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While these articles and Venable's client alerts cannot serve as legal advice, each of our attorneys welcome the opportunity to discuss how these challenges impact your specific situation. Please do not hesitate to contact a member of Venable's Life Sciences Practice Group.

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Improper Calculations of Patent Term Adjustment Where Responses are Timely Filed Under the Next Business Day Rule

The Patent Act authorizes the U.S. Patent Office (PTO) to set a deadline from 30 days to six months for an applicant to respond to any PTO action. *See* 35 U.S.C. §133. The act further specifies that:

> "when the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or fee paid, on the next succeeding secular or business day."

See 35 U.S.C. § 21(b). Applicants commonly use this so-called next business day, *see* 37 C.F.R. § 1.7, M.P.E.P. 710.05, to timely file responses, which are due on a weekend or federal holiday, on the next business day.

The Patent Act also allows for the adjustment of a patent's term when the PTO fails to take certain actions within a specified period (so-called "PTO delay"). *See* 35 U.S.C. § 154(b). Determination of patent term adjustment takes both PTO delay and applicant delay (i.e. applicant's failure to timely respond to PTO actions) into account. The current PTO interpretation of the Patent Act, as it pertains to patent term adjustment, is that a response timely filed under the next business day rule nevertheless results in one day of applicant delay.

Recently in *Arqule, Inc. v. Kappos*, the PTO interpretation of the Patent Act was challenged. 793 F.Supp.2d 214 (D. D.C. 2011). During the prosecution of the patent at issue, Arqule timely filed a response under the next business day rule, but as a result, Arqule was deducted one day of applicant delay. *Id.* at 3. The court sided with Arqule and held that any response timely filed under the next business day rule does not result in applicant delay. *Id.* at 16. Therefore, the PTO cannot reduce the period of patent term adjustment for applicant delay where an applicant timely files a response to any notice or action by the PTO within three months of the mailing date under the weekend/holiday exception. *Id.*

Despite this decision, PTO has not yet revised its rules. Accordingly, responses timely filed under the next business day rule are still indicated as resulting in a day of applicant delay. When reviewing the patent term adjustment determination of an allowed application, practitioners need to be mindful of this error on the side of the PTO and should consider filing requests for reconsideration prior to payment of the issue fee. Subsequent to the district court decision, petitions on this point have been granted. Furthermore, to avoid incurring the cost of filing such requests for reconsideration, applicants may also consider filing responses without relying on the next business day rule.

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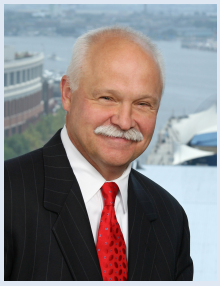

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FDA Regulations and the Regulation of Constitutionally Protected Speech

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"Speech in aid of pharmaceutical marketing…is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell v. IMS Health*, Inc., 131 S. Ct. 2653, 2659 (2011). That sentence, which appears prominently in the first paragraph of the Court's decision last term in *Sorrell*, doomed a Vermont law restricting the sale of pharmacy records of individual doctors. The principles which underlie that sentence sweep more broadly than that, however, to cast a First Amendment shadow over a range of governmental regulatory activities, including those of FDA. This shadow may well have important implications for product liability tort litigation.

Various government regulations impact speech, sometimes compelling speech and sometimes prohibiting or restricting speech. Government compels speech when, for example, a statute or an agency rule requires warnings or disclosures on packages or other materials. Government limits or prohibits speech when, as in *Sorrell*, a statute restricts the sale of information or when a regulatory regime prohibits the off-label promotion of an approved drug.

Tobacco warnings and compelled speech

A current example of a regulation which compels speech is FDA's rule requiring cigarette companies to display graphic warnings on cigarette packages. In the Family Smoking and Prevention Act, Congress directed FDA to promulgate a rule mandating the display on cigarette packages of graphic images depicting the negative consequences of smoking. FDA did as it was told and developed a set of dramatic images. FDA then issued a rule mandating that these images, along with blunt textual warnings, occupy 50 percent of each cigarette package.

In response to FDA's rule, several tobacco companies filed suit, challenging the rule on First Amendment Free Speech as well as Administrative Procedure Act grounds. The United States District Court for the District of Columbia (Judge Leon) granted the companies' motion for a preliminary injunction. The court found that there was a substantial likelihood that the companies would prevail on their First Amendment claim. See *R.J. Reynolds Tobacco Co. v. FDA*, Civil Case No. 11-1482 (November 7, 2011). The government's appeal is pending.

