Lyle E. Craker v. Drug Enforcement Administration
Transcription of Oral Arguments

May 11, 2012 at 9:30 AM

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Judges Torruella, Lipez, Howard

Transcriber's Note: there are three judges hearing this case, Torruella, Lipez and Howard. As they questioned the attorneys they did not identify themselves. In the transcript I was unable to distinguish one judge from another, and so I use the general term "Judge" to identify each.

Annotator's Note: I'm Rick Doblin, Executive Director of MAPS, the non-profit organization working with Prof. Lyle Craker. I'm adding several comments as inserts in parentheses [ ] and track changes mode. My comments are meant to correct factual errors, either accidental or intentional.

Judge: Mr. Metzler, Good Morning.

Metzler: Good morning your honor, and may it please the court. My name is Jack Metzler and I represent the petitioner in this case. I'd like to reserve three minutes of my time for rebuttal.

Judge: You may.

Metzler: The Controlled Substances Act states the DEA shall register an applicant to manufacture a Schedule I drug like marijuana if the application is consistent with the public interest and the United States treaty obligations. Professor Craker's application met both of these criteria and DEA should have granted his application. The DEA has raised a jurisdictional challenge however, and I will address that first. The government's jurisdictional challenge should be rejected. Professor Craker challenges the January 14th 2009 final order of the DEA. He filed a timely petition for a review of that order. Even if the order would not have been considered final while Professor Craker's motion for reconsideration was pending, this court had held the petition for review in abeyance during that time. There's no question the DEA's order was final when this court lifted the stay and directed the case to proceed.

Judge: But you say it's final now?

Metzler: That's correct your honor. And it was also final at the time Professor Craker filed his petition for review. Professor Craker did not challenge any aspect of the order on reconsideration. As the Supreme Court has said in ICC v. Locomotive Engineers, the only aspect of that order that would be reviewable is the legality of the denial of reconsideration. Here Professor Craker challenges the merits of DEA's final order. Two Courts of Appeals have permitted jurisdiction under similar circumstances and a finding of jurisdiction would also be consistent with how the practice under federal rule of appellate procedure 4a.

Judge: Counselor I know that issue is raised, it's an important issue, but, it's well briefed, I think you might be better served by going on to the merits of your argument.

Metzler: Thank you your honor. The DEA's decision to deny Professor's application was arbitrary and capricious in three respects. First, DEA applied an interpretation of the Controlled Substances act that was contrary to its own interpretation that it applied for thirty years. That interpretation is also inconsistent with the plain language of the statute. As the agency itself interpreted the statute, DEA is permitted to limit the number of manufacturers of Schedule 1 controlled substances like marijuana based on the adequacy of competition or supply only if those limits will serve the interests of maintaining effective controls against diversion.

Judge: How would this, sort of play out in terms of the burden on a client such as yours. Is it your position that if at the outset your client could established that the granting of a new registration would not create a problem with the possible diversion of marijuana, there'd be no increased risk of improper diversion, that once that's established there's no need to go on and address the issues relating to adequacy of supply and competitiveness? Is that your position?

Metzler: That's correct your honor, and that is the interpretation the DEA has itself applied for more than thirty years. There was no risk of diversion in this case but DEA went beyond what your honor suggests and put upon Professor Craker the burden to show that supply or competition was inadequate. That interpretation cannot be squared with the plain language of the statute. The second reason that DEA's decision in this case was…

Judge: Excuse me, I'm just looking at that language and it seems to me that it does lend itself to a reading that the concern for the risk of diversion is a given and in light of that, in order to get a new registration the applicant would have to address the issues of

adequacy of supply and competitiveness in order to overcome, if you will, that underlying concern with the risk of diversion. It seems that's the way the statute is set out. It begins with that stated concern about diversion. Now I realize that's not the way it was read for a long time, but that argument does seem to be consistent with the language.

Metzler: Well the way that the statute is written, is this is the first public interest factor that DEA has directed to consider, And what it was directed to consider is maintenance of effective controls against diversion by limiting the number of manufacturers based on supply and competition. In other words the question is if we limit based on supply and competition, will that assist with the maintenance of effective controls against diversion. And where the DEA has determined that diversion will be controlled either way, then there's no purpose to going on and considering supply and competition. Now to the extent the DEA's order could be read to find that there is some underlying risk of diversion that exists in any case, first DEA hasn't argued that and they haven't relied on that, but I think that the agency would be required to make a finding, that finding being subject to the standard of 21 USC 77, and could only be upheld if there were substantial evidence to support it. And I'm not aware of any evidence on the record that increasing the number of manufacturers in this case from one to two would have any risk of diversion.

