

# IP OnTrial

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### Stent Patents, HD TV and NARB Appeals

- Our lead article discusses our success in overcoming an "obviousness" defense in two widely-celebrated patent suits involving the stent device used in heart surgery.
- The second article discusses a breakthrough decision by the Second Circuit in a false advertising case involving the relative quality of HD broadcasts by DIRECTV as compared to cable providers (see p. 3).
- Our final article explores the role of the National Advertising Review Board ("NARB") in appeals from the NAD, including our success in two significant NARB cases (see page 5).

## DOES IT MAKE SENSE TO PRESENT AN OBVIOUSNESS DEFENSE FOR A PIONEERING PATENT?

*Eugene M. Gelernter*

Accused infringers understandably are reluctant to forego an obviousness challenge, but attacking a pioneering invention as obvious presents a daunting challenge and can even be counter-productive. Two of our recent trials illustrated just how daunting that challenge can be.

In both of the recent trials, we accused the defendants of infringing a patent on an invention that revolutionized the treatment of coronary artery disease — the balloon-expandable stent. That invention transformed medical practice, supplanting the prior treatment (balloon angioplasty). It saved thousands of lives and created what today is a multi-billion dollar industry.

Our client, Johnson & Johnson, acquired Dr. Palmaz's patents on balloon-expandable stents and began selling stents practicing the Palmaz inventions in the early 1990s. By the late 1990's, other major medical device companies — Boston Scientific, Medtronic and Guidant — had entered the market with infringing stents. On behalf of Johnson & Johnson's Cordis subsidiary, we brought an infringement suit against all three companies.

Not long after bringing suit, Johnson & Johnson reached an agreement that shifted the Guidant case out of court and into arbitration, with an agreement that Johnson & Johnson would receive \$425 million in damages if it prevailed. We then tried the Guidant infringement case before a panel of three arbitrators. The panel unanimously ruled in our client's favor on all issues, leading to a \$425 million award.

Meanwhile, the cases against Boston Scientific and Medtronic were tried separately to juries in Delaware. Once again, we prevailed. At trial, both Boston Scientific and Medtronic chose not to assert an obviousness defense for the Palmaz patent, and instead concentrated on

other issues. After hearing the evidence, the Boston Scientific jury awarded \$324 million in damages in our client's favor. The Medtronic jury awarded damages of \$271 million.

The story did not end there. Following the verdicts, the district court granted JMOL for Medtronic and ordered a new trial for Boston Scientific. We then appealed the grant of JMOL for Medtronic. The district court stayed further proceedings as to Boston Scientific while that appeal went forward. On appeal, the Federal Circuit ruled in our favor on all issues. It held that prosecution history estoppel did not bar us from asserting the doctrine of equivalents and it rejected the district court's claim constructions as unduly narrow. See *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352 (Fed. Cir. 2003).

Instead of entering judgment on the earlier verdicts, the district court gave the defendants a second bite at the apple, allowing them to re-try obviousness and infringement (for one claim limitation). The cases were then re-tried. This time, both defendants mounted an obviousness defense. Although both defendants relied on the same prior art reference — a patent on a fixation sleeve that was issued to Dr. Robert Ersek — their defenses took various forms.

As for Medtronic, it offered Dr. Ersek as an expert witness. However, the district court granted our *Daubert* motion excluding any expert testimony he could offer, based largely on the fact that he had not practiced in a relevant medical specialty for three decades. After a brief career as a vascular surgeon (during which he filed the prior art patent that Medtronic relied on), Dr. Ersek had left vascular surgery and become a plastic surgeon. His practice ever since had concentrated on liposuction, breast augmentation and the like.

Although the *Daubert* ruling prevented Medtronic from calling Dr. Ersek as an expert, it did not preclude Medtronic from calling him as a fact witness — and Medtronic did exactly that. After hearing his testimony, it is easy to question the wisdom of that decision. On cross-examination, Dr. Ersek acknowledged that he had performed liposuction, *on himself, on television*. He also described his current medical practice of turning teenagers into celebrity look-alikes. After hearing this testimony, the jury could readily have viewed Dr. Ersek as an inveterate seeker of publicity — someone who would be all too eager to seek undeserved credit for Dr. Palmaz's pioneering invention.

