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# Intellectual Property News



## “Full Scope” Enablement – An Invalidity Bonanza

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Recent rulings from the Federal Circuit on the issue of claim enablement have become an important focus for infringement defendants in their attempts to invalidate a plaintiff’s patents.

Understandably, inventors and their patent attorneys try to claim an invention as broadly as the prior art will allow. Even if such claims are found to be distinguishable over the prior art during examination of the application, the enablement requirement of Section 112 of the Patent Act may present an intractable dilemma for patent holders. Section 112 requires,

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## Trademark Use on the Internet

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As technology continues to develop, particularly in cyberspace, courts have been presented with infringement claims involving new forms of trademark use. Specifically, courts are being called upon to answer questions as to whether new, computer-based trademark uses are “uses in commerce,” whether they create a “likelihood of confusion,” or whether they should be excused as “fair use.”

One example of an emerging trademark use is an on-line keyword program. The most widely known keyword program is Google’s Adwords program, one of the largest programs in the \$4.8 billion Internet advertising industry. The program allows domain name owners or parking companies, which act as collective agents between domain name owners or registrars and an advertising company, to buy sets of keywords. In some instances these keywords may represent registered trademarks. When a user searches for one of the keywords, a business that has bought the keyword appears as a sponsored result. In theory, a business could purchase its competitors’ trademarks as keywords so that when a user searches for any of the terms, the business’s site

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## Tennessee Uniform Trade Secrets Act—A Primer for Trade Secret Holders

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The Tennessee Uniform Trade Secrets Act (TUTSA) was enacted by the Tennessee General Assembly to provide protection to individuals and businesses who possess trade secrets. Thus, Tennesseans who have trade secrets should be guided by the Act and the case law interpreting the Act.

### What is a “trade secret”?

The Act defines a “trade secret” to be information which is “technical, nontechnical, or financial data, a formula, pattern, compilation, program, device, method, technique, process, or plan” that: (1) derives independent economic value from not being generally known; and (2) would provide economic value to others from its disclosure. In addition, the information must be (3) subject to “reasonable” efforts to maintain its secrecy. Tenn. Code Ann. §47 25 1702(4). While “absolute secrecy is not required,

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## “Full Scope” Enablement – An Invalidity Bonanza, *continued*

in part, that the “specification ... contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...” Over the years, courts have required that the specification of a patent application, i.e., the drawings and the description of the preferred embodiments, describe the invention in enough detail to enable a person skilled in the art to practice the claimed invention without undue experimentation.

In *Automotive Technologies, Inc. v. BMW, et al.* (Federal Circuit 2007), the patent contained claims to a side impact crash sensor for automotive airbags. The claim was broad enough to cover both mechanical and electronic sensors. The mechanical sensor was well described and illustrated in multiple figures. However, the electronic sensor was described in broad terms and illustrated in only a single conceptual figure. Rejecting ATI’s argument that the specification must only enable one mode of practicing the invention, the Federal Circuit ruled that the claim was invalid. The court stated that the electronic sensor must be particularly enabled because it is “distinctly different” from the enabled mechanical sensor. Thus, the specification failed to enable the “full scope” of the claims that include both mechanical and electrical sensors. In its ruling, the court recalled its decision earlier that year in *Liebel-Flarsheim v. Medrad* (Federal Circuit 2007) in which claims to a jacketed needle holder were invalidated because they were not fully enabled.

Most recently, in *Sitrick v. Dreamworks* (Federal Circuit

2008), the court reviewed claims directed to a method for combining user-generated audio and visual effects into video games or movies. The asserted claims were construed as covering both video games and movies. The court, though, determined that use in movies was insufficiently enabled. Citing its *Automotive* decision last year, the court reiterated that the full scope of the claimed invention must be enabled. It further stated that the scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.

The above decisions do not appear to bode well for broad or generic patent claims, even when the claim is fully enabled for at least one preferred embodiment. In fact, most claims which use open terminology, such as “comprising” or “including,” necessarily contemplate a wide range of additional elements or limitations which may not be fully enabled in the specification. Because these decisions are sure to form the basis for invalidity contentions from accused infringers, at least two cautionary notes are in order. First, patent applicants and their attorneys should reconsider the breadth of their claims during prosecution in view of the specific embodiments described. Second, in the litigation context, plaintiffs should carefully structure their arguments pertaining to claim interpretation and scope, as proffering an overly broad construction may expose such claims to enablement problems.