Judge: Can I ask you something? Your client is engaged in research?

Metzler: Yes your honor.

Judge: Has he been doing research up to now?

Metzler: He has been doing research on the medicinal uses of plants for many years; he has not been doing research on marijuana, however.

Judge: Now if he wanted to, could he receive whatever supplies he needed to conduct his research from the University of Mississippi?

Metzler: Well, Professor Craker does not propose to himself engage in research, that's not the purpose of his application. The purpose of his application is to be a supplier to other researchers who would conduct research.

Judge: OK

Metzler: So even if the text…

Judge: So let me just follow up then. Could those Professors also, if they wanted to, get that supply from the University of Mississippi?

Metzler: They cannot your honor. Well, they could in certain circumstances. Currently the National Institute on Drug Abuse conducts a review and if they approve of the research protocol, then the University of Mississippi will supply marijuana to the project. But if they don't, and the evidence in this case is that they haven't approved at least some research protocols that had already been approved by DEA, excuse me by FDA, then they cannot obtain marijuana. And that goes to the question of supply. Even if DEA were permitted to interpret the statute as it has, there's no basis for it affirmatively requiring a showing of inadequate competition or supply. On supply DEA read the statute contrary to its plain text. The supply that has to be required, or that must be adequate and uninterrupted, is the supply for legitimate research purposes. And DEA's position is that only NIDA, the National Institute on Drug Abuse, can qualify research as legitimate. But I don't think there's any question that research protocols that have been approved by the Food and Drug Administration, which is the agency that is responsible for approving new drug applications are legitimate. Moreover, the DEA has said, well, the NIDA review is mandated by the treaty and by the statute, it performs the review of the scientific merit of research protocols under 21 USC 823 (f). But in fact, as our

brief shows, that review has been delegated from HHS to FDA, and that makes sense because FDA is the agency dealing with new drug approval. So the supply of marijuana for medical research purposes is inadequate because there are some projects that exist, that are approved by FDA that are legitimate, and University of Mississippi simply cannot provide, cannot supply them, because of its contractual relationship with NIDA. As to competition, The DEA applied a…

Judge: Excuse me. So there are two different views as to what is legitimate research. Am I correct?

Metzler: That's right.

Judge: And your client would be a third, or would he also be in one of the two camps?

Metzler: His view on the, well he would say that supply is inadequate because there are certain research…

Judge: So we're talking about what is the standard for interpreting what is legitimate research.

Metzler: I see. His, our position is that the standard for legitimate research is research that is approved by the Food and Drug Association, and that is conducted under the overriding system of controls provided by the Controlled Substances Act and the Food and Drug Act.

Judge: As I understand the DEA takes the position that allowing what your client wants would be in violation of the treaty.

Metzler: That's right.

Judge: That's the international treaty on drugs control, whatever the name of it is.

Metzler: Yes your honor.

Judge: Now, is there anything in the brief, or is there anything we can refer to? How has this treaty been interpreted outside the United States?

Metzler: Well, in the United Kingdom for example, the government has a system of licensing much like the system in place in this country for other drugs. But they have a system specifically for marijuana where they license the manufacturers, and all aspects. And the opinion of the UK is that complies with the treaty.

Judge: Counselor, as you describe what the new situation would be if your client got the registration that he seeks, there would be a new supplier out there beyond the University of Mississippi, it sounds like you would argue that NIDA should no longer have any role in deciding what kind of scientific research would be appropriate to take advantage of this new source of supply, so right away, at least superficially it suggests that there's an increased risk of diversion. It is a less circumscribed process than there was before. Why isn't it legitimate for DEA to be concerned about that when the very situation you are trying to create, does seem to create a greater risk of diversion?

