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THE MANY FACES OF ADMINISTRATIVE ADJUDICATION IN THE EUROPEAN UNION

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Despite enormous variation in the details**,** federal and state administrative adjudication in the United States fits comfortably into a procedural template. Whether the adjudication is "formal" or "informal," and whether or not an Administrative Procedure Act (APA) is applicable, we would expect to see some sort of adversarial trial-type hearing employed to resolve disputes between private parties and government agencies. Private parties have a fair chance to make their case and confront the evidence against them. The hearing will be presided over by a reasonably impartial administrative judge. Agency prosecutors and investigators cannot be the decisionmakers or furnish ex parte advice to the decisionmakers. The heads of the agencies make the final agency decision which is broadly reviewable by courts. A similar adversarial template exists in

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the United Kingdom. In the UK, administrative adjudication is usually conducted by a tribunal that is organizationally independent of the government agency that is a party to the case.

Although the European Union (EU) engages in a huge array of administrative adjudication, there is no procedural template like those in the US or UK. Instead, adjudicatory proceedings in each regulatory sector are different from the other sectors. The procedure for investigation and hearing is inquisitorial rather than adversarial. Over time, EU courts have imposed some due process norms on this structure, although the development and application of such norms varies from sector to sector. This article introduces the reader to the world of administrative adjudication in the EU.

The article is intended as a practical and descriptive rather than a theoretical account of EU adjudicatory administrative procedure. It focuses on six regulatory sectors: competition, trade regulation, trademarks, food safety, pharmaceutical licensing, and state aids. These six sectors account for the great majority of adjudication conducted by the EU. The article is written from the perspective of American observers and uses US administrative procedures as its frame of reference, drawing frequent comparisons between the processes observed in the EU and those that exist in the US and UK.

I. ADJUDICATION IN THE EUROPEAN COMMUNITY: GENERAL THEMES

To set the stage: This article concerns adjudicatory decisions taken at the level of the European Commission (EC), not those taken at the member state level. Most regulatory schemes involving private companies are administered by member states (often pursuant to legislation adopted at the Community level), but this article does not

concern itself with member state adjudication. The article considers adjudicatory procedures at the administrative level, not issues relating to judicial review by Community courts. The emphasis is on procedural protections available to private parties in connection with these proceedings.

For purposes of this article, the term "Commission" includes not only the Commission itself but also European "agencies" empowered to play key roles in making individualized decisions.[1] These agencies include the Office of Harmonization in the Internal Market (OHIM) which administers the EU trademark law; the European Medicines Agency (EMEA) and its Committee for Medicinal Products for Human Use (CHMP) which play key advisory roles in pharmaceutical licensing; and the European Food Safety Authority (EFSA) which carries out risk analysis functions in food safety regulation.

The article concerns decisions of specific applicability (that is, adjudication), not decisions of general applicability (that is, rulemaking), although in some cases the Commission's final decision takes the form of a rule rather than an individualized decision. Adjudicatory decisions involve the application of general norms to particular facts and impose legal consequences (such as penalties, denial or grant of permissions or licenses, changes in legal status, or orders to alter conduct) on parties (usually private parties but sometimes member states). The article refers, where applicable, to the duty of

[1] For discussion of EU independent agencies, see Wolfgang Weiss, "Agencies vs. Networks: From Divide to Convergence in the Administrative Governance in the EU, __ ADMIN. L. REV. __ (2008); Jens-Peter Schneider, "A Common Framework for EU Agencies and the *Meroni* Doctrine," __ ADMIN. L. REV. __ (2008); Alexandra Gatto, "Governance in the European Union: A Legal Perspective," 12 COLUM. J. EUR. L. 487, 505-08 (2006); Damien Geradin, "The Development of European Regulatory Agencies: What the EU Should Learn From American Experience," 11 COLUM. J. EUR. L. 1 (2005).

good administration provided for in the Charter of Fundamental Rights,[2] which was incorporated in the recent Treaty of Lisbon.[3] If ratified, the Lisbon Treaty may broaden the procedural rights discussed in this article.

A. EC adjudicatory procedures are heterogeneous

1. Differences between the sectors

A striking aspect of the six sectors we studied was the heterogeneity of process. Each set of procedures has its own foundation in the Treaty of the European Community or in statutes, each is administered by a separate bureaucratic structure, each has its own procedural regulations, each has its own historical development, and each has a different relationship with decision-making processes in the member states. Nevertheless, as pointed out in Part I.C., decisions of the European courts have prompted a certain amount of procedural convergence between the sectors.

This sub-section describes the wide differences between the adjudicatory procedures in the six sectors: competition, trade remedies, trademarks, food safety,

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[2] Art. 41(2) of the Charter of Fundamental Rights of the European Union (2000) provides for a right to "good administration." Good administration means that every person has a right to have his or her affairs handled impartially, fairly, and within a reasonable time; every person has a right to be heard before any measure which would adversely affect him or her is taken; every person has a right of access to his or her file, while respecting the legitimate interests of confidentiality and professional and business secrecy; and the administration is obligated to give reasons for its decision. See Paul Craig, EU ADMINISTRATIVE LAW 385-87 (2006); Klara Kańska, "Toward Administrative Human Rights in the EU: Impact of the Charter of Fundamental Rights," 10 EUR. L. J. 296 (2004); Mario P. Chiti, "Forms of European Administrative Action," 68 LAW & CONTEMP. PROBS. 37, 43-44 (2004).

[3] See http://europa.eu/lisbon_treaty/index_en.htm, Arts. 1(8) and 6(1). If ratified, the Treaty of Lisbon will rename the Treaty of the European Community (TEC) as the "Treaty on the Functioning of the European Union" (TFEU). While the right to "good administration" already exists as a general principle of Community law, see Hanns Peter Nehl, PRINCIPLES OF ADMINISTRATIVE PROCEDURE IN EC LAW 13-39 (1999), the incorporation of the Charter into the Treaty might extend administrative hearing rights to certain sectors in which they are not yet fully recognized.

pharmaceutical licensing, and state aids. Part II of this report briefly summarizes adjudicatory procedures in those sectors.[4]

EU adjudicatory procedures vary depending on whether they are triggered by an initial application for a benefit (merger applications, trademark applications, food licensing, pharmaceutical licensing, state aids) or whether they are triggered by administrative action that could lead to a sanction or deprivation of an existing status (competition, trade remedies, trademark oppositions, changed circumstances or sanctions in pharmaceutical cases). In two areas (state aids, food licensing), the decisional process seems more political rather than adjudicatory in nature.

Each sector follows its own investigative procedure which enables the relevant directorate of the Commission to inform itself about the facts and circumstances of a dispute.[5] In certain competition cases, the Directorate General for Competition (hereinafter DG COMP) conducts an intrusive investigation that can include unannounced site visits and inspections of non-business premises including residences.[6] In other cases, such as trade remedies, food safety, state aids, and pharmaceutical

[4] A more detailed summary of procedures in the six sectors is contained in the Adjudication volume of *Administrative Law of the European Union* (2008). The full-length version of the reports prepared by our sectoral reporters is available on the website of the ABA Section on Administrative Law and Regulatory Practice. http://www.abanet.org/adminlaw/eu/home.html#Sector.

[5] Generally in American administrative law, agencies have broad investigatory powers to subpoena documents. While subpoenas must be judicially enforced, the agency needs to show only that the documents in question are relevant to a subject the agency is authorized to investigate. See American Bar Association, Section of Administrative Law and Regulatory Practice, A GUIDE TO FEDERAL AGENCY ADJUDICATION (Michael Asimow, editor) 47-57 (2003) (hereinafter ABA Guide).

[6] In American administrative law, an agency generally must secure a warrant to inspect business premises, but the requirements for obtaining such warrants are much less demanding than in criminal cases. Marshall v. Barlow's Inc., 436 U.S. 307 (1978).

licensing, the Commission or independent agencies such as EFSA conduct an active investigation based primarily upon documents furnished by the parties or by experts in the field. In the trademark area, OHIM conducts an initial trademark search and thereafter relies on complaining parties or member states to provide the necessary data. In the area of state aids, the Commission's investigation consists primarily of requesting information from member states.

Rights of access to the Commission's file also vary widely. In some areas, such as competition and trademarks, the parties have broad access to all documents in the Commission's file, other than material protected by confidentiality (such as the identity of informers or business secrets) or internal Commission documents.[7] However, non-parties (such as complainants) have more limited access to files. In other areas, the parties have access only to non-confidential versions of the documents in the files (trade remedies). In state aids, neither Member states nor private parties have access to the Commission's file.

Another significant area of variation relates to oral hearings. Hearings involving oral testimony are routinely allowed upon request in some areas (competition, trade remedies, pharmaceutical licensing), occur rarely in some areas (trademarks), and are never held in other areas (food safety, state aids). In many cases, the parties are entitled

[7] In American administrative law, neither the APA nor due process requires agencies to provide discovery of documents in their files because the discovery rules applicable in civil cases do not apply to administrative litigation. See ABA Guide, supra note 5 at ¶4.03. However, many agencies have adopted rules permitting parties to discover material in the agency's files. Alternatively, such information is available on demand to anyone (including third parties) under the Freedom of Information Act (FOIA). However, under FOIA exceptions, an agency is not required to disclose pre-decisional agency memoranda. 5 U.S.C. §552(b)(5); NLRB v. Sears, Roebuck & Co., 421 U.S. 132 (1975). In addition, under FOIA, an agency is not required to disclose various documents compiled for law enforcement purposes, such as those that might disclose the identity of a confidential source. 5 U.S.C. §552(b)(7).

only to a written rather than an oral exchange. In state aid cases, interested parties are entitled to submit written comments (to which member states can reply) and to engage in informal meetings with the staff, but no oral hearing is provided. In contrast, oral adjudicatory hearings are the norm in US administrative law.[8]

In EU adjudication, oral hearings are usually conducted by the team of case handlers who are engaged in investigating the matter.[9] The case handlers do not write proposed decisions after conducting the hearings. However, in competition cases, oral hearings are conducted by hearing officers who specialize in conducting hearings (and dealing with data requests and confidentiality issues), but do not conduct investigations. [10] Hearing officers in competition cases are responsible to the Commission, not to DG COMP. They file a report on whether the procedural rules have been observed. The report may but need not contain substantive observations on the Commission's internal

[8] In the US, administrative adjudication normally entails oral presentation of testimony by witnesses followed by cross-examination. APA §556(d) provides: "A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." Nevertheless, relying on the last clause of the provision just quoted, the courts allow agencies to dispense with cross-examination when credibility is not at stake, such as in cases involving only differences of expert testimony. See ABA Guide, *supra* note 5, ¶5.08. An oral hearing can be denied entirely if there are no disputed issues of fact. See, e.g., Weinberger v. Hynson, Westcott & Dunning, Inc., 412 US 609 (1973) (upholding summary judgment procedure at Food & Drug Administration). An oral hearing can also be denied in cases involving claims for money or benefits or initial licensing when "a party will not be prejudiced thereby." APA §556(d), last sentence. .

