depend on the limitations of the claimed method (process). Thus, if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. This prevents an applicant from obtaining a patent on a prior product merely by claiming the product in terms of a new process.

During examination of product-by-process claims, the U.S. Patent and Trademark Office has a lower burden of proof in establishing a \textit{prima facie} case of obviousness than for a product that is claimed in a conventional manner. The reason for this lower burden is that the U.S. Patent and Trademark Office is not equipped to manufacture products by different processes and to make comparisons between the resulting products. Thus, once an examiner makes a rational showing that the claimed product appears to be the same as or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant. The burden requires the applicant to come forward with evidence establishing a nonobvious difference between the claimed product and the prior art product.
In order to come forward with evidence, it may be necessary for the applicant to present data in the form of a declaration under 37 C.F.R. §1.132 showing that the product claimed in product-by-process format has a nonobvious difference in comparison to a product disclosed in the prior art. The objective evidence of nonobviousness can show that the claimed product has a superior and/or unexpected characteristic or a nonobvious structural difference in comparison to the prior art product. For example, if a catalyst is claimed by the process by which it is made, data could be presented showing that the catalyst has a superior and/or unexpected property (e.g., activity or selectivity), or a nonobvious structural feature (e.g., porosity), as compared to prior art catalysts.

In view of the low burden of the Patent Office in establishing obviousness for product-by-process claims, unless the product is incapable of being defined other than by the process by which it is made, applicants should not rely strictly on product-by-process claims to provide patent protection for a product. Instead, whenever possible, a product should be claimed in the conventional way according to its structure. Also, separate process claims directed to the method of making the product and of using the product should be considered to broaden the protection.

Design Patents - The Overlooked Product Protection

Rebecca C. Swann

Protection for a product’s ornamental design may be available if the appearance of the product is novel and primarily non-functional. When developing new products, companies often spend substantial time and resources in deciding how the product should look in order to appeal to consumers. The way the product looks, as marketing people are well aware, can frequently determine the success of the product. However, design patents are often over-looked and under valued.

Section 171 of the Patent Act declares that:

Whoever invents any new, original and ornamental design for an article of manufacture may obtain a patent therefore, subject to the conditions and requirements of this title.

The Patent Office Manual of Patent Examining Procedure, in addressing applications for design patents, provides additional guidance as to the subjects of such patents:

Since a design is manifested in appearance, the subject matter of a design patent application may relate to the configuration or shape of an article, to the surface ornamentation applied to an article, or to the combination of configuration and surface ornamentation.

It is also a requirement of design patent protection that the patented design features be non-functional. Thus, if the design of a product serves a real, and not imaginary or merely advertised, function, the product design is not patentable. While a lamp has the function of lighting, and as such may be the subject of a utility patent, the shape of the lamp, its surface ornamentation, or the combination of both may also be patented for its novel and purely aesthetic design.

Those familiar with patent law in countries other than the United States may not be aware of a benefit U.S. patent law affords design patents. In most countries, designs are filed and are simply registered by the national Patent office. This does not assure the applicant that the design is patentable over the existing art in the field. In the United States, however, new designs are examined by Patent Office Examiners who review the prior art in order to determine whether or not the applicant’s design is in fact novel. Once granted in the United States, the design patent offers the patentee a high level of confidence that it is protected from infringement by those who would copy the novel design.
The products that are viable subjects of design patents are ubiquitous. An industry that makes valuable use of design patents to protect their novel designs is the automotive industry. Vehicle manufacturers make a substantial investment in designing the exterior and interior look of their vehicles, including the body, wheels, headlights, dashboards, and bumpers. All of these elements of a car can be protected by design patents. For those parts so protected, only genuine patented replacement parts will avoid infringement. After market parts manufacturers, distributors, and retailers of spare parts have no choice but to obtain a license from the patent owner or face a lawsuit if they attempt to make, use or sell parts with the design patent without the permission of the patentee.

