THE NEW YORK PATENT, TRADEMARK AND COPYRIGHT LAW ASSOCIATION

NYPTC BULLETIN

VOLUME 25 MAY 1986 NUMBER 5

Record Attendance at This Year's Judge's Dinner

As has by now become customary, the Association's Sixty-Fourth Dinner in Honor of the Federal Judiciary held at the Waldorf Astoria on March 21, 1986 set a new attendance record. Over 1,700 members and their guests filled the Ballroom and an ever-increasing number of annex rooms to capacity.

The dinner was presided over by the Association President, John O. Tramontine. The honored guests at the dinner included six judges from the United States Circuit Courts of Appeals, twenty-two judges from the United States District Courts, three judges from the Bankruptcy courts, six United States magistrates, four judges from the United States Court of International Trade, five justices from the New York Appellate Division, sixteen justices from the New York Supreme Court, seven court clerks, the Commissioner of Patents and Trademarks, the Register of Copyrights and twenty-one representatives of various associations.

Our speaker this year was Hon. Roger J. Miner of the United States Court of Appeals for the Second Circuit. Judge Miner chose to speak on the origins of the Patent Clause (Article I, Section 8, Clause 8) of the United States Constitution. He delivered a humorous, tongue-in-cheek account of the "after hours" meetings held by the framers of the Constitution in a tavern owned by one Ebenezer Tramontine, a distant relative of our current President. It seems that this tavern owner, who served as the first lobbyist, succeeded in assuring employment for future patent attorneys, including his own illustrious descendent.

The evening concluded with after dinner drinks and dancing in the Basildon Room.

Gray Market Goods Discussed at Luncheon Meeting

Jacob Laufer and Kenneth Umans addressed a luncheon meeting of the Association last Fall on the timely subject of gray market goods. Laufer began the discussion with a "real life" example of a client who was planning to sell a medical device in the U.S. retailing for about $99.00. That same product was slated to be sold in China at a retail price of $20.00. This fact pattern will give rise to the parallel import problem since it gives someone an economic incentive to move goods from the Chinese market to the U.S. market.

Laufer suggested that the law of unfair competition was developing on a case by case basis to address the problem of parallel imports even though the statutes and regulations seem to make it clear that there is not even an issue to be considered. He noted that the patent and copyright laws prevented importation of a product protected under those laws. Although the Trademark Act does the same thing, there is still a difficulty in preventing the importation into the United States of a parallel imported product.

Laufer referred to Customs Regulations which set forth exactly what must be done to record a trademark registration with Customs and which provided that Customs will prevent the importation into the United States of products bearing the recorded trademark without the consent of the trademark owner. He found that part of the problem was that many trademark owners did not follow the recordation procedure provided by Customs. Another problem was the manner in which Customs has applied and the courts have interpreted certain exceptions in the Customs regulations.

Laufer cited the early *Bourjois* case which involved a fact pattern which has repeated itself in subsequent decisions. In that case, a European company had been selling a popular face powder in the United States under the BOURJOIS trademark. The company sold the mark to a U.S. company which continued to package and sell the product in the United States. The defendant in that case decided to import face powder into the United States under the same mark from the European company which was selling the product for less money and to sell it in competition with the U.S. company. Laufer characterized this as the classic parallel import situation.

The Second Circuit refused to block this parallel importation. Congress came to the rescue and enacted a broad statute which went beyond the narrow situation where a U.S. company had purchased trademark rights from a foreign company. There is thus a legislative intent that goes one way and a statute that goes another way. After the statute was enacted the U.S. Supreme Court reversed the Second Circuit and held that the foreign company's goods could not be sold in the United States after it had sold the trademark to the U.S. company.

Laufer suggested that Customs had taken an evolutionary approach to this statute. Although Customs initially was blocking entry of all parallel imports, it later recognized that more complex relationships had developed between foreign and U.S. companies, which required further regulations limiting the situations in which a U.S. company could block importation. For example, foreign imports would no longer be blocked if the foreign and domestic companies had a common control.

Continued on page 2

GRAY MARKET

Continued from page 1

Laufer then discussed the more recent *Mamiya* case, where a camera company had attempted to block the parallel importation of its foreign-produced cameras into the United States. The District Court enjoined such importation on the ground that it constituted trademark infringement. This decision prompted an increase in such litigation.

Laufer suggested that each of these cases was being decided on a case by case basis by the trial judge. In other words, liberal, consumer-minded judges tended to decide cases in favor of parallel importation, while more conservative, big business judges tended to decide in favor of the trademark owner against parallel importation.

Laufer cited certain economic factors and practical considerations which seemed to be determinative in these cases. First, the greater the price differential, the more likely a judge will be to let the product into the country. Second, a judge might be persuaded to exclude the foreign product if it differed in appearance from the U.S. product. For example, the U.S. trademark owner could create something unique about the product being sold in the United States which distinguished it from the products sold abroad under the same mark.