[9] In U.S. practice, adjudicatory hearings are generally subject to separation of functions, meaning that the hearing officer has not played any adversarial role in respect to the pending case. For further discussion, see text at notes 26-27, *infra.*

[10] The post of hearing officer was first established in 1982 in order to enhance the impartiality and objectivity of competition proceedings before the Commission. Their use was formalized by the Commission decision of May 23, 2001. OJ (L 162) 21. See generally VAN BAEL & BELLIS, COMPETITION LAW OF THE EUROPEAN COMMUNITY §10.15 (4th ed. 2005).

draft decision. DG TRADE has also introduced independent hearing officers in trade remedies cases, although the precise ground rules have not yet been formalized.[11]

The ultimate Commission decision generally takes the form of an individualized decision addressed to the parties. However, in some cases (such as trade remedies and most food safety cases) the decision may take the form of a broadly applicable rule.[12] An individualized decision must state reasons that are sufficient to allow for judicial review and must contain discussion of both law and facts, but the necessary detail of the statement of reasons varies with the circumstances of the case.[13]

Generally there is no opportunity for administrative reconsideration. However, in trade remedy cases, after one year parties may apply for an interim review of the definitive measures imposed by the Commission. In trademark cases, OHIM provides a board of appeals to reconsider the agency's initial decisions.

The relationship between decisions at the Commission level and decisions at the member state level varies as between the six sectors. In the competition area, enforcement is divided between the Commission and competition authorities in the member states, although the member states must follow the law established at the EU level. In pharmaceutical licensing, under the centralized process, licensing occurs at the

[11] See Natalie McNelis, "A Hearing Officer for Trade," 3 Global Trade & Customs J. 77 (2008); http://ec.europa.eu/trade/issues/respectrules/ho/index_en.htm. See text accompanying note 92, *infra,* for further discussion of hearing officers in trade remedy cases.

[12] In American practice, adjudicatory disputes are resolved by a decisional document produced by the agency heads or heads. The decision is individualized and addressed to the parties. APA §556(b).

[13] In American practice, the APA requires a statement of findings of fact, conclusions of law, and reasons for discretionary decisions. APA §557(c); ABA Guide, *supra* note 5 ¶6.021. So-called post-hoc rationalizations (reasons supplied by agency counsel at the judicial review stage are not allowed). Due process also requires a statement of reasons even though the APA does not apply. *Id*. ¶6.021 n.7.

Commission level, but under the decentralized process it occurs at the member state level. In trademarks, licensing of community trademarks occurs at the Commission level but member states license trademarks that are enforceable within that state. A large amount of trademark litigation occurs in courts of the member states. In the case of food safety, most regulation is at the Commission level. In the case of novel foods, however, applications are lodged in a member state which performs the initial assessment, while the final decision occurs at the Commission level. In the areas of trade remedies and state aids, decisionmaking is lodged exclusively at the Commission level.

2. Reasons for differences between sectors

There are several reasons why adjudicatory procedures have developed in such a diverse manner. These include differences in the history of direct Commission involvement in the particular sector, the involvement of member states in the area, the different types of parties affected by the procedures, and the development of separate agencies outside the Commission.

First, administrative procedures evolved in each of the sectors independently and in tandem with the development of the EU's regulatory role. The Commission began to function in each of the areas studied at different times, and procedures developed as necessary to address the growing scope of Commission involvement. Over time, guided by practical experience and by decisions of the European courts, the Commission honed and expanded its adjudicatory procedures.

Competition law provides a clear case in point. Competition was one of the earliest fields in which the Commission enjoyed adjudicatory competence. Its authority

dates back to 1962 when it was granted broad powers to enforce the competition rules contained in the 1957 Treaty of Rome, the forerunner of the current EC treaty.[14] The adjudicatory procedures developed in competition cases were applied to merger cases when Commission gained power to review and investigate merger transactions in 1990.[15] By contrast, in the area of pharmaceutical licensing, a centralized procedure directly involving the Commission was not introduced until 1995. Similarly, the European Food Safety Authority (EFSA) was not established until 2002.[16]

Second, in some areas the Commission shares the field with regulatory bodies of the member states, while in other areas the Commission has sole competence. For example, the Commission co-administers customs cases with member state customs authorities.[17] The varying involvement of Member states in the different areas studied is one possible cause of variations in procedure.

Third, adjudicatory procedures must address the needs of the different types of entities involved. For example, in the state aid field, the parties to the proceeding are the Commission and the member state granting the aid. Beneficiaries of the aid or their competitors are not parties. Clearly, issues relating to access and procedural fairness in cases where member states are parties are quite different from those in which private

[14] Council Regulation 17/62 of February 6, 1962, First Regulation implementing Articles 85 and 86 of the Treaty. OJ 13, 21.2.1962.

[15] Council Regulation (EEC) No. 4064/89 of December 21, 1989, Corrigendum, 1990 O.J. (L. 257), on the control of concentrations between undertakings. OJ L 395 30.12.1989.

[16] Regulation EC No. 178/2002. See Alberto Alemanno, "The Evolution of European Food Regulation: Why the European Food Safety Authority is not an EU-Style FDA," in WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY (C. Ansell & D. Vogel eds. 2006); Alberto Alemanno, "The European Food Safety Authority At Five," 1 EUR. FOOD & FEED L. REV. 2 (2008).

[17] See discussion of customs remission and repayment cases in text at note 65, *infra*.

parties oppose the Commission. Further, the involvement of a member state injects a political element into the process. In trade cases, the Commission investigates an entire industry; the remedies are often duties or restrictions imposed on imports from some foreign country or countries. In such cases, certain procedural rights, such as the right to inspect the file, may be extended to any person with some interest in the industry—manufacturers, exporters and importers, industry associations, users and consumer organizations. By contrast, in other areas such as trademarks and pharmaceutical licensing, Commission decisions typically only affect private parties or corporations and the procedural protections are more tailored to private parties.

Fourth, procedures may have developed differently because of the establishment of specialist bodies with a defined range of functions, such as the OHIM, EFSA, EMEA and CHMP.[18] Since such bodies are specially constituted and are not part of the Commission, they have considerable freedom to establish administrative procedures within their specific mandates. The OHIM, for example, is the only institution we studied that provides for an internal appeal process before parties seek judicial review. In addition, the OHIM imposes a form of separation of functions, with different officials working at different stages of the proceedings.[19] At the other end of the spectrum, the EFSA has very limited procedural protections for private parties, since it is primarily a scientific body engaged in risk assessment and not responsible for the ultimate risk management decision. In addition, EU food safety regulation is a hybrid of adjudicatory and rulemaking methodologies and private protections are less significant in rulemaking

[18] See text at note 1, *supra.*

[19] See PartII. C., *infra.*

than in adjudication. Similarly, the EMEA perceives its role as an independent and scientific (as opposed to political) body. Interestingly, the EMEA and CHMP have developed procedures for party involvement in its review of pharmaceutical licensing applications and imposition of penalties, even though these bodies serve only an advisory function and have no decision-making authority of their own.

In light of the above, it is questionable whether harmonization of processes across the various sectors is a realistic or desirable goal. It certainly has not been a focus of Commission attention, possibly in part due to resource constraints. There are many demands on Commission resources, in particular due to the active involvement of member states in the implementation of EU law and the need to devote resources to translation. Certain aspects of adjudicatory procedure can require the expenditure of significant resources, such as the need for extensive hearings in cases where many parties have an interest,[20] and for this reason may be disfavored in some areas. Further, substantial development and convergence of decision-making processes has taken place at the DG level and through common-law type development of administrative law principles through the ECJ and CFI.[21] For these reasons, there does not appear to be any impetus within the Commission or from the wider legal community for additional procedural harmonization.

B. Commission procedures are inquisitorial rather than adversarial

[20] In one antidumping investigation in the footwear industry, Commission staff in DG TRADE gave hearings to approximately 70 interested parties.

[21] See discussion in Part I.C., *infra*.

In the US model of agency decision-making, the investigative stage and the adjudicative stage are separate. First, the agency staff conducts an investigation and decides to issue a complaint (in the case of violations of law) or to reject an application (in cases that have been triggered by an application for a license or benefit). Second, the target of the complaint or the rejected applicant is furnished a hearing before an impartial and previously uninvolved hearing officer[22] followed by a final decision made by the agency head or heads.[23]

Most American administrative hearings are adversarial in nature and are similar to a judicial civil trial.[24] Normally, parties present their cases through the introduction of

[22] In cases covered by the APA, the trial is conducted by an administrative law judge (ALJ). An ALJ works for the agency for which the ALJ decides cases, but is hired according to a strictly defined procedure administered by the Office of Personnel Management. The independence of ALJs is protected by a variety of statutory provisions. For example, ALJs engage exclusively in hearing cases and never conduct investigations. ALJs cannot receive ex parte communications from other agency staff members with respect to "facts in issue." ALJs work for the agencies for which they decide cases but cannot be supervised by staff members who engage in adversary functions. Agencies are not allowed to conduct evaluations of their ALJs. See ABA Guide, *supra* note 5, at ¶¶ 10.05, 10.10. Many agencies to which the APA's adjudication provisions do not apply also employ a large staff of hearing officers who perform no tasks other than hearing cases. In other non-APA agencies that provide fewer hearings, any staff member can be designated as the hearing officer, but customarily that person will not have participated in the investigation of the case under consideration. .

[23] See APA §557(b); ABA Guide, supra note 5, ¶6.03.

