# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BENTLEY A. HOLLANDER,	:	CIVIL ACTION
Plaintiff/Relator, v.	: : :	
RANBAXY LABORATORIES INC.,	:	NO. 10-793
Defendant,	:	
v.	:	
UNITED STATES OF AMERICA,	: :	
Intervener.	·	

#### MEMORANDUM REGARDING CONSTITUTIONALITY OF 35 U.S.C. § 292(b)

Baylson, J. July 18, 2011

#### I. Introduction

Plaintiff Bentley A. Hollander ("Hollander") initiated this <u>qui tam</u> action against

Defendant Ranbaxy Laboratories, Inc. ("Ranbaxy") for alleged violations of the False Marking

Statute, 35 U.S.C. § 292. Section 292 penalizes the marking of products with false or expired

patent numbers and allows "[a]ny person" to sue for the statutory penalty. <u>See</u> § 292(a), (b). The

Court previously denied Ranbaxy's Motion to Dismiss for failure to state a claim and

Hollander's Cross-Motion for Judgment on the Pleadings. (Order, ECF No. 31.) Ranbaxy has

now filed another Motion to Dismiss arguing that § 292(b) violates the Take Care Clause of

Article II of the Constitution. (Mot. to Dismiss, ECF No. 45); <u>see</u> U.S. Const. Art. II, § 3 ("[The

President] shall take Care that the Laws be faithfully executed.").

Hollander initiated this qui tam action in connection with Ranbaxy's marking of certain

dermatology products with expired patent numbers. Hollander alleges that Ranbaxy has marked these products with, and used in advertising, expired patent numbers for the purpose of deceiving the public. (Compl., ECF No. 1 ¶¶ 27-28.) He seeks imposition of a fine, up to \$500 for each "offense," one-half of which will be paid to the United States and the other half he will retain.

(Id. at 9); see 35 U.S.C. § 292(b).

The Court is now faced with the latest challenge to the False Marking Statute – whether § 292(b) violates the Take Care Clause of Article II by failing to afford the Executive Branch sufficient control over litigation which clearly intends to benefit the government. Several district courts have already weighed in on this issue, some very briefly and others with more extensive and insightful analysis. According to Hollander, a "veritable avalanche" of decisions – all of about ten cases as of the time of this Memorandum – hold § 292(b) constitutional. (Opp'n, ECF No. 48 at 2.) On the other hand, Ranbaxy can point to only two decisions that have found § 292(b) unconstitutional – one now pending appeal to the Federal Circuit and the other from this District. (Mot. to Dismiss Memo., ECF No. 45-1 at 10-15; Suppl. Auth., ECF No. 81); see Rogers v. Tristar Prods., Inc., No. 11-1111, 2011 WL 2175716, at \*10-11 (E.D. Pa. June 2, 2011) (Robreno, J.). On June 23, 2011, the Court entered an Order denying Ranbaxy's Motion to Dismiss. (Order, ECF No. 90.) This Memorandum will state the reasons.

The Court also denied Ranbaxy's Motion to Stay (Mot. to Stay, ECF No. 51) in its June 23, 2011 Order. In light of subsequent events, particularly both houses of Congress passing legislation to amend § 292(b) to require a false-marking relator to have suffered a competitive

injury,¹ which Hollander agrees he cannot show, the Court has reconsidered the merits of a stay. Because the proposed legislation would vitiate Hollander's standing to proceed as a <u>qui tam</u> relator, and to prevent the parties from incurring the unnecessary costs of continued litigation, and after a hearing on the issue on July 8, 2011, the Court concludes it is appropriate to stay this matter for ninety (90) days after the close of discovery on July 15, 2011. An appropriate Order will follow.

#### **II.** Parties' Contentions

Ranbaxy contends that § 292(b) lacks sufficient controls to allow the President to comply with his constitutionally assigned duty "to take Care that the Laws be faithfully executed." See U.S. Const. Art. II, § 3. Ranbaxy asserts that the False Marking Statute is a criminal statute and, therefore, the Supreme Court decision in Morrison v. Olson, 487 U.S. 654 (1988), establishes the requisite controls. Not only does § 292(b) lack the controls found sufficient in Morrison, it also lacks the controls found sufficient for the False Claims Act, a civil action, to survive constitutional scrutiny. In particular, § 292(b) does not require notice to the United States of the relator's false marking case and does not provide the United States any control over the course of the litigation.