As we await the outcome of the appeal in *R.J. Reynolds,* it is worth noting that there is other relevant precedent invalidating a regulatory regime which compels speech. In *Entertainment Software Ass'n v. Blagojevich,* 469 F.3d 641 (7th Cir. 2006), for example, a case upon which the district court in *R.J. Reynolds* relied, the court invalidated an Illinois statute which required electronic video game retailers to place large warning labels on video machines and to provide other written warnings about the content of the games.

Off-label drug promotion and prohibited speech

The government has been successful in recent years in recovering substantial sums of money from pharmaceutical companies through False Claims Act settlements arising from the companies' alleged "off-label promotion" of FDA approved drugs. These settlements include Merck ($950 million), Pfizer ($2.3 billion), and GlaxoSmithKline ($3 billion). The theory on which these cases are based needs to be examined using the lens of the First Amendment.

Only slightly oversimplified, the government's chain of logic in "off-label promotion false claim" cases is as follows: FDA approves a drug for certain specified uses (indications); those approved uses are stated on the drug's label; if a drug company makes factually true statements in generally distributed brochures or by its sales force about uses of the drug other than those which FDA has approved and as stated on the drug's label, such statements are impermissible offlabel promotion of the drug; and if federal funds have been paid (through Medicare, for example) for these promoted non-approved uses, the government has received and paid "false claims" for which the government is entitled to civil penalties plus treble damages. 31 U.S.C. § 3729.

The critical point for First Amendment purposes is that the government's theory in these off-label false claims cases does not require that the companies' claims about a drug are false or misleading; rather, the government's theory allows a company to be held liable when, for example, the company's sales force promotes the fact that the drug has been used successfully in a clinical trial even if that statement is true so long as the clinical trial involves a non-FDA approved use of the drug. Under the government's theory, a company's right to speak about an FDA approved drug is limited to speech about the drug's approved uses/labeling.

The broad contours of First Amendment constraints on regulatory actions

The government may compel speech to protect consumers by requiring disclosure of "purely factual and uncontroversial information," *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985), "in order to dissipate the possibility of consumer confusion or deception." *Id.* (quotation omitted). See also *Nat'l Elec. Mfrs. Ass'n v. Sorrell,* 272 F.3d 104, 114-16 (2d Cir. 2001) (applying Zauderer rationale to uphold mandatory food labeling statute). However, even when the compelled speech satisfies this "purely

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factual" standard, "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech." Zauderer, 471 U.S. at 651.

In preliminarily enjoining FDA's graphic tobacco warnings, the district court concluded that the warnings were not entitled to the more relaxed *Zauderer* level of scrutiny because, in the court's view, the warnings were not "purely actual and uncontroversial." The court thus subjected the warnings rule to "strict scrutiny." The district court concluded that FDA's tobacco warnings regulation could not withstand "strict scrutiny." Few laws can.

Governmental prohibitions of speech, including prohibiting a pharmaceutical company from making truthful statements about a drug, raise a separate set of constitutional objections. In *Sorrell*, the Supreme Court observed that "[f]acts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs." 131 S. Ct. at 2667. That observation is hard to square with the government's efforts to restrict speech in off-label promotion false claims cases where the allegedly offending promotional statements are factually true and not misleading.

U.S. v. Caronia, 576 F. Supp. 2d 385 (E.D.N.Y. 2008) (appeal pending), is a pre-*Sorrell* case in which the court gave serious consideration to the question of the constitutionality of the government's approach to off-label promotion cases. While the court in *Caronia* ultimately denied the defendant's First Amendment based motion to dismiss an indictment for violating the misbranding provisions of the Food, Drug, and Cosmetic Act, the court noted that "the constitutional issues raised in *Caronia's* motion are very much unsettled, not only in this circuit but nationwide." 576 F. Supp. 2d at 394. The appeal in *Caronia* will be decided in light of the Supreme Court's decision in *Sorrell*.

Given the enormous sums of money involved in pharmaceutical off-label false claim cases and the obvious seriousness with which the courts take First Amendment arguments, the question is why have these cases settled and not been litigated to determine the constitutionality of the government's approach? Certainly part of the answer to that question involves the unacceptably high reputational and business risks to a public company of being indicted. These risks create a powerful incentive to avoid indictment and settle. A closely related consideration similarly incentivizing avoiding indictment through settlement is the risk of disqualification from participation in federal health care programs (effectively the "death penalty") if convicted. *See* 42 U.S.C. § 1320a-7.

