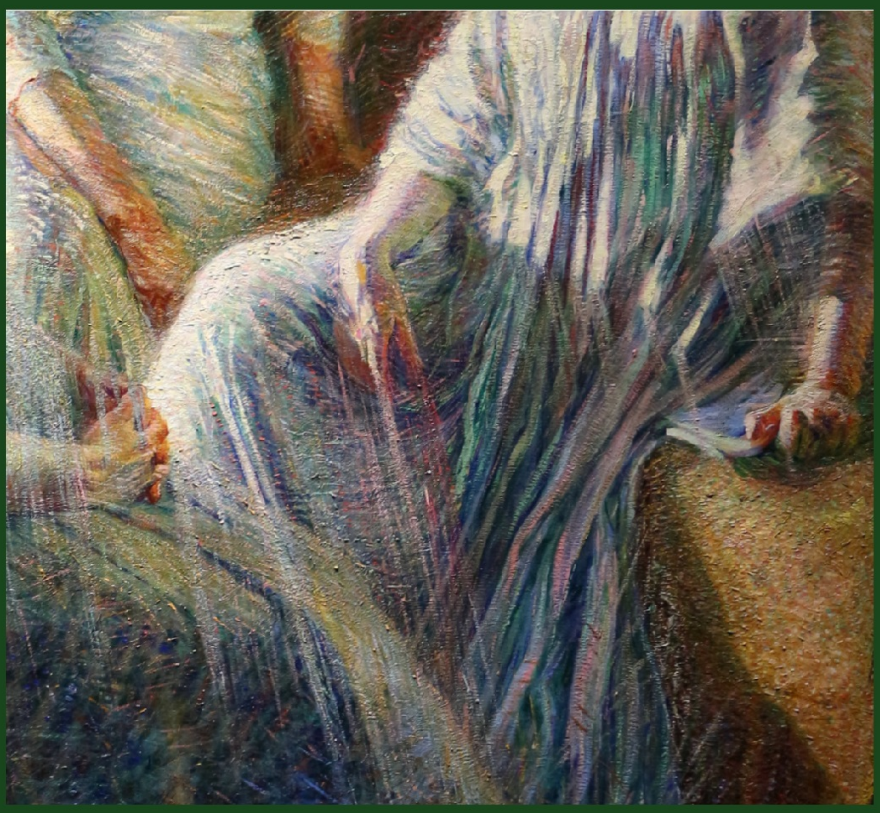
The Italian Law Journal

Vol. 07 No. 01 (2021)



EDIZIONI SCIENTIFICHE ITALIANE

www.theitalianlawjournal.it

THE ITALIAN LAW JOURNAL

An International Forum for the Critique of Italian Law

Vol. 07 – No. 01 (2021)

www.theitalianlawjournal.it

ISSN 2421-2156 June 2021 DOI 10.23815/2421-2156.ITALJ

Table of Contents

The Italian Law Journal
Vol. 07 – No. 01 (2021)

History and Projects

Essays

Hard Cases

Malebolge

Corporate and Financial Markets Law

Short Symposium: 'The Terrible Duty. Legitimacy and Usefulness of Punishment'

Science at the Italian Bar: The Case of Hydroxychloroquine

Paola Monaco*

Abstract

Due to the increasing number of legal questions which cannot be answered without recourse to scientific knowledge, the issues surrounding the relation between science and the law have become a hot topic in legal debate. For this reason, it is not surprising that the tragedy of COVID-19 is raising many questions for lawyers to be debated in court. In the light of this, the paper aims to analyse one very interesting example of the use of scientific knowledge by an Italian (administrative) court: order no 9070 of the Italian Council of State (Consiglio di Stato) of 11 December 2020, through which the highest administrative court suspended the decision of the Italian Medicines Agency (AIFA) to forbid the off-label use of a drug (hydroxychloroquine – HCQ) in the treatment of COVID-19. After having analysed the main points on which the Italian Council of State decision is based, the essay will offer some considerations on how legal scholarship, across both common and civil law jurisdictions, has tried to offer some solutions to the problem of courts dealing with scientific or technical knowledge. In the conclusions it will be verified whether these principles might be useful and applicable before administrative courts as well.

I. Science and the Law: The Never-Ending Story

There is nothing new in science entering Western courtrooms.[1] Due to the increasing number of legal questions which cannot be answered without recourse to scientific knowledge, the issues surrounding the relation between science and the law have become a hot topic in legal debate, both in common and civil law.[2] This means that courts have the difficult task of devising legal methods for determining the proper evidentiary place to be given to science in judicial disputes. In some jurisdictions – such as the US – the courts have mostly handled the problem by trying to establish the standards for the

* PhD and Contract Researcher at Bocconi University (Milano, Italy).