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## Trademark Use on the Internet, *continued*

appears as a sponsored result, often above the site of the competitor.

Several district courts in the Second Circuit have concluded that the sale of trademarks as keywords for sponsored links does not constitute use for the purpose of the Lanham Act.<sup>1</sup> These cases rely on the reasoning of a Second Circuit decision holding that using trademark terms to trigger pop-up advertisements on the Internet does not constitute trademark infringement.<sup>2</sup> In *1-800-Contacts*, the court explained that a “company’s internal utilization of a trademark in a

way that does not communicate it to the public is analogous to a[n] individual’s private thoughts about a trademark. Such conduct simply does not violate the Lanham Act.”

There are, however, contrary decisions where courts have ruled against the search engine. Google and American Airlines recently settled a trademark infringement suit that accused the search engine of misleading consumers with the sponsored links. In October, the court declined to dismiss the suit.<sup>3</sup> Another court noted that

Google generated revenue from the goodwill associated with the trademark and that the hyperlink and description that appeared as one of Google’s sponsored results additionally incorporated the trademark as the first word in the description of the website.<sup>4</sup> Relying on the initial interest confusion theory of trademark infringement liability, the court held that “source confusion need not occur; rather, in the Internet context, the wrongful act is the defendant’s use of the plaintiff’s mark to divert consumers to a website that consumers know is not [the

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## Trademark Use on the Internet, *continued*

plaintiff's] website."

In another type of trademark use, a domain name owner "parks" or licenses the domain name to a company that acts as an aggregator to place Internet advertising on a site to generate revenue. By deciding what advertisements would be profitable on websites with domain names that are confusingly similar to registered trademarks, these companies may traffic in the domain names and could be liable for violations of the Anticybersquatting Consumer Protection Act (ACPA). There is little law regarding the liability of these intermediary "parking companies." However, a pending case in the Northern District of Illinois includes several parking companies as defendants along with Google. So far the court has concluded that there is adequate evidence that the parking companies may "traffic in" or "use" domain names, sufficient to withstand motions to dismiss on violations of the ACPA and Lanham Act.<sup>5</sup>

Using metatags is an additional way to direct traffic to a website that may infringe trademark rights. Metatags are words or phrases in a website's HTML code that Internet search engines use to

determine which websites correspond to the search terms entered by a user. Search engines have different methods for producing their results, some relying more or less on metatags but, generally, the more often a term appears, the more likely it is to appear in the results list.

Several courts of appeal have held that using trademarks in a website's metatags is actionable under the initial



interest confusion theory of liability.<sup>6</sup> Under this theory, although a consumer is not ultimately confused about the source of goods or service, they were diverted from their intended destination. However, the nominative fair use defense may serve as a defense depending on the factual situation. For

example, the Ninth Circuit has held that a former playboy playmate's use of the trademarked terms "playboy" and "playmate" in her website's metatags was nominative fair use based on the following analysis:

1. The product or service in question must be one not readily identifiable without use of the trademark;
2. Only so much of the mark or marks may be used as is reasonably necessary to identify the product or service; and
3. The user does nothing that would, in conjunction with the mark, suggest sponsorship or endorsement by the trademark holder.<sup>7</sup>

Because infringement suits for emerging types of trademark use on the Internet have received mixed results, it is particularly important to understand the technology at issue to determine how traditional trademark law may apply.

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1. *Fragrancenet.com, Inc. v. Francrancel.com, Inc.*, 493 F. Supp. 2d 545 (E.D.N.Y. 2007); *Rescuecom Corp. v. Google, Inc.*, 456 F. Supp. 2d 393 (N.D.N.Y. 2006); *Merck & Co., Inc. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402, 408 (S.D.N.Y. 2006).

2. *1-800 Contacts v. When U.com, Inc.*, 414 F.3d 400 (2d Cir. 2005).

3. *American Airlines Inc. v. Google, Inc.*, No. 4:07-cv-00487 (N.D. Tex. filed Oct. 24, 2007).

4. *Gov't Employees Ins. Co. v. Google, Inc.*, 2005 WL 1903128 (E.D. Va. 2005).

5. *Vulcan Golf, LLC v. Google Inc.* — F. Supp. 2d —, 2008 WL 818346 (N.D.Ill. March 20, 2008) (granting motion to dismiss in part and denying in part).

