Bright Ideas

A publication of the Intellectual Property Law Section of the New York State Bar Association

Message from the Chair

As I write this just a couple of days before the vernal equinox and the official end of winter (if not the actual end of winter; the current forecast calls for yet more snow), we can appreciate how the best laid plans remain subject to the whim of nature. Take, for example, our Section's Annual Meeting program, scheduled for January 27, which just happened to coincide this year with



Charles Weigell

the first of what would eventually be a number of major snow storms punctuating (!) this winter season.

We all recall how the storm led New York City to shut down preemptively on the evening of January 26. That night I attended the NYSBA Diversity Reception at the New York Hilton along with a fraction of the normal number of attendees. Afterwards, walking back to my hotel, the scene was almost surreal. Sixth Avenue in Midtown Manhattan was entirely deserted—there were almost no cars, very few people, and a light snow falling and adding to a white frosted landscape (which would soon change from white to gray and then to black in only a day or two).

Apart from giving the city a winter postcard feel, the storm also forced the cancellation of our Annual Meeting. The program was rescheduled for February 9, giving us only a short time to coordinate the various presentations and the schedules of the presenters, some of whom had traveled long distances to take part. We also were concerned that attendance would suffer because of the rescheduling.

Happily, and largely due to the efforts of NYSBA personnel as well as program co-chairs Ashford Tucker, Danielle Gorman, and Alexandra Goldstein, all of whom were chairing a large meeting for the first time, we pulled

everything together, and the rescheduled meeting was a great success. Despite frigid temperatures and more snow that morning, we had few cancellations, and nearly all of the original program speakers participated. Topics covered included patent post-grant review, advertising and social media compliance, the ethical rules applicable to inadvertent disclosures, international trademark registration strategies, and Supreme Court intellectual property cases. The program was highly informative, engaging, and very well received.

Rescheduling the Annual Meeting program was a test we passed with hard work and dedication. The same hard work and dedication is also going into organizing our schedule of programs for this year. The Section is presenting more programs and thereby engaging more of our membership than in previous years. In fact, the Section held three programs in March: On March 4 we held a four-hour workshop on professional development, with a networking reception afterwards, that attracted more than sixty attendees. This event was organized through the Diversity Committee; Committee Co-Chairs

Inside

Best Practices in Sharing Trade Secrets With Other Organizations and Their Employees	. 3
Federal Circuit Provides Guidance on Jury Instructions on Apportionment of Patent Damages (Kimberly J. Schenk and John G. Plumpe)	.11
When Worlds Collide: The Intellectual Property and Public Health Implications of Combating Counterfeit Pharmaceuticals	16
Second Circuit Deconstructs Architectural Works Copyrights (Michael A. Oropallo)	25
Scenes from the Intellectual Property Law Section	20



Deborah Robinson and Joyce Creidy did a fantastic job putting the program together. We also want to thank Viacom for hosting the event and reception in a beautiful conference space overlooking Times Square.

On March 12, the Advertising Law Committee held a panel discussion at Davis & Gilbert LLP, organized by Brooke Singer, co-chair of the Committee, on native advertising. Finally, on March 25, the International Intellectual Property Law Committee held an engaging and topical program on trademark protections in Cuba.

As the weather continues to improve, and the snows of the past winter recede into memory, the Section is committed to planning new events and programs. We co-sponsored programs in April on intellectual property issues in the auto industry (especially issues arising

from electronic content and platforms in cars) and on the basics of trademark law (the latter in partnership with the NYSBA CLE Section). We are planning a program in early May on trademark enforcement in China and one on June 16 on trade secrets. Stay tuned also for our annual Women in IP event in June and for the launch of our IP Law Section on-line communities page (through nysba.org) within the next couple of months.

Undaunted by rain, sleet, snow, or preemptive closures related thereto, the Section keeps moving ahead. If there are ways we can better connect with you as a member, or if there are program topics you would like to see more of, let us know. Or better yet, contact us and become involved.

Charles Weigell



Best Practices in Sharing Trade Secrets With Other Organizations and Their Employees

By Victoria A. Cundiff

I. Introduction

Many news accounts about trade secrets focus on threats from outside—hacking, spying, espionage—or on the risks which can result when key employees or groups move to competitors. Business and legal blogs are filled with stories detailing suits filed when competitors ranging from Bimbo Bakeries to IBM to Apple to Amazon.com to Texas Instruments to Medtronics to Motorola to talent agency IMG have asserted that by moving to competitors, key employees have diverted trade secrets, or at the least threaten to do so.

But true outsiders and former employees are not the only possible vectors for transmitting trade secrets. Business relationships with other businesses—joint ventures, suppliers, and even customers—and with prospective business partners, while facilitating the commercialization of ideas protected as trade secrets, can also put trade secrets at risk. Trade secrets law provides a remedy to the trade secrets owner against misappropriation by such "arms length insiders." As Professor Mark Lemley has observed in his oft-cited article The Surprising Virtues of Treating Trade Secrets as IP Rights, 61 Stan. L. Rev. 311, 335 (2008), one of the primary reasons to enforce trade secrets law is that by giving certain rights to the holder of the secret, trade secrets law allows him to disclose information he would otherwise have been unwilling to share and therefore permits business negotiations that can lead to commercialization of the invention or sale of the idea, serving both the disclosure and incentive functions of IP law.

An analysis of trade secrets litigation in federal courts suggests that 31% of the trade secrets claims filed in 2008 were directed to former business partners, with an even higher percentage from 1950-2007.¹

Some of the largest recent damages claims and awards for trade secrets claims arose where a party that received trade secrets in the course of exploring or conducting a business relationship continued to retain and use the trade secrets after the relationship came to an end. Frequently the same individuals who had learned the trade secrets under a non-disclosure agreement (NDA) went on to build competing products after the relationship came to an end—the same issue that parties who lose key employees focus on when enforcing non-compete agreements or asserting that misappropriation is "threatened" or even "inevitable." Recent findings of liability, damages awards, and injunctions underscore that businesses that are parties to NDAs must take their obligations seriously once the reasons for sharing the information have ended.²

Misuse of trade secrets following the demise of a business relationship also can lead to enterprise-threatening equitable relief. In *Airvana Network Solutions, Inc. v. Erics*-

son, Inc.,³ for example, Airvana supplied Ericsson with hardware and software to run large wireless data networks. Over time, Ericsson's predecessor, Nortel, took over supplying the hardware on condition that it would continue to use Airvana's software and pay royalties on any hardware built "based on" Airvana's confidential designs. Ericsson eventually discontinued using Airvana's software and paying royalties to Airvana. At the preliminary injunction hearing, Airvana offered evidence that the new Ericsson hardware was based on confidential Airvana design documents subject to Airvana's non-disclosure agreement with Ericsson.

While Ericsson asserted that the new hardware had been "independently" developed, the court found that in fact the starting point for the new hardware had been Airvana's drawings, even though the new hardware over time came to differ from the original Airvana hardware. Accordingly, the court found that Airvana was likely to prove its breach of contract claims (for which Airvana sought \$330 million in damages) and entered a preliminary injunction prohibiting Ericsson from using hardware allegedly based on Airvana's confidential designs unless the hardware was executing software licensed from Airvana. In support of its claim of irreparable harm, Airvana asserted that absent the injunction and the resulting royalty payments from Ericsson, Airvana would default on its bank covenants and go out of business. After subsequent motion practice over whether Ericsson was continuing to use the hardware in violation of the injunction, prompting Ericsson's assertion that it could lose its own \$3 billion contract with Sprint if it were held to be in contempt rather than found to be using its own designs, the matter settled on undisclosed terms.

Installing and following robust non-disclosure agreements is serious business when sharing business information. The prevalence of such post-breakup claims of misappropriation shows that businesses need to bring the same attention to guarding against unauthorized use of trade secrets when they enter into and unwind business relationships that they do when key employment relationships end.

II. Rule Number One for the Disclosing Party: Know Who Will Be Receiving Your Trade Secrets and Disclose Them No More Broadly Than You Intend

The owner of the purported secret must take reasonable precautions not to disclose the secret more widely than necessary for its own business purposes. There may be many legitimate reasons for a company to disclose information it views as secret: it may need to reveal some information to lenders or financial partners in order to satisfy

them that the investment makes sense, for example, and that the so-called innovation is not simply the equivalent of an unworkable perpetual motion machine. It may need to reveal some technical information (and receive reciprocal information) to a prospective joint venture partner to see whether the two technologies are compatible. It may choose to exploit its trade secret through licensing it to others. It may need to reveal design information to a prospective customer so that both parties can determine whether the proposed approach will satisfy their needs.

Before making any disclosures, however, the trade secrets owner should develop and follow a plan for controlling those disclosures. The process should begin by evaluating the company, and perhaps even the specific individuals, to whom disclosure is proposed to be made. Due diligence may reveal information suggesting whether the prospective recipient is a trustworthy counterparty. Does it have a history of entering into non-disclosure agreements with many industry players but never entering into an actual business arrangement? Does it announce "alliances" that never seem to progress? This history may suggest that a receiving party's interest is not so much in evaluating a potential transaction as in conducting competitive intelligence.

Has the prospective receiving party or its principals been sued, or sued others, for trade secrets misappropriation or for other forms of intellectual property misappropriation? What procedures does the receiving party have in place to safeguard its own confidential information? How scrupulously does it appear to follow these procedures? Detailed references to other third-party information during initial discussions may offer a clue that the receiving party does not always respect the agreements to which it is bound.

What non-disclosure agreements does the receiving party use for its own business? What other safeguards does it use?

The same issues that arise when key employees of the company leave to work for competitors are equally important in business-to-business disclosures, except that in many cases the employee receiving the trade secret in discussions already works for a competitor and will continue working for that competitor if joint activities break down. In light of that fact, the disclosing party should devote particular attention to considering what team does the receiving party propose to allow to access the information it will be receiving? Does the proposed team make sense in light of the disclosing party's business objectives? What other kind of work do these team members do? Does every team member need to have access to all of the trade secrets that are being disclosed? What restrictions are in place prohibiting team members from moving to a competitor? What restrictions may need to be put into place to prevent receiving team members from competing with the disclosing party, at least in a way that compromises the disclosing party's confidential information?

The concerns underlying the "inevitable disclosure" doctrine are not confined to concerns that the trade secret owners' own employees will necessarily call upon confidential information in a subsequent job. They should include the concern that outside recipients of trade secrets may be engaged in simultaneous or subsequent activities for the receiving party that could be improved through use of the trade secrets or that they will continue to pursue the objectives of the business arrangement under consideration in competition with the disclosing party if a final deal is not concluded.

In some cases, the disclosing party may want to require each recipient to enter into a non-disclosure agreement. At the least it will likely want the receiving party to maintain a list of the names and addresses of each recipient, and obtain confirmation that each recipient has been instructed as to the obligation to keep the information secret and to use it only for the specified purpose. The disclosing party may want to establish a plan for reaching out to recipients if the business relationship comes to an end to remind them of their ongoing obligations and to retrieve information that was provided under the NDA. The disclosing party may also want to negotiate a requirement that the recipients advise the disclosing party of any new employment during a specified period or even, where highly sensitive information is disclosed, an agreement that specific recipients of particular trade secret information will not engage in competing activity for a limited period.

Business recipients of confidential information need to keep these same concerns in mind. Regardless of the contractual obligations, thoughtlessly (or intentionally) assigning "tainted" employees to perform work that compromises trade secrets or continuing to refer to documents protected by an NDA once the business arrangement comes to an end can subject the receiving company to litigation and, ultimately, liability for trade secrets misappropriation, putting in jeopardy even independent work that winds up being commingled with the disclosing party's trade secrets.

III. Disclose Trade Secrets for a Reason and Document the Reason

Business discussions often proceed in stages. Limited information may be disclosed initially so that the parties can determine whether it makes sense to form an ongoing relationship. As time goes on, the parties may decide to proceed to establish a joint venture, or supplier, or customer relationship. More information is disclosed. Eventually the parties—or one of them—may "feel" that they have a new form of business relationship, but the original documentation remains in place. That documentation, though, may have expired or may no longer fit the relationship. The initial documentation, for example, may have imposed a time limit on non-use/non-disclosure obligations. Such a limitation may have made sense if only limited information having a short time value was disclosed. But as further disclosures are made, it makes sense to determine whether later disclosures should be subject to the same rules as the earlier disclosures.

Conversely, the disclosing party may intend that even as more information is disclosed, it should be used by the receiving party solely for the original limited purpose of deciding whether to enter into a more formal relationship. If that is the case, the disclosing party should first determine whether it makes sense to continue to disclose additional detailed confidential information while the potential relationship is still simply under evaluation. Second, the disclosing party must periodically underscore that the *only* use to which the information may be put is for evaluation. The receiving party may have concluded that the relationship has already reached a new level, permitting greater use of the information. Finally, if the disclosing party is in fact aware that the information is being used for other purposes, it needs to change the situation, either contractually or in fact. Otherwise, the receiving party may be able to make a showing that the trade secret owner acquiesced in the use.

IV. Keep Track of What Information Is Disclosed and Received

Often if a relationship never progresses, or if it unravels, the disclosing party will claim that it provided a vast array of confidential information subject to a non-disclosure agreement and that the information is at risk unless some form of injunction is entered. There may be a dispute about what was actually disclosed. As discussed below, it will be incumbent upon the trade secrets owner to identify in any litigation what trade secrets are alleged to be at risk, but the process of identifying what information is actually being shared, and what information is to be treated as a trade secret, is also critical at the contracting and disclosure stage, not simply in a lawsuit.

Depending on the reasons and scope of the disclosures, it may be feasible to clearly document and restrict the disclosures. For example, if an electronic "virtual data room" was established so that potential bidders could evaluate a company, the disclosing party can keep a copy not only of the universe of documents that was made available for review but also of the requests the receiving party made for information. Depending on the technical details of the data room, it may be possible to confirm what user code was used to access each particular piece of information, for how long and on how many occasions.

If the interaction unfolds over a longer period and is more interactive, the disclosing party still can use electronic measures to record many disclosures. Thus, for example, the disclosing party may consider establishing a secure "intranet" to which it controls access; this intranet will likely be able to generate and retain activity logs showing what information was provided and accessed. If disclosures took place over an extended period and in oral discussions as well as through documents, it may be appropriate for the disclosing party to prepare brief minutes of those discussions that can be used in the future to identify the information that was disclosed. Depending on the context of the discussions, it may make sense to circulate the minutes and get signoff to prevent future disputes. It

should be noted, however, in the documents that the minutes are simply that—brief notes, not verbatim accounts of each disclosure. These "minutes," of course, should also be designated as confidential information to be protected under the agreements.

If the parties are going to engage in actual discussions, rather than simply an exchange of documents, they should realize that formalistic requirements, such as the commonly suggested but rarely implemented provision that every trade secret disclosed orally must be identified as such in a subsequent writing, can be difficult, if not impossible, to follow. Such provisions are in practice often unworkable and may put the disclosing party at risk in a subsequent dispute. Instead, both the disclosing and the receiving party should try to keep and periodically share records that indicate the subject matter of the disclosures and listing documents provided, recognizing that they will not be entirely complete. If the contract between the parties requires specific formalities, however, those formalities should be scrupulously honored or amended. Otherwise, a disclosing party may be found to have waived its right to protection.⁴

The receiving party, of course, should have the same interest in documenting what it has received, and when, as the disclosing party. Whether contractually obliged to do so or not, it will be well-served by keeping records showing who within the organization has had access to what specific information. If the receiving party is considering a number of potential business partners, it should scrupulously segregate the information received from each disclosing party and should consider whether it is feasible to have different teams review the details of each party's disclosure rather than having a handful of employees gain trade secrets from multiple parties, increasing the likelihood that they will inadvertently use trade secrets of one or more disclosing parties once the discussions end. The use of consultants or retired or retiring internal experts who will not have ongoing responsibility for similar projects may make sense.

If it is clear that a more elaborate relationship is not going to be reached, the receiving party will want to insure that all confidential information it has received is returned or destroyed—even if the governing contract does not expressly require this step. It may be appropriate to protect both parties to request that the disclosing party keep a copy of all such material that is returned in the event of any disputes.

V. Be Sure To Identify What Information Is Supposed To Be Protected as a Trade Secret

A. Litigation Considerations

The threshold issue in any trade secrets dispute is "what's the secret"? "In order to obtain an injunction prohibiting disclosure of an alleged trade secret, the plaintiff's first hurdle is to show that the information it seeks to protect is indeed a trade secret." The requirement that the claimant identify its trade secret with specificity exists so that the defendant knows what constitutes the trade

secret so that it will not encroach upon that secret; so that the defendant can defend itself at any trial; and so that the court can make appropriate decisions about the scope of discovery and the contours of any injunction it may order. Stanford's Professor Mark Lemley observes that in trade secrets litigation, "plaintiff should be required to 'clearly define [] what it claims to own, rather than (as happens all too often in practice), falling back on vague hand waving." Recent caselaw from throughout the country has emphasized the critical importance of requiring the claimant to identify the trade secret at issue with particularity at an early stage of the lawsuit.

