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President's Corner

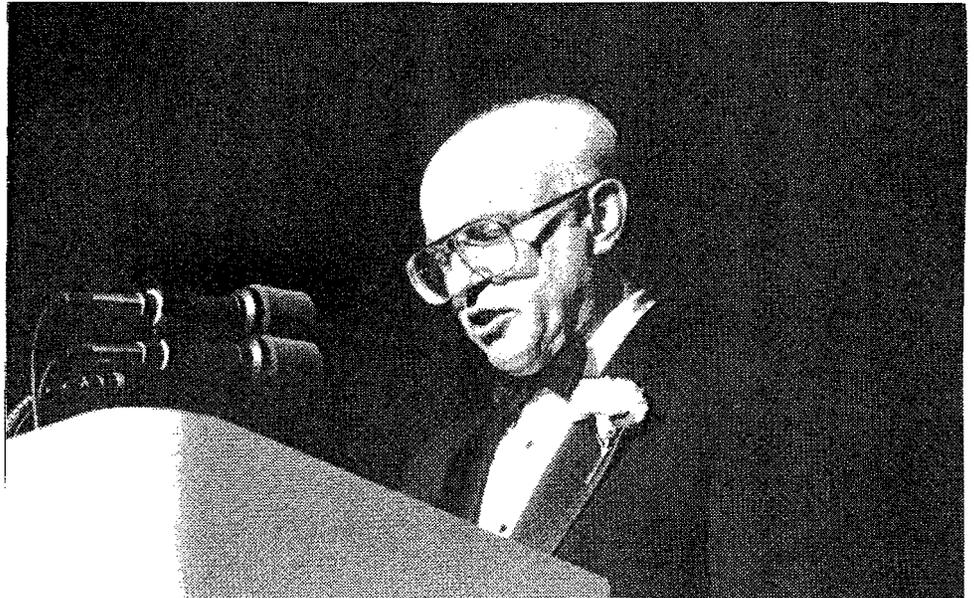
By the time you receive this Bulletin, the 1986/87 Association Year, like all good things, will have come to an end. It will have been an active and productive year and I want to take this opportunity not only to recap the events and accomplishments but also, in particular, to pass out accolades and thanks to those who "made it happen."

Luncheon Meetings A Mainstay

As a mainstay of our Association Year, we have had a series of successful monthly luncheon meetings - seven to be exact - at the 60 East Club on a variety of topical subjects in such areas as trade secrets and best mode, trademark oppositions, Patent and Trademark Office automation, patent infringement damages, patent infringement via new drug application filings and, as a grand finale, a debate between our George Whitney and Don Dunner of Washington, D.C. on whether the U.S. interference system should be eliminated and replaced by a first-to-file system.

Special events were the joint dinner meeting in January with the New Jersey Patent Law Association at which Senator Mathias, "a friend of a strong intellectual property system," regaled us with reminiscences of his 25 years on Capitol Hill; the Third Annual Joint Patent Seminar in Philadelphia in April, in cosponsorship with the Connecticut, New Jersey and Philadelphia Patent Law Associations; and our CLE Weekend Seminar at Skytop, PA. in the beginning of May. Both seminars featured excellent speakers and programs. In August of 1986 our Association hosted a widely-acclaimed reception at the Windows-on-the-World for the ABA-PTC Section at its annual meeting.

As always, the highlight, of course, was the 65th "Judges Dinner" at the Waldorf-Astoria on March 27, 1987 with record attendance of honored guests and record overall attendance. The charisma and magnetism of the guest speaker



Karl Jorda, Association President introducing Judge Markey at Annual Judges Dinner on March 27, 1987.

speaker, the Honorable Howard T. Markey, Chief Judge, Federal Circuit and his powerful message about the Constitution, the Citizen and the Lawyer, the '87 Judges Dinner was indeed a most memorable one. A copy of Judge Markey's speech had been reprinted in this Bulletin.

Legislation and Rule Making Important

Apart from educational meetings and seminars, significant progress was also made in the areas of "staying on top" of pending Congressional legislation and PTO rule-making as well as ongoing international efforts aimed at harmonization of PTC laws and practices.

Our Immediate Past President, John O. Tramontine, has recently again testified on the Hill on process patent infringement bills, repeating and refining the NYPTC proposal regarding liability only for importation or first sale in the U.S. Our Association also provided substantial input and comment to

the PTO's Board of Patent Appeals and Interferences on how to reduce its *Ex parte* backlog.

And with respect to harmonization initiatives, the NYPTC was represented by Samson Helfgott as our observer at the Third WIPO Harmonization Session, held in Geneva at the end of March. And Sam did not just attend and listen; he presented NYPTC positions developed on all matters under consideration at Harmonization Committee and Board of Directors meetings, the latter being attended also by Mr. Mike Kirk, PTO's Assistant Commissioner for External Affairs, as a guest of the Board. I would also like to acknowledge gratefully in this context the very capable representation of the NYPTC by

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Reminder!

