Federal Preemption in Class III Medical Device Cases

By Donna B. DeVaney and Patrick Hamilton

I. Introduction

The Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, set forth a comprehensive regulatory scheme governing the sale of medical devices in the United States.[1] The MDA divides medical devices into three classes.

Class I devices, such as tongue depressors and elastic bandages, pose little or no risk of illness or injury, and are "subject only to minimal regulation."[2]

Class II devices, such as powered wheelchairs and some pregnancy test kits, are "potentially more harmful," and manufacturers of such devices "must comply with federal performance regulations known as 'special controls.'"[3]

Finally, the most strictly regulated devices—Class III devices, such as pacemakers and breast implants—are "devices that either 'presen[t] a potential risk of illness or injury,' or which are 'purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.'"[4]

Plaintiffs' attorneys litigating claims involving Class III medical devices approved through the PMA process will almost certainly face a motion for summary judgment based on express and implied preemption.

Before a manufacturer can market a Class III device, it must obtain approval from the FDA. There are three distinct routes to obtain approval. Under the first route, devices can be sold if they are cleared under the so-called 510(k) process, 21 U.S.C. § 360(k), which allows manufacturers to sell devices that are "substantially equivalent" to a device that pre-dates the MDA. The 510(k) process merely establishes whether a pre-1976 device and a post-1976 device are equivalent, and places no "requirements" on the device.[5]

Under the second route, devices representing new technology may be marketed under an investigational device exemption ("IDE"), an experimental regimen that allows for unapproved devices to be used in human clinical trials.[6] "The application for an IDE is itself fairly extensive, and the FDA will not approve an IDE if there is reason to believe the device will be ineffective or present unreasonable safety risks to patients."[7]

Under the third route, manufacturers may obtain approval through the FDA's "premarket approval" or "PMA" process, in which "the manufacturer must provide the FDA with 'reasonable assurance' that the device is both safe and effective."[8] The PMA is a "rigorous" process under which "[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission."[9]

Approval of a Class III medical device through the PMA process often begins with an IDE clinical trial. Near the end of the clinical trial, the manufacturer will submit a PMA application seeking FDA approval to sell the device in the United States. Applications include a summary of the device's safety and effectiveness, including contraindications, warnings, and precautions; detailed device description and manufacturing information; performance standards; technical manuals; and package inserts and labels. The manufacturer will also provide the FDA with information about the design of its device and its components, including specifications for the various materials used to manufacture the device.

The device may then be reviewed by a panel of non-governmental experts such as the Orthopedic and Rehabilitation Devices Panel ("Panel"), a group designated to review and provide the FDA with recommendations on PMA applications for orthopedic devices.

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The Panel determines whether the data submitted by the manufacturer meets the safety and effectiveness criteria required by the FDA and, if so, recommends approval of the manufacturer's PMA application. The FDA reviews the Panel's suggestions and often asks that additional information be provided to determine whether there is "reasonable assurance that the device is safe and effective for its intended use."[10]

Upon FDA approval of a PMA application, the medical device can be sold in the United States. Device manufacturers must then manufacture and market devices in conformity with the design, manufacturing and labeling requirements the FDA established. They are prohibited from deviating from these processes in any way that would affect the safety or effectiveness of the device.[11]

II. Federal Preemption

The affirmative defense of federal preemption is a product of our nation's dual federal-state system. Under the Supremacy Clause of the United States Constitution, state law must give way to federal law when Congress intends a preemptive result.[12] Congress evidences its intent to preempt state law either through express statutory language or by creating a federal statutory scheme that implies a preemptive intent.[13]

When Congress enacted the MDA and gave the FDA the authority to regulate medical devices, it sought to protect innovations in device technology from being "stifled by unnecessary restrictions."[14] To accomplish that goal, Congress included in the MDA the following provision, which expressly preempts certain state law requirements governing medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is **different from, or in addition to**, any requirement applicable under this [Act] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].[15]

A. Express Preemption

The United States Supreme Court's decision in *Medtronic, Inc. v. Lohr* (*Lohr*) provides the framework for preemption analysis under Section 360k(a).[16] In *Lohr*, the Supreme Court addressed whether the MDA expressly preempted state tort claims involving a Class III medical device approved through the 510(k) process. The *Lohr* court read section 360k(a) to demand three things: (1) the imposition of a specific federal requirement that (2) applied to a particular device and (3) focused on the safety and effectiveness of the device.[17] If those criteria are satisfied, states are prohibited from having "requirements" that are different from or in addition to the FDA's requirements regulating the device.