[1] S. Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Cambridge: Harvard University Press, 1995); D.L. Faigman, *Legal Alchemy: The Use and Misuse of Science in the Law* (New York: W.H. Freeman and Co, 1999); Id, *Laboratory of Justice: The Supreme Court's 200-Year Struggle to Integrate Science and the Law* (New York: Times Books/Henry Holt, 2004).

[2] P. Monaco, 'Scientific Evidence in Civil Courtrooms: A Comparative Perspective', in F. Fiorentini and M. Infantino eds, *Mentoring Comparative Lawyers: Methods, Times, and Places.* Liber Discipulorum *for Professor Mauro Bussani* (Cham: Springer, 2020), 95-110.

admissibility of scientific evidence in (civil) proceedings,[3] while in other jurisdictions – such as on the European continent – the courts have largely focused on the rules for choosing the experts who will assist judges in decisions involving scientific matters.[4]

It is not surprising that the tragedy of the COVID-19 pandemic has given rise to (and, unfortunately, will give rise to) numerous scientific questions for lawyers to be debated in court. And it not surprising that judges are finding more difficulty than ever in trying to deal with these new and delicate issues, because of the fact that this new field raises questions in legal proceedings to which science has not provided many answers yet.

One very interesting example of the use of scientific knowledge before the Italian (administrative) courts stems from decision no 9070 of 11 December 2020, by the Italian Council of State (Consiglio di Stato), the highest Italian administrative court.[5] The case stemmed from a proceeding for interim relief against the decision of the Italian Medicines Agency (AIFA) to forbid the off-label use of a drug (hydroxychloroquine – HCQ) in the treatment of COVID-19. As we will see in this paper, the Consiglio di Stato overruled the decision of AIFA.

After a brief introduction of the framework in which the order of Consiglio di Stato was reached (section II), we will summarise the main points on which the Consiglio di Stato decision is based (section III), focusing our attention on the use of scientific principles in legal reasoning. Then, some considerations will be presented on how legal scholarship, across both common and civil law jurisdictions, has tried to offer some solutions to the problem of courts dealing with scientific or technical knowledge, especially in civil proceedings (section IV). We will then verify whether these principles might be useful and applicable before administrative courts as well (section V).

II. The Context of the Order 9070/2020

In the aftermath of the explosion of the COVID-19 pandemic, hydroxychloroquine, an antimalarial drug used to treat systemic lupus erythematosus and rheumatoid arthritis, was suggested as a possible method of prevention or treatment for the new illness thanks to the evidence of its in-vitro inhibition of severe acute respiratory syndrome.[6] This is why, lacking an effective therapy to treat the illness, many national medicine agencies,[7] including the

[3] See below section IV.

[4] ibid.

[5] The order is available – in Italian – at www.giustizia-amministrative.it.

[6] F. Turone, 'Ruling Gives Green Light for Controversial COVID-19 Therapy. Administrative Judges Overrule Regulator to Authorize Hydroxychloroquine' *nature.com*, 18 December 2020.

[7] See for example the authorisation of March 2020 (now revoked) of the Food and Drug Administration (FDA) in the USA: https://tinyurl.com/3zzm3yfp (last visited 30 June 2021), and

Italian Medicines Agency (AIFA), allowed an emergency authorisation for its off-label use.[8]

However, soon after the availability of new studies and data showed the lack of efficacy of the drug and even an increase in adverse events in patients. Under such conditions, hydroxychloroquine was no longer recommended in COVID-19 patients by the medicine agency regulators.[9] So AIFA, with two notes (the first on 26 May 2020 and the second on 22 July 2020) suspended the authorisation for the off-label use of hydroxychloroquine outside of clinical trials.[10]

As we will explain in the next section, a group of doctors did not agree with the decision of AIFA. On the contrary, they maintained they had observed that HCQ was able to provide certain benefits in early-stage patients and for this reason they presented a claim to attempt to have this provision suspended.

III. The Claim

As we said above, a group of specialist physicians presented a claim to the administrative court of first instance – the Regional Administrative Court of Lazio (TAR Lazio) – to ask for an interim suspension of the decision of AIFA of 22 July 2020,[11] which allowed the off-label use of hydroxychloroquine in the treatment of COVID-19 patients only in randomised clinical trials. Since TAR Lazio rejected the doctors' claim, the decision was appealed in front of the Council of State.[12] The Council of State reformed the order of the TAR Lazio and suspended the decision of AIFA. The case is now being debated in front of the TAR on its merits.

the Société Française de Pharmacologie et de Thérapeutique (SFPT - France).