6. See, e.g., *North American Medical Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211 (11th Cir. 2008); *Australian Gold, Inc. v. Hatfield*, 436 F.3d 1228 (10th Cir. 2006); *Century 21 Real Estate Corp. v. Lendingtree, Inc.*, 425 F.3d 211 (3d Cir. 2005); *Promatek Industries, Ltd. v. Equitrac Corp.*, 300 F.3d 808, 812-13 (7th Cir.2002); *Brookfield Communications, Inc. v. West Coast Entertainment Corp.*, 174 F.3d 1036, 1062 (9th Cir. 1999).

7. *Playboy Enterprises, Inc. v. Welles*, 279 F.3d 796, 803-804 (9th Cir. 2002).

## Tennessee Uniform Trade Secrets Act – A Primer for Trade Secret Holders, *continued*

there must be a substantial element of secrecy.” (*Hickory Specialties v. B & L Labs, Inc.*, 592 S.W.2d 583 (Tenn. Ct. App. 1979)). To “constitute a trade secret, it must be difficult for anyone outside the confidential relationship to acquire the information by proper means.” *Wright Med. Tech., Inc. v. Grisoni*, 135 S.W.3d 561 (Tenn. Ct. App. 2001).

Even information that is in the public domain, and thus having no independent economic value, can be protectible to the extent that it is combined with other non-public information to form a trade secret. *Wright Med. Tech., Inc. v. Grisoni*, 135 S.W.3d 561 (Tenn. Ct. App. 2001) (if portions of information are publicly known, the integration of those portions into a unitary whole may still be protectible). As one commentator has put it, “[t]he fact that some or all of the components of the trade secret are well known does not preclude protection for a secret combination, compilation, or integration of the individual elements.” The Connecticut Supreme Court in *Elm City Cheese Co. v. Federico*, 752 A.2d 1037 (Conn. 1999), determined that a “plaintiff’s ability to combine these elements into a successful . . . process, like the creation of a recipe from common cooking ingredients is a trade secret entitled to protection.”

Trade secret protection is not limited to just “technical” information such as secret formulas or computer programs. Business information can also be a trade secret. Note that TUTSA provides coverage for things such as “nontechnical, or financial data.” See, e.g., *Int’l Security Mgmt. Group, Inc. v. Sawyer, et al*, 2006 WL 1638537 (M.D. Tenn. Jun. 6, 2006) (pricing information). See also *Cam Int’l L.P. v. Turner*, 1992 WL 74567 (Tenn. Ct. App. Apr. 15, 1992) (“information concerning customers’ specialized requirements, need and product preferences” may be entitled to protection) (decision prior to enactment of TUTSA).

### Misappropriation of a Trade Secret

Generally, there are three elements necessary to prove misappropriation of a trade secret: “(1) the existence of a trade secret; (2) misappropriation of the trade secret by the defendant; and (3) resulting detriment to the plaintiff.” *Partylite Gifts, Inc. v. Swiss Colony Occasions*, 2006 WL 2370338 (E.D. Tenn. Aug. 15, 2006). Liability for trade secret misappropriation is determined in part by Tenn. Code Ann. §47 25 1702(2) which defines various types of “misappropriation.”

In basic terms, misappropriation can include not only the

acquisition of the trade secret by improper means, but also the disclosure or use of the trade secret. Of critical importance, a third party – not the initial “misappropriator” – can be liable for misappropriation if the third party uses the trade secret and knows or should have known that the trade secret has been improperly acquired. For example, in *PMC, Inc. v. Kadisha*, 78 Cal. App. 4th 1368 (2000), a California court held that once the defendants knew or had reason to know of the use of misappropriated trade secrets, they were liable for the misappropriation even though they did not take part in the initial misappropriation: “[M]isappropriation is not limited to the initial act of improperly acquiring trade secrets; the use and continuing use of the trade secrets is also misappropriation.” *Id.* (citing California statute identical to Tenn. Code Ann. §47 25 1702). Courts in Wisconsin and Pennsylvania have held likewise. Therefore, a trade secret holder need only show that a defendant either acquired trade secrets through improper means or disclosed or used the trade secrets of another under one of the listed conditions in the statute.