[24] Some large systems of US administrative adjudication do not fit the adversary model. In adjudications conducted by the Social Security Administration, the SSA is not represented by counsel. The ALJ is responsible for representing the agency, safeguarding the interests of the applicant (especially if the latter is not represented by counsel), and then deciding the case. This inquisitorial approach was approved by the US Supreme Court in Richardson v. Perales, 402 U.S. 389 (1971). Similarly, the Court upheld a provision prohibiting the payment of more than $10 to an attorney for a claimant for veterans' benefits, stating that Congress was not required to follow adversarial procedures, at least in cases of benefit determinations. Walters v. Ntl. Ass'n of Radiation Survivors, 473 U.S. 305 (1984). In addition, administrative adjudication is often much less adversarial than civil or criminal litigation. For example, hearing officers are not supposed to serve as passive umpires. Instead, hearing officers are expected to play an active role in structuring issues and questioning witnesses or assisting unrepresented parties, whereas such actions are quite problematic for trial judges.

oral and written testimony and are entitled to cross-examine opposing witnesses. The decisionmaker may consider only evidence that was presented at the hearing (and material that is officially noticed). The decision (both at the stage of initial hearing and at the agency-head level) contains a statement of findings and reasons. Judicial review on the administrative record is almost always available, but the reviewing court's powers are constrained. In the UK, a tribunal (the members of which were not previously involved in the case) provides the hearing at which a party can challenge an administrative determination. The tribunal is independent of the agency that made the adverse decision; judicial review is on the record and judicial power is constrained.[25]

The US model generally provides for *separation of functions*, meaning that persons who have functioned in adversary roles (prosecutors, investigators, or advocates) are not permitted to serve as decisionmakers in the same case (either hearing officer or agency head).[26] In addition, neither outsiders nor adversary staff members are permitted to engage in ex parte communications with the hearing officer or the agency heads. Separation of functions is not complete since, in most cases, hearing officers are employees of the agency that has conducted the investigation.[27] However, hearing

[25] See H. W. R. Wade & C. F. Forsyth, ADMINISTRATIVE LAW ch. 23 (9th edition 2004).

[26] APA §554(d). The APA does not require separation of functions in initial licensing. APA §554(d)(A). In practice, however, agencies frequently separate functions in initial licensing. Many federal adjudicatory schemes are not covered by the APA but the general rules of separation of functions are observed in practice in non-APA adjudication. Due process may require separation of functions in some instances, but the case law is sketchy. See ABA Guide, *supra* note 5, ¶7.061 n. 76.

[27] In some situations (involving industrial injuries and mine safety, among others) federal law provides for two separate agencies, one engaged in rulemaking, investigation and prosecution, another engaged in investigation. Scholars who have studied these independent adjudicating agencies have not assessed them positively. See Daniel J. Gifford, "Adjudication in Independent Administrative Tribunals: The Role of an Alternative Agency Structure," 66 NOTRE DAME L. REV. 965 (1991).

officers are organizationally separated from adversaries and generally have considerable de facto independence.

EU administrative adjudication does not follow this adversarial model,[28] nor does it follow the administrative procedures employed in most civil law countries. Some European countries provide for relatively little formal procedure at the administrative level, but specialized administrative courts furnish in-depth review of the administrative action.[29]

Instead the model resembles that of the inquisitorial criminal justice system used in civil law countries.[30] Inquisitorial criminal law systems vary greatly, but, generally speaking, a magistrate judge supervises the investigation by the police and prosecutors and assembles a dossier. The magistrate can dismiss the case at any time. If a criminal

[28] See Craig, *supra* note 2 at 370-72. Craig observes that the European courts have tersely dismissed claims by litigants that the lack of an independent administrative tribunal in EU regulatory cases violates §6(1) of the European Convention on Human Rights. This section mandates that in the determination of civil rights or obligations, "everyone is entitled to a fair and pubic hearing within a reasonable time by an independent and impartial tribunal established by law." Craig speculates that the fairly intensive judicial review provided by CFI should be viewed as the independent and impartial tribunal referred to by §6(1), especially in conjunction with the array of administrative procedural rights discussed in Part I.C. below.

[29] Francesca Bignami, "Creating European Rights: National Values and Supranational Interests," 11 COLUM. J. EUR. L. 241, 260, 266-69 (2005). The administrative courts generally receive new evidence and entertain new objections to the administrative decision. Nevertheless, the administrative courts tend to be quite deferential to the administration. In contrast, administrative hearings at the agency level are required under Germany's administrative procedure law. See Jürgen Schwarze, EUROPEAN ADMINISTRATIVE LAW 1255-69 (1992).

[30] See Mirjan R. Damaŝka, THE FACES OF JUSTICE AND STATE AUTHORITY (1986); Máximo Langer, "From Legal Transplants to Legal Translations: The Globalization of Plea Bargaining and the Americanization Thesis in Criminal Procedure," 45 HARV. INT'L L. J. 1 (2004), for discussions of inquisitorial systems and a comparison to adversarial systems. The term "inquisitorial" carries unfortunate connotations, suggesting to some readers a connection with the Spanish inquisition. Of course, the inquisitorial approach utilized by civil law countries has nothing in common with the Spanish inquisition. It might be better to employ some term like "inquiry" or "investigational" rather than "inquisitorial." See Henry Friendly, "Some Kind of Hearing," 123 U. PENN. L. REV. 1267, 1290 (1975). Friendly wrote: "Whoever baptized the continental system as 'inquisitorial' did a disservice to American legal thought. Call it 'investigatory' and the pejorative connotation fades away." Nevertheless, this article sticks with the term "inquisitorial" since it is in common use.

case is not dismissed, a trial ultimately takes place, usually before a different judge. The trial is based primarily on the written materials contained in the dossier. There may be oral testimony by witnesses and by the accused, but the judge controls the proceedings. Broadly speaking, a criminal trial under most civil law systems is viewed as the end point of the investigation, not as an event that is separated from the investigation.

EU administrative procedure in the sectors we examined resembles the inquisitorial criminal law model. The specialized staff members of the relevant directorate of the Commission conduct an investigation of a proposed enforcement action or of an application for a benefit. The investigation concludes with a notice to the target or applicant setting forth the Commission's tentative findings.

At some point in the investigation, a hearing may take place, but the nature of that hearing is quite different from those that typically occur in the US or UK. The same case handlers who conducted the investigation also conduct the hearing. The hearing is viewed as an opportunity for the investigated party to state its side of the case or clarify the circumstances of the dispute. Parties do not engage in cross-examination or confrontation of adverse witnesses. In competition and trade regulation cases, however, the hearing is conducted by an independent officer who specializes in presiding at hearings and who has not been involved in the investigation. The hearing officer's job is to make sure the target's procedural rights are respected, not to make findings on the substantive issues in the case.[31] Whether the hearing is provided by case handlers or an independent hearing officer, the hearing does not result in a proposed decision.

[31] See text accompanying notes 10-11, *supra.*

An exception to the generally inquisitorial mode of decision-making occurs in trademark opposition cases; here the responsible agency (OHIM) functions as an impartial arbiter in a dispute between an applicant for a Community trademark and the holder of an existing mark that alleges the new mark would be infringing.[32] Most of the investigation in these cases is left to the parties and the Office resolves the dispute based on the submissions of the opposing parties.

C. Trends in favor of providing procedural protections

1. Overview

While the adjudicatory procedures of the EU remain inquisitorial in nature, an important evolutionary process has occurred over the last three decades. During that period, there has been a steady accretion of procedural protections for private litigants and member states engaged in adjudicatory disputes with EC regulators. These rights relate to investigations, access to Commission files, adequate notice, provision of a hearing (oral or written), decision within a reasonable time, and a statement of reasons. These rights are derived from several different sources: i) provisions in the Treaty, ii) regulations applicable to specific sectors, and iii) a body of European Court of Justice (ECJ) and Court of First Instance (CFI) case law that has catalyzed the process of procedural norm creation.[33] The case law seems similar to the case-by-case evolution of

[32] Trademark cases also include a form of separation of functions in that officials who participated in one phase of the trademark process (such as an opposition) cannot be the same officials who worked on the earlier application. Members of the Board of Appeals cannot have participated in any prior proceedings.

[33] See Craig, *supra* note 1, ch. 10-11; Joanne Scott & Susan Sturm, "Courts as Catalysts: Re-Thinking the Judicial Role in New Governance," 13 COLUM. J. EUR. L. 565 (2007); Jürgen Schwarze, "Enlargement, the European Constitution, and Administrative Law," 53 INT'L & COMP. L. Q. 969, 969-76 (2004); Koen Lenaerts & Jan Vanhamme, "Procedural Rights of Private Parties in the Community Administrative Process, "34 COMMON MARKET L. REV. 531 (1997).

the standards of US procedural due process[34] and of UK natural justice.[35] As a result, there has been a convergence between procedural norms governing adjudication in the EU on the one hand and the US and UK on the other.[36]

We believe that this process of convergence will likely stop short of adoption of the full panoply of rights presented in the adjudicatory system of the US. The expansion of the rights of defense of private parties in Community adjudication has both benefits and costs. The costs of providing oral hearings, for example, in complex cases such as competition and trade remedies can be quite substantial, since there may be many parties who wish to be heard and highly complex economic issues to be resolved. Further, the existence of multiple Community languages adds cost and complexity to many aspects of administrative proceedings. The Commission probably lacks the financial and human resources needed to apply detailed due process rights in all sectors of its operations.

2. **Early procedural protections and UK accession**

The "right of defense" for parties who are targets of administrative action has long been recognized in the law of Member states, particularly in France, and was recognized in Community law as well. However, in earlier years, the rights of defense were rather sketchy by the standards of US or UK law. For example, in competition cases, the target company's right of defense included notification of the Commission's objections, a summary of the contents of the Commission's file, an opportunity to make known its views and provide exculpatory evidence, and a right to a statement of reasons

[34] See ABA Guide, *supra* note 5, ch. 2.

[35] See Wade & Forsyth, *supra* note 25 at ch. 12-14.

sufficient for the parties and reviewing courts to understand whether a decision was lawful.[37]

These rights have evolved over time, largely through judicial consideration of competition cases. Some commentators believe this was a natural evolution.[38] Others argue that the judicial decisions are, in part, attributable to the UK's accession to the EU treaty in 1973.[39] British commentators criticized Community procedures in competition cases because they fell short of satisfying UK standards of "natural justice."[40] Natural justice is the British analogue to due process. It includes an unbiased decisionmaker as well as the right to notice, right to know the government's case, and an appropriate, usually oral, hearing. In order to respond to these objections, the EU expanded the target's rights. These changes were reflected first in critical reports by an EU Advocate General (who was British); by critical reports of a Select Committee of the House of Lords; and then in a series of ECJ decisions.[41]

3. **Development of the right of defense through competition cases: *Transocean* and *Hoffman-La Roche***

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[36] In the event that the Treaty of Lisbon is ratified, the process of convergence between the US and EU systems of adjudication may be accelerated because the Treaty incorporates the duty of good administrative embodied in the Charter of Fundamental Rights. See text at notes 2-3, *supra.*

[37] Bignami, *supra* note 29 at 259-65.

[38] *See generally* Nehl, *supra* note 3 at 10-13.

[39] Bignami , *supra* note 29 at 269-72.

[40] See generally Wade & Forsyth, *supra* note 25 at ch. 12-14.