Another product line which is a proper subject of design patent protection is jewelry. Jewelry is ornamental and non-functional by its nature. Design patent protection enables the designer-inventor to exclude others from making “knock-offs” (counterfeits) of the jewelry. Without investing the time and money required to create the original design, counterfeiters are able to sell their products at lower prices and unfairly compete with the designers in the absence of patent, trademark or copyright protection. Design patents can serve as a warning to the would-be counterfeiter or as a means to prevent and to penalize those who fail to heed the warning.

In addition to the products mentioned above, any item of manufacture with novel ornamental and nonfunctional configuration and/or surface ornamentation may also be protected by design patents. Some common examples include: telephones (mobile and desk style), computer hardware (such as monitors and the mouse), furniture, golf club heads, eyeglass frames, door handles, toys, and pottery.

In conclusion, it is important to consider all of the possible ways to protect the novel features of a new product before it is launched in the marketplace. New products should, of course, be protected by utility patents whenever possible. However, the non-functional shape and ornamentation of the product should also be considered for design patent protection. If those features are novel, a design patent will preserve and protect your valuable intellectual asset from duplication as surely as a utility patent would protect it.

The Antitrust/IP Relationship – Bush Administration to Address in Public Hearings

Jeane A. Thomas

The Bush administration has repeatedly emphasized the importance of focusing antitrust enforcement resources on the intersection between intellectual property (“IP”) and competition law and policy. Indeed, Federal Trade Commission Chairman Tim Muris recently announced that the FTC and Department of Justice will co-host a series of public hearings beginning in January 2002 “to develop a better understanding of how to manage the issues at the intersection of competition and intellectual property law and policy.” The hearings will be designed to promote discussion among the government, business and legal communities on antitrust and IP policies that affect innovation in today’s knowledge-based economy. Specifically, Chairman Muris intends the hearings to focus on the following recent developments in law and policy that have significant implications for competition and innovation:

• The explosion in the number of patents issued by the PTO and how this trend affects the commercialization of new technology. For example, what is the competitive effect of a company’s formation of a “patent thicket” that requires other companies to enter into
cross-licenses or patent pools in order to compete in an area of technology?

• The difference between the “legal life” and “economic life” expectancy of a patent. For example, what are the competitive implications of a strong technology company that can extend the economic significance of a patent beyond its corresponding “legal life”?

• The increase in potentially “overbroad” patents and business method patents. For example, do overbroad patents (particularly in the area of basic research) inhibit follow-on innovation, and do business method patents that may not meet standards for novelty and non-obviousness stifle innovation?

• The expanding role of the Federal Circuit. For example, has the court expanded its jurisdictional scope to reach more antitrust issues and how does the court’s choice to apply its own law (rather than regional circuit law) impact the overall development of competition law?

• The continuing tension between the statutory right to refuse to license IP and the antitrust prohibition against a monopolist engaging in exclusionary conduct. For example, what limits (if any) do the antitrust laws impose on the rights of a patent or copyright holder to refuse to deal?

• The increasing proliferation of industry standards that rely on specific IP. For example, do standards that rely on specific IP serve to entrench the IP holder’s monopoly position or unfairly raise its rivals’ costs, or do such standards encourage innovation that flows after the standard is established?

In an information-based economy, a firm’s IP portfolio is often its most valuable asset. Not surprisingly, Crowell & Moring’s Antitrust and IP Groups have witnessed a brisk expansion in the areas in which antitrust and IP laws intersect, and increased interest by the federal antitrust agencies in making sure that IP rights are not misused to unduly stifle competition. The agencies’ decision to hold public hearings to enhance their understanding in this area is an important step toward developing antitrust policies that respect legitimate IP rights while promoting innovation and consumer welfare.

Crowell & Moring is advising a number of clients on participation in the FTC/DOJ hearings, as the agencies have specifically requested written comments and/or live participation from members of the business community. To learn more about the FTC/DOJ public hearings, please contact Randy Smith at 202-624-2700 (wsmith@crowell.com) or Jeane Thomas at 202-624-2877 (jthomas@crowell.com).

