UNITED STATES v. MCGUFF

781 F. Supp. 654 (1991) | Cited 0 times | C.D. California | November 27, 1991

OPINION

This matter came on to be heard before the Court on May 29, 1991.

The issue in this case is whether the Court must find the defendant guilty as charged in a criminal contempt indictment for violation of a consent decree where the defendant acted reasonably in response to bad faith on the part of the governmental agency, and where the indictment came down four years after tee violation occurred. After considering the papers presented, and hearing the arguments thereon, the Court holds that although the defendant Gil W. McGuff violated the consent decree at issue, he did not do so wilfully [1]" and therefore cannot be held in criminal contempt. The Court determines, therefore, that he is not guilty on all counts. The court further holds that even if McGuff's violation is deemed to be wilful, in the circumstances of this case, the Court is not required to hold McGuff in criminal contempt, and declines to do so.

I. FACTS

During the period relevant to these proceedings, McGuff was the owner and chief executive officer of Reis Biologicals, Inc., a corporation involved directly, and through subsidiaries, in a number of businesses, primarily as a distributor. For more than twenty years prior to 1984, Reis had been a leading manufacturer of hemodialysis concentrate ("concentrate"), a chemical solution used in kidney dialysis. Reis had shipped concentrate sufficient for more than 600,000 dialysis applications, with only one reported incident of adverse patient reaction to the product.

Sometime in 1984, Diversified Medical Services ("DMS"), a wholly-owned subsidiary of Reis, began to manufacture concentrate in its California facility. In that year, the Federal Drug Administration (the "FDA") investigated DMS's manufacturing operation and concluded that it failed to meet FDA requirements. The record is unclear as to the precise nature of DMS's shortcomings, but apparently they included "inadequate cleaning of the equipment used in producing devices such as hemodialysis concentrate," Government's Trial Brief at 4, insufficient control of product labelling, and inadequate testing of existing inventory.

The FDA commenced litigation in the Central District of California, seeking an order requiring, among other things, that Reis, its subsidiaries and McGuff cease and desist manufacturing and selling medical devices. The defendants were represented in this action by John Anderson, a lawyer who had had no prior food and drug law experience.

The lawsuit was resolved by a consent decree executed by then District Judge Pamela Rymer on June 24, 1985. The consent decree ordered the company, and its officers and directors, not to manufacture or sell any "article of device." The phrase "article of device" is defined broadly in 21 U.S.C.A. section 321(h) (West Supp. 1991), a provision of the Federal Food Drug and Cosmetic Act (the "FDC Act"), 21 U.S.C.A. sections 301 to 394 (West 1972 & Supp. 1991),

as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is --

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purpose.

The consent decree order was drafted by the FDA. It did not define the term "article of device," and did not refer specifically to the FDC Act. If the FDA intended to give "article of device" the peculiar meaning ascribed to that phrase under the FDC Act, the agency did not explain that intention to either Anderson or McGuff.

Both Anderson and McGuff were given to understand by the FDA representatives that the purpose of the consent decree was to get the matter at hand settled, and to give the FDA an immediate judicial remedy in the event of future violations. They were also given to understand that, as soon as the consent decree was signed, it would be a short and simple matter to secure FDA approval for Reis and its subsidiaries to resume manufacturing and selling concentrate.

The FDA visited the Reis facility shortly after the consent decree was signed, but did not give its approval for resumed operation. An extended period of negotiations followed in which McGuff tried unsuccessfully to get the FDA to identify precisely what would have to be done to secure such approval.

During the period of negotiations, Reis suffered substantial losses because it could not ship product. ultimately its continuing inability to ship product forced Reis into bankruptcy. In 1986, McGuff formed a new corporation, Pegasus Medical Services, Inc. ("Pegasus"), and went into business through Pegasus as the successor to Reis. Although the record is not clear in this regard, Pegasus

appears to have succeeded to some or all of the assets of Reis, including the inventory of concentrate which Reis was precluded from selling by the consent decree.

When all attempted negotiations proved futile, McGuff concluded that the FDA was not negotiating in good faith over how Reis could return to business in compliance with the FDC Act, as contemplated by the consent decree, but rather was deliberately trying to force Reis out of the business of manufacturing concentrate. The record more than amply supports this contention, and the FDA introduced no evidence to negate it. The Court finds that the FDA in fact did not proceed in good faith during the negotiations over what it would take to secure approval for the resumption of operations. [2"]

After more than eight months of being unable to deal successfully with the FDA, McGuff decided to give up the business entirely. He began to negotiate for the sale of Pegasus to DMS, and during these negotiations McGuff caused Pegasus to sell a substantial quantity of concentrate to DMS.