Hollander opposes Ranbaxy's Motion and relies on the United States's brief filed with the Federal Circuit in Wham-O. (Opp'n Ex. 8.) The United States argues that the False Marking Statute is constitutional because <u>qui tam</u> statutes have a long history in England and the American colonies and Congress has the power to choose the method of enforcement. Further, §

See Patent Reform Act of 2011, S. 23, 112th Congress § 2(k) (as passed by Senate Mar. 8, 2011); America Invents Act, H.R. 1249, 112th Congress § 16(b) (as passed by House June 23, 2011).

292(b) does not facially aggrandize Executive power or impermissibly undermine Executive power because Article II does not make the Executive the sole means of law enforcement. The United States also contends Morrison is distinguishable because a false marking relator does not sue as the United States, but only in the name of the United States, and the United States has sufficient means of controlling the litigation. Finally, there is no constitutional concern under the facts as applied in this case because the United States has intervened.<sup>2</sup> (See Order, ECF No. 76.)

In reply, Ranbaxy adopts the amicus brief of the United States Chamber of Commerce in Wham-O. (Reply, ECF No. 49 Ex. E.) Unlike the False Claims Act, § 292(b) has no internal control mechanisms and there is no guarantee the United States could intervene in all cases.

Further, the history of qui tam actions, which is relevant to the question of Article III standing, is not relevant to the Article II question.<sup>3</sup> Further, Article II does not draw a distinction between

One argument in favor of § 292(b)'s constitutionality is that the allegedly aggrieved party, the Executive Branch, consistently intervenes in support of the provision. See Pequignot v. Solo Cup Co., 640 F. Supp. 2d 714, 728 (E.D. Va. 2009). "But the separation of powers does not depend on the views of individual Presidents, nor on whether the encroached-upon branch approves the encroachment." Free Enter. Fund v. Pub. Co. Accounting Oversight Bd., 130 S. Ct. 3138, 3155 (2010) (citation and quotation omitted); see also Stern v. Marshall, No. 10-179, 2011 WL 2472792, at \*26 (U.S. June 23, 2011) ("Although it may be that it is the obnoxious thing in its mildest and least repulsive form, we cannot overlook the intrusion: illegitimate and unconstitutional practices get their first footing in that way . . . .") (quotations and alteration omitted).

The Chamber argues Article III standing relies on the common understanding, at the time of the framing of the Constitution, as to which "cases" or "controversies" were traditionally the sort amenable to and resolved by judicial proceedings. See Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 774 (2000). The Chamber suggests that the American structure of government, with power vested in three separate but coordinate branches, was novel and, hence, there could be no common understanding regarding separation of powers. The Supreme Court apparently disagrees, asserting that "the Constitution's central mechanism of separation of powers depends largely upon common understanding of what activities are appropriate to legislatures, to executives, and to courts." Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-60 (1992) (citing The Federalist No. 48, at 256 (James Madison)

criminal and civil laws and, therefore, the requisite degree of control under <u>Morrison</u> should not differ even if § 292(b) is a civil action.

#### III. Discussion

#### A. The False Marking Statute

Under § 292(a), "[w]hoever marks upon, or affixes to . . . any unpatented article, the word 'patent' or any word or number importing that the same is patented for the purpose of deceiving the public . . . [s]hall be fined not more than \$500 for every such offense." To state a claim under § 292, a plaintiff must show (1) a marking on an unpatented article, (2) done with intent to deceive the public. Forest Grp., Inc. v. Bon Tool Co., 590 F.3d 1295, 1300 (Fed. Cir. 2009). Marking a product with an expired patent constitutes marking an unpatented article. See Pequignot v. Solo Cup Co., 608 F.3d 1356, 1361 (Fed. Cir. 2010). Further, any person may sue to collect the penalty under § 292(b) and need not have personally suffered an injury-in-fact to have standing. See Stauffer v. Brooks Bros., Inc., 619 F.3d 1321, 1325 (Fed. Cir. 2010). The person filing suit under § 292(b) can collect the penalty on a per article basis. Forest Grp., 590

<sup>(</sup>George Carey & James McClellan eds., 1990)).

The Federal Circuit did not consider the Eastern District of Virginia's ruling on the constitutionality issue in this decision because the court considered a subsequent decision of the district court granting Solo Cup summary judgment. See Pequignot, 608 F.3d at 1357.

The Court notes that the fine imposed is "not more than \$500," which contemplates a fine less than \$500 per offense. In appropriate circumstances, a fine of \$1, or possibly even less, could be appropriate to sufficiently punish and deter the defendant for falsely marking its products with patents. See Forest Grp., 590 F.3d at 1304 (indicating in some circumstances, "a court has the discretion to determine that a fraction of a penny per article is a proper penalty"); S. Rep. No. 82-1979, at 22 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2424 (clarifying fine is a maximum). Hollander concedes the amount of the fine "is committed to the sound discretion of the district court" and "is a matter of law reserved to the courts." (Mot. to Strike Memo., ECF No. 88-1 at 2, 6.)