Medtronic's difficulties in addressing obviousness were compounded by its reliance on a medical expert who had published extensively in the field and had lavished praise on the Palmaz invention. On cross-examination, Medtronic's medical expert conceded that Dr. Palmaz's invention was "pioneering," that it was "breakthrough technology" and that it could fairly be called a "modern medical miracle." Needless to say, his opinions on obviousness could not be squared with these concessions.

As for Boston Scientific, it took a different tack — but with no greater success. Its strategy was to give Dr. Palmaz credit, but not for the pioneering invention covered by the asserted claim. For example, its expert tried to explain away the numerous awards that prominent medical societies had given to Dr. Palmaz as merely a "testament to somebody who worked so hard." This faint praise may well have backfired in the jury room.

After a verdict in our client's favor in both of the re-trials, the district court ruled in our favor in denying the defendants' post-trial motions. And recently, the Federal Circuit rejected the defendants' appeals and ruled

(Continued on back)

## SECOND CIRCUIT EASES BURDENS ON PLAINTIFFS IN FALSE ADVERTISING CASES

*Saul B. Shapiro*

One of the biggest obstacles faced by plaintiffs in false advertising cases is that unless the ad in question is literally false, the plaintiff needs to provide consumer survey evidence about the meaning of the ad, and surveys can be expensive and time consuming to obtain. For that reason, for years plaintiffs have urged courts — and the Second Circuit in particular — to adopt a broader definition of literal falsity that includes ads that are false "by necessary implication," which means that an ad that does not explicitly make a false claim could still be found literally false if the ad nonetheless necessarily and unambiguously conveys that false claim. In a case we brought on behalf of Time Warner Cable against DIRECTV, the Second Circuit finally adopted this "false by necessary implication" doctrine. *Time Warner Cable Inc. v. DIRECTV, Inc.*, 497 F.3d 144 (2d Cir. 2007) (Opinion by Straub, J., joined by Kearse and Pooler, JJ.). In the same decision, the Second Circuit also made it easier for plaintiffs in markets with limited competition to meet the "irreparable harm" requirement for obtaining a preliminary injunction, holding that in such cases irreparable harm may properly be presumed if the ad makes a comparative claim, even if the ad does not refer to the plaintiff by its name.

### Background

Time Warner Cable had successfully sought a preliminary injunction regarding several DIRECTV television ads falsely claiming superior high-definition or "HD" picture quality. See *Time Warner Cable Inc. v. DIRECTV, Inc.*, 475 F. Supp. 2d 299 (S.D.N.Y. 2007) (Swain, J.). In one television ad, the actor Jessica Simpson stated "You're just not gonna get the best picture out of some fancy big screen TV without DIRECTV. It's broadcast in 1080i [the HD standard]." In another, the actor William Shatner stated "I wish he'd just relax and enjoy the amazing picture clarity of the DIRECTV HD we just hooked up. . . . Settling for cable would be illogical." Both ads ended with the tag line, "For an HD picture that can't be beat, get DIRECTV."

The District Court found that both ads were literally false, without relying on the doctrine of "false by necessary implication," because they claimed that DIRECTV's HD picture quality is superior to cable's, while it was undisputed that the parties had equivalent HD picture quality. Because the District Court found that the ads were literally false, Time Warner Cable was spared the time and expense of proving falsity through consumer surveys or other means. The District Court also found, without the time and expense of discovery, that it could presume that Time Warner Cable would suffer irreparable harm from DIRECTV's false ads — even though DIRECTV did not explicitly refer to Time Warner Cable in making a comparison between its HD picture and others' HD picture — because in markets where Time Warner Cable operates, it essentially is "cable," and DIRECTV is its primary competitor. The case went from the filing of the complaint to a decision enjoining the ads in eight weeks.