McGuff made these sales in the good faith belief that, because the FDA had not honored its own obligations in the manner contemplated by the consent decree, the decree would not be enforceable in Court at the behest of the FDA. He admitted forthrightly, however, that he did not seek counsel in this regard, or do anything to seek clarification or modification of the order from Judge Rymer. He explained these failures on the basis that he was in financial extremis, and could not afford the expense of a lawyer.

The FDA first learned of the concentrate sales made by Pegasus to DMS in 1986. The agency at that time did not go directly to Judge Rymer so that she could immediately enforce her order and thus prevent future violations, and perhaps prevent resale of the concentrate by DMS. Instead, the FDA "sat on" what it perceived to be a violation while it conducted an investigation to see what else it could find with which to charge McGuff.

What the FDA found was nothing. After more than four years, the FDA came to court in 1991, with a criminal contempt indictment alleging only the sales known to have been made more than four years previously, and four sales of potassium chloride and/or sodium bicarbonate made by Pegasus in 1988. The latter sales were made upon Anderson's good faith advice, which was believed by McGuff, that these products (the former a common salt and the latter commonly known as baking soda) were not covered by the consent decree.

The testimony of both McGuff and Anderson was entirely credible in all aspects, and was wholly uncontradicted. This testimony, and the exhibits introduced into evidence at the hearing, were more than sufficient to establish the relevant facts.

II. LACK OF WILFULNESS

At the conclusion of the evidence, the Court held that McGuff had wilfully violated the consent decree, by causing the sales from Pegasus to DMS, but expressed displeasure at the FDA's behavior. The Court noted that the agency had first trivialized the alleged violation of the consent decree by ignoring the violation for years after learning the facts, and then overreacted to it by electing to seek redress through criminal proceedings. Because of its disapproval of the FDA's handling of the matter, the Court invited argument and ultimately further briefing on whether the determination that McGuff had wilfully violated the consent decree required the Court to hold McGuff in criminal contempt. In light of its expressed views, the Court invited the FDA to consider withdrawing the indictment, but the FDA elected instead to try to force the Court to find McGuff guilty of contempt.

In its previous deliberations, the Court concluded that because McGuff admitted he knew that concentrate sales were prohibited by the consent decree, the decision to sell concentrate in deliberate disregard of the order, based upon his own untrained speculation about the law, was wilful.

Upon further consideration of the evidence, the briefs and the relevant law, however, the Court has concluded that the finding of wilful violation was in error. That finding is hereby vacated. McGuff sold the concentrate only after the FDA failed, despite McGuff's best efforts, to uphold its obligations as a party to the decree. McGuff acted out of his good faith belief that the FDA's failure to tell him how to comply with agency requirements excused him from upholding his own obligations under the decree. Cf. United States v. Armstrong, 781 F.2d 700, 706 (9th Cir. 1986) ("[A] defendant's good faith belief that he is complying with the order of the court may prevent a finding of wilfulness . . .") (citations omitted).

Moreover, the Supreme Court has stated that "since consent decrees and orders have many of the attributes of ordinary contracts, they should be construed basically as contracts . . . ." United States v. I.T.T. Continental Baking Co., 420 U.S. 223, 236, 95 S. Ct. 926, 934, 43 L. Ed. 2d 148 (1975). The evidence leaves no doubt that the FDA breached its obligations under the consent decree. consequently, under Continental Baking, there is serious doubt that the FDA could have enforced the decree against McGuff even had it tried to do so in a timely manner. McGuff's good faith belief that he was excused from performing was legally tenable.

III. AGENCY CONDUCT PRECLUDES A FINDING OF CONTEMPT

It seems very likely to this Court that even if the FDA had discovered in advance that the proposed sales were to made, and had sought to have them enjoined, Judge Rymer would have done so only in conjunction with some procedure to test the concentrate so that it could have been released for sale within a reasonable time. [3]"

The Court considers the conduct of the FDA throughout these proceedings to have been little short of outrageous. [4]" If the FDC Act is administered in good faith, it cannot be as difficult as it was for McGuff for a manufacturer of medical devices, which has been in business for more than twenty

years without serious incident, to secure permission to sell existing inventories in compliance with the requirements of the Act.

In its brief the FDA responds to McGuff's contention in this regard, with the simple ipse dixit that:

"FDA was not being unreasonable in withholding approval; McGuff never demonstrated to FDA that he had come into compliance with the relevant good manufacturing practices." Government's Trial Brief at 8.

