



OCPLA NEWSLETTER

Orange County Patent Law Association
www.ocpla.org

Vol. 11, No. 6

June 2005

JUNE LUNCHEON MEETING

Please join us at our next luncheon meeting on Wednesday, June 22, 2005, when we are pleased to present **Scott L. Whiteleather** of Whiteleather & Associates, who will speak on "One Tiger, Two Robots & Three Stooges: Recent Right of Publicity Expansions and Limitation"

The lunch will be held at noon at the Wyndham Garden Hotel.

JULY BOARD MEETING

On June 29, 2005 the OCPLA Board of Directors is holding its monthly meeting at noon at the offices of Klein O'neill & Singh, LLP, in Irvine. Members who wish to present items for the Board's consideration should contact our president, Margaret Kivinski, to have their item placed on the agenda, and to verify the time and location of the meeting.

MARK YOUR CALENDARS . . .

June 22, 2005	One Tiger, Two Robots & Three Stooges: Recent Right of Publicity Expansions and Limitation
July 27, 2005	Inequitable Conduct: How to Lose Your Patent Rights

E-MAIL DISTRIBUTION OF THE NEWSLETTER



The Newsletter is now being transmitted solely by electronic mail. If you know of anyone who should be, but is not getting this e-mail distribution, please have them

contact Neal Cohen at nmc@cohen-sak.com.

MESSAGE FROM THE PRESIDENT

BY MARGARET KIVINSKI
THEROX, INC.
mkivinski@therox.com



At our May meeting we heard from Bill Thompson, joined by Wei-ning Yang, both of Hogan and Hartson's Los Angeles office, regarding actions before the International Trade Commission (ITC) and their experiences during the highly publicized Energizer battery ITC patent dispute. As we learned, Bill and Wei-ning represented nine of twenty eight Chinese battery makers against whom Energizer filed a complaint and asked the trade panel to bar the Chinese battery makers from importing and selling various batteries in the U.S. Bill and Wei-ning were faced with a number of challenges, including co-defendants settling on the eve of the proceedings and the sudden loss of key witnesses. Despite the challenges, they were successful in defending Energizer's complaint, ultimately obtaining a decision of invalidity of Energizer's patent on a rarely used indefiniteness ground. The presentation materials include an overview of Section 337 Proceedings, key differences between Section 337 Investigations and federal court litigation, strategic considerations (for the offense or defense), as well as some interesting facts and statistics relating to the ITC. If you were unable to join us, but would like to receive a copy of the materials, e-mail me at mkivinski@therox.com.

In June, we will have a presentation by Scott Whiteleather, of Whiteleather & Associates, on recent rights of publicity issues. His presentation, entitled "One Princess, Two Robots & Three Stooges," promises to be both informative and entertaining. Mr. Whiteleather will discuss the most current cases involving the right of publicity including the Wendt, Hoffman, Comedy Three and Toney cases.

He will also address issues of copyright and trademark as they relate to this ever-changing area of law. I hope you will be able to join us.

RSVP ON TIME FOR MONTHLY LUNCHES

To reduce the likelihood of additional rate increases associated with last minute reservations, and attendance without advance reservations, we encourage you to RSVP early, i.e., no later than by noon on the Friday preceding the meeting, so that we can provide more accurate numbers of luncheon attendees to the hotel. Your efforts to register at least five days in advance of the lunches will be greatly appreciated, both by the hotel and the OCPLA Board of Directors.

As a reminder, the costs for the monthly luncheon meetings for student members is \$15.

2005 MEMBERSHIP RENEWAL

Dues for 2005 will remain at \$35 for attorneys and agents and entitle you to receive the monthly OCPLA newsletter, frequent announcements, and reduced rates for the monthly luncheons and seminars. A membership form is included in this month's newsletter and is also available on our website, at www.ocpla.org. Please renew early to reduce delays in processing your application.

NEW MEMBERS

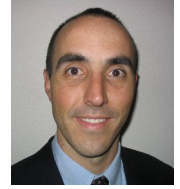
There are no new members to announce this month. Please encourage your friends and colleagues to join OCPLA!

OCPLA WEBSITE

Check the OCPLA website at www.ocpla.org for copies of the OCPLA newsletter, for membership information and for current events of interest to members. Let us have your comments. We will be making changes and improvements as time passes, and your comments will be useful in knowing what to change and what to leave alone. Send comments to "webmaster@ocpla.org."

