



# SDIPLA News

## UC Berkeley Center for Law & Technology

In 2008, the UC Berkeley Center for Law & Technology conducted the first comprehensive survey in the United States on patents and entrepreneurship. After six months of collecting data from nearly 1,500 startup and early-stage companies in the biotechnology, medical device, software, and hardware industries, the research team is now in the process of tabulating and analyzing the results.

Ted Sichelman--who is currently a research fellow at Berkeley and will start as a professor at University of San Diego School of Law this fall--will present some of the preliminary results at our next dinner meeting on Tuesday, May 12th. In particular, he will discuss patent filing, search, and licensing strategies; the perceived importance of patents relative to copyrights, trademarks, and other "barriers to entry"; the role of patents in financing, acquisition, and IPOs; and views on patent reform.

**Please join us on Tuesday, May 12, 2009  
at the *La Jolla Marriott***

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#### Date/Time/Location:

May 12, 2009  
6:30 p.m.—9:00 p.m.  
La Jolla Marriott  
4240 La Jolla Village Drive,  
La Jolla, CA 92037

#### Notes:

This is a TUESDAY dinner meeting.  
Valet Parking \$7  
Self Parking \$5

#### Directions:

North on I-5. Exit La Jolla Village Drive  
(Turn Right)  
Hotel is approximately 3/4 mile to east  
on left side.

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**UPCOMING EVENTS**

**May 12th:** La Jolla Marriott  
Prof. Sichelman of USD/UC Berkeley will discuss trends in IP protection

**June 11th:** La Jolla Hyatt  
J. Panetta, CEO of BIOCOM will discuss the Obama Administration's impact on Biotechnology  
plus annual elections

Online registration for these events will be available at: <http://www.acteva.com>

**June 12-14:** SPRING SEMINAR  
SDIPLA / LAIPLA  
Lake Arrowhead, CA

***Please Join Us For These Exciting Events***

The SDIPLA thanks our Sponsors for the monthly meetings:

**Knobbe Martens Olson & Bear LLP  
[www.kmob.com](http://www.kmob.com)**

**Perkins Coie LLP  
[www.perkinscoie.com](http://www.perkinscoie.com)**

**Townsend and Townsend and Crew LLP  
[www.townsend.com](http://www.townsend.com)**

(listed alphabetically)

# Reservation Form for May 12, 2009 Dinner Meeting

## Featuring Professor Sichelman from USD / UC Berkeley discussing the UC Berkeley Center for Law & Technology Survey Results

**Tuesday, May 12th  
Dinner Meeting**

**La Jolla Marriott**

Registration starts at 6:30 p.m.  
Cocktails at 6:30 p.m.  
Dinner starts at 7:00 p.m.  
Discussion at 7:30 p.m.

**The Menu**

Spinach and Arugula Salad

With one of the following entrees:

Herb-Crusted Bone-in Chicken

With Sage Roasted Mushrooms and Potatoes

**\*\* OR \*\***

Lime-Marinated Salmon

With Mango Relish, Almond Rice

**\*\* OR \*\***

Portobello Napoleon, Eggplant, Tri-colored Peppers

Served with buffalo mozzarella, tomatoes, potatoes

Chocolate Velvet Bombe

Coffee and Tea

Due to the large number of attendees expected at this event, the SDIPLA is again requesting **Pre-Registration and Pre-Payment**.

To reserve your place, please fill out the below registration, and send it **WITH YOUR CHECK MADE PAYABLE TO 'SDIPLA'** to:

John E. Peterson  
SDIPLA Secretary  
Perkins Coie, LLP  
1620 26th St., 6th Fl. South Tower  
Santa Monica, CA 90404  
(310) 788-3346  
Fax: (310) 788-1272  
JEPeterson@PerkinsCoie.com

On-line reservation available- go to [www.acteva.com](http://www.acteva.com) and search for SDIPLA or follow the link at [www.SDIPLA.org](http://www.SDIPLA.org)

**Please fill out a separate form for each attendee.**

### REMINDERS

- Please mail, fax, or e-mail your reservation to John Peterson at the address, fax, or e-mail address indicated for receipt **no later than May 10th, 2009**.
- The reservation deadline is dictated by the hotel and not by the SDIPLA.