The scope of exemption from national patent laws, granted to pharmaceutical companies during times of public health crises, was debated recently at a meeting of WTO countries. Public health emergencies normally wouldn’t strike one as being part of the international trade agenda. However, the issues were joined as trade ministers from the more than 140 countries that are members of the Geneva-based World Trade Organization (WTO) met in Doha, Qatar, from November 9-14. Their objective was to hammer out a work program for the next round of global trade liberalization negotiations. The agencies’ decision to hold public hearings to enhance their understanding in this area is an important step toward developing antitrust policies that respect legitimate IP rights while promoting innovation and consumer welfare.

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threatening epidemics such as HIV/AIDS, malaria and tuberculosis.

In the weeks preceding the Doha Ministerial, the “access to medicines” issue became highly emotionally charged, portrayed by health activists as pitting resource-poor developing countries facing health crises against the wealthy and powerful research-based pharmaceutical companies. Developing countries, led by Brazil and South Africa, were seeking a complete exemption from IP obligations for patented medicines, arguing that patents priced drugs out of the reach of poorer countries already overwhelmed by national health emergencies.

The challenge facing U.S. trade negotiators was to find a balance that would enable governments needing to obtain quick access to drugs the latitude under global trade rules to negotiate the necessary special arrangements, while also respecting patent holders’ rights. Moreover, to add to the drama, just as governments and companies were struggling to find a solution to the debate, the U.S. Government found itself grappling with the dilemma of whether to issue compulsory licenses authorizing the production of Bayer AG’s anthrax antidote Cipro®. The U.S. resolved its own situation by negotiating a lower price per pill with the patent holder, thus demonstrating vividly that the TRIPS agreement already enabled governments to meet emergency health needs without eroding companies’ exclusive rights.

In Doha, trade ministers reaffirmed in the “Declaration on the TRIPS Agreement and Public Health,” that the TRIPS Agreement contained the necessary flexibilities to enable governments to address public health emergencies, including epidemics. However, WTO Members remain completely free to determine what constitutes a national public health emergency or other “extreme urgency.” The Declaration states, “We agree that the TRIPS Agreement does not and should not prevent [WTO] Members from taking measures to protect public health.” (Emphasis added.) The WTO also acknowledged the particular needs of least-developed countries, largely concentrated in Sub-Saharan Africa, by giving them an additional 10 years – to 2016 – by which to undertake TRIPS obligations regarding patent protection for pharmaceutical products.

While the outcome from Doha averted the need to reopen the TRIPS text – a step that could have dangerously undermined IP protections – it nevertheless sets a precedent that may lead to future litigation over the scope of patent holders’ rights. The real test of the Doha Ministerial outcome will be its practical application by governments as they seek to address public health emergencies by resorting to the compulsory licensing and parallel importation provisions – or other means — already contained in the TRIPS agreement.

The Declaration leaves open the possibility that key questions will have to be settled on a case-by-case basis under the WTO’s binding dispute settlement provisions. Global health activists and developing countries alike were elated by the agreement on the public health Declaration. They are certain to seek to build on the WTO outcome by using the document to justify future public policy actions putting key IP protections at risk.
The Festo Corner

In a decision which has substantially limited the doctrine of equivalents in U.S. patent law, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 56 U.S.P.Q.2d 1865 (Fed. Cir. 2000) (en banc), cert. granted, 121 S. Ct. 2519 (2001), the United States Court of Appeals for the Federal Circuit has expanded the application of the doctrine of prosecution history estoppel to completely bar equivalents for claims which were subject to narrowing amendments.

In delivering a severe blow to the doctrine of equivalents, the Federal Circuit held that: (i) prosecution history estoppel exists for all narrowing amendments relating to patentability, not just for amendments which overcome prior art; (ii) voluntary narrowing amendments give rise to prosecution history estoppel; (iii) when a claim amendment creates prosecution history estoppel, no range of equivalents is available for the amended claim element; and (iv) unexplained amendments are entitled to no range of equivalents.

In an unpublished decision in the case of Instituform Technologies, Inc. v. CAT Contracting, Inc., 5 USPQ2d 1392 (Fed. Cir. 2001), the Federal Circuit expanded the temporal limits of its Festo decision. The Court held that Festo must be given full retroactive effect in all cases still open on direct review and for all events, regardless of whether the events predate or postdate the announcement of the rule.