PTO UPDATE

BY GREG S. HOLLRIGEL
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Beginning July 1, 2005, the USPTO is implementing certain fee changes related to the fee changes that were enacted on December 8, 2004.

Under the final rule, any application filed under 35 U.S.C. 111(a) that fails to include the basic filing fee, the search fee, or the examination fee will require a surcharge when any of these fees are paid after the filing date of the application. Similarly, a surcharge will be required if the search fee and/or the examination fee is paid after the national stage commencement date of an international PCT application.

The USPTO is also eliminating the process and retention fee practice under 37 CFR 1.21(l). Under the final rule, the USPTO is requiring the basic filing fee to retain a patent application, which may be used as a basis under 35 U.S.C. 120 and 37 CFR 1.78(a).

Changes are also being made to 37 CFR 1.52(f)(1) and (f)(2) regarding the way the USPTO calculates application size fees for applications that are filed in whole or in part in an electronic medium. For an ASCII text document containing 30 lines of text with about 50-65 characters per line, each three kilobytes of content will be counted as a sheet of paper. For applications filed using the electronic filing system, the paper size equivalent of the specification and drawings will be considered to be seventy-five percent of the number of sheets of paper present in the specification and drawings of the application when entered into the USPTO's file wrapper.

MINUTIAE

BY NEAL M. COHEN
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**Trademark File Wrappers**

What do you call the documents that make up the correspondence file in a trademark application? Well, I call them file wrappers. Some people laugh at me, but I'm not alone (in calling them file wrappers). Anyway, just to remind all trademark practitioners, there is a "View Documents" link from the main USPTO web page under Trademarks. That link allows viewing of the trademark file wrappers. So in case you're missing an Office action, or would like to see a competitor's Office action, help yourself.

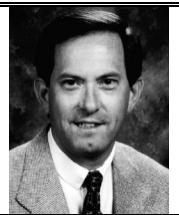
Patent Act 2005

On June 8, 2005, Congressman Lamar Smith (R-Texas) introduced the Patent Reform Act of 2005. As of now, Google is probably the best first source to try to locate a copy of the Act as introduced.

Please e-mail any questions, comments, or submissions for future Minutiae columns, to Neal M. Cohen, at nmc@cohen-sak.com. (Note: all submissions must be approved by the Editor prior to publication).

RECENT INTERESTING IP CASES

BY LEONARD R. SVENSSON
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BIRCH, LLP
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1. Supreme Court Determines That "Safe Harbor" of §271(e)(1) for FDA Approval May Be Broader Than You Expected

Merck KGAA v. Integra Life Sciences I, Ltd., et al., 545 U.S. ____; Slip Opinion Case No. 03-1237 (2005)

Issue: Is the safe harbor exemption from infringement of 35 U.S.C. §271(e) broad enough to cover pre-clinical studies related to a drug's efficacy, mechanism of action, pharmacokinetics, and pharmacology?

Answer: Yes.

Facts: Integra owns several patents ("the RGD patents"), all of which are related to a tri-peptide segment of fibronectin having the sequence Arg-Gly-Asp ("the "RGD peptide"). The RGD peptide is involved with cell adhesion in the body by interacting with $\alpha_v\beta_3$ integrins. It had been speculated that inducing better cell adhesion and growth may promote wound healing and biocompatibility of prosthetic devices. On the other hand, inhibiting the interaction of RGD peptide with $\alpha_v\beta_3$ integrins has been shown to inhibit angiogenesis and possibly inhibit tumor growth. Merck entered an agreement with Scripps to identify potential drug candidates that might inhibit angiogenesis and to fund the "necessary experiments to satisfy the biological bases and regulatory (FDA) requirements for the implementation of clinical trials" with one particular compound "EMD 66203" or a derivative thereof. Scripps scientists conducted several experiments "to evaluate the specificity, efficacy, and toxicity of EMD 66203, 85189 and 121974 for various diseases, to explain the mechanism by which these drug candidates work, and to determine which candidates were effective and safe enough to warrant testing in humans." Integra sued Defendants Merck and Scripps for infringement of the RGD patents for the work done in identifying and screening candidate compounds for clinical trials.