## The Second Circuit's Adoption of the "False by Necessary Implication" Doctrine

In considering DIRECTV's appeal of the District Court's decision, the Second Circuit readily agreed that the Simpson Ad was literally false. 497 F.3d at 154. However, it found that the Shatner Ad's statement that "settling for cable would be illogical" presented a more difficult problem, because it was not an explicit comparison between DIRECTV's HD picture quality and cable's HD picture quality. *Id.* DIRECTV, relying on *American Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160 (2d Cir. 1978), had argued that the statement could not be literally false because it did not explicitly compare DIRECTV HD to cable HD, and that the District Court must therefore have based its decision improperly on its subjective perception of the ad as a whole. *Id.* Time Warner Cable, relying on *Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381 (2d Cir. 1986), had argued that the District Court had properly determined that the statement was literally false by considering its language in the context of the rest of the ad, which was entirely about HD picture quality. *Id.* at 154-55.

The Second Circuit explained that *American Home Products* and *Avis Rent A Car* appear to conflict: the first holds that evidence of consumer confusion — *i.e.*, consumer survey evidence — must be considered if an ad does not make an explicitly false statement, while the second holds that a court may find an ad that uses literally accurate words to be literally false — without evidence of consumer confusion — by considering the overall context of the ad (including the context of the business at issue). *Id.* at 157. The Court then explained that *American Home Products* does not contradict the principle that an ad's meaning should be determined in context, and stated that to reconcile the two decisions, it would formally adopt the

"false by necessary implication" doctrine recognized by other Circuits. *Id.* at 157-58. Thus, the Court held that "an ad can be literally false even though it does not explicitly make a false assertion, if the words or images, considered in context, necessarily and unambiguously imply a false message." *Id.* at 148. Applying this doctrine, the Court upheld the District Court's decision that the Shatner Ad was literally false. *Id.* at 158.

## The Second Circuit's Expansion of the Presumption of Irreparable Harm

The Second Circuit also held that the District Court had properly presumed that Time Warner Cable would suffer irreparable harm. In previous cases, the Court had established that while irreparable harm must usually be demonstrated, it may be presumed where a false comparative ad mentions the plaintiff's product by name. *Id.* at 161-62. Here, neither television ad mentioned Time Warner Cable, and the Simpson Ad did not even use the word "cable" or any equivalent term. Nonetheless, the Court agreed with Time Warner Cable that the presumption also should apply "where the plaintiff demonstrates a likelihood of success in showing that the defendant's comparative advertisement is literally false and, that, given the nature of the market, it would be obvious to the viewing audience that the ad is targeted at the plaintiff, even though the plaintiff is not identified by name." *Id.* at 148. Thus, the Court agreed that the presumption was proper as to the Shatner Ad, which mentioned "cable," because Time Warner Cable is "cable" in markets where it operates. The Court also agreed that the presumption was proper as to the Simpson Ad, which did not mention "cable," because most consumers have either satellite or cable service, and therefore it "would be obvious" that DIRECTV's claims were directed at cable service providers. *Id.* at 162. ♦

## **NARB APPEALS**

*Christine H. Miller*

Most companies that engage in significant advertising are familiar with the National Advertising Division of the Better Business Bureau ("NAD"), which monitors advertising and provides a self-regulatory forum for resolving competitive disputes over advertising. In recent years, however, an increasing number of NAD decisions have been appealed to the National Advertising Review Board ("NARB"), the self-regulatory appellate body. In light of this trend, it is becoming increasingly important to understand the NARB process and plan for the possibility of an appeal.

### **NARB Appellate Procedure**

NARB is an advertising peer review group comprised of 70 volunteers drawn from the marketing, advertising and public sectors. NAD appeals are heard by a panel of five members of NARB. In the typical panel, three members are marketing executives, generally brand managers or vice presidents. One panelist comes from an advertising agency. The final panelist (usually a professor of marketing or communications) represents the public, and chairs the panel. Unlike the NAD staff, NARB panelists are not attorneys. They are assisted, however, by the General Counsel of NARB.

At the conclusion of an NAD challenge, the advertiser has an automatic right to appeal any part of NAD's decision. During the pendency of the appeal, the advertiser is not required to comply with the portion of NAD's decision that is under review by NARB. The challenger, on the other hand, must request permission to appeal unless the advertiser has appealed a split decision, in which case the challenger has the right to appeal too.