In a fractured opinion (4-4-1), the *Lohr* court held that section 360k(a) did not preempt state tort claims involving Class III medical devices approved through the 510(k) process because the FDA's review of a 510(k) application addresses "substantial equivalence" rather than "safety and effectiveness."[18] The Court found that because the less-rigorous 510(k) process focuses on a device's "equivalence" to an already-existing product rather than safety, the 510(k) process did not give rise to any "specific" federal "requirement," and section 360k(a) was not implicated.[19] The court stated, however, that "[t]he § 510(k) notification process is by no means comparable to the PMA process"[20] and suggested that its analysis and decision would have been different if the device had weathered the PMA process.[21]

1. Device-Specific Federal Requirements

Unlike the 510(k) notification process at issue in *Lohr*, the PMA process addresses the "safety and effectiveness" of Class III medical devices and, therefore, has been found to preempt state law claims. Indeed, "the entire purpose of the PMA process is for the FDA to obtain a 'reasonable assurance' that the device is safe and effective."[22] Manufacturers argue that FDA regulation of Class III medical devices approved through the PMA process constitutes the imposition of "specific" federal "requirements" that focus on the device's "safety and effectiveness" thereby preempting state tort law claims that would impose "requirements" that are different from or in addition to the FDA's requirements.

For example, device manufacturers contend that when a jury holds a manufacturer liable for using (or not using) a particular design or warning, it is imposing specific "requirements" on the medical device.[23] Therefore, the central question to a PMA preemption analysis is whether common law duties imposed by state tort law are "requirement[s] that are different from, or in addition to, any requirement applicable…to the device under the MDA, and therefore explicitly preempted by 21 U.S.C. § 360k(a)."[24]

Since *Lohr*, the overwhelming majority of the federal circuit courts of appeal to have decided the issue—including the Third, Fifth, Sixth, Seventh and Eighth Circuits—have concluded that: (1) the PMA process results in FDA-imposed "specific" federal "requirements"; and (2) state law tort claims made with respect to such PMA-approved devices can impose requirements on the design, manufacture and marketing of medical devices, and can therefore amount to a "specific" state "requirement" triggering preemption.[25] A vast majority of federal district courts have also reached the same conclusion.[26] In addition, numerous state courts have also found that the PMA process creates "specific" federal "requirements."[27]

In *Horn v. Thoratec Corp.*, the Third Circuit addressed preemption in a case involving the HeartMate heart pump.[28] Thoratec received an IDE by the FDA to begin clinical trials and later received FDA approval to sell the Heartmate after a PMA and PMA Supplement review process.[29] The *Horn* court concluded that there was "no doubt" that the lengthy PMA process "imposed *mandatory conditions*… pertaining to the HeartMate's manufacturing, packaging, storage, labeling, distribution and advertising" that triggered federal preemption.[30] The court, noting that "it is firmly established that a 'requirement' under § 360k(a) can include legal requirements that

arise out of state common-law damages actions," dismissed plaintiff's common law negligence claims because the claims would impose substantive requirements on Thoratec that would conflict with, or add to, those imposed by the FDA.[31]

Similarly, the Eight Circuit in *Brooks v. Howmedica, Inc.* concluded that the FDA's PMA review does impose specific federal requirements which preempt state law tort claims.[32] The *Brooks* court was influenced by six facts:

1. the manufacturer's submissions to the FDA included detailed information concerning the design, possible side effects and post-operative complications, manufacturing procedures, testing, and proposed labeling;

2. the FDA took significant time in reviewing the initial PMA application;

3. the FDA reviewed the device's safety and warnings when concerns were raised after approval;

4. the FDA imposed specific conditions in granting PMA approval, including provisions for specific language for the device warning label;

5. the FDA prohibited the manufacturer's deviation from the specific labeling requirements; and

6. the FDA specifically found the device was sufficiently "safe and effective" to allow marketing.[33]

The Eighth Circuit determined that plaintiff's claims conflicted with the FDA's requirements and dismissed the case, holding:

> A jury finding of negligent failure to warn would be premised on the fact that the label for [the device] was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements.[34]