May 28, 1987 - Annual Meeting and Inventor-of-the-Year Award with District Court Judge Ward as Guest Speaker and Dr. Sternbach as Awardee - Grand Hyatt Hotel.

Discussion On Recent CAFC Cases On Patent Damages

by Patrick J. Birde

At a recent Association Luncheon, John Artz of Harness, Dickey and Pierce presented an interesting and informative review and analysis of recent trends in the Federal Circuit's treatment of damages in patent litigations. In view of recent Federal Circuit decisions, Mr. Artz advises that patent owners are well advised to seek "justice" from infringers, especially wilful infringers - "just as" much as they can get.

Pendulum Swinging Toward Patentees

The pendulum which swung so heavily in favor of infringers during the 60's and 70's has now swung in favor of the patent owners. The Federal Circuit Court may continue to enlarge patent owners rights to injunctive relief and even greater damages.

For example, Kodak's Instant Camera Division went out of business and several thousand workers lost their jobs shortly after an injunction went into effect *Polaroid Corp. v. Kodak*, 789 F.2d 1556; 239 U.S.P.Q. 561 (Fed. Cir. 1986). The Federal Circuit affirmed a district court's damage award of \$204 million in *Smith v. Hughes*; and \$44 million in *Shiley, Inc. v. Bentley Laboratories*, 794 F. 2d 1561, 230 U.S.P.Q. 112 (Fed. Cir. 1986).

The press and corporate America have gotten the message that patent infringement doesn't pay. "The Surprising New Power of Patents" *Fortune Magazine* p. 57, June 1986. The Federal Circuit has significantly improved Patent Owners' chances for getting favorable decisions on validity and infringement while making it easier to prove traditional damages, particularly, lost profits, and higher percentages for reasonable royalties.

Prejudgment Interest Increasing Awards

Prejudgment interest has also significantly increased awards, for example, \$70 million of the \$204 million damage award in *Smith International v. Hughes Tool*, supra, was interest and in *Devex Corp. v. General Motors*, 494 F. Supp. 1369 (D. Del. 1980); 569 F. Supp. 1354 (D. Del. 1983); *aff'd* 667 F. 2d 347 (3d Cir. 1981) the damage award was \$8.8 million and the interest was about an additional \$11 million.

One of the more significant recent Federal Circuit cases considering

damage issues was *Radio Steel & Mfg Co. v. MTD Products, Inc.*, 788 F. 2d 1547 (Fed. Cir. 1986) which reaffirmed the Panduit test for recovering lost profits, may indicate a lessening of the burden of proving the "non-infringing alternative" element of that test. The damage award in *Radio Steel* included lost profits, a 10 percent reasonable royalty and prejudgment interest. The defendants argued that there were non-infringing alternatives to plaintiff's patented wheelbarrow on the market for many years which performed the same function and that could be easily purchased by the consumer to do the same job. The Federal Circuit rejected that argument because it ignored the new and improved features of the patented wheelbarrow, particularly, that is was different from the prior art, more convenient in use and shipment, and had a shin scraper between its legs.

The \$44 million damage award in *Shiley, Inc. v. Bentley Laboratories, Inc.*, supra, included \$17.5 million for lost profits, a reasonable royalty of 12 percent, prejudgment interest and double damages for wilful infringement.

In *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F. 2d 268, 227 U.S.P.Q. 352 (Fed. Cir. 1985), the court indicated that the infringing and patented product formed a niche or mini-market, thus narrowing the range of available, acceptable non-infringing substitutes.

In *TMW Mfg. Co. v. MTD Products, Inc.*, 789 F. 2d 895, 229 U.S.P.Q. 525 (Fed. Cir. 1986), the damages awarded by the District Court based on a 30% reasonable royalty were upheld by the Federal Circuit based on a top management memo predicting a 52% gross profit on the infringing sales. Another important aspect of this case was reaffirmation of the "entire market rule" which permits anticipated sales of unpatented products that would have been made with the patented product to be included in the base from which the reasonable royalty is calculated. Obviously, increasing the royalty base is another factor that leads to larger damage awards in the future.

As to prejudgment interest, *GM - Devex*, supra, is the standard and indicates that prejudgment interest will ordinarily be allowed unless certain facts and conditions indicate otherwise. *Laitram Corp. v. Cambridge Wire Cloth Co.*, 785 F. 2d 292, 228 U.S.P.Q. 935 (Fed.