B. Identifying Information To Be Treated as a Trade Secret During Business Discussions

As critical as it is to identify trade secrets with particularity during litigation, it is at least equally important to identify information as a trade secret when it is being shared with third parties. Doing so can help prevent disputes from occurring at all. As the court explained in *Big Vision*:

The legal point here is not complicated. In order to avail itself of trade secret protection, Big Vision must have, at the absolute minimum, notified DuPont of its trade secret. It need not have said the words "trade secret" or put forth the same degree of detail as would be appropriate in litigation, but it must have done something. Big Vision indisputably made no such disclosure at the First Trial [its demonstration to DuPont]. It did not inform anyone orally or in writing of its alleged trade secret; it did not mark the [various documents it shared] as confidential; and it did not designate anything that happened at any [subsequent demonstration] as Confidential under the NDAs.... Its disclosure was so "vague and indefinite" that, as a matter of law, DuPont could not have been on notice of Big Vision's alleged trade secret (emphasis in original).9

To prevent such doubts, business parties who will be disclosing trade secrets to one another during the course of the relationship often agree on specific procedures for identifying what is to be treated as confidential. These measures can range from establishing virtual "storage rooms" containing the specific information at issue, with access to be controlled by the party owning the information and terminated at the conclusion of the business relationship, to setting forth legending and confirmation requirements, to setting up advisory alerts or committees to address issues as they may arise during the disclosure process, to holding periodic meetings to provide more specific guidance concerning what particular information is intended to be confidential. Some agreed approaches place the burden on the receiving party to challenge confidentiality designations within a specified time. For example, an NDA could require the receiving party to tell the disclosing party within [x] days of receiving information legended as confidential that the information is in fact already known to the receiving party and could establish procedures for verifying such a claim early on.

The procedures to identify information as confidential during the course of the business relationship need to match the purposes of the relationship, the sophistication of the parties, the nature of the information being disclosed, the reputation of the receiving party, and the practical willingness and ability of the parties to comply with the designation requirements. These issues should be carefully considered *before* the disclosures with both business people and lawyers. "One size fits all" usually doesn't.

Thus, as the court observed in *Big Vision*, had the plaintiff disclosed information about the chemical composition of its recyclable banners to a stranger who had no technology or background of its own in the field, a designation, whether in a written contract or orally at time of disclosure, that "everything related to recyclable banners is confidential" might have been appropriate. Since the disclosure was actually being made, however, to a party that had developed advertising banners for decades, held numerous patents in the field, and had at least two divisions in North America alone that were developing and testing the products, far greater specificity was required. In this circumstance, the court concluded, the disclosing party was required to do more than make a "unilateral declaration of confidentiality relating to an entire commercial field" to put a sophisticated, knowledgeable company like DuPont on notice of the limits of Big Vision's confidential information. Relying on Composite Marine Propellers, Inc. v. Van Der Woude, 10 the court found that much greater specificity of the information to be held in confidence is required when the receiving party already holds a patent in the field, lest the scope of the patent be unfairly diminished. Had specific information been identified to DuPont as confidential, the court suggested, DuPont either could have challenged the designation or known how to comply; as it was, the failure to identify the specific information to be protected constituted a failure to protect it. Allowing a party to "belatedly and unilaterally declare that 'everything we do is confidential" would be absurd and would create a "perverse incentive" not to engage in collaborative sharing of information.¹¹

The need to specify the contours of the information claimed to be confidential is of crucial importance whenever trade secrets are shared, whether with employees or third-party businesses. A non-disclosure agreement with an employee who may work in an organization over an extended period of years will likely be less prescient and specific about each type of confidential information the employee will receive than may be the case with an agreement to share information with another business for a time-limited, focused purpose. But the need to ensure that each person who receives trade secrets understands the full reach of the obligation to hold information in confidence is vitally important in both contexts. As to both employees and long term business partners, training programs throughout the

relationship illustrating what information falls within the "confidential information" category, appropriate legending, and thoughtful exit or wind-down procedures should help avoid doubt.

VI. Guidance for the Receiving Party: Benchmark the Knowledge Base on Hand and Document Independent Development

The receiving party already may have developed or otherwise learned substantial information relating to the subject matter of the discussions long before receiving a single disclosure under a non-disclosure agreement. If discussions fall apart, however, absent adequate records of the information that was already on hand, the receiving party may not be able to rebut claims that it has misappropriated the same information provided under a non-disclosure agreement. While many non-disclosure agreements include a provision exempting information that was already known to the recipient, the recipient will need to establish what information it already knew. A sophisticated recipient therefore might consider placing into escrow even before it receives a single disclosure a "snapshot" of the information it has independently gathered or developed. It should be mindful never to commingle the information received subject to a non-disclosure agreement with this escrowed information.

If the receiving party determines early on that the information it is receiving is information it already knew, it may decide that to prevent further misunderstandings it is prudent to so advise the disclosing party at once and to offer proof—even if the NDA does not require that it do so. Conversely, the disclosing party may want to include a provision in the non-disclosure agreement requiring the receiving party to notify it and provide proof within a specified period if it claims that it already knew or had developed the information prior to the disclosure.

Many non-disclosure agreements also provide a carveout for information that is independently developed or received from others having no duty of confidentiality to the disclosing party. The receiving party must recognize that the price of receiving information under a confidentiality agreement is the practical need to document the source of information received or developed outside the agreement that relates to the subject matter of information actually received. The burden typically will be on the receiving party to prove that particular information falls within a contractual carve-out.

Finally, to the extent that the receiving party engages in independent development work *after* receiving disclosures pursuant to a non-disclosure agreement, it should maintain documentation showing *who* did the independent development and *how*, relying on *what* resources. Whether or not the non-disclosure agreement requires it, the receiving party should strongly consider excluding from the independent development process individuals who have received confidential information that might assist that development process. Otherwise it may face the

claim, and worse, the reality, of actual misappropriation of trade secrets.

VII. Reduce Risks From Multiple Disclosures: Be Wary of Fixed Durations on Non-Disclosure Obligations

Sometimes a trade secrets owner might be simultaneously considering different potential business relationships and may, therefore, be making multiple simultaneous disclosures of the same information. That fact itself, of course, can place the information at practical risk. It can also increase legal risk. The trade secrets owner should appreciate that the initial agreements with unrelated parties may have an impact on its ability to protect its trade secrets later on even after it has entered into a final contract with one of the receiving parties. If, for example, it has entered into agreements with prospects a, b, and c providing that particular information is to be held in confidence for a one-year period, they will likely be free to use the information after one year even if prospect d ultimately enters into a long-term relationship and agrees to protect it for a longer period. A court may well conclude that by limiting the period that a, b, and c are to hold the information in confidence, the trade secrets owner cannot ask the court to treat the information as a trade secret beyond that period.

It may be more workable to specify that the information is to be held in confidence until such time as it becomes generally known as confirmed by the disclosing party upon request or to provide that that it must be returned and cannot be used or disclosed without further permission after the receiving or disclosing party advises in writing that the discussions are over.

VIII. Revise and Verify Compliance With Non-Disclosure Agreements as the Discussion Progresses: Avoiding Common Pitfalls

In many cases, of course, the initial discussions lead the parties to enter into a more formal relationship: a joint development agreement; a joint venture; a purchase or a sale; a license agreement; a strategic alliance. In drafting the new agreement reflecting the formal relationship, the parties should consider how best to implement and integrate the confidentiality obligations that may appear in multiple agreements.

Some drafters make the potentially disastrous, or at the least confusing, mistake of drafting an integration clause in a new agreement (e.g., a formal license agreement or operating agreement) that eviscerates earlier protections. Thus, the new agreement may contain a confidentiality provision but may further provide that it supersedes all prior agreements on the same subject matter or that it does not apply to information that was previously lawfully in the possession of the receiving party—that is, information that was previously disclosed only subject to a confidentiality agreement. If the new agreement is not carefully drafted to define confidential information to include all information that was already disclosed under a prior confidentiality agreements as well as under the new agreement,

the upshot may be a document that on its face makes the confidential information previously disclosed available for use. While the disclosing party may be able to persuade a court to take a commonsense approach to interpreting the obligations and to view them as cumulative rather than conflicting, careful drafting can prevent the need for motion practice or parole evidence on the subject.

Where multiple agreements address the protection of confidential information, it is also prudent to consider issues such as whether any of the agreements along the way include a fixed time limit on non-use/non-disclosure that should be addressed in the final agreement. For example, if an earlier agreement said that particular information should not be used or disclosed for two years post-disclosure, a joint venture agreement entered into during that two-year time period might state that notwithstanding any prior agreements, all confidential information previously provided by A to B shall be treated in accordance with the joint venture agreement, which would presumably extend the non-use/non-disclosure provision. An alternative approach that may make sense in some cases if the original restrictions were addressed to specific categories of information (e.g., financial information, technical information) is for the final agreement to state that specified agreements remain in effect.

When a final agreement is entered into, some disclosing parties go to considerable lengths to specify in detail the particular safeguards the receiving party must use to protect their information. Such precautions may be entirely appropriate, particularly if the receiving entity has not previously had to protect similar types of information. But the disclosing party must consider whether the receiving party is actually likely to implement the proposed safeguards. The "nuts and bolts" of protection need to be worked through together and most likely need to be the subject of continuing communications and policies.

Some companies engaging in business-to-business disclosures opt for efficiency by requiring the receiving party to treat the confidential information being disclosed under the NDA "in the same manner that it treats its own most sensitive information." Before agreeing to such a provision, it makes sense for the disclosing party to find out what those procedures are and how they may have changed and been enforced since the initial due diligence into the business partner. Agreeing that inadequate procedures will be followed as to new disclosures as well as to the recipient's own information simply reinforces inadequate measures.

If the final agreement includes a non-competition provision with the receiving entity as a means for protecting the trade secrets, the disclosing party should consider—and should evaluate against the patchwork of conflict state and international laws governing non-compete agreements—whether to also require that the employees of the disclosing party who will have the most intimate access to the disclosing party's trade secrets enter into non-competition agreements as a condition to gaining access to the information. The discussion may, at the very least, lead to

an agreement by the receiving party to narrow the number and functions of its employees who will be given access to the disclosing party's trade secrets. If the parties do agree to the use of post-disclosure restraints as to receiving employees, they will want to discuss and negotiate who has the right to enforce any such agreement.

IX. Precautions in Disclosing Trade Secrets in International Transactions

The precautions outlined above are equally important, if not more important, when dealing with business partners outside the United States. While non-disclosure agreements are a reasonable tool to be used in protecting trade secrets in the United States, they are not strictly required by law, and it is possible to establish a confidential relationship without entering into a contractual non-disclosure arrangement as a prerequisite. Many non-U.S. jurisdictions, however, place particular emphasis on the importance of using non-disclosure agreements to claim trade secrets rights. Further, many international business arrangements require that U.S. companies that engage individuals outside the United States to perform services for them contract with businesses—basically hiring parties—rather than directly with employees. The U.S. company may not have a direct relationship with the individual receiving access to the trade secrets. This means the disclosing party must put substantial care into negotiating agreements with any intermediary, including learning who has had access to the information and demanding return of information at the termination of the relationship. These written obligations can be particularly important when contracting abroad in order to enforce rights abroad or to enlist the aid of the International Trade Commission in enforcing trade secrets obligations.

While Congress continues to focus on whether to enact a Federal civil statute affording a private right of action for trade secrets misappropriation, the International Trade Commission has determined that Section 337 of the Tariff At of 1930, 19 U.S.C. § 1337, authorizes the International Trade Commission to investigate and remedy trade secret misappropriation that occurs in whole or in part in a foreign country where the complaint alleges that the products developed or manufactured through the misappropriation are being imported into the United States and threaten a domestic industry.¹² This determination was affirmed by the Federal Circuit in TianRui Group Company Limited v. International Trade Commission. 13 In TianRui the ITC found that the complainant had entered into non-disclosure agreements with the Chinese entity employing Chinese workers to exploit the intellectual property and had required the Chinese organization to bind the workers to these obligations. A competitor hired away the employees and used them to learn the complainant's trade secrets. After a 10day evidentiary hearing, the Administrative Law Judge found "overwhelming direct and circumstantial evidence that TianRui obtained its manufacturing process for cast steel railway wheel[s] through the misappropriation of [Amsted's] ABC Trade Secrets," primarily through inducing the employees retained in China to violate their nondisclosure agreements. The ITC found that this constituted trade secrets misappropriation and thus unfair competition under the Tariff Act and entered a limited exclusion order barring importation of goods made using trade secrets that had been disclosed in violation of the non-disclosure agreements.

The case has paved the way for additional investigations of trade secret misappropriation occurring outside the United States. ¹⁴ In each case, the information had passed because employees of third-party Chinese organizations with which the trade secret owner had entered into non-disclosure agreements had breached their non-disclosure obligations.

Recently the ITC affirmed a ruling in Certain Rubber Resins and Processes for Manufacturing Same, Inv. No. 337-TA-849 (ITC), that third-party contractors had misappropriated the complaining party's trade secrets even though it was hotly contested factually and legally in the ITC and in a parallel proceeding in China. Complainant SI Group Inc. ("SIG") alleged that competitor Sino Legend (Zhangjiagang) Chemical Col. Ltd. had acquired its secrets by poaching an employee from SIG's Shanghai office to steal SIG's trade secrets, enabling Sino Legend to replicate in short order a portfolio of rubber resins it had taken SIG over 25 years to develop. The employee was subject to a non-disclosure agreement between a Chinese organization under contract to Complainant. SIG first filed suit in China, but the employee denied he was employed by Sino Legend, and, SIG complained, the Chinese courts did little to help SIG in its investigations to sort through a veritable maze of Chinese companies. In the ITC, the ALJ determined that misappropriation had occurred, entering its decision the same day as a ruling by the Shanghai No. 2 Intermediate People's Court that much of the information at issue was not a trade secret and that misappropriation had not occurred.

The ITC affirmed the ALJ's determination as to some, but not all, of the accused products, accepting the finding that "this is classic misappropriation of trade secrets, with copying down to the thousandth decimal place." While respondent argued that the products it currently sold were different from the products as to which information had allegedly been misappropriated, the ITC found that the current products were largely derived from the misappropriated information and concluded that "it is our view that the overall combination of elements is protectable since it incorporates several valid trade secrets and has been misappropriated." The Commission followed Tian Rui's holding that it is an act of unfair competition under the Tariff Act for a party to ship goods into the United States made through trade secrets misappropriation as defined by Federal common law. After opening the matter to public comment as to an appropriate remedy, the full commission entered a ten-year limited exclusion order on January 16, 2014, rejecting respondent's argument that it would have taken only six months to develop the information at issue legitimately. "In fact, respondents were not successful in reverse-engineering most of Complainant's

process and resorted to hiring Complainant's employees in order to copy Complainant's processes." Each side has subsequently declared victory. Of critical importance, had the complainant not ensured that contracts were in place with the Chinese company employing the individuals who were privy to its trade secrets, it might not have been unable to prevail. While some relationships seem to be employment relationships, they need to be carefully scrutinized as business-to-business relationships as well, and the disclosing party must work to ensure that all necessary non-disclosure agreements and procedures are fully in place at each link in the chain of disclosure, not simply on paper but in fact.

X. Conclusion

Parties who disclose trade secrets in the course of business relationships need to be aware of, guide, limit, and investigate the flow of trade secret information for reasons outside the scope of the business relationship. "Inevitable disclosure" and "threatened misappropriation" concerns can be as important in the business context as in the employment context. When an employee who was authorized to receive information under a business-to-business non-disclosure agreement subsequently continues work for the receiving organization in which the information received under NDA could be useful or is actually used, all parties are potentially placed at risk. Disentangling from a business-to-business relationship poses the same risks and requires the same care at each step of the way as disengaging from any employment relationship.

Endnotes

- Almeling, Snyder, Sapoznikow, McCollum and Weader, A Statistical Analysis of Trade Secret Litigation in Federal Courts, 45 Gonzaga L. Rev. 291 (2009/10).
- See, e.g., Altavion, Inc. v. Konica Minolta Systems Laboratory Inc., 226 Cal. App. 4th 26 (2014) (affirming award of \$1.5 million in royalty damages and interest plus an award of more than \$3 million in attorneys' fees where defendant was found to have used information disclosed in confidential exploratory discussions to apply for patents on document authentication processes learned in discussions); Grail Semiconductor, Inc. v. Mitsubishi Electric and Electronics USA, Inc., 225 Cal. App. 4th 786 (Apr. 22, 2014) (affirming liability determination that defendants had misappropriated trade secrets disclosed in presentations exploring possibility of developing a business relationship and remanding for recomputation of damages because amount awarded did not take into account the fact that plaintiff had retained the ability to use the trade secrets itself); TechForward, Inc. v. Best Buy Co., Inc., Case No. CV 11-01313 ODW (JEMx) (C.D. Cal 2011) (awarding \$22 million in damages under an unjust enrichment theory; \$5 million in punitive damages; and \$5 million in attorneys' fees for breach of NDAs entered into in connection with exploring a business relationship); Wellogix, Inc. v. Accenture, LLP, No. 11-20816, 2013 WL 2096356 (5th Cir. May 15, 2013), cert. denied__ U.S. __, 2014 WL 834013 (June 9, 2014) (affirming award of \$26.2 million in actual damages and \$18.2 million in punitive damages; for breach of an NDA where internal Accenture documents urged "Use Wellogix content"; "better deliver similar or better functionality than Wellogix or we may have a problem," and referenced "harvesting IP" from Wellogix); Hallmark Cards Inc. v. Monitor Clipper Partners LLC, No. 4:08-cv-00840 (W.D. Mo. Nov. 19, 2012), aff'd, Case No. 13-1905 (8th Cir. July 15, 2014) (awarding \$21.3 million in actual damages and \$10 million in punitive damages where jury found that Monitor Clipper, a private equity firm, had used trade secrets learned by its affiliate Monitor Company

Group L.P., in work as a consultant to Hallmark, to guide its own purchase of a Hallmark competitor; this award came on top of a settlement payment to Hallmark of \$16.6 million in an arbitration directly against Monitor Company Group L.P. for its breach of the NDA with Hallmark), and *USA Power, LLC v. PacifiCorp, et al.*, No. 050903412 (Salt Lake Co. Utah May 22, 2012) (awarding \$134 million in damages where plaintiff charged that PacifiCorp and USA Power had initially worked together on a design for building a power plant but that once the relationship ended, PacifiCorp used plaintiff's confidential plans and information to build a power plant in the same area. PacifiCorp also hired plaintiff's lawyer, who worked for both companies simultaneously, as a means of acquiring additional information).

