

Adli Law Group P.C.

February 2012 Newsletter

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U.S House Committee Passes Bill Requiring Independent Scientific Analysis of E15 Gasoline

The U.S. House Science Committee approved a bill (H.R. 3199) directing the National Academy of Science to conduct a scientific assessment on how gasoline blended with 15 to 20 percent ethanol (E15 and E 20) may impact gasoline-powered engines, vehicles and related equipment. The analysis would consider a variety of issues including tailpipe and....

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Recent California Decision Provides Tips for Drafting Enforceable Arbitration Provisions

Andrew Shupe
Associate Attorney

A recent opinion issued by the California Court of Appeal offers guidance to those drafting contractual arbitration provisions (and those opposing motions to compel arbitration). In *Sanchez v. Valencia Holding Co., LLC*, 2011 WL 5865694 (Cal.App. 2 Dist., Nov. 23, 2011), the Court of Appeal held that a car dealership's arbitration provision was unconscionable in that it involved oppression and surprise due to unequal bargaining power and contained harsh one-sided terms that favored the car dealer. First, the Court cited *Armendariz v. Foundation Health Psychcare Services, Inc.*, 24 Cal.4th 83, 114 (2000) for the rule that both "procedural" and "substantive" unconscionability must both be present for a court to refuse to enforce a contract provision, with procedural unconscionability focusing on oppression or surprise due to unequal bargaining power, and substantive unconscionability focusing on overly harsh or one-sided results favoring the party that drafted the provision.

The *Sanchez* Court found procedural unconscionability because (1) the entire sale contract was crammed onto two sides of one pre-printed page and was signed or initialed on the front side but not the back side, where the actual arbitration clause was located; (2) on a take-it-or-leave-it basis, the plaintiff was told where to sign the document and was not given an opportunity to read the terms, while no one at the dealership mentioned the arbitration clause; (3) the use of a contract of adhesion establishes a minimal degree of procedural unconscionability even if the consumer could have sought alternatives in the market; and (4) the general rule that "failure to read the terms of

a contract is no excuse" does not apply to contracts of adhesion, and the failure to read the contract helps establish the element of surprise.

The Court then ruled that the arbitration provision was substantively unconscionable as well, based on four clauses in the provision; 1. Either party could appeal an arbitrator's award exceeding \$100,000. Though seemingly neutral, this provision was unfairly tilted toward the dealer so there was no likely scenario under which a car dealer would win an award exceeding \$100,000 against an individual consumer; 2. The provision was unfair because it allowed the losing party to appeal an award containing injunctive relief; again, it would be the buyer, not the dealer, who would have an interest in seeking injunctive relief to enforce consumer laws; 3. The provision required the appealing party to pay up-front the arbitration appeal fees for both parties, with no procedure for relief from unaffordable fees; 4. The provision exempted self-help remedies such as repossession from the arbitration requirements, but only the dealer was likely to employ repossession. The consumer has no self-help remedies against the dealer, while the remedy was repossession. Thus, the provision was unconscionable because it provided for the arbitration of claims most likely to be brought by the weaker party, but exempted claims brought by the stronger party.

Based on this case, an attorney drafting an arbitration provision for a consumer contract can increase the chances of its enforcement by: A) printing the contract in a legible type-face on a standard-sized document, with a space for the consumer's initials adjacent to the arbitration provision; (B) making clear to the client that its employees should allow customers the opportunity to read the document; (C) avoiding terms allowing only appeals that are likely to be made by your client; (D) avoiding terms that impose excessive financial burdens on the appealing party; and (E) avoiding terms that allow for alternative procedures, if your client is the only party who will have any use for such remedies.



Useful IP Strategies for the Pharmaceutical Industry

John Weatherspoon
Senior Attorney

The importance of having valid, enforceable patent protection is certainly essential, and the pharmaceutical industry knows this all too well. Solid intellectual property (IP) protection is critical especially for attracting investors, corporate partners, licensing, entering into strategic alliances, and for other approaches for commercializing new therapeutics. By “solid” IP protection, and in the case of patent protection, this of course refers to patents that are ultimately deemed both valid and enforceable.