### NOTE MEAL PRICES

SDIPLA members: \$55.00

nonmembers: \$65.00

## Registration

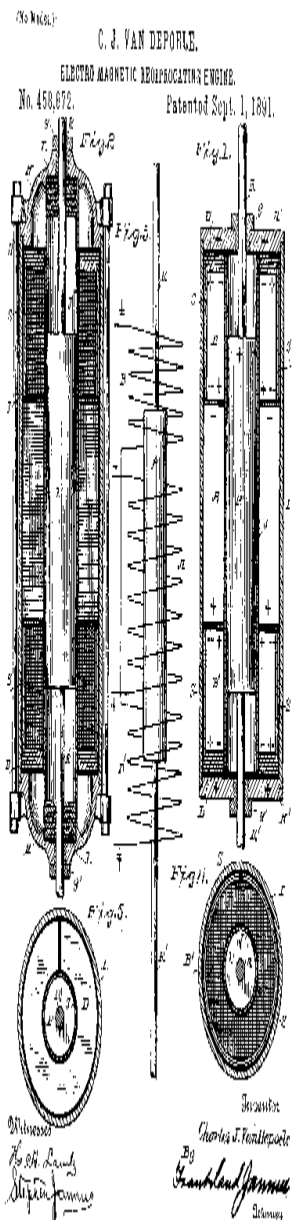
Name: \_\_\_\_\_ E-Mail Address: \_\_\_\_\_

Firm/Employer: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Member of SDIPLA? (circle one) YES NO

Entrée Choice: \_\_\_\_\_ Chicken \_\_\_\_\_ Salmon \_\_\_\_\_ Vegetarian



# CALL FOR NOMINATIONS

## SDIPLA 2009 BOARD ELECTION

- Active members of the SDIPLA who wish to run for Treasurer, please submit your nominations with statement of candidacy to John Peterson at [jepeter-son@perkinscoie.com](mailto:jepeter-son@perkinscoie.com).
- Nominations for Treasurer are due on or before May 22, 2009.
- Election for Treasurer will be held at the last dinner meeting, June 11, 2009.
- Proxy vote form will be available in the May 2009 newsletter.

***If you have an article, news bulletin, update, case summary, employment notice or other announcement that you would like to include in the SDIPLA Newsletter, please contact SDIPLA Secretary John E. Peterson at [John.E.Peterson.Ph.D@gmail.com](mailto:John.E.Peterson.Ph.D@gmail.com).***

## Wyeth v. Levine: Important Implications for Drug Manufacturers

04.02.2009

The recent Supreme Court decision in *Wyeth v. Levine* [1] has important implications for drug manufacturers. In a 6-3 decision, the Court held that the FDA's approval of drug warning labels for Wyeth's product, Phenergan, did not preempt state law failure-to-warn claims.

### Summary of the Case

Plaintiff Diana Levine was injected with Phenergan, an anti-nausea drug manufactured by Wyeth, while being treated for a migraine and accompanying nausea. The clinician injecting the Phenergan used the "IV-push" method, in which a drug is injected directly into a patient's vein. The drug entered an adjacent artery, and Levine developed gangrene, requiring amputation of her forearm.

After settling a malpractice suit against the health clinic and clinician, Levine brought a product liability claim in Vermont state court. She alleged that Wyeth had failed to provide an adequate warning about the significant risks of administering Phenergan by the IV-push method. The trial court rejected Wyeth's arguments that Levine's claims were preempted by federal law because Phenergan's labeling had been approved by the federal Food and Drug Administration (FDA). Following a five-day trial, the jury found that Wyeth was negligent and its product defective because of inadequate warnings and instructions. The court awarded Levine damages in the amount of \$7.4 million. The Vermont Supreme Court affirmed, and the U.S. Supreme Court accepted Wyeth's petition for certiorari.