- 3. No. 650360/2012 (Sup. Ct. N.Y. Co. Mar. 19, 2013).
- 4. See generally, e.g., Big Vision Private Ltd. v. E.I. DuPont, No. 11 Civ. 8511 (KPF), 2014 WL 812820, *21 (S.D.N.Y. Mar. 3, 2014) (noting plaintiff's general failure to identify information as confidential during the disclosure process as required by the NDA and dismissing claim for misappropriation and breach of contract); Convolve, Inc. v. Compaq Computer Corp., 527 F. App'x 910, 925 (Fed. Cir.) (not precedential), cert. denied _U.S.__, 134 S. Ct. 801 (2013) (affirming summary judgment dismissing breach of contract and trade secrets claim because plaintiff did not follow the procedures set forth in the NDA to identify as confidential, and thereby protect, the information it shared, so no duty ever arose on the part of the receiving party to protect the information disclosed).
- DVD Copy Control Assn, Inc. v. Bunner, 116 Cal. App. 4th 241, 251 (2004).
- 6. See, e.g., Big Vision, 2014 WL 812820, *26; New Castle Beverage, Inc. v. Spicy Beer Mix, Inc., No. B249205, 2014 WL 2737814 (unpublished decision) (C.D. Cal. June 17, 2014) (noting that the trial court, in denying a requested injunction because the plaintiff had not identified its alleged trade secret with sufficient particularity, properly asked, "If I were [to] grant your [requested] preliminary injunction on the record as it stands right now, how would we ever know whether it was violated or not?").
- The Surprising Virtues of Treating Trade Secrets as IP Rights, 61 Stan. L. Rev. 311, 344 (2008), cited with approval in, e.g., Altavion, Inc. v. Konica Minolta Systems Laboratory Inc., 226 Cal. App. 4th 26 (2014).
- 8. See, e.g., Big Vision, 2014 WL 812820, *26 ("several district courts within this Circuit have adopted this particularity requirement and this Court now joins them"); Givaudan Fragrance Corp. v. Krivda, No. 08-4409 (PGS), 2014 WL 2109948 (D.N.J. Oct. 25, 2013) (dismissing most of plaintiff's claims for failure to identify trade

secrets with particularity, citing with approval the conclusion in *Sutra, Inc. v. Iceland Express, EHF,* 2008 U.S. Dist. LEXIS 52849, *8 (D. Mass. July 10, 2008), that "It is hornbook law that 'the parties and the court cannot accurately decide the question of whether a trade secret exists without first understanding what precisely is asserted as a secret."") (in the wake of this decision, the jury subsequently found against plaintiff on its remaining claims for trade secrets misappropriation, 2014 WL 987154); *Switch Comm'n Group v. Ballard*, 2012 WL 2342929, *5 (D. Nev. June 19, 2012) (gathering caselaw from throughout the United States demanding early particularized identification of trade secrets with particularity in trade secrets disputes).

- 9. 2014 WL 812820, *27.
- 10. 962 F. 2d 1263, 1266 (7th Cir. 1992) (per curiam).
- 11. Big Vision, 2014 WL 812820, *28.
- 12. The Tariff Act had long been interpreted to permit the ITC to act against trade secret misappropriation as an act of "unfair competition" upon a showing that the misappropriation threatens a domestic industry. See, e.g., Process for Manufacture of Skinless Sausage Castings 337-TA-169 (1983) (10 year exclusion order); Viscofan, S.A. v. U.S. Int'l Trade Comm'n, 787 F. 2d 544, 548 (Fed. Cir. 1986) (affirming ITC exclusion order). TianRui focused on a situation in which the alleged acts of misappropriation all occurred outside the United States.
- 661 F.3d 1322 (Fed. Cir. 2011), reh'g and reh'g en banc denied, 2012 U.S. App. LEXIS 4790 (Fed. Cir. Feb. 1, 2012).
- 14. See, e.g., In re Certain Paper Shredders, Inv. No. 337-TA-863 (Nov. 20, 2013), and In re Robotic Toys and Components Thereof, Inv. No. 337-TA-869 (July 9, 2013) (both concluding with settlement agreements imposing bans on further importation of products incorporating trade secrets at issue); Electric Fireplaces, Components Thereof, Manuals for Same, Inv. Nos. 337-TA-826/791 (2011/2012) (consolidated proceedings) (May 15, 2013) (banning the importation of electronic fireplace units made by the Chinese company Shenzhen Reliap through misappropriation of trade secrets and infringement of copyrighted drawings).
- Cf. "Victory for SI Group in Landmark ITC Case," http://www.siigroup.com/pressrelease.asp?ArticleID=189; "Victory in China Court and Limited Exclusion Order by ITC Final Determination," http://www.sinolegend.com/show.asp?articleid=283.

Victoria A. Cundiff is Chair of the Global Trade Secrets Practice Group at Paul Hastings LLP.





The 8th edition of the ILASA will take place on June 24 at the Crowne Plaza Hotel in New York City. It will gather over 500 senior representatives of the leading law firms, General Counsel, Chief IP Counsel, and Tax Directors from more than 40 countries. For further information, contacts and registration please visit http://ilasummit.com

Federal Circuit Provides Guidance on Jury Instructions on Apportionment of Patent Damages

By Kimberly J. Schenk and John G. Plumpe

I. Introduction

The recent decision by the Federal Circuit in *Ericsson v. D-Link*¹ provided guidance on several issues relevant to the calculation of patent damages. Much attention has been drawn to the fact that this decision was the first from the Federal Circuit to deal with the determination of reasonable and non-discriminatory ("RAND") royalty rates for standard essential patents ("SEPs"). However, the opinion also provides meaningful guidance on the issues of profit apportionment and the application of the *Georgia-Pacific* factors that can be applied to patent infringement cases not involving SEPs.

This article focuses on the court's guidance in *Ericsson* on properly instructing the jury on the entire market value rule ("EMVR") and profit apportionment. We begin by reviewing three notable prior cases in which the courts were faced with this issue. We then describe the Federal Circuit's ruling in *Ericsson* as it relates to apportionment and its suggestion that parties look to the Supreme Court's 1884 decision in *Garretson v. Clark*² when crafting jury instructions related to apportionment. We then review the relevant language in *Garretson* and conclude by offering practical advice for trial counsel when proposing jury instructions in cases that involve EMVR and/or apportionment issues.

II. Seymour v. McCormick (1854)

More than 150 years ago, the U.S. Supreme Court recognized the need to properly instruct the jury on issues of apportionment when calculating patent damages. In the 1854 case *Seymour v. McCormick*, the patents at issue related to "certain new and useful improvements in the machine for reaping all kinds of small grain" and "certain improvements upon the aforesaid patented reaping machine." The trial court's charge (i.e., jury instructions) contained the following direction for calculating damages:

It has been suggested by the counsel for the defendants, that inasmuch as the claims of the plaintiff in question here are simply for improvements upon his old reaping machine and not for an entire machine and every part of it, the damages should be limited in proportion to the value of the improvements thus made, and that therefore a distinction exists, in regard to the rule of damages, between an infringement of an entire machine and an infringement of a mere improvement on a machine. I do not assent to this

distinction. According to my view of the law regulating the measure of damages in cases of this kind, the rule which is to govern is the same whether the patent covers an entire machine or an improvement on a machine. Those who choose to use the old machine have a right to use it without incurring any responsibility; but if they engraft on it the improvement secured to the patentee, and use the machine with that improvement, they have deprived the patentee of the fruits of his invention, the same as if he had invented the entire machine; because it is his improvement that gives value to the machine on account of the public demand

On appeal, the defendant argued that "these rules with regard to damages, as thus laid down by the court, are incorrect, and have produced a verdict for most ruinous damages, far beyond any thing [sic] justified by the facts of the case." The Supreme Court agreed, being "of opinion that the plaintiffs in error have just reason of complaint as regards these instructions and their consequent result." It explained:

[T]he jury were instructed that the measure of damages for infringing a patented improvement on a machine in public use is the same as if the defendant had pirated the whole machine and every improvement on it previously made, and as a consequence that the plaintiff below had a right to recover as great damages for the infringement of the patent in his second count as if he had proceeded on both counts of his declaration and shown the infringement of all the patents claimed, and that in consequence of these instructions they have been amerced in damages to the enormous sum of \$17,306.66, and with costs to nearly the round sum of \$20,000.6

• • •

We think...that it is a very grave error to instruct a jury "that as to the measure of damages the same rule is to govern, whether the patent covers an entire machine or an improvement on a machine."

The Supreme Court thus reversed the trial court's judgment.⁸

III. Lucent v. Gateway (2009)

In this case, Lucent alleged that Microsoft infringed one of its patents through the sales and use of Microsoft Money, Microsoft Outlook, and Windows Mobile, based on the inclusion of a "date picker" feature in these products. At trial, Lucent's theory of damages was based on eight percent of sales revenue for the accused software products, and it asked the jury to award \$561.9 million based on Microsoft's infringing sales. Microsoft countered that a lump-sum payment of \$6.5 million would have been the correct amount for licensing the protected technology. The jury awarded Lucent damages of \$357.7 million. On appeal to the Federal Circuit, Microsoft argued, among other things, that the jury should not have applied the entire market value rule to the value of its three software products.

Amicus briefs were filed by a number of parties, including one by a group of ten technology-based companies that included SAP America, Inc., Bank of America Corporation, Coverity, Inc., Intel Corporation, Micron Technology, Inc., Palm, Inc., Regulatory DataCorp, Inc., Symantec Corp., Trimble Navigation Limited, and Yahoo! Inc.¹⁴ The brief stated:

The Supreme Court has historically policed the law of patent damages carefully to insure that patentees are not overcompensated or undercompensated. That Court has repeatedly admonished trial courts to provide legally coherent guidance to factfinders in cases involving complex patent damages. Amici here now ask this Court to reinvigorate this tradition. In particular, we ask the Court to require trial courts to act as vigorous gatekeepers when it comes to the introduction of damages evidence, and the instruction of juries on damages issues, in patent infringement cases.¹⁵

The amici made two main arguments: (1) the EMVR has no appropriate place in reasonable royalty calculations, and (2) portfolio licenses covering thousands of patents provide no basis for measuring damages for infringement of a single patent. The brief recommended that juries be guided by the following instruction:

Where a party's reasonable royalty calculation purports to be based on existing licensing norms that are expressed as a customary percentage times a customary royalty base, the party introducing such evidence must at a minimum show by a preponderance of the evidence that, as compared to the hypothetical license for the patent in suit, the licenses introduced as evidence show (i) a similar royalty base and (ii) a similar royalty percentage that has previously been used in (iii)

a similar license covering (iv) a similar patent.¹⁷

The amici argued that such an instruction was

essential to help juries make sense of and properly apply the amorphous list of *Georgia-Pacific* factors. Such an instruction would serve two functions. First, it would screen tendered evidence for legal salience, eliminating from jury consideration licenses that bear no reasonable relationship to the hypothetical license at issue in a particular reasonable royalty case. Second, it would help frame the evidence presented, calling the jury's attention to the importance of comparability, out of the welter of sometimes confusing information permitted under *Georgia-Pacific*. ¹⁸

Although the Federal Circuit called the amicus brief "informative," it concluded that it "need not address its assertion regarding jury instructions given or not given, for the simple reason that neither party at trial challenged any damages instruction that was given nor proposed an instruction and objected when it was not given." The court agreed with Microsoft's argument that substantial evidence did not support the jury's verdict, finding that to the extent the jury relied on an entire market value calculation to arrive at the damages amount, the award was not supported by substantial evidence and was against the clear weight of the evidence. Accordingly, the court vacated the award and remanded for a new trial on damages. In the control of the evidence of the evidence of the evidence of the evidence.

IV. VirnetX v. Cisco (2014)

In *VirnetX*, the Federal Circuit addressed the proper way to instruct the jury on the entire market value rule. This case involved four patents related to technology for providing security over networks such as the Internet.²² VirnetX's expert presented damages figures based on the application of several methodologies, including one that involved applying a one percent royalty rate to a royalty base consisting of the lowest sale price of each model of the accused devices containing the accused features.²³ This approach resulted in claimed damages of up to \$708 million.²⁴ At trial, the jury found that Apple infringed all four of the patents-in-suit and that none of the infringed claims were invalid.²⁵ It awarded reasonable royalty damages totaling \$368.2 million.²⁶

On appeal, Apple argued that the district court's jury instructions misstated the law on the EMVR. The district court had instructed the jury as follows:

In determining a royalty base, you should not use the value of the entire apparatus or product unless either: (1) the patented feature creates the basis for the customers' demand for the product, or the patented feature substantially creates the value of the other component parts of the product; or (2) the product in question constitutes the smallest saleable unit containing the patented feature.²⁷

The Federal Circuit "agree[d] with Apple that the district court's instruction misstates our law."²⁸ It explained:

To be sure, we have previously permitted patentees to base royalties on the "smallest salable patent-practicing unit." However, the instruction mistakenly suggests that when the smallest salable unit is used as the royalty base, there is necessarily no further constraint on the selection of the base. That is wrong. For one thing, the fundamental concern about skewing the damages horizon—of using a base that misleadingly suggests an inappropriate range—does not disappear simply because the smallest salable unit is used.

Moreover, the smallest salable unit approach was intended to produce a royalty base much more closely tied to the claimed invention than the entire market value of the accused products. Indeed, that language first arose in the *Cornell* case, where the district court noted that, rather than pursuing a "royalty base claim encompassing a product with significant non-infringing components," the patentee should have based its damages on "the smallest salable infringing unit with close relation to the claimed invention." In other words, the requirement that a patentee identify damages associated with the smallest salable patent-practicing unit is simply a step toward meeting the requirement of apportionment. Where the smallest salable unit is, in fact, a multi-component product containing several non-infringing features with no relation to the patented feature (as VirnetX claims it was here), the patentee must do more to estimate what portion of the value of that product is attributable to the patented technology. To hold otherwise would permit the entire market value exception to swallow the rule of apportionment.²⁹

Thus, the court concluded:

[T]he district court's jury instruction regarding the entire market value rule was legally erroneous. Moreover, that error cannot be considered harmless, as VirnetX's expert relied on the entire value of the iOS devices as the "smallest salable units," without attempting to apportion the value attributable to the VPN On Demand and FaceTime features. Thus, it is clear that the jury's verdict was tainted by the erroneous jury instruction.³⁰

For this reason and others, the court vacated the damages award and remanded for further proceedings.³¹

V. Ericsson v. D-Link (2014)

Ericsson was a suit for infringement of three of Ericsson's patents generally related to Wi-Fi technology employed by electronic devices for accessing the Internet.³² Ericsson's damages expert relied on previous Ericsson Wi-Fi licenses to determine a per-unit royalty for each licensed product.³³ The expert then applied his per-unit royalty to the accused products to calculate a reasonable royalty.³⁴ Before trial, D-Link moved to exclude certain portions of the expert's testimony, arguing that it violated the EMVR.³⁵ Specifically, D-Link argued that because the damages calculations were based in part on licenses that were themselves tied to the entire value of the licensed products, even though the technology being licensed related to only a component of those products, the testimony was impermissible as a matter of law.³⁶ In denying that motion, the district court explained that the expert's reference to the prior licenses was not improper because the expert properly apportioned any damages calculations based on those licenses to account for the value of the patents at issue.³⁷

D-Link had also proposed the following jury instruction regarding the EMVR:

Under the "entire market value" rule, a patent owner may recover a reasonable royalty based on the value of an entire apparatus or product containing several features, even though only one feature is patented. However, the "entire market value" rule only applies where the patent owner establishes that the patented feature creates the basis for customer demand or substantially creates the value of the component parts.³⁸

Ericsson objected to this instruction on the ground that the court had already held that the entire market value rule was not implicated in this case, ³⁹ and the court's final jury instructions did not contain an EMVR instruction. ⁴⁰

At trial, the jury found D-Link infringed the asserted claims of the three patents and awarded roughly \$10 million in damages—approximately fifteen cents per infringing device. After post-trial motions, the district court upheld the jury's infringement and validity findings and refused to grant a new trial based on an alleged violation of the EMVR and/or allegedly deficient jury instructions

regarding the standard-setting context and Ericsson's RAND licensing obligations derived from that context.⁴²

On appeal, D-Link argued that the district court prejudicially erred by not excluding Ericsson's damages expert's testimony on the challenged licenses. 43 Ericsson responded that the jury award was consistent with comparable Ericsson licenses and that the Federal Circuit had found comparable licenses to be the best evidence of a reasonable royalty rate.⁴⁴ Ericsson further argued that the jury award was consistent with "industry norms" and in accord with its damages expert's testimony. 45 According to Ericsson, its expert conducted a rigorous analysis that separated the value of the patents at issue from any other patents covered by the licenses he referenced. 46 Because of this apportionment, Ericsson asserted that neither its damages calculation nor its expert's reference to actual industry licenses was improper under the EMVR or otherwise.47