[8] AIFA, 'COVID-19 - AIFA autorizza nuovo studio clinico sull'idrossiclorochina', 9 April 2020, available at https://tinyurl.com/y23y4m9h (last visited 30 June 2021).

[9] See for example the decisions of the European Medicines Agency (EMA), 'COVID-19: chloroquine and hydroxychloroquine only to be used in clinical trials or emergency use programmes', 1 April 2020, available at https://tinyurl.com/e7j96uxy (last visited 30 June 2021); Medicines and Healthcare products Regulatory Agency (MHRA – UK), 'MHRA suspends recruitment to COVID-19 hydroxychloroquine trials', 16 June 2020, available at https://tinyurl.com/m86wnm68 (last visited 30 June 2021); FDA, 'Letter revoking EUA for chloroquine phosphate and hydroxychloroquine', 15 June 2020, available at https://tinyurl.com/p9nvjxes (last visited 30 June 2021); German Bundesinstitut für Arzneimittel und Medizinprodukte (BFARM), 'Hydroxychloroquin: Risiko für schwerwiegende Nebenwirkungen bei Anwendung zur Behandlung von COVID-19', 29 April 2020, available at https://tinyurl.com/3f9jjm83 (last visited 30 June 2021).

[10] AIFA, 'AIFA sospende l'autorizzazione all'utilizzo di idrossiclorochina per il trattamento del COVID-19 al di fuori degli studi clinici', 26 May 2020, available at https://tinyurl.com/2ptvstry (last visited 30 June 2021).

[11] The same physicians had already presented a claim to ask for an interim suspension of the decision of AIFA of 26 May 2020, but this was rejected by the Tribunale amministrativo regionale Lazio Roma 14 September 2020 no 5911: Consiglio di Stato 24 November 2020 order no 9070, point 2.3, available at www.giustizia-amministrativa.it.

[12] Tribunale amministrativo regionale Lazio Roma 16 November 2020 no 7069, available at www.giustizia-amministrativa.it.

1. The Theses of the Appellants and Respondents

The reasoning of the Council of State begins by giving some scientific details about hydroxychloroquine (HCQ). For many years – the court explains – HCQ has been used as an antimalarial drug, and also as a treatment for systemic lupus erythematosus and rheumatoid arthritis, used by about 60,000 patients in Italy.[13] After the development of the SARS-CoV-2 pandemic, HCQ use was suggested as a possible method of prevention or treatment for COVID-19.[14] Even if its efficacy was demonstrated by evidence of in-vitro inhibition of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the in-vivo studies benefits were much debated in the scientific community.

After having offered a brief overview of the scientific studies about the drug,[15] the Council of State illustrates that at the outbreak of the pandemic AIFA consented to the off-label use of HCQ, but on 26 May 2020 it modified the product information label for these medicines (also according to the recommendations of the European Medicines Agency, EMA) suspending its off-label use. This decision was based on two reasons. First, the available data were not consistent and did not demonstrate a clear clinical benefit; second, there was a risk of cardiac toxicity from high doses usage.[16]

The Council of State then goes on to describe the position of the claimants/appellants. According to the doctors who brought the request for interim relief, the drug was effective and the decision of AIFA was lacking in a proper investigation of the data. Furthermore, in the appellant doctors' opinion, the decision of AIFA violated their autonomy – as guaranteed by the Italian Constitution and by the law – in prescribing under their own responsibility the drug to non-hospitalised subjects who have given their informed consent.[17]

These arguments were rebutted by AIFA. AIFA maintained that its decisions, far from being taken without a profound study of the evidence as the appellant tried to demonstrate, were based on the last and best available evidence in the light of the safest guarantee for patients. For this reason, according to AIFA, its decision on the matter represented the fruit of their very technical discretion the merits of which the court cannot evaluate (especially during an interim proceeding like the one in front of the Council of State).[18]

In response to this, highlighting the undisputed role of AIFA in the protection of public health, and the equally undisputed scientific basis of the determinations of AIFA, the Council of State stresses that there are no decisions – no matter how

[13] Consiglio di Stato, n 11 above, point 1.2.

[14] J. April, 'Hydroxychloroquine in the prevention of COVID-19 mortality' 3 *The Lancet Rheumatology* (2020).

[15] ibid points 1.5 to 1.6.

[16] ibid point 1.9. See the first AIFA communication on the use of hydroxychloroquine: https://tinyurl.com/26pa83pe (last visited 30 June 2021).

[17] ibid points 2-2.1.