Bell rings

Metzler: I see my time has expired. Your honor the situation would be that NIDA would not be involved in determining the merits of the research protocols that Professor Craker would supply. However, the entire system of controls put in place by the Controlled Substances Act and the Food and Drug Act would be in place. DEA cannot point to any statute or any regulation that requires or permits or gives the authority to NIDA to conduct research on, or to approve research protocols for marijuana or any other drug and in fact they don't purport to do, to review the scientific merit of research protocols for any drug other than marijuana. So the situation would be that as with every other controlled substance, the existing set of controls that exist for licensing the manufacturers, researchers, dispensers

of the controlled substances Act would apply to marijuana just like every other drug.

Judge: I have another question before you sit down. The government takes the position as I understand it that, on this question of competition, that this contract goes out for bids and that you have an opportunity to bid, and therefore the fact that you haven't won that contract doesn't [mean] there isn't competition. What do you have to say to that?

Metzler: Well there are several, at least two or three answers to that. One is that the competition to be the monopoly supplier isn't competition in the market to supply the drug the way we would ordinarily consider it. And DEA's own regulation which we've cited in our brief talks about how it will evaluate the adequacy of competition in regards to an application under 21 USC section 952. And those factors all contemplate that the competition that we're talking about is competition among suppliers to supply the drug. For a second reason, the NIDA contract with the University of Mississippi isn't simply to be the producer of marijuana. It also requires the contractee to take in samples and test their potency, and other factors that Professor Craker is not interested in. And finally the competition that NIDA, that DEA suggests to be appropriate, simply maintains a monopoly and monopoly is the opposite of competition.

Judge: Thank you.

Metzler: Thank you.

Judge: Mr. Quinlivan, good morning.

Quinlivan: Morning Judge Torruella, may it please the court. I do want to spend a few moments, and I'll get back to the question of jurisdiction mindful of Judge Lipez's admonition. But I want to start by responding to the question of how this system works, because the petitioner's argument here reflects a fundamental

misunderstanding of the new drug approval process and the Secretary of Health and Human Services' obligations under the Controlled Substances Act. When a new drug application is filed the Food and Drug Administration has the opportunity within thirty days to put a hold on the application if it has concerns about safety. That's with respect to any new drug application. There are specific controls set forth in the controlled substances act when you're talking about controlled substances and they appear in section 823 (f), which provides that the Secretary of Health and Human Services for a research protocol that involves controlled substances shall pass on both the competency of the researcher, and the scientific and medical merits of the protocol. Now, with respect to marijuana, in 1999 HHS set forth guidelines for how that process would be implemented, and you'll find them at pages 133-136 of the petitioner's appendix. It is not, contrary to my brother's assertion, NIDA that passes on the scientific or medical merit of the research protocol. It is an interdisciplinary panel of the public health service, of which NIDA is only one component, that passes on the scientific and medical merit of the research protocol, implementing the Secretary's responsibilities under section 823 (f). What the petitioner's argument here is, is that in the context of interpreting the statutory term uninterrupted and adequate supply the administrator couldn't look to the fact, as she found, that the University of Mississippi had at the time of the hearing one thousand fifty five kilograms of marijuana available, enough to satisfy all existing research protocols that had been proposed, that was ninety times the amount Dr. Craker was proposing to produce. That that doesn't satisfy the term adequate and uninterrupted supply, but rather, the argument is that only the FDA can fulfill the Secretary's responsibilities under section 823 (f). And in the context of interpreting that phrase in section 823 (a) (1) the Administrator would have to dictate to the Secretary of HHS how to assign responsibilities within her agency. In the context of an administrative action where the Department of Health and Human

Services is not even a party. That's what this case is essentially all about, is their assertion that only the FDA can fulfill the Secretary's responsibilities under section 823 (f). That's fundamentally wrong, it's not the proper subject of an administrative action seeking to both manufacture and it is certainly not something that the administrator has authority to do, or by extension I would submit, this court has authority to do. If any of the researchers in this case who that interdisciplinary panel finds there are concerns about the protocol takes that position, they can take administrative action against the Secretary and that potentially would be subject to review, but you cannot possibly read the term adequate and uninterrupted supply to require the administrator to be passing judgment on how the secretary of HHS assigns her statutory authority. And again that's what this case is all about.

Judge: Counselor there seems to be something a little circular about this adequacy of supply point, I mean, the reality seems to be that there are so few scientific inquiries approved involving the use of marijuana that there is no problem with the adequacy of supply because nobody, almost nobody's allowed to explore the medicinal use of marijuana. Isn't that fundamental to what's going on here?