Cir. 1986), *Radio Steel & Mfg Co. v. MTD Products, Inc.*, and subsequent cases demonstrate the infringer's lack of success in finding exceptions or excuses to avoid prejudgment interest. In *Laitram*, the Federal Circuit reversed a Magistrate's denial of prejudgment interest holding that since there was no evidence of record which excused prejudgment interest, it had to be awarded. In *Radio Steel*, both the lower court and the Federal Circuit rejected the argument that prejudgment interest should be excused where the patent owner continued making his product with a patent notice after the patent expired. The Federal Circuit indicated that this excuse had no relevance to the damage issue. This decision suggests that a relationship between an excuse and the damage issue will be required.

Enhanced Damages

Finally, on the issue of enhanced damages, it is no longer necessarily true that enhanced damages won't be awarded where the infringing activity began before the patent issued or before the defendant became aware of the patent. In *Shiley v. Bentley*, supra, the Federal Circuit found wilful infringement and awarded double damages although the infringing activity began before the patent in suit had issued. Although this decision appears to contradict *State Industries v. A. O. Smith*, to the effect that to wilfully infringe a patent, the patent must exist and one must have knowledge of it. However, the Court opined that these and its other decisions of wilful infringement are harmonious because they apply a "totality of the circumstances" approach. In *Power Lift v. Lang Tools*, 774 F. 2d 478, 227 U.S.P.Q. 435 (Fed. Cir. 1985), a patentee's immediate offer of a license upon issuance of the patent in suit was flatly rejected by the defendant. Suit was brought nine days later and the Court found wilful infringement.

In sum, these cases extend the affirmative duty to exercise due care to avoid infringement of patent *Underwater Devices v. Morrison-Knudsen*, 717 F. 2d 1380, 219 U.S.P.Q. 569 (Fed. Cir. 1983). Where a company is aware that it may be infringing a patent or is put on notice by a third party, the company must make a thorough investigation of the matter and take a reasonable approach toward resolving it.

The Constitution, The Citizen, And The Lawyer

Editor's Note: This is a reprint of the speech by Chief Judge Howard T. Markey of the Court of Appeals for the Federal Circuit at Annual Judges Dinner on March 27, 1987.

In the next few moments, I propose to visit with you about the newest, shiniest, most revolutionary proposition in the political history of the world. The proposition is so new that most of the world's people have never heard of it – and, even today, most people in the world would be startled if anyone ever told them about it. The proposition is embodied in that many-splendored document we call the Constitution of the United States, which was signed this morning in History's eye. At once profound and precise, the proposition can be stated in five words – human beings *can* govern themselves. They say the best after dinner speech is just five words, "I'll take the check," but I propose to concentrate on five really important words – human beings *can* govern themselves.

Think about it. It was absolute nonsense in 1787 to believe that government power could be limited by a mere document, that government derived its power from consent of the people, that powerful chiefs of government could be turned out by the people without violence, or that every citizen had rights neither government nor powerful citizens could infringe. Those premises vivify the Constitution and rest on the proposition that human beings can govern themselves.

For two hundred years we Americans have been testing, we are testing today, and our children will be testing, whether this new proposition is truly valid. Ours is and has always been a searching, seeking, not a settled society, as we determine whether this experiment in liberty we call the United States – what Edmund Randolph in the Constitutional Convention called "this selective experiment" – shall endure.

In this year of the bicentennial of the Constitution I have, like many others, been telling everywhere the fascinating story of its miraculous genesis, its brilliant, dedicated framers, and its glorious history. I will not presume, however, to lecture here on the details of Freedom's birth certificate – not on this happy night among lawyers who share

with me the privileged joy of working every day at the heartbeat of a free society – the Law – and who also share my lifelong love affair with the Constitution. Nor, with so many patent lawyers present, is it necessary to point out that the only form of property

"They say the best after dinner speech is just five words, 'I will take the check,' but I propose to concentrate on five really important words – human beings can govern themselves."

expressly mentioned in the Constitution is intellectual property.

No, tonight I want to visit about what the Constitution means to each of us, as citizens first and then as lawyers.

First, the Constitution belongs not to lawyers, or judges, or Congress, or the Supreme Court. It belongs to you, the people, who, as the Preamble says, "do ordain and establish" it every day. All the lawyers and judges and law professors and politicians who ever lived could not preserve the Constitution for one day if the people turned away. That is what Chief Justice Marshall had in mind when

he said the people made the Constitution and the people can unmake it. It lives only by their will."

We can "unmake" the Constitution as much by negligence and neglect as by device and design. We have always a choice. But no society can be free and dishonest. We can stand firm with the freedom and responsibility inherent in the Constitution – we can govern ourselves – or we can accept an insidious chipping away – a little inroad on freedom here and there – always blamed on technology or societal complexity and always presented for our own good. If we choose the latter course, we will not survive as free men and women – and we won't deserve to.