[18] ibid point 8.1.

delicate the issue at stake is, such as the off-label use of drugs against COVID-19 – which could not be judged by the administrative court to control the correct use of the technical discretionary powers. In fact, under Art 113 of the Italian Constitution, the judicial safeguarding of rights before the bodies of administrative justice is always permitted against acts of the public administration, and cannot be excluded for or limited regarding particular categories of acts, such as the elements of the information sheet on the use of HCQ forbidding its off-label use.[19] From the perspective of the court, the off-label prescriptions could be restricted by AIFA only if two conditions are met: when according to scientific knowledge and experimental evidence the use of the HCQ proves to be ineffective and unsafe.[20]

As we will discuss below,[21] given the fact that judicial review is admitted on this type of decision, what kind of control is the court entitled to carry out? The answer to this question represents the core of the decision, and the crucial point of our analysis. The reasoning of the court on this matter is discussed in the next section.

2. Form or Substance Under Review?

Once the Council of State recognised the admissibility of the judicial review of a decision of a public administration in a case that involves technical discretion, the next hot topic to discuss for the highest administrative court is if this control could be exercised only on the *extrinsic* side of the act (ie, only on the form), or also on the *intrinsic* sphere of the act (ie, on the reasoning underpinning the decision).

For a long time, the control of the administrative court on the technical decisions of public administrations was interpreted as a merely formal control on the logical reasoning followed in reaching a decision.[22] However, the most recent interpretations[23] allow the administrative court to perform a truly direct control of the coherence and correctness of the technical criteria used by the administrative authority to reach the decision.[24]

As underlined by the Council of State, this does not imply that the administrative court is charged with a jurisdictional control on the merits of debatable choices; rather, the task of the administrative court is to verify the rational credibility of the scientific knowledge underlying these choices.[25] In this light, the judicial review is not a mere extrinsic control, but an intrinsic one, involving the use of the same scientific knowledge applied by the public

[19] ibid points 8.2-8.3.
[20] ibid point 7.
[21] See below section V.
[22] See below section V.
[23] See, for example, Consiglio di Stato 6 July 2020 no 4322, available at www.giustizia-amministrativa.it.
[24] M. Clarich, *Manuale di Diritto Amministrativo* (Bologna: Il Mulino, 2019), 131.
[25] Consiglio di Stato, n 11 above, point 9.1

administration in its acts in order to assess the reliability, coherence, correctness of the methodology and the conclusions adopted.[26]

In this context, the Council of State interpreted its task as an entitlement and an obligation to check whether the decision of AIFA to forbid the off-label use of HCQ for COVID-19 patients had a solid scientific base, in the light of the limited available evidence.[27] In other words, the Council of State had to verify the latest scientific knowledge to understand whether the ban of the off-label use of HDQ was reasonable or not.

3. Scientific Criteria for the Solution

The Consiglio di Stato continues by illustrating that medical science has to indicate the most appropriate and safe treatment for a disease, and the dominant approach in accomplishing this task is the so-called *evidence based medicine* (EBM). Under EBM, the choice of treatment should be based on the best evidence of efficacy and on randomised controlled trials (RCT) which represent the so-called gold standard of medical research.[28]

Applying this scientific methodology in the COVID-19 pandemic, however, was (and is) not straightforward. The urgency of the situation did not permit the collection of significant and final findings on the best type of treatment, and specifically on the benefits of the use of hydroxychloroquine as a treatment for COVID-19 patients with a non-serious condition and in the early stages of the disease.

The Council of State therefore had to establish whether the technical discretion of AIFA in the application of the scientific laws made the suspension of the use of HCQ logical and proportionate. In other words, the Consiglio di Stato had to analyse whether the temporarily suspension of the administration of the drug in patients with non-serious symptoms responded to the necessity to ensure the most (1) *appropriate* and (2) *safe* therapy in the interest of public health.[29]

As to the *appropriateness* of the cure, the Consiglio di Stato observes that there were no medical studies demonstrating the *unquestionable inefficacy* of HCQ in the early treatment of COVID-19 patients (even if the results tend towards its inefficacy), and that most of the studies lack internal and external validity because of the urgent conditions in which the clinical trials were conducted.[30]

[26] ibid point 9.2.
[27] ibid point 10.
[28] ibid point 11.4.
[29] ibid point 12.
[30] ibid points 13-13.1. The court illustrates that the problem concerned, for example, the so called 'endpoint' of the studies, ie, the measure to consider the success or otherwise of the therapy: the most indicative endpoint for the use of HCQ in the early stage of the illness should have been 'how many of the treated patients needs to be treated in the hospital after the treatment', and not for example – as considered in many trials – the percentage of mortality or the number of days spent in hospital. In addition, the problem also lays in the difficulty of collecting reliable evidence on the