F.3d at 1295. According to some, this series of decisions from the Federal Circuit has spurred hundreds of lawsuits throughout the country. <u>See Michael R. O'Neill, False Patent Marking</u>

Claims: The New Threat To Business, 22 Intell. Prop. & Tech. L.J. 22, 22-23 (2010).

The § 292(b) qui tam action is civil in form though it arises under what various courts describe as a criminal statute. See Pequignot, 608 F.3d at 1363; Filmon Process Corp. v. Spell-Right Corp., 404 F.2d 1351, 1355 (D.C. Cir. 1968). The Federal Circuit characterizes the penalty under § 292 as a civil fine. Pequignot, 608 F.3d at 1363; Clontech Labs., Inc. v. Invitrogen

Corp., 406 F.3d 1347, 1352 (Fed. Cir. 2005). This understanding is consistent with the legislative history of the False Marking Statute. The original version, enacted in 1842, and the revised version, enacted as part of the Patent Act of 1870, authorized private suits as the exclusive means of enforcing its provisions. See Rogers, 2011 WL 2175716, at \*4 (citing Patent Act of 1870, ch. 230, § 39, 16 Stat. 198, 203); Act of Aug. 29, 1842, ch. 263, § 5, 5 Stat. 543,

The Federal Circuit has not expressly held that § 292 is a criminal statute, and this Court does not read that characterization as essential to the Federal Circuit's decision in <a href="Pequignot.">Pequignot</a>. See <a href="Pequignot">Pequignot</a>, 608 F.3d at 1363-64. Even so, as discussed in more detail below, this characterization is not dispositive of the constitutional question before the Court regarding the civil enforcement mechanism in § 292(b). <a href="See also Pequignot">See also Pequignot</a>, 640 F. Supp. 2d at 727 n.17 (noting confusion regarding criminal-civil distinction of § 292, but concluding § 292(a) defines a criminal offense whereas § 292(b) provides a civil remedy).

Congress's use of the term "fine" in § 292(a) does not answer the criminal-civil question, nor does Congress's reference in § 292(b) to the fine as "the penalty." A "fine" relates to a "pecuniary punishment or civil penalty payable to the public treasury," Black's Law Dictionary 664 (8th ed. 2004), and a civil penalty is a type of fine assessed for violation of a statute or regulation, see Cudjoe v. Dep't of Veterans Affairs, 426 F.3d 241, 247 (3d Cir. 2005) (citing Black's Law Dictionary 1168). Further, many courts use the terms civil penalty and fine interchangeably. See, e.g., Tull v. United States, 481 U.S. 412, 422 n.7 (1987) (noting civil penalty is a type of fine); United States v. Global Distribs. Inc., 498 F.3d 613, 616, 620 (7th Cir. 2007). Thus, use of the term "fine" does not necessarily mean a statute is criminal. See also Hudson v. United States, 522 U.S. 93, 99-100 (1997) (stating multiple-step test for determining criminal or civil nature of statute for Double Jeopardy purposes).

544. Congress amended the False Marking Statute in 1952 so that either the United States or a qui tam relator can enforce its provisions.<sup>8</sup> Id. (citing S. Rep. No. 82-1979, at 9 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2403).

#### B. Morrison

In Morrison v. Olson, the Supreme Court considered whether the Ethics in Government Act of 1978 ("EGA") violated the separation of powers principle embodied in the Constitution. 487 U.S. at 659-60. The Court re-affirmed the importance of separation of powers to our structure of government, but noted that it has never required the three branches to operate with absolute independence. Id. at 693-94; see Stern v. Marshall, No. 10-179, 2011 WL 2472792, at \*14 (U.S. June 23, 2011) (acknowledging "that the three branches are not hermetically sealed from one another"). One branch violates separation of powers when it arrogates power to itself at the expense of another or takes action which impermissibly undermines another, such as by disrupting the proper balance between the coordinate branches by preventing the Executive from accomplishing its constitutionally assigned functions. See Morrison, 487 U.S. at 694-95; see also Stern, 2011 WL 2472792, at \*14 ("Separation-of-powers principles are intended, in part, to

Through its Reply, Ranbaxy contends that the United States cannot initiate an action under § 292(b) because there is a longstanding presumption that a statutory "person" does not include the United States. (See Reply Ex. E at 14 (citing Vt. Agency, 529 U.S. at 780-81).) This issue is not nearly as clear as Ranbaxy's briefing suggests. The presumption – which is just that, a presumption – stands for the proposition that the sovereign, by employing the term "person," has not authorized suit against itself. Vt. Agency, 529 U.S. at 797-98 (Stevens, J., dissenting). Section 292(b), however, authorizes the initiation of litigation by any "person," not against any "person." Therefore, the presumption may not apply in this case.