In *Kemp v. Medtronic, Inc.*, the Sixth Circuit found plaintiff's product liability claims were preempted because "PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" and is "specific to the product."[35] The court further explained that it is the "totality of the design, manufacturing processes, and labeling—when coupled with the prohibition against modifying them—that represents the specific federal requirement applicable under [the MDA] to the device."[36] The court cautioned that "[t]o permit a jury to find Medtronic negligent for a manufacturing defect would be to impose a requirement different from and in addition to those established by the FDA."[37]

Most recently, the Seventh Circuit in *McMullen v. Medtronic, Inc.*, held that plaintiffs' common law claims involving a Class III medical device approved through the PMA process were preempted by the MDA.[38]

The Eleventh Circuit is the only federal circuit court of appeals to have decided that the PMA process does not result in FDA-imposed federal requirements in a case involving a Class III medical device.[39] However, state courts in Florida, Georgia and Alabama are not bound by the opinions of the Eleventh Circuit Court of Appeals. Instead, opinions of the Eleventh Circuit are considered merely persuasive authority.[40] Moreover, as the Eleventh Circuit itself candidly acknowledged, its decision is "at odds with the results reached in a number of cases both before and after the Supreme Court's decision in *Lohr*."[41]

2. Safety and Effectiveness

Manufacturers typically argue that products liability claims clearly seek to impose state law requirements that affect the safety and effectiveness of the medical device at issue, which are different from or additional to those imposed by the FDA. Therefore, any jury verdict in the plaintiff's favor would necessarily challenge the FDA's safety and efficacy determinations as well as the design, manufacturing processes and warning labels the agency approved.

To illustrate, in cases where a plaintiff alleges that a manufacturer was negligent in designing, testing and manufacturing a device, the manufacturer will argue that any such claims which seek, among other things, to redesign the device and change the manufacturing process by injecting a standard of care different from, or more than, the exacting standards imposed by the FDA are expressly preempted because the claims are directly at odds with the FDA's determination that the device is safe and effective without the changes.

The argument is the same with respect to failure to warn claims. Failure to warn claims necessarily depend on the impermissible contention that the FDA-approved label should contain something "in addition to or different from" the language that the FDA allowed or required. Because the plaintiff seeks to prevail by imposing safety and effectiveness requirements other than those approved by the FDA in the PMA process, manufacturers have successfully argued that failure to warn claims are preempted.[42]

3. The FDA Endorses Preemption

The FDA's most recent activity bolsters device manufacturers' preemption defense. The FDA recently began intervening in cases where plaintiffs seek to impose—via state law tort claims—requirements in addition to or different from FDA-imposed requirements for medical devices. The FDA has submitted *amicus curiae* briefs endorsing preemption principles in a number of medical device cases. It filed its most recent *amicus* brief in *Horn*, in which it endorsed preemption principles consistent with the majority view of the Third, Fifth, Sixth, Seventh and Eighth Circuits and unequivocally expressed the opinion that state common law claims involving Class III medical devices approved through the PMA process are preempted.[43]

The FDA explained that the rigorous PMA and PMA Supplement processes involve careful, expert weighing of complex scientific issues and impose specific federal design, label and manufacturing requirements.[44] The FDA also stated that common law tort actions not only conflict with those federal requirements but "threaten the statutory frame work for the regulation of medical devices."[45]

"There are very strong public policy considerations that support the government's view that PMA ap-

proval by [the] FDA preempts a state common law tort suit that would, if successful, impose liability when a manufacturer is doing only what FDA approved."[46] These include the danger posed by litigation that:

> [C]reate pressure on manufacturers to add warnings that [the] FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective. This situation can harm the public health by retarding research and development and by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.[47]

B. Implied Preemption

In addition to express preemption arguments, Class III medical device claims are likely to face a motion for summary judgment based on implied preemption.[48] Implied preemption differs from express preemption in that it turns on an "actual conflict" rather than an express statutory preemption clause.[49] That is, when state law conflicts with, interferes with, or otherwise presents "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," the state law is impliedly preempted. It also arises when a state law tort claim imposes a standard that "makes it impossible for private parties to comply with both state and federal law."[50]

In *Buckman Co. v. Plaintiffs' Legal Comm.*, the United States Supreme Court considered whether a conflict between the FDA's medical device regulatory regime and certain state tort claims gave rise to implied preemption.[51] There, the plaintiffs argued that the defendant medical device manufacturer had made fraudulent representations to the FDA to obtain FDA approval for its device. Plaintiffs argued that but for those alleged fraudulent disclosures, the agency would not have approved the device, and thus plaintiffs would not have used the device.[52]