In its brief to the Supreme Court, Wyeth made two preemption arguments: first, that the claims were preempted because it would have been impossible to do what the Vermont jury's verdict required—modify Phenergan's labeling—without violating federal law; and, second, that recognition of Levine's state tort action created an unacceptable obstacle to the accomplishment of the purposes and objectives of Congress in enacting the Food, Drug, and Cosmetic Act (FDCA).

The Court rejected Wyeth's first preemption argument—that Levine's state law claims were preempted because it was impossible for Wyeth to deviate from the wording of the Phenergan labeling that had been previously approved by the FDA. Specifically, Wyeth argued that a manufacturer may change a drug label only after the FDA has approved a supplemental application based on "newly acquired information." The Court rejected this construction of the law and pointed out that the FDA's "changes being effected" (CBE) regulation permits certain labeling changes that add or strengthen "a contraindication, warning, precaution, or adverse reaction" or "an instruction about dosage and administration that is intended to increase the safe use of the product." Under the CBE regulation, Wyeth could have unilaterally added a stronger warning about IV-push administration, and there was no evidence that the FDA would not have accepted such a change. The Court emphasized that a central

premise of the FDCA and federal drug regulations is that the manufacturer bears responsibility for the content of its label at all times.

The Court also rejected Wyeth's second argument—that requiring it to comply with a state law duty to provide a stronger warning would interfere with Congress's purpose of entrusting an expert agency with drug labeling decisions. In advancing this argument, Wyeth relied on the preamble to a 2006 FDA regulation governing drug labeling in which the agency had stated that FDA approval of labeling preempted contrary state law. The Court rejected these contentions based on several factors. First, Congress had never included an express preemption provision for drugs in the FDCA, despite numerous congressional amendments to the statute over decades in which it had to have been aware of product liability suits against drug manufacturers. This was in contrast to the inclusion in the FDCA of an express preemption provision for medical devices. Second, the FDA's 2006 regulatory preamble was not a regulation with the force of law. Third, the preamble reversed, without a reasoned justification, a longstanding agency policy that its labeling requirements provided minimum standards that would not preempt state tort actions.

### Implications

The Supreme Court decided *Levine* under a line of cases that have found certain state laws to be preempted because they conflict with federal law. Other preemption doctrines—express preemption and field preemption—are unaffected. In addition, the Court's reasoning was very specific to the regulatory history of drugs and will not be directly applicable to other federally regulated products.

Following *Levine*, drug manufacturers will face substantial obstacles in asserting implied preemption as a defense to state law failure-to-warn claims and may see an increase in state tort claims alleging inadequate drug labeling. However, the Supreme Court did not completely foreclose the possibility of a preemption defense to drug labeling failure-to-warn claims. The Court concluded its decision by recognizing that “some state-law claims might well frustrate the achievement of congressional objectives” and left open a possible preemption defense under different facts. The Court also made clear that it was not deciding whether a state court verdict could be based on a contention that a drug label should have contraindicated a use that had been approved by the FDA.

The Court pointed out that there was no regulation at issue in *Levine*, only the FDA's assertions in the preamble to the FDA regulation. Thus, where there is “an agency regulation with the force of law,” that regulation may still preempt conflicting state requirements. Additionally, the Court held that it was not clear from the FDA's consideration of the risks related to IV-push administration of Phenergan that the FDA would not have approved a change to the drug's label. This effectively puts the burden of disproving the possibility of such a hypothetical FDA approval on the manufacturer. It also means that where there is “clear evidence” that the agency with expertise on the issue at hand has had real oversight over the specific risk at issue, an implied preemption argument might still be successful. Even in such a case, the manu-

facturer will likely need to demonstrate that the FDA has considered and rejected a warning against the particular hazard complained of by an injured drug user. And it is now considerably less likely that these issues will be decided as a matter of law by a judge; instead, they will be submitted to juries.