At trial, Merck urged that that the work by Scripps scientists with the RGD peptide fell under the common-law research exemption and the safe harbor afforded by 35 U.S.C. §271(e)(1). When the case was submitted to the jury, the following instruction was submitted on the §271(e)(1) exemption:

"To prevail on this defense, [Merck] must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [Merck's] and Scripps' situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question.

“Each of the accused activities must be evaluated separately to determine whether the exemption applies.

“[Merck] does not need to show that the information gathered from a particular activity was actually submitted to the FDA.”

The jury found that Defendants were liable for infringement and awarded damages. The District Court denied Merck’s post-trial motion for judgment as a matter of law, explaining that “any connection between the infringing Scripps experiments and FDA review was insufficiently direct to qualify for the [§271(e)(1) exemption].”

On appeal, Court of Appeals for the Federal Circuit affirmed in part, and reversed in part, affirming the denial of judgment as a matter of law to petitioner, on the ground that §271(e)(1)’s safe harbor did not apply because “the Scripps work sponsored by [petitioner] was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds.” 331 F. 3d, 860, 866 (Fed. Cir. 2003). It reversed the District Court’s refusal to modify the damages award, and remanded for further proceedings.

The Supreme Court granted certiorari to review the Court of Appeals’ construction of §271(e)(1).

Holding: The Supreme Court held that “the use of patented compounds in preclinical studies is protected under §271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce ‘the types of information that are relevant to an IND or NDA.’” Slip Op. at 14 (citing Brief of United States as *Amicus Curiae* 23).

Reasoning: Looking first at the statutory language, the Court found that the language of 35 U.S.C. sec. 271(e) “provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.” *Id.* at 8. The Court explained “[t]his necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the

basis of the phase of research in which it is developed or the particular submission in which it could be included.” *Id.* at 8-9.

Integra (the Patentee) had urged that activities such as preclinical studies related to a drug’s efficacy, mechanism of action, pharmacokinetics, and pharmacology were not reasonably included in an IND or an NDA, and therefore should be considered outside the scope of the exemption. But the Court looked at the FDA regulations and noted that the “FDA requires that applicants include in an IND summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals.” *Id.* at 9.

The Federal Circuit had explained its position by concluding that the statutory exemption “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.” 331 F. 3d at 867. But the Supreme Court criticized that reasoning, explaining:

“Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not “reasonably related to the development and submission of information” to the FDA. It does not follow from this, however, that §271(e)(1)’s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.” Slip Op. at 12.

The Supreme Court went on to explain its broader reading of the statutory exemption as follows:

“Congress did not limit §271(e)(1)’s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create

an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug. Rather, it exempted from infringement *all* uses of patented compounds “reasonably related” to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs. (citation omitted) We decline to read the “reasonable relation” requirement so narrowly as to render §271(e)(1)’s stated protection of activities leading to FDA approval for all drugs illusory. Properly construed, §271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drug maker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is “reasonably related” to the “development and submission of information under . . . Federal law.” §271(e)(1).

For similar reasons, the use of a patented compound in experiments that are not themselves included in a “submission of information” to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the “development and submission of information” to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA.”

Conclusion and Disposition of the Case:

As a result of its reading of the statutory language, the Supreme Court found “that the use of patented compounds in preclinical studies is protected under §271(e)(1) at least as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the

experiments will produce the types of information relevant to an IND or NDA.”

Since, in the Supreme Court’s opinion, the evidence had not yet been reviewed by the Appeals Court under the standard’s set forth in the jury instructions (which the court found proper with its construction of the statute), the case was remanded to the Court of Appeals.

2. “Consisting Of” Does Not Exclude Irrelevant Components

Norian Corp. v. Stryker Corp., 363 F.3d 1321, 70 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. Apr. 6, 2004)

Issue: Does the transitional phrase “consisting of” always exclude any additional element, step, or ingredient not specified in the claim?

Answer: No.

Facts: U.S. Patent No. 6,002,065 (the ‘065 patent, to Norian) used “consisting of” language to claim the chemical components (calcium source and phosphoric acid source) of a bone repair kit, where the claim only claimed the chemicals and no other components of the kit. The defendant (Stryker) marketed a bone repair kit that not only included the chemicals claimed in the ‘065 patent, but also included a spatula and a set of instructions. Norian sued Stryker for infringement of the ‘065 patent, and Stryker made a motion for summary judgment of non-infringement. The district court granted Stryker’s motion, holding that because Stryker’s bone repair kit contained a spatula, and Norian’s ‘065 claims did not recite a spatula, the claims could not be infringed as a matter of law.