The Supreme Court held that plaintiffs' "fraud on the FDA" claims were impliedly preempted because allowing them to proceed would threaten the federal regulatory regime for medical devices.[53] The Court noted that "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes [would] dramatically increase the burdens facing potential applicants," such that medical device manufacturers might refuse to submit potentially beneficial devices for regulatory approval out of fear of "unpredictable civil liability."[54]

Similarly, in *Webster v. Pacesetter, Inc.*, the United States District Court for the District of Columbia held plaintiff's failure to warn and fraud claims were impliedly preempted where plaintiff alleged the defendant had failed to comply with the FDA's various requirements pertaining to labeling, design and adverse event reporting.[55] In doing so, the court rejected the plaintiff's argument that if the FDA had known of the alleged product defect and if the defendant had investigated all the adverse events, the plaintiff would not have been injured, and warned that plaintiff's approach would "only invite a jury to speculate about what the FDA…might do if the facts were different."[56]

III. Conclusion

Plaintiffs' attorneys litigating claims involving Class III medical devices approved through the PMA process will almost certainly face a motion for summary judgment based on express and implied preemption. Until the United States Supreme Court directly addresses whether the MDA preempts state tort claims involving medical devices approved through the PMA process, all products liability counsel, whether they represent plaintiffs or defendants, should educate themselves on the principles of preemption as it has worked as a bar to many state law tort claims involving Class III medical devices filed throughout this country in both state and federal courts. ❖

Endnotes

[1] *Medtronic v. Lohr*, 518 U.S. 470, 476 (1996).
[2] *Id.* (citing 21 U.S.C. § 360c(a)(1)(A)).
[3] *Id.* (quoting 21 U.S.C. § 360c(a)(1)(B)).
[4] *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)).
[5] *See id.*
[6] *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000).
[7] *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1370 (11th Cir. 1999) (citing 21 C.F.R. § 812.30(b)(4)).
[8] *Medtronic v. Lohr*, 518 U.S. 470, 476-77 (1996) (quoting 21 U.S.C. § 360e(d)(2)).
[9] *Id.*
[10] *Id.*
[11] 21 U.S.C. § 360e(d)(6).
[12] U.S. Const., art. VI, cl. 2; *see also Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000).
[13] *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 792 (8th Cir. 2001) (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).
[14] H.R. Rep. No. 94-853, at 12 (1976).
[15] 21 U.S.C. § 360k(a) (emphasis added).
[16] 518 U.S. 470 (1996).
[17] *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1372 (11th Cir. 1999).
[18] *Medtronic v. Lohr*, 518 U.S. 470, 492-94 (1996).
[19] *See Id.* at 492-493, 501.
[20] *Id.* at 478-79.
[21] *See Id.* at 500-501.
[22] *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1372 (11th Cir. 1999) (quoting 21 U.S.C. ¶ 360c(a)(1)(C)).
[23] *Martin v. Medtronic, Inc.*, 254 F.3d 573, 579-83 (5th Cir. 2001).
[24] *Moore v. Sulzer Orthopedics, Inc.*, 336 F. Supp. 2d 1002, 1007 (N.D. Ohio 2004).
[25] *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488 (7th Cir. 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163, 2004 U.S. App. LEXIS 14942, at *16-17, 37 (3d Cir. 2004); *Brooks*, 273 F.3d at 795-797 (8th Cir.), *cert. denied*, 535 U.S. 1056 (2002); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 579-85 (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-27 (6th Cir. 2000), *cert. denied*, 122 S. Ct. 48 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911, 913-14 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *see also Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997), *cert. denied*, 522 U.S. 862 (1997) (holding that state tort claims constitute device specific requirements for purposes of preemption, in a case involving a Class II device that did not undergo the PMA process).
[26] *See Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 432, 434 (E.D. Pa. 2004); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 453, 455 (D.N.J. 2003); *Carey v. Shiley, Inc.*, 32 F. Supp. 2d 1093, 1104-06 (S.D. Iowa 1998); *In re Medtronic*, 96 F. Supp. 2d 568, 570-71 (E.D. Tex. 1999); *Baker v. Medtronic, Inc.*, 2002 WL 485013, at * 4-5 (S.D. Ohio Mar. 28, 2002); *Gilleon v. Medtronic, Inc.*, 2002 WL 31300694, at *5 (N.D. Cal. Aug. 28, 2002);