*Levine* is already having an impact. For example, the plaintiff in *Longs v. Wyeth* [2] moved the court to vacate a judgment dismissing her claims on preemption grounds following *Levine*. The court denied the motion, however, and distinguished *Levine* on the grounds that (1) the action did not involve a failure-to-warn claim and (2) *Levine* focused on the manufacturer's actions *post-FDA* approval, which gave rise to different duties. Plaintiffs in *In re: Medtronic, Inc. Sprint Fidelis Lead Products Liability Litigation* [3] were recently granted leave to amend their complaint to plead claims consistent with *Levine*. A federal trial court has held that the reasoning of *Levine* also applies to generic drugs and declined to find preemption. [4] And the Supreme Court remanded two cases to the Third Circuit for reconsideration in light of *Levine*.

In light of *Levine*, drug manufacturers should strive to develop a clear record of the FDA's consideration of the specific risks associated with their products and the agency's decision making concerning the content of warnings. Manufacturers should also regularly reevaluate their labeling based on adverse events and, where appropriate, update labeling under the CBE regulations.

Authors: Christian Moller, James R. Lisbakken, Jeffrey J. Miller Ph.D., David J. Burman, Grant (Joe) Josiah Silvernale, III and David T. Biderman, all attorneys at Perkins Coie, LLP.

[1] No. 06-1249, slip op. (U.S. Mar. 4, 2009), available at <http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf>.

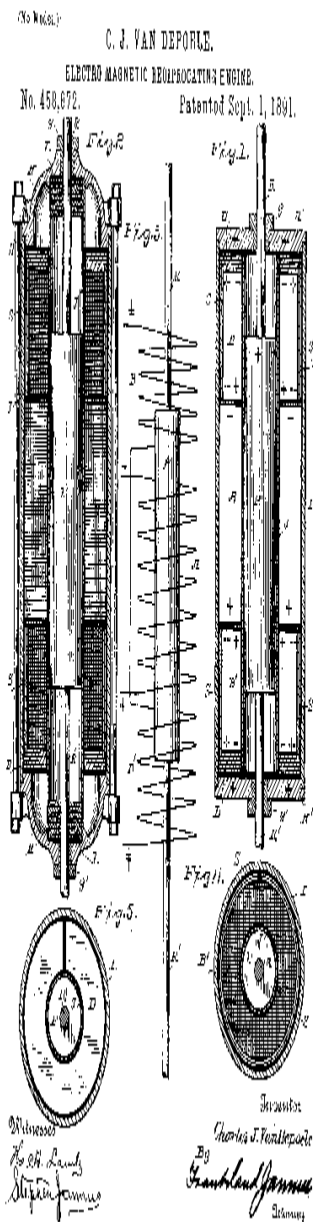
[2] Order, Case No. 1:03 CV 2042 (N.D. Ohio Mar. 20, 2009).

[3] MDL No. 08-1905-RHK-JSM (D. Minn. Mar. 9, 2009).

[4] *Stacel v. Teva Pharm., USA*, No. 08 C 1143, 2009 WL 703274 (N.D. Ill. Mar. 16, 2009).

***If you have an article, news bulletin, update, case summary, employment notice or other announcement that you would like to include in the SDIPLA Newsletter,***

***Please contact SDIPLA Secretary  
John E. Peterson at [John.E.Peterson.Ph.D@gmail.com](mailto:John.E.Peterson.Ph.D@gmail.com).***



## Internet Sightings column for April 2009

Heading - *Internet Sightings* by Jim Hawes

This column highlights some of the more notable recent internet notices, newsletters and blogs dealing with IP prosecution issues. It may be a distillation by the editor of the submitted IS column. The full IS column, with compilations of some of the sources such as Hal Wegner's newsletter, is now up and available at [www.internetsightings.com](http://www.internetsightings.com). Check it out.