To obtain permission to appeal, the challenger must submit a detailed letter (no more than 20 pages) explaining its reasons for seeking NARB review. The advertiser and NAD then submit responsive letters explaining why they believe NARB is unlikely to reach a different decision than NAD. The Chairman of NARB decides whether to accept the appeal. Years ago, very few challenger appeals were granted. This policy has changed somewhat under the current NARB Chairman, Howard Bell, who has granted permission for several challenger appeals in recent years.

At the time a party announces its intention to appeal, it must specify the particular issues for which it seeks NARB review. Any issue not so identified will not be considered by NARB. Furthermore, throughout the appellate process, the parties are not allowed to raise arguments or cite evidence not considered by NAD. Thus even though NAD may be very familiar with your product category as a result of prior challenges, it behooves the parties to include any information in the record that might be necessary to educate a NARB panel that knows little about the issues in dispute.

Once NAD transmits the record to NARB, the party who filed the appeal has two weeks to file a letter (not to exceed 30 pages) explaining the factual and legal basis for the appeal. NAD and the opposing party each submit a responding letter. There is no reply submission, so any rebuttal arguments should be anticipated and addressed in the appellant's initial letter.

After receiving the written submissions, the Director of NARB appoints a panel and schedules a hearing. Unlike NAD proceedings, where the parties meet separately with NAD, the NARB hearing is a more formal face-to-face proceeding. And, unlike a judicial appeal, where the trial judge has no role, NAD appears before the NARB panel to explain and defend its decision.

The chair of the NARB panel presides over the hearing and sets time limits for the presentations — usually fifteen minutes for each initial presentation and five minutes for each rebuttal. NAD typically speaks first, followed by the party that filed the appeal, followed by the responding party. Any handouts or PowerPoint presentations must be submitted to NARB, NAD and the opposing party in advance of the hearing. The oral presentations typically are made by attorneys; however, representatives of the parties are encouraged to attend and may answer questions posed by panel members, so long as their answers do not go beyond the evidence in the record.

The NARB panel deliberates immediately after the hearing. The General Counsel of NARB then prepares a draft written decision that is circulated among panel members. While most NARB decisions are unanimous, on occasion, dissenting opinions are filed.

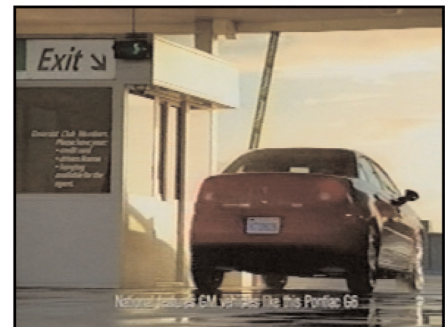
Regardless of who filed the appeal, NARB's decision is forwarded to the advertiser before it is released to the challenger and the public. As with NAD decisions, the advertiser submits an Advertiser's Statement indicating whether it agrees to abide by NARB's recommendations. The opinion and Advertiser's Statement are published in the NAD Case Reports and a press release is issued to the news media. There is no further self-regulatory recourse after NARB's decision. If the advertiser does not accept NARB's recommendation, the matter is referred to the appropriate regulatory authority (usually the FTC) for enforcement.

## Recent NARB Appeals Handled by Patterson Belknap

In the past two years, NARB decided nine appeals, two of which were handled by Patterson Belknap. In one case we obtained a reversal of NAD's decision on behalf of our client, The Hertz Corporation. In the other, we obtained an affirmance on behalf of Abbott Laboratories.

### National Car Rental — NARB Panel #136

This dispute involved advertising for National Car Rental, which was airing a series of humorous 15-second commercials promoting the speed and convenience of its Emerald Club expedited rental service. After



a funny opening vignette showing a quick event, the commercials said "with the Emerald Club you can bypass the counter, choose your own car and get an e-receipt." During this sequence there was a brief visual image of a car driving through the National exit gate without stopping, similar to the way a car might pass through an "Easy Pass" tollbooth. Hertz challenged this visual because, in actuality, Emerald Club renters must stop at the exit gate to process their transaction.