Laufer saw a valid argument that the distributor in the U.S. has spent money on advertising the product for sale in the U.S. and that a parallel importer is able to take a free ride on the good will and reputation established by the U.S. trademark owner. Yet, the trademark owner still has to be able to explain why there is a price differential between the foreign and domestic versions of the product.

Laufer then offered some practical applications as to what was going on today to provide protection against parallel importation. For example, he suggested that there is no reason why there must be common ownership or control of the domestic distributor and the foreign manufacturer. A U.S. distributor could own the mark and record it with Customs in order to exclude parallel imports. The product could also be packaged or sold so that the American consumer believes he is getting more from the U.S. product than from the imported product. He concluded that the issue ultimately will be determined in the marketplace.

Ken Umans next offered his views on parallel importation and explained that they center on the core issue of likelihood of confusion, which is the foundation of trademark law. He defined parallel imports as a situation where goods bearing the trademark of a given U.S. trademark owner are imported into the United States without the trademark owner's authorization. Such imported goods are not counterfeit and are generally made by the same manufacturers who produce goods for the U.S. trademark owner. Often, these goods are first sold overseas by the U.S. trademark owner or by a related company or foreign licensee. Umans noted that the gray market problem reached its peak only when the U.S. dollar became strong, making economically feasible, the importation of goods already sold or distributed in foreign markets.

Umans reviewed the *Bourjois* case and noted that it involved a straightforward trademark assignment whereby the consumer, after the U.S. company received an assignment from the foreign manufacturer, came to associate the trademark in question with the U.S. company. Further, the U.S. company maintained total control over the trademark as used in the United States. Based on these facts, it was easy to resolve this case on the basis of the likelihood of confusion test.

Umans next discussed the *Mamiya* case and one of the arguments raised by the trademark owner in that case concerning the incontestability of the mark at issue. It had argued that incontestability gave it the exclusive right to use the mark and that it did not have to show likelihood of confusion. Umans suggested that incontestability did not override the express language of Section 32 of the Lanham Act stating that the use by the alleged infringer of a registered trademark must be likely to cause confusion in order to give rise to a civil action. From this he reasoned that if you seek injunctive or equitable relief in a trademark infringement action, you have to establish likelihood of confusion.

Umans explained that there should be no gray market problem where the facts parallel the *Bourjois* situation. That is, an independent U.S. company with an independent good will should have no trouble in enjoining the importation of goods bearing a copy of its trademark. This is the territoriality principle for which *Bourjois* stands. As a general rule, it is only those situations where the U.S. trademark owner is not truly independent and/or does not own an independent good will where problems arise. For example, he referred to the *Mamiya* situation where Mamiya, the foreign manufacturer of the cameras in question, was the original owner of the U.S. trademark. Obviously, Mamiya could not stop its own goods from coming into the United States, even by a non-authorized distributor, since there could be no colorable claim of likelihood of confusion. Prior to the importation of cameras by the defendant, Masel, Mamiya had historically given alleged assignments of its U.S. trademark to exclusive U.S. distributors. Such "assignments" had reversion back clauses which could be triggered by the unilateral cancellation of the distribution agreement by Mamiya. Subsequently, in order to create a *Bourjois* fact pattern for itself, Mamiya, in concert with its worldwide distributor, formed a series of U.S. subsidiaries and allegedly "assigned" the U.S. trademark to one of those subsidiaries. There was an interlocking Board of Directors and no real evidence that the U.S. subsidiaries independently controlled the trademark or had achieved a good will separate and apart from Mamiya. Umans questioned the validity of such an assignment and deemed it a disguised license. He referred to a section of the Internal Revenue Code which stated that if an assignor retained any significant control over the trademark after

Continued on page 3

Speech on Biotechnology Given at Luncheon Meeting

The New York Patent, Trademark and Copyright Law Association held a luncheon meeting on December 5, 1985. The guest and speaker at the luncheon meeting was John P. White. Mr. White is a member of Cooper, Dunham, Clark, Griffin & Moran and has extensive experience with genetic engineering/ biotechnology patent matters. His talk focused on developments in this area over the past two years.

Mr. White discussed prosecution trends at the United States Patent and Trademark Office as well as litigation related to the biotechnology area of patent law, and ended the formal presentation with a consideration of future trends. Mr. White then responded to questions.

The patentability of life forms was

Continued on page 4

GRAY MARKET

Continued from page 2

the assignment, the assignment would be ruled a sham and treated as a license for purposes of taxation. This would mean that the IRS would tax any monies received from the assignment as ordinary income rather than long-term capital gains. Umans then suggested that this same rule could be applied to assignments of trademarks for purposes of determining whether a company had, in fact, received a bona fide assignment thus validly fitting into a *Bourjois* fact pattern.