The Federal Circuit concluded that the district court had "properly admitted evidence of the licenses to which D-Link objects," but it went on to state that

when licenses based on the value of a multi-component product are admitted, or even referenced in expert testimony, the court should give a cautionary instruction regarding the limited purposes for which such testimony is proffered if the accused infringer requests the instruction. The court should also ensure that the instructions fully explain the need to apportion the ultimate royalty award to the incremental value of the patented feature from the overall product. ⁴⁹

The court acknowledged that the *Georgia-Pacific* factors, on which the jury was instructed, do include some reference to apportionment. But it observed:

[W]hile the court told the jury about the *Georgia-Pacific* factors—which do take the concepts of apportionment into account to some extent—it did not separately caution the jury about the importance of apportionment.... While factors 9 and 13 of the *Georgia-Pacific* factors allude to apportionment concepts, we believe a separate instruction culled from [*Garretson v. Clark*] would be preferable in future cases.⁵⁰

Elsewhere in the decision, the court referred to *Garretson* as "precedent which covers apportionment of damages in situations" in which the patents "claim only small portions of multicomponent products." It also cited *Garretson* for the proposition that "where multicomponent products are involved, the governing rule is that the ultimate combination of royalty base and royalty

rate must reflect the value attributable to the infringing features of the product, and no more"⁵² and that "a jury must ultimately 'apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features' using 'reliable and tangible' evidence."⁵³

In *Garretson*, the Supreme Court explained the requirements of apportionment as follows:

When a patent is for an improvement, and not for an entirely new machine or contrivance, the patentee must show in what particulars his improvement has added to the usefulness of the machine or contrivance. He must separate its results distinctly from those of the other parts, so that the benefits derived from it may be distinctly seen and appreciated. The rule on this head is aptly stated by Mr. Justice Blatchford in the court below: "The patentee," he says, "must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features, and such evidence must be reliable and tangible, and not conjectural or speculative; or he must show, by equally reliable and satisfactory evidence, that the profits and damages are to be calculated on the whole machine, for the reason that the entire value of the whole machine, as a marketable article, is properly and legally attributable to the patented feature."54

The patent at issue in *Garretson* involved an improvement in the method of moving and securing in place the movable jaw or clamp of a mop-head.⁵⁵ The plaintiff had produced no evidence to apportion the profits or damages between the improvement constituting the patented feature and the other features of the mop, instead providing evidence of only the cost of the whole mop and the price at which it was sold.⁵⁶ The trial court held that Garretson was entitled to only nominal damages, and the Supreme Court affirmed, noting that "of course it could not be pretended that the entire value of the mop-head was attributable to the feature patented."⁵⁷

VI. Discussion

Reasonable royalty damages cases often involve issues related to the application of the EMVR and apportionment. The Federal Circuit has made it clear that when trying a case where one or both of these issues is implicated, the jury must be provided with proper instructions on these complex topics.

Ericsson provides useful guidance for cases in which a patent holder relies on prior license agreements that include a royalty based on a percent of sales of a multi-

component product where the patented technology does not comprise the basis of the demand for the product. In such cases, the alleged infringer should request a cautionary instruction regarding the limited usefulness of these license agreements. *Ericsson* also provides guidance on how to instruct the jury on apportionment, in particular by modeling the instruction after the language the Supreme Court used in *Garretson*.

It can be expected that district courts, taking guidance from the Federal Circuit, will be more inclined to include specific jury instructions on the EMVR and apportionment in the future rather than relying on more generic instructions based on the *Georgia-Pacific* factors. Parties on both sides of cases should keep this in mind throughout the entire litigation process, particularly during the discovery phase. Collecting the evidence necessary to present a detailed case on EMVR and/or apportionment issues may require devoting additional resources to discovery, but it ultimately will help counsel present its damages case in a manner consistent with the charge given to the jury.

Endnotes

- Ericsson, Inc. v. D-Link Systems, Inc., 2014 U.S. App. LEXIS 22778, *51 (Fed. Cir. 2014).
- 2. Garretson v. Clark, 111 U.S. 120, 121 (1884).
- 3. Seymour v. McCormick, 57 U.S. 480, 485 (1854).
- 4. Id. at 486, 487.
- 5. *Id.* at 488.
- 6. Id
- 7. *Id.* at 490-91.
- 8. *Id.* at 491.
- Lucent Technologies, Inc. v. Gateway, Inc., 580 F. 3d 1301, 1308-09, 1337-38 (Fed. Cir. 2009).
- 10. *Id.* at 1323 (citing *Lucent Techs.*, 580 F. Supp. 2d at 1042 & n.7).
- 11. Id
- 12. Id. at 1309.
- 13. Id. at 1323.
- Brief for Ten Amici Curiae Technology-Based Companies in Support of Appellant Microsoft Corp., 22, Lucent Technologies., Inc. v. Gateway, Inc., 580 F.3d 1301 (Fed. Cir. 2009) (Nos. 2008-1485, -1486, -1487, -1495), 2008 U.S. Fed. Cir. Briefs LEXIS 168, *1.
- 15. *Id.* at *1-2.
- 16. *Id.* at *15, *25.
- 17. *Id.* at*3.
- Id. at *3-4 (citing Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970)).
- 19. Lucent Technologies, 580 F. 3d at 1339.
- 20. Id. at 1324.
- 21. Id. at 1340.
- VirnetX, Inc. v. Cisco Systems, Inc., 767 F. 3d 1308, 1314 (Fed. Cir. 2014).
- 23. Id. at 1325.
- 24. *Id.*
- 25. *Id.* at 1313.
- 26. Id.

- 27. Id. at 1327.
- 28. Id.
- Id. at 1327, 1328 (citing Laser Dynamics, Inc. v. Quanta Computer, Inc., 694 F.3d 51, 67 (Fed. Cir. 2012), and Cornell Univ. v. Hewlett-Packard Co., 609 F. Supp. 2d 279, 287-88 (N.D.N.Y 2009)).
- 30. Id. at 1328.
- 31. Id. at 1334.
- 32. Ericsson, 2014 U.S. App. LEXIS 22778, *4.
- Ericsson Inc. v. D-Link Corp., 2013 U.S. Dist. LEXIS 71564 (E.D. Tex. May 20, 2013).
- 34. Id.
- 35. Ericsson, 2014 U.S. App. LEXIS 22778, *50-*51.
- 36. *Id.* at *51.
- 37. Id.
- Ericsson, Inc. v. D-Link Systems, Inc., E.D. Tex., Case 6:10-cv-00473-RWS, Doc. 475-1.
- 39. Id
- Ericsson, Inc. v. D-Link Systems, Inc., E.D. Tex., Case 6:10-cv-00473-RWS, Doc. 504.
- 41. Ericsson, 2014 U.S. App. LEXIS 22778, *4.
- 42. Id.
- 43. *Id.* at *51.
- 44. Id. at *52.
- 45. *Id.* at *51.
- 46. Id.
- 47. Id.
- 48. Id. at *53.
- 49. Id. at *59.
- 50. Id. at *59-60.
- Id. at *70. The court also cited Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1318 (Fed. Cir. 2011), and Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1336 (Fed. Cir. 2009).
- 52. Ericsson, 2014 U.S. App. LEXIS 22778, *53.
- 53. Id. at *54.
- 54. 111 U.S. at 121.
- 55. Id.
- 56. *Id.*
- 57. *Id.* at 121-23.

Kimberly J. Schenk and John G. Plumpe are Principals in the Intellectual Property Practice of Charles River Associates (www.crai.com). They act as experts in the analysis of damages in intellectual property and complex commercial disputes. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates or any of the organizations with which the authors are affiliated. Any opinion expressed herein shall not amount to any form of guarantee that the authors or Charles River Associates have determined or predicted future events or circumstances, and no such reliance may be inferred or implied. The authors and Charles River Associates accept no duty of care or liability of any kind whatsoever to any party, and no responsibility for damages, if any, suffered by any party as a result of decisions made, or not made, or actions taken, or not taken, based on this article.

When Worlds Collide: The Intellectual Property and Public Health Implications of Combating Counterfeit Pharmaceuticals

By Amy Deroo

Introduction

In early 2012, counterfeit versions of the cancer drug Avastin infiltrated U.S. supply chains. Marketed in 120 countries for the treatment of colon, lung, kidney, and brain cancers, Avastin was Roche Holding AG's second best-selling drug that year. As a result, the scandal spread quickly. By February of 2013, the U.S. Food and Drug Administration ("FDA") reported that 134 U.S. doctors in 28 states had been hit with counterfeit versions of the lifesaving drug. By then, many unsuspecting cancer patients had already consumed the fakes, likely shaving months off their lives.

Meanwhile, another counterfeit drug scandal was brewing on the other side of the world. On May 13, 2013, Ranbaxy, a multinational generic pharmaceutical company, agreed to pay an unprecedented \$500 million in criminal and civil penalties to the FDA—the largest fine of its kind in history—after admitting that it sold adulterated drugs and falsified data for drug applications.⁵ The charges against Ranbaxy described systemic criminal practices at two of its largest manufacturing plants in India and involved an assortment of drugs, including antibiotics, acne medications, and drugs used to treat epilepsy and nerve pain.⁶ A little over a year later in November of 2014, yet another scandal broke when at least twelve women died at sterilization camps in central India.⁷ The likely culprit: "clearly spurious" antibiotics and painkillers given to the women after surgery.8

As these episodes demonstrate, the problem of counterfeit medicine is not confined to poorly regulated markets in developing countries, nor is it limited to small-time criminals in cottage industries. The global market for counterfeit pharmaceuticals generates upwards of \$75 billion each year, and the World Health Organization ("WHO") estimates that more than ten percent of all pharmaceuticals sold worldwide are counterfeit. Still, the worst may be yet to come. As the Ebola virus rips through Western Africa and beyond, so does the risk of counterfeit medicine. In times of pandemic, medicine supply is low, demand is high, and the opportunity for criminals to profit from putting fake drugs into the global supply chain is even higher.

Despite the high stakes, not much has been done to solve the problem. Because counterfeit medicine implicates public health and intellectual property issues, stakeholders remain deadlocked over how to reconcile issues of drug quality and access to affordable medicines with enforcement of intellectual property rights. Unfortunately, an unintended consequence of this battle has been

to facilitate the production and distribution of counterfeit medicine. Accordingly, this article suggests steps that can be taken to combat counterfeit medicine. Part I begins by classifying the various types of counterfeit medicines. Part II attempts to explain why international lawmakers have been unable to devise a universal definition of counterfeit medicine and the consequences of this for implementing a legal framework to tackle the problem. Part III explores additional challenges posed by counterfeit medicine worldwide. Finally, Part IV proposes potential new terms for a multilateral treaty designed to combat counterfeit medicine and discusses new ways to engage the pharmaceutical industry in the fight against counterfeits.

I. What Is Counterfeit Medicine?

Counterfeit medicine comes in a variety of forms. The most common forms include medicines containing no active ingredients, those with the wrong quantity of active ingredients, those containing different, often toxic, ingredients than the genuine product, and those that are exact copies of the genuine product. Other common forms of counterfeit medicine involve fake packaging. For example, counterfeiters frequently repackage expired genuine medication to reflect a legitimate expiration date. Similarly, so-called "hybrid counterfeits," or medicines made with recycled genuine ingredients, also have been identified as a frequently occurring type of counterfeit medicine.

Because counterfeiters have not limited their activities to any one category of drug, the risks posed by counterfeit medicines are widespread. Counterfeit drugs not only cost pharmaceutical companies approximately \$35 billion per year, but also expose drug manufacturers to liability and threaten brand integrity. 16 Likewise, the public health risks range from the relatively innocuous—as in instances of counterfeit "lifestyle drugs" such as sleeping pills or weight loss supplements, where the patient simply experiences no relief from symptoms—to serious illness and death, at times on a massive scale. 17 For example, cough syrup has been a popular target for counterfeiters who are able to easily replace the glycerin used in legitimate syrup with diethylene glycol, a cheaper, sweet-tasting industrial solvent used in antifreeze. 18 This toxic syrup was responsible for 365 deaths in Panama between 2006 and 2007.¹⁹ Similarly, at least 84 children died in Nigeria in 2009 after being given teething syrup poisoned with diethylene glycol.²⁰ Yet another risk arises where counterfeit drugs notably, antibiotics and antimalarials—contain the correct active pharmaceutical ingredients ("APIs") as the genuine product but in too low of a dose, thereby causing patients

to build up resistance to the drug and rendering future treatment ineffective.²¹ Finally, while counterfeits have surfaced in an assortment of medicines, the drugs hardest hit tend to be low in supply but high in demand. This point was illustrated in Kenya in 2011 when nearly 3,000 HIV/AIDS patients were affected by a fake, moldy batch of antiretroviral drugs.²²

II. Defining the Problem

Despite the serious threats to public health and intellectual property rights posed by counterfeit medicine, it remains unclear what legally constitutes counterfeit medicine. Currently, there is no universally agreed-upon definition of the term and, consequently, no coherent legal framework to properly address the problem.²³ As a starting point, the term "counterfeit medicine" is somewhat of a misnomer. Traditionally, the word counterfeit has been used in an intellectual property context and primarily in relation to trademark infringement.²⁴ Trademark infringement, in turn, applies to situations where a product appears too similar, either in brand name or appearance, to an existing product from the rightsholder's perspective.²⁵ Under international law, for example, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") defines counterfeit trademark goods, including counterfeit medicine, as:

Any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.²⁶

As noted above, however, a variety of defective medicines have been dubbed counterfeit. These deficiencies fall roughly into two categories: (1) substandard medicines and (2) fake medicines. According to the WHO, substandard medicines are "genuine medicines produced by manufacturers authorized by the NMRA (National Medical Regulatory Authority) which do not meet quality specifications set for them by national standards."²⁷ Substandard medicines may depart from quality standards in various ways, often as a result of negligence or human error—whether from contamination, poor packaging or storage protocols, or containing too little of an active ingredient.²⁸ Fake medicines, on the other hand, are deliberately and fraudulently mislabeled as to identity and source.²⁹ These medicines frequently contain no active ingredients and/or have been adulterated with toxic substances as part of a malicious criminal endeavor to imitate the genuine product at a cheaper price.³⁰ This understanding of the term fake medicine is consistent with the WHO's definition of counterfeit medicine:

One which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.³¹

Although counterfeiting in the purely intellectual property sense of trademark infringement can occur simultaneously with what is now known as counterfeiting in the public health sense of unsafe medicine, the issues are conceptually distinct and need to be treated as such for two reasons. First, unlike the average dispute over counterfeit goods, which generally is confined to remedying private economic losses to the rightsholder, counterfeit medicine involves danger to public health.³² From a public health perspective, the issue of drug quality is paramount, and, contrary to popular legal definitions, not all instances of counterfeit medicine involve trademark infringement.³³ Most notably, generic medicines, which by definition have no association with trademarks, are a popular target for counterfeiters.³⁴ Second, in the case of the typical trademark infringement dispute, the burden is on the rightsholder to pursue civil action in the event of infringement.³⁵ With counterfeit medicine, however, criminal measures are needed to properly deter people from engaging in malicious behavior that poses a threat to public health.³⁶

Nevertheless, these fundamental differences have not been accurately reflected in legal nomenclature. The main problem is that current legal definitions of counterfeit medicine are often overly broad—specifically, in failing to differentiate private, civil trademark infringement from deliberate, criminal counterfeiting.³⁷ For example, the Council of Europe's Medicrime Convention, a proposed treaty to criminalize the manufacture and trade of counterfeit drugs, framed the issue of counterfeit medicine so that "the term counterfeit shall mean a false representation as regards identity and/or source."38 Problematically, using such sweeping terms allows civil trademark infringement to be treated the same as criminal counterfeiting in the eyes of the law, which has in the past caused confusion for law enforcement relying on similarly broad legal definitions of counterfeit medicine.³⁹

The consequences of conflating these issues played out in the European Union in 2008 and 2009 when EU customs officials detained at least nineteen separate shipments of legitimate generic drugs in transit from India to Latin America, Oceania, and Africa. The shipments contained drugs used to treat HIV, heart disease, and other serious illnesses—none of which were patented in India or any of the other destination countries; the drugs therefore were legitimate generics lawfully in transit. Nevertheless, EU officials seized the shipments pursuant to European Council Regulation 1383/2003, which defines

counterfeit goods as "goods, including packaging, bearing without authorization a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holder's rights." Under this catchall definition, EU officials claimed that the generics were counterfeits since the drugs were still under patent in the EU. Ultimately, this example illustrates a key concern for policymakers: that access to affordable, legitimate generic drugs for developing countries will be hampered by placing an intellectual property label on a public health problem.