Enlow v. St. Jude Med., Inc., 171 F. Supp. 2d 684, 689 (W.D. Ky. 2001); *Pipitone v. Biomatrix, Inc.*, 2001 WL 568611, at *5-7) (E.D. la. 2001); *Dunlap v. Medtronic, Inc.*, 47 F. Supp. 2d 888, 897-98 (N.D. Ohio 1999); *Isbell v. Medtronic, Inc.*, 97 F. Supp. 2d 849, 861 (W.D. Tenn. 1998); *Rogerson v. Telectronics Co.*, 1998 WL 559788, at *7 (N.D. Ill. Aug. 25, 1998); *Lake v. TPLC*, 1 F. Supp. 2d 84, 86-87 (D. Mass. 1998); *Richman v. W.L. Gore Assocs.*, 988 F. Supp. 753, 758 (S.D.N.Y. 1997); *Chmielewski v. Stryker Sales Corp.*, 966 F. Supp. 839, 842-43 (D. Minn. 1997); *Salazar v. Medtronic, Inc.*, 1997 WL 1704284, at *4-5 (S.D. Tex. Aug. 8, 1997); *Easterling v. Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 374-75 (E.D. La. 1997).

[27] *See Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997), *cert. denied*, 522 U.S. 952 (1997); *Rowen v. Medtronic, Inc.*, No. 78-020, slip op. at 4-5 (Iowa July 15, 1997); *Green v. Dolsky*, 685 A.2d 110, 117-118 (Pa. 1996), *cert. denied*, 522 U.S. 1168 1997); *Steele v. Collagen Corp.*, 54 Cal.App.4th 1474, 1486-89 (1997); *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 792-93 (2002); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998), *cert. denied*, 524 U.S. 954 (1998); *Stefl v. Medtronic, Inc.*, 916 S.W.2d 879, 881-82 (Mo. 1996).

[28] 376 F.3d 163 (3d Cir. 2004).

[29] *Id.* at 169.

[30] *Id.* (emphasis in original.)

[31] *Id.* at 173, 176.

[32] 273 F.3d 785 (8th Cir. 2001).

[33] *Id.* at 798.

[34] *Id.* at 796.

[35] 231 F.3d 216, 226-27 (6th Cir. 2000).

[36] *Id.* at 228.

[37] *Id.* at 230.

[38] 421 F.3d 482, 488 (7th Cir. 2005).

[39] *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). *See also Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997)(finding no federal preemption in a Class II medical device case).

[40] *Raymond James Fin. Servs. v. Saldakas*, 851 So. 2d 853, 857 (Fla. 2d DCA 2003) ("this court is not bound by decisions of the Eleventh Circuit on issues of federal law. Rather, this court is bound only by the United States Supreme Court on issues of the interpretation of a federal statute").

[41] *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999).

[42] *See* FN. 25, FN 26, and FN 27.

[43] *See* FDA Amicus Brief in *Horn v. Thoratec*, 2004 WL 11443720, at 17-18; *see also* Statement of Interest filed by FDA in *Murphree v. Pacesetter, Inc.*, No. 005429-00-3 (Tenn. Cir. Ct. Dec. 12, 2003) (arguing that PMA approval by the FDA "triggers preemption of a wide array of requirements imposed under state law").

[44] FDA Amicus Brief in *Horn*, 2004 WL 1143720 at *6-8, 15-18, 21, 24, 29.

[45] *Id.* at 18, 25-26.

[46] *Id.* at 25.

[47] *Id.* at 25-26.

[48] *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-71 (2000) (rejecting notion derived from earlier cases such as *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), that an express preemption clause bars the ordinary application of implied preemption principles).

[49] *Geier*, 529 U.S. at 884.

[50] *Id.*

[51] 531 U.S. 341 (2001).

[52] *Id.* at 346-47.

[53] The court in *Buckman Co.* described the FDA's system for approving medical devices, even under the less rigorous 510(k) process, as a "comprehensive scheme," spelling out exactly what a manufacturer must submit to the FDA, empowering the FDA to demand further information, and authorizing the FDA to investigate and punish any suspected violation of its rules. *Id.* at 348-49.

[54] *Id.* at 350.

[55] 259 F. Supp.2d 27, 36-39 (D.D.C. 2003) ("plaintiffs cannot bootstrap their arguments regarding defendant's alleged failure to report and to investigate adverse incidents to the FDA into a defective warning case").

[56] *Id.* at 37.

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