If the presumption does not apply, this also defeats Ranbaxy's argument that the United States cannot intervene because it cannot file the pleading required under Federal Rule of Civil Procedure 24(c). If the United States is a "person" under § 292(b), it could file a complaint. See Fed. R. Civ. P. 7(a) (identifying a complaint as a pleading). Resolution of these issues does not effect the Court's ultimate conclusion.

protect each branch of government from incursion by the others.").

The EGA "allows for the appointment of an 'independent counsel' to investigate and, if appropriate, prosecute certain high-ranking Government officials for violations of federal criminal laws." Morrison, 487 U.S. at 660. The EGA grants the independent counsel "full power and independent authority to exercise all investigative and prosecutorial functions and powers of the Department of Justice [and] the Attorney General." Id. at 662. This includes authority to conduct grand jury proceedings and other investigations; participate in civil or criminal proceedings; and appeal any decisions in which the counsel participated. Id.

The Court considered whether "taken as a whole, the [EGA] violates the separation of powers by reducing the President's ability to control the prosecutorial powers wielded by the independent counsel." Id. at 685. Although recognizing that "[i]t is undeniable that the [EGA] reduces the amount of control or supervision that . . . the President exercises over the investigation and prosecution of a certain class of alleged criminal activity . . . the [EGA] does give the [President] several means of supervising or controlling the prosecutorial powers that may be wielded by an independent counsel." Id. at 695-96. In particular, the President, through the Attorney General, can remove the independent counsel for good cause; only the Attorney General can seek appointment of independent counsel and the Attorney General's decision not to appoint independent counsel is not reviewable; the independent counsel's jurisdiction is limited to the facts submitted by the Attorney General; and the EGA requires the independent counsel to abide by Department of Justice policies and procedures. Id. at 696. In light of these means of control, the Court concluded the EGA gives "the Executive Branch sufficient control . . . to ensure that the President is able to perform his constitutionally assigned duties." Id.

#### C. The False Claims Act and Morrison

The Court believes that the history of the False Claims Act is relevant to the Court's analysis of the False Marking Statute. Accord Pequignot, 640 F. Supp. at 725. For one, these statutes are two members of a fading group of qui tam actions. See Vt. Agency, 529 U.S. at 768 n.1 (noting False Claims Act and False Marking Statute are two of few remaining qui tam statutes). But on a more relevant point, the False Marking Statute in its current form bears remarkable similarity to the False Claims Act in its original form.

In 1863, Congress passed the first version of the False Claims Act, which established a criminal offense and a civil enforcement alternative. Act of Mar. 2, 1863, ch. 67, §§ 1, 4, 12 Stat. 696, 696-98. Both the United States and private citizens initiated their respective actions. In fact, some private litigants based their claims on allegations in indictments secured by the United States. See United States ex rel. Marcus v. Hess, 317 U.S. 537, 545-46 (1943) (considering whether False Claims Act prohibited civil action derived from criminal indictment). In light of these and other abuses, Congress considered abolishing the False Claims Act. See J. Randy Beck, The False Claims Act and the English Eradication of Qui Tam Legislation, 78 N.C. L. Rev. 539, 556-61 (2000) (providing history of amendments to False Claims Act).

Instead, in 1943, Congress amended the statute to its current format. See Act of Dec. 23, 1943, Pub. L. No. 78-213, ch. 377, § 1, 57 Stat. 608, 608-09. Congress changed only the civil action, see id. § 1, 57 Stat. at 608-09, but later re-codified the criminal action, see 18 U.S.C. § 287. Subsequent amendments maintain this basic structure. See False Claims Amendments Act of 1986, Pub. L. No. 99-562, §§ 2, 3, 100 Stat. 3153, 3153-57.

Congress's delegation to private litigants of the power to initiate claims under the False

Claims Act prompted several constitutional challenges to the statute's validity. For example, the defendants in those earlier cases argued that private litigants do not have standing under Article III. The Supreme Court rejected this argument in Vermont Agency of Natural Resources v.