It has long been appreciated that it is particularly critical to protect the full scope of IP assets surrounding new therapeutics, including new pharmaceutical products or “Active Pharmaceutical Ingredients” (APIs). The importance of solid IP protection can’t be emphasized enough, especially in today’s challenging economic climate. In the case of emerging biopharmaceutical companies seeking investor funding, a solid IP portfolio is essential. There are also many instances where a major innovator pharmaceutical company seeks to in-license or acquire the IP of a target company, in order to expand its product portfolio. Having a solid IP portfolio is critical for companies in the highly competitive pharmaceutical industry.

With interested parties, e.g., investors and/or potential corporate partners, seeking a sound investment, partnership, or potential acquisition, it’s all but guaranteed that the interested party conducting their due diligence

will evaluate not only the target company’s proof-of concept regarding their technology, as well as their marketability assessment, business plan, financials, and of course the leadership team, but most certainly there will be a thorough evaluation of the scope, validity and thus the enforceability of the target company’s patent portfolio. With the pharmaceutical industry facing increasing challenges within the U.S. and globally, and given that an ideal and often elusive target for pharmaceutical companies is to acquire patent protection for a novel composition of matter (or, in other words, a chemical compound deemed a new chemical entity or NCE), this article will discuss some key factors that should be considered when developing, and leveraging an IP portfolio, in particular, a portfolio that seeks to cover a new composition of matter.

Regarding the development of solid patent protection for a composition of matter, as an initial point, has a thorough patentability search and analysis been performed? An initial determination of patentability is critical. For instance, the importance cannot be overstated of established caselaw holding anticipation by enabling prior art that discloses a single chemical species. Having good IP counsel that really understands the nuances of the caselaw is essential. It’s also better to know the IP landscape *before* seeking patent protection on a purportedly new composition of matter that may (potentially unknown to the applicant) already have been disclosed in the prior art. Moreover, once an innovator company has identified a core structure, and the medicinal chemists have contemplated all the conceivable rational substitutions on the core structure, has the entire genus and all potential permutations been adequately disclosed in the patent specification? Even though the structure and structural modifications are themselves adequately described in a patent specification, does the specification actually *enable* one to

make and use the preferred compositions of matter, which may also be the lead compounds?

Here are examples of other essential considerations: have all material references been disclosed during the course of prosecution? What is the scope of protection in the claims? What is the full scope of the disclosure? For instance, for APIs, have all rational and conceivable salt forms been disclosed? If there is evidence that a particular salt form of the compound has preferred properties, are there enabling examples that teach a person of ordinary skill in the art how to make and use that specific salt form? For instance, for an API that may ultimately be developed as a hydrobromide salt, succinate salt, tosylate salt, or other specific salt form, having an enabling disclosure, which clearly teaches how to make and use that specific salt form is essential to a solid patent disclosure.

What has been disclosed about formulations? Have all various types of pharmaceutical formulations been contemplated and disclosed? Also, what has been disclosed about routes of administration? Specific dosage forms, and dosage names? What is known and what has been disclosed in the patent specification, regarding pharmacokinetic (PK) properties? These are all potentially extremely valuable aspects of IP protection that broadly cover a pharmaceutical product.

One preferred strategy is to disclose these features (such as specific dosages, routes of administration, salt forms of the API, PK properties, etc.) as early as possible, keeping in mind that it's all but guaranteed that competitors – especially in the very highly competitive pharmaceutical industry – will, once a commercially valuable patent issues, make every effort to challenge the patent and/or design around the innovator's patent(s). Thus, contemplating in advance some of these important features relating to a pharmaceutical

innovation, and thinking strategically about how to build the most comprehensive and solid patent disclosure possible, after conducting thorough landscape and due diligence investigations, will be tremendously advantageous in building a solid IP portfolio.