### Improvements or Modifications to a Trade Secret

As a general principle, a party may not use another’s trade secret, even with independent improvements or modifications, so long as the product or process is substantially derived from the trade secret. *American Can Co. v. Mansukhani*, 742 F.2d 314 (7th Cir. 1984); *Atochem North America v. Gibbon*, 1991 WL 160939 (D.N.J. Aug. 15, 1991) (“[S]light modifications or improvements of a trade secret will not defeat the misappropriation claim.”); *Olson v. Nieman’s LTD*, 579 N.W.2d 299 (Iowa 1998) (minor modification is not a defense to trade secret misappropriation).

### Relief Under TUTSA

Under Tennessee’s adoption of the Uniform Trade Secrets Act, a plaintiff may recover *both* monetary and injunctive relief. Tenn. Code Ann. §§ 47 25 1703 and 1704.

- **Injunctive Relief**

An injunction can issue for both “actual” and “threatened” misappropriation. At the outset of a lawsuit, a trade secret owner can seek a preliminary injunction to prevent the alleged misappropriator from using or disclosing the trade secret while the lawsuit is pending. At the conclusion of trade secret cases, courts have granted two types of permanent injunctions: (1) a

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## Tennessee Uniform Trade Secrets Act – A Primer for Trade Secret Holders, *continued*

permanent “use” injunction (to protect the trade secret) and (2) a “head start” injunction (to eliminate any commercial advantage improperly gained by defendant’s misappropriation). See *Chemetall GMBH v. ZR Energy, Inc.*, 138 F. Supp.2d 1079 (N.D. Ill. 2001); and *Gen. Elec. v. Sung*, 843 F.Supp. 776 (D. Mass. 1994).

- **Monetary Relief**

TUTSA provides that “[d]amages can include both the actual loss caused by misappropriation and the unjust enrichment caused by misappropriation that is not taken into account in computing actual loss.” Tenn. Code Ann. §47-25-1704. Moreover, damages may be measured by “a reasonable royalty” where appropriate. *Id.*

TUTSA also provides for discretionary exemplary damages “in an amount not exceeding twice” the amount

awarded for, in essence, compensatory (or “actual loss”) damages. Tenn. Code Ann. §47-25-1704(b). Courts have awarded exemplary damages in double the amount of actual damages, resulting in a total award of *three times* the amount of actual damages. These damages can be sought when the misappropriator is found to have acted willfully and maliciously.

### Conclusion

TUTSA can be a powerful tool for those who hold trade secrets. However, in order to avail itself of this law, those who possess trade secrets must make sure that they exercise “reasonable” efforts to maintain the secret nature of the trade secret.

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## The Problem of Metadata

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Metadata is data that is embedded or hidden in other data. It is sometimes called “data about data.” A problem with metadata arises when one sends an email or a document unwittingly disclosing confidential information.

The term “metadata” has come into prominence lately in the context of electronic information. In this context, metadata describes the contents, location, physical attributes, type and form of the electronic information. Typically, metadata tracks the changes and developments within a document and may contain information such as the author’s name, the name of the server or disk where the document was saved, properties or summary information about the document, the names of previous authors and revisions to the documents. In essence, metadata addresses the who, what, when, where and how of the underlying data.

Metadata is encoded in order to allow it to be processed by a computer program. It may be encoded by using different protocols or schemes. The basic

purpose of metadata is to allow electronic information to be located, organized and used. Depending on its type, metadata may assist in identifying the location of the information by supplying call numbers or other identifying information much like those used in library identification systems, such as the Dewey Decimal System. Those identifying systems might be based on logical groupings of the elements of the data.

Metadata may be attached to the underlying document in a number of ways. It can be embedded in the document itself. It may be in a separate document that is linked to the underlying data. Finally, it may be in a separate database. Ordinarily, metadata is created automatically by a computer tool.

If emails or other electronic data are transmitted in native format (or, in other words, in original format), the recipient will be able to access this metadata. It may contain information that the sender does not want revealed. A typical example would be a draft of an agreement.

The metadata might show previous drafts of the agreement and give the other side in the transaction a strategic advantage in the conduct of the negotiations. In the discovery process in litigation, this information can be crucial. Whether metadata is supplied or not needs to be considered by both the client and lawyer before electronic information is disclosed to the other side in negotiations or litigation.

Metadata can easily be removed in a number of different ways. The document can be printed or scanned into PDF; it can be transferred to another program in a way that removes the metadata; or it can be scrubbed by a software tool that removes the metadata. Whether to remove metadata is a decision that needs to be on the checklist of every client and attorney engaged in any significant business negotiation or any litigation.

