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New Drug Price Competition and Patent Term Restoration Act Discussed at NYPTC Evening Meeting

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), signed into law by President Reagan on September 24, 1984, was the topic of a spirited but friendly discussion sponsored by the New York Patent, Trademark and Copyright Law Association at the Grand Hyatt Hotel on November 27, 1984. In addition to moderator Robert L. Baechtold, Esq., of Fitzpatrick, Cella, Harper & Scinto, the speakers included Peter Hutt, Esq., of Covington & Burling, and Alfred B. Engelberg, Esq., of Amster, Rothstein & Engelberg. Mr. Hutt represented the Pharmaceutical Industry Association during Congressional consideration of what eventually became Public Law 98-417.

The format of the discussion, in which Mr. Engelberg and Mr. Hutt alternated in discussing various portions of Public Law 98-417, brought into sharp focus the area of disagreement between the generic drug industry and the research-based drug industry. The cordial and sometimes humorous way in which the two men aired their disagreements resulted in an entertaining as well as extremely informative session for the attendees.

Mr. Baechtold opened the meeting by stating five items Public Law 98-417 (the Act) tries to accomplish:

(1) The Act provides for an Abbreviated New Drug Application procedure (ANDA) for what are known as post 1962 drugs (those drugs approved by the Food and Drug Administration (FDA) after 1962);

(2) The Act creates an FDA-based period of market exclusivity for new drug applications;

(3) The Act provides for the time lost because of the regulatory process;

(4) The Act provides basic changes for challenging and enforcing drug patents in courts; and finally,

(5) The Act overrules *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984) in which the Court of Appeals for the Federal Circuit held that experimental testing for purposes of obtaining FDA approval on a drug is an infringement of a patent, even though the infringer intends not to engage in any commercial activity until the patent expires.

Mr. Hutt addressed his initial remarks to a brief history of the Act. After outlining some basic FDA statutory history, Mr. Hutt noted that the Pharmaceutical Manufacturers Association ("PMA") set its sights on some sort of legislated patent term restoration or extension as early as 1980. That legislative effort took four years through many stormy legislative sessions.

Finally, in January 1984, representatives of PMA sat down with Representative Henry Waxman of California to begin hammering out the legislation which would eventually become the Act. Representative Waxman wanted a procedure in which generic drugs could be brought onto the market faster and easier. PMA wanted patent term restoration. The two interests worked together to fashion a compromise bill.

Throughout the evening both Mr. Hutt and Mr. Engelberg stressed that the Act was a result of numerous legislative compromises with no one interest group fully satisfied with the final result.

Four aspects of the bill were focused on by the speakers:

(1) patent certification;

(2) periods of market exclusivity provided by FDA;

(3) patent term extension or restoration; and

(4) reversal of *Roche v. Bolar*.

Patent Certification

Patent certification (Sections 102 and 103 of the Act), the process whereby the later generic drug applicant faces at a minimum a thirty month period in which its application will not be made effective by FDA because of the existence of a patent, was strenuouslv fought for by the so-called pioneer drug companies. Mr. Hutt stated that the pioneer companies only agreed to the Section 101 provisions of the Act (easier

Seminar on Chemical Patent Practice to be Held May 7

The NYPTC is co-sponsoring with the Connecticut Patient Law Association, the New Jersey patent Law Association and the Philadelphia Patent Law Association a seminar on chemical patent practice. This seminar will be held May 7 at the New York Penta Hotel.

The program will present six panels comprised of over 45 experts in the field. They will consider such topics as new patent legislation, patent litigation strategy, PTO practice, foreign patent practice, biotechnology and recent CAFC decisions. For further information consult the insert in this issue of the Bulletin.

and faster ANDA approval for generic drug applications, reflecting Representative Waxman's interest in opening further the market for generics) so long as patent certification was included in the bill.

The patent certification provisions decree that a generic company filing an ANDA for a drug covered by a product or use patent (the number and expiration date of which had been filed by the prior approved applicant) faces denial of approval by FDA until the patent expires unless the generic company utilizes a special statutory procedure to challenge the patent. The patent certification procedure may only be used for patents which cover the drug itself or its use, not the process of making the drug.

If a generic applicant wishes to challenge, it files an ANDA and simultaneously notifies the patentee of its challenge. The generic applicant must specify for the patentee the reasons the patent is invalid or noninfringing. If the patentee then files an infringement suit within forty-five days of receiving this notice, the FDA is precluded from making the generic ANDA application effective for thirty months unless a court rules earlier that the patent is invalid. If the patentee does not file an infringement suit in response to the challenge, then the generic ANDA application may be declared effective, and the patentee may then exercise its patent rights against the generic company, as provided by current law, if it so desires.