<u>United States ex rel. Stevens, 529 U.S. 765 (2000)</u>. The Court concluded that a <u>qui tam</u> relator is a partial assignee of the United States's damages claim, and the government's injury-in-fact – both to its sovereign interest arising from violation of its laws and its proprietary injury resulting from the fraud – suffices to confer standing on <u>qui tam</u> relators. Id. at 771, 773-74. The Court found support for this conclusion in the tradition of <u>qui tam</u> actions, which date back to the thirteenth century in England, and continued into the American colonies both before and after the framing of the Constitution. Id. at 774-76. The Court concluded this history was "well nigh conclusive" on the issue of standing, <u>id.</u> at 777, but expressly declined to consider whether <u>qui tam</u> actions violate Article II's Take Care Clause, <u>see id.</u> at 778 n.8 (declining to consider because the petitioner did not challenge the False Claims Act under Article II and there is no need to consider Article II <u>sua sponte</u> because it does not implicate jurisdiction). Compare id. at

Some parties and courts focused on this feature of <u>Vermont Agency</u> to argue false marking relators, particularly non-competitors, lack standing because their claims implicate only the United States's sovereign interest and not its proprietary interests. The Federal Circuit rejected this argument in the standing context. <u>See Stauffer</u>, 619 F.3d at 1325. But false marking defendants also employ the argument in the Article II context to argue that only the United States's sovereign interest is implicated, which means the Executive should have exclusive control over suits vindicating that interest. <u>Cf. Morrison</u>, 487 U.S. at 691 ("There is no real dispute that the functions performed by the independent counsel are 'executive' in the sense that they are law enforcement functions that typically have been undertaken by officials within the Executive Branch."). But <u>Morrison</u> stands in contradiction to this proposition – so long as the Executive retains sufficient control, Congress can enact legislation that permits a party independent of the Executive Branch to perform this core function. <u>See id.</u> at 696; <u>see also Marcus</u>, 317 U.S. at 542 (stating Congress has power to choose method to protect government interests).

801 (Stevens, J., dissenting) (claiming history is similarly conclusive of Article II question).

Several courts of appeals have considered the Article II issue and have, to some extent, applied Morrison's "sufficient control" standard to uphold the False Claims Act. In United States ex rel. Kelly v. Boeing Co., the Ninth Circuit applied the Morrison sufficient control analysis to conclude that the False Claims Act, taken as a whole, affords the Executive Branch a degree of control over gui tam relators that is not distinguishable from the degree of control found in Morrison. 9 F.3d 743, 755 (9th Cir. 1993). In particular, the Ninth Circuit identified the following provisions in the False Claims Act which supported its conclusion: the government can intervene and then take primary responsibility for conducting the litigation; it can seek judicial limitation of the relator's participation; it can seek a stay of the relator's discovery; and it can seek dismissal or settlement over the relator's objection. Id. at 753. The Second and Sixth Circuits relied on the President's "sufficient control" to uphold the False Claims Act against Article II challenges, even though the Second Circuit did not cite Morrison and the Sixth Circuit did not offer in-depth analysis of Morrison. See United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co., 41 F.3d 1032, 1041-42 (6th Cir. 1994); United States ex rel. Kreindler & Kreindler v. United Tech. Corp., 985 F.2d 1148, 1155 (2d Cir. 1993).

The Fifth Circuit, however, concluded that Morrison does not apply to the False Claims Act because the relator sues in the name of the United States rather than as the United States, and the EGA permitted criminal prosecutions whereas the False Claims Act creates a civil cause of action. Riley v. St. Luke's Episcopal Hosp., 252 F.3d 749, 754-55 (5th Cir. 2001) (en banc). The court nevertheless considered whether the Executive Branch retains sufficient control over the relator, noting that the civil nature necessitated a different type of control to satisfy Article II.

<u>Id.</u> at 753, 755-56. These controls include the government's right to notice, to receive pleadings, and to intervene and take over the litigation; its ability to veto a relator's proposed settlement or settle or dismiss the case over the relator's objection; and the government's right to move for a stay of discovery. Id. at 753-54.

#### D. Cases Holding § 292(b) Constitutional

Turning to the statute and issue before this Court, the Court is aware that several district courts upheld § 292(b) against Take Care Clause challenges. Several courts point to the same history relied on in <a href="Vermont Agency">Vermont Agency</a> in support of their conclusions. <a href="See, e.g.">See, e.g.</a>, <a href="Luka v. Procter & Gamble Co.">Luka v. Procter & Gamble Co.</a>, <a href="No. 10-2511">No. 10-2511</a>, <a href="2011 WL 1118689">2011 WL 1118689</a>, at \*6 (N.D. III. Mar. 28, 2011); <a href="Hy-Cite Corp. v.">Hy-Cite Corp. v.</a></a>
<a href="Regal Ware, Inc.">Regal Ware, Inc.</a>, <a href="No. 10-168">No. 10-168</a>, <a href="2011 WL 1206768">2011 WL 1206768</a>, at \*4 (W.D. Wisc. Mar. 15, <a href="2011">2011</a>); <a href="Pequignot">Pequignot</a>, <a href="204">640 F. Supp. 2d at 726</a>; <a href="cf. Riley">cf. Riley</a>, <a href="252 F.3d">252 F.3d at 752-53</a> (asserting it is "logically inescapable" that the history of <a href="qui tam">qui tam</a> suits conclusive on the Article III question of standing under the False Claims Act is similarly conclusive on the Article II question) (citing <a href="Yt. Agency">Yt. Agency</a>, <a href="529 U.S.">529 U.S.</a> at 801 (Stevens, J., dissenting)).