The danger is that the Constitution's protections so permeate the ordinary events of our every day living as to be easily taken for granted. Last week, for example, I joined hundreds of thousands of Americans in traveling across the country to cities like Los Angeles, Miami, and Philadelphia – and I joined some 200 people on the plane that brought me here tonight – and not one of us even *thought* of asking a government official permission!

I digress for a moment to tell you what happened on the plane today. At 25,000 feet, I saw a nun working her beads through white knuckles. I said, "Sister, you of all people! You know the Lord said, 'I am with you always.'" She



Chief Judge Howard Markey addressing Association at Judges Dinner on March 27, 1987.

Judge Markey Speaks at Annual Judges Dinner, Con't.

said "No sir, the Lord said, 'Lo, I am with you always.'"

But we not only travel where and when we wish, next weekend millions of the fortunate people in this beloved land will need no one's approval to attend the synagogue or mosque or church of their choice. Over the years, in company with many others, my little family has moved our home many times and joined many new organizations in our new neighborhood, all without leave of any other person. Millions of Americans choose and change careers as they and they alone decide. Millions of us read in our newspapers this morning what free editors, free reporters, and free columnists wanted to tell us, not what some government official thought it was safe for us to know. Rarely do we stop to realize that it is the Constitution, enforced by an independent judiciary, that makes all that possible.

But, while every citizen owes a responsibility to uphold the Constitution by respecting the rights of every other citizen, the lawyer has a special responsibility. As workers in the vineyard of justice, persons who bear the ancient

to only some parts of the law and to some fact patterns, like the blind man who felt the elephant's leg and called the elephant a tree. But science cannot be the lodestar of the law, for our society would then be ruled by cold, despotic facts, and jurisprudence would become "jurisience." Sociology cannot be the lodestar of the law, for that can turn judges into unelected politicians, legislators, and social engineers, and can risk the legitimacy of social review. Nor can economics be our lodestar, for man does not live by bread alone, and to the economics theorist, the Constitution is economically inefficient. There is no economic efficiency in a synagogue or church that makes no products and pays no taxes. There is no economic efficiency in sending police to insure the people's right to assemble, or in quartering soldiers in barracks instead of in your houses, or in the sixth amendment's right to counsel, or in the seventh amendment's right to a jury.

To the scientist, the sociologist, and the economist, the law must say, "I will listen to you – and learn from you – but I will never surrender."

heart, and respect for the dignity and rights of every multi-faceted person with whom each of us shares this planet for such a little while. Those and other values are the moral circuitry, the warp and woof, the very *stuff* of the law in a free society. To bleach the law of its moral distinctions is to leave it nothing but naked force. To abandon the values of the centuries is to give up on this experiment in liberty we call America and fail the lawyer's duty to help the

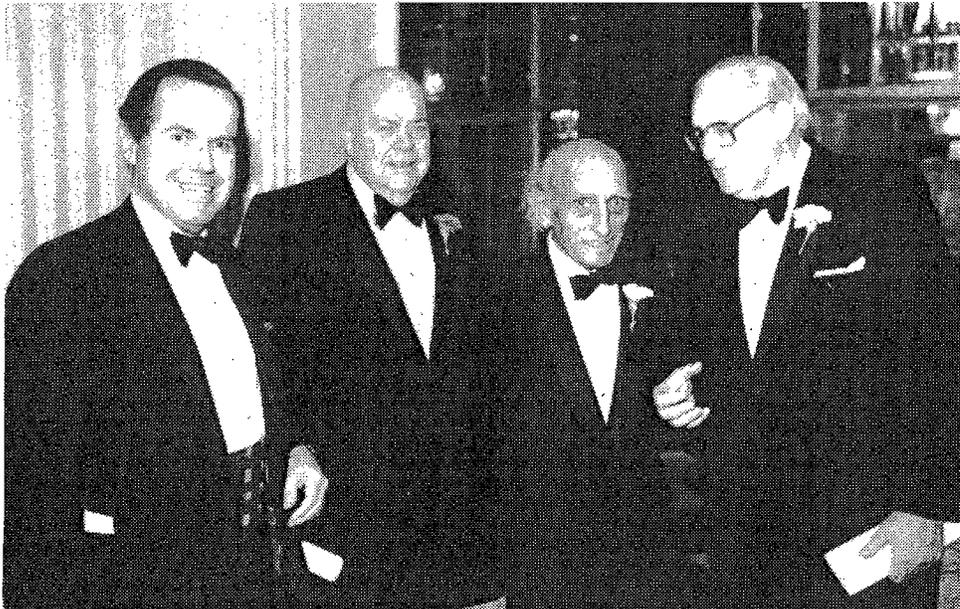
"To bleach the Law of its moral distinctions is to leave it nothing but naked force. To abandon the values of the centuries is to give up on this experiment in Liberty we call America and fail the lawyer's duty to help the people govern themselves."

people govern themselves.