Quinlivan: I respectfully disagree Judge Lipez, it's the opposite, in fact one of the things the administrator noted of the seventeen research protocols that have been submitted by the California medicinal, the acronym is CMCR, every single one of those 17 had been approved. The only ones the petitioner complains about are ones the administrator explained were denied for reasons of lack of scientific or medical merit under section 823 (f). And some of them, after the concerns had been addressed, and a new research protocol was submitted, NIDA provided the marijuana [RD: After the protocol was redesigned from looking at medical benefits of marijuana to looking at potential risks of marijuana use]. I think the record shows the exact opposite of what the petitioner is suggesting.

Judge: How many projects have been approved in the entire nation?

Quinlivan: I don't have an answer for that right now. I do know, I can point to, what the administrator pointed to, which was that at the time of the initial order there had been, all 17 of CMCR had been approved, and again the only ones the petitioner can point to in which marijuana wasn't supplied, it wasn't because NIDA made the determination that it didn't lack scientific merit, it was particularly for those postdated 1999…[RD: CMCR's studies were not intended to develop marijuana into an FDA-approved prescription medicine, as are MAPS' studies.]

Judge: This research in medicinal marijuana…

Quinlivan: I'm sorry Judge?

Judge: The 17 that have been approved have been dealing with medicinal marijuana?

Quinlivan: In various forms yes, yes Judge Torruella that's right.

Judge: Well I'm wondering why that was done, because I was under the impression from your brief that the government doesn't recognize medicinal marijuana.

Quinlivan: Because right now it is a Schedule 1 substance it has not been proven safe or effective or determined safe or effective by the FDA. That doesn't prevent the possibility that at some future date based on appropriate studies that determination could be made, and that's why NIDA, that's why the University of Mississippi through NIDA supplies medical researchers, for that very reason.

Judge: I was under the impression in your brief, or in the government's brief, that one of the objections to this request was because it has to be judged under the international treaty, under the standards for opium.

Quinlivan: That's right Judge Torruella.

Judge: And, although you indicate there is such a thing as medicinal opium, as differentiated from, I guess normal opium, that was not the case with marijuana, there was no such thing as medicinal marijuana.

Quinlivan: That's right Judge Torruella, and I make a distinction between, medicinal marijuana is, in the terms of the treaty, and let me direct your honors' attention to pages 21 and 22 of the commentary to the treaty which you can find at pages 94-95 of the appendix. How that was defined as medicinal opium, was a special kind of opium that was used in treatment, medical treatment.

Judge: It had been processed?

Quinlivan: That's right. Now marijuana has not reached that point. Marijuana is being studied to determine if at some point in time it might be determined to be safe and effective…

Judge: Isn't it a fact that marijuana is being used in the United States for medicinal purposes?

Quinlivan: As a matter of federal law, no it is not. There are states that have legalized marijuana, or decriminalized marijuana for medicinal use, but that's the very point of the Supreme Court's unanimous decision in Oakland cannabis where the 9th Circuit carved out a medical necessity exception to a preliminary injunction barring the distribution of marijuana, and the Supreme Court unanimously held that given that marijuana has not been determined not to be safe and effective by the FDA and remains to be a Schedule 1 as a matter of federal law, it has no approved medical use.

Judge: Is it your position that because the government does not yet recognize the concept of medicinal marijuana that the very terms of the treaty would prevent the government from admitting the kind of registration?

Quinlivan: No, absolutely not, the argument is this, what the treaty does is it requires the government to basically create a national monopoly on the import, export, wholesale trading in these substances. And that has been done in this country through the process of NIDA and the contract that is currently used through the University of Mississippi. And therefore when a research protocol is approved, that marijuana is provided to the researcher. The petitioner's argument here is that he can, that that requirement that there be a national government agency that controls those functions doesn't apply to him because medicinal marijuana is akin to medicinal opium. And for the reasons I've explained, there may come a point in time where it's determined to be safe and effective, but marijuana to date is being studied to determine if it has medicinal qualities. It is not the same thing as medicinal opium.

Judge: Is it of any relevance to this case how this treaty has been interpreted by other countries who are signatories?