Many of these courts also apply Morrison's sufficient control test, but require a lesser degree of control than the EGA because § 292(b) imposes a civil fine, which does not infringe on the Executive's more core function of enforcing criminal laws. See, e.g., Hy-Cite, 2011 WL 1206768, at \*4; Shizzle Pop, LLC v. Wham-O, Inc., No. 10-3491, 2010 WL 3063066, at \*3 (C.D. Cal. Aug. 2, 2010); Pequignot, 640 F. Supp. 2d at 726-27. Moreover, the controls found sufficient in the context of the False Claims Act do not set a constitutional floor that every qui tam provision must satisfy. See Simonian v. Allergan, Inc., No. 10-2414, 2011 WL 1599292, at \*3 (N.D. Ill. Apr. 28, 2011); Luka, 2011 WL 1118689, at \*7. Although § 292(b) does not have

any internal control mechanisms, courts find other sources of law provide sufficient control: the United States is entitled to notice of any patent litigation, 35 U.S.C. § 290; the United States has a right to appear in any action in which it has an interest, 28 U.S.C. §§ 517, 518; the United States can seek to intervene, Fed. R. Civ. P. 24; and, if it does intervene, the United States can prevent settlement by withholding its consent to voluntary dismissal, Fed. R. Civ. P. 41(a). <u>E.g.</u>, <u>Simonian</u>, 2011 WL 1599292, at \*5; <u>Luka</u>, 2011 WL 1118689, at \*7; Transcript of Oral Argument at 119-20, <u>Harrington v. CIBA Vision Corp.</u>, No. 08-251 (W.D.N.C. May 29, 2009); Pequignot, 640 F. Supp. 2d at 727-28.

Finally, others note that if the Federal Circuit were concerned with the constitutionality of § 292(b) under Article II, it would have raised the issue <u>sua sponte</u> in any number of false marking cases it considered. E.g., <u>Simonian</u>, 2011 WL 1599292, at \*5; <u>Public Patent Found.</u>, <u>Inc. v. GlaxoSmithKline Consumer Healthcare, LP</u>, No. 09-5881, 2011 WL 1142917, at \*4 (S.D.N.Y. Mar. 22, 2011).

#### E. Cases Holding § 292(b) Unconstitutional

To date, two courts have found § 292(b) unconstitutional. Both base their conclusions on the fact that the False Marking Statute is criminal in nature, and rely on Morrison to find that it lacks sufficient controls to ensure the President can perform his constitutionally assigned duty to "take Care that the Laws be faithfully executed." See Rogers, 2011 WL 2175716, at \*9-11; Unique Prod. Solution Ltd. v. Hy-Grade Valve, Inc., 765 F. Supp. 2d 997, No. 10-1912, 2011 WL 649998, at \*4-6 & n.6 (N.D. Ohio Feb. 23, 2011), aff'd on reconsideration, 2011 WL

The Federal Circuit expressly declined to consider this issue for the same reason the Supreme Court declined to address it in <u>Vermont Agency</u>: the parties-in-interest did not raise and brief the issue. Stauffer, 619 F.3d at 1327 (citing Vt. Agency, 529 U.S. at 778 n.8).

924341 (N.D. Ohio Mar. 14, 2011).

Judge Polster applies Morrison because there is no material difference between filing suit in the name of the United States, as under the False Claims Act and § 292(b), and as the United States, as under the EGA. Unique Prod., 2011 WL 649998, at \*5. Further, the criminal-civil distinction is immaterial because courts of appeals apply Morrison in the civil context. Id. at \*3 (citing Taxpayers Against Fraud, 41 F.3d at 1041). Judge Polster concludes that, under Morrison, the United States lacks sufficient control – the notice requirement of § 290 is insufficient because it sends notice to the Patent and Trademark Office, not the Department of Justice, and a relator can settle the dispute before the notice deadline; § 292(b) represents a wholesale delegation of criminal law with none of the protections the False Claims Act provides; and the maximum penalty of \$500 per article exacerbates the danger of privatizing criminal law enforcement. Id. at \*6.