What then, you say to me, should be the lodestar of our law? My answer may raise a few eyebrows. It will sound to some simplistic, to others subtle. To the pure pragmatist who does not value values, it will have a hollow ring of moral idealism. The answer deserves more than a few moments, but in a free society the lodestar of the law is Love.

A popular song of my youth was "Love Makes The World Go 'Round." No question that it does; the only question is "which way?" If wealth, power, and winning are the sole objects of our love, we move the world back into the caves. If our families, our free society, and the administration of justice be the objects of our love, we can help move our part of the world toward high, sunlit uplands of peace and harmony and we can really help our society govern itself.

By choosing love as the lodestar of the law, I mean that the law should steer by the star of love for the community. love for our free society, love for the principles of our Constitution, love for liberty, our own and everyone else's, love for our fellow citizens, whatever we may think of their actions, love for justice, for fairness in law fairly administered to all, love and respect for the law profession



Present and former judges and Association officers salute the evening.

title "lawyer," can do much to aid our people's effort to govern themselves. But to do that, the lawyer must, I put it to you, the lawyer *must* select a lodestar, a star to steer by.

Some legal scholars have built reputations on attempts to shoe-horn all law into a single theory, a lodestar, only to find that the theory is really applicable

In seeking the lodestar of our law, we must not learn the price of everything and the value of nothing. We must never forget the values that are no less real because unseen – values like mercy and compassion, justice, individual liberty, reverence for family and for the gift of life, the admiration for morality and ethics that resides deep in every human

Judge Markey's Speech, Continued

id the judicial process. I mean the love described in the Torah as the keeping of wisdom's laws. I mean what Chief Judge Re said one time: "I have never seen the administration of Justice. All I have ever seen is people." I mean what our forefathers meant when in the Declaration they pledged their lives, their fortunes, and their sacred honor "to each other" – not to a higher standard of living, or to the Gross National Product, or to any special interest or pressure group, or to science, sociology, or economics – they pledged their lives, their fortunes, and their sacred honor only and simply "to each other."

So I invite you to put more lovin' in your lawyerin'. When love is your lodestar, you will always be able to disagree without being disagreeable. You will no longer measure success only in dollars. You will abandon the "winning is the only thing" approach that treats law as a sport and causes so much abuse of the judicial process and lowered respect for lawyers. You won't find it so hard to avoid going beyond the limit lines of lawyering and the zenith of zeal. You will no longer engage in the legal lunacy we see in too many cases. When love is your lodestar of the law, you will become a blessed peacemaker who can help us reconcile our rights and soften our cutting edges by your devotion to the soothing, saving solace of settlement, and you can truly help us govern ourselves.

It all comes down to this: each of us has been handed a precious, gleaming jewel – the Constitution and all it represents – fought for and died for by many brave men and women before us. We hold it only a little while on this earth and must, someday, pass it on to those who come after us. As a judge, I am at liberty only to ask question, but I think it behooves us all to occasionally, while we enjoy the protection of the Constitution, what have we done to study and understand that jewel so that we might keep it intact and untarnished? To spread its rays to others? To protect it from devaluation, compromise, abuse, or even loss? To show by our actions our love for its principles? Have we ever even told our children about it? When we see a reference to human rights "granted" by the Constitution, do we point out that it grants *no* such rights – that it is based on the concept that people have rights and must be free to

exercise them *because* they are people? Are we in danger of allowing a cancer, a departure from the values on which the Constitution rests, to chip away at the soul of our freedoms? Do we think and act as if ours is a completed society, which has achieved its purposes, and which has no need of our love and no further great business to transact?

Each of us must answer for himself or herself – but answer we must – to history if to no other. Like war and generals, the Constitution is too important to leave to judges, so the answers must come from people as governors of this society, not from its judges.

But if enough of us are willing to study and know the Constitution and all it means – and then set out to sell it – to our friends and neighbors and children and grandchildren – to honor the rights

"Each of us must answer for himself or herself – but answer we must – to history if to no other. Like war and generals, the Constitution is too important to leave to judges, so the answers must come from people as governors of this society, not from its judges."

it recognizes as belonging to every person we meet – we may indeed preserve the heritage of those who fought at Yorktown to make our Constitution possible, and the heritage of those who fought and died in our wars to keep it. Indeed, we may savor something of what an American POW in Hanoi had in mind when, risking torture and death, he scrawled on the wall of his prison cell, "Freedom has a special taste for those who fought and almost died that the protected will never know."