The Festo case has been appealed to the U.S. Supreme Court and that court heard arguments on January 8, 2002. In its decision to review the Festo case, the Supreme Court agreed to consider two of the four holdings of the Federal Circuit, namely:

1. Whether every claim narrowing amendment designed to comply with any requirement of the Patent Act – including those not related to prior art – automatically creates prosecution history estoppel.

2. Whether every finding of prosecution history estoppel completely bars every application of the doctrine of equivalents.

Amicus Curie (so-called “friends of the court”) briefs by interested parties were heavily weighted against Festo.

We will be reviewing the Supreme Court’s Festo decision in a future edition of The Inquisitive Mind. To get the latest on this important decision, please revisit the Festo Corner.

On the Horizon – New PCT Procedure

At the Assembly of the PCT Union held between September 23 and October 3, 2001, the time limit under PCT Article 22(1) for national phase entry was changed from 20 months to 30 months from the priority date. As a result, it is no longer necessary to enter Chapter II by filing a Request for Preliminary Examination before the previous 19 month deadline under PCT Article 39(1)(a) in order to delay entering the national stage. In the United States, this delay from 20 to 30 months for entering the national stage does not take effect until April 1, 2002, so that any Chapter II 19 month deadlines for PCT applications before March 1, 2002 must still be met.

Cases of Interest

Prior Art References & Patent Unenforceability

In GFI, Inc. v. Franklin Corp, 60 USPQ2d 1141 (Fed. Cir. 2001), the Court of Appeals for the Federal Circuit held that references which are not prior art may still be material if they embrace any information that a reasonable examiner would be likely to consider important in deciding whether to allow an application to issue as a patent. Applying this holding, the Federal Circuit found U.S. Patent No. 5,064,244 for a reclining sofa unenforceable as a result of the inequitable conduct of the applicant in failing to disclose references which
were not cumulative of those before the Examiner.
In Jazz Photo Corp. v. ITC, 59 USPQ2d 1907 (Fed. Cir. 2001), the Court of Appeals for the Federal Circuit held that failure to cite cumulative references is not inequitable conduct. The simple absence of a reference from the prosecution record does not prove deceptive intent; there must be evidence sufficient to show, clearly and convincingly, the intent to withhold material information in order to deceive or mislead the examiner.

Patents and New Drug Filings

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires a pharmaceutical company seeking to manufacture a new drug to file a New Drug Application (NDA) with the U.S. Food and Drug Administration. The NDA must include a list of clinical trials of the drug’s safety and efficacy as well as a list of patents claiming the drug. If the FDA approves the New Drug Application, the drug and its patents are listed in the FDA’s “Orange Book.”

A drug manufacturer seeking expedited FDA approval to market a generic version of a previously approved drug may submit an Abbreviated New Drug Application (ANDA), under the Drug Price Competition and Patent Term Restoration Act of 1984, to the FDA. In the Abbreviated New Drug Application, the drug manufacturer submits data showing that the generic drug demonstrates bioequivalence with the previously approved drug.

The Federal Food, Drug and Cosmetic Act does not provide a cause of action to delist a patent from the Orange Book; delisting can only be initiated by the FDA. Thus, if an Abbreviated New Drug Applicant has a dispute regarding a listing, they must contact the FDA and request an inquiry.

In Mylan Pharmaceuticals, Inc. v. Tommy G. Thompson, et al., No. 01-1257 (Fed. Cir. Oct. 12, 2001), Mylan sought to delist from the Orange Book Bristol Myer’s patent for a method of using the metabolite of the drug buspirone. The Mylan lawsuit for declaratory judgment and delisting was intended to preempt Bristol Myers from suing Mylan for patent infringement but the Mylan strategy failed. The Federal Circuit held that because Mylan failed to allege non-infringement of Bristol’s patent its lawsuit was barred under the FFDCA.

In Eli Lilly and Co. v. American Cyanamid Co., et al., No. IP95-0536-C-B/S (S. D. Ind. Nov. 9, 2001), Zenith’s Abbreviated New Drug Application had been denied by the FDA. Zenith responded to the denial by filing suit against Eli Lilly for violation of the antitrust laws. Zenith alleged that Lilly had entered horizontal agreements with bulk manufacturers of cefaclor, the subject of two of Lilly’s expired patents. The district court rejected Zenith’s allegations and dismissed the action on the ground that Zenith could not prove bioequivalence of its generic drugs.