[41] Bignami, supra note 29 at 272-79, observing that Community officials were concerned that UK national courts might not enforce decisions that failed to meet the standards of natural justice. Others attribute the evolutionary development of defense rights to the establishment in 1989 of the CFI which sees itself as an administrative court. Still others attribute the development to concerns within the EU that constitutional courts in Member states such as Germany might question the Community's decisionmaking procedures.

In the *Transocean* decision in 1974,[42] the ECJ considered the complaint of an association of marine paint manufacturers that had earlier received a five-year exemption of the Treaty for various anti-competitive practices embodied in its agreement. The Commission renewed the exemption but inserted a new condition requiring the members to report any common managers or directors between the members and non-member paint companies. The association objected to the fact that the Commission had imposed the condition without giving it notice and an opportunity to be heard.

The Court decided that the failure to give notice of the precise condition violated the requirements of notice and hearing in the competition regulations:

> It is clear, however, both from the nature and objective of the procedure for hearings. . . that this Regulation. . . applies the general rule that a person whose interests are perceptibly affected by a decision taken by a public authority must be given the opportunity to make his point of view known. This rule requires that an undertaking be clearly informed, in good time, of the essence of conditions to which the Commission intends to subject an exemption and it must have the opportunity to submit its observations to the Commission. . . .[43]

Thus *Transocean* construed the regulations implementing the competition law broadly to assure that a party subject to adverse action is entitled both to adequate notice and to an opportunity to make its objections known.

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[42] Transocean Marine Paint Assoc. v. Commission, Case 17/74, 1974 ECR 1063.

[43] *Id*. at 1079-80. The Advocate General in *Transocean* was English and had strongly argued that the principles of natural justice applied before European courts. For discussion of the evolution of the right to appropriate notice, see Craig, *supra* note 2 at 363-65.

Transocean might be viewed narrowly as involving only an interpretation of the competition regulations. Two years later, however, in *Hoffmann-La Roche*, the ECJ generalized the requirements of procedural fairness articulated in *Transocean* into broad principles of Community law, at least in cases involving a sanction.[44] In sweeping dictum, the Court declared:

> Observance of the right to be heard is in all proceedings in which sanctions, in particular fines or penalty payments, may be imposed, a fundamental principle of Community law which must be respected even if the proceedings in question are administrative proceedings. . . .The undertakings concerned must have been afforded the opportunity during the administrative procedure to make known their views on the truth and relevance of the facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of Article 86 of the Treaty.[45]

4. **Subsequent competition cases—the right to inspect the file**

Subsequent decisions by European courts vindicate the right of the parties in competition cases to inspect all non-confidential documents in the file.[46] Clearly, the right

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[44] Hoffmann-La Roche & Co. v. Commission, Case 85/76, 1979-1 ECR 461.

[45] *Id*. at 511-12. A recent application of the right of defense occurred in a merger case. The Commission breached the right of defense of one of the merger partners (which still existed as a separate entity) by failing to permit it to defend itself. The Commission allowed the merged entity to submit observations but was obliged to allow the constituent company to submit objections also. Thyssenkrupp Stainless GmbH v. Commission, Cases C-65/02P &C-73/02P, 2005 E.C.R. I-06773.

[46] For detailed discussion of cases involving access to Commission files, including the application of the access right in complex multi-party cases, see Craig, *supra* note 2 at 365-69; Lenaerts & Vanhamme, *supra* note 33 at 541-49. For discussion of the general right of access to all EU-agency documents (the EU equivalent of the US Freedom of Information Act) see *Administrative Law of the European Union, supra* note 4; Craig *supra* note 2 at 350-60. Section 41(1)(b) of the Charter of Fundamental Rights provides for a

to inspect the file is an essential aspect of the right of defense, particularly given the inquisitorial, document-based approach taken in EU cases. For example in *Hercules*,[47] the target complained that only selected documents in the Commission's file had been disclosed prior to the hearing. The CFI ruled that the Commission was bound by its own regulations to disclose all of the information in the file (other than business secrets or internal Commission documents or information disclosed to the Commission under a promise of confidentiality).[48]

Similarly, in the *Soda Ash* cases,[49] the CFI used the phrase "equality of arms" to describe the target's need for broad access to possibly exculpatory documents in the file.[50] "It is sufficient for it to be established that the non-disclosure of the documents in question might have influenced the course of the procedure and the content of the decision to the applicant's detriment . . . if the documents in question might . . . have had a significance which ought not to have been disregarded."[51] The Court added:

"right of access to individual file." If the Charter becomes enforceable by Community courts, the right of access will apply to all of the Commission's adjudicatory functions. [see text at notes 4-5, supra]

[47] S.A. Hercules Chemicals N.V. v. Commission, Case T-7/89, [1991] II-1711, 1739-40, ¶¶53-54. Cases with II before the page number are decisions of the Court of First Instance (CFI), whereas cases with I- before the page number are decisions of the European Court of Justice (ECJ). Similarly, cases with a T- number are CFI decisions; cases with a C- number are ECJ decisions.

[48] However, the failure to disclose the responses of other targets to the statement of objections was not prejudicial since disclosure could not have led to a different result. *Id*. at 1740, ¶56.

[49] Solvay SA v. Commission, Case T-30/91, 1995 II-1775.

[50] *Id*. at 1802, ¶59, quoting *Hoffmann-La Roche*.

[51] *Id*. at 1806 ¶68.

> It cannot be for the Commission alone to decide which documents are of use for the defense. Where, as in the present case, difficult and complex economic appraisals are to be made, the Commission must give the advisers of the undertaking concerned the opportunity to examine documents which may be relevant so that their probative value for the defense can be assessed. . . . Having regard to the general principle of equality of arms, which presupposes that in a competition case the knowledge which the undertaking concerned has of the file used in the proceeding is the same as that of the Commission, the Commission's view [that it can decide what documents are exculpatory] cannot be upheld in such a situation. The rights of defense which the applicant enjoys during the administrative procedure would be excessively restricted in relation to the powers of the Commission, which would then act as both the authority notifying the objections and the deciding authority, while having more detailed knowledge of the case-file than the defense.[52]

Of course, the right of access to the file must be balanced against the obligation to maintain the confidentiality of the business secrets of other undertakings, a right protected by the Treaty. This requires a delicate balancing of the right of defense against the right of confidentiality.[53]

5. **Expansion of the right of defense to other sectors**

[52] *Id*. at 1811-12, ¶¶81, 83.

[53] *Id*. ¶88, allowing access to documents with narrow deletions to preserve confidentiality. See Lenaerts & Vanhamme, *supra* note 33 at 541-49 for discussion of the process of balancing access to documents against confidentiality. See also Sison v. Council of the European Union, Cases T-110/03, T-150/03, T-405/03, [2005] 2 CMLR 29 (CFI) (individual whose assets were frozen as part of the fight against terrorism did not have right of access to his file nor to names of states that furnished information about him).

Subsequent decisions by European courts have expanded the rights of defense to regulatory sectors other than competition.

a. **Trade remedies.** In *NTN Toyo Bearing Co.*,[54] the Advocate General urged that the principles of disclosure of files developed in competition law should apply in the area of trade remedies as well, regardless of the absence of regulations that required it. In *Al-Jubail Fertilizer,*[55] the Court endorsed this view. It overturned an anti-dumping duty because of the Commission's failure to disclose critical information to a target exporter. The undisclosed material included information on European costs of production and prices of fertilizer, which had served as the basis for concluding that the domestic industry had been injured. The regulations required disclosure only of information relevant to the defense of the exporters' interests or that the Commission had used in the investigation. However, the Court declared:

> [F]undamental rights form an integral part of the general principles of law, whose observance is ensured by the Court. Consequently, it is necessary when interpreting . . . the regulation to take account in particular of the requirements stemming from the right to a fair hearing, a principle whose fundamental character has been stressed on numerous occasions in the case-law of this court. . . Those requirements must be observed not only [in penalty cases] but also in investigative proceedings prior to the adoption of anti-dumping regulations which,

[54] Case 113/77, NTN Toyo Bearing Co. v. Council, 1979 ECR 1185. See report of the Advocate General at 1261-65.

[55] Al-Jubail Fertilizer Co. v. Council, Case C-49/88, 1991 ECR I-3187.

despite their general scope, may directly and individually affect the undertakings concerned and entail adverse consequences for them.[56]

b. **State Aids.** The Treaty provides for a notice and comment procedure in the area of state aids that is open not only to member states but to beneficiaries of the aid and to competitors of the aided industry.[57] That provision has been supplemented by regulations that require the Commission to provide an opportunity for comments in doubtful cases.[58]

In the *Netherlands* case,[59] the statement of objections to a state-aid scheme was not sufficiently specific. In addition, the Netherlands was not given an opportunity to make known its position on the consultations the Commission had conducted with organizations of persons that competed with the aided company. As a result, the Member state's rights of defense were infringed.[60] Similarly, PTT, the direct beneficiary of the aid in question, was also entitled to be heard by the Commission since the contested decision related directly to it and the economic consequences directly affected it. PTT was entitled

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[56] *Id.* at I-3241. This decision reflected the views of the Advocate General that *Hoffmann-La Roche* applied to anti-dumping cases. Id. at I-3221-22.

[57] Art. 88(2): "If, after giving notice to the parties concerned to submit their comments, the Commission finds that aid granted by a State or through State resources is not compatible with the common market. . . " The ECJ held that this provision must be followed in all cases in which the Commission finds that a state-aid scheme presents difficulties of deciding whether it is compatible with the common market. As the result, the Court annulled a Commission decision that declined to challenge an aid scheme because a competitor of the aided industry was not invited to submit comments. Cook v. Commission, Case C-198/91, 1993 ECR I-2487, 2529-31.

[58] Reg. 659/1999, Art. 6(1).

[59] Kingdom of the Netherlands v. Commission, Joined Cases C-48/90 and C-66/90, 1992 ECR I-565, I-638-40.

[60] *Id*. ¶¶44-49

to receive a specific statement of objections and a right to be heard.[61] In addition, competitors of an aided entity have a right to a statement of reasons for the Commission's determination that no state aid exists.[62]

c. **Customs duties.** Although most decisions relating to customs duties are administered at the member state level, certain customs disputes are considered at the Commission level. In *Technische Universität München*,[63] the Court determined that the competent institutions have a duty to examine carefully and impartially the relevant aspects of the individual case, and the person concerned has a right to make its views known and to have an adequately reasoned decision. The Court determined that all three of those obligations were infringed.