**Hal Wegner's** newsletter – a lot of great stuff – Contact: [hwegner@foley.com](mailto:hwegner@foley.com)

The 3/3/09 newsletter discusses Hal's current top ten cases on appeal list. See also his emails on 3/5, 3/7, 3/8, 3/9, 3/11, 3/26, and 3/28. A second 3/3/09 email discusses the just introduced Conyer's Patent Reform Bill.

The 3/12/09 email reports the Natures Remedies CAFC decision in which a 102 rejection was affirmed based on prior art of limited availability submitted to Danish medicinal regulatory authorities. More info is given in the Pat-O posting for 3/13/09.

Another 3/12/09 email discusses the "flourishing" IP programs at four DC law schools.

The 3/18/09 email discusses the Larson CAFC decision and a request by one panel member for the court to resolve the inequitable conduct conflicting standards. See also Pat-O for 3/19/09 and 3/24/09.

The 3/20/09 newsletter reports the Tafas CAFC decision affirming the DCED Va. decision that the PTO lacked authority to implement new rules concerning continuation applns. etc. (but rules limiting claims are OK). See also the Pat-O posting on 3/20.

The 3/24/09 email reports the ClearValue CAFC decision nailing patent counsel for suppressing critical test results from the PTO. Another 3/24/09 offering discusses the Golden Hour CAFC decision holding a patent (found by a jury to be infringed) to be unenforceable due to withholding from the PTO a brochure describing prior art.

For those who like to watch sausage made, Hal's 3/25/09 email summarizes the various efforts in Congress to amend the patent laws.

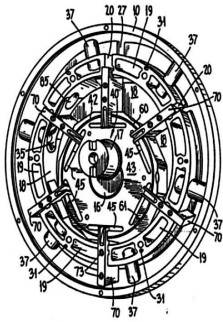


FIG. 2.



He predicts that a bill will be passed by August '09. The 3/26/09 email discusses the Clock Spring CAFC decision, 102(b) and experimental use (which Hal points out is not applicable most anywhere else in the world).

**Patently-O** – a blog written by Dennis Crouch – [www.patentlyo.com](http://www.patentlyo.com).

The 3/2/09 blog discusses nine BPAI February decisions based on sec. 101 and the Bilski decision.

The 3/4/09 email discusses the changes proposed in the various recently introduced patent reform bills.

Another 3/4 /09 email reprints the PTO's guidance memo to examiners re Bilski issues.

If you are considering an inter partes reexamination filing, you should check the 3/9/09 blog and the reference it cites.

Another 3/9/09 posting says that Prior Smart for a small fee will monitor and report activities in any patent file open to the public. If you are having PAIR problems, here's the answer.

The 3/10/09 email includes a thorough discussion of hot topics in US patent reexamination by Rob Sterne.

The 3/18/09 blog discusses the ICU Medical CAFC decision, focusing on the written description requirement.

The 3/19/09 posting discusses the Crown Pkg. CAFC decision, especially the gradual restriction of the doctrine of equivalents over recent decades, and the requirements for proper marking a patented article.

The 3/24/09 email reports that patent filings (and the PTO's budget?) are down 16% so far in 2009 (which the PTO later said was wrong).

If you would like to see how your fellow patent attys. respond to a client who thinks he's been overcharged for a simple mechanical pat. appln. check out Dennis' posting on 3/25/09.

The 3/26/09 posting presents an excellent memo to inventors about how to keep the cost of a patent application down. Check it out.

The 3/29/09 email notes that improper revival of an application may be on its way to becoming a defense to patent infringement.

**Carl Oppedahl** – emails of IP practice matters: [carl@oppedahl.com](mailto:carl@oppedahl.com).

The 3/16/09 email reports that there is a new PCT forms manager available from WIPO.