Against this background of uncertainty regarding the usefulness of HCQ, which was admitted – as the court stresses – by AIFA itself,[31] the appellants submitted to the courts an expert opinion based on several randomised studies which, on the contrary, suggested the efficacy of the treatment in a non-advanced stage of the illness.[32]

The Consiglio di Stato makes clear that if, on the one hand, it is beyond its competence to decide on the efficacy or otherwise of HCQ against COVID-19 in the early stage of the illness, on the other hand, it is up to the administrative court to point out that this uncertainty regarding the efficacy of HCQ is not sufficient from a legal point of view to justify the suspension of its possible use.[33] In the face of the limited experimental evidence available and of divergent medical opinions, the decision to suspend the use of the drug does not even allow testing the slightest efficacy of HCQ in patients in the early stage of the illness, and delays its experimentation to a point in the future in which it would be probably not be useful.[34] The strict and severe scientific methodology has to deal with the emergency of the pandemic situation and, lacking an alternative therapy, the use of a drug which could be even slightly useful could not be denied, unless its risks clearly outweigh its benefits.[35]

In this situation of uncertainty, the Consiglio di Stato maintains that the choice to use or not to use a drug should lie with the autonomy of the physician, with the informed consent of the patient, and not on a generalised and aprioristic ban on using it, based on a principle expressed 'in the name of a pure scientific model'.[36]

As to the requisite of the *safeness* of the treatment, the Consiglio di Stato illustrates that AIFA itself recognised that the last clinical trials seemed not to demonstrate a higher risk of toxicity (especially an increased risk of heart problems) and did not show any difference between patients who use it or not in terms of mortality.[37] As to the psychiatric disorders pointed out by the safety committee of EMA, these are related to higher doses of HCQ.[38]

On these premises, the Council of State could reach only one decision. Given the abovementioned considerations regarding the (limited) efficacy and the (apparent) safeness of the treatment, the court states that, on the basis of the available scientific knowledge and considering the possibility of any further

usefulness or not of HCQ in patients who were at home and at an early stage of the disease, because for example much of the data was collected by telephone or online.

[31] Consiglio di Stato, n 11 above, point 14.5.

[32] ibid point 14.5.

[33] ibid point 15.

[34] ibid point 16.

[35] ibid point 17.1.

[36] ibid point 17.2.

[37] ibid point 19. See also AIFA, 'Hydroxychloroquine in the treatment of adult patients with COVID-19', available at https://tinyurl.com/7fcb25se (last visited 30 June 2021).

[38] Consiglio di Stato, n 11 above, point 19.3.

investigation by the trial court and AIFA itself, the evaluation of the risks/benefits of the drug demonstrated that the suspension of the off-label use of HCQ and of its prescription by doctors, under their responsibility, in the treatment at home of COVID-19, was not reasonable.

On these grounds the claim of the doctors was accepted. On 23 December 2020, AIFA updated its recommendations on the use of hydroxycloroquine (HCQ) in patients with COVID-19.[39] The case is now being discussed in the trial court.

IV. The Intersection Between Science and Law from a Comparative Perspective

The reason why the order of the Council of State is interesting for lawyers is of course not related to the usefulness or not of HCQ as a treatment for COVID-19. What is interesting to analyse is the use by the judge of the scientific reasoning to decide the case. Even if the decision we are commenting on was adopted by an administrative court, the power and position of which vis-à-vis the parties are in many respects different from the ones of ordinary courts in civil proceedings, it is reasonable to assess the decision in question against the legal debate on science and law emerging in the context of civil procedure. Since these problems are shared by both the common law and civil law traditions, it is also useful to analyse how they are viewed and approached on the two sides of the Atlantic.

The legal debate on science and law focuses mostly on doubts about the ability of a judge to arrive at sound inferences from scientific or technical data. This is why it becomes crucial for legal scholars to study and understand the admissibility standards of access of evidence in judicial proceedings.[40]

Since the principal (albeit not the only) means through which scientific evidence enters the courtrooms is the expert testimony, the majority of criteria for the evaluation of scientific data before courts has been developed in relation to the standard for admitting scientific expert testimony in trials.

In this light, the first and most important example comes from the common law experience. The reference is to the US leading case *Daubert* v *Merrell Dow Pharmaceuticals, Inc.* 509 US 579 (1993) and the so-called Daubert Trilogy.[41]

[39] AIFA, 'AIFA recommendations on hydroxychloroquine', available at https://tinyurl.com/f64ksnfb (last visited 30 June 2021).