Perhaps the most troubling example of an overinclusive definition of counterfeit medicine surfaced in Kenya's 2008 Anti-Counterfeit Act, Section 2 of the Act defined counterfeiting as:

Taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods—(a) the manufacture, production, packaging, re-packaging, labeling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods.⁴⁵

By defining counterfeit in expansive terms such as "substantially similar copies of the protected goods," the Act left legally manufactured generic versions of medicines patented in Kenya vulnerable to being classified as counterfeit and blocked from importation.⁴⁶ Given that generics make up an estimated ninety percent of all medicines consumed in Kenya, the bulk of which are currently used to treat diseases such as HIV/AIDS, tuberculosis, and malaria,⁴⁷ the threat to public health in this case was particularly grave. Worse yet, despite its objective to "prohibit trade in counterfeit goods,"48 the Act had the opposite effect: by interfering with the availability of quality, affordable generic medicines, people were forced to turn to underground channels for relief. 49 In 2012, the High Court in Kenya finally responded to the controversy, ruling that the Act was "vague and could undermine access to affordable generic medicines," since it failed to clearly distinguish between counterfeit and generic medicines."50 Accordingly, the Court struck down the law, calling upon the legislature to "remove ambiguities that could result in arbitrary seizures of generic medicines under the pretext of fighting counterfeit drugs."51

The degree to which national definitions of counterfeit medicine vary adds another dimension to the problem. Consider the discrepancies in national standards for counterfeit medicine in bordering nations such as India and Pakistan. At one end of the spectrum, India has

distinguished the problem of fake drugs from substandard drugs, labeling the former "spurious" and including numerous types of illegitimate drugs in its definition.⁵² According to India's Drug and Cosmetics Act:

[A] drug shall be deemed to be spurious: (a) if it is imported under a name which belongs to another drug; or (b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or (c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product.⁵³

At the other end of the spectrum, Pakistan defines counterfeit drugs in intellectual property terms as "a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive, the label or outer packing of a drug manufacturer."⁵⁴ Given the global nature of counterfeit medicine, counterfeiters have been able to exploit variations in conflicting national legislation, carrying on their enterprise in nations whose laws do not cover such activities.⁵⁵ As such, harmonization is needed at the international level to ensure that counterfeit drugs do not slip through cracks in national legislation.

While there is no doubt about the need for a universal definition of counterfeit medicine that separates the intellectual property concept of trademark infringement from the public health issue of medicine quality, attempts by international lawmakers to craft such a definition have been largely unsuccessful. For example the WHO has not been able to gain worldwide support for its previous definitions of counterfeit medicine primarily because of the competing interests of stakeholders that make up the WHO's governance structure. ⁵⁶ As of 2012, the WHO's answer to this problem has been to merge the various concepts of counterfeit medicine into one: substandard/ spurious/falsely-labelled/falsified/counterfeit medicines ("SSFFC").⁵⁷ However, such an all-encompassing label is problematic because categorizing these distinct concepts together once again blurs the issue of intellectual property rights with safety and quality-control measures. While this label has not garnered much support, it remains the WHO's last word on the definition of counterfeit medicine.⁵⁸ Accordingly, lack of consensus on a clear definition of counterfeit medicine remains the initial barrier to

mobilizing a unified international approach to combating counterfeit medicine.

III. Contributing Factors and Challenges To Combating Counterfeit Medicine

To the counterfeiter, counterfeit medicine is the perfect crime: the profit margins are high, since active ingredients can be replaced by cheap ingredients, and the risk of getting caught is low because counterfeiting is difficult for the consumer to detect without sophisticated chemical analysis. The low barriers to entry on the supply side and corresponding rise in counterfeit medicine in recent years can be attributed to a number of factors. This section examines three of the most prominent ones: the complexity of the global supply chain, the Internet, and weak regulatory and enforcement regimes.

A. Complexity of the Global Supply Chain

In purely illicit distribution channels, counterfeiters often reach consumers directly in street markets. While these underground channels are problematic, they do not even begin to compare to the problems posed by infiltration of legal supply chains. Worth an estimated \$800 to \$900 billion a year, the legitimate pharmaceutical industry is far more lucrative and, consequently, a far more attractive target for counterfeiters.⁵⁹ Moreover, globalization of supply chains has made access to legitimate pharmaceutical supply chains much easier for counterfeiters. Because labor is cheap overseas, and, consequently, so are the drugs and APIs produced there, many pharmaceutical supply chains are outsourced abroad. 60 For example, in the United States approximately forty percent of prescription drugs are made elsewhere in the world.⁶¹ Likewise, around eighty percent of the sites that manufacture APIs used in drugs made in the United States are located outside U.S. borders.⁶²

But even cheap labor and cheap supplies come with a price: exports from overseas are not subjected to the same rigorous inspection protocol as medicines made and sold domestically.⁶³ As a result, eighty percent of all counterfeit drugs in the United States come from overseas, 64 and production of counterfeits is disproportionately high in countries where labor is cheap, with the world's largest shares of counterfeit medicines detected in China, India, and elsewhere in Southeast Asia. 65 India—the world's third largest pharmaceutical industry in terms of volume—exports more than half of its total pharmaceutical production.⁶⁶ Even though these exports are a substantial component of the Indian economy, export controls in India are lax compared to the scrutiny Indian officials give to products made for domestic use.⁶⁷ Likewise, although India is the second-largest exporter of over-the-counter and prescription drugs to the United States, many facilities that manufacture India's pharmaceutical exports do not comply with United States standards for quality control, inspection, and maintenance.⁶⁸ Accordingly, India has become a major hub for counterfeit medicine, and an estimated one in five drugs made in India is fake.⁶⁹

In addition, counterfeiters have been able to operate undetected easily due to the intricacies of the global supply chain, which make it difficult to pinpoint where breaches occur. For example, the average global supply chain has many different links, including suppliers of raw materials and packaging, manufacturers, warehousers, distributors, wholesalers, secondary wholesalers, pharmacies, retailers, hospitals, and so on.⁷⁰ Counterfeit drugs are introduced at various points through freight companies, importers, diverters, wholesalers, and individual purchasers.⁷¹ Typically, in the standard legitimate U.S. supply chain, medicines are sold directly by pharmaceutical companies to major authorized distributors.⁷² These distributors then supply the medicines to hospitals and pharmacies, where they are then distributed to patients.⁷³ Medicines also may move sideways from authorized distributors to secondary wholesalers. 74 As a result, hundreds of secondary wholesalers have access to prescription drugs before they reach the consumer.⁷⁵ Compounding the problem, drug supplies are often mixed in the exchange back and forth between secondary wholesalers and major wholesalers, making counterfeit drugs indistinguishable from their legitimate counterparts. ⁷⁶ Given the complexity of the global pharmaceutical supply chain and the involvement of many different players in many different locations, counterfeiters are often long gone before their crimes are even discovered.

B. The Internet

The Internet poses an enormous threat to the legitimacy of medicines. The convenience of e-commerce coupled with the high cost of prescription drugs has driven consumers to seek cheaper alternatives online. According to the WHO, over half of the medicines sold online in 2008 were counterfeit.⁷⁷ And the problem continues to worsen; in 2012, the National Association of Boards of Pharmacy reported that a staggering 96.61 percent of the 9,677 online pharmacies in the United States were illegitimate.⁷⁸

In the United States, the hallmarks of illegitimate online pharmacies include deep discounts; the ability to purchase medicines without a prescription; the absence of licensing by a state pharmacy board as well as of a licensed pharmacist on hand to answer questions; the absence of a physical address; and location outside the United States. 79 Specifically, as to location outside the United States, many rogue online pharmacies have infiltrated the market posing as "Canadian pharmacies" while actually operating from other countries.⁸⁰ This model has been especially attractive to counterfeiters due to the anonymity of the Internet and the ease with which websites can be created and destroyed.⁸¹ Moreover, because the machinery used to duplicate medicines easily can be purchased online, additional barriers to entry have been eliminated by the Internet.⁸² Ultimately, since the Internet is both pervasive and without territorial borders, more

concerted international efforts must be made in this area to curb counterfeit medicine.

C. Weak Regulatory and Enforcement Mechanisms

Because counterfeiting is opportunistic, it thrives where weak regulation and enforcement allow it to go unnoticed. According to WHO, of its 191 member states, only twenty percent are known to have well-developed drug regulations, while thirty percent either have no drug regulations or regulatory authorities have such limited capacity as to be effectively non-functioning.⁸³ Such patchwork regulation throughout the international community facilitates counterfeiting where counterfeiters are able to work their way into well-regulated countries via their poorly regulated counterparts. The United States illustrates this problem on a national level. In the United States, the FDA regulates drug approval and manufacturing exclusively, but it has allowed states to implement their own laws regarding drug distribution, repackaging, and dispensing.⁸⁴ This has been problematic for implementing effective anti-counterfeiting technology where, for example, only slightly more than half of the states require drug distributors to maintain pedigree systems that "track and trace" transaction histories of drugs they sell.⁸⁵ The purpose of such technology is defeated when counterfeit drugs are able to infiltrate legitimate distribution chains in states with no "track and trace" requirements. 86 Accordingly, minimizing regulation inconsistencies among the states—and, analogously, among countries at the international level—through a comprehensive, uniform approach is essential to combating counterfeit medicine.

Moreover, even in countries with developed regulatory oversight, enforcement efforts remain primitive. Often this is because the criminal penalties imposed are not strict enough to deter medicine counterfeiting. In the United States, for example, under the Food, Drug, and Cosmetic Act (FDCA), penalties for counterfeiting medicine (including adulteration and misbranding) are limited to: a misdemeanor violation carrying a maximum of one year in prison, a \$1,000 fine, or both; or a felony violation carrying a maximum three-year prison sentence, a fine not to exceed \$10,000, or both.⁸⁷ While counterfeit medicine may be subject to penalties carrying a maximum of ten years imprisonment under trademark law,88 prosecution under the FDCA is far more common.⁸⁹ Weak penalty schemes likewise have been a problem in the EU. For example, Allen Valentine, the leader of a British counterfeit drug ring that at one point was responsible for generating 500,000 fake tablets daily, was convicted on multiple charges of medical fraud but received only a meager five-and-a-half-year prison sentence.⁹⁰

Furthermore, enforcement measures are only as good as the people enforcing them. In China, where penalties for producing adulterated drugs are rather draconian—including the death penalty—rampant corruption precludes them from being meaningful deterrents. ⁹¹

For example, from 2003 through 2005, Zheng Xiaoyu, the director of China's State Food and Drug Administration at the time, was discovered to have accepted more than \$850,000 worth of bribes from eight pharmaceutical companies seeking expedited approval of new medicines and Good Manufacturing Practices certification. Pathough Zheng was subsequently executed for accepting bribes, his execution has been criticized as a political move by China to save its stature as the world's largest exporter of consumer goods rather than a sincere effort to clean up manufacturing practices. Consequently, a number of counterfeit medicine outbreaks and associated fatalities continue to stem from China, proving that even the strictest regulations are nothing without meaningful enforcement.

IV. Proposed Solutions

A. Treaty Legislation

Given the scope of the problem, there is no question that a treaty is needed to establish a set of harmonized international standards. Absent international agreement, it remains difficult to conduct cooperative cross-border investigations, extradite perpetrators from one country to another, and prosecute individuals and organizations in proportion to the global nature of their crimes. Of course, the starting point for enacting an effective agreement is to develop a more accurate definition of the problem—specifically, a definition that pertains to public health (or more precisely, drug quality) as distinct from trademark infringement.

Due to the friction between intellectual property rights enforcement and public health, the word "counterfeit" should not be associated with fake or substandard medicine. In this respect, the newly transposed EU Directive 2011/62, whereby "the term 'falsified' is used to distinguish infringement to intellectual property rights, so-called 'counterfeits'" is instructive and could serve as a model for multilateral treaty terms. ⁹⁵ This directive went into effect in January of 2013 and defines falsified medicines as:

Fake medicines that pass themselves off as real, authorized medicines. Falsified medicines might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose—either too high or too low. As they have not been properly evaluated to check their quality, safety and efficacy—as required by strict EU authorization procedures....⁹⁶

This is a step in the right direction and serves as a good baseline definition because it is less vague and speaks to the issue of drug quality as wholly distinct from intellectual property. However, a few crucial elements are missing from this definition—notably, a provision governing substandard medicines. A more constructive definition would further qualify falsified medicines as deliberate

and willful acts that—crucial to achieving proper deterrence levels—carry significant criminal penalties. Moreover, to avoid criminalizing unintentional mistakes by manufacturers, the term "substandard medicine" should be confined to unintentional or negligent errors, consistent with the WHO's current definition of substandard medicine.⁹⁷

This alternative offers a number of benefits to both intellectual property rights enforcement and public health. First, in separating criminal behavior from civil trademark infringement, the definition allocates the proper levels of deterrence needed to combat counterfeit drug crimes commensurate to the public health harm caused. Crucially, defining counterfeit medicine distinct from trademark infringement would merely add a criminal violation but would not eliminate separate claims for civil enforcement of intellectual property rights in instances where trademark infringement actually occurs. This not only has the advantage of eliminating the threat to legitimate generic medicines caused by sweeping language in current definitions, but also allows intellectual property rightsholders to benefit from the added level of deterrence from enhanced criminal sanctions while still maintaining claims for trademark infringement. Second, implementing an international standard would help compensate for the problem of patchwork regulation and gaps among nations, thereby reducing the opportunity for counterfeiters to seek out poorly regulated nations as havens for counterfeit activity. Finally, from a pragmatic standpoint, adopting the EU terms as a baseline would likely garner political support from major players in EU member states.

Nevertheless, the political and ideological divide across public health and intellectual property lines continues to be a major hurdle to even initiating talks of an international agreement, let alone reaching one. As such, it is critical that stakeholders learn from the shortcomings of recent global initiatives to combat counterfeit medicine before coming to the bargaining table. In this respect, a reoccurring issue has been lack of transparency. 98 For example, the Anti-Counterfeiting Trade Agreement (ACTA), a multinational treaty creating global intellectual property enforcement mechanisms, was written and negotiated behind closed doors from 2007 through 2010 by the United States, the EU, Switzerland, Canada, Australia, New Zealand, Mexico, Singapore, Morocco, Japan, and South Korea. 99 Although only a small number of countries participated in drafting the ACTA, its impact was intended to be global, with parties taking on stricter standards and enforcement obligations. 100 As a result, the ACTA has been heavily criticized by the public and developing countries alike. 101 These stakeholders argue that key terms such as "counterfeit" are never clearly defined, thus threatening access to generic medicines. 102 More generally, the ACTA's critics claim that the treaty caters to industrial groups with aggressive intellectual property

rights agendas without regard for public input. 103 Accordingly, currently only Japan has ratified the ACTA. 104

Moreover, even where multinational bodies such as the WHO have led efforts to form an international agreement, talks have broken down largely due to a perceived lack of neutrality on the issues. For example, in 2006 the WHO formed the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) as an international partnership between public and private sector actors with the goal of building "coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines."105 However, many member states criticized IMPACT, arguing that as a public health agency, the WHO should not be engaged in intellectual property enforcement measures. 106 IMPACT has since lost the WHO support and participation. ¹⁰⁷ Overall, a takeaway from these recent examples is that future treaty talks must be held in a more transparent and democratic forum (such as the WHO) and must be representative of all the issues at stake in order to gain universal support.

B. Engage the Private Sector

Because the legitimate pharmaceutical supply chain is such a popular target for counterfeiters, engaging the private sector in the fight against counterfeit medicine is imperative and something that can be done with or without a treaty. Beyond anti-counterfeiting technology, which can be costly, complex, and time-consuming to roll out, ¹⁰⁸ there also are inexpensive and more immediate avenues for the private sector to pursue. Public awareness campaigns using social media, for example, are costeffective and quick. 109 Given the amount of money spent by the pharmaceutical industry on direct-to-consumer advertising yearly, these campaigns also provide companies yet another platform to interact with consumers and bolster brand integrity. 110 Notably, Pfizer employed such a strategy in its 'Counterfeiters Are Smart. You Can Be Smarter' campaign, which features a video series on YouTube devoted to informing consumers about counterfeit medicine and its detection.¹¹¹ In this respect, it would behoove policymakers and regulators to team up with the private sector to help raise awareness to consumers; such measures not only would help protect public health but also would help protect intellectual property rights.

Above all, the pharmaceutical industry must make more of an effort to secure supply chains. Pharmaceutical companies may be influenced to do this through the tort system. Previously, manufacturers could avoid liability for harm caused by counterfeit medicine by arguing that criminal counterfeiting was an unforeseeable intervening criminal act. However, the 2011 case of *Johansen v. Baxter Healthcare Corp.* has signaled a change in the standard of care pharmaceutical companies must take with respect to their supply chains. *Johansen* stemmed from the 2007 contamination of Baxter's blood thinner, heparin. Specifically, in 2007, after receiving multiple reports of

patients suffering allergic reactions after taking heparin, scientists discovered that heparin's API had been contaminated with oversulfated chrondroitin sulfate, a synthetic compound with anticoagulant properties that mimic heparin. Baxter had obtained these ingredients from Chinese suppliers, and its previous quality tests had not detected the contaminant. 116

As such, Baxter claimed that an unidentified third party intentionally introduced the sulfate into Baxter's heparin supply chain in China, thereby relieving Baxter of liability. However, the plaintiff argued that Baxter could have both foreseen the contamination given the prevalence of counterfeiting in China and prevented it by using better quality-control processes, impurity identification procedures, and supervision of its supply chain. Ultimately, the plaintiff prevailed on this theory and received a jury award of \$625,000 in damages. How Accordingly, the tort system has the potential to deter counterfeit medicine and all the intellectual-property and publichealth problems that come along with it by inducing pharmaceutical companies to employ higher standards of care in their global supply chains.

V. Conclusion

Touching both the developed and developing worlds, brand names and generics, lifesaving and lifestyle drugs, and so on, the problems caused by counterfeit medicine are far-reaching. At the heart of the matter, efforts to ensure the quality and safety of medicine are pitted against concerns over enforcing intellectual property rights. Understanding that these conflicting interests likely won't be resolved overnight, this article set out to analyze past and current legal and policy issues associated with counterfeit medicine in hopes of learning from prior mistakes and aligning the interests of various stakeholders. Among the findings, there is little doubt that an international agreement is needed to tackle what has become an enormous transnational issue. Such an agreement must begin by defining counterfeit medicine in terms separate from trademark infringement. Supplementing a new definition with provisions addressing the challenges discussed in this article—complex global supply chains, the Internet, and enforcement measures and regulatory authority—also will be vital to an international agreement on counterfeit medicine. Ultimately, while an international treaty is desirable in the long run, other more immediate options exist, including engaging the private sector in the global fight against counterfeit medicine.