The 3/29/09 posting notes that various countries change from and to

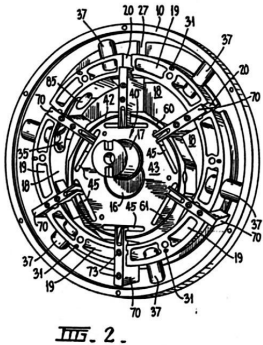


FIG. 2.



daylight savings time on different dates, so time differences between countries will change while this is happening.

**IP law 360** – a newsletter covering all IP, but focusing mainly on litigation – web address: [www.iplaw360.com](http://www.iplaw360.com)

The 3/10/09 newsletter opines that patent portfolios can pull companies out of a “financial rut” if used effectively.

The 3/11/09 email relays a WIPO report that 2008 was a record year for trademark application filings.

The 3/12/09 issue reports that the EU’s trademark office is flush with cash, and expects to reduce fees by 40% shortly.

**Daily Dose of IP** – a grab-bag of various IP matters by Mark Reichel – [www.dailydoseofip.com](http://www.dailydoseofip.com).

The 3/3/09 dose reports that the PTO is again seeking nominees for the National Medal of Technology. See the PTO website for forms etc.

The 3/5/09 dose reports that the EPO has announced various changes in its electronic filing procedures. For more info, check the EPO website.

The 3/18/09 bag reports that the PTO has received “a significant number” of int’l. applns. that chose an ISA not competent to review the claimed invention – eg a business method (EPO and IP Aust. won’t search such claims).

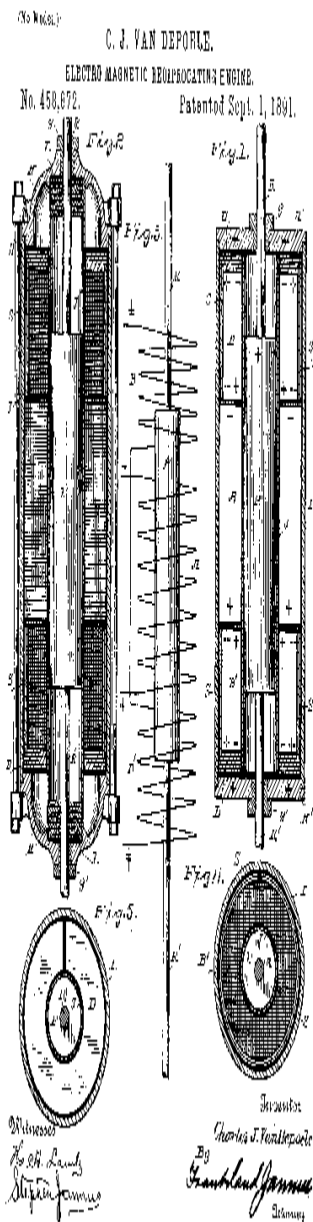
**Cal Bar IP Section** – alerts when appropriate – [www.calbar.org/ipsection](http://www.calbar.org/ipsection)

The 3/6/09 eBulletin of the IP section discusses the proposed Patent Reform Act of 2009, and invites comments.

**AIPLA Direct** – a newsletter issued from time to time [http://www.aipla.org/Content/ContentGroups/About\\_AIPLA1/AIPLA\\_Reports/AIPLA\\_Reports\\_TOC.htm](http://www.aipla.org/Content/ContentGroups/About_AIPLA1/AIPLA_Reports/AIPLA_Reports_TOC.htm)

A reminder – the Association’s Spring Meeting this year will occur in San Diego at the Hotel Coronado on May 13-15. Sign up now.

If you are interested in the currently pending bills in Congress to revise the patent laws, the Association has a number of committees actively engaged in reviewing and comparing various aspects of the bills. If you are not interested, you should be.



### PTO notices – [www.uspto.gov/main/newsandnotices](http://www.uspto.gov/main/newsandnotices)

The PTO and others are sponsoring a day long Design Day series of events at the PTO on 4/6/09.

From time to time the PTO holds a customer partnership meeting. One will be held at the AIPLA Spring Meeting on 6/2/09. Notes and materials about it are available from the AIPLA.