There was no dispute that Stryker’s bone repair kit contained all of the chemical components claimed in the ‘065 patent. However, Stryker took the position that the “consisting of” transitional language of the claim excluded a kit that had any other component, such as a spatula. Norian held the view that while “consisting of” limits the claimed invention, this transitional phrase does not limit aspects unrelated to the invention. Accordingly, Norian appealed.

Reasoning: “Consisting of”

... limits the kit to the claimed chemicals and no other chemicals; that is, the kit "consists of" only the chemicals described as contained in the kit... The invention is a kit containing specified chemicals and the claims are explicitly limited in that no other chemical can be included in the composition.

However, the CAFC reasoned that

[w]hile the term "consisting of" permits no other chemicals in the kit, a spatula is not part of the invention that is described.
...

It is undisputed that the ... kit contains the same chemicals as set forth in claims 8-10 of the '065 patent. Infringement is not avoided by the presence of a spatula, for the spatula has no interaction with the chemicals, and is irrelevant to the invention.

Conclusion: The summary judgment is reversed and the case is remanded for further proceedings. Infringement of a claim using the transitional phrase "consisting of" may not be avoided by the presence of an additional element which is irrelevant to the invention.

3. Patentee Not Required to Establish Experimental Use by "Clear and Convincing Evidence"

Lisle Corp. v. A.J. Mfg. Co., 398 F.3d 1306, 73 U.S.P.Q.2d (BNA) 1891 (Fed. Cir. Feb. 11, 2005)

Issue: When attempting to rebut a *prima facie* showing of public use, must the patentee prove that the prior use was merely "experimental" by clear and convincing evidence? **Answer:** No.

Facts: Lisle Corp. ("Lisle") owns U.S. Patent No. 5,287,776 ("the '776 patent"), directed to a tool for facilitating servicing tie rods in an automobile. In a patent infringement suit brought against A.J. Manufacturing Co. ("A.J."), the district court granted summary judgment of infringement of the '776 patent and

denied A.J.'s motion for judgment as a matter of law (JMOL) after the jury declined to find the '776 patent invalid based on prior public use of the claimed invention. A.J. appealed.

Argument/Reasoning: A.J. contends that the trial judge committed legal error because the jury instruction on the issue of public use failed to require that Lisle prove that the prior use was merely experimental by "convincing" evidence.

The CAFC disagreed that the jury instruction on public use constituted reversible error, emphasizing that the party challenging patent validity bears the burden of proving invalidity by clear and convincing evidence. When such a party has presented evidence establishing a *prima facie* case of public use, the patentee may preserve validity by submitting rebuttal evidence of experimental use that is sufficient to prevent the challenging party from satisfying its "clear and convincing" burden. Although relevant precedent has stated that the patentee's rebuttal evidence must be "convincing," this is not comparable to the "clear and convincing" evidentiary burden imposed on the party asserting invalidity.

In this case, although Lisle provided prototype tools to four different automobile repair shops without a formal confidentiality agreement in place, Lisle presented inventor testimony stating that company protocol was followed to contact the mechanics to receive testing feedback and to modify the tool design based on these comments. The inventor further testified that although there was no formal confidentiality agreement, Lisle had prior working relationships with those mechanics, and that the mechanics knew that the prototype tool was given to them for experimental purposes. Based on this evidence, a reasonable jury could have found that the prior use was experimental, thereby negating the *prima facie* showing of an invalidating public use. Specifying "convincing" evidence in the jury instruction may have created confusion with respect to the "clear and convincing" evidentiary standard, and the trial judge's failure to require "convincing" evidence in the jury instruction on public use was not prejudicial.

Conclusion: The Court of Appeals affirmed the district court's decision and found that the evidence presented by Lisle was sufficient to rebut a *prima facie* case of public use.

OCPLA POLICY

Although we are open to comments and suggestions, present policy concerning publication of advertisements in this newsletter is as follows: (1) "Positions Wanted," "Positions Available," and other similar ads will be printed free of charge and, unless otherwise requested, will run for two months; (2) Other ads such as word processing, legal support services, and firm announcements will be published for \$15 per issue or \$150 per year (for all 12 issues), payable in advance. We reserve the right to edit each advertisement. Please contact the Newsletter editor to place your ad or with your comments and suggestions.