Endnotes

- Associated Press, Counterfeit Avastin: FDA Warns of New Batch of Fake Cancer Drug, HUFFINGTON POST (Feb. 6, 2013, 5:12 AM), http:// www.huffingtonpost.com/2013/02/06/counterfeit-avastin-fakecancer-drug-fda_n_2633123.html.
- 2. *Id*
- 3. S. Imber, *Update on Fake Avastin—FDA Warnings in 28 States,*Six Prosecutions, SafeMedicines.org (Feb. 5, 2013), http://www.

- safe medicines. org/2013/01/fda-warnings-in 28-states-six-prosecutions-511. html.
- See Christopher Weaver & Jeanne Whalen, How Fake Cancer Drugs Entered U.S., WALL St. J. (July 20, 2012, 3:02 PM), http://online.wsj. com/articles/SB10001424052702303879604577410430607090226.
- Press Release, U.S. Dept. of Justice, Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013), http://www.justice.gov/opa/pr/2013/ May/13-civ-542.html.
- Id
- Suhasini Raj & Ellen Barry, Post-Mortems of Victims Point to Tainted Medication in India Sterilization Deaths, N.Y. TIMES (Nov. 13, 2014), http://www.nytimes.com/2014/11/14/world/asia/tainteddrugs-suspected-in-india-sterilization-deaths.html?_r=0.
- 8. Id
- 9. *See, e.g.*, Weaver & Whalen, *supra* note 4 ("'The Avastin case was a watershed moment for law enforcement to recognize that this is not a problem that can be restricted to one part of the world."").
- World Health Org. [WHO], Growing Threat from Counterfeit Medicines, 88 Bull. Of the World Health Org. 241, 247–48 (2010), available at http://www.who.int/bulletin/ volumes/88/4/10-020410/en/ [hereinafter Growing Threat].
- 11. See Michelle Ratpan, Counterfeiting Ebola: Fakes, Frauds and Other Malarkey, OpedSpace (Oct. 15, 2014), http://opedspace.com/2014/10/15/counterfeiting-ebola-fakes-frauds-and-other-malarkey/ ("The current Ebola outbreak...has resulted in more than 8,300 confirmed and suspected cases, and more than 4,000 deaths...[i]t is at this moment, in the face of the ever-spreading Ebola virus, that the risk of proliferation of counterfeit medications should be paramount on our minds.").
- WHO, Spurious/Falsely-Labelled/Falsified/Counterfeit (SSFC) Medicines (2010), available at http://www.who.int/mediacentre/factsheets/fs275/en/ [hereinafter SSFC Medicines].
- 13. K. Degardin, et al., *Understanding and Fighting the Medicine Counterfeit Market*, 87 J. Pharm. Biomed. Anal. 167, 169 (2013).
- 14. Id.
- 15. Id.
- Pharmaceutical Counterfeiting, Tampering, and Diversion: Solutions for Addressing a Growing Threat, JDS UNIPHASE CORP., at 7–8 (2013), http://www.jdsu.com/ProductLiterature/Pharmaceutical_White_ Paper.pdf.
- 17. See Amir Attaran, How to Achieve International Action on Falsified and Substandard Medicines, British Med. J. (Nov. 13, 2012), http://www.bmj.com/content/345/bmj.e7381#ref-16.
- Adam Powell, Benchmark Legislation: A Measured Approach in the Fight Against Counterfeit Pharmaceuticals, 61 HASTINGS L.J. 749, 755 (2010).
- 19. Id.
- Lydia Polgreen, 84 Children Are Killed by Medicine in Nigeria, N.Y. TIMES (Feb. 6, 2009), http://www.nytimes.com/2009/02/07/ world/africa/07nigeria.html?_r=2&scp=2&sq=nigeria&st=cse&.
- 21. SSFC Medicines, supra note 12.
- HIV/AIDS in Kenya: Majority of Patients with Suspect Zidolam-N Receive Follow-up Consultations, Medecins sans Frontieres (Nov. 30, 2011), http://www.msf.ca/themes/news-reader/2011/11/hivaids-in-kenya-majority-of-patients-with-suspect-zidolam-n-receive-follow-up-consultations/.
- See Marv Shepherd, Beef Up International Cooperation on Counterfeits, 16 Nature Med. 366, 369 (2010), http://www.nature.com/nm/ journal/v16/n4/full/nm0410-366.html.
- 24. WHO, GENERAL INFORMATION ON COUNTERFEIT MEDICINES, http://www.who.int/medicines/services/counterfeit/overview/en/ (last visited Nov. 1, 2014) [hereinafter General Information].

- 25. Charles Clift, Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?, Chatham House Ctr. on Global Health Security, at 5–6 (Nov. 2010), http://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/1110bp_counterfeit.pdf.
- TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 51, Footnote 14, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
- WHO, WHAT ARE SUBSTANDARD MEDICINES?, http://www.who.int/medicines/services/counterfeit/faqs/06/en/ (last visited Nov. 1, 2014) [hereinafter WHAT ARE SUBSTANDARD].
- 28. Clift, supra note 25, at 11.
- 29. General Information, supra note 24.
- 30. Id.
- 31. *Id*.
- 32. See Clift, supra note 25, at 6.
- 33. See Tariq Almuzaini, Imti Choonara & Helen Sammons, Substandard and Counterfeit Medicines: A Systematic Review of the Literature, 3 BMJ Open 1 (2013), http://bmjopen.bmj.com/content/3/8/e002923.full.pdf+html.
- 34. See Clift, supra note 25, at 6.
- 35. *Id*.
- 36. Id.
- 37. Roger Bate & Amir Attaran, *A Counterfeit Drug Treaty: Great Idea, Wrong Implementation*, Am. Enter. Inst. (Oct. 29, 2010), http://www.aei.org/publication/a-counterfeit-drug-treaty-great-ideawrong-implementation/.
- European Commission on Crime Problems, Draft Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health, at 4 (Nov. 9, 2009), available at http://www.coe.int/t/dghl/standardsetting/medicrime/ CDPC%20_2009_15Fin%20E%20Draft%20Convention%2009%20 11%2009CM.pdf.
- 39. See, e.g., Monika Ermert, Medicrime: Another Anti-Counterfeiting Convention Emerges in Europe, IP WATCH (Apr. 24, 2010), http:// www.ip-watch.org/2010/04/24/medicrime-another-anticounterfeiting-convention-emerges-in-europe/ (""[F]alse representation as regards source' where source should, according to the explanatory report to the convention, be understood in a 'wide sense,' as well as the term 'counterfeit' itself which is used by the WTO with respect to trademark infringement.").
- Gian Luca Burci, Public Health and "Counterfeit" Medicines: The Role of the World Health Organization, 17 INSIGHTS 1, 2 (2013), http:// www.asil.org/insights/volume/17/issue/2/public-health-and-"counterfeit"-medicines-role-world-health-organization.
- 41. Press Release, Government of India Ministry of Commerce and Industry, India EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit (July 28, 2011), http://pib.nic.in/ newsite/erelease.aspx?relid=73554 [hereinafter Seizure of Indian Generic Drugs in Transit].
- EC No. 1383/2003, Art. 2(a), available at http://eur-lex.europa.eu/ LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF.
- 43. See Seizure of Indian Generic Drugs in Transit, supra note 41.
- ROGER BATE, MAKING A KILLING: THE DEADLY IMPLICATIONS OF THE COUNTERFEIT DRUG TRADE 61 (2008).
- 45. The Anti-Counterfeit Bill, (2008) (Kenya), available at http://infojustice.org/wp-content/uploads/2012/04/Kenya-AC2008.pdf [hereinafter Kenya Anti-counterfeit Bill].
- See AIDS Law Project, Generic Drugs Save Lives: Intellectual Property and Access to Essential Medicines (2011), available at

- http://www.aidslawproject.org/wp-content/uploads/2013/03/ALPComic-Booklet2011.pdf.
- 47. Id
- 48. Kenya Anti-counterfeit Bill, supra note 45.
- 49. Id.
- Kenyan High Court's Overturning of Anti-Counterfeit Law Hailed, IP WATCH (Apr. 21, 2012), www.ip-watch.org/2012/04/21/kenyan-high-courts-overturning-of-anti-counterfeit-law-hailed/.
- 51. Id.
- See The Drugs and Cosmetics Act, No. 23 of 1940, INDIA CODE (1982), available at http://indiacode.nic.in.
- 53. *Id*
- 54. General Information, *supra* note 24.
- 55. See Bate, Making a Killing, supra note 44.
- 56. See Burci, supra note 40.
- 57. Id.
- 58. Id.
- 59. Barbara Moran, Cracking Down on Counterfeit Drugs, PBS (Aug. 20, 2013), http://www.pbs.org/wgbh/nova/next/body/uncovering-counterfeit-medicines/.
- 60. Robert Handfield, *Major Trends Impacting the Pharmaceutical Supply Chain Ecosystem*, NC State Supply Chain Res. Coop. (Mar. 29, 2014), http://scm.ncsu.edu/blog/2014/03/29/major-trends-impacting-the-pharmaceutical-supply-chain-ecosystem/.
- 61. Counterfeit Drugs: Fighting Illegal Supply Chains: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm on Energy and Commerce, 113th Cong. (2014) (statement of Howard Sklamberg, Deputy Comm'r for Global Regulatory Operations and Policy, Food and Drug Admin., Dep't of Health and Human Servs.).
- 62. Id.
- 63. See Michael Bennet, How Safe is Your Medicine Cabinet?, POLITICO (Sept. 13, 2011, 9:46 PM), http://www.politico.com/news/stories/0911/63405.html ("In some cases, drug makers buy ingredients from foreign suppliers without actually knowing who those suppliers are. As a result, products show up on our shelves that do not meet basic U.S. safety standards.").
- 64. Moran, supra note 59.
- Brian D. Finlay, Counterfeit Drugs and National Security, STIMSON, at 9 (2011), available at http://www.stimson.org/images/uploads/ research-pdfs/Full_-_Counterfeit_Drugs_and_National_Security. pdf.
- Mandar Madhukar Kodugle, Growth of Indian Pharmaceutical Industry: Impact of Indian, US and European Patent Laws and Regulatory Requirements, 44 Pharma Times 45 (2012).
- Saurabh Verma, Rajender Kumar & P.J. Philip, The Business of Counterfeit Drugs in India: A Critical Evaluation, 4 INT'L J. OF MGMT. & INT'L BUS. STUD. 141, 145 (2014).
- 68. See Gardiner Harris, Medicines Made in India Set Off Safety Worries, N.Y. TIMES (Feb. 14, 2014), http://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries. html?_r=0 (reporting that the FDA found "conditions such as flies 'too numerous to count' in critical plant areas" while inspecting a major Indian pharmaceutical manufacturing facility). Moreover, in an interview, India's Drug Controller General, G.N. Singh, reportedly stated: "[i]f I have to follow U.S. standards in inspecting facilities supplying to the Indian market, we will have to shut almost all of those." Sushmi Dey, If I follow US Standards, I Will Have to Shut Almost All Drug Facilities: G N Singh, Bus. Standard (Jan. 30, 2014), http://www.business-standard.com/article/economy-policy/if-i-follow-us-standards-i-will-have-to-shut-almost-all-drug-facilities-g-n-singh-114013000034_1.html.
- 69. Harris, supra note 68.

- Cynthia Challener, Acute Need for Supply Chain Transparency, PHARMTECH (Aug. 4, 2014), http://www.pharmtech.com/ pharmtech/QC%2FQA/Acute-Need-for-Supply-Chain-Transparency/ArticleStandard/Article/detail/850754.
- 71. Peggy E. Chaudhry & Stephen A. Stumpf, *The Challenge of Curbing Counterfeit Prescription Drug Growth: Preventing the Perfect Storm*, 56 Bus. Horizons 189, 191–92 (2013).
- 72. Id.
- 73. *Id*.
- 74. Id.
- 75. Id.
- 76. Id.
- 77. *Growing Threat, supra* note 10.
- 78. NAT'L ASS'N OF BDS. OF PHARMACY, INTERNET DRUG OUTLET IDENTIFICATION PROGRAM: UPDATED PROGRESS REPORT FOR STATE AND FEDERAL REGULATORS, at 4 (2012), available at http://www.nabp.net/news/assets/IDOIReportApril11.pdf.
- 79. The Counterfeit Drug Problem, PHRMA, http://www.phrma.org/counterfeit-drugs (last visited Nov. 1, 2014).
- 80. See Powell, supra note 18.
- 81. Id.
- 82. See Chaudhry & Stumpf, supra note 71, at 192.
- 83. General Information, supra note 24.
- 84. Press Release, U.S. Senate Committee on Health, Education, Labor, & Pensions, Senate, House Health Policy Leaders Announce Bipartisan, Bicameral Legislation to Address High-Risk Drug Compounding Practices and Secure the Pharmaceutical Supply Chain (Sept. 25, 2013), http://www.help.senate.gov/newsroom/press/release/?id=549b94cd-bca0-470d-aa39-3cfe1cea055f.
- 85. Id.
- 86. Id.
- 87. See 21 U.S.C. § 333(a).
- 88. See 18 U.S.C. § 2320(a)(1).
- Pew Health Grp., After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs, at 53 (2011), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/ Reports/Health/Pew_Heparin_Final_HR.pdf.
- P'ship for Safe Medicines, Counterfeit Drugs in Europe Fact Sheet (2005), available at http://www.safemedicines.org/resources/ europe.pdf.
- 91. Chenglin Liu, Leaving the FDA Behind: Pharmaceutical Outsourcing and Drug Safety, 48 Tex. Int'l L.J. 1, 21 (2012).
- 92. Id. at 22.
- Joseph Kahn, China Quick to Execute Drug Official, N.Y. Times (July 11, 2007), http://www.nytimes.com/2007/07/11/business/ worldbusiness/11execute.html?pagewanted=all.
- 94. See Liu, supra note 91.
- 95. Falsified Medicines, European Comm'n, http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm#geninf (last revised July 2013).
- 96. Council Directive 2011/62/EU (2011).
- 97. See What are Substandard, supra note 27.
- 98. Carolina Rossini, Maira Sutton & Gwen Hinze, Anti-Counterfeiting Trade Agreement, Electronic Frontier Found., https://www.eff.org/issues/acta (last revised Aug. 2013).
- 99. Id.
- 100. Id.
- 101. See Anti-Counterfeiting Trade Agreement Could Endanger Lives of People Needing Affordable Medicines, Oxfam Int'l (June 29, 2010),

- http://www.oxfam.org/en/pressroom/pressrelease/2010-06-29/acta-could-endanger-lives-people-needing-affordable-medicines.
- 102. Id.
- 103. Id.
- 104. Rossini, et al., supra note 98.
- 105. WHO, Int'l Medical Prods. Anti-Counterfeiting Taskforce, http://www.who.int/impact/about/en/ (last visited Nov. 1, 2014).
- 106. Tim K. Mackey, Global Health Diplomacy and the Governance of Counterfeit Medicines: A Mapping Exercise of Institutional Approaches, 1 J. Health Diplomacy 1, 13 (2013).
- 107. Id.
- 108. For example, in 2010, global sales of anti-counterfeiting packaging technologies reached \$64 billion. This value is projected to be at \$74.2 billion by 2015. See Dipika Bansal, Swathi Malla, Kapil Gudala & Pramil Tiwari, Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective, 81 SCIENTIA PHARMACEUTICA 1, 1–13 (2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3617666/.
- 109. Mark Davison, *Protecting and Educating Consumers, in*Pharmaceutical Anti-Counterfeiting: Combating the Real Danger from Fake Drugs 51–54 (2011).
- 110. See id.
- 111. Press Release, Pzifer, Facing Off Against Counterfeit Online Pharmacies: Pfizer Launches New Purchasing Website To Help Alleviate the Guesswork Around Buying Legitimate Viagra Online (May 6, 2013), http://press.pfizer.com/press-release/facing-against-counterfeit-online-pharmacies-pfizer-launches-new-purchasing-website-he.
- 112. Caitlin C. Blanche & Ellen L. Darling, New Angles for Potential Manufacturer Liability Stemming from Pharmaceutical Counterfeiting: How Industry Can Protect Brand and the Public Health at the Same Time, 53 No.10 DRI FOR DEF. 74, 74–75 (2011).
- 113. CN 2009-L-011175 (Ill. Cir. Cook Co. 2011).
- 114. See Acute Allergic-Type Reactions among Patients Undergoing Hemodialysis—Multiple States, 2007, U.S. CTRS. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT (Feb. 1, 2008), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5705a4.htm.
- 115. Blanche & Darling, supra note 112.
- 116. Id.
- 117. Id.
- 118. Id.
- 119. Id.
- 120. This is certainly not to suggest that criminals who perpetrate medicine counterfeiting should go unpunished (a point previously explored in this article). Instead, requiring a higher standard of care in pharmaceutical supply chains could work in conjunction with enhanced criminal sanctions for counterfeiters to combat the problem across all fronts. See generally Thomas Ebel, Katy George, Erik Larsen, Ketan Shah & Drew Ungerman, McKinsey & Co., Insight into Pharmaceuticals and Medical Products: Building New Strengths in the Healthcare Supply Chains, Pharmaceuticals and Medical Products Operations 1–11 (2013) (discussing strategies to help pharmaceutical companies strengthen global supply chains and corresponding benefits to both pharmaceutical companies and

Amy Deroo is a third-year student at the Georgetown University Law Center. A version of this article won first prize in the Section's annual Law Student Writing Competition.