Quinlivan: I think the Administrator explained why she said no, the statute delegates to the attorney general, and by extension to the Administrator how to interpret it, and as she noted, if any international body were to be looked at, it would be the International Narcotics Control Board, which is the UN entity charged with enforcing the single convention, and that body has interpreted the single convention consistent with the administration's.

Judge: Has that body enforced this treaty in any way as you're saying in other countries which have enforced it differently?

Quinlivan: The only one I'm aware of is the petitioner's pointed to in the United Kingdom, and I'm not aware that the INCB actually has that authority to do that. [The INCB does have the authority to criticize signatory countries for non-compliance with the treaty and has done so in criticizing US State medical marijuana laws. The UK policy on medical marijuana production has never been criticized by

the INCB.] If I could take a quick moment on the jurisdictional question.

Judge: Before you do that, I just had one question on the chevron step two 823 (a)(1) part of your brief where you say, contrary to what the other side says that the DEA has taken inconsistent positions in the last three decades. Could you just clarify that a little more, because I was unable to run that to ground.

Quinlivan: Sure, it is clear as the Administrator forthrightly admitted both adjudicative decisions which she has now abandoned, had been taken by the DEA. In two cases however, Roxanne Laboratories and the Pennant Corporation case, the issue of competition had been considered even where there had been no finding of a question of diversion, now quickly I note that in the reply brief the petitioner says that Roxanne considered a different statute, all you have to do is look at that case and you'll see that combinations, that section 823 (1) was specifically considered.

Judge: In light of that history, the way 823 (a) (1) has been applied either contrary to your position now or inconsistently, how can you now argue that the plain meaning supports the position you're now taking. That seems to bely any plain meaning argument.

Quinlivan: I recognize the point you're making Judge Lipez, and I would answer it in this way. What the Administrator did in this way, saying she was going to reconsider this point is basically conduct a de novo review, looking at the statute, the text, the structure, legislative history, treaty considerations and prior interpretations. And then reached the conclusions that this was indeed the best if not possibly the only reading of the statute. Now if it's too far to say that given the prior interpretations a court would not be willing to find that it's required by the plain meaning, this clearly is the best reading of the statute because the statute sets forth the statutory objection to limit diversion, and then how that would be done, specifically in the context of Schedule 1 and 2 controlled

substances, and that is by limiting the number of manufacturers to that which can provide an adequate and uninterrupted supply under adequately competitive conditions.

Judge: I take it since the parties do not provide us with legislative history showing what congress would have meant by "adequately competitive conditions", that we're not going to get any help by looking there ourselves.

Bell

Quinlivan: Judge Howard you will get help because in the Administrator's decision she went through both the legislative history of that term and how it had been applied at Roxanne Laboratories and made the point that it had been looked at, they wanted to make sure there wasn't price gouging in the industry. Here where marijuana is provided at cost to privately funded researchers and at no cost to NIH funded researchers, then the determination was made that adequately competitive conditions did exist. Judge Torruella, just one point, I know I've run out of time, on the jurisdictional point I just wanted to note section 877 by its terms says it must be a final decision of the administrator, that is a jurisdictional requirement, and as the Supreme Court made clear in Bowles v Russell, courts cannot create equitable exceptions to jurisdictional requirements. The final decision in this case, unquestionably, was not the 2000 final order, the 2009 final order; it was the 2011 final order.

Judge: Is it final now?

Quinlivan: It is final now.

Judge: Does that make any difference?

Quinlivan: It does because, if Dr. Craker had petitioned for review within thirty days after notice of that decision, as the statute requires, this case would be properly before this court.

Judge: He actually did it before.

Quinlivan: He did, but that decision, and under well settled Supreme Court authority, Locomotive Engineers, that decision was rendered non final because the final agency determination was when the administrator denied the motion for reconsideration on the merits, modified the administrative record and supplemented her decision, and I point that…

Judge: The question that frankly comes to my mind, he filed it early; thereafter the administrator cured the defect by making it final. So why is this an argument of substance?

Quinlivan: Two answers Justice Torruella, First the Supreme Court's decision in Locomotive Engineers makes clear that when an agency considers and denies a motion for reconsideration on the merits, that is the final agency action, and indeed, that comes as no surprise to Dr. Craker. When he actually wrote the administrator and expressly raised this concern, that the pendency of this motion for reconsideration rendered the original order non final…

Judge: Wasn't there a question whether this whole reconsideration process is extra-legal given the agencies own rules do not provide for.