Moreover, having a solid IP position, and being able to rely on thorough and comprehensive due diligence and landscape analyses, and ensuring that the prosecution is carried out effectively, with full disclosure of all material references, will greatly enhance the chances of retaining a patent that is ultimately deemed valid and enforceable when it is challenged in litigation under Hatch-Waxman.

In summary, with regard to building solid patent protection for pharmaceutical APIs, strategic IP planning and conducting thorough and comprehensive due diligence in *advance* are essential to building the IP portfolio, and before approaching an investor or potential corporate partner.

Under current U.S. law, the rewards for innovator companies can be significant. For instance, with FDA approval of an NCE, the innovator may be granted a highly sought-after five-year period of marketing exclusivity in the U.S. Moreover, while the FDA rewards innovator companies with this type of marketing exclusivity, innovator pharmaceutical companies also benefit from patent protection for their discoveries. By taking such steps *in advance* to ensure solid patent protection, an innovator will be in a much better position to withstand litigation challenges to their valuable Orange Book-listed patents, especially in an increasingly competitive global marketplace.



Outsourcing Your Attorneys: The Next Wave?

Alex Angarita
Counsel

Outsourcing arrangements, under which companies hire service providers to perform non-core functions such as Information Technology (IT), have been around for decades. In recent years, many companies have aggressively begun to pursue opportunities in the area of business process outsourcing (BPO), creating markets for outsourced business processes such as human resources, finance and accounting. Some professional service firms, such as investment banks and accounting firms, have quickly adopted BPO as a cost-cutting strategy and continue to expand the type of business processes that are being outsourced. However, the legal services sector has, until quite recently, been slow to adopt BPO as a standard business practice. This may be about to change. Last year, Office Tiger, an outsourcing company based in India that has successfully convinced Wall Street investment banks to outsource work typically performed by junior investment bankers, teamed up with Hildebrandt International, a legal consultancy in the U.S. The joint venture promises to shake up many of the perceptions of how, and where, legal support services can be performed. According to Joseph Sigelman, co-founder of Office Tiger, "Unlike elsewhere, the legal services industry has not yet experienced the pressure to adopt more efficient ways of business. Offshoring to India can achieve that." In 2004, an estimated 12,000 legal jobs were sent offshore, according to research by the U.S. Bureau of Labor Statistics and Forrester Research. The same research predicts that number will rise to 79,000 by 2015. The expanding list of legal services offshored to companies include such substantive functions as knowledge management, document drafting, preparing initial briefs, advising clients on

behalf of American attorneys, and drafting patent applications as well as less substantive functions like document indexing and scanning, word processing, legal transcription, coding, converting data into electronic form, and digital dictation.

One of the most likely drivers for outsourcing legal services is the substantial cost savings it potentially brings to law firms. These cost savings can be transferred directly to law firm clients to offer more competitive pricing or be reinvested in the firm. The business model is simple: service providers take advantage of wage arbitrage opportunities between countries to offer the same service for a substantially reduced price. Many of the same functions that junior associates and legal staff perform today in law firms can be performed for about one third of the cost in India. Legal outsourcing provides law firms with a strategy to ease the tension between maintaining high billing rates and increasing profits per partner while reducing client legal cost.

In addition to achieving cost savings (if well managed) the outsourcing relationship can lead to increased flexibility and enhanced levels of client service. In the ideal outsourcing relationship, law firms could benefit from a service provider's ability to exploit economies of scale to spread the costs of cutting edge delivery models across multiple clients. This is particularly true for mid-market firms that can take advantage of a leveraged platform from "shared service" arrangements, where several firms work with a common service provider. Larger firms may employ the "captive" law firm model, whereby an offshore law firm provides legal services for one or two U.S. firms, capitalizing on customization and greater control. From the practitioner's perspective, outsourcing lifts the burden of performing certain routine functions so that the firm can focus on those aspects of a legal practice that provides maximum value to its clients, such as providing strategic legal and business advice, drafting and negotiating complex arrangements, and litigating and resolving disputes. An attorney

in New York could conceivably “drop off” a routine research assignment at the end of the day to a service provider in Bangalore (10.5 hours ahead of EST). The assignment could be completed by the morning at a rate of \$50-\$60 per hour, rather than the \$275 or more per hour typically charged for a junior associate in the U.S. This is the essence of outsourcing, allowing a company to focus on core competencies while providing non-core services at reduced rates.