### EPO notices – [www.epo.org](http://www.epo.org)

On 3/26/09 the EPO announced amendments limiting opportunities to file divisional patent applications.

### Copyright Office News [http://www.copyright.gov/newsnet/past\\_issues.html#2007](http://www.copyright.gov/newsnet/past_issues.html#2007)

On 3/27/09 the Office announced adoption of amendments relating to Notices of Termination.

On 3/30/09 the Office announced that it seeks comments by 4/21 about certain changes to its public availability of records practices.

### Other Stuff –

Maintenance fee issues are discussed at [www.latepatents.net](http://www.latepatents.net).

LSI is sponsoring a conference concerning Copyright Counseling, Management and Litigation on 4/23-24/09 in Seattle.

Linex Legal reports that New Zealand has instituted some changes to its patent practices.

LSI is sponsoring an Open Source Software seminar in San Francisco on 6/8/09.

For those BPAI watchers among us, check [bpaivatchdog.blogspot.com](http://bpaivatchdog.blogspot.com).

The IP Watchdog recently pointed out that pat. appln. allowances by the PTO have fallen from 70% to a recent low of 42%. No wonder you're having trouble.

A new Fair Pay Act prohibits discriminatory compensation etc. and may pose problems for law firms.

LSI is offering a Patent Enforcement and Early Stage Litigation workshop in SF on 6/19/09.

For more information about any of the patent topics mentioned consult *Patent Application Practice* published by West and updated twice a year.

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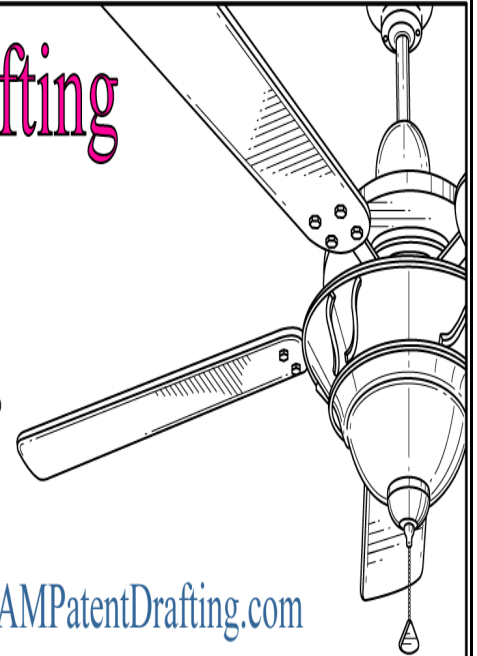
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## Two Job Openings for HTC Corporation

### Patent licensing director:

- in San Diego or Seattle/Bellevue
- at least 4 years experience in patent licensing; not necessary to be an attorney, but must have good business sense and knowledge of patent licensing terms
- negotiation experience preferred
- will report directly to General Counsel or Chief Patent Counsel
- resumes can be sent to [heidi\\_hui@htc.com](mailto:heidi_hui@htc.com) and [alex\\_chen@htc.com](mailto:alex_chen@htc.com)

### Patent litigation counsel:

- in San Diego or Seattle/Bellevue
- 3-7 years experience in patent litigation working at a law firm or managing outside counsel
- Undergraduate degree in engineering or physics preferred
- registered attorney to practice law in at least one State
- must be a team player and a responsible case manager
- experience in mobile phone technologies preferred
- willingness to travel within U.S. 1-3 days per month preferred
- will report directly to Chief Patent Counsel
- must have at least 3 work references
- resumes can be sent to [heidi\\_hui@htc.com](mailto:heidi_hui@htc.com) and [alex\\_chen@htc.com](mailto:alex_chen@htc.com)

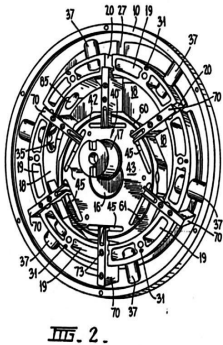


FIG. 2.