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## Regulation of Biosimilars

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Congress is currently considering legislation similar to the Hatch-Waxman Act of 1984 to authorize expedited Food and Drug Administration (FDA) approval of generic biologic drugs, or “biosimilars.” Biosimilars are biologic drugs that are “similar” to their patented, FDA-approved biopharmaceutical counterparts. Although the expedited approval process works well for traditional chemically-synthesized drugs, it may not work as well for biopharmaceuticals.

Biopharmaceuticals are nucleic acid or protein-based medications derived from the manipulation of living organisms. They are the result of modern biomedical research and include many different kinds of medications. These include recombinant human insulin; erythropoietin (EPO); vaccines; and monoclonal antibodies. Unfortunately, biopharmaceuticals can also be very expensive, with some costing more than \$100,000 per patient, annually.

As innovative biopharmaceuticals lose patent protection, the market for their biosimilar counterparts opens. However, there is no expedited pathway for FDA approval of biosimilars. Small-molecule chemically-synthesized drugs are approved by the FDA under the Food, Drug and Cosmetic Act (FDCA), which Congress amended via the Hatch-Waxman Act to provide for expedited approval of generic drugs. By limiting the degree of testing required for generic drugs, and by allowing reference to the FDA’s prior findings of safety and efficacy for reference innovator drugs, Congress helped lower generic drug costs and sped the drugs to market. Almost all biopharmaceuticals, though, are approved under the Public Health Service Act (PHSA), which has no comparable provisions for expedited approval. Consequently, a manufacturer seeking FDA approval for a biosimilar is required to submit a completely new application — including the results of full clinical trials — without reference to the FDA’s prior findings of safety and efficacy for a reference innovator biopharmaceutical.

Congress recognizes that an expedited FDA approval process is needed for biosimilars. In fact, four bills addressing this issue have been introduced since February 2007. An analysis of the bills, though, suggests that a

limited testing paradigm — which works so well for small-molecule drugs — may not be so easy to legislate.

The “Access to Life-Saving Medicine Act” (H.R. 1038), introduced by Representative Henry Waxman in February 2007, would require a demonstration that a biosimilar is “comparable to or interchangeable with” a reference biopharmaceutical, and that it contains “highly similar principal molecular structural features, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns.” The “Biologics Price Competition and Innovation Act of 2007” (S. 1695), introduced by Senator Edward Kennedy, is similar to the Waxman bill and would require a showing of “biosimilarity” based upon “analytical studies that demonstrate that the biological product is highly similar

to the reference product notwithstanding minor differences in clinically inactive components; animal studies; and a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency.” The “Pathway for Biosimilars Act” (H.R. 5629) introduced by Representative Anna

Eshoo in March 2008, would require analytical studies demonstrating that the biosimilar is “highly similar” — a term that is not defined by the bill. Each of these three bills would grant the Secretary of the Department of Health and Human Services (DHHS) broad discretion to determine whether or not to waive certain requirements, including laboratory studies, animal studies and clinical studies. In contrast, the fourth bill, known as the “Patient Protection and Innovative Biological Medicines Act of 2007,” (H.R. 1956) introduced by Representative Jay Inslee, contains none of the exceptions of the other three bills. The Inslee bill would require the submission of “data demonstrating the stability, compatibility ... and biological and physiochemical integrity of the active ingredient,” results of “physical, chemical, and biological assays fully characterizing” the biosimilar, “data from comparative nonclinical studies,” “data from comparative clinical trials,” and “a plan for postmarketing safety monitoring.”

The Hatch-Waxman paradigm for approval of generic small-molecule drugs works well because demonstrating



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## Regulation of Biosimilars, *continued*

“bioequivalence” between these drugs and their reference compounds is relatively simple. Demonstrating bioequivalence requires, for example, administering the generic drug and the reference drug to volunteer subjects in a cross-over study, and then assaying plasma samples for drug (or metabolite) concentrations over time. The pharmacokinetic parameters derived from these data allow determination of the drugs’ comparability.