[40] From a comparative perspective see, for example, P. Monaco, *Sostanze tossiche e danni. Profili di diritto globale, europeo e nazionale* (Napoli: Editoriale Scientifica, 2020). For common law see, among many, D. Faigman et al, *Modern Scientific evidence: the law and science of expert testimony* (St. Paul: West Pub Co, 2010), III; P.C. Giannelli and E.L. Imwinkelried jr, *Scientic Evidence* (Newark: LexisNexis, 2007); in Italian: M. Taruffo ed, *La prova nel processo civile* (Milano: Giuffrè 2012); Id, *La semplice verità. Il giudice e la costruzione dei fatti* (Bari: Editori Laterza, 2009).

[41] *Daubert* v *Merrell Dow Pharmaceuticals*, Inc 509 US 579 (1993).

Daubert is a toxic tort case regarding the tragedy of Bendectin, a drug prescribed during pregnancy to reduce 'morning sickness'. Here the plaintiffs argued that the drug caused deformities

In Daubert, the Supreme Court of the United States proffered new standards for the admissibility of scientific evidence. In particular, the Supreme Court stated that judges had to consider

> (1) whether the theory or technique (…) has been tested; (2) whether it has been subjected to peer review or publication; (3) its known or potential error of rate (…); and (4) whether it has attracted widespread acceptance within a relevant scientific community.[42]

But perhaps the most important statement of the Daubert decision is the one in which the Supreme Court vested the judge with the role of gatekeeper of the trial, entrusted with ensuring that 'all scientific testimony or evidence admitted is not only relevant, but reliable'.[43] To stress again the importance of the topic of science and law, it is worth emphasising how revolutionary this judicial task is in an adversarial system like that of the US, where the proceedings are usually controlled by the parties and their attorneys, while the judges acts as a passive umpire, basing their decision on the evidence presented by the parties.[44]

As for the civil law tradition, the field of science in courtrooms is treated from a slightly different perspective. Despite the fact that the rules on the participation of experts in litigation differ across civil law jurisdictions, European legal systems converge on the fact that is the judge, and not the parties, as in the US adversarial model, who exercise the control on the evidence phase of the proceedings, and consequently also on the choice of and the tasks given to the expert, the main instrument through whom scientific evidence enters the courtroom. The main worry in continental Europe about experts' reports concern the evaluation of their competence.[45] That is why the gatekeeping role could belong to the judge

in children exposed to it while in utero. The problem was with the admissibility of expert testimonies sustaining the existence of a causation between the use of the drug and the deformities. On the Daubert decision see, among the many, M.A. Berger, 'The Supreme Court's Trilogy on the Admissibility of Expert Testimony', in M.A. Berger et al eds, *Reference Manual on Scientific Evidence* (Federal Justice Center, 2nd ed, 2000), 9; D. Bernstein, 'The Misbegotten Judicial Resistance to the Daubert Revolution' *Notre Dame Law Review*, 29 (2013); M.A. Berger, 'Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation' 64 *Law & Contemporary Problems*, 289-326 (2001). In Italian, P. Monaco, *Sostanze tossiche e danni* n 40 above, 84.

[42] *Daubert* v *Merrell Dow Pharmaceuticals*, Inc. 509 US 579, 592 (1993).

[43] ibid 589. After Daubert, two other decisions completed the framework of the discipline. The first, *General Electric Co.* v *Joiner* 522 US 136 (1997), regarded the standard for federal appellate courts to review the evidentiary determination of the lower court. The second decision, *Kumho Tire Company Ltd.* v *Carmichael* 526 US 137 (1999) considered the question of whether Daubert's reliability test was extended also to non-scientific expert testimony, in this case the plaintiffs' expert witness – an expert in tire industry, who testified that the defective car tire has caused the accident where one passenger died and others were injured. These three cases are commonly known in the legal debate as the Daubert Trilogy: M.A. Berger, 'The Supreme Court's Trilogy' n 41 above.

[44] P. Monaco, *Sostanze tossiche e danni* n 40 above, 92.

[45] P. Monaco, 'Scientific Evidence' n 2 above; P. Monaco, *Sostanze tossiche e danni* n 40 above, 271.

while appointing the expert and defining their duties,[46] as well as while checking the notions and methodology employed by the expert. In their role, it is said, the judge need not be an expert. But at this point, as noted by legal scholars,[47] a paradox appears. If judges need to be assisted by an expert because they lack the required specific knowledge, how can they have the ability to evaluate the soundness of the final technical report? The answer to this problem is that (perhaps) they should only deal with the knowledge of the necessary conditions under which information could be considered to possess scientific validity.[48]

Could these principles born and developed in the civil proceedings be valid when applied in front of an administrative court? We will try to answer this question in the next section.