The issue was whether an electron microscope similar to that which the University wanted to import from Japan was manufactured within the Community. If not, the instrument could be imported duty-free from Japan. A committee of experts that was not shown to be qualified made the decision. "The right to be heard in such an administrative procedure requires that the person concerned should be able, during the

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[61] *Id*. ¶¶50-53.

[62] Commission v. Chambre Syndicale Nationale des Enterprises de Transport de Fonds et Valeurs (Sytraval and Brink's France), Case C-367/95 P, 1998 ECR I-1719, ¶¶58-59, 64. In Union Francais de l'Express (UFEX) v. Commission, Case T-613/97, 2006 ECR II-1531 (June 7, 2006), CFI set aside a Commission decision in a state aid case because of an inadequate statement of reasons. The issue was whether assistance given by the French Post Office to SFMI was state aid and this turned on whether the price charged SFMI covered variable costs and was an adequate contribution to fixed costs. The Commission failed to explain how various approximations of variable cost were made. The court required the Commission to furnish a summary of its analytical accounting calculations. For discussion of the Commission's obligation to exercise due care in considering state aid complaints, see Craig, *supra* note 2 at 376-78.

[63] Hauptzollamt München-Mitte v. Technische Universität München, Case C-269/90, 1991 ECR 5495. See Jürgen Schwarze, "Judicial Review of European Administrative Procedure," 68 LAW & CONTEMP. PROB. 85, 94-96 (2004).

actual procedure before the Commission, to put his own case and properly make his views known on the relevant circumstances and, where necessary, on the documents taken into account by the Community institution."[64]

Certain cases in which importers seek remission or repayment of customs duties are also decided at the Commission level. The Court of First Instance held that "respect for the rights of the defence in all proceedings which are initiated against a person and are liable to culminate in a measure adversely affecting that person is a fundamental principle of Community law which must be guaranteed, even in the absence of any rules governing the procedure in question." As a result, the Commission had to provide an opportunity for a party seeking remission or repayment of customs duties to effectively make its views known and to provide full access to non-confidential material in the Commission's file (not merely to material that the Commission considered relevant).[65]

d. **Other regulatory functions.** The community courts have generalized the rights of defense that have evolved in specific sectors of regulation. They apply in any area of Commission regulation, regardless of whether procedural rights are provided for in regulations or even if the regulations purport to negative hearing rights.

[64] Id. at 5501. Scott & Sturm observe: "[T]he court is seeking to promote a process whereby Commission-appointed scientific experts enter into discussions with other parties in possession of information which may reasonably be thought to be indispensable in answering the question with which they have been presented." Scott & Sturm, *supra* note 33 at 584-85.

[65] Eyckeler & Malt v. Commission, Case T-42/96, 1998 ECR II-401. ¶¶ 77-80; Primex Produkte Import-Export GmbH & Co. v. Commission, Case T-50/96, 1998 ECR II-3773, ¶¶57-64. However, CFI did not accord the applicant an oral hearing in a remission/repayment case, in the absence of a showing of reasons that why written procedure was inadequate. Common Market Fertilizers v. Commission, Case T-134/03 and 135/03, 2005 E.C.R. II-3923 ¶¶ 105-09. In the *Suproco* case, discussed in text at notes 78-80, *supra,* CFI based its decision in a customs case entirely on the Commission's failure to state the reasons for its decision in sufficient detail for the court to review the decision and the parties to understand the reason why their petition was rejected.

For example, in *Lisrestal*,[66] a case involving a claim by the European Social Fund (ESF) for the repayment of a subsidy to a Portuguese training facility because of irregularities in the application process, ECJ said:

> Observance of the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. . . .That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they may effectively make known their views.

Lisrestal is notable because the responsibility for enforcement of the conditions of the grant was shared between ESF and a Portuguese agency, but the latter had followed the decision of ESF without providing any procedural protection to the recipient of the subsidy. Thus CFI could have placed responsibility for providing a hearing on the member state agency, but it chose not to do so.

Similarly, *Air Inter SA v. Commission*[67] involved the Commission's decision to open up particular air routes in France to new competition. The existing carrier that would be damaged by the new competition was entitled to claim the rights of defense. CFI noted: "It must be observed that the application of the fundamental principle of the rights of the defence cannot be excluded or restricted by any legislative provision.

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[66] Lisrestal v. Commission, Case C-32/95, 1996 ECR I-5373, ¶21, affirming a CFI decision, T-450/93, 1994 ECR II-1177. Fiskano v. Commission, Case C-135/92, 1994 ECR I-2885, ¶38, held that the right of defense applies where the Commission sent a letter to the government of Sweden imposing sanctions on the owner of a fishing boat accused of fishing without a license. The vessel owner has a right of defense, even though it was also penalized by Sweden.

[67] Case T-260/94, 1997 ECR II-997, ¶60.

Respect for that principle must therefore be ensured both where there is no specific legislation and also where legislation exists which does not itself take account of that principle."

5. **Development of specific procedural rights**

a. **Attorney-client privilege.** The Court recognized that a limited form of attorney-client privilege applies to investigations undertaken by the Commission.[68] The privilege applies to written communications between lawyer and client but with two important conditions: i) the communications are made for the purposes and in the interests of the client's rights of defense;[69] and ii) they emanate from independent lawyers registered with an EU bar (that is, lawyers who are not bound to the client by a relationship of employment).[70]

The CFI has also addressed the procedure that the Commission must employ to identify and segregate documents subject to claims of privilege. It held that the staff's quick review of such documents prior to their removal in a "dawn raid" was improper, and that company officials may refuse to allow even a cursory glance if they believe that there are appropriate grounds to assert privilege. The disputed documents must be kept in a sealed envelope and the Commission must issue a formal decision rejecting the company's claim of privilege, which decision may be appealed. The Commission may

[68] Australian Mining & Smelting Europe Ltd. v. Commission, Case 155/79, 1982 ECR 1575, 1611 ¶21-28.

[69] This means that privilege applies to "all written communications exchanged after the initiation of the administrative procedure" though it may be extended to "earlier written communications which have a relationship to the subject matter of that procedure." *AM&S* ¶23.

[70] Subsequently, the CFI confirmed earlier case law by holding that the privilege does not protect communications between a company and its in-house counsel. Akzo Nobel Chemicals Ltd. and Akcros Chemicals Ltd. v. Commission, Joined Cases T-125/03, T-253/03 (17 September 2007). *See generally* Eric Gippini-Fournier, "Legal Professional Privilege in Competition Proceedings before the European Commission: Beyond the Cursory Glance," 28 FORD. INT'L L. J. 1967 (2005).

not open the sealed envelope until the CRI has ruled or the time for making such appeal has expired.[71]

b. **Confidentiality.** Article 287 of the Treaty provides that Community personnel "shall be required . . . not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components." The community courts have implemented this provision and often engaged in a delicate balance between the rights of the target to examine documents in the file and the confidentiality rights of those who have submitted information to the Commission.[72]

In the *Adams* case,[73] the ECJ held that this obligation runs to individuals as well as to undertakings. The confidentiality obligations apply to information supplied voluntarily by an informant to the Commission. The information consisted of redacted documents from which a target company was able to deduce the identity of the informant. The Court held that the Commission breached its duty by failing to warn the informant that he was in serious danger of prosecution by the Swiss authorities for business espionage if he returned from Italy to Switzerland.

c. **Decision within a reasonable time.** Both the investigatory phase and the administrative decision phase must be completed within a reasonable time.[74] The

[71] *Akzo Nobel*, *supra* note 70 at ¶¶ 82-90.

[72] See Lenaerts & Vanhamme, *supra* note 33 at 541-49.

[73] Adams v. Commission, Case 145/83, 1985 ECR 3539, 3585-91. See Schwarze, *supra* note 63 at 96.

[74] See Lenaerts & Vanhamme, *supra* note 33 at 567; Kańska, *supra* note 2 at 313-15. Article 41 of the Charter of Fundamental Rights provides for a right of good administration, including the right of every person to have his or her affairs handled impartially, fairly and within a reasonable time. In the event that Article 41 becomes enforceable as a constitutional principle, the right to timely decision may become considerably stricter than it is at present. See text at notes 2-3, *supra.*

reasonableness of a particular delay is appraised in light of the circumstances specific to each case. In particular, the court should weigh the importance of the case for the person concerned, its complexity, and the conduct of the applicant and of the competent authorities.[75]

d. **Statement of reasons.** Art. 253 of the Treaty established the right to a statement of reasons,[76] a right frequently enforced by the Community courts[77] as well as in the legal systems of member states. The rationales for this obligation are that the requirement to state reasons forces agencies to consider their decisions more carefully, enables parties subject to the decisions to understand them and to decide whether to seek judicial review, and enables the court to determine the rationality of the decision. Requiring a decisionmaker to give reasons also facilitates various forms of legislative and executive oversight of administrative decisionmaking.

In *Suproco,*[78] the CFI's decision annulling the Commission's decision was based entirely on the Commission's failure to state its reasons in sufficient detail for the court to

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[75] Limburgse Vinyl Maatschappij NV v. Commission, Joined Cases C-238-99, 2002 ECR I-8375, 8685 ¶193-94. In this case, the court held that an investigation lasting four years and 10 months was not excessive, given the complexity of the case, the amount of documents that had to be considered, and the large number of parties. In addition, the ten-month period of adjudication could not be considered excessive.

[76] "Regulations, directives and decisions adopted jointly by the European Parliament and the Council, and such acts adopted by the Council or the Commission, shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty." *See* Lenaerts & Vanhamme, *supra* note 33 at 562-66.

[77] *See* Craig, *supra* note 2 at 378-81; Koen Lenaerts, Dirk Arts, & Ignace Maselis, PROCEDURAL LAW OF THE EUROPEAN UNION 301-08 (2d ed. 2006); Jerry L. Mashaw, "Reasoned Administration: The European Union, the United States, and the Project of Democratic Governance," 76 GEO. WASH. L. REV. 99 (2007) (arguing that reasoned administration is a fundamental human right).

[78] Suproco NV v. Commission, Case T-101/03, 2005 ECR II-3839 ¶20. Similarly, see Ireland v. Commission, Joined Cases T-50/06, T60/06, T62/06 and T 69/06 (2007) (CFI raised issue on its own motion that Commission had stated a conclusion but not the reasoning for a key portion of its decision).

review the decision and for the parties to understand the basis for the Commission's rejection of their petition for customs relief. The decision in question (which related to whether imported sugar products from Curaçao qualified for tariff relief and which involved highly technical regulations) indicated the Commission's conclusion but not its reasoning. The *Suproco* court said:

> According to settled case-law, the statement of reasons required by Article 253 EC must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Community Court to exercise its power of review.