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OCPLA NEWSLETTER

Orange County Patent Law Association

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The OCPLA reserves the right to determine which, if any, submitted articles will appear in this Newsletter.

We hope that the Newsletter is helpful, informative, entertaining and interesting. Comments, ideas, announcements, proposed articles, suggestions and any other communications concerning the content, form or other aspect of this newsletter may be directed to:

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Patent Associate: Ideal candidate has 1-3 years patent prosecution experience, high academic credentials. Duties include primarily patent prosecution, and would also include trademark prosecution, and litigation support.

Experienced Patent Legal Assistant: Ideal candidate has 5+ years experience as legal assistant for patent attorneys, knowledge of U.S. and foreign prosecution, federal court litigation, and is familiar with all aspects of PTO website, PAIR, docketing procedures, and Microsoft Word. Knowledge of trademark prosecution a plus. Duties include providing primary legal support for two partners, and part-time support for up to three other attorneys, all with permanent part-time assistance and support.

Please visit our website at www.cohen-sak.com for more information about our firm.

Send resume by mail only to:

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 Irvine, CA 92614

Short inquiries may be e-mailed to Neal Cohen at nmc@cohen-sak.com.

Ad: xzft0601NC4

Orange County Patent Law Association

June Meeting

Date: Wednesday, June 22, 2005

Time: 12:00 Noon; Lunch will be served promptly at 12:15 p.m.

Location: Wyndham Garden Hotel
3350 Avenue of the Arts
Costa Mesa, California

Topic: One Tiger, Two Robots & Three Stooges: Recent Right of Publicity Expansions and Limitation

Speakers: **Scott L. Whiteleather** of Whiteleather & Associates

Cost: \$30 for members, \$15 for students (proof of student status required), and \$35 for non-members

Reservations: Please make reservations by filling out the form below and mailing it with a check to T.J. Singh to reach his office address given below, by the Friday before the meeting. If time is short, please also email T.J. at tjsingh@koslaw.com or call in your reservation to the OCPLA Reservations Line number at (949) 955-1920.

The Orange County Patent Law Association certifies that this activity has been approved for minimum Continuing Legal Education credit by the State Bar Association of California in the amount of 1.0 hour. The Orange County Patent Law Association certifies that this activity conforms to the standards for approved education activities prescribed by the rules and regulations of the State Bar of California governing Minimum Continuing Legal Education. The Orange County Patent Law Association is a State Bar of California MCLE-approved provider.

Reservation Form

Enclosed is a check for \$_____ payable to ORANGE COUNTY PATENT LAW ASSOCIATION for the OCPLA General Membership luncheon on Wednesday, June 22, 2005 for the following person(s):

This form and check should be mailed to:

T.J. Singh
Attention: OCPLA Lunch Reservations
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Orange County Patent Law Association

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2005 MEMBERSHIP APPLICATION/RENEWAL FORM

This is an application for (please circle one): **Membership Renewal or New Membership**

Member / Applicant Information:

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Are you a member of the California bar?	___	___	Bar No. _____
Are you a member of the bar of another state or the District of Columbia?	___	___	Jurisdiction/Bar No. _____
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Please circle not more than TWO committees in which you would like to participate:

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Dues Membership Year 2005 (please circle one):

		(New Member After 07/01/05)
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New Applicants please complete the following:

I believe I qualify for membership in the Orange County Patent Law Association.

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Send Application to OCPLA P.O. Box 7632 Newport Beach, CA 92658

Two OCPLA member sponsors are required for new applicants. Two undersigned members hereby recommend the above-signed applicant for membership into the Orange County Patent Law Assn.

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2005 OCPLA EVENTS SCHEDULE

Date	Location	Speaker/Event	Topic
June 22, 2005	Wyndham Garden Hotel	Scott L. Whiteleather Whiteleather & Associates	One Tiger, Two Robots & Three Stooges: Recent Right of Publicity Expansions and Limitation.
July 27, 2005	Wyndham Garden Hotel	Frederic Douglas Klein, O'Neil & Singh	Inequitable Conduct: How to Lose Your Patent Rights



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