He then stated that a company should not be able to get around *Bourjois* by use of sham assignments. He expressed concern that such assignments will be given credibility at the expense of our trademark system in that entities not truly controlling the trademark in question or maintaining the quality of goods bearing the mark could bring bogus trademark infringement suits. He thought that the problem of parallel imports might be better dealt with by legislation and that we should avoid solutions to the gray market problem which merely exalt form over substance.

BIOTECHNOLOGY

Continued from page 2

addressed in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). There the Supreme Court held that micro-organisms produced by genetic engineering were not excluded by 35 U.S.C. §101.

Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The Examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that mircoorganisms are "products of nature", and (2) that as living things they are not patentable subject matter under 35 U.S.C. §101. The Patent Office Board of Appeals affirmed the Examiner. The Court of Customs and Patent Appeals reversed on the authority of its prior decision in *In re Bergy* 563 F.2d 1031, 195 USPQ 344 (1977) which held that "the fact that microorganisms . . . are alive . . . [is] without legal significance" for purposes of the patent law. The Supreme Court granted a writ of certiorari. Chief Justice Burger wrote that Chakrabarty's micro-organism qualifies as patentable subject matter. The claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter - a product of nature having a distinct name, character [and] use". Mr. White pointed out that the Court of Customs and Patent Appeals held in *In re Kratz and Strasburger* 201 USPQ 71 (1979) that purified natural products may be patentable.

In general the PTO had treated higher life forms as unpatentable. Plants are granted protection as a result of two pieces of legislation: the 1930 Plant Patent Act, which affords patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorizes patents for certain sexually reproduced plants but excludes bacteria from its protection.

In *Ex parte Hibberd*, 227 USPQ 443 (1985), the United States Patent and Trademark Office Board of Appeals and Interferences took the view that plants could also receive patent protection under 35 U.S.C. §101. *Hibberd* involved an appeal from the Examiner's decision finally rejecting claims relating to maize plant technologies, including seeds, plants, and tissue cultures which have or are capable of producing plants or seeds having increased free tryptophan levels. The rejections were based on the Examiner's position that the claims comprise subject matter which is inappropriate for protection under 35 U.S.C. §101. The Examiner asserted that to the extent the claimed subject matter could be protected under the Plant Variety Protection Act or the Plant Patent Act, protection under 35 U.S.C. §101 would not be available.

The court reversed the Examiner's decision. The court stated that the question presented by this case was whether the scope of Section 101 had been narrowed or restricted by reason of the enactment of the plant-specific Acts. The court asserted that the Supreme Court in *Chakrabarty* interpreted the language of Section 101 "to include everything under the sun that is made by man". The board found that neither the Plant Patent Act nor the Plant Variety Protection Act expressly excludes any plant subject matter from protection under Section 101, and that the legislative history of these Acts did not indicate an intent to restrict or limit the scope of patentable subject matter available pursuant to 35 U.S.C. §101. The Examiner stated that passage of plant-specific Acts implicity narrowed Section 101 but the court rejected this view in light of the overwhelming weight of authority which supports the view that repeals by implication are not favored.

Two cases were mentioned which addressed the issue of 35 U.S.C. §112 enablement in patents claiming micro-organisms, *In re Lundak* 773 F.2d 1216, 227 USPQ 90(1985) and *Ex parte Jackson et al.* 217 USPQ 804 (1982).

Lundak was decided in the Federal Circuit Court of Appeals. The appeal from the United States Patent and Trademark Office Board of Appeals concerned the administrative role of the PTO whereby an inventor in the field of mircobiology is required to deposit a sample of relevant biological materials with an independent depository on or before the date the inventor files a patent application. The deposit requirement applies only to biological materials that are not readily reproducible from their written description. The Board of Appeals affirmed the Examiner's rejection of two claims of a patent application entitled "High Fusion Frequency Fusible Lymphoblastoid Cell Line" for failure to meet requirements of 35 U.S.C. §112, first paragraph, due to Lundak's failure to make such deposit on or before his filing date. Inventor Lundak sought to change his filing date to the date of deposit of the microorganism, but the Commissioner denied the petition, stating there was no indication the application was not complete as of the original filing date. Lundak appealed to the Board of Appeals contending that he had deposited the cell line with colleagues at the University of California. The Board held that such a deposit was inadequate because they were not "recognized depositories" which could guarantee permanent availability. The Board held that Lundak's deposit seven days after the filing date was "new matter".