The FDA did not address with argument or evidence McGuff's contention, which seems clearly correct from the evidence, that he was prevented from doing that by the FDA's refusal to advise him affirmatively what it would take to come into compliance, and by it's petty rejections of all of the proposals which he made in his own behalf.

Instead, the FDA attempts to avoid this evidence by urging in its brief:

"More important [sic], whether or not FDA was acting unreasonably in its dealings with McGuff is irrelevant in this prosecution. It is not a defense to a charge of criminal contempt that the underlying order is invalid or that it is being enforced in an unreasonable manner." Id.

For this proposition, the FDA cites two cases. The first citation is to dicta contained in Maness v. Meyers, 419 U.S. 449, 95 S. Ct. 584, 42 L. Ed. 2d 574 (1975), in which the Supreme Court reversed a criminal contempt conviction of a lawyer who advised his client during trial to disobey, on Fifth Amendment grounds, a court order to disclose. The second, In Re Establishment Inspection of Hern Iron Works, Inc., 881 F.2d 722 (9th Cir. 1989), involved simple disobedience of a court order because of doubt as to its validity. Neither of the cited cases involves any issue concerning the contractual nature of consent decrees or the manner in which the order was enforced by the agency responsible for bringing the indictment. Neither of these cases involves the difference between criminal contempt proceedings, in which the court is asked to enforce provisions of its own orders, and ordinary criminal proceedings, in which the function of the court is to enforce statutes promulgated by Congress.

The FDA cites no case in which a court has enforced by criminal sanction an order requiring a party to cease and desist from any action, when the evidence indicates that the party took the prohibited action only after the governmental agency refused to go forward in good faith to take action required on its part. Indeed, such authority as exists on this point indicates that the result would be to the contrary. See United States v I.T.T. Continental Baking Co., 420 U.S. 223, 95 S. Ct. 926, 43 L. Ed. 2d 148 (1975). More significantly, perhaps, the FDA cites no case in which a district court has been required by any appellate court to enforce its own order in a manner which the district court considers to constitute a miscarriage of justice. The Court considers it to be within its inherent judicial power to refuse to enforce its own order in such a way, and is not surprised that there are no

reported cases purporting to challenge its authority in this regard.

Were McGuff to be deemed to have violated the consent decree wilfully, the issue posed for decision here would not be whether the Court has the power, in the exercise of its discretion, to hold the defendant in contempt, but rather whether the FDA could force the Court to hold McGuff in criminal contempt, against the Court's own sense of the interests of justice.

In this regard, it must be noted that the facts of this case are virtually sui generis, and that McGuff is no longer in the business of manufacturing or selling concentrates. There is, therefore, only slight deterrent value, either general or special, in holding McGuff in criminal contempt at this late date. See United States v. Barnett, 346 F.2d 99, 100 (5th Cir. 1965) (dismissing criminal contempt charges, stating, "Nor does such further prosecution appear necessary for the purpose of deterring others from committing offenses like or similar to the alleged acts of contempt.")

The only real purpose of this proceeding, so far as this Court is able to see, is to allow the FDA to emerge as the ultimate winner in the kind of contest that cannot be politely described. The Court is neither required nor willing to help the FDA to achieve this result.

Since the above decision is on the merits, and the defendant is found not guilty, the Court need not address the FDA's contention that McGuff's motion to dismiss the prosecution is untimely.

DATED: Nov. 27, 1991

J. Spencer Letts

United States District Judge

1. At the conclusion of the evidentiary hearing the Court announced from the bench its finding that McGuff had acted wilfully. Upon reconsideration, that finding is hereby vacated. See infra.

2. In making this determination, the Court does not consider any of the volumes of materials submitted before trial, but not introduced into evidence, which, if considered, would erase any doubt of the shoddy treatment of McGuff by the FDA.

3. There is no evidence that the concentrate in question was defective in any way.

4. In fact, the Court considers the FDA's overall behavior in is case to be as outrageous in its own way as the prosecutorial misconduct in United States v. Simpson, 927 F.2d 1088 (9th Cir. 1991) (government employed as informant a prostitute, heroin user and fugitive from Canadian justice, and allowed her to carry on a sexual relationship with the suspect and to keep $ 10,000 profit from a heroin sale she arranged). The Ninth Circuit in Simpson refused to dismiss the indictment because the Court's exercise of its supervisory powers in dismissing substantive criminal indictments is to be construed narrowly to preserve the separation of powers. The present case involves not an indictment for a substantive criminal

offense but an indictment for criminal contempt. Consequently, the Court's power to dismiss must be construed much more broadly. Since the Court is deciding when to prosecute individuals for violating its own orders, separation of powers is not an issue.