Mr. Engelberg expressed a number of concerns about patent certification. He noted that a generic applicant had to do its homework on the patent validity question prior to challenging, possibly at considerable expense. Further, a bio-equivalence study must be undertaken prior to filing the ANDA. Even if the generic applicant overcomes these hurdles, Mr. Engelberg noted that it still faced, in effect, a thirty month preliminary injunction with an uncertain final result.

Mr. Engelberg also mentioned some areas of ambiguity in the patent certification procedure. For instance, he questioned what would happen:

(1) if the generic challenger presented only general reasons of patent invalidity to the patentee;

(2) if after a challenge, the patentee brought an infringement suit with no chance of success, in order to take advantage of the thirty-month moratorium provision; and

(3) if the patentee, at the time it filed its new drug application, listed pursuant to the Act more patents than it was entitled to list.

The certification provisions do, however, provide some protection for the generic manufacturer who makes a certification of patent invalidity. FDA cannot approve a second generic application for the same drug (1) within six months of the first generic company being on the market or (2) until after six months have elapsed since the time a court held the patent invalid. Basically, as Mr. Engelberg noted, this gives a six month exclusivity period for the generic manufacturer who decides to invest in a patent challenge. Otherwise, he stressed, there would be "no economic incentive to challenge a patent" under the certification procedures.

Market Exclusivity

Mr. Hutt briefly described the market exclusivity portion of the statute (Section 103(d)). He stressed that these provisions had nothing to do with patents and were totally an FDA matter. Basically, certain drugs are given various periods of market exclusivity before FDA may approve another applicant. Mr. Hutt noted that the patent bar needed to keep the concept of market exclusivity in mind because the applicant first approved is entitled to the period of market exclusivity or the life of the patent, which ever is longer. The two "rights" (market exclusivity and patent protection) are separate and distinct.

Stating that FDA rules concerning market exclusivity are very complex, Mr. Hutt briefly stated the statutory provisions for determining how much market exclusivity a drug is entitled to. Mr. Hutt cautioned that, because the market exclusivity statutory provisions came about as a result of a complicated legislative compromise, many of the provisions are difficult to follow.

Mr. Engelberg called the time periods of market exclusivity set up by the statute "meaningless" in economic terms, whereas Mr. Hutt viewed the market exclusivity time periods as an important guarantee to the pioneer drug manufacturer of at least a minimum period of exclusivity as an incentive for development. Mr. Engelberg countered by labelling this exclusive period outside of the patent law "a terrible give away."

Patent Term Extension

The third major area addressed by Mr. Hutt and Mr. Engelberg was patent term extension or restoration (Title II, Section 201 of the Act) embodied in 35 U.S.C. 156. At this point in the discussion the two men initially engaged in a semantic disagreement over whether the concept of 35 U.S.C. 156 should be called patent term extension (Mr. Engelberg) or patent term restoration (Mr. Hutt). The concept is that the period of patent life "lost" while performing the steps necessary to get FDA approval can be regained or restored in part through the new statutory provisions.

Only unexpired patents are eligible for extension, and the time looked at is at the time of the new drug application (NDA) approval. From that point in time the patentee has sixty days to file for a patent term extension. The maximum extension period for a "pipeline drug" (whose patent was granted and IND was submitted to FDA prior to the enactment of the statute) is two years and for a "nonpipeline drug" is five years, with a fourteen year cap from the date of the NDA approval to the expiration of the patent. The extension time available is based on the regulatory review period for the NDA which is computed as follows:

(1) the clinical study period from the effective date of the IND until NDA submission (one half of that time is available for patent term extension); and

(2) the period the FDA is reviewing the application (this entire period is available for patent term extension).

The extension may be reduced for the time the applicant failed to exercise due diligence in purusing approval for the drug. Mr. Engelberg called this provision "window dressing", but Mr. Hutt ~~period "window dressing", but Mr. Hutt~~ said that the provision could turn out to have some teeth in it, depending upon how the FDA approaches the matter.

During the period of extension, the patent claims are construed differently from normal claim construction. During the extended period the claim covers *only* the product, use or method *actually approved* by the FDA.

Mr. Engelberg and Mr. Hutt disagreed as to how many extensions were available under the Act, Mr. Engelberg taking the view that it was one extension per drug, while Mr. Hutt quoted the statute which allows only one extension per regulatory review period. In Mr. Hutt's view, a patent on an entirely new use or entirely new process entitles the patentee to another period of patent extension.