Judge Robreno agrees that Morrison is the appropriate test because it facilitates the inquiry into whether sufficient Executive controls exist for qui tam actions, which always reflect at least some delegation of law enforcement authority. Rogers, 2011 WL 2175716, at \*9.

Further, § 292(b) represents a delegation of criminal law enforcement authority in light of the statute's legislative history. Id. at \*10. Moreover, the civil enforcement mechanism does not change the criminal nature of the statute and § 292 exists only to vindicate the United States's sovereign interest arising from violations of its laws. Id. Judge Robreno then concludes that § 292(b) and other sources of law fail to provide even a basic degree of control, as illustrated by comparison to the False Claims Act. Id. at \*11. Notice under § 290 is not expedient enough and the prospect of intervention and corresponding procedures do not go far enough, assuming the

Court even permits intervention. <u>Id.</u> Even if it intervenes, the United States cannot take over, cannot limit discovery, and cannot settle or dismiss the case over the relator's objections. In short, the process of the litigation remains "subject to the whims of whomever sees fit to bring the suit" and impermissibly undermines the President's ability to exercise his constitutionally assigned functions. Id. at \*10-11.

### F. Analysis

The undersigned has great respect for my colleague, Judge Robreno, whose scholarly opinion in <u>Rogers</u> deserves a great deal of respect. But I respectfully disagree with his interpretation of and reliance on Morrison.

Initially, in a broad political context, Morrison has unique significance, which does not exist in the present case. See Samuel Dash, Independent Counsel: No More, No Less a Federal Prosecutor, 86 Geo. L.J. 2077, 2077-79 (1998) (recounting unique backdrop of EGA enactment). The independent counsel law under review in Morrison was a watershed event in American history. The situation revolving around the Watergate prosecutor had threatened the stability of the Executive Branch, and Congress acted prudentially and quickly to draft a statute which it thought served the national interest in the broadest context. See id. at 2078 (acknowledging strong public reaction to President's conduct in wake of Watergate revelations). In doing so, Congress made a unique contribution to the ever-evolving interdependent relationship among the executive, legislative, and judicial branches of our government. See Earl C. Dudley, Jr., Morrison v. Olsen: A Modest Assessment, 38 Am. U. L. Rev. 255, 265 (1989) (suggesting political context of Morrison did not favor Court's broad view of executive power); Susan Bartlett Foote, Independent Agencies under Attack: A Skeptical View of the Importance of the

<u>Debate</u>, 1988 Duke L.J. 223, 224 (noting EGA was one piece of Congress's efforts to combat "imperial" presidency in wake of Watergate scandal).

Further events have shown that the statute under review in Morrison has served our country well. See, e.g., Dash, supra at 2079 (indicating both Republican and Democratic administrations have, alternately, suffered and championed independent counsel investigations); Beth Nolan, Removing Conflicts from the Administration of Justice: Conflicts of Interest and Independent Counsels under the Ethics in Government Act, 79 Geo. L.J. 1, 17 (1990) (stating that, in enacting EGA, "Congress was concerned with the public perception of fairness in the investigation and prosecution of high-level officials"). Because Morrison stands as an unparalleled case decided in a unique context, I am unwilling to give Morrison significant precedential impact on the factual and statutory situation presently under consideration.

Second, I strongly endorse the point made by Judge Brinkema in <u>Pequignot</u>, that <u>Morrison</u> is, at its fundamental core, about a statute regarding criminal prosecutions. <u>See</u> <u>Pequignot</u>, 640 F. Supp. 2d at 726-27. Judge Brinkema convincingly makes the point:

"Quite simply, enforcement of the substantive provisions of § 292 is not the type of executive function whose delegation to an authority not controlled by the Executive Branch would presumptively raise serious Article II questions. Moreover, the actual power wielded by a relator under § 292(b) pales in comparison to that granted to the independent prosecutor in Morrison. The independent counsel was given 'full power and independent authority to exercise all investigative and prosecutorial functions and powers of the Department of Justice.' In stark contrast, a qui tam relator under § 292(b) can maintain only one type of suit – an action for false marking patent – and must do so at his own expense."

#### <u>Id.</u> at 727 (citation omitted).

Lastly, the Supreme Court addressed specific questions in Morrison, neither of which arises in this case.

"The first is whether the provision of the [EGA] restricting the Attorney General's power to remove the independent counsel to only those instances in which he can show 'good cause,' taken by itself, impermissibly interferes with the President's exercise of his constitutionally appointed functions. The second is whether, taken as a whole, the [EGA] violates the separation of powers by reducing the President's ability to control the prosecutorial powers wielded by the independent counsel."