India is the most likely destination for would-be outsourcers of legal services since their legal system is grounded in the traditions of British common law, their legal education is conducted solely in English, and their legal opinions are written in English. Much like the case with engineers, computer programmers and MBAs in India, financial rewards offered to graduates of Indian law schools will result in a more competitive and better-trained talent pool. India has developed a very effective niche market for providing globalized services in many business sectors, and legal services will likely not be an exception.

Some of the biggest challenges faced by U.S. law firms planning to pursue legal outsourcing are ensuring the quality of the outsourced legal services and protecting client confidentiality. In addition, these firms must take steps to safeguard against promoting the unauthorized practice of the law, prevent waivers of the attorney-client privilege, and avoid conflicts of interest and running afoul of similar regulatory and ethical restrictions. Attorneys have addressed some of these issues through close supervision of and steady communication with the service provider. Some law firms have approached these concerns by investing in extensive up-front training, reasoning that this initial cost will be more than made up in the cost savings that outsourcing will provide. Along these lines, law firms have also considered

designating full-time staff to manage service delivery and ensure that client confidentiality procedures are being followed. To reduce the potential for malpractice, law firms have been careful to ensure that outsourced legal services not involve any discretion that might affect or impair the lawyer’s independence, the attorney-client relationship, or the integrity of the legal profession. Lawyers outsourcing legal work have also stressed the importance of service providers having a physical presence in the U.S., thereby giving the client firms or companies recourse in U.S. courts should something go wrong. However, given the unique nature of the attorney-client relationship and the many restrictions while meeting ethical obligations will remain a challenge to the outsourcing of legal services.

A well-managed relationship with an offshore service provider can be a powerful tool for U.S. law firms seeking to increase market share in an increasingly competitive landscape for legal services. In fact, as BPO generally becomes a more widely accepted business practice within corporate America, many companies will demand that their outside counsel use similar strategies to deliver efficient legal solutions.



Breaking News!!!

U.S. House Committee Passes Bill Requiring Independent Scientific Analysis of E15 Gasoline

The U.S. House Science Committee approved a bill (H.R. 3199) directing the National Academy of Sciences to conduct a scientific assessment on how gasoline blended with 15 to 20 percent ethanol (E15 and E20) may impact gasoline-powered engines, vehicles and related equipment. The analysis would consider a variety of issues including tailpipe and evaporative emissions, impact on OBD systems, materials compatibility and fuel efficiency. The National Academy of Sciences would have 18 months to conduct its analysis. HR 3199 will now be considered by the full House of Representatives.

We Urge You to Contact Your Congressional Representative to Request Their Support for H.R. 3199

- H.R. 3199 acknowledges that E15 causes corrosion with incompatible parts. Ethanol increases water formation which can then create formic acid and corrode metals, plastics and rubber. The EPA allows use of E15 in 2001 and newer vehicles, but agreed to make it “illegal to fuel pre-2001 vehicles” with E15. A required warning label on the gasoline pump will not protect consumers from accidentally misfueling these vehicles/engines.
- H.R. 3199 recognizes that E15 is not yet in the marketplace. It is still the subject of several lawsuits and Congress could enact legislation to block the sale.
- H.R. 3199 prevents the EPA from permitting the sale of E15 before the report has been submitted to the House Science Committee.
- H.R. 3199 potentially protects millions of vehicles and engines that can be harmed from E15. The EPA was premature in permitting the sale since it is still unclear how E15 impacts tailpipe and evaporative emissions, OBD systems, materials compatibility and fuel efficiency.

DON'T DELAY! Contact your member of the U.S. House of Representatives to request their support of H.R. 3199.