The court stated that MPEP §608.01(p)C does not specify whether the deposit be in a private or public depository. Its requirement that the deposited culture be available to the PTO during pendency of the patent application is satisfied by compliance with a request from the PTO to the applicant. The court concluded that 35 U.S.C. §112 does not require the transfer of a sample of invention to an independent depository prior to the filing date of the patent application. The court concluded that Lundak's specification as filed met the requirements of constructive reduction to practice and that insertion of depository data after filing is not new matter. Lundak's written description along with the availability of a sample to the public after the patent has issued will meet the enablement requirement of 35 U.S.C. §112.

Continued on page 4

BIOTECHNOLOGY

Continued from page 3

Jackson was decided in the United States Patent and Trademark Office Board of Appeals. It was an appeal from an Examiner's rejection of several claims in a patent application. The applicants discovered three bacterial strains which produce a new antibiotic. The antibiotic is the subject of claim 1, which was allowed. The three strains were classified as a new species which was given the species name recited in the claims. The three strains were deposited in a recognized depository and are identified in claims by their depository culture number. Claim 2 described a process for producing the antibiotic and recited the species broadly. Claims 3-6 identified each strain by their depository culture number.

Claims 3 to 5 were rejected as being based on insufficient disclosure of how to practice the invention claimed with respect to mutations of recited mirco-organisms. Since it is well known that spontaneous mutation is common occurance in mircoorganisms and the mutations can be intentionally produced by a variety of known procedures, the court did not affirm the Examiners rejection of claims 3-5. Claim 2 was finally rejected as being based on insufficient disclosure with respect to the recitation *Micromonospora pilosospora* broadly. The court stated that the issue is whether a verbal description of a new species could enable one of ordinary skill in the relevant art to obtain strains of the species over and above the specific strains made available through deposit in one of the recognized culture depositories. The court cited *In re Argoudelis*, 59 CCPA 769, 434 F.2d 1390, 168 USPQ 99 (1970), for the view that "a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given. The court concluded that only deposit of a new microorganism can satisfy the enablement requirement of 35 U.S.C. §112. The court affirmed the examiner's rejection of claim 2.

Mr. White discussed a recent decision which concerned the issue of obviousness relating to an assay which employed monoclonal antibodies.

Hybritech Inc. v. Monoclonal Antibodies, Inc., 227 USPQ 215 (1985) was decided in the United States District Court in the Northern District of California. The suit was brought by Hybritech, Inc. for alleged infringment by Monoclonal Antibodies, Inc. of U.S. Patent No. 4,376,110, entitled "Immunometric Assays Using Monoclonal Antibodies", issued March 8, 1983, on application filed August 4, 1980. The invention was a method of analyzing fluids for antigens employing monoclonal antibodies and taking advantage of their unique properties to obtain an extremely fast, sensitive and accurate analysis. The method was a "sandwich" assay. The Examiner rejected the claims in view of Cuello, who described the use of monoclonal antibodies in "competitive" assays, and other references, which describe the use of polyclonal antibodies in sandwich assays. The claims were allowed when amended to include a numerical limitation regarding the affinity of the antibody to the corresponding antigen.

The court found the patent in issue invalid and held the matter of infringement to be moot. The court held the alleged advantages were expected, not significant, and not applicable to all monoclonal antibodies claimed by Hybritech. The substitution of known high affinity monoclonal antibodies for polyclonal antibodies of similar affinity in a known sandwich assay for the known advantage of monoclonal antibodies over polyclonal antibodies in immuno assays was determined to be unpatentable. Evidence was presented that the claimed invention was reduced to practice by LaJolla Cancer Research Foundation in November 1979, and by Oi and Herzenberg in July, 1978. The specification failed to teach how to obtain monoclonal antibodies having the claimed affinities, why the affinity limitation was significant, or how the affinity is measured. Judgment was granted in favor of defendant.

The biotechnology area of patent law is also experiencing an increase in multi-party interferences where three or four parties may be involved in an interference, and in settlements such as the one devised by Hoffman La Roche and Schering Plough which included a covenant not to sue.

Mr. White discussed future trends in the biotechnology area of patent law. He stated that covenants not to sue would become more common in settlements between parties. Mr. White also said that there would be an emphasis on patents in the future but that there would be difficulties regarding priority of invention. More products, such as insulin and animal and human vaccines, will be brought to market in the future and the potential for litigation will greatly increase.

The New York Patent, Trademark and Copyright Law Association, Inc.

Volume 25 May 1986 Number 5

The BULLETIN is published periodically for the members of the New York Patent, Trademark and Copyright Law Association. Annual Non-Member Subscription is $15.00/year. Single copies $2.00. Correspondence may be directed to the Chairman-Subcommittee-Bulletins, Howard B. Barnaby, 330 Madison Avenue, Suite 206, New York, NY 10017. Telephone (212) 682-9640.