The Commission is not required to furnish all the details of the factual and legal aspects of every decision. In *Suproco,* the court noted:

> The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations."[79] Thus the reasons for a decision that follows a well-established line of authority may be given in summary fashion by reference to the

[79] *Id.* See also Windpark Groothusen GmbH & Co. Betriebs KG v. Commission, Case C-48/96 P, [1998] ECR I-2873, 2909 ¶34-35; Société Française des Biscuits Delacre v. Commission, Case C-350/88, 1990 ECR 395, 422 ¶15.

prior decisions, but the Commission must give an explicit account of its reasoning if the decision goes appreciably further than the previous decisions.[80]

6. **Procedural protections in application cases**

The law relating to the procedural rights of persons who have applied for benefits is less well developed than the law relating to parties who are subject to some kind of sanction or other loss of status. *Technische Universität München*[81] involved an application to import a scientific instrument into the Community without payment of duty. The ECJ held that the applicant had procedural rights, including a right to make its objections known to the Committee which made the decision. In the trademark area, rejected applicants are entitled under the regulations to a right to file observations (and in unusual cases to an oral hearing) even when no opposition has been filed.[82] In the area of pharmaceutical licensing, there is a right to submit written observations and to an oral hearing before Committee for Medical Products for Human Use (CHMP) which is processing an application. There is also a right to have the CHMP opinion reviewed by the Commission.

In *Windpark,*[83] the applicant applied for financial aid to construct a wind park under a program whereby various recipients of energy projects could receive aid. There were about 700 proposals. The applicant was not selected to receive support but was

[80] Delacre, ¶17-19. *Delacre* held that the Commission was not required to explain the details for setting a subsidy level for butter. The subsidy is adjusted every two weeks and the industry is familiar with the process for setting the price.

[81] See text at notes 63-64, *supra.*

[82] Reg. 40/94.

[83] Windpark Groothusen GmbH & Co. Betriebs KG v. Commission, Case C-48/96 P [1998] ECR I-2873 (affirming Case T-109/94, 1995 ECR II-3007 (CFI))

placed on the reserve list. Later, in response to a letter, the Commission stated that available funds had been exhausted. In this situation, there was no right to a detailed statement of reasons for the decision rejecting the application for financial support, including comparative information on the competing projects that were selected. The reason for the making an exception to the normal requirement of stating reasons is that the rejected applicant's legal position remained unchanged. Its sole entitlement was to an objective examination of the application.[84]

In *Windpark,* the Court also decided that the rejected applicant was not entitled to a hearing, because that right arises only where the Commission contemplates the imposition of a penalty or adoption of a measure likely to have an adverse effect on that person's legal position. In addition, the fact that there were hundreds of applicants militates against giving any of them a hearing. However, this decision did not resolve the issue of whether there is a right to hearing in connection with the rejection of an application for a specific license or permission, such as to market a food or drug, or rejection of a trademark application (as opposed to an application for funding where only some of the applicants can be funded).

II. SUMMARY OF ADMINISTRATIVE PROCEDURE IN THE SIX SECTORS

This section contains brief summaries of the adjudicatory practice in the six sectors of EU administration that we studied. [85]

[84] *Id*. I-2909-10, ¶¶ 34-39.

[85] Practitioners who need a more detailed account of these procedures should consult *Administrative Law of the European Union, supra* note 4. The full accounts of EU procedure contributed by our sectoral reporters are available on the internet. http://www.abanet.org/adminlaw/eu/home.html#Sector. The six sectors

A. *Competition*.[86]

Article 81(1) of the Treaty prohibits various anti-competitive practices that are incompatible with the common market. Broadly speaking, this provision parallels section 1 of the US Sherman Act. Article 81(3) provides that the prohibition of Article 81(1) may be declared inapplicable to certain restrictive practices that are found to be economically beneficial and justified.

Under regulation 1/2003, which went into effect in 2004, the Commission no longer has a monopoly on granting such exemptions; they may now be granted by member states. Courts of the member states can adjudicate cases arising out of both public and private enforcement of the competition law articles of the Treaty. The prior practice of requiring parties to notify the Commission of anti-competitive practices has been abolished (although it still exists in some member states). Article 82 of the Treaty prohibits abuse of a dominant position and thus roughly parallels the monopolization provision of Section 2 of the US Sherman Act. Finally, the Commission regulates mergers that have a Community dimension.

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described herein do not exhaust all the areas of adjudication and dispute settlement that involve the Commission. For example, cases involving customs duties are sometimes adjudicated at the Commission level. See Part I.C. In addition, the "clearance of accounts" process concerns disputes between member states and the Commission about agricultural subsidies. Each year, the Commission seeks to recover improper payments and member states frequently dispute its conclusions. Prior to seeking relief in the Community courts, member states and the Commission resort to a conciliation procedure. The Conciliation Body hears the dispute and seeks to "reconcile the divergent positions of the Commission and the Member state." At the conclusion of the process, the mediation body draws up a non-binding report on the outcome of its efforts, including making remarks on the unresolved points of dispute. See Reg. 442/94, Art. 1.

[86] For a thorough discussion of the administrative process in competition cases, see Christopher S. Kerse & Nicholas Khan, EC ANTITRUST PROCEDURE 1-444 (5th ed. 2005); Ivo Van Bael & Jean-Francois, Bellis, *supra* note 10 at 857-76 (mergers), 1021-1166 (antitrust) (4th ed. 2005); Luis Ortiz Blanco, EC COMPETITION PROCEDURE (2nd ed. 2006). For a brief summary see Craig, *supra note* 2, at 387-91.

DG COMP may initiate an investigation of a possible violation of Articles 81 and 82 in response to a complaint. It may also initiate investigations following referral by a member state or on its own initiative. A team headed by a DG COMP case manager and consisting of several case handlers conducts the investigation. The investigation usually includes an on-the-spot inspection. The investigators may seek additional information informally or through a formal decision requiring information to be furnished. In some cases, non-business premises can be searched.

If DG COMP decides to proceed further (with the approval of the Legal Service and the Competition Commissioner and, in some cases, of an advisory committee of competition authorities from Member states), it issues a "statement of objections" (SO) consisting of a factual description of the conduct involved and a legal assessment. If a compromise is reached, the Commission issues a "preliminary assessment" which contains commitments by the companies involved.

In merger cases, the process is initiated by prior notification to the Commission of a proposed merger. Generally, pre-notification contacts occur between the applicants and Commission staff. The Commission conducts a Phase I investigation of the proposed merger and may grant clearance at that stage. If it concludes that the proposed concentration raises serious doubts as to its compatibility with the Common Market, it initiates a Phase II investigation and issues an SO. "State of play" meetings occur during Phase II to facilitate exchange of information.

The SO (in both antitrust and merger cases) informs the target companies of the charges against them (or the Commission's doubts about a proposed merger) and sets a

time limit within which they may inform the Commission of their views. The parties may file written objections and attach relevant documents or can request a hearing. The Commission must provide full access to all documents in its file to the target companies, other than business secrets or other confidential information or internal Commission documents. Complainants (as opposed to targets) have access only to the non-confidential version of these documents.

While the right to be heard is primarily exercised through filing written materials, the Commission must provide an oral hearing upon request in antitrust and merger cases. At the hearing, the targets (or the parties in a merger case) have the right to make their views known about the facts and circumstances alleged against them and to support their claim that they have not infringed the Treaty. The hearing follows a detailed order of presentation and may include both the testimony of live witnesses and experts. There is no right of cross-examination or confrontation, but the Commission officials may question any witness who appears. If the SO is significantly amended, an additional hearing must be provided. Complainants may also be heard but this is discretionary with the Commission. As pointed out earlier, the hearing officer is an independent official rather than the case-handlers. The official prepares a report on the procedural aspects of the case.[87]

The case handlers then draft the preliminary decision. The preliminary decision is reviewed by the Commission's Legal Service and presented for consultation to the

[87] See text at notes 10-11, *supra.*

Advisory Committee (consisting of Member state representatives).[88] The final decision is made by the College of Commissioners. The hearing officer does not make a substantive (as opposed to a procedural) decision. However, the hearing officer may comment on the preliminary decision. Such comments are not made available to the parties.

The final decision must contain a sufficient statement of reasons, so that a reviewing court may exercise its supervisory function and the parties can ascertain whether the decision is well founded. The statement of reasons must include both the factual and legal grounds on which the decision is based, including comment on the evidence. It must be more fully reasoned if it sets forth a new legal interpretation.

B. *Trade Remedies*

Under the law of trade remedies, the Commission can protect EU industry from dumping[89] and from governmental subsidies that give foreign competitors an unfair advantage.[90] In dumping and subsidy cases, the conduct that has been complained of must cause material injury. Anti-dumping and anti-subsidy cases can result in the imposition of additional duties on foreign goods. In addition, the EU can take "safeguard" measures that protect Community industry with temporary relief against

[88] We understand that the Legal Service provides an important checking role in the process of Commission consideration of preliminary decisions. When the full Commission makes the decision, it can override a negative opinion of the Legal Service. However, in many situations, the Commissioners decide a case by written procedure without discussion or the decision is delegated to a single member of the Commission. In the latter two situations, the act can be adopted only if it is in accord with the opinion of the Legal Service.

[89] A product is considered to be dumped if its export price to the Community is less than a comparable price for the like product established for the exporting country.

[90] The basic anti-dumping regulation is Council Reg. 384/96 (Dec. 22, 1995), as last amended by Council Reg. 2117/2005 (Dec. 21, 2005). The basic anti-subsidy regulation is Council Reg. 2026/97 (Oct. 6, 1997), as last amended by Council Reg. 461/2004 (Mar. 8, 2004).

foreign competition that causes serious injury. Safeguard cases, which are quite rare, usually result in quantitative restrictions on imports from all countries.[91]

Anti-dumping and subsidy cases usually begin with a written complaint on behalf of Community industry. Before lodging such a complaint, companies tend to engage in informal exchanges with DG TRADE in order to address specific legal issues about which the potential complainant has doubts.

During a 45-day period, the Commission evaluates the complaint and the representativeness of the complainants. Thereafter, it publishes a relatively brief notice of initiation of investigation and invites interested parties to come forward (within ten days) and submit information and request a hearing (within forty days). The Commission advises particular importers and exporters (and relevant associations) that it knows to be concerned of the initiation of the investigation. If the Commission rejects the complaint, there is no public announcement of the decision.

Separate teams of case-handlers evaluate the existence of dumping or subsidization and of material injury. A Head of Section supervises each team of case handlers. The overall timing of the investigation is short and inflexible: nine months for provisional remedies, fifteen months for dumping and thirteen months for subsidy. An advisory committee, consisting of member state representatives, is consulted at each critical stage. Consultation with other DGs is also routine.