Overruling of Roche v. Bolar

The final area discussed related to the Act's overruling of *Roche v. Bolar*, 733 F.2d 858 (Fed. Cir. 1984). The CAFC held in *Roche* that experimental testing of a drug a

a preliminary to seeking FDA approval is a patent infringement even though there is no intent on the part of the entity conducting the test to market the drug prior to the expiration of the patent. Mr. Engelberg said the *Roche* holding represented probably a two year extension for the patentee. Mr. Hutt disagreed, stating that the time gained varied from six months to two years, depending upon the sophistication of the generic manufacturer.

Some areas of controversy still remain in this area even after the overruling of *Roche v. Bolar*. These include:

(1) Is this portion of the statute retroactive - does it affect experiments carried out prior to the date of enactment? Mr. Engelberg noted that as of November 1984, two courts had refused to issue preliminary injunctions for such situations.

(2) Is this portion of the statute unconstitutional because the right to sue for unauthorized use as an infringement is part of the patent grant? Mr. Hutt said this point is an important one and may be litigated.

Mr. Baechtold stated his view that the Act went far beyond overruling *Roche v. Bolar*, because the Act states that "It shall not be an act of infringement to make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs." (Section 202(e)(1)). Mr. Baechtold pointed out that the CAFC had only said in *Roche* that it was an infringing use to test a product. Mr. Baechtold suggested that it was not an infringement under the Act for a company to make patented drugs to supply to generic houses. Mr. Engelberg endorsed Mr. Baechtold's broad view of the Act, prompting Mr. Hutt to disagree with this interpretation of the statute, stating that in his view the Act does not permit infringement across the board in all aspects of drug testing.

After a final round of questions to the panelists, the meeting adjourned.

Joint Dinner Meeting Hears Talk on Patent Law Reform Act of 1984

David Beier, counsel for the House Judiciary Committee, addressed the January 17, 1985 joint meeting of the New York Patent, Trademark and Copyright Law Association and the New Jersey Patent Law Association. Mr. Beier spoke on the subject of the Patent Law Reform Act of 1984, Public Law 98-622, or, as it is colloquially known the "Patent Housekeeping Bill". Both provisions of the "housekeeping" bill which were enacted and a portion of the bill which was not enacted were addressed.

By way of background, Mr. Beier noted that the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the Committee on the Judiciary has long had direct legislative and oversight responsibilities for the American patent system. Part of the subcommittee's job is to secure for the owners of intellectual property, including patent holders, a workable, efficient, and vigorous set of laws to protect their creations. Mr. Beier reflected the view that by implementation of the constitutional mandate of encouraging the sciences and the useful arts it is possible to spur the inventive spirit that has made the United States a world leader. Indeed, he characterized the United States' ability to foster innovation as a central element to national security, for without technological and scientific developments, it would not be possible to maintain the current standard of living or hope for the diminution of unemployment caused by foreign competition.

Mr. Beier further noted that the United States patent law makes reward to the owner a secondary consideration. The stimulation of creativity by providing large corporations with more money or extended monopoly rights is not the paramount goal of the patent laws. Rather, the principal interest of the United States and the primary object of granting patent rights lies in the general benefits derived from the work of the inventors. The housekeeping bill enacted last fall was intended to satisfy the "public interest" test of patent law reform.

Legislative History of the Bill

The bill was originally suggested, in part by the Commissioner of Patents and Trademarks, Assistant Secretary of Commerce, Gerald Mossinghoff, and, in part, by an *ad hoc* committee of patent law experts. These individuals (Rudolph J. Anderson, Robert B. Benson, Donald W. Banner, Homer O. Blair, Harry F. Manbeck, John E. Mauer, Pauline (now Judge) Newman, Donald J. Quigg, Richard C. Witte, Arthur R. Whale) worked long and hard to refine the proposals.

Originally separate bills were introduced on a variety of subjects, including "defensive patents," process patent protection, and changes in the rules relating to licensee estoppel. On the House side these bills were introduced by Congressman Kastenmeier. On the Senate side two separate bills were introduced by Senator Mathias, Chairman of the Subcommittee on Patents, Trademarks and Copyright. Extensive hearings were held in both houses, and special emphasis was placed on the developments of a consensus approach to reform. Both Congressional committees benefited from the expert advice of various bar organizations, including the NYPTCLA and the NJPLA. In addition, the committees sought out the advice of independent patent law experts. This process of informal consultation permitted the Patent Law Reform Act of 1984 to proceed to the floor without going through the usual legislative process.