The Allergan company sought to thread this needle by bringing a declaratory judgment action to challenge on First Amendment grounds FDA's rules on off-label promotion. *See Allergan v. USA*, No. 09-1879 (D.D.C.). The parties in *Allergan* filed cross-dispositive motions in which the First Amendment arguments were briefed extensively; however, the case was dismissed as part of a larger overall settlement prior to the court's ruling on those motions.

Sorrell, R.J. Reynolds, Entertainment Software, Caronia, and *Allergan* individually and collectively reflect an increased awareness on the part of regulated entities of the constitutional implications of regulatory regimes and an increased willingness on the part of those entities to challenge those regimes on constitutional grounds. A number of the cases which have gone to judgment reflect growing judicial skepticism for the government's justifications for actions which adversely impact constitutionally protected speech.

Is tort law next?

The arguments developed in First Amendment cases have potential applicability to product liability cases involving allegations that a defendant pharmaceutical company unlawfully promoted the off-label use of a drug. Plaintiffs in these cases assert negligence claims and demands for punitive damages predicated on allegations that the plaintiff suffered injuries from off-label use of a drug as promoted by the defendant. The constitutional cloud which hangs over the government's right to restrict speech, see, e.g., *Sorrell*, may well extend to these private tort cases.

The argument would be that the requisite governmental action to implicate constitutional protections exists because the tort plaintiff's assertion that the defendant's off-label promotion is unlawful depends entirely on the web of federal statutes and regulations. But for those statutes and regulations, the plaintiff would have no basis for complaining about the defendant's truthful, non-misleading statements. If, however, the government cannot constitutionally prohibit the defendant from making truthful, non-misleading statements, then a private plaintiff should not be able to impose tort liability for the same constitutionally protected activity. The state regulates through its tort law and plaintiffs are invoking that state regulatory power to restrict speech when plaintiffs seek to impose liability and recover damages, including punitive damages, for off-label promotion of drugs and devices when that promotional activity involves truthful, non-misleading statements.

Defense counsel making these constitutional arguments should highlight the contradiction between the prohibition against off-label prohibition and the lawfulness of physicians' prescribing drugs off-label. See generally *Caronia*, 576 F. Supp. 2d at 393. Not only may a physician lawfully prescribe a drug off-label, but in certain situations such off-label use is the "medically recognized standard of care and therefore it is important for physicians to have access to accurate information about off-label uses." *Id.* at 393. The contradiction is that the manufacturer often has the most current information to provide physicians so that they may lawfully prescribe the drug, and yet the plaintiff's off-label claim seeks to severely restrict the manufacturer and its representatives from speaking truthfully about the off-label use of the drug.

As the law in this area continues to develop, defense counsel in product liability cases involving off-label promotion of drugs and devices should be mindful of the availability of constitutional defenses and, where appropriate, counsel should raise and preserve those defenses.

Conclusion

There is more to come on this entire topic. It is a virtual certainty that there will be future First Amendment challenges to federal and state regulatory statutes and rules. The cases to date suggest that a significant number of those challenges will prevail.

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FDA Releases Global Engagement Report

On April 23, 2012, the Food and Drug Administration (FDA) issued a report on the FDA's plans for increased global engagement. The report focuses on the challenges which a U.S. domestic regulatory agency faces in protecting U.S. consumers who are increasingly using products from non-U.S. manufacturers and facilities.

The report begins by noting the enormous volume of imports of FDA-regulated products. In 2009, for example, "$2 trillion worth of FDA-regulated products manufactured in more than 300,000 foreign facilities entered the United States from more than 150 countries." Between 2002 and 2011, imports of FDA-regulated products have grown substantially. This increase in imports results in, as the report states, "increased potential risks to the U.S. public."

In addition to the large volume of imports of FDA-regulated products, including food and medical products, the report observes that "[t]he increasing number of [medical product] clinical trials conducted abroad adds to the complexities of FDA reviews of product applications." These clinical trials are often conducted in "nations with limited regulatory capacity."

The FDA's global engagement strategies include the following:

- The FDA has opened offices in China, India, Latin America, Europe, South Africa and the Middle East. Through these offices, the FDA seeks greater knowledge of the regulatory systems of other countries, fosters relationships with other regulators and develops information for inspection of foreign facilities.
- The FDA proposes to work with the governments of other countries to strengthen their regulatory systems in recognition of the stake which the FDA and U.S. consumers have in the regulatory systems of other countries.
- The FDA recognizes the need for greater harmony in global science-based regulatory standards.
- Because inspection resources are limited, the FDA is focused on developing tools to effectively identify the products which pose the greatest health risks.