[91] The basic safeguard rules for WTO members are contained in Council Reg. 3285/94 (Dec. 22 1994), as last amended by Council Reg. 2474/2000 (Nov. 11 2000); for non-WTO members, Council Reg. 519/94 (Mar. 7, 1994), as last amended by Council Reg. 427/2003 (Mar.3, 2003).

The investigation consists of sending detailed questionnaires to the Community industry, foreign exporters and governments. On-site verification visits generally follow. Furnishing information is voluntary, but companies generally provide it because the Commission can proceed on the basis of the "facts available" in the case of "non-cooperation." Non-confidential versions of all written submissions to the Commission are available to other parties. Oral statements made to case-handlers during on-site verifications can be quite significant; if such statements are "relied on," a non-confidential summary must be provided to other parties.

Complainants, importers, exporters, and their representative associations, as well as users and consumer organizations, have a right to inspect all information made available by any party to an investigation. The general public has no inspection rights. All written submissions and questionnaire replies must be accompanied by a non-confidential version. The non-confidential version is placed in the file for inspection. There is no disclosure of confidential information or of the Commission's internal memoranda and mission reports. Lawyers generally stay in contact with the Commission officials to find out if a file has been updated.

The Commission summarizes its conclusions in a "provisional disclosure letter" that is provided to the parties at the same time as a regulation imposing provisional measures is adopted. Other interested persons can request a copy. The provisional disclosure letter discloses the facts and considerations on the basis of which provisional measures were imposed. The provisional disclosure letter also contains a section addressed only to individual companies that analyzes confidential information. A final

disclosure letter precedes definitive duties and the parties have at least ten days in which to comment.

Dumping and subsidy investigations can be "settled" after the issuance of the provisional determination if the Commission accepts the undertaking of the affected company or government. An undertaking in a dumping case is usually be a promise from the exporter to charge at least a certain amount for the product in the future. In a subsidy case, the government might promise to cease subsidization or particular companies might agree to discontinue exports or charge at least a certain price. After undertakings have been accepted, the EU usually proceeds to adopt a definitive regulation and impose a definitive duty, which would apply to companies that did not conclude an undertaking or that may apply if the undertaking is breached.

Prior to adoption of the provisional regulation, an oral hearing is provided to a target company as a matter of right. Beginning in August, 2007, independent hearing officers conduct such hearings.[92] The main tasks of the hearing officer in trade remedy cases are to guarantee the proper exercise of rights of defense in trade proceedings before the Commission, as well as advising DG TRADE on issues relating to due process and good administration and presenting observations on any matter arising out of trade proceedings. The hearing officer is an experienced official of DG TRADE who works independently from the Commission investigative services and reports directly to the Director General.

[92] See Natalie McNelis, "A Hearing Officer for Trade," 3 Global Trade & Customs J. 77 (2008); http://ec.europa.eu/trade/issues/respectrules/ho/index_en.htm.

Oral hearings furnish an opportunity for companies to make their views known on the circumstances alleged against them and on the evidence relied on by the Commission. In addition, other interested parties generally are entitled to a hearing on request. After a hearing, a party will often submit a written copy of its presentation in both confidential and non-confidential versions. The officials handling the case may, in their discretion, provide an additional hearing after adoption of the provisional regulation.

Essentially, the interested party determines what happens at the hearing. The officials are there to listen but usually will not enter into a dialogue. The case handlers and their immediate superiors attend the hearing and sometimes ask questions of the company representatives. The hearing is considered part of the information-gathering process and thus is inquisitorial rather than adversarial in nature. Historically, the hearings have been informal and unstructured; their function was to provide an opportunity to bring specific facts, circumstances, or arguments to the attention of the case-handlers. With the introduction of independent hearing officers, however, the hearings may become more structured.

Parties can bring witnesses, but the witnesses are subject to being questioned by the officials and a refusal to answer questions might be viewed negatively. No transcript is made; instead, the officials take notes. A party may provide a written copy of its presentation in confidential and non-confidential form. The regulations contain a provision for a confrontational hearing but these are exceedingly rare.

The hearing is not followed by issuance of a proposed decision. The first decision is the Commission's provisional regulation, which is adopted not later than nine months

after initiation of the procedure. Later the Council imposes the definitive anti-dumping or countervailing duty. The decisions must state reasons and make findings on all relevant issues, including the question of whether imposition of duties is against the Community's interest. The decisions must disclose the details underlying the essential facts and considerations on the basis of which duties were imposed. Provisional and final decisions are published. The final decisions are in the form of regulations of general application but these regulations contain individualized as well as generalized measures.

Provisional dumping and subsidy measures are imposed by a Commission regulation which must be approved by simple majority of the College of Commissioners. Only the Council imposes definitive measures. Safeguard measures can be taken by a vote of the Commissioners, but if a Member state objects, it can refer the matter to the Council for approval by qualified majority.

After the expiration of a one-year period following the imposition of definitive measures, interested parties may apply for an interim review which considers the need for continued imposition of measures or whether the measures ought to be changed. There is also provision for a newcomer review on behalf of a company that was not exporting the product during the investigation period. Definitive anti-dumping and anti-subsidy measures expire after 5 years unless it is determined in an expiry review that they should be continued. The procedures that apply to investigations also apply to these various forms of post-adoption review. There is also provision for reviews on the part of Community industry in the event that the exporters have "absorbed" the additional duties or "circumvented" the measures previously imposed.

C. *Trademarks*

A Community trademark (CTM) provides Community-wide protection for distinctive signs used to distinguish a product or service from those of competitors.[93] A CTM must be registered with the Office for the Harmonization in the Internal Market (OHIM) in Alicante, Spain. The OHIM is an agency outside the European Commission that is responsible for enforcing Community trademark law. Private parties can challenge a CTM by means of an "opposition" that complains of a likelihood of confusion. Prior trademark owners can also file an application for "invalidity" or for "revocation" (in the event of nonuse or that the mark has become generic). Member states also register trademarks which provide protection in that state only. Litigation about the validity of trademarks can be conducted both before Community courts and courts in member states.

An application for a CTM is filed with OHIM either in writing or on line. Non-European applicants must be represented by European lawyers. The application must contain a list of the goods or services in respect of which registration is requested using the classification system in the Nice Agreement. A CTM application must be filed in any of the official languages of the Community and a second language must also be specified. After filing, OHIM considers whether the application meets all requirements and whether any grounds for refusal are present. Applicants can meet informally with the examiner to discuss a CTM application. OHIM then conducts a Community search to discover earlier identical marks that may be invoked as grounds for refusal to register the mark in an opposition proceeding. After the search report is communicated to the applicant, the

[93] The basic regulation concerning trademarks is Reg. 40/94.

general public is informed of the application through publication in the Community Trademarks Bulletin.

OHIM has no investigatory powers other than those already mentioned. Further investigation is left to private parties who may choose to file a notice of opposition within three months after the application has been published. Opponents may also file an application to hold a CTM invalid or file a counterclaim in member-state infringement proceedings. A two-month cooling-off period applies after an opposition petition is filed. Thereafter the opponent files arguments and documents within the time periods set by OHIM and the applicant files responding documents. The files arising out of an application or an opposition are open to inspection (other than material that is confidential or an internal OHIM document). Settlements of trademark disputes are possible during the cooling off period or after proceedings have begun. Examiners sometimes suggest settlements.

Proceedings before OHIM are mainly written. Oral hearings are uncommon (other than the informal meetings held during the application process as mentioned above). An oral hearings may occur if OHIM feels one is necessary or if a party requests a hearing and OHIM deems it expedient. If a hearing is held, the hearing officers are the same officials who are working on the underlying application or opposition proceeding. The hearing is an informal conference; it provides an opportunity for a party to convey its arguments or highlight the evidence it has submitted to OHIM. The OHIM officials can ask questions of the parties or witnesses. An agenda will set forth the points to be discussed.

If OHIM decides that an oral hearing is needed, it selects the witnesses and frames the issues. OHIM will issue a summons for the attendance of the witnesses. If a party requested the hearing, it selects the witnesses and frames the issues and OHIM will issue a summons to those witnesses. The officials working on a trademark case or an appeal may not have any personal interest in the matter and may be disqualified for partiality. Ex parte contacts are not allowed.

Trademark proceedings entail a form of separation of functions: officials working on an opposition cannot also have worked on the application; members of the cancellation division cannot have participated in application or opposition proceedings; and members of the Boards of Appeal cannot have participated in any prior proceedings. The primary record is contained in minutes that must be approved by the witnesses (though a recording of the hearing is also made). There is no specific time limit on making a trademark decision; it depends on the complexity of the case and the workload of the responsible officials.

Parties may appeal OHIM decisions to a Board of Appeals within two months after notification of the decision complained of. The Board will invite the parties to file observations and is empowered to take any action OHIM could have taken originally or it can remit the matter to OHIM. Board of Appeal decisions can be further appealed to CFI and ECJ. After an appeal is filed, the OHIM division that took the original decision can "revise" it.

The OHIM or Board of Appeals decision must provide the legal interpretations and reasoning on which the decision is based. The statement of reasons must be detailed

and respond to all arguments submitted by the parties (though if one or more of these arguments are sufficient to justify the decision, the opinion need not consider all other arguments). Decisions are published in the Community Trademarks Bulletin. A CTM is recorded in the Register of Community trademarks.

D. *Food safety*

Food safety decisionmaking is triggered by an individual application for approval of a new food product.[94] The outcome is the promulgation of a regulation that allows any manufacturer that meets the standards to import the food item into the Community and market it.[95] The exceptions are novel foods and genetically modified foods,[96] which result in an individualized decision covering only the particular applicant. Regardless of whether the process results in a rule or an individualized decision, the process used seems more appropriate to rulemaking than adjudication.

Depending on the particular type of product, an application to introduce food products is filed with a member state (in the case of novel foods) or with the European Food Safety Agency (EFSA) (in case of other food products). This application triggers an extensive scientific assessment process by EFSA.[97] In the case of novel foods, member

[94] See generally Reg. 178/2002.

[95] It is unclear whether decisions of individual impact that are stated in regulations are judicially reviewable by the undertaking affected. See Boehringer Ingelheim Vetmedica GmbH v. Council, Case T-125/96, [1999] II-3427, ¶¶ 161-73 (indicating that the applicant for permission to market a veterinary medical product that is prohibited in a regulation has standing to challenge that regulation).

[96] See Reg. 258/97 (novel foods) and Reg. 1829/2003 (genetically modified food).