Quinlivan: They don't provide for it, but the Administrator in her decision expressly allowed the petitioner to file a motion for reconsideration in fifteen days. And then in response to that not only reopened the proceedings but allowed several rounds of supplemental briefing on any of the arguments that had been raised below and any additional arguments the petitioner might want to raise. And, one quick point, the final decision modified the original point in one extremely significant point. The original order denied it on three independent grounds, the public interest factor, the treaty factor, and the involvement of Mr. Doblin. Now, in her order denying reconsideration, she said, if the other two considerations

did not exist, then perhaps an accommodation could be reached with respect to Mr. Doblin.

Judge: Mr. Doblin is the one who smokes marijuana?

Quinlivan: Yes, that's right. Now if what is before this court is the 2009 final order, and only the 2009 final order, then that stands as a separate and independent ground that the petitioner hasn't challenged, and that just shows why it wasn't a final agency decision. Because what this court has said, is the agencies last word on the subject. And that is unquestionably the 2011 final order. That is what the statute requires and again, no equitable exceptions under Bowles v Russell can be made when you're talking about a statutorily find jurisdictional requirement.

Judge: Is what you're saying now then, that if we should say perhaps because of the interplay of our orders where we say it should proceed, etc. That the appeal of the 2009 order has been preserved, but the 2011 one has not, that that's just the end of the case?

Quinlivan: That's the end of the case, because a petition for review can only be taken from a final decision. The 2009 final order was no longer a final decision.

Judge: But what if we disagree with that, what do we do with the 2011 order that has not been appealed?

Quinlivan: I think that, Judge Howard, I think that just underscores why the 2009 final order can't be a final decision, because then you'd be reviewing an order that the administrator has expressly said that she has supplemented…

Judge: But they're not going to object to our reviewing the 2011 order, so what do you say about that, if they don't preserve an appeal from the 2011 order?

Quinlivan: I don't see how this court, I guess it comes down to the fact, in our view the 2011 final order has to be the final decision, this court can't review the 2009 final order, because it wasn't a final decision. I know I'm not directly responding to your question, but that just underscores why the 2009 final order isn't the final decision in this case, because how would this court take into account, the final statement of the agency on this subject? I know I'm well over my time, thank you your honor.

Judge: Thank you. Mr. Metzler.

Metzler: Thank you your honor. DEA says in its reply that this is all about supply, but our position is not that only FDA can approve research protocols for marijuana. Our position is that FDA has been delegated that authority, and even in his presentation, my brother did not point to any statutory or regulatory authority that would justify NIDA's participation. Second, this can't be all about supply, because even if their counter-textual of section 823 is correct, the administrator said that either a showing of insufficient supply or competition would be sufficient to register an additional manufacturer in the public interest. For the reasons we discussed earlier DEA's holding on competition cannot be upheld. On the treaty, the DEA continues to say that there is some requirement of government approval before marijuana can be considered medicinal. But that's not what the treaty says. The treaty has a definition of what medicinal opium is, and that applies also to medicinal marijuana. The definition is, it needs to be prepared to be used as a medicine. You can certainly use something as a medicine regardless of whether a government official has approved it as being efficacious for that purpose. And that's also not what the dictionary definition says, the dictionary says that medicinal means used as a medicine. And there's no question that all the marijuana Professor Craker proposes to produce would be used as a medicine. As to the jurisdiction, I agree with my brother that ICC v Brotherhood of Locomotive Engineers is an important case, but what that case says

is that on a motion for reconsideration that doesn't change the substance of the final order; the only thing that is reviewable is the decision not to reconsider. And we are not challenging that, we are only challenging aspects of the 2009 decision. I think, in response to your question Judge Howard, it would be no problem for this court to say we have not preserved a review of the 2011 petition or order, because we're not challenging anything in that order. As to the government's statement regarding the holding on Mr. Doblin, I think that the court would be well within its authority to take judicial notice that FDA [He meant DEA] no longer maintains that position, so it doesn't presents an obstacle to Dr. Craker's registration. If there are no further questions, we ask that the court to reverse the DEA's determination and remand with instructions to grant Professor Craker's application.

Judge: Thank you.