NAD sided with National. It held that the fleeting shot of the exit gate would not be construed by consumers as an actual demonstration of the rental process, but rather simply reinforced National's message that Emerald Club members enjoy fast

service. Hertz disagreed. It felt that NAD improperly ignored legal precedent requiring visual representations of an advertiser's product to be literally accurate. We therefore petitioned the Chairman of NARB, and were granted permission to appeal.

Although NARB generally upholds NAD's interpretation of commercials, in this instance it reached a different conclusion. The panel posed tough questions to National about why it elected to show the car driving through the exit gate without stopping — and what message National intended to convey by this sequence. Interestingly, the advertising agency member of the panel pointed out that, in a 15-second commercial, every visual image counts — no matter how brief. The panel eventually concluded that the exit gate visual was an inaccurate representation of National's rental process that could mislead consumers. It recommended that National modify or discontinue the challenged advertisements.

### **Bayer Healthcare – NARB Panel #142**

This challenge involved consumer and professional advertising for devices used by people with diabetes to monitor their blood sugar levels. Special test strips are inserted into these meters each time a blood test is conducted. Because of minor manufacturing variations in the production of test strips, most strips come with a calibration code that the user manually enters into the meter when starting a new package of strips. Bayer's meter, however, automatically reads the calibration code and does not require manual coding.

Rather than highlighting the convenience of this feature, Bayer portrayed it as a safety advantage. Its advertising claimed that coding errors with traditional meters could skew test results by up to 43% and cause

serious clinical consequences. Claims like this obviously could scare consumers and damage a competitor's market share.

Our client, Abbott Laboratories, sells a popular blood glucose meter that requires manual coding. The Abbott meter, however, is engineered so that coding errors rarely happen and, when they do, the most likely types of errors do not produce inaccurate readings. Abbott therefore challenged Bayer's advertising on the grounds that it falsely disparaged manually coded meters and misrepresented the significance of coding errors. NAD agreed with Abbott and recommended that Bayer discontinue its campaign. Bayer appealed, arguing that it was entitled to inform consumers about the theoretical consequences of a potential coding error, no matter how remote.

The record in the challenge was enormous, including extensive scientific literature and technical information. Nevertheless, the NARB panelists arrived at the hearing familiar with the scientific and legal arguments. There was active questioning during the presentations and the panel's decision reflects an impressive grasp of the issues in dispute. Happily for our client, the panel agreed with NAD that the studies relied upon by Bayer were not conducted under consumer relevant conditions and did not demonstrate that coding errors with Abbott's meter could place diabetic patients in danger.

In both of these appeals, the NARB panelists took their responsibilities seriously, and issued pragmatic and well-reasoned decisions. They seemed particularly appreciative of clear, concise and polite presentations — and while they certainly were deferential to NAD, the *National Car Rental* appeal shows that NARB is not reluctant to take a fresh look at the issues. ♦

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in our client's favor on all liability issues. See *Cordis Corp. v. Medtronic Vascular, Inc.* and *Boston Scientific Corp.*, 511 F.3d 1157 (Fed. Cir. 2008).

Of course, the outcome in our favor on obviousness was not entirely unexpected. After all, Dr. Palmaz's invention revolutionized the practice of medicine and created a multi-billion industry. Moreover, both defendants were relying on a prior art reference whose function, purpose and structure was fundamentally different from that of the patented invention, and which the Patent Office had carefully considered. These facts made the validity of the Palmaz patent difficult, if not impossible, to challenge.

It is impossible to know whether our adversaries would have fared better in the re-trials if they had chosen to forego an obviousness defense. Certainly, they did not fare better in the initial trials, when they both chose to forego an obviousness challenge. In any event, attacking a pioneering patent as obvious in the re-trials clearly did not aid their cause. ♦

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***IP OnTrial* is a newsletter prepared by attorneys in the Intellectual Property Litigation Practice Group of Patterson Belknap Webb & Tyler LLP for our clients and other interested friends.**

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