V. The Administrative Court Dealing with Science

The administrative trial also represents a special laboratory to test the intersection between law and science, particularly because it is closely linked to the judicial review of the administrative action. In fact, an extensive debate between administrative courts and scholars has developed around the justiciability of so-called 'technical discretion'.[49] As is well known, administrations enjoy the technical discretion when decisions have to be taken on the basis of specific technical expertise which, when applied, presents profiles of uncertainty or questionability because it depends on divergent scientific opinions.[50] This is the case, for example, with AIFA forbidding the off-label use of HCQ.

As the litigation herein commented on makes clear, the judicial review of administrative technical acts raises a number of questions, such as: how far can

[46] See for all, M. Taruffo, 'La prova scientifica nel processo civile' *Rivista trimestrale di diritto e procedura civile*, 1110-1111 (2005).

[47] ibid 1079-1111.

[48] ibid 1110-1111.

[49] For M. Clarich, *Manuale* n 24 above, 130-131; S. Cognetti, 'Potere amministrativo e principio di precauzione fra discrezionalità tecnica e discrezionalità pura', in S. Cognetti et al eds, *Percorsi di diritto amministrativo* (Torino: Giappichelli, 2014), 131. In English: See G. della Cananea, 'Judicial Review of Administrative Action in Italy: Beyond Deference?', in G. Zhu ed, *Deference to the Administration in Judicial Review* (Cham: Springer, 2019), 271. On judicial review of technical discretion of Independent Administrative Authorities see G. Sigismondi, 'Il sindacato sulle valutazioni tecniche nella pratica delle Corti' *Rivista Trimestrale di Diritto Pubblico*, 705 (2015); G. De Rosa, 'La discrezionalità tecnica: natura e sindacabilità da parte del giudice amministrativo' *Diritto e Processo Amministrativo*, 513 (2013); A. Travi, 'Il giudice amministrativo e le questioni tecnico-scientifiche: formule nuove e vecchie soluzioni' *Diritto pubblico*, 439 (2004); P. Lazzara, *Autorità indipendenti e discrezionalità* (Padova: CEDAM, 2001).

[50] On the contrary, 'administrative discretion' involves choices of political nature. On this point seminal are the studies of M.S. Giannini, *Il Potere Discrezionale della Pubblica Amministrazione, Concetto e Problemi* (Milano: Giuffrè, 1939). More recently: M. Clarich, *Manuale* n 24 above, 130. On the technical discretion see D. de Pretis, *Valutazione amministrativa e discrezionalità tecnica* (Padova: CEDAM, 1995).

the technical discretionary power be scrutinised by the court? Is the judicial review limited to verifying compliance with the procedural rules or can the judge scrutinise more profoundly the decision of the authority? As discussed above, one of the defences of AIFA was that its decision to forbid the use of HCQ was the fruit of the expression of its technical discretion and therefore could not be subjected to judicial review, even more so in an ad interim proceeding.[51]

For a long time, the tendency of the Italian administrative judiciary was to deny the judicial review of choices stemming from a technical discretion.[52] But recently things have changed, as the Council of State pointed out in the decision we are commenting on.[53] The path changed in particular in 1999, with the leading case on the matter by the Council of State, section IV, of 9 April 1999, no 601.[54] In this decision, the Consiglio di Stato made it clear that it is true that judicial review is not possible if related to the direct evaluation of the public interest underlying the merits of the choice made by the authority (ie, administrative discretion properly intended), but on the contrary the control of the court is not excluded for assessments based on technical standard.[55]

From this perspective, the judicial review by the administrative judge is no longer limited simply to the existence of formal errors of assessment in the decision of the authority, but also includes the evaluation of whether technical assessments have been made following a rational credibility supported by scientific and technical argumentations correctly applied in the specific context.[56] This is the reason why the Consiglio di Stato, in its order 9070/2020, engaged in a profound analysis of the available scientific data supporting the decision of AIFA as regards HCQ. The court is entitled to check if the assessment adopted by the administrative authority is correct, in the light of the technical and scientific rules which have been applied.[57]

Once it is admitted that the administrative court has the power to evaluate scientific knowledge, we return to the problem we discussed above with regard to judges in civil courts: how can the judge have the ability to control a very

[51] See above, section 1. Point 8.1 of the Consiglio di Stato, n 1 above.

[52] M. Clarich, *Manuale* n 24 above, 130-131.

[53] See above, section 2.