For more information, contact Stuart Gosswein at stuartg@sema.org

Article courtesy of Sema Action Network (SAN)



New Addition

John Weatherspoon Senior Attorney

John Weatherspoon is a diligent life sciences attorney with a Ph.D. in Pharmacology and extensive, in-depth experience advising corporate legal departments, in particular in the pharmaceutical and biotechnology industries. Dr. Weatherspoon possesses extensive experience counseling clients on developing their intellectual property portfolios; and preparation, prosecution and management of U.S. and foreign patent dockets. Additionally, Dr. Weatherspoon has extensive experience providing IP counseling for strategic research; enforcing IP rights (through licensing; litigation; settlement; etc.); providing competitor intelligence; also conducting patentability, freedom to operate, infringement, validity and product clearance analyses for commercial and research activities.

Areas of Practice: □ • Patent Litigation □ • Trademarks □ • IP Licensing • Rendering Legal Opinions □

Education: □ • George Mason University School of Law, Arlington, Virginia; J.D., Giles Sutherland Rich Moot Court Award □ (2001-2002 Competition).

• The George Washington University, Washington, DC; Ph.D., Pharmacology; Dissertation: “Molecular Mechanisms of Catecholamine Release”; Medical Center Fellowship, George Washington University

Prior Legal Experience: □ • Stein McEwen LLP □ • Morgan Lewis Bockius LLP □ • Winston & Strawn, LLP



New Addition

Jai Rho Senior Attorney

Jai Rho joined Adli Law Group P.C. as a Senior Associate. His practice includes litigation of patent, trademark, copyright, trade secret and related antitrust, unfair competition, business and commercial matters. Mr. Rho is also very well versed in the areas of mediation, arbitration, counseling, licensing and other practical and efficient legal solutions for achieving business goals.

Mr. Rho has extensive experience in litigation of intellectual property matters before the Court of Appeals for the Federal Circuit, the Court of Appeals for the Ninth Circuit, as well as the International Trade Commission and District Courts.

Areas of Practice: □ • Litigation □ • Patent Litigation □ • Trademark □ • Copyright □ • Intellectual Property □ • Licensing □ • Civil Business Litigation □

Education: □ • UCLA, J.D. □ • Harvard, B.A.

Prior Legal & Non-Legal Experience: □ • Jai Rho, Attorney at Law • Keats McFarland & Wilson, LLP □ • Infotech Enterprises, Inc. □ • Hogan & Hartson, LLP

EVENTS



MBOD2012 MINORITY BUSINESS OPPORTUNITY DAY

Adli Law Group P.C. is proud to be a sponsor at Minority Business Opportunity Day (MBOD) 2012 in the City of Industry, CA. MBOD 2012 will take place on **February 23, 2012** at the Pacific Palms Conference Center.

Minority Business Opportunity Day exposes minority businesses to progressive workshops and seminars that optimize business potential and/or enhance business growth. MBOD also provides valuable opportunities for MBEs to network with Southern California Minority Business Development Council member corporations who sponsor and fund the events and activities. Member corporations value MBOD as a forum for meeting new MBE suppliers and vendors.

As a sponsor of MBOD 2012, **Adli Law Group P.C.** will have a booth for giveaways and a feature of our company profile in the main video loop. The firm will be represented by Nicolette Hachem-Sawaya, Director of Operations, and Robin Le Grand-Moore, Marketing Director.

HAPPY NOWROOZ



PERSIAN NEW YEAR



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*Dr. Dariush Adli, founder of
Adli Law Group P.C.,
cordially invites you and a friend to
attend our Nowrooz celebration on*