I speak, of course, only for myself, but when my work is done and my time has run, it is my fervent fevered hope that my children and grandchildren, taking note of the words in the Preamble to the Constitution, might say of me, "He helped preserve for us the blessings of Liberty."

Senator Mathias Addresses Joint Meeting

Senator Charles Mathias addressed a recent joint meeting of the New Jersey Patent Law Association and the New York Patent, Trademark and Copyright Law Association. Senator Mathias noted the importance given intellectual property by the drafters of the 1777 Constitution as reflected in their protection of no rights other than those of authors and inventors. In Senator Mathias' opinion, the bicentennial of the Constitution presents an opportunity to educate the public and Congress in the area of intellectual property, an area which is important to national interests.

The recent history of Congressional action in the area of intellectual property and the growing attention to this field was then outlined by Senator Mathias. In 1976, Congress had dissolved the Patent, Trademark and Copyright Subcommittee only to revive it in 1983. By 1986 it had grown to be the largest subcommittee of the Judiciary Committee driven by issues based on new technology such as video-cassettes and an interest in enhancing protection of the American corporate position in interdependent world trade.

Legislative actions have included passage of the Semiconductor Chip Protection Act in 1984 and refusal to extend the manufacturing clause of the Copyright Act. The Electronic Communication Privacy Act was another legislative item originating in the subcommittee. Trade bills and process patent protection have both been considered in previous Congresses and in Senator Mathias' view are likely again to be addressed in this Congress.

Patent Term Restoration Act Discussed

by Henry J. Renk

In September, 1984 Congress passed the so-called Drug Price Competition and Patent Term Restoration Act. Title II of the act amended Section 271 of the patent laws by adding new subsection (e), which did two things. Clause (1) modified the Federal Circuit's decision in *Roche v. Bolar* so that the use of a patented substance in tests for submission to the FDA for approval to market a drug does *not* constitute an infringing act. Clause (2) created a new act of infringement; namely, the submission of either an Abbreviated New Drug Application (ANDA) or a so-called paper new drug application for a patented drug or whose use is patented, if the purpose is to obtain approval to commercially make, use or sell the drug before the expiration of the patent.

The 1984 Act

Under the generic drug approval provisions of the 1984 act, the Federal Food, Drug and Cosmetic Act was amended to generally extend the ANDA procedures used to approve generic versions of *pre*-1962 pioneer drugs to *post*-1962 pioneer drugs. Pursuant to the act, patent owners were required to submit information to the FDA regarding product and use patents that covered pioneer drugs. Based on that information, the 1984 Act required ANDA and paper ANDA applicants to make certain certifications in their applications in order to obtain FDA approval for their generic drugs. These requirements may present some unique questions in infringement litigation.

Patent Certifications by Applicant

The applicant must certify (1) that the required patent information has not been filed by the patent owner, or (2) that the patent has expired, or (3) the date on which the patent will expire, or (4) that the patent is invalid or will not be infringed by the manufacture, use of sale of the drug for which the application is submitted. In the event of the last certification, the applicant must inform the patent owner that the ANDA or paper NDA has been submitted to obtain approval to commercially manufacture, use or sell the drug in question before expiration of the patent referred to, thus making the submission an act of infringement under 35 U.S.C. Section 271(e)(2). The notice must also include a "detailed statement of the factual and legal basis of the applicant's

opinion that the patent is not valid or will not be infringed." There are no guidelines or requirements in the statute as to what constitutes a *detailed* factual and legal statement.

Approval

Focusing specifically on the patent certifications only, the effective date of FDA approval is the last to occur of these three events: first, where the applicant certifies only that no patent information was filed or that the patent has expired, approval may be made effective immediately; second, where the applicant certifies the expiration date of the patent, approval may be made effective on that date, or third, where the applicant certifies patent invalidity or non-infringement, approval may be made effective immediately *unless* a patent infringement action is brought with 45 days of the patent owner's receipt of the required notice in which event, approval is effective 30 months after the notice is received. This 30-month period was designed to allow the patent infringement litigation to proceed and presumably conclude.

Conduct of Infringement Action

The 45-day period has been criticized as too short and as the "legal equivalent of immediately" [Ryan, *Food Drug & Cosmetic Law Journal*, 40 at 346 (1985)]. It may also be argued that under the 1984 act, a generic drug manufacturer can force infringement litigation – and quickly – on an unwilling patent owner, unlike the Declaratory Judgment act which requires at least some minimum acts by the patent owner to enforce its patent.