Second Circuit Deconstructs Architectural Works Copyrights

By Michael A. Oropallo

I. Introduction

In Zalewski v. Cicero Builder Dev. Inc., 1 the Second Circuit recently explored the limits of copyright protection for architectural works. Architectural works are a relatively new category of intellectual property, first afforded copyright protection in the United States by the 1990 Architectural Works Protection Act, an amendment to the Copyright Act of 1976 made to comply with U.S. obligations under the Berne Convention. As such, there is a fairly limited body of cases construing the scope of copyright protection for architectural works. Zalewski helps to illuminate the scope of protection for architectural works and technical drawings; how traditional copyright principles apply to this new form of intellectual property; and how infringement of such works should be analyzed—an issue on which the Second Circuit expressly parted ways with the Eleventh Circuit.

II. The Facts and District Court Proceedings

James Zalewski, a self-employed architect doing business under the name Draftics, Ltd., claimed to have created copyrighted designs for colonial-style buildings in the Capital Region of New York State that he licensed to several construction companies. Zalewski claimed the construction companies breached their licenses and infringed his copyrights by allowing other architects to modify his copyrighted architectural works and drawings and to use portions of his plans to design custom homes. Upon discovering these claimed transgressions, Zalewski filed a lawsuit in the Northern District of New York against the architects, the builders, and a variety of related parties, including those who marketed the properties at issue, other builders, engineers, architects, real estate agents, and owners of the purportedly infringing homes. Zalewski subsequently voluntarily dismissed his claims against several of the defendants and filed an amended complaint limited to the defendants who were involved in either the modification of his plans and drawings or who used them to construct homes.

Zalewski alleged that the remaining defendants infringed his copyrights by customizing his designs without permission and by constructing homes from the pirated plans. Among other things, Zalewski claimed the defendants "copied the overall size, shape, and silhouette of his designs, as well as the placement of rooms, windows, doors, closets, stairs, and other architectural features." Zalewski also asserted a cause of action under section 1202(b) of the Digital Millennium Copyright Act

(DMCA) for removing his copyright notice. The district court dismissed the amended complaint but granted Zalewski leave to amend. The defendants then moved to dismiss the second amended complaint and, in the alternative, for summary judgment, arguing, among other things, that their designs did not infringe because they were not substantially similar to Zalewski's designs. The court granted summary judgment for the defendants on Zalewski's copyright infringement claims. The court granted Zalewski permission to file an amended complaint specifying the basis for his DMCA claim, but he failed to do so, and final judgment was entered in July 2012. Several of the defendants then moved for an award of costs and attorneys' fees, which the court granted. Zalewski appealed.

III. The Appeal

The Second Circuit, in an opinion by Judge Richard C. Wesley, joined by Chief Judge Robert A. Katzmann and Judge Raymond J. Lohier, Jr., affirmed. The court began by reviewing the genesis of copyright protection for architectural works. It noted that the Copyright Act of 1976 provided protection for "original works of authorship" for certain artistic works, including literary works, sound recordings, and pictorial, graphic, and sculptural works,³ but not including architectural works. Certain architectural plans and drawings were given protection as "pictorial works," but there was no prohibition against using them to construct a building or protection for buildings. After the United States acceded to the Berne Convention in 1988, however, Congress crafted legislation to protect architectural works.

The Architectural Works Protection Act,⁴ which took effect on December 1, 1990, amended the Copyright Act to include protection for architectural works. An "architectural work" was defined as "the design of a building as embodied in any tangible medium of expression, including a building, architectural plans, or drawings." It includes "the overall form as well as the arrangement and composition of spaces and elements in the design, *but does not include individual standard features*." [S]tandard configurations of spaces and individual standard features, such as windows, doors, and other staple building components, as well as functional elements whose design and placement is dictated by utilitarian concerns" are not protected.⁷

Copyright protection for architectural works prohibits copying the building or structure. The protection for

"technical drawings," on the other hand, extends only to the drawings themselves. The copyright owner "cannot prevent a third party from using [the technical] drawing to construct an actual building" because "the copyright in a work that portrays a useful article does not give the owner of that work the right to control 'the making, distribution, or display of the useful article.""9

The Second Circuit explained that the elements of a copyright infringement cause of action are (1) the work is protected by a valid copyright; (2) the defendant copied the work; and (3) the copying was wrongful.¹⁰ The court noted, however, that the second and third elements—copying and wrongful copying—"are often confused."11 Copying of the unprotectible elements of a work, the court pointed out, "is not wrongful, and thus not all copying is wrongful."12 To illustrate this distinction, Judge Wesley noted that someone could independently compose a paragraph, which, by coincidence, was very similar with or identical to a law review article by one of his law clerks. This not copying. 13 Similarly, quoting at length from a court opinion is not infringement (wrongful copying) because the opinion is in the public domain.¹⁴ Although the similarity of an accused work to, or identity of an accused work with, the copyrighted work as a whole leads one to reasonably believe the former was copied from the latter, "[w]hen an original work contains many unprotected elements...a close similarity between it and a copy may prove only copying, not wrongful copying."15

With this background, the court stated that "substantial similarity" refers only to similarity between "the *protected* elements of a work and another work." By contrast, the term "probative similarity," used for similarities that relate only to *unprotectible* elements, is probative only of copying, not of *wrongful* copying. Applying this principle, the court held that any copying of Zalewski's plans was not wrongful because there was no copying of protectible elements of his works. 18

In reaching this conclusion, the court looked to the "ordinary observer" test, which considers whether an ordinary observer, unless he set out to detect the disparities between the original work and the copy, would be disposed to overlook them.¹⁹ Because of the tendency of courts and juries to focus on both the protectible and unprotectible elements of a work when evaluating substantial similarity, the Second Circuit has recognized the need to be "more discerning" than the traditional ordinary observer test by filtering out unprotectible elements of the plaintiff's work from the analysis.²⁰ Because copyright only protects "original works of authorship," non-original elements of a work, such as "the history it describes, the facts it mentions, and the ideas it embraces," are "in the public domain free for others to draw upon."²¹

[A]ny author may draw upon the history of English-speaking peoples, but no one

may copy from *A History of the English-Speaking Peoples*. Any artist may portray the Spanish Civil War, but no one may paint another *Guernica*. And anyone may draw a cartoon mouse, but there can only be one Mickey.²²

The court discussed the various copyright doctrines that distinguish the protectible from the unprotectible elements of a work. Under the "scènes-à-faire" doctrine, for instance, stock characters and story elements are not protectible. Cowboys, bank robbers, and gun fights in the Wild West are all standard features that authors of Westerns are free to use. ²³ Similarly, under the merger doctrine, if an idea can only be expressed in one or a limited number of ways, the expression "merges" with the idea and is not protectible. ²⁴ Otherwise, protecting the expression would give the author a monopoly over the idea.

Turning to architectural works, the court likened their use of ideas and public-domain elements to compilations, citing the Supreme Court's decision in Feist Publications, Inc. v. Rural Telephone Service Co.25 Feist involved a compilation of uncopyrightable facts—names and telephone numbers—listed alphabetically in a telephone book. The Supreme Court recognized that compilations can use unprotectible elements in a protectible manner as a result of the author's original selection and arrangement of those elements.²⁶ But the Supreme Court held that the time, effort, and money expended in creating the compilation was not a basis for copyright protection, rejecting the "sweat of the brow" doctrine.²⁷ Instead, as provided in the Copyright Act, a protectible compilation consists of "preexisting materials or...data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship."28

The Second Circuit took issue, however, with the Eleventh Circuit's treatment of architectural works as compilations. In *Intervest Constr.*, Inc. v. Canterbury Estate Homes, Inc.,²⁹ the Eleventh Circuit addressed the question of whether the allegedly copied features of the plaintiff's architectural works were unprotectible "standard" features or protectable expression. The court stated that all copyrightable works fall into three categories—(1) "creative" for original works; (2) "derivative" for variations on the original; and (3) "compiled" for compilations of unoriginal material.³⁰ The court held that architectural works fall into the third category and are thus only are entitled to the "thin" protection attributable to the original "selection, coordination, or arrangement" of architectural elements.³¹ Ultimately, the *Intervest* court held that any copying of the plaintiff's house designs involved only standard features arranged in standard ways and thus was not wrongful.

While agreeing with the ultimate conclusion reached by the Eleventh Circuit, the Second Circuit disagreed with the categorization of architectural works as compilations (as defined in the Copyright Act), noting that "[e]very kind of work at some level is a compilation, an arrangement of uncopyrightable 'common elements.'"³² In explaining its reasoning, the Second Circuit observed:

No individual word is copyrightable, but the arrangement of words into a book is. No color is copyrightable, but the arrangement of colors on canvas is. Likewise, doors and walls are not copyrightable, but their arrangement in a building is. Some architectural designs, like a single-room log cabin, will consist solely of standard features arranged in standard ways; others, like the Guggenheim, will include standard features, but also present something entirely new. Architecture, in this regard, is like every art form.³³

Having concluded that courts should treat architectural works no differently than other types of works, the court looked to its prior decisions involving architectural works³⁴ and to cases involving other functional forms of creative expression³⁵ for guidance as to assessing infringement. The court determined that under the "more discerning" ordinary observer test, it was appropriate to filter the unprotectible elements of Zalewski's designs out of the substantial similarity comparison.³⁶ Doing so, the court found that the defendants had copied only unprotected elements of the designs.³⁷ First, many of the similarities were "a function of consumer expectations and standard house design generally."38 Second, "the overall footprint of the house and size of the rooms" were "'design parameters' dictated by consumer preferences and the lot the house will occupy, not the architect."39 Finally, most of the similarities were "features of all colonial homes, or houses generally"; in seeking to design a colonial house, Zalewski "was bound by certain conventions."40

The court noted that there are "only so many ways to arrange four bedrooms upstairs and a kitchen, dining room, living room, and study downstairs" and that Zalewski had made "no attempt to distinguish those aspects of his designs that were original to him from those dictated by the form in which he worked."41 The court concluded that the parties' respective layouts were in fact "different in many ways," including "exact placement and sizes of doors, closets, and countertops" and the arrangements of rooms. 42 Because Zalewski "adhered to a pre-existing style," his original contribution was "slight' and his copyright "very thin," such that only "very close copying would have taken whatever actually belonged" to Zalewski."43 Finding no such copying—"Defendants' houses shared Plaintiff's general style, but took nothing from his original expression"—the court affirmed the district court's finding of no infringement.

Finally, the court affirmed the dismissal of the DMCA claim and remanded the award of attorneys' fees.

IV. Conclusion

Zalewski provides guidance on the scope of copyright protection for architectural works, specifically, how to determine what constitutes wrongful copying of such works. Notably, the court disagreed with the Eleventh Circuit's treatment of architectural works as compilations and thus allowed for potentially broader protection of such works. But Zalewski leaves a number of questions unanswered. When does an architectural design cross the line between an unprotectible "standard" design in a particular architectural style and protectible original expression? What consumer expectations make a feature "standard"? How are protectible elements distinguished from unprotectible ones in determining whether copying is wrongful? These questions will be addressed on a case-by-case basis, consistent with the analytical approach outlined in Zalewski.

Endnotes

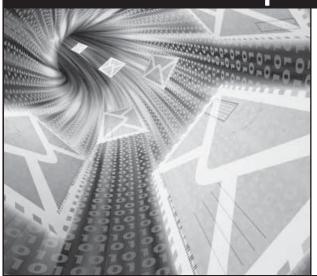
- 1. 754 F.3d 95 (2d Cir. 2014).
- 2. Id. at 99.
- 3. Id. at 100; 17 U.S.C. § 102(a).
- 4. AWPA, Pub. L. No. 100-568, § 4(a)(1)(A), 102 Stat. 2853 (1988) (codified at 17 U.S.C. § 101).
- 5. 17 U.S.C. § 101.
- 6. Id. (emphasis added).
- 7. See generally Copyright Office Circular 41: Copyright Claims in Architectural Works (www.copyright.gov).
- 8. *Id*
- 9. 17 U.S.C. § 113(b).
- Zalewski, 754 F.3d at 100; see also Arnstein v. Porter, 154 F.2d 464, 468, 472-73 (2d Cir. 1946); Laureyssens v. Idea Group, Inc., 964 F.2d 131, 139-41 (2d Cir. 1992).
- 11. Zalewski, 754 F.3d at 100.
- 12. Id
- Id. at 101; see also Folio Impressions, Inc. v. Byer Cal., 937 F.2d 759, 765-66 (2d Cir. 1991).
- 14. Zalewski, 754 F.3d at 101; see also 17 U.S.C. §§ 105, 301-305 (i.e., expired copyright term, works of the United States Government).
- 15. Zalewski, 754 F.3d at 101 (emphasis in original).
- 16. Id. (emphasis added).
- 17. Id.
- 18. *Id.* at 101-02.
- 19. *Id.* at 102; see also Laureyssens, 964 F.2d at 141.
- 20. Zalewski, 754 F.3d at 102.
- 21. Id
- 22. *Id.* (footnotes omitted).
- Id.; see also Hoehling v. Universal City Studios, Inc., 618 F.2d 972, 979 (2d Cir. 1980).

- Id. at 102-03; see also Morrissey v. Procter & Gamble Co., 379 F.2d 675, 678-79 (1st Cir. 1967).
- 25. 499 U.S. 340, 348 (1991).
- 26. Id.
- 27. Id.
- 28. 17 U.S.C. §§ 101, 103.
- 29. See 554 F.3d 914, 919 (11th Cir. 2008).
- 30. Id
- 31. Id.
- 32. Zalewski, 754 F.3d at 103.
- 33. Id. at 103-04.
- 34. Id. at 104-05. The court analyzed Attia v. Society of the New York Hosp., 201 F.3d 50 (2d Cir. 1999) (copying went to unprotected ideas/concepts rather than concrete expression); Peter F. Gaito Architecture, LLC v. Simone Dev. Corp., 602 F.3d 57, 68 (2d Cir. 2010) (copying went to only ideas and not protectable expression); and Sparaco v. Lawler, Matusky, Skelly, Eng'rs, LLP, 303 F.3d 460, 468-69 (2d Cir. 2002) (preliminary site plan sufficiently detailed).

- Zalewski, 754 F.3d at 105; see also Computer Assoc. Int'l., Inc. v. Altai, Inc., 982 F.2d 693 (2d Cir. 1992) (describing abstraction/filtration/comparison test).
- 36. Zalewski, 754 F.3d at 106.
- 37. Id
- 38. Id.
- 39. Id.
- 40. Id.
- 41. Id. at 107.
- 42. Id.
- 43. Id.

Michael A. Oropallo is a partner with Hiscock & Barclay in Syracuse.

Request for Articles



If you have written an article you would like considered for publication, or have an idea for one, please contact the *Bright Ideas* Editor-in-Chief:

Jonathan Bloom, Esq. Weil, Gotshal & Manges LLP 767 5th Avenue New York, NY 10153-0119 jonathan.bloom@weil.com

Articles should be submitted in electronic document format (pdfs are NOT acceptable), along with biographical information.

www.nysba.org/BrightIdeas





Scenes from the Intellectual Property Law Section ANNUAL MEETING

















New York Hilton Midtown • New York, NY February 9, 2015

NEW YORK STATE BAR ASSOCIATION

From the NYSBA Book Store >

New York Contract Law

Section Members get 20% discount* with coupon code PUB3046N

A Guide for Non-New York Attorneys

Also Available as a Downloadable PDF!

AUTHOR

Glen Banks, Esq., Norton Rose Fulbright

New York Contract Law: A Guide for Non-New York Attorneys is an invaluable reference allowing the practitioner to quickly and easily gain an understanding of New York Contract Law. Many contracts involving parties outside the United States contain a New York choice-of-law clause and, up until now, the foreign practitioner had no practical, authoritative reference to turn to when they had a question regarding New York Law. New York Contract Law: A Guide for Non-New York Attorneys fills this void. In addition to lawyers outside the United States, this book will also benefit lawyers within the United States whose practice includes advising clients regarding contracts governed by New York Law.

Written by Glen Banks, Esq., a recognized authority on contract law with over 35 years' experience, this book is presented in an easy-to-read question-and-answer format to allow easy access to a wide array of topics. All aspects of contract law are covered, from the basic requirements of a valid contract to a contract's termination, assignment or repudiation. Particular agreements and clauses are discussed as well as the role of counsel when working on a transaction governed by New York Law. Resources for further study and to keep up on changes in New York Law are also provided.

For your convenience, New York Contract Law: A Guide for Non-New York Attorneys can be purchased in hard copy (which includes a CD containing the entire book in a searchable, pdf format) or can be downloaded as an e-book in a pdf format.

Key Discussions

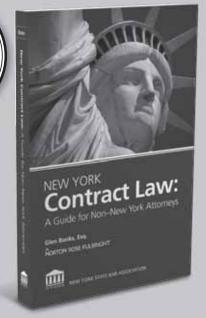
Is there a binding agreement? Is that agreement valid and enforceable? How is meaning given to the terms of the agreement? What constitutes a breach of the contract? When is a breach excused? How is action taken to enforce the contract after a breach? What remedy can the court grant to redress a breach?

Get the Information Edge

1.800.582.2452 www.nysba.org/pubs

Mention Code: PUB3046N

*Discount good until June 30, 2015.



PRODUCT INFO AND PRICES

2014 • 622 pp., softbound PN:4172 - Book & CD PN: 4172E - Downloadable PDF

Order Now! NYSBA Members

\$95 \$120

Non-members

A \$60 fee is charged for shipping and handling outside the continental U.S. A \$5.95 shipping and handling fee applies to orders shipped within the continental U.S. Prices do not include applicable sales tax

"All told, a genuine gift to those in search of the ready, reliable New York contract law answer, whether they are located in, or beyond, our state's borders."