*Friday, March 2, 2012
from 6pm-8pm*

**Traditional Persian buffet
*DJ playing all evening
* Great professional networking opportunities*

** Professional/Cocktail Attire Required*

**Please RSVP by February 25, 2012
Kohl.Iverson@AdliLaw.com**

**US Bank Tower Building
Adli Law Group, P.C.**

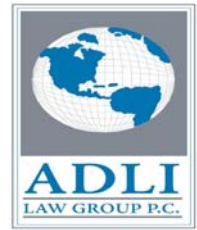
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**COME CELEBRATE PERSIAN NEW YEAR WITH ADLI LAW
GROUP P.C. ON FRIDAY, MARCH 2, 2012 FROM 6:00PM-8:00PM.
ENJOY A TRADITIONAL PERSIAN BUFFET STYLE DINNER,
NETWORK WITH OTHER LOCAL PROFESSIONALS AND ENJOY
OUR SPECTACULAR 69TH FLOOR SKYLINE VIEW AT NIGHT!**

PLEASE RSVP TO Kohl.Iverson@AdliLaw.com



Adli Law Group P.C. Sponsors Rotary Club Los Angeles LA5



On February 3, 2012, Dr. Dariush Adli was one of two featured speakers at a sold-out luncheon for Rotary Club of Los Angeles members. He gave an impressive speech about Adli Law Group P.C. and his leadership on the new California Pro-Bono Inventor Assistance Program.

Rotary Club of Los Angeles is the fifth oldest Rotary Club in the world with membership of more than 400 men and women. A majority of the club's income is used to support many philanthropic projects around the world.



El Rodeo
Club No. 5 | Organized June 26, 1909 | Over 100,000 Year

Program Sponsor
Dariush Adli

This Week's Program

Madeleine Pickens is an internationally known equine authority whose extensive credentials range from philanthropic efforts on the behalf of America's wild mustangs to co-ownership and management of Brookside Farms, one of the country's most successful breeding and racing operations. Millions of racing fans in the 1980s and 1990s saw Pickens journey to the winner's circle alongside legendary champions such as Cigar, Arazi, and Theatrical. During this same era, equine professionals witnessed her hands-on management style at Brookside's three facilities: a 1,600-acre breeding farm in Kentucky, and two training facilities in Florida and California. During her tenure at Brookside, Pickens enjoyed extensive one-on-one dealings with the nation's leading equine professionals, including equine surgeons, breeding specialists, nutrition experts, and trainers. At its peak, Brookside Farms was a \$20 million global operation that ran more than 800 horses, bred 150 foals annually, and carried a payroll in excess of 250 employees. The total value of the farm and its holdings, including the bloodstock, was upwards of a quarter of a billion dollars.

[Read more...](#)
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Dr. Dariush Adli Holds Litigation and Patent Law Seminars In Japan



Earlier this month, Dr. Adli, President/Founder of [Adli Law Group P.C.](#), held several seminars throughout Japan on fact discovery in U.S. patent suits and patent law reform in the United States. He shared his expertise on these topics with guests in Osaka, Nagoya and Tokyo. Dr. Adli was accompanied by Victor Sai, an Associate Attorney at Adli Law Group P.C., a native Japanese speaker who can read and write in Japanese as well.



Robin Le Grand-Moore

Marketing Director

Robin.Legrand@AdliLaw.com

Adli Law Group, P.C. prides itself in offering its clients **premium services at competitive rates**. For more information about Adli Law Group, P.C. please visit www.adlilawgroup.com. For information on obtaining brochures or other firm materials, please contact Robin Le Grand-Moore, Marketing Director, at (213) 623-6546 or you may email her directly at robin.legrand@adlilaw.com.

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LOS ANGELES

Los Angeles
633 W 5th Street
69th Floor
Los Angeles, CA
90071
213-623-6546
213-623-6554



LONDON

London
81 Oxford Street
London, W1D 2EU
United Kingdom
+44 (0) 207 903 5077
+44 (0) 207 903 5333



TAIPEI

Taipei
37F, Taipei 101 Tower
No. 7
Xin Yi Road
Section 5, Xin Yi District
Taipei City, 110 Taiwan
R.O.C.
+866 2 8758 2735
+866 2 8758 2999



TOKYO

Tokyo
Level 20, Marunouchi
Trust Tower-Main
1-8-3 Marunouchi Chiyoda-ku
Tokyo 100-0005 Japan
+81 (3) 6269 3143
+81 (3) 6269 3131