The statute requires the parties to such an infringement action to "reasonably cooperate in expediting the action" although it is otherwise silent on what "reasonable cooperation" constitutes. Moreover, instead of the 30 month period during the pendency of such an action, the court may order a shorter or longer period because either party to the action failed to reasonably cooperate in expediting it. Of course, there are exceptions to the 30 month period if, before that time: (1) the court decides the patent is invalid or not infringed, then the approval is effective on the date of that decision; (2) the court decides the patent has been infringed, then the approval is effective no earlier than the expiration date of the patent, or

(3) the court grants a preliminary injunction pending decision of the issues of patent validity and infringement and if the court finds the patent invalid or not infringed, then the approval is effective on the date of that decision.

During the 45-day period the patent owner has to bring an infringement action, the statute specifies that "no [Declaratory Judgment] action may be brought with respect to the patent" and further that any such action shall be brought in the district where the defendant has its principal place of business or a regular and established place of business. This is more limited than the venue normally available to a declaratory judgment plaintiff.

The Food, Drug and Cosmetic Act does not otherwise regulate the conduct of such an infringement action but the 1984 amendments to the patent act, codified at Section 271(e)(4), limit the remedies available to the patent owner for such infringement. These remedies are the *only* remedies which a court may grant for the infringement *except* that attorney fees may be awarded under Section 285.

Cases

There have been no reported decisions of infringement actions filed under Section 271 (e)(2) based on submission of an ANDA or paper ANDA. However, in the August 1986 decision of *Scripps Clinic v. Genentech*, 2312 U.S.P.Q. 978 the Northern District of California noted that the 1984 act to which Section 271 (e)(2) relates "establishes a mechanism for expediting claims by a generic manufacturer that a drug patent is not infringed," referring to the 45-day period for the patent owner to file suit following notice of an ANDA.

The Future

It seems reasonable to expect that generic drug manufacturers will use the procedures of the 1984 act to force pioneer drug companies to litigate their patents. In the course of these litigations, given the inventiveness of trial lawyers, I would expect that some of the more unique provisions of the 1984 act will be hotly contested. By "unique," I mean only by comparison to normal patent infringement litigation where these requirements do not exist. For example, just how "detailed" a statement must the generic drug manufacturer provide in its

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Recent Decisions Of Interest

by Thomas O'Rourke

Patentability - Animal Life Forms Held Patentable

The Patent Office Board of Patent Appeals and Interferences has recently held that claims to oysters are patentable subject matter. In *Ex parte Allen*, 33 B.N.A.P.T.C.J. 638 (P.O.B.P.A.I., April 16, 1987) the product by process claims to polyploid Pacific oysters were rejected by the Examiner on the ground, *inter alia*, that they contain nonstatutory subject matter. According to the Examiner, "polyploid oysters are held to be living entities and do not fall within the statutory subject matter of 35 U.S.C. § 101." The Examiner also argued that the animal produced by the method claimed is "controlled by laws of nature and not a manufacture by man that is patentable."

The Board refused to sustain the rejection relying on *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), where the Supreme Court noted that § 101's use of "any" in connection with "manufacture" and composition of matter":

plainly contemplated that the patent laws be given wide scope. 447 U.S. at 306.

The board in *Allen* held:

The examiner's position that the claimed polyploid oysters are 'held to be living entities' is not controlling on the question of whether the claims are drawn to patentable subject matter under 35 U.S.C. 101 because the Supreme Court made it clear in its decision in *Diamond v. Chakrabarty*, *supra*, that Section 101 includes man-made life forms. The issue in our view, in determining whether the claimed subject matter is patentable under Section 101 is simply whether that subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable subject matter under Section 101.

The Board accordingly reversed the Examiner on the § 101 rejection but affirmed the rejection under § 103.

Trademarks - Reverse Confusion and Dilution

A small Ohio corporation that reclaims industrial oils, Ameritech, sued the holding company of five Bell telephone companies, American Information Technologies Corp., for infringement of the AMERITECH trademark in *Ameritech Inc. v. American Information Technologies Corp.*, 33 B.N.A.P.T.C.J. 429 (6th Cir., March 5, 1987).

In 1983 when the defendant announced its intent to use the trade name AMERITECH in an advertisement taken in the *Cleveland Plain Dealer*, plaintiff wrote to the newspaper complaining about the use of the name and possible customer confusion. An article appeared in the paper shortly thereafter on the parties overlapping use of AMERITECH and mentioned the potential for customer confusion.

The district court granted defendant's motion for summary judgment on the ground there was no likelihood of confusion. The Sixth Circuit reversed because the district court did not evaluate plaintiff's reverse confusion and dilution claims. The Sixth Circuit held that while a plaintiff must have a distinctive mark in order to succeed on a dilution claim, the mark need not be nationally famous. A mark that is strong in a particular geographical or product area also deserves protection according to the Court.