From the Foreword by Judith S. Kaye, Former Chief Judge of the State of New York



Welcome New Members

Jacob D. Albertson Chisom Charlene Ananaba Olta Andoni Vitali Anfimov Jeremy Apple Christopher G. Asberry Robert C. Atkinson Scott L. Baker Nicholas Richard Bartelt Aja Ittasyah Baxter Charles W. Baxter Scott L. Bittman Johnnie Leandra Bocanegra Andrew David Bochner M. Franklin Boyd Mary Sue Brooks Matthew John Brophy Christina A. Brown Raymond T. Burkhard India Campbell Michael K. Cantwell Ta Shiou Chang Angele Nicole Chapman Augustine Vincent Cheng Nathan Chun Jennifer Chung Andrew Joel Cochran Christopher J. Coulson Jeanne C. Curtis Eli Damatov Caitlin Dance Gregory De Tolla Joseph V. DeMarco Heather DeSerio Tal Efriam Dickstein Musetta Caruso Durkee Mirentxu R. Echenique **Brian Eddings** Louis S. Ederer Obianuju Yvonne Erokwu Michael R. Ertel Katherine Fang Ava Farshidi Amanda Rose Fisher Walter J. Forman Alejandra Sonia Franco Jesse Mark Frankel Paul Fraulo Frank A. Freda Adam Freedman

Elana S. Freeman

Jessica R. Friedman Raj Suresh Gandesha Jessica Megan Garrett James T. Gaskill Abbey Gauger Edward S. Gershuny Phaik Goh Stella Goldstein Sylvia Elizabeth Groden Kristina S. Groennings Pamela Lesly Grutman Elizabeth A. Hall Claire Marie Hankin Melissa R. Heller Elise Hiller Nicholas Himonidis Huidian Hu Shirazi Zavahir Jaleel-Khan Sherry Lynne Jetter Jason Douglas Jones Kevin Charles Jones Taneem Kabir Steven Michael Kalogeras Neliva Karimova Jason A. Keith Gabi Klemm Andrew J. Klyde Willard R. Knox Eugene David Kublanovsky Michael Kucher Dane Kulpa Kofi B Kwarteng Philip S. Kwon Anita Lam **Jacqueline Lamer** Ebonie V. Lamont Gregory W. Lane Richard David Lane Bernard Lau Christine M. Lauture Lindsey Laveaux Tanya Simone Layne Vivian Yuen Yun Lee Young Shin Lee Hayden Lerner Carol Ann Marie Lewis Daria Rafi Licausi Alvin Chien-chih Lin David Dong Ann Lin Scott Lipschitz

Song Liu Dana Clinton Lumsden Heather Victoria Lynch Cosmin Maier Klodiana Malellari Ashley H. Malisa Anisha Mangalick Erica Marxuach Rubaiat Mashraq Dilip N. Massand Elizabeth Ann McKenzie Rayna McKenzie Anna Giulia Medri Oleg A. Mestechkin Amy Catherine Meyer Yousef M. Mian Perri Michael Mark Elsas Miller Stephanie L. Miller Loretta Miraglia Robyn P. Mohr Francesca M. Montalvo Andrew Moses Benjamin Moskowitz Reid Patrick Mullen Alexandra M. Murdocca Stephen R. Shaheen Nale Khashayar Naraghi Dana Fiona Nelson Danielle Kathleen Nolan Luis Vincent Nunez Audrey Grace Ogurchak Dustin W. Osborne Mickey H. Osterreicher Felipe Paez Wesley Paisley Erica M. Palaia Michael Pampalone Genevieve E. Perez Sofya Peysekhman Allyson Evelyn Planders Roberto Portillo Togno Peter Pottier Sarah L. Prutzman April Pyatt Robert I. Reicher Maurice Arthur Reichman Lisa Marie Riad Caroline V. Rider Judit Rius Sanjuan Vivian Rivera-Drohan

Raylene Janice Robinson Rebecca N. Rivka Rodal Milagros Romero Phillip Alan Rosenberg Sandra Sung Ju Rueck Aneil K. Sahota Robert P. Santandrea Samuel I. Sarofeen Daniel J. Scott Christopher Serbagi Milin Y. Shah Corey Shapiro Robert J. Shapiro Joshua Shirley Eli Shmulik Marc L. Silverman Daniel John Simonetti Melissa Maria Sink Frances Codd Slusarz Jackson Robert Smith **Jason Sosa** Tarley Stevenson Lila Christine Subramanian Tracev Renato Thomas Mark Edward Traphagen Charlotte Tschider Anahid M. Ugurlayan Vikas Varma Iulie Thanh Thao Vo Michael Wamil Adam Scott Wandt Daniel Thomas Weglarz Jonathan Weisbrod William H. Weisman Karvn Wilson John Kevin Winters Andrea Woloski Erica Marie Womer David Yang Florina Yezril Oliver C. Young Ruihui Yu Giuseppe M. Zaccagnini Sebastian Zar Qian Zhou Deh-Ming Michael Zhu Shaobin Zhu Eleonora Zlotnikova

Alan Yu-lun Liu

MEMBERSHIP APPLICATION New York State Bar Association INTELLECTUAL PROPERTY LAW SECTION

Membership in the New York State Bar Association's Intellectual Property Law Section is a valuable way to:

- enhance professional skills;
- keep up-to-date with important developments in the legal profession;
- join colleagues in exciting Section events.

OPPORTUNITIES FOR EDUCATION

The Intellectual Property Law Section offers both the experienced and novice practitioner excellent opportunities to enhance their practical and legal knowledge and expertise. Through Section activities, including conferences on intellectual property (an annual Winter event), members may examine vital legal developments in intellectual property law. The Section's Web site provides current information regarding Section events and offers "members only" access to current issues of *Bright Ideas* and current Committee bulletins providing updates on intellectual property law. The Section sponsors continuing legal education (CLE) credit-bearing programs for Section members at reduced rates. Recent programs offered by the Section related to computer software and biotechnology protection, conducting intellectual property audits, and practical considerations in trade secret law. Now, with Mandatory Continuing Legal Education (MCLE) requirements, Intellectual Property Law Section membership is more valuable than ever before! The Section also sponsors joint programs with Law Schools including an annual writing contest for law students wherein the winning articles appear in an issue of *Bright Ideas*.

OPPORTUNITIES FOR PROFESSIONAL DEVELOPMENT

Intellectual Property Law Section committees address unique issues facing attorneys, the profession and the public. The Section offers opportunities to serve on committees such as Copyright Law; Diversity Initiative; Ethics; Greentech; International IP Law; Internet & Technology Law; Legislative/Amicus; Litigation; Patent Law; Pro Bono and Public Interest; Trademark Law; Trade Secrets; Transactional Law; and Young Lawyers.

Committees allow you to network with other attorneys from across the state and give you the opportunity to research issues and influence the laws that can affect your practice. Committees are also an outstanding way to achieve professional development and recognition. Law students are automatically members of the Young Lawyers Committee. Section members may join more than one committee.

A VOICE IN THE ASSOCIATION

The Intellectual Property Law Section takes positions on major professional issues that affect practitioners and advocates those positions within the New York State Bar Association, the legislature, and the public.

See page 33 to become a member of the Intellectual Property Law Section

COMMITTEE ASSIG	NMENT REQUEST
Please designate, from the list below, those committee Committee Chairs and their e-mail addresses, please re	
Advertising Law (IPS3000)	Litigation (IPS2500)
Copyright Law (IPS1100)	Membership (IPS1040)
Diversity Initiative (IPS2400)	Patent Law (IPS1300)
Ethics (IPS2600)	Pro Bono and Public Interest (IPS2700)
Greentech (IPS2800)	Trademark Law (IPS1600)
In-House Initiative (IPS2900)	Trade Secrets (IPS1500)
International Intellectual Property Law (IPS2200)	Transactional Law (IPS1400)
Internet and Technology Law (IPS1800)	Young Lawyers (IPS1700)
Legislative/Amicus (IPS2300)	
Please e-mail your committee selection(s) to Intellectu	alProperty@nysba.org
* *	*
To be eligible for membership in the Intellectual Prop NYSBA.	perty Law Section, you first must be a member of th
As a member of the NYSBA, I enclose my payment of (Law student rate: \$15)	• •
☐ I wish to become a member of the NYSBA and the Inter- Association and Section application with my payment	
\square Please send me a NYSBA application. No payment is $\mathfrak c$	enclosed.
Name	
Office	
Office Address	
Home Address	
E-mail Address	
Office Phone No.	
Office Fax No.	
Home Phone No	
Please return payment	
Membership I New York State B One Elk Albany, New Telephone: 51	ar Association Street York 12207
FAX: 518/4	87-5579
http://www.nysba.c	org/membership

NYSBA Bright Ideas | Spring/Summer 2015 | Vol. 24 | No. 1

From the NYSBA Book Store





PRODUCT INFO AND PRICES*

2014-2015 / 886 pp., softbound PN: 405194

NYSBA Members

\$120

Non-members

\$135

Order multiple titles to take advantage of our low flat rate shipping charge of \$5.95 per order, regardless of the number of items shipped. \$5.95 shipping and handling offer applies to orders shipped within the continental U.S. Shipping and handling charges for orders shipped outside the continental U.S. will be based on destination and added to your total.

*Discount good until June 30, 2015.

Authors

Michele A. Santucci, Esq.

Attorney at Law, Niskayuna, NY

Professor Leona Beane

Professor Emeritus at Baruch College and Attorney at Law, New York, NY

Richard V. D'Alessandro, Esq.

Richard V. D'Alessandro Professional Corporation, Albany, NY

Professor Ronald David Greenberg

Larchmont, NY

Thomas O. Rice, Esq.

Attorney at Law, Garden City, NY

This practice guide covers corporate and partnership law, buying and selling a small business, the tax implications of forming a corporation and banking law practice. It covers many issues including the best form of business entity for clients and complicated tax implications of various business entities.

Updated case and statutory references and numerous forms following each section, along with the practice guides and table of authorities, makes this edition of *Business/Corporate* and *Banking Law Practice* a must-have introductory reference.

The 2014–2015 release is current through the 2014 New York legislative session and is even more valuable with the inclusion of **Forms on CD**.

Get the Information Edge

NEW YORK STATE BAR ASSOCIATION

1.800.582.2452 www.nysba.org/pubs

Mention Code: PUB3047N



Section Committees and Chairs

The Intellectual Property Law Section encourages members to participate in its programs and to contact the Section Officers or Committee Chairs for information.

Advertising Law

Brooke Erdos Singer Davis & Gilbert LLP 1740 Broadway New York, NY 10019 bsinger@dglaw.com

Copyright Law

Paul Matthew Fakler Arent Fox LLP 1675 Broadway New York, NY 10019 paul.fakler@arentfox.com

Oren J. Warshavsky Baker & Hostetler LLP 45 Rockefeller Plaza New York, NY 10111 owarshavsky@bakerlaw.com

Diversity Initiative

Deborah Robinson Viacom Media Networks 1515 Broadway New York, NY 10036-8901 deborah.robinson@viacom.com

Joyce L. Creidy Thomson Reuters 530 Fifth Avenue, 7th Fl. New York, NY 10036 joyce.creidy@thomsonreuters.com

Ethics

Philip Furgang Furgang & Adwar, LLP 1325 Avenue of the Americas, 28th Fl. New York, NY 10019 philip@furgang.com

Rory J. Radding Edwards Wildman Palmer LLP 750 Lexington Avenue New York, NY 10022 RRadding@edwardswildman.com

In-House Initiative

Chehrazade Chemcham
Colgate-Palmolive
300 Park Avenue
New York, NY 10022
Chehrazade_Chemcham@colpal.com

International Intellectual Property Law

Na Du Kilpatrick Townsend and Stockton LLP 1114 Avenue of the Americas, 21st Fl. New York, NY 10036-7703 ldu@kilpatricktownsend.com

Internet and Technology Law

Richard L. Ravin Hartman & Winnicki, PC 115 West Century Rd Paramus, NJ 07652 rick@ravin.com

Legislative/Amicus

Charles Eric Miller Sills, Cummis & Gross, P.C. 101 Park Avenue, 28th Fl. New York, NY 10112 cmiller@sillscummis.com

Litigation

Paul W. Garrity Sheppard, Mullin, Richter & Hampton LLP 30 Rockefeller Plaza, 39th Fl. New York, NY 10112-0015 pgarrity@sheppardmullin.com

Marc A. Lieberstein Kilpatrick Townsend & Stockton LLP 1114 Avenue of the Americas, 21st Fl. New York, NY 10036-7709 mlieberstein@kilpatricktownsend.com

Membership

William Robert Samuels W.R. Samuels Law PLLC 280 Madison Avenue, Ste. 600 New York, NY 10016 bill@wrsamuelslaw.com

Robin E. Silverman Golenbock Eiseman Assor Bell & Peskoe LLP 437 Madison Avenue New York, NY 10022 rsilverman@golenbock.com

Patent Law

David B. Bassett Wilmer Hale LLP 7 World Trade Center 250 Greenwich St. New York, NY 10007-2140 david.bassett@wilmerhale.com

Michael A. Oropallo Hiscock & Barclay LLP One Park Place 300 South State Street Syracuse, NY 13202-2078 moropallo@hblaw.com

Pro Bono and Public Interest

Debra Resnick Charles River Associates 1155 Avenue of the Americas, 18th Fl. New York, NY 10036 dresnick@crai.com

Paula Joanne Estrada De Martin Baker Donelson Bearman Caldwell & Berkowitz P.C. 201 St. Charles Avenue, Ste. 3600 New Orleans, LA 70170 pestradademartin@bakerdonelson.com

Trade Secrets

Douglas A. Miro Ostrolenk Faber LLP 1180 Avenue of the Americas, 7th Fl. New York, NY 10036 dmiro@ostrolenk.com

Andre G. Castaybert Castaybert PLLC 830 Third Avenue, 5th Fl. New York, NY 10022 acastaybert@ac-counsel.com

Trademark Law

William Robert Samuels W.R. Samuels Law PLLC 280 Madison Avenue, Ste. 600 New York, NY 10016 bill@wrsamuelslaw.com

Transactional Law

Joseph John Conklin Coty Inc. 350 5th Avenue New York, NY 10118 Joseph_Conklin@cotyinc.com

Robin E. Silverman Golenbock Eiseman Assor Bell & Peskoe LLP 437 Madison Avenue New York, NY 10022 rsilverman@golenbock.com

Young Lawyers

Teige Patrick Sheehan Heslin Rothenberg Farley & Mesiti P.C. 5 Columbia Circle Albany, NY 12203 tps@hrfmlaw.com

Nyasha S. Foy IILP 185 West Broadway New York, NY 10013-2921 nyasha.foyesq@gmail.com



ADDRESS SERVICE REQUESTED

NON PROFIT ORG. U.S. POSTAGE PAID ALBANY, N.Y. PERMIT NO. 155

Submission of Articles

Anyone wishing to submit an article, announcement, practice tip, etc., for publication in an upcoming issue of *Bright Ideas* is encouraged to do so. Articles should be works of original authorship on any topic relating to intellectual property. Submissions may be of any length.

Submissions should preferably be sent by e-mail to Jonathan Bloom, Editor-in-Chief, at the address indicated on this page. Submissions for the Fall 2015 issue must be received by June 29, 2015.

Accommodations for Persons with Disabilities:

NYSBA welcomes participation by individuals with disabilities. NYSBA is committed to complying with all applicable laws that prohibit discrimination against individuals on the basis of disability in the full and equal enjoyment of its goods, services, programs, activities, facilities, privileges, advantages, or accommodations. To request auxiliary aids or services or if you have any questions regarding accessibility, please contact the Bar Center at (518) 463-3200.

At-Large Members of the Executive Committee

David B. Bassett Daniel Korn
Rachel L. Berger Raymond A. Mantle
Rebecca Leigh Griffith Andrew Ashford Tucker

Bright Ideas is a publication of the Intellectual Property Law Section of the New York State Bar Association. Members of the Section receive a subscription to the publication without charge. Each article in this publication represents the author's viewpoint and not that of the Editors, Section Officers or Section. The accuracy of the sources used and the cases, statutes, rules, legislation and other references cited is the responsibility of the respective authors.

Copyright 2015 by the New York State Bar Association. ISSN 1530-3934 (print) ISSN 1933-8392 (online)

BRIGHT IDEAS

Editor-in-Chief

Jonathan Bloom Weil, Gotshal & Manges LLP 767 Fifth Avenue New York, NY 10153-0001 jonathan.bloom@weil.com

Executive Editor

Rory J. Radding Edwards Wildman Palmer LLP 750 Lexington Avenue New York, NY 10022 RRadding@edwardswildman.com

Section Officers

Chair

Charles Thomas Joseph Weigell, III Fross Zelnick Lehrman & Zissu PC 866 United Nations Plaza New York, NY 10017 cweigell@fzlz.com

Vice-Chair

Erica D. Klein Kramer Levin Naftalis & Frankel LLP 1177 Avenue of the Americas New York, NY 10036-2714 eklein@kramerlevin.com

Treasurer

Lisa W. Rosaya Baker & McKenzie LLP 452 Fifth Avenue New York, NY 10018 lisa.rosaya@bakermckenzie.com

Secretary

Robin E. Silverman Golenbock Eiseman Assor Bell & Peskoe LLP 437 Madison Avenue New York, NY 10022 rsilverman@golenbock.com