Regulated industry faces issues which mirror those which the FDA is facing. Industry shares the FDA's interest in safe products irrespective of the product's country of origin. The challenge for industry is finding effective ways to work with the FDA and regulators in other countries to build an effective and reasonably efficient global regulatory system. If achieved, products can move across borders and be consumed in the United States and elsewhere with confidence that the products are safe and are what they purport to be.

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Supreme Court Invalidates Personalized Medicine Patents on Grounds They Are Unpatentable Subject Matter Under Patent Act

In a unanimous decision, the Supreme Court invalidated personalized medicine patents on grounds they are unpatentable subject matter under Section 101 of the Patent Act.

In a long-awaited decision addressing patentable subject matter, the Supreme Court invalidated patents directed to customizing methods of treatment. *Mayo Collaborative Serv. v. Prometheus Labs*, 566 U. S. ___ (2012). This was the second time in recent years that the Court opined on the scope of patentable subject matter under 35 U.S.C. § 101. *See Bilski v. Kappos*, 561 U.S. ___ (2010).

The patents at issue, U.S. Patent Nos. 6,355,623 and 6,680,302, pertained to methods of optimizing the therapeutic efficiency of thiopurine drugs in a patient suffering from an autoimmune disease. The Court's analysis focused on claim 1 of the '623 patent because the "other claims in the patents do not differ significantly from claim 1." *Slip op. at 6.* Claim 1 of the '623 recites as follows:

> 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) *administering* a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) *determining* the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, *wherein* the level of 6-thioguanine less than about 230 pmol per 8 x 108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject; and *wherein* the level of 6-thioguanine greater than about 400 pmol per 8 x 108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject. '623 patent, col. 20, ll. 10-20 (emphasis added).

To reach its decision, the Court's analysis began with the well-established exclusionary rule that "laws of nature, natural phenomena and abstract ideas' are not patentable." *Mayo*, slip op at. 1 quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). The Court determined that the claims were directed to processes reciting laws of nature and, therefore, unpatentable. Slip op. at 8. In doing so, the Court overruled the Federal Circuit, which held that claims "do not encompass laws of nature or preempt natural correlations." *See* slip op. at 8.

The Court recognized that there must be some balance in the application of the exclusionary rule. "[T]oo broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Slip op at 2. Thus, "an application of a law of nature or mathematical formula to a known structure or process may be well deserving of patent protection." *Id.* quoting *Diehr,* 450 U.S. at 187 (emphasis in original). However, "to transform an unpatentable law of nature into patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words." *Id.* at 3 (emphasis in original).

To determine the patentability of the claims, the Supreme Court posed the question:

> whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?

Slip op. at 8. In answering the question "no," the Court noted that process claims reciting a law of nature are not patentable unless the claim "has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." Slip op. at 9. Simply reciting the law of nature with instructions to "apply the law" is insufficient. *Id.*

The Court found that the claims at issue lacked such additional features. "The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered." Slip op. at 9. These

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correlations are specified in the "administering," "determining" and "wherein" steps. These steps while "not themselves natural laws" were insufficient "to transform the nature of the claim" to render the claim patentable. *Id.* The "administering step" was insufficient because it merely refers to a specific audience – i.e. doctors treating patients with the drug. As the court noted, "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular environment." Slip op. at 9 citing to *Bilski*, slip op. at 14. Similarly, the "wherein" steps were insufficient because they "tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating a patient." *Id.* Since the "determining" step merely recites commonly practiced conventional activity by those in the field, it was also insufficient to impart patentability. Such "[p]urely 'conventional or obvious' '[pre]solution activity' is normally not sufficient to transform an unpatenable law of nature into a patent eligible-application of such law." *Id.* at 10, quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978). Similarly, the combination of the three steps also was insufficient:

> "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities." *Id.* at 11.

The Court also provided some guidance to patentable subject matter under Section 101. "[S]imply appending conventional steps, specified at a high level of generality to laws of nature, natural phenomena, and abstract ideas" does not render a claim patentable. *Id.* at 14. Integrating a mathematical formula, which alone would be unpatentable, into a process thereby "transform[ing] the process into an inventive application of the formula" is sufficient. *Id.* at 11. Similarly, process claims that contain both laws of nature and "several unconventional steps…that confine[] the claims to a particular, useful application of the principle" are also patentable. *Id.* at 15. The Court rejected the argument that the claims were transformations and reductions of an article to a different state and also refused to carve out new rules of patentable subject matter for diagnostic laws of nature. *Id.* at 19.