Biopharmaceuticals, though, are far more complex than small-molecule drugs, and demonstrating simple “bioequivalence” may not be sufficient. Biopharmaceuticals are roughly 100 to 1,000 times larger than chemically-synthesized drugs, they possess complex three-dimensional structures, and may exist as mixtures of isoforms. A major shortcoming of biopharmaceuticals is their tendency to evoke an immune response (the formation of harmful antibodies). Not only can these antibodies affect drug efficacy by neutralizing the drug itself, they may produce serious clinical consequences if they are directed against endogenous (“self”) proteins. For example, beginning in 1998 the incidence of a rare form of anemia associated with the production of erythropoietin-neutralizing antibodies increased dramatically in patients receiving epoetin- $\alpha$ . While the causes remain unclear, they were positively correlated with changes to the product formulation, the

route of administration, and storage and handling issues. The scientific and medical communities have learned that relatively minor differences between protein products — including sequence variations, posttranslational modifications, contaminants, impurities, and formulation differences — can have profound effects on their immunogenicity. Ironically, the Waxman bill would define biosimilars having differences “solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence,” as well as differences in glycosylation — all major determinants of immunogenicity — as containing “highly similar principal molecular structural features.”

Because relatively minor changes to biopharmaceuticals may cause significant alterations in immunogenicity, and because an individual’s immune system can respond to alterations that current analytical techniques may not detect, it appears likely that biosimilars will require more extensive clinical testing than generic drugs. Consequently, the savings enjoyed with generic small-molecule drugs may not be realized with biosimilars, and biosimilars may not enter the market as rapidly as their generic small-molecule cousins.

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## Effective IP Management of Biotechnology in China Through Good Business Practices

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Various research and development services are available through research and development (R&D) centers in China.<sup>1</sup> These R&D centers are sometimes referred to as contract research organizations or CROs. Intellectual property used or created in a contract R&D situation should be protected by good business practices.

### A. Due Diligence

Research and development services are available in China through various scientific organizations. An example is a laboratory that provides contract clinical testing to support a regulatory

filing. Other examples are wholly foreign-owned enterprises (WFOE), government-sponsored R&D organizations, and strictly private enterprises. “China’s more than 300 CROs form an integrated service chain, addressing everything from pharmacogenomics to clinical trials, new drug applications, new drug transfers and exporting. The majority of Chinese CROs are small and simply provide regulatory consultation, drug application and clinical trial assistance to overseas pharma firms. Of these, more than 100 are capable of conducting R&D.”<sup>2</sup>

In any instance, the CRO should

be examined. Before selecting a CRO, the prospective service provider should be carefully investigated to verify respect for intellectual property and contractual obligations. One provider of clearance services is PAC-US.

### B. Terms for a CRO contract

Certain terms should be considered for a service contract in China. First, the service contract defines the services contracted for and the payment provision. Also, the contract should set out the obligation to assign intellectual property developed by the service provider while providing the

## Effective IP Management of Biotechnology in China through Good Business Practices, *continued*

service. The service provider should provide a statement of inventory of intellectual property ownership prior to the effective date of the contract. A warranty statement should be provided in the contract that the service provider is not currently providing a similar service to another company in the same field. The service provider should warrant that it will not provide the same service for another company in the same field if the contract is terminated for a period of "X" years. The definition of "same service" should be defined; e.g., animal toxicity for a small molecule analog of a cell receptor (for the treatment of disease "A").

The specific level of performance should be defined. This may include an acceptance provision and performance warranties. In addition, the service provider should provide representations (1) that the R&D activities will be conducted in a manner so as to not infringe any intellectual property, and (2) it will not develop a product that infringes on other's intellectual property rights. In many cases, these clauses

are limited to actual knowledge and will have territorial limitations such as the U.S. and China. The service



provider must agree to keep the service confidential and not to use the results of the service. For example, an important provision in the service contract is the representation that the service provider will not file a patent or trademark application on the technology provided to it or developed as part of the service contract.

### C. Audit Rights

For either a WFOE or an independent service provider, it is critical to have audit rights to frequently inspect the facility and electronic data. In many WFOEs, an employee of the parent is part of the management team in China. This employee is tasked with intellectual property compliance.

### D. Enforcement

The key to protecting intellectual property in China is enforcement. The fastest way to enforce intellectual property rights is through an injunction. An injunction is an equitable remedy that consists of an order by civil authorities preventing a person or an entity from doing something. In China, an injunction can be ordered by either a civil court or an administrative court. New rules are scheduled to take effect in 2008 in the State Intellectual Property Office (SIPO) of the People's Republic of China.<sup>3</sup>

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1. Zhou, *Contract Research Drives China's Pharma Sector*, Pharma Manufacturing.com (Aug. 2006)

2. <http://pac-us.tv/about.html>

3. <http://news.sina.cn/012007-10-09/094812693529.shtml>

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