[54] Consiglio di Stato 9 April 1999 no 601, available at www.giustizia-amministrativa.it. The case concerned the claim of a civil servant who maintained that his illness was caused by his administrative activity. The lower administrative court endorsed the respondent's argument that the claim was not substantiated on the basis of objective standards and that technical assessments made by the administration escaped judicial review. The Council of State reversed the decision of the lower court.

[55] See G. della Cananea, 'Judicial Review' n 49 above, 271.

[56] The importance of this decision is most evident in some very specific areas, such as for example the one of antitrust: see R. Chieppa, 'Il differente controllo del Giudice amministrativo sulle attività di regolazione e giustiziali delle Autorità amministrative indipendenti', in R. Chieppa et al eds, *Il controllo del giudice amministrativo sulla discrezionalità tecnica e, in particolare, sugli atti delle autorità indipendenti* (Milano: Giuffrè, 2009), 47.

[57] Consiglio di Stato, n 11 above, point 9.3.

specialised act, adopted by a highly qualified authority? An easy answer is that the administrative judge can and should do so with the support of experts, whose appointment is possible, when necessary, in administrative proceedings as well.[58] But, as we mentioned above, allowing the participation of experts in judicial proceedings means opening a Pandora's box of other problems, related to the ability of judges to govern and control such experts and the knowledge they provide in the litigation. What is certain is that this topic is also far from being settled in administrative proceedings.

VI. Conclusion

As we observed at the beginning of our analysis, the relationship between science and law has never been one of simple understanding. Owing to the increasing number of legal questions which can (or even have to) be resolved by resorting to scientific knowledge, in recent years the challenges posed by the use of scientific evidence became a hot topic in legal debates. Problems arising from scientific evidence are shared by the legal traditions and by the different areas of law.

As to the common law and civil law traditions, despite the divergence of attitudes and solutions proposed by the US and continental European legal systems, when we look at the operational results we find a surprising convergence. On the US side, Daubert not only fixed the standards for admitting scientific evidence, but also attacked one of the pillars of the US adversarial system, the traditionally passive role of the judge. After Daubert, both federal and state judges no longer neutrally umpire the proceedings, but actively intervene in the development of evidence and in the whole process itself. As to the situation in Europe, the situation seems, at the first glance, to be very different, since it is the judge, and not the parties, who exercises control over the evidentiary phase of the proceedings. However, if we dig a little deeper under this surface, we will discover that these divergences are less clear. Continental European judges do not only experience the same difficulties as their US colleagues in dealing with scientific problems, but, in the end, they also behave in the same way: they are the ultimate gatekeepers of the submission of scientific evidence in the courtroom.[59]

The same observations also apply to the context of the decision we are commenting on. The scientific and medical issues which exploded with the

[58] Art 63(5) of the Code of Administrative Procedure foresees the possibility for the judge to order any of the means of evidence provided by the Civil Procedure Code, included the assistance of an expert. On the expert in administrative proceedings see, for example, F. De Luca, 'I differenti tipi di misure cautelari', in F. Freni ed, *La tutela cautelare e sommaria nel nuovo processo amministrativo* (Milano: Giuffrè, 2011), 74; F. Cintioli, 'Consulenza tecnica d'ufficio e sindacato giurisdizionale della discrezionalità tecnica' *Consiglio di Stato*, 2371 (2001).

[59] For more extensive comment see P. Monaco, 'Scientific Evidence' n 2 above, 108.

COVID-19 pandemic have given rise to many related legal aspects which will end up on the desks of legal scholars and judges. Order no 9070 of 11 December 2020 of the Council of State represents a good example in this context.

In this decision the problems stemming from the uncertainty of medical reasoning are reflected in the difficult challenge for the judge who had to deal with complex scientific data. This was an occasion for the Consiglio di Stato to stress the boundaries of its role and make it clear that judicial review in the administrative context is not merely limited in the verification of the logic and consistency of the conclusions reached by the administration. On the contrary, when the assessment under the scrutiny of the court concerns the technical discretion of an administration (ie, discretion involving decisions based on technical and scientific expertise), the administrative judge is allowed to go further: they are entitled to verify whether the technical choices are based on a logical argumentation and a valid scientific knowledge. In other words, they act as the gatekeeper of scientific knowledge debated in front of them.

In conclusion, to secure the promise of effectively allowing only 'good' science to enter the courtrooms, it seems that the solution found in common law and civil law jurisdictions, as well as in front of civil and administrative courts, is converging: the gatekeeper of the scientific and technical knowledge is everywhere the judge. Whether these standards built and followed by courts actually work represents another big question, one that only time might answer.