H.R. 6286 was introduced in the House by Congressman Kastenmeier on September 20, 1984. On October 1, 1984 the bill was taken up and passed by the full House on the Suspension Calendar (Congressional Record, H. 10522). The Senate took the bill up on October 11, 1984, adopted some minor amendments and returned it to the House. (Congressional Record, S. 14248). Then the House took up the Senate-passed version of the bill, struck one of the Senate amendments, passed the bill, and returned it to the Senate. (Congressional Record, H. 12231). Finally, in the closing hours of the Congress on October 11th, the Senate acceded to the House and accepted the bill on November 9, 1984.

As a result of this legislative process, there is no official committee or conference report for the legislation. There is, however, a section-by-section description of the hill reprinted in the Congressional Record of October 11, 1984. In addition, copies of the House and Senate hearings on these bills are available.

Summary of the Bill

Section 101 of the bill provides that a product's patent protection cannot be avoided through the manufacture of component parts within the United

States for assembly outside the United States.

Section 102 establishes a new procedure for a statutory invention registration, thereby creating an optional procedure by which an inventor may secure patent protection that is strictly defensive in nature. This new option will be very useful to those with limited resources such as universities and small businesses who will now be able to select, in appropriate cases, a less expensive alternative to the more costly patent process.

Section 103 provides that unpublished information known to the inventor does not constitute prior art in the field of the invention, and therefore cannot serve to defeat the patentability of that invention. This latter change will be of material benefit to university and corporate research laboratories where the free exchange of ideas and concepts may have been hampered by the current state of the law with respect to what constitutes "prior art."

Section 104 of the bill provides that two or more inventors may obtain a patent jointly even though each inventor has not contributed to each and every claim found in the patent application. This technical amendment should also be of benefit to universities and corporations which rely on team research.

Section 105 authorizes parties involved in patent interferences to arbitrate such disputes. This change parallels a provision of Public Law 97-297 which authorizes arbitration with respect to questions of patentability.

Title II of Public Law 98-622 is designed to improve interference proceedings in the Patent and Trademark Office of the Department of Commerce. Under existing law, the Board of Patent Interferences had not been authorized to address all questions of patentability of the invention. This restriction on the Board's jurisdiction unduly complicated the procedures for obtaining patents for applicants involved in interference proceedings. By combining the Board of Patent Interferences with an existing board having patentability jurisdiction — the Board of Appeals of the Patent and Trademakr Office — procedures for patent applicants and patentees involved in interferences will be simpler, more expeditious, and less costly.

Title III of the Bill creates a National Commission on Innovation and Productivity. During the past decade, the need to promote creativity and stimulate innovation has become a catch phrase. Much debate has revolved around improving the patent and copyright systems, creating new forms of intellectual property, and establishing corporate incentives — such as tax and investment credits. Little discussion has occurred about how to accomplish agreed-upon objectives at an employee level. The purpose of the National Commission, therefore, is to focus and redirect attention on the issue of employee inventors' rights.

Title IV of the new law contains miscellaneous provisions designed to bring United States law into conformity with internationl patent law and treaty obligations, to correct drafting mistakes in recently-enacted public laws, and to augment the salary level of members of the Trademark Trial and Appeal Board.

Protection of United States Process Patents

After outlining the portions of the "housekeeping" bill which were enacted, Mr. Beier focused his attention on protection for United States process patents, a portion of the bill which was not enacted. That portion of the bill had addressed the problem of process patent owners who are faced with domestic competition from persons who use the patented process to create a product overseas and then ship it into the United States. In these situations the patent owner cannot sue for patent infringement, but rather is relegated to the International Trade Commission to seek limited non-monetary relief.

During the last Congress legislation was introduced to redress this deficiency. Each of the bills had as its core the belief that process patents deserved greater protection. One of the bills, H.R. 4526 — and its successor H.R. 6286 — provided that importation, use or sale of a product made outside the United States in violation of a process patent constitutes an act of patent infringement. The other bill, H.R. 3577, did not distinguish between products made using a patented process within the United States and those made outside the United States. While these bills differed as to scope, they were both intended to reach the same deficiency.

The wisdom of extending greater protection to process patents was accepted by the House of Representatives during the last Congress when it passed H.R. 6286. Unfortunately the portion of that bill relating to process patents was stalled in the waning hours of the Congress in the Senate by opposition from generic drug manufacturers. In Mr. Beier's view, it is virtually certain, however, that this issue will be revisited by the Congress during the next two years.

In conclusion, Mr. Beier solicited the advice of groups like the NYPTCLA and NJPLA respecting the bill.

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