[97] See Alberto Alemanno, "The Evolution of European Food Regulation: Why the European Food Safety Authority is not a EU-Style FDA," in WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY (C. Ansell & D. Vogel eds.) 2006; Alberto Alemanno, "The European Food Safety Authority At Five," 1 EUR. FOOD & FEED L. REV. 2 (2008).

state officials conduct an initial assessment which is forwarded to member states for comment; further investigation is carried out by EFSA. The assessment process can take between one and five years.

There is no opportunity for an adjudicatory hearing or other procedural protections in cases involving applications to introduce foods into the Community, even if the ultimate decision will be individualized or have an individualized impact.[98] A recent ECJ judgment (which involved procedures whereby a food supplement could be approved for sale in the EU) contains dictum that might, in the future, be the basis for a judicial decision (or for procedural regulations) that provide such protections. [99] The Court suggested that EFSA procedures must meet the requirements of good administration. In particular, there must be provision for an applicant to make its views known and for a reasoned decision within a reasonable time.

The procedure used to approve an application to introduce a new food product begins with adoption of general legislation. For example, the responsible Commission service (DG SANCO) might initiate a legislative text dealing with a broad subject such as "obesity." After ad hoc consultations, consultations with advisory groups from Member states, and inter-service consultations, the draft text is submitted to the College of Commissioners for approval.

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[98] Some recently adopted regulations provide for an undefined appellate process to the Commission from any act or omission by EFSA. However, this process as yet unused and its impact cannot be assessed. There are serious uncertainties surrounding the procedure. See Food Contact Material Regulations 1935/2004, Art. 14.

[99] The Queen on the Application of Alliance for Natural Health v. Secretary of State for Health, Joined cases C-154/04 and C-155/04 ¶¶72, 73, 82 (July 12, 2005).

The second stage is the adoption of rules that include the approval of new food products. Once the products are approved, other manufacturers can then introduce identical products without securing approval. The Commission submits its decision to approve the product to SCFCAH (Standing Committee on Food Chain and Animal Health), which consists of food safety officials from member states. The process of approval is politicized and ex parte contacts and political pressures are common. Generally the Commission submits draft proposals to SCFCAH to see whether there will be problems and it attempts to work out the problems in advance. If a proposal receives a qualified majority in SCFCAH, it must be adopted by the Commission; if it fails to achieve a qualified majority, the decision is made by the Council. There are relatively limited opportunities for input by the applicant or by other interested parties.

E. *State Aids*

Under Articles 87 to 89 of the EC Treaty, member states may not grant subsidies or other advantage to entities unless first authorized to do so by the Commission.[100] Such subsidies have the potential to distort competition in the internal market and thus should be viewed as complementary to the regulation of private competition and monopoly.

States must notify the Commission of schemes of new aid. If a state has granted aid without prior authorization, it must recover the aid from the beneficiaries. The Commission may authorize various forms of aid if compatible with the common market

[100] "Save as otherwise provided in this Treaty, any aid granted by a Member state or through State resources in any form whatsoever which distorts or threatens to distort competition by favoring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member states, be incompatible with the common market." Treaty Art. 87(1). The details of state-aid regulation are set forth in Reg. 659/1999. For a brief treatment of procedural rights in state aids cases, see Craig, *supra* note 2 at 392-93.

(such as aid to make good the damage caused by natural disasters or aid to promote economic development of underdeveloped areas).

State aid proceedings are between the Commission and the member state that grants the aid. Neither beneficiaries of the aid nor competitors of the beneficiary are parties to the proceedings. The Commission initiates a Phase I investigation when it receives a notification or receives information from a complainant that state aid will be or has been granted. Phase I lasts a maximum of two months following receipt of a complete notification. If the measure raises doubts about whether the aid is compatible with the common market, the Commission initiates a Phase II investigation. It notifies the concerned Member state of the decision to go to Phase II and publishes it in the Official Journal. The decision must summarize the relevant issues of fact and law and contain a preliminary assessment of the measures and set out the Commission's doubts about compatibility with the common market.

Phase II investigations generally take at least a year and often more than 18 months. The Commission's investigation targets member states, not private enterprises. If the State does not reply to a request for information, its notification is deemed withdrawn. In practice, the member state usually consents to the Commission's questioning the beneficiary of the aid, though the member state controls the process. The one area in which the Commission takes investigative action directly against private parties involves compliance monitoring. The Commission does not give member states access to its file, but it does inform the states of relevant information in its file. Private parties have no access to the file though the Commission usually discusses issues with the beneficiary of the aid.

During Phase II, the member state concerned and any other interested parties can submit comments. The member state can respond to any third-party comments. There is no oral hearing, but there are informal meetings between Commission staff, member state representatives, and other interested parties.[101]

The proceeding closes with a Commission decision stating one of three possible outcomes: the measure does not constitute state aid, the measure is authorized, or the measure is not authorized. A final decision is taken by a majority of the Commissioners. The decision states the reasons for the Commission's conclusions. The Commission need not enter into a dialogue by addressing every issue of fact or law raised by any party, but it is required to consider all submissions. Decisions closing a Phase II investigation are published in full in the Official Journal. The Council may, by unanimous vote, authorize a state aid in exceptional circumstances.

F. *Pharmaceutical licensing*

A manufacturer wishing to introduce a pharmaceutical product into the EU market must obtain a marketing authorization to do so.[102] Licensing of new medicines requires a delicate balance between the benefits of the medicine and its risks. The regulatory scheme extends not only to the decision about whether a new medicine may be introduced but also considers such specifics as the composition, therapeutic indications, prescription status, persons involved in the manufacturing process, method of packaging

[101] *See* Reg. 659/1999, Arts. 6(1), 20(1).

[102] This study focuses on the licensing system of pharmaceuticals for human use. Similar procedures exist for veterinary medicines. The current procedural rules relating to pharmaceutical licensing are Directive 2004/27/EC and Reg. No. 726/2004.

and package sizes, the wording of the package leaflet, labeling on the containers, and prescribing information for physicians.

The pharmaceutical licensing systems distinguish between centrally and decentrally approved products. The centralized procedure is administered at the Commission level and applies to biotechnology medicines and other innovative products, sometimes on an optional basis. The decentralized procedure is administered at the member state level and applies to other medicinal products.

In the centralized procedure, the Commission makes decisions with the assistance of the European Medicines Agency (EMEA) and the Committee for Medical Products for Human Use (CHMP) which is a division of the EMEA. The CHMP brings together scientific and regulatory expertise from the member states and provides scientific assessment of medicines for human use. The Commission can vary, suspend or withdraw a marketing authorization if new scientific evidence alters the risk-benefit assessment. The Commission can also impose a range of financial sanctions in cases of infringement of the obligations contained in marketing authorizations.[103] In general, proceedings in pharmaceutical cases are inquisitorial in nature rather than adversarial. A separate Standing Committee on Medicinal Products for Human Use (Standing Committee) represents member states and is consulted by the Commission as part of the comitology process.

In the decentralized procedure (and the similar mutual recognition procedure), the decision on marketing authorization is prepared by the "reference member state" (in

[103] See Reg. No. 658/2007.

which the application was filed). As a rule, the other concerned member states follow the decision. A Coordination Group mediates disagreements between member states under the decentralized procedure. In the event of further disagreement, the CHMP renders an arbitral opinion, which is the basis of a Commission decision that is binding on the involved member states.

Applications for approval contain a great deal of data, particularly concerning clinical trials of the medicine. Applications under the centralized procedure are filed with EMEA in London. EMEA requests a six-month pre-filing announcement and applicants generally engage in a pre-submission meeting with EMEA to obtain procedural and regulatory advice. A project manager is appointed during the pre-filing period.

In general, the process within the CHMP should be completed within 210 days after an application is validated, but there are various clock-stops that extend the process.[104] After validation, the CHMP appoints a rapporteur and a co-rapporteur to evaluate safety, efficacy, and quality and provide a preliminary assessment to the CHMP. Scientific advisory committees are often employed during this process. The CHMP ordinarily sends a list of questions and a positive or negative recommendation to the applicant who has up to six months to answer the questions and provide additional information.

Based on the applicant's response, the rapporteurs provide their joint assessment to the CHMP. A copy is provided to the applicant. The CHMP may request further oral responses. If CHMP's report is negative (in part or in total), the applicant may request

[104] For a summary of the various time periods involved in an application , see http://www.emea.europa.eu/pdfs/human/regaffair/7540106en.pdf

reassessment. The CHMP then drafts a final opinion which is provided to the applicant and the Commission.

Applicants for marketing authorization and targets of regulatory review action have an opportunity to furnish written or oral explanations to the CHMP. These hearings are part of the investigation process and are conducted together with scientific evaluation of a medicine or the investigation of alleged infringements of marketing authorization obligations.[105] The applicant can bring in experts or other witnesses to further explain its position. Third parties (such as scientists who oppose licensing a medicine) have no right to participate in these hearings, or more generally, in the licensing procedures, but their views should be taken into account.[106] No hearing officer is appointed. The CHMP then provides its detailed and reasoned opinion to the Commission along with extensive documentation. The Commission makes the final decision, which must contain a detailed statement of reasons. It involves the Standing Committee in the decision-making process. In the event the Commission disagrees with the Standing Committee, the Council makes the final decision. In cases of such disagreement, the Commission often refers the case back to the CHMP. All such decisions are posted on the Commission's web site.

III. CONCLUSION

In the 21st century world of globalized business, a great many clients of US lawyers will find themselves in proceedings before EU regulatory agencies. These

[105] See http://www.emea.eu.int/pdfs/human/regaffair/239001en.pdf. This web page contains specific and practical information about CHMP hearings. [this cite didn't work and needs to be updated]

[106] See Olivieri v. Commission, Case T-326/99, [2003] II-6053. This case concerned a scientist who opposed an application for marketing authorization on the basis of her own research. CFI held that she had a right to have her opinion considered by CHMP but not to participate further in the proceedings which are bilateral between the applicant and the Commission. As a consequence, she also lacked standing to seek annulment of the Commission's decision approving the application.

lawyers must come to terms with the procedures employed in EU administrative adjudication. These procedures are highly diverse and sector-specific. They mostly conform to the inquisitorial rather than to the adversarial model of adjudication to which Americans are accustomed. Despite the many procedural innovations prompted by pathbreaking decisions of ECJ and CFI, Americans may still feel uncomfortable with the EU's adjudication style. Nevertheless, it is our belief that those procedures are mostly fair and afford ample opportunity for private parties to make their views known. We hope that this account of EU adjudicatory process will help to smooth the way for Americans to understand and to utilize those processes in the interests of their clients.