Crowell & Moring IP Group News

Merger of Evenson, McKeown, Edwards & Lenahan with Crowell & Moring

On May 1, 2001, the law firm of Evenson, McKeown, Edwards & Lenahan merged its intellectual property law practice with Crowell & Moring. The combination offers the lawyers and the clients of both law firms an expansive base of legal and consulting services to draw upon. In addition to the synergies of the IP Group, the Antitrust Group, the Biotechnology Group, the Corporate Group, and others, C&M International, (C&M’s international trade consulting group), is a valuable resource for C&M’s intellectual property clients. (See Melissa Coyle’s article in this edition, “World Trade Organization Outcome Permits Developing Countries to Waive IP Protections in Public Health Crises.”)

Partners Lead Professional Associations

On June 1, 2001, at the Annual Luncheon of the Bar Association of the District of Columbia, the IP Group’s Jim
McKeown completed a one-year tenure as the Association’s President. Jim had the distinction of being the first patent lawyer to serve as the President of the Bar Association of D.C. Jim continues to serve as a member of the Board of Directors of the Bar Association. Jim will also be the Chairman of a roundtable on intellectual property and antitrust law co-sponsored by Crowell & Moring and the American Bar Association, to be held in Washington, D.C. on June 14, 2002. (See note below)

John Lenahan, a partner in the IP and Litigation Groups, completed his term as President of the Giles Sutherland Rich American Inn of Court in June 2001, and continues to serve as the Past President of the Inn. Named after the leading patent jurist, Giles Sutherland Rich, the Inn brings together judges, lawyers, and law students at the Federal Circuit monthly to share the experiences of the members and to participate in programs presented by the members. The program topics focus on the litigation of IP cases and the goals of the American Inns of Court movement, namely, to promote competence, professionalism, and civility in the practice of law.

Additions to the Intellectual Property Group

Robert L. Grabarek, Jr., joined the firm as Counsel in October 2001, with six years of experience in all aspects of patent practice, including applications, opinions, and product clearances in the fields of mechanics, medical technology, software and telecommunications. Bob received his Bachelors degree from the United States Naval Academy, a Masters degree in Operations Research and Industrial Engineering from Virginia Polytechnic Institute and State University, and his law degree from the University of Baltimore. Prior to engaging in the practice of law, Bob served in the United States Navy and as a civilian employee in the Procurement Office of the Assistant Secretary of the Navy.

Song Zhu, Ph.D., joined the firm as Counsel in November 2001. Song has a Doctorate degree in mechanical engineering from the University of Wisconsin and a law degree from Georgetown University. He was previously employed by General Motors as an engineer in the Powertrain Division where he worked on projects related to dynamics, engines, computer-controlled systems, fuel economy, ABS systems and steering systems. His patent law experience prior to joining Crowell & Moring included patent prosecution, representation of clients in joint venture negotiations, and advising clients in the development of corporate patent programs.

Kening Li, Ph.D., joined the firm as an associate in December 2001. Kening received his Bachelors and Master degrees in biology from Nanjing University in China, and his Doctorate degree in Plant Pathology from the University of Wisconsin. He received his Juris Doctor degree with honors from the University of Wisconsin Law School. Prior to joining Crowell & Moring, Kening served as Senior Counsel in the legal department of E. I. du Pont de Nemours and Company. His practice has focused on biotechnical, chemical, and pharmaceutical patent applications and strategies.

IP Antitrust Roundtable

The Intellectual Property Group and the Antitrust Group of Crowell & Moring will co-sponsor along with the Antitrust Litigation Committee of the Litigation Section of the American Bar Association a Roundtable Discussion to be held at the National Press Club in Washington, D.C. on June 14, 2002. Jim McKeown, a member of the IP Group, is the Chairman of the Roundtable, which will include representatives from industry, the government, and academia, to participate in an interactive program covering a range of related IP and antitrust topics.