487 U.S. at 685. The first question concerns the Appointments Clause of Article II,<sup>11</sup> which Ranbaxy did not raise in its Motion to Dismiss. <u>See id.</u> 685-93; (Mot. to Dismiss Memo. at 8-18). The Court's framing of the second issue underscores the preceding point: <u>Morrison</u> was concerned with the use of "prosecutorial powers" in criminal actions.

For some, it is the criminal nature of § 292(a) that implicates the analysis in Morrison.

E.g., Rogers, 2011 WL 2175716, at \*10. But § 292 is unlike the circumstances in Morrison because the EGA permitted an independent counsel to prosecute criminal actions. Section 292(b) does not permit prosecution of criminal actions, but creates a civil enforcement alternative. For this reason, § 292 also differs from the False Claims Act, which creates a standalone civil action with a separately codified criminal companion. In this sense, § 292 is unique. For all of these reasons, and the other reasons discussed by Judge Brinkema, I am unwilling to give Morrison much weight in determining whether § 292(b) is constitutional.

As in many situations, history provides guidance for the Court's analysis. For almost a century, the False Claims Act followed the same form as § 292 – it created a criminal action with

The Appointments Clause provides:

<sup>&</sup>quot;[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . all other Officers of the United States . . . but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments."

a civil enforcement alternative. Prior to the 1943 amendments, the Supreme Court did not consider the False Claims Act unconstitutional under Article II. See generally Marcus, 317 U.S. 537. Indeed, the Supreme Court's interpretation of the False Claims Act in Marcus prompted Congress to act. See Beck, supra at 557-58. Thus, it was Congress that acknowledged the abuses of the False Claims Act and added many of the safeguards various courts have found sufficient to comply with the Take Care Clause. Judge Robreno acknowledges as much, noting "Congress, after all, found it necessary to increase the United States' control of False Claims Act qui tam litigation despite the existence of the same protections cited as adequately protecting the United States' interests in false marking litigation." Rogers, 2011 WL 2175716, at \*11 n.16. Further, the Court is aware of no decision that required these safeguards as necessary for the False Claims Act to conform to Article II before Congress took action in 1943.

This may be because, as the Supreme Court recognized, qui tam statutes are entrenched in our nation's history. See generally Vt. Agency, 529 U.S. at 774-78. Although Vermont Agency concerns Article III standing rather than separation of powers, this history nonetheless shows the unique concepts that underlie the nature of qui tam statutes during early English common law and throughout much of our own history. Qui tam statutes also work well. The media routinely reports huge settlements, often requiring large pharmaceutical companies which earn millions of dollars from government business, to reimburse the government for improper or false claims uncovered by qui tam plaintiffs. See, e.g., Dep't of Justice, Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-label Promotion of Topamax (Apr. 29, 2010), http://www.justice.gov/opa/pr/2010/April/10-civ-500.html. The social value of the qui tam mechanism has been proven over and over again, and it is not necessary, in my

judgment, for a federal district court to upset and declare unconstitutional such a long-existing and well-working mechanism that Congress has approved and has not changed.

Instead, the proper redress for the False Claims Act is also the appropriate remedy for the perceived abuses of the False Marking Statute. Both houses of Congress have agreed to amend § 292 by requiring a false marking relator to have suffered a competitive injury as a result of the alleged false marking. See Patent Reform Act of 2011, S. 23, 112th Congress § 2(k) (as passed by Senate Mar. 8, 2011); America Invents Act, H.R. 1249, 112th Congress § 16(b) (as passed by House June 23, 2011). Several provisions in these bills differ, and thus passage is not assumed. As with the original verison of the False Claims Act, judicial restraint is appropriate to permit Congress to redress concerns for abuse of which it is already aware. See Evan Caminker, Comment, The Constitutionality of Qui Tam Actions, 99 Yale L.J. 341, 360-62 (1989) (arguing Congress is proper branch to make policy decision regarding manner and method of enforcing statutes which seek to vindicate public interests). The original False Claims Act survived for eighty years before Congress took action and the False Marking Statute has followed a similar path. The concerns of Ranbaxy and other false marking defendants are more appropriately voiced to Congress, the proper forum to effect the changes they seek. The Court declines to find the False Marking Statute unconstitutional under these circumstances.

## IV. Conclusion

For the foregoing reasons, the Court denied Ranbaxy's Motion to Dismiss. An appropriate Order was previously entered.

BY THE COURT:

/s/ Michael M. Baylson
Michael M. Baylson, U.S.D.J.

 $O: \\ Todd\\ 10-793\ Hollander\ v.\ Ranbaxy\\ Hollander\ -\ Constitutional\ MTD\ Memo\ -\ FINAL.wpd$