Although many have asserted the decision creates a significant uncertainty as to whether personalized medicine methods are patentable, it is worth noting that the U.S. Patent Office has already issued interim guidelines on the decision. Interestingly, the PTO states that the examiners "should continue to examine patent applications for compliance with section 101 using the existing interim Bilski guidance factoring additional considerations" discussed in *Prometheus*.

According to these guidelines, patentable claims "are not directed to an exception to the eligibility such that the claim amounts to a monopoly on the law of nature, natural phenomenon, or abstract idea itself." PTO Interim Guidelines at 2 (emphasis in original). Patentable claims "amount to significantly more than a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto." *Id.* (emphasis in original). Claims drawn to an exception under 101 (i.e. laws of natural, natural phenomena or abstract ideas) should be rejected as being directed to non-statutory subject matter. *Id.* at 2-3. In response to such a rejection, applicants should explain why the claims are "not drawn solely to the exception and point to the limitations in the claim that apply the law of nature, natural phenomena or abstract idea." *Id.* at 3. The PTO is in the process of developing further detailed guidance on patentable subject matter under Section 101. *Id.*

In a subsequent decision, the Court vacated the judgment in *Association for Molecular Pathology v. Myriad Genetics, Inc.* and remanded the case to the Federal Circuit for further consideration in light of *Mayo*. The *Myriad* case was pending in the Supreme Court to address the patentability of DNA-based inventions. Recently the District Court for the District of Columbia invalidated a patent claiming a system and method to guide the selection of therapeutic treatments using a computer program relying on *Prometheus*. *See SmartGene v. Advanced Biological Laboratories*, No. 1:08-CV-0642 (BAH), 2012 WL 1059611, ___ F. Supp. 2d ___ (D.D.C., March 30, 2012).

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Federal Circuit Clarifies the Scope of Intervening Rights

A recent Federal Circuit *en banc* decision clarified the scope of intervening rights as they pertain to patents that have been reexamined. *Marine Polymer Technologies, Inc. v. HemCon, Inc.*, 2010-1548 (Fed. Cir. March 15, 2012). The Federal Circuit held that under 35 U.S.C. § 307, after a patent emerges from *ex parte* reexamination, rights are available "only with respect to 'amended' or 'new' claims in the reexamined patent," slip op. at 20, i.e. when the text of the claim changes during reexamination or when new claims are added. In doing so, the Federal Circuit sided with positions taken by Marine Polymer and several of the *amici curiae*, including the Biotechnology Industry Association (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA), who "argu[ed] for a faithful reading of the statutory text." (Slip op. at 18, 25). Venable submitted the *amicus* brief on behalf of BIO and PhRMA. (www.Venable.com/federal-circuit-vacates-opinion-in-marine-polymer-technologies-inc-v-hemcon-inc-02-16-2012).

To reach its conclusion, the court relied on the dictionary definition of "amended," the statutory language of section 307, and patent prosecution practice. *Id.* at 22-23. First, the dictionary definition of "amended" is "to alter formally by adding, deleting or rephrasing" and thus, the court held, does not include argument. Second, the court determined that any interpretation of section 307 that encompasses disavowal or disclaimer by argument would be contrary to the statutory language because "it is difficult to envision how arguments about claim meaning could be 'incorporated into a patent' by the Director of the PTO." *Id.* Third, the court recognized that in patent prosecution, the term "amended" denotes formal changes to the actual language of the claim (with additions and deletions marked in the text). *Id.* Accordingly, Judge Lourie, writing for the 6-4 *en banc* majority, noted that "[w]e thus cannot agree that a claim can be 'amended' for the purposes of §307(b) without changing the claim language itself." *Id.* at 23-24.

The court adopted a two-step analysis for determining if intervening rights arise during reexamination: (1) whether the asserted claim is amended or new; and (2) whether any such amended or new claims were substantially changed. *Id.* at 21. However, "[o]nly if the claim at issue is new or has been amended may a court proceed to the second step of the analysis and assess the substantive effect of any such change." *Id.*

While the case pertains only to *ex parte* reexamination, given the similarities in statutory language, the holding should also apply to reissued patents, *inter partes* reexaminations, and the new post-grant review and *inter partes* review proceedings under the America Invents Act. The Federal Circuit was split 6-4, with the dissent taking the position of the vacated panel decision, that "amended" can include patentee arguments about claim scope made during reexamination. The district court's holding of infringement and assessment of damages was affirmed, and unless HemCon successfully petitions for *certiorari*, the case is closed.