As to the reverse confusion claim the Court held that the district court should have considered plaintiff's claim of reverse confusion as "the senior user's interests in the trademark can be suffocated by the junior user who takes the trademark as his own and consumers can be confused that the senior user's products come from the junior user or that the senior user has become associated with the junior." The Court of Appeals concluded:

In this era of corporate diversification, and on this record which shows defendant intends to expand into other high-technology markets we cannot say the ordinary prudent consumer would not assume defendant brought plaintiff as a subsidiary and is sponsoring plaintiff's product. 33 B.N.A.P.T.C.J. at 430.

On Sale Bar - Reduction to Practice is Not Always A Prerequisite

On July, 1967 U.M.C. Electronics offered to supply the Navy with an improved aviation counting accelerometer (ACA) in response to a request for solicitation of proposals. In response to a Navy inquiry, on August 2, 1967 after the critical date UMC submitted a technical proposal which described the improved ACA in detail and included test results and schematic drawings. The patent application was filed on August 1, 1968. The Navy later cancelled the

request to which the submission was directed and awarded the contract to a third party.

The Court of Claims upheld the validity of the patent in suit and rejected the government's "on sale" argument, relying on *Timely Products Corp. v. Aaron*, 523 F. 2d 288 (2d Cir. 1975) which required that in order for there to be an "on sale" bar there must not only be conception of the invention but also a right to practice.

On appeal in *U.M.C. Electronics Co. v. U.S.*, 33 B.N.A.P.T.C.J. 661 (C.A.F.C. April 23, 1987) the government argued that "substantial attempted commercial exploitation of the claimed invention contravenes the policies of the 'on sale' bar despite the absence of a complete embodiment and thus raises the 'on sale' bar." U.M.C. contended that unless the claimed invention had been reduced to practice before the critical date there is no "on sale" bar as a matter of law.

In reversing the Court of Claims, the C.A.F.C. held that "reduction to practice of the claimed invention has not been and should not be made an absolute requirement of the on sale bar." The Court went on to state:

All of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention must be considered and weighed against the policies underlying § 102 (b).

The C.A.F.C. in reviewing the facts held that the patent in suit was invalid because of prior sale. The Court based its conclusion on the fact that much of the invention was embodied in a tangible form and that the sole feature of the invention that was not taught by the prior art had been sufficiently tested to demonstrate to the inventor's satisfaction that the invention would work for its intended purpose.

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Drug Price Competition and Patent Term Restoration, Con't.

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required notice to the patent owner? What constitutes "reasonable cooperation" in expediting the infringement action and what "shorter or longer" periods of time for ANDA approval will the courts order for failure of a party to cooperate? Once the 30-month period expires, even though the infringement action is not concluded, the 1984 act on its face nevertheless appears to require approval of the ANDA. However, a patent owner who ultimately prevails in the infringement action presumably would be entitled to damages for the post-approval infringing sales of the generic drug. The question of an injunction at that point may then involve the fact that the generic drug maker has already been on the commercial market.

In addition, what can the FDA properly do regarding the effective date of approval of an ANDA where the applicant has prevailed in the trial court but the patent owner has appealed that adverse decision prior to the expiration of the 30-month approval period? A 1986 law review article [*Catholic University Law Review*, Vol. 35 at 460 n. 138] and other commentators [Hutt, *Legal Times*, September 24, 1984 at 8] assert that once an ANDA applicant secures a favorable trial court judgment, the FDA must make an approved ANDA effective since the 1984 act does not extend the approval period to the full 30 months if the trial court judgment is appealed. I do not read the act as requiring this result inasmuch as one reason for lengthening the approval period from 18 to 30 months was so that the litigation will be concluded before the generic drug maker begins marketing.

It remains to be seen whether and to what extent the congressional intent in passing the 1984 act will be fulfilled or whether most clarifications will come by way of court decisions or congressional action. It appears to me that the full impact of the act, hailed as the most important drug legislation since 1962, will not be quickly apparent.

President's Corner ~

(continued from page 1)

Dave Kane and John Pegram at WIPO sessions in Geneva on Anti-Counterfeiting and Trademark Cooperation Treaties.

As I mentioned in my first "President's Corner" in the November 1986 issue, the Committees are the backbone of our Association and I would like to express the Associations gratitude as well as my own to them and their chairpersons for the meetings held and the efforts made which, no doubt, will be reflected in their final reports now being submitted. We owe a great debt of gratitude to Dave Kane, Dale Carlson/Jim Foster, and Bill Dippert for the admirable jobs they and their committees did in organizing the "Judges Dinner," CLE Weekend Seminar and the series of luncheon meetings, respectively.

Let me also convey special thanks to our hard-working Secretary, Peter Saxon, and Treasurer, Mary-Ellen Timbers, and the other officers and all Board members for having kept us on an "even keel" administratively, financially and otherwise